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Exploring Tai Chi as an Early Intervention to Improve Balance and Reduce Falls Among Stroke Survivors – A Randomized Feasibility Study

EXPLORING TAI CHI AS AN EARLY INTERVENTION TO IMPROVE BALANCE AND REDUCE FALLS AMONG STROKE SURVIVORS – A RANDOMIZED FEASIBILITY STUDY

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Copyright statement

Abstract

Stroke is a major cause of disability worldwide, with many stroke survivors being at high risk of falling. Falling leads to an increasing amount of hospital admissions, placing substantial economic burden on health services. It has previously been shown that exercise programmes improve balance and reduce falls in older people. Tai Chi has been shown to reduce falls in older people. Therefore, it may show similar benefits early in stroke rehabilitation.

The aim of this randomised controlled feasibility study is to explore the acceptability and adherence of a bespoke Tai Chi programme for stroke survivors. Additionally, the suitability of the outcome measures has also been examined, along with the implementation, demand and practicalities of the programme.

Twenty-three potential participants completed the study and were identified and recruited at the point of discharge at a local hospital on a stroke unit. Participants were randomised into two groups: Tai Chi with usual care (experimental) (n=14) or usual care (control) (n=9). The experimental group attended one-hour Tai Chi classes twice a week and participated in home practice for 12 weeks.

Primary outcome measures were fall rates and the Berg Balance Scale [BBS] to measure falls risk and balance ability. Secondary outcome measures included the Geriatric Depression Scale [GDS] to measure depression levels, the Tinetti Falls Efficacy Scale [FES] to measure fear of falling, and the SF 12 to measure Quality of Life [QoL]. Semi-structured interviews were conducted with the experimental group to gain participants' perspectives of the programme.

This study found Tai Chi is feasible for stroke survivors as an adjunct to their rehabilitation. Further, Tai Chi may empower them to take control over their own recovery at home. Recommended outcome measures include the number of fallers with the BBS, GDS and FES as secondary outcome measures. Future larger RCTs may consider a 24-week intervention and more advanced professional home practice materials. Adopting a wait-list design and including hospital-based introductory classes are recommended to improve recruitment. Mid-intervention assessment and long-term follow-ups of six and twelve months or longer are also recommended in a future trial.

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Dedications and Acknowledgements

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To my family, especially my son, Laurence, who has had to unwillingly put up with my absence.

This thesis is dedicated to Lou Reed.

List of Abbreviations

Abbreviations	*Definitions*
ADLS	Activities of Daily Living
BBS	Berg Balance Scale
CONSORT	Consolidating Standards of Reporting Trials
CVA	Cerebral Vascular Accident
DH	Department of Health
ESD	Early Supported Discharge
FES	Falls Efficacy Scale
GCP	Good Clinical Practice
GDS	Geriatric Depression Scale
HrQoL	Health-related quality of life
ICF	International Classification of Functioning, Disability and Health
IRAS	Integrated Research Application System
MRC	Medical Research Council
MRHA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NIMH	National Institute of Mental Health
QoL	Quality of Life
RCN	Royal College of Nursing
RCP	Royal College of Physicians
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
SIGN	Scottish Intercollegiate Guidelines Network
SREP	School Research Ethics Panel
SF-12	12-item Short Form Health Survey
TC	Tai Chi
YAS	Yorkshire Ambulance Service
WHO	World Health Organization

Academic Biography

The author of this thesis has been a teacher of German and French for ten years in various secondary schools after successfully completing a four-year BA (Hons) course in German and Linguistics based at the University of Central Lancashire, followed by a one-year PGCE training course at Keele University. Other teaching qualifications include a certificate in Teaching English as a Foreign Language [TEFL] from Aston University, as well as a TAPP course as part of postgraduate training at Huddersfield University.

My teaching career has been succeeded by one of a medical nature, after completing a BSc in Adult Nursing at the University of Huddersfield. I still offer my care and compassion to stroke survivors on the stroke and neurology ward at Pinderfields Hospital, Wakefield.

Introduction

The purpose of this introductory chapter is to discuss the rationale of a multi methods feasibility study on 'exploring Tai Chi as an early intervention to improve balance and reduce falls in stroke survivors.'

The researcher involved in this multi methods study has been a registered nurse on a stroke unit at a hospital trust in West Yorkshire. Over the last decade, the researcher has observed many re-admissions of stroke survivors because of a fall. Contact with stroke survivors who have fallen through talking to carers, communication with patients and significant others have helped to develop a deeper understanding of the stroke patient's journey from having a stroke at home to adapting and coping once discharged. Understanding the patient's experience generated an interest in conducting this study.

Stroke is a leading cause of disability in the UK (Royal College of Physicians [RCP], 2016). Moreover, stroke has a greater disability impact than any other long-term disease (Luengo-Fernandez et al., 2013). One impact of disability is falling (Nyberg & Gustafson, 1995). The RCP (2016) recognise that there is a high incidence of falls among stroke survivors and suggest this is due to impairments of cognitive function, motor weakness, dual tasking and the planning and execution of tasks, on top of non-stroke factors that increase the risk of falling in older people. However, some research has suggested that stroke survivors may not necessarily fall more frequently than the general healthy population (Tan & Tan, 2016). Tan and Tan (2016) further suggest that those with severe stokes may fall less frequently due to restrictions in mobility, masking the risk of falls. Nevertheless, with one in three healthy people falling at some point over the age of 65, falls prevention programmes are required to reduce the financial burden placed on the NHS because of the consequences of falls (Public Health England, 2018).

A UK survey found that around 300,000 stroke survivors are living with moderate to severe disabilities (National Audit Office, 2010). Moreover, "due to a combination of reduced limb and trunk motor control, altered sensation and sometimes centrally determined alteration in body representation such that the person misperceives their posture in relation to the upright" (RCP, 2016, p.73), people experience balance impairment following a stroke, thus reducing confidence in Activities of Daily Living [ADLs] and increasing the risk of falls (RCP, 2016).

A Cochrane review by Gillespie et al. (2012) found strong evidence that certain exercise programmes prevent falls. Although Gillespie et al. (2012) recommended Tai Chi as a group exercise to reduce the risk of falls, it was not recommended for those at high risk of falls. It may be that Tai Chi with adjustments may be suitable for those at high-risk of falling because according to the Department of Health [DH] (2011), exercise programmes to prevent falls should be adjusted to individual need and be designed according to health condition and ability. It has been suggested that older people living in the community with recurrent falls and/or balance and gait deficits are likely to benefit from Tai Chi classes (National Institute for Health and Care Excellence [NICE], 2013; 2015). However, there are only a few studies which have investigated the effects of Tai Chi following a stroke. It should be noted while these studies have shown potential benefits, the 'dose' (duration, frequency and intensity) is unclear, and it is not known if Tai Chi will be accepted and adhered to in the UK within an NHS setting.

The research reported in this thesis aims to explore if Tai Chi as an early intervention is feasible following a stroke as an adjunct to community rehabilitation in the UK setting, and to determine the feasibility of a randomized controlled trial.

Chapter 1 – Background, rationale and context

1.1. Stroke overview

A stroke has been defined by the World Health Organisation [WHO] (2016) as 'a rapidly developing focal (or global) brain dysfunction of vascular origin lasting more than 24 hours, thus encompassing ischaemic stroke, intracerebral haemorrhage, subarachnoid haemorrhage and cerebral venous sinus thrombosis'. Medical practitioners often refer to stroke as cerebrovascular accident [CVA], cerebro meaning brain, vascular signifying blood vessels, and accident being when blood flow to the brain stops as a result of the occlusion or rupture of one of the blood vessels leading to or within the brain (Stroke Association, 2018). Lack of blood flow to the brain results in lack of oxygen to the brain (mainly in the internal capsule). This causes disruption of major inhibitory and facilitatory descending motor influences (Montague, Watson & Herbert (2005). Depending on the severity of disruption, weakness or paralysis of one side of the body (hemiplegia) occurs at the site of damage. Sensory loss is a major deficit following a stroke; the extent of loss depends on the extent to which sensory pathways in the internal capsule are damaged (Montague et al., 2005). Thus, stroke survivors have varying degrees of disability. The main symptoms of a stroke are facial weakness, limb weakness and speech difficulties.

1.2. Epidemiology of stroke

Epidemiology is the study of how often a disease occurs in different populations and why the disease occurs (Barker, Coggon & Coggan, 2003). Through epidemiological studies, data can be used to work out ways to prevent disease, as well as to guide the management of patients who already have this disease. To prevent disease and guide the management of patients already with the disease, disease outcomes (the condition of a person at the end of the disease process, i.e. how well the person is and what continuing care, support or medication is needed) need be measured (Barker et al., 2003). The two main measures of disease frequency are incidence (to work out the number of new cases of a disease) and prevalence (to find out the number of people living with the disease (Barker et al., 2003).

Incidence is the rate at which new cases occur in a population during a specified period (Barker et al., 2003). Incidence gives an indication of how many people are diagnosed with a disease during a specific period, which helps understand how many people will need services and resources. For example, stroke incidence provides more useful information on stroke burden than, for instance, stroke mortality because mortality figures reflect people who have died from the disease. Obviously, people who have died from a disease do not require services and resources (Warlow, 2005). Additionally, Warlow (2005) reports that if mortality is used as a measure of overall impact; it does not capture deterioration of quality of life or emotional and physical impact.

In developed countries, the total incidence of stroke is expected to rise substantially over the next 20 years due to the ageing population (Gibson, 2013). However, in the UK, it appears that the incidence of stroke is reducing (Lee, Shafe & Cowie, 2011), with stroke incidence rates falling by 19 per cent from 1990 to 2010 (Stroke Association, 2018), and by 29 per cent between 1999 and 2008 (Lee et al., 2011). In 2016, the Stroke Association reported that there were approximately 152, 000 strokes in the UK each year, whereas in 2017, the Stroke Association reduced the incidence of stroke to about 100,000 per year. Lee et al. (2011) suggested that the reason for the decreased stroke incidence may be due to improved drug treatment in primary care, as well as better control of risk factors before and after a stroke incident, i.e. control of cardiovascular risk factors. Therefore, the incidence of a first stroke in the UK may be reducing due to better control of risk factors, and a second stroke may be prevented due to improved drug treatment. However, despite the reduced incidence rate, the stroke survival rate is increasing, perhaps because of innovations in stroke recovery (Lee et al., 2011), thus increasing demand on services. Due to the increasing number of people living with disabilities following a stroke, more resources will be needed to accommodate the increase in rehabilitation demand.

As previously explained, prevalence of a disease refers to the proportion of a population with the disease at one point in time (Unwin, Carr, Leeson & Pless-Mulloli, 1997). Prevalence can be measured at a specific point in time (point prevalence), over a given time period of interest, e.g. past 12 months (period prevalence) or at some point in a person’s life having had the disease (lifetime prevalence) (National Institute of Mental Health [NIMH], 2017). There is a wide variation in prevalence of stroke, published in many countries, making it difficult to make international comparisons (Bonita, Solomon & Broad, 1997). Bonita et al. (1997) suggest this may be due to different methods of measurement, age structure and definition of stroke, yet also may reflect the decline of fatal cases, showing an increasing number of stroke survivors.

Bonita et al. (1997) further suggest the number of stroke survivors is increasing because survivors are living longer, and this number is set to rise. More people are surviving stroke than ever before (Stroke Association, 2018). According to the Quality and Outcomes Framework [QOF] (2015), there were about 1.2 million stroke survivors in the UK in 2015, with 966,093 in England alone (Stroke Association, 2018). Stroke survivors pose an economic burden onto the NHS with all stroke costs (including direct, indirect and informal) amounting to approximately £9 billion per annum in the UK (Hisham & Bayraktutan, 2013).

An additional important metric is the prevalence of stroke disability. This may be useful to predict service need and availability of resources. Hisham and Bayraktutan (2013) highlighted that more than 250,000 people in the United Kingdom [UK] are living with disabilities caused by stroke. However, the Stroke Association (2018) suggests that the number of people with stroke disabilities in the UK was 300,000 and is set to rise. Comparatively, the US National Stroke Association (2018) found that only ten per cent of US stroke survivors fully recovered, with 25 per cent recovering with minor impairment, and a further 40 per cent experiencing moderate to severe impairments, requiring specialist care. The proportion of stroke survivors in the UK receiving community services was 90 per cent in 2016/17, which increased from 70 per cent in 2013/14 (Stroke Association, 2018). This implies that most stroke survivors receive community services, which in turn suggests that they have a residual disability. However, with 1.2 million stroke survivors in the UK, and 300,000 people with stroke disabilities, it might seem that the greater proportion of stroke survivors in the UK do not have a disability or that there is an error in the data, and that some eventually improve. However, due to the bias in measuring prevalence as mentioned above, it is possible that the prevalence of stroke disability has been underreported. Additionally, bias could have occurred by only using data obtained from those using community services. This means that those stroke survivors who refuse (or cannot access) specialist help and those who have already been discharged from the services, but still have a disability, may not have been considered.

Mortality

With a decreased stroke incidence rate and an increased stroke prevalence rate (NICE, 2015; Stroke Association, 2018), it is not surprising that stroke mortality (incidence of death from a disease) rates have fallen in the UK by almost half between 1990 and 2010 (Stroke Association, 2018). A decline in stroke mortality has also been observed globally over recent decades (Feigin, Lawes, Bennett & Anderson, 2003), with this global trend in decreasing stroke mortality remaining apparent in data from western countries up to 2011 (Zhang, Chapman, Plested, Jackson, & Purroy, 2012). However, the decrease in global stroke mortality rates is surprising because according to Feigin et al. (2003), stroke incidence and prevalence rates have remained constant on a global scale. This leads to the question, how can stroke mortality rates decrease when stroke incidence and prevalence rates for stroke survivorship remain stable?

Warlow (2005) explains that the prevalence of stroke survivors is more open to bias than incidence due to the underrepresentation of fatal cases. This is because reporting of fatal cases can be misleading due to misclassifications of the underlying cause of death on death certificates. Therefore, the reporting of the number of fatal cases may be underrepresented leading to bias in reporting cause-specific mortality (Halynych, Shuaib, Parmer, Tanikella & Howard, 2011). For example, more women in the UK die from stroke (at a greater age) than men because women live longer than men (Stroke Association, 2018). With older women making up a large proportion of the stroke population, it is possible that a lot of these deaths are not being classified as being from a stroke due to co-morbidities associated with age. Another reason why stroke mortality might be underrepresented is because stroke mortality rates are usually derived from death certificates. According to Warlow (2005), death certificates do not record milder, non-fatal strokes, which means the number of fatalities from stroke may be higher than is reported. Similarly, Brown, Giles, & Greenlund (2007) suggest that accurate and reliable determinations of cause of death after stroke are not feasible. Woodfield, Grant and Sudlow (2015) found limited published information about improving accuracy in stroke epidemiological data.

Gender and age have been shown to be associated with stroke: stroke statistics compiled by the Stroke Association (2018) show that men are at a higher risk of having a stroke at a younger age than women. The average age of a man to have a stroke is 74 years, compared to 80 years for a woman (Stroke Association, 2018). Over the age of 75 years, it is women who are most at risk from having a stroke, thought to be due to having a longer life expectancy than men (Seshadri et al., 2006). This longer life expectancy in women results in them having poorer functional outcomes than men because poorer outcomes are associated with older age (Seshadri et al., 2006). Hence, women above 75 years are likely to comprise the greater proportion of stroke-related mortality, as well as stroke disability (Gibson, 2013), thus requiring a long-term need for an on-going commitment of resources from the UK healthcare system (Saka, Serra, Samyshkin, McGuire & Wolfe, 2009), and generating an increase in hospital care costs (Luengo-Fernandez et al., 2013).

Reflections
In the UK, stroke incidence and mortality are declining, whilst stroke prevalence rates are increasing (Stroke Association, 2018), suggesting an increasing demand on NHS services by the increasing number of stroke survivors. Stroke is a leading cause of disability (RCN, 2016) with a greater disability impact than other chronic diseases (Luengo-Fernandez et al., 2013). Increased age is associated with poorer physical outcomes; over the age of 75 years, women are at more risk of having a stroke than men due to women living longer (Seshadri et al., 2006). Thus, women make up a greater proportion of people with stroke-related disability (Gibson, 2013).

1.3. Physiology of stroke

There are two types of stroke: ischaemic (or clot, resulting from an occluded blood vessel supplying blood to the brain) and haemorrhagic (or bleed, following a ruptured blood vessel) (Uchino, Pary & Grotta, 2011).

1.3.1. Ischaemic stroke

An ischaemic stroke occurs when a cerebral or cervical artery supplying the brain becomes occluded (blocked) and blood flow to the brain is interrupted, which causes the death of brain tissue within two to three minutes of onset. This death of brain tissue results from a lack of oxygen and glucose to the brain (Dirnagl, Iadecola & Moskowitz, 1999). The lack of oxygen and glucose damages brain cells, which change how the nervous system works; messages from the brain will be blocked, slowed or confused (Robbins & Swanson, 2014). Approximately 85 per cent of strokes are ischaemic (Uchino et al., 2011).

Ischaemic strokes are caused by an interruption of blood flow to the brain by a blood clot. The most common cause of blood flow interruption and occlusion in ischaemic strokes is atherosclerosis. Atherosclerosis is the narrowing of the neck (carotid) and head (middle cerebral, anterior cerebral and posterior cerebral) arteries. If the arteries become too narrow, the blood will start collecting and clots will develop. A clot may form in the blood vessels in the brain and cause occlusion (thrombosis). A stroke caused by a thrombosis is known as a thrombotic stroke. Thrombotic strokes account for 50 per cent of all strokes, of which there are two types: large vessel, which occurs in the larger arteries such as the carotid or middle cerebral; and small vessel, which occurs in the small vessels (Uchino et al., 2011). Thrombosis occurring in the small blood vessels of the brain also results in a lacunar infarct (dead brain tissue resulting from lack of oxygen due to obstruction of blood supply (Uchino et al., 2011). Atherosclerosis is often a main cause of embolism, another cause of ischaemic stroke. A stroke caused by an embolism is known as an embolic stroke. In an embolic stroke, a piece of atherosclerotic plaque or blood clot may tear away and travel through the blood stream, blocking the blood vessel to the brain (Saric & Tompkins, 2017). However, not all embolisms have an atherosclerotic cause. Indeed, anything travelling through the blood stream may form an embolism (Saric & Tompkins, 2017).

Ischaemic stroke can be classified according to presenting characteristics. The most popular stroke classification system used in British hospitals for ischaemic stroke is the Bamford Classification of Stroke (Bamford, Sandercock, Dennis, Warlow & Burn, 1991). The Bamford (or Oxford) Stroke Classification has four categories:

1. Lacunar infarcts

This type of stroke is also referred to as mild stroke or small vessel disease (Spokoyny et al., 2015). Lacunar strokes are less than 15mm diameter in size and account for 20-30 per cent of strokes (Uchino et al., 2011).

2. Total anterior circulation infarcts

Patients with this type of stroke have a high mortality rate and poor functional outcome (Mant, Winner, Roche & Wade, 2005).

3. Partial anterior infarcts

A person experiencing a partial anterior circulation infarct is more likely to die early or have a recurrent stroke (Mant et al., 2005).

4. Posterior circulation infarcts

Patients may die early and are at risk of early recurrent stroke (Bamford et al., 1991).

1.3.2. Haemorrhagic stroke

Haemorrhagic stroke (bleed to the brain) accounts for 15% of all strokes. There are two types of haemorrhagic stroke. The first type of haemorrhagic stroke is intracerebral haemorrhage, found in 10 per cent of stroke-related bleeds (Stroke Association, 2014). A haemorrhage is due to spontaneous rupture of a vascular structure. This type of bleed usually occurs in the basal ganglia, thalamus, pons or cerebellum due to drug abuse (e.g. cocaine), aneurysm, amyloid angiopathy, cerebral vein thrombosis, tumour or trauma. The second type of haemorrhagic stroke is subarachnoid haemorrhage, found in 5 per cent of stroke-related bleeds (Stroke Association, 2014). Subarachnoid haemorrhage is bleeding into the subarachnoid space around the brain and accounts for 5 per cent of stroke deaths. Other causes of subarachnoid haemorrhage include trauma, drug abuse, vasculitis, and arterial dissection; when a cerebral haemorrhage occurs, there is leakage from small intracerebral arteries damaged by chronic hypertension (Uchino et al., 2011). Hence, perfusion to the brain is disrupted. The destruction of brain cells changes how the nervous system works; messages from the brain will be blocked, slowed or confused (Robbins and Swanson, 2014).

1.4. Consequences of stroke

The main problematic consequence of stroke is the resulting disability. Stroke may or may not lead to disabilities, but when it does, the nature of the disability depends on the part of the brain affected, with the severity of the disability depending on the extent of the lesion. The most common disabilities resulting from a stroke are weakness and paralysis (Stroke Association, 2018), with variable scope for improvement.

1.4.1. Disability

Disability is the interaction between individuals with a health condition, and personal and environmental factors (WHO, 2011). Due to the variable need for health and social care resources by people living with a disability, the WHO has developed a conceptual framework for measuring health and disability at both individual and population levels to record information on the functioning and disability of an individual (the International Classification of Functioning, Disability and Health [ICF]). The ICF defines disability as an umbrella term for impairments, activity limitations and participation restrictions. It is not clear by this definition, however, if the term refers to short-term effects on ability. The UK Equality Act 2010 defines disability as "a physical or mental impairment that has a 'substantial' and 'long-term' negative effect on your ability to do normal daily activities", such as getting around unaided, walking short distances, sitting, standing, bending, or reaching. 'Substantial' has been defined as 'more than minor', with 'long-term' meaning 12 months or more (Office for Disability Issues, 2010). The Equality Act (2010) recognises stroke as a condition resulting in substantial and long-term disability. However, stroke does not come under the category 'automatically treated as a disability' under the Equality Act, but rather under the category, 'conditions which might be treated as a disability', where stroke is defined as a condition affecting certain organs.

Activity limitation

According to the WHO (2018a), disability is not just a health problem; the World Report on Disability (2011) stresses that disability should be not be viewed solely as medical or solely social, but a combination of the two. Indeed, disability can prevent people from carrying out their ADLs, such as walking. According to the WHO (2018), an activity limitation is 'a difficulty encountered by an individual in executing a task or action'.

Activity limitation is one of the factors that adversely affect the activities of daily living of stroke survivors with hemiplegia. One of the reasons stroke survivors are restricted from performing ADLs is because they are unable to shift body weight symmetrically in response to motion, which reduces balancing ability, thus leading to asymmetrical physical balance (Choi & Kang, 2015). A survey conducted in 2015 by the Stroke Association (2018) found that out of 1000 stroke survivors, four in ten reported the physical impact of stroke was the hardest to deal with and needed help with daily activities following discharge: 45 per cent of stroke survivors reported that they did not receive social support and felt abandoned and 30 per cent perceived care at home as poor or very poor. It is not clear, however, if the Stroke Association surveyed only those requiring community services. Should this not be the case, it is likely that some respondents did not need such services, but this is unclear from the survey because personal need and response rate were not reported. Help with ADLs may be offered in the form of social support and community services, which come with a financial cost to the NHS. Without this help and support stroke survivors are at risk from further activity limitation due to an unaddressed loss of balance.

Participation restriction

As well as experiencing limitations with ADLs, stroke survivors may find it difficult to participate in activities within society. According to the WHO (2018a), a participation restriction is a 'problem experienced by an individual in involvement in life situations.' For example, a negative attitude from society and environmental barriers, such as a lack of service provision and accessibility to public amenities may prevent people with a disability from participating in society on equal basis with others (WHO, 2011). The WHO (2007) further highlight that to increase adherence to community services, change is needed in terms of falls prevention interventions, beliefs, attitudes and behaviour of older people. A cross-sectional study of stroke survivors and a cohort of non-stroke controls aged 65 and over by Skolarus, Burke, Brown & Freedman (2013) found that stroke survivors have more participation restrictions than the general population. To optimise stroke survivorship, the authors highlight the necessity to not only understand participation restrictions but to also understand the role of physical capacity. The authors conclude that stroke survivors with a physical disability have low physical capacity and are less likely to go out for family visits and leisure activities.

One area of life where it may be difficult for stroke survivors to participate in, due to a lack of service provision and accessibility, is using transport. It has been recognised by the WHO (2018a), for example, that older people will participate in a community-based exercise class if they:

- are able to do so
- can see a benefit for themselves
- have access to the resources

Unable to use transport may lead to another participation restriction: leisure. According to the WHO (2007), improving impairment will only come to fruition if older people adhere to exercise classes and continue exercising once classes have ended. Thus, transportation issues may hinder the success of participating in exercise. Transportation is an important issue to consider for this study. With the availability of transport, participating in an exercise class may benefit stroke survivors by improving their balance.

Disability is common among stroke survivors, limiting their activities, such as carrying out their ADLs. Disability can also prevent stroke survivors from engaging in social situations. Barriers to participation among stroke survivors include lack of transport and lack of social provision. This is a major concern when offering an exercise programme to prevent falls among stroke survivors because if they do not have access to transport, stroke survivors may not be able to participate in the exercise programme.

Balance impairment

Impairment is defined by the WHO (2018a) as a problem in body function or alterations in body structure e.g. paralysis, and is found under the International Classification of Functioning, Disability and Health [ICF] subdomain, 'Body Function and Structures.' Impairment is the injury, likely to result in loss of physiological or psychological function, whereas disability is the difficulty encountered by an individual to perform a task (WHO, 2018a).

Balance impairment has been defined as the inability to maintain an upright position within the limits of stability or base of support (Bronstein, Brandt & Woollacott, 1996). The human balance system is complicated and comprises of three sources of information required to be received by the brain. These sources of information are the ears (vestibular), eyes (visual), and sensors embedded in joints, muscles and skin (proprioception). In order for the brain to be able to accurately work out where an individual's body part is located in relation to other parts and the environment, it requires input from all three sources. Without the input of all three sources, the brain will receive suboptimal information, which may be insufficient to maintain balance. The part(s) of the brain affected by stroke determines the extent of the disability.

Hemiparesis

One impairment affecting body function is hemiparesis (muscular weakness or partial paralysis to one side of the body) (Merriam-Webster, 2018). With hemiparesis, the arm or leg may be affected, or a combination of both (National Stroke Association, 2018). According to the Stroke Association (2014), 80 per cent of stroke survivors are affected by hemiparesis. Salbach et al. (2016) reported that 80 per cent of stroke survivors experience a deficiency in their walking ability at stroke onset, suggesting that 80 per cent of stroke survivors affected by hemiparesis have difficulty walking. Hence, this may also suggest that 80 per cent of stroke survivors experience a loss of balance. Muscle weakness is a characteristic of hemiparesis, and there is growing evidence that muscle weakness is a major limiting factor in physical function following stroke (Kim & Eng, 2003).

Muscle weakness

Muscle weakness is essentially a lack of, or reduction in, strength in the muscle(s). There are many causes, including stroke, where the weakness may be associated with spasticity. Muscle tone may change following a stroke, resulting in stiff spastic muscles, making limb movements difficult. Lomaglio and Eng (2004) suggest that muscle weakness may lead to impaired postural control which, in turn, leads to asymmetrical limb loading. Although it is recognised that stroke survivors experience balance impairments due to muscle weakness, there is little evidence on how muscles can be strengthened to improve balance in stroke survivors. Stroke survivors who have just been discharged from hospital may benefit from long-term muscle-strengthening exercises as a supplement to community physiotherapy. Understanding which muscles cause the balance impairment can help with the development of a suitable exercise programme. For example, weakness of the extensor muscles may cause difficulty with sit-to-stand movements in some stroke survivors, whilst some experience trunk weakness, affecting postural stability and balance (Mead & van Wijck, 2013). During walking, Mead and van Wijck (2013) found that one of the most common problems was weakness in muscles that extend the ankle and lift the forefoot, thus impairing heel strike, leading to a loss of balance. Generally, muscle weakness following stroke was found to have a poor influence on dynamic balance (Kligytė, Lundy-Ekman & Medeiros, 2003).

Dynamic balance

Dynamic balance is the ability to balance whilst in motion or switching between positions (de Oliveira, de Medeiros, Frota, Gretas & Conforto., 2008). In other words, dynamic balance is required for walking. Stroke survivors commonly cite improved walking as a goal for rehabilitation (Kim & Eng, 2003). Therefore, an exercise programme to improve balance should focus on maintaining dynamic balance. Before developing such a programme, an understanding of how dynamic balance is maintained is needed. Better dynamic balance can be gained through improved stabilisation of the head and trunk, better muscular compensation through the nonparetic leg, improved multisensory integration, and progressive and increased self-confidence (de Oliveira et al., 2008). Cromwell, Newton and Forrest (2002) agree that head stabilisation contributes to dynamic balance, especially during ambulation, especially during walking. Cromwell et al. (2002) further add that maintaining a fixed gaze whilst aligning the head with the rest of the body reduces imbalance. The authors suggest that this is because vision facilitates the head stabilisation process for older adults to compensate for loss in other sensory systems promoting dynamic balance. Stroke survivors have altered head motions, suggesting an underlying impairment in sensorimotor integration (Lamontagne, Paquet & Fung, 2003). This means that if stroke survivors maintained a fixed gaze whilst aligning the head with the rest of their body, they may experience balance improvement.

Static balance

Head motions are also important in maintaining static balance. Static balance refers to a person's ability to maintain balance whilst being stationary (Lamontagne et al., 2003). Lamontagne et al. (2003) suggest that in the general population, voluntary head motions whilst maintaining static balance should be smooth and fast. However, in stroke survivors, postural adjustments to voluntary head movements are executed during standing, resulting in an inability to maintain static balance (Lamontagne et al., 2003). This suggests that maintaining head alignment is always necessary and should be incorporated into exercises.

As well as head motions, arm motions may also pose a threat to balance (Lamontagne et al., 2003). Voluntary arm raising whilst standing may disturb balance due to a change in body configuration, resulting in a displacement of centre of mass with respect to the base of support (Lamontagne et al., 2003). It may be that to help maintain balance, an exercise programme for stroke survivors including the control of arm movements may be beneficial.

Weight-bearing asymmetry

Whilst adjustment of movement of the upper extremities contributes to the inability to maintain balance, it has been observed that the lower extremities are also instrumental (Genthon et al., 2007). Genthon et al. (2007) comment that the disturbed upright stance of stroke survivors is characterised by weight bearing asymmetry with more weight on the non-paretic limb, reducing reliance on the paretic limb. This preference of the non-paretic limb stems from the difficulty maintaining a weight shift to their paretic limb (Mansfield, Danells, Zettel, Black & Mellroy., 2013). However, despite preferring the non-paretic leg for safety, Genthon et al. (2007) suggest that stroke survivors are able to put 50 per cent or more of their weight onto the paretic side but choose to weight bear on the non-paretic leg. Lamontagne et al. (2003) also found that stroke survivors avoided weight-bearing on the paretic limb whilst standing. Weight-bearing on the paretic limb would lead to instability due to its reduced capacity to control balance (Mansfield et al., 2013). Furthermore, the non-paretic limb is unable to completely compensate for the insufficency of the paretic limb, and thus, the non-paretic limb may be involved in the overall postural instability of the stroke survivor (Genthon et al., 2007). Therefore, in order to achieve balance control post-stroke, the distribution of weight between legs is required (Mansfield et al., 2013). It is for this reason that being able to control the weight distribution between both the paretic and non-paretic legs shall be included in the exercises.

Stroke survivors have more assymetrical body-weight distribution, more centre of pressure sway, and lower rate of sit-to-stand manoeuvres than those without stroke (Cheng et al., 1998; Cheng, Wu, Liaw, Wong & Tang, 2001; Kao, Dingwell, Higginson & Binder-Macleod, 2014; Carver, Nadeau & Leroux, 2011). Symmetrical body-weight distribution training may, therefore, seem logical to prevent falls (Cheng et al., 1998).

Spasticity

Spasticity has been defined as 'a velocity-dependent increase in tonic stretch reflexes' (Singer, Mansfield, Danells, McIlroy & Mochizuki, 2013), colloquially known as stiffness. Spasticity can develop into contractures, where changing muscle shape and length, become fixed so they cannot straighten to their full length, thus restricting joint motion (Stroke Association, 2014). Although there is little research about the influence of post-stroke spasticity on balance control, Singer et al. (2013) showed that weight bearing assymetry increased in stroke survivors with spasticity, and suggest that stroke survivors with spasticity may face more challenges with postural control than those without. The authors explain that this was because stroke survivors were unable to change the centre of pressure beneath the affected limb. However, it is estimated that spasticity occurs in approximately 30% of stroke survivors (Urban et al., 2010), suggesting that most stroke survivors do not have a problem with spasticity. Nevertheless, spasticity should be taken into accout when designing an exercise programme for stroke survivors.

Proprioception

Balance in stroke survivors is dependent on limb control and proprioception (sensory dysfunction) (Keenan, Perry & Jordan, 1984). Proprioception is the "the afferent information arising from peripheral areas of the body that contributes to joint stability, postural control and motor control" (Niessen et al., 2008, p.333). Jerosch and Prymka (1996) define proprioception as position sense. Maintaining stability becomes difficult for stroke survivors because they may not be aware of how much weight is loaded onto the paretic leg (Bohannon, 2007; Chu, Hornby & Schmit, 2015). It is estimated that more than half of stroke survivors experience sensory loss within the sensorimotor system (Carey, 1995; Tyson, Harvey, Chillala & Selley, 2008). The sensorimotor system plays an important part in maintaining stability (Niessen et al., 2008); the motor control system needs to receive accurate sensory information from the limbs in order to mobilise without loss of balance (Chu et al., 2015). In order to help maintain balance, it seems possible that stroke survivors could possibly benefit from exercise which focuses on improving proprioception.

Self-efficacy

Self efficacy is the extent to which a person believes they are able to do certain things (Bandura, 1977). According to Bandura's (1986) self-efficacy theory, increased self-efficacy leads to increased resources such as time and effort devoted to a task, and is known to be one of the most consistent predictors of exercise adherence (Jones, Harris, Waller & Coggins, 2005). However some researchers have argued that it is high performance leading to self-efficacy rather than vice versa (Jones et al., 2005). Additionally, others have argued that violation of high expectations has encouraged the individual to give up (Desharnais, Bouillon & Godin, 1986). Indeed, Jones et al. (2005) found that overly optimistic expectations of inexperienced exercisers may lead to disappointment. Therefore, it may be important to maintain realistic expectations throughout an exercise programme for stroke survivors to increase self-efficacy and adherence.

Balance and self-efficacy

Balance self-efficacy is the level of confidence a person has in performing tasks without losing balance or becoming unsteady (Pang, Eng & Miller, 2007). Therefore, where a lack of self-efficacy may lead to a lack of adherence to tasks such as exercise, a lack of balance self-efficacy may lead to poor balance. For example, Cheng et al. (2001) found that stroke survivors with less balance self-efficacy and confidence were more unsteady. In short, increasing balance self-efficacy has the potential to improve balance in stroke survivors. Indeed, enhancing self-efficacy is associated with restoring balance sense, exercise function, and walking ability (Choi & Kang, 2015). Moreover, improvements in balance self-efficacy in stroke survivors have been made after group-based exercise programmes in the form of weight-shifting exercises (Brouwer, Walker, Rydahl & Culham, 2003; Marigold et al., 2005), including Tai Chi (Li, Fisher, Harmer & McAuley, 2004).

Ataxia

Stroke survivors may also have problems with ataxia (inability to coordinate movement); the individual is clumsy on the affected side of the body, with the leg usually being more affected than the arm, leading to balance impairment (National Stroke Association, 2018). Ataxia develops because of damage to the cerebellar part of the brain (National Health Service [NHS], 2018). Therefore, ataxia is more common after cerebellar stroke, which have a much lower incidence rate than cerebral hemispheric strokes (Caplan, 2005): an exercise programme including exercises focusing on coordinating movement may improve balance in those with a cerebellar stroke, just as it might for people not showing ataxia. This makes Tai Chi even more appealing for stroke survivors wanting to improve balance because Tai Chi involves coordination of movement.

Depression

It is possible that balance impairment among stroke survivors may not be due to physical impairment alone. Although there is little evidence investigating the correlation between depression, balance and physical functioning, some researchers suggest that depression is linked with poor balance. Three studies link depression post-stroke to reduced balance and physical function, with less intense depressive symptoms being associated with better physical abilities (Alghwiri, 2016; Hama et al., 2007; West, Hewison, Knapp & House, 2010). It may be that an exercise programme can elevate mood in post-stroke depression, thus contributing to balance improvement through reducing depression.

Overall, it has been agreed by many researchers that there are many factors involved in balance impairment among stroke survivors, such as hemiparesis, muscle weakness, spasticity, proprioception, fear of falling, falls efficacy, ataxia and balance. As well as physical factors, psychological factors may also play a role in balance impairment, such as depression (Alghwiri, 2016; Hama et al., 2007; West et al., 2010). Weight shifting exercises have been found to improve lower limb strength, walking ability, spasticity and balance self-efficacy in stroke survivors (Choi & Kang, 2015; Gray, Ivanova & Garland, 2012). Weight shifting exercises that also include maintaining an upright stance and coordination of all four limbs may help reduce balance impairment in stroke survivors by addressing all the above factors. If all factors associated with balance impairment are contained in one exercise programme, it is possible that balance would be improved.

1.4.2. Falls

Most studies do not provide a standard definition of falls consistently, leaving interpretation of results open (WHO, 2018b). In studies which do include a definition of falls, definitions vary, making it difficult to rely on results (Dickinson et al., 2011; Gelbard et al., 2014; O'Neal et al., 2015; Sherrington & Tiedemann, 2015; WHO, 2018b). For example, an older person may consider a fall to be losing one's balance, perhaps bumping into a wall, but not necessarily landing on the floor, whereas a healthcare professional may define a fall as an event resulting in injury or deterioration in health (Ambrose, Geet & Hausdorff, 2013; Peel, 2011; Zecevic, Salmoni, Speechley & Vandervoort, 2006). The WHO (2018b) defines a fall as "an event which results in a person coming to rest inadvertently on the ground or floor or other lower level, excluding intentional change in position to rest on furniture, wall or other objects". The exclusion criterion is notable: a definition of falls with an inclusion and exclusion criterion is important because many studies do not state clearly (or state at all) what is meant by a fall, leaving interpretation open. To avoid confusion in healthcare, NICE (2015, p.45), provides exclusion criteria regarding medical problems and defines a fall as "an unintentional or unexpected loss of balance resulting in coming to rest on the floor, the ground or an object below knee-level. A fall is distinguished from a collapse that occurs due to an acute medical problem such as an acute arrhythmia, a transient ischaemic attack or vertigo". Despite both the WHO and NICE agreeing that 'for an event to be classified as a fall, the act needs to be unintended with the faller coming to rest on the ground, floor or lower level', their definitions differ in that NICE includes 'the unexpected loss of balance'.

Lack of a definition of falls leads to the question of how studies convey the concept of falls and, thus, enable comparison between studies? Whilst definitions of falls by the WHO and NICE are often disregarded in studies, researchers often use agreed concepts such as 'unintentional' and 'landing on the floor, ground or other lower level.', but frame the description of a fall around the study's purpose. For example, studies which aim to count the number of falls and identify factors that impair balance control tend to use the definition formed in 1987 by the Kellogg International Working Group on the Prevention of Falls in the Elderly [ProFaNE], which includes "other than a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or seizure" (Ambrose et al., 2013; Fleming, Matthews & Brayne, 2008; Lord, Sherrington, Menz & Close, 2007). A study on risk factors for falling, used the falls definition by the National

Database for Nursing Quality Indicators [NDNQI], which again included the agreed concepts ‘unplanned’ and ‘descent to the floor’, but included “with or without an injury to the patient” (Callis, 2016). Tuuainen, Rasku, Jäntti & Pyykkö (2014) include the concepts ‘unintentional’ and ‘coming to rest on the ground or lower level’ but included “with or without loss of consciousness.” This addition by Tuuainen et al. (2014) to the agreed concepts of the definition leads to confusion because the Kellogg study excludes ‘loss of consciousness’ as contributing to a fall.

In order to conduct a study on falls, a definition is needed to avoid misinterpretation which may lead to the inaccurate reporting of results. For the purpose of the study reported in this thesis, the NICE definition of a fall will be used to highlight the fact that if a person prevents themselves from falling by holding onto furniture etc, this would not be classed as a fall but a near miss. Using NICE’s definition of a fall, contributes to the standardisation of a definition by which to compare other studies within the UK.

1.4.3. Epidemiology of falls

Despite a lack of consistency in the definition of falls within studies, leading to uncertainty in what contributed to a fall, epidemiological studies have generated significant data. In the case of falls, epidemiologic studies have identified the population most at risk being adults over the age of 65 years (Ambrose et al., 2013; Callis, 2016; Close, Lord, Hylton, Menz & Sherrington, 2005; Dickinson et al., 2011; Gelbard et al., 2014; Tuunainen et al., 2014; Sherrington & Tiedemann, 2015). Adults over the age of 65 years, experience the greatest number of fatal falls, making falls the second largest cause of unintentional injury death following road traffic collision worldwide, and the fifth largest cause of death overall in the United States (WHO, 2018b). The number of people aged 65 years and above is estimated to rise to by over 40 per cent to more than 16 million in the next 17 years (Office for National Statistics, 2015), with 30 per cent falling once a year (NICE, 2013). For those aged 80 years an above, it is 50 per cent (NICE, 2013). Comparatively, in the UK, 30 per cent of people aged 65 years and above fall at least once a year, with 50 per cent aged 80 years and above falling at least once a year (NICE, 2013).

Epidemiological studies have also contributed to knowledge regarding consequences related to falling (e.g. recovery, injury, disability, mortality). By using this data, the greatest problems for the health service can be identified (Bonita, Beaglehole & Kjellström, 2006). One consequence of falls is injury. Injuries related to falls have been prioritised by the health service worldwide as a public health concern due to the implications of the health needs of an ageing population (WHO, 2007). For example, as the population ages, if effective falls prevention strategies are not implemented, the number of falls necessarily will rise. Annual incidence rates for injury due to falls are high in Western Australia and the UK with a rate of 5.5 to 8.9 per 10,000 population total; countries such as Australia, Canada and the UK have high rate of hospitalisation due to a fall in people over the age of 60 years, yielding 1.6 to 3.0 per 10,000 population total (WHO, 2018b).

To gather significant data on falls as above, it is important to find out the most appropriate method of data collection. Falls epidemiology is examined by calculating falls incidence. It has been recommended that the preferred method of recording falls is by using prospective daily recording and a notification system with a minimum of monthly reporting, with missing data being chased via telephone or face-to-face interview (Lamb, Jørstad-Stein, Hauer & Becker, 2005). Using rigorous data collection methods, epidemiologic information can help with falls prevention planning (Bonita et al., 2006). For example, the greatest population at risk can be identified, as well as where the risk is most burdensome for the health service with causal associations often evident (Landers, Oscar, Sasaoka & Vaughn, 2016). Overall, there is a need for consistency of the use of falls definitions among epidemiological studies in order to compare them.

Risk factors for falling

Although increasing age is a risk factor for falling, people do not fall just because they get older. In fact, there may be multiple underlying risk factors involved (Bath & Morgan, 1999; Campbell, Reinken, Allan & Martinez, 1981; Campbell, Borrie & Spears, 1989; Lord et al., 2007; O'Laughlin, Robitaille, Boivin & Suissa, 1993; Prudham & Grimley-Evans, 1981; Wu et al., 2013). Understanding the causes, or at least the risk factors for falling is a pre-requisite for a fall prevention intervention. Falls usually result from a combination of several associated factors, so prevention strategies need to be directed at more than one factor (Bonita et al., 2006). To reduce the risk of falls, risk factors need to be modifiable. However, not all risk factors are modifiable, and those that are might not be conducive to an exercise programme. Thus, remains the question, which modifiable falls risk factors are suitable to consider when developing a falls prevention exercise programme? Table 1 below presents a list of both non-modifiable and modifiable risk factors from multiple sources. Modifiable risk factors which may be reduced through exercise are asterisked, most of which are discussed above.

Table 1 Evidence table for fall risk factors in the general population

Modifiable Fall Risk Factors	Comment	Reference
Balance impairment*	Different causes of balance (muscle weakness, dizziness, visual disturbance).	Campbell et al.(1981); Campbell and Borrie (1989); Campbell and Matthews (2010); Chu, Chi & Chiu (2005); Graafmans (1996); Kamińska et al. (2015); Lamb et al. (2003); Mackintosh et al. (2004); Morrison et al. (2011); Murphy et al. (2013); Nyberg and Gustafson (1997); Horak et al. (2006); O'Laughlin et al. (1993); Olsson, Lofgren, Gustafson and Nyberg (2005); Rabaldi (2008); Rubenstein et al. (2006); Stapleton, Ashburn and Stack (2001); Teasell (2002); Wallman (2009);
Fear of falling*	70 per cent of fallers develop fear of falling. Fear of falling is associated with balance impairment.	Batchelor et al. (2012); Campbell and Matthews (2010); Chen et al. (2011); Cho, Yu and Rhee (2015); Chu et al. (2005); Dionyssiotis (2012); Dueñas et al. (2016); Gazibara et al. (2016); Jalayondeja, Sullivan and Pichaiyongwongdee (2014); Kumar et al. (2014); Lord, Sherrington, Menz and Close (2007); Mackintosh, Goldie and Hill (2004); Pang and Eng (2008); Schmid and Rittman (2009); Wallmann (2009)
Poor vision	Contributes to balance impairment.	Dionyssiotis (2012); Kamińska et al. (2015)
Depression*	Geriatric patients with depression are three times more likely to fall than those without depression; causation is unclear because	Biderman et al. (2002); Tinetti, Baker and McVay (1995); Friedman et al. (2002); Kojima et al. (2015); Kvelde et al. (2014); Sheeran et al. (2004); Sjösten, Vaapio and Kivelä (2008); Turcu et al. (2004);

	depression may cause a fall and vice versa; depression and falls are related to functional disability.	
Muscle weakness*	Makes ADLs difficult to perform safely.	Horak et al. (2006)
Medications	Some researchers argue it is not depression but depression medication that causes falls; antipsychotics, psychotropics, benzodiazepines, diuretics, sedatives, digoxin, anti-arrhythmic drugs, anti-hypertensives; polypharmacy. Some researchers say there is no relationship between psychotropic medications and falls in stroke survivors. However, it was anxiety that was associated with falling; medications were not found to be associated with falling among stroke survivors. Stroke survivors taking anti-depressants had slightly greater odds for falling.	Bloch et al. (2011); Czemuszenko and Czlonkowska (2009); Dionyssiotis (2012); Kamińska et al. (2015); Martin (2011); Schmid et al. (2010)
Environmental (home) hazards	The cause of 50 per cent of falls.	Dionyssiotis (2012)
Lack of physical activity*	Elderly people are less active; atrophy of muscle	Dionyssiotis (2012)

	around an unstable joint develops.	
Performing ADLs*	Increased activity whilst having multiple risk factors for falls.	Batchelor et al. (2012); Cho, Yu and Rhee (2015); Dionyssiotis, 2012; Gazibara et al. 2016); Jaylondeja et al. 2014; Mackintosh et al. (2004); Schmid et al. (2013)
Falls efficacy*	Low perceived confidence in ability to avoid a fall; associated with balance impairment.	Hadjistavropoulos et al. (2011)
Chronic medical conditions	Elderly people with chronic medical conditions tend to have four or more risk factors for falls.	Dionyssitosis (2012)
Non-modifiable risk factors	**Comment**	**Authors**
Advanced Age	Older people are more at risk of falling due to muscle weakness, poor vision and chronic conditions.	Bird (2013); Chang and Do, (2014); Chu et al. (2005); Dionyssiotis (2012); Grundstrom, Guse and Layde (2012)
(Female) Gender	Women are at most risk of sustaining an injury following a fall due to osteoporosis.	Dionyssiotis (2012); Gazibara et al. (2016); Grundstrom et al. (2012)
History of falls	Once a person has fallen, if the causes have not been addressed, they are likely to fall again.	Chu et al. (2005); Kamińska et al. (2015); Mackintosh et al. (2004)

A fall prevention exercise programme may improve balance and reduce falls multi-fold by addressing multiple falls risk factors because according Gillespie et al. (2012), falls are multifactorial. Older people who fall may develop a fear of falling and thus experience unnecessary activity restrictions (Gazibara et al., 2016; Wallmann, 2009), increasing the risk of future falls (Chu, Chi & Chiu, 2005; Dionyssiotis, 2012). Among the general population who fall, up to 70 per cent develop a fear of falling (Dionyssiotis, 2012). According to Dueñas, Bernat, del Horno, Aguilar-Rodríguez and Alcántara (2016), the number of fallers who develop a fear of falling is 73 per cent within the previous year. Fear of falling can increase fall-risk in older adults (Young & Williams, 2014) and can be defined as "low perceived self-efficacy" (Tinetti, Richman & Powell, 1990) about balance (Pang & Eng, 2008). "Self-efficacy is the belief and confidence in one's ability to avoid a fall" (Hadjistavropoulos, Delbaere, & Fitzgerald, 2011), a concept based on the strong theoretical assumption of Bandura (1977) about the cognitive process which underlies emotions.

Another definition of fear of falling is 'an ongoing concern about falling that ultimately limits the performance of daily activities' (Lord et al., 2007). Fear of falling is associated with previous falls, poor health status, functional decline and frailty, and has been correlated to restriction and avoidance of activity, reduced quality of life, depression and social isolation (Lord et al., 2007). Fear of falling has been associated with balance impairment (Kumar, Carpenter, Morris, Iliffe & Kendrick, 2014). Balance impairment is a risk factor for falls (Campbell et al., 1981; Campbell et al., 1989; Campbell & Matthews, 2010; Chu et al., 2005; Graafmans, 1996; Horak, 2006; Kamińska, Brodowski, & Karakiewicz., 2015; Lamb, Ferrucci, Volapto, Fried & Guralnik, 2013; Morrison et al., 2011; Murphy, Dubin & Gill, 2003; O'Loughlin et al., 1993; Rubenstein, 2006; Wallmann, 2009). However, Morrison et al. (2011) found that impaired balance as a risk factor was not consistent across rehabilitation settings. The authors reported that balance impairment was not significantly associated with falls for those receiving inpatient rehabilitation. The authors acknowledged that this may be due to hospital procedures protocols in place to prevent falls in those who at high-risk. Balance impairment may be due to the inability to control balance and posture, which in turn leads to falling in the elderly (Wallmann, 2009). According to Horak (2006), balance impairment is caused by different things in different people, for example dizziness and muscle weakness. Therefore, Horak (2006) suggests that to improve balance, treatment must target the cause.

According to Biderman, Cwikel, Fried & Galinsky (2002), depression is associated with falls among the elderly. Some studies have demonstrated that depression in the general population, aged above 64 years, is a risk factor for falls (Friedman, Munoz, West, Rubin & Fried, 2002; Kvelde et al., 2013; Kojima et al., 2015; Sjösten, Vaapio & Kivelä, 2008; Turcu et al., 2004). Sheeren, Brown, Nassisi & Bruce (2004) found that geriatric patients with depression were nearly three times more likely to have a fall than those without depression. Tinetti, Doucette, Claus and Marottoli (1995) found a high score on depression, one of four predisposing factors for falls. However, the order of causation is unclear because depression may precede a fall, and vice versa. Biderman et al. (2002) suggest that a third factor may be involved and found that depression and falls are related to chronic medical conditions, particularly functional disability.

Kamińska et al. (2015) found that other researchers suggest that depression is not a risk of falls itself, but the administration of antidepressants that is the cause of falling. Indeed, a meta-analysis by Bloch, Thubaud, Dugué, Brèque and Kemoun (2011) confirms the association between psychotropic drugs and falls. Dionyssiotis (2012) also suggests that benzodiazepines and psychotropics increase the risk of falls, as well as diuretics and sedatives. The author also highlighted the use of digoxin and anti-arrhythmic drugs as contributing factors. The risk of falling further increases if four or more medications are taken (Dionyssiotis, 2012).

Figure 1 below highlights fall risk factors in the general population. Falls are often multifactorial (Gillespie et al., 2012) with the rate of falling increasing from 27 per cent for those with zero or one risk factor to 78 per cent for older people with four or more risk factors (Dionyssiotis, 2012). It is interesting to note that some of the risk factors shown in Figure 1 are linked. For example, some risk factors are associated with balance impairment and have been discussed above. How these risk factors are linked to stroke is shown in Figure 2.

Exposure to the environment plays an important part in falling (see Figure 1 and Figure 2) because it has been shown that between 30 per cent and 50 percent of falls are due to home hazards (Dionyssiotis, 2012). This means that if home hazards are reduced, the risk of falling has been greatly reduced. Fall risk can be reduced even further by addressing the remaining modifiable falls risk factors. Encountering home hazards often occur when individuals are performing ADLs. Exposure to ADLs is associated with falls, whether the individual experiences a deterioration or improvement in performing them (Stenhagen, Ekström, Nordell & Elmståhl, 2013).

Avoidance of ADLs may be due to fear of falling. In order to understand and reduce fear of falling, fear of falling needs to be measured. Falls efficacy is associated with and is a measurement of fear of falling (see Fig. 1 & 2) (Lord et al., 2007; Tinetti et al., 1990;). Falls efficacy has been defined as ‘low perceived self-efficacy of avoiding falls during essential, non-hazardous activities of daily living’ (Tinetti et al., 1990). Therefore, in order to find out if an exercise programme to reduce fear of falling reduces the risk due to this fall risk factor, falls efficacy needs to be measured.

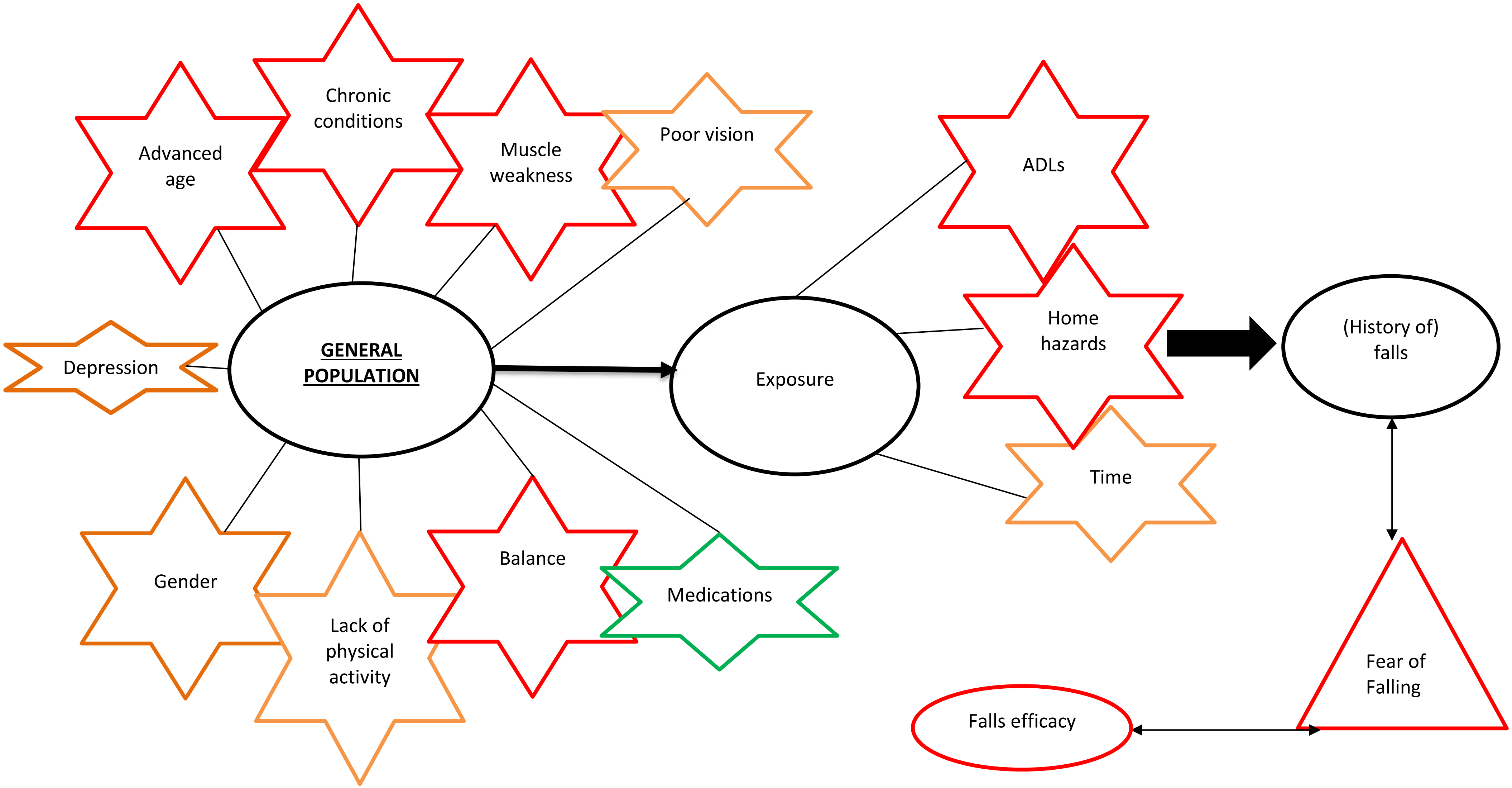


Figure 1 Fall risk factors in the general population

1.4.4. Fall risk factors and stroke survivors

Stroke survivors are more at risk of falls than the general population (Jørgensen, Engstad, & Jacobsen, 2002). Indeed, a high number of fallers were stroke survivors in a study by Homann et al. (2013) in which they were six times more likely to fall than a healthy elderly population. Although exposure to time plays a role in falling among the general population, it is extremely important for stroke survivors because the probability of falling persists some time beyond the initial stroke event, and this risk period covers an excess of six months (Forster & Young, 1995). More recent research by Jaylayondeja, Sullivan, & Pichaiyongwongdee (2014) has found that this risk period can be up to 12 months. Therefore, an exercise programme to prevent falls may be beneficial as early as possible from discharge from hospital.

Fall risk factors associated with stroke survivors are shown in Figure 2, with those specific to the consequences of stroke shown in the red box. Table 2 presents the evidence for risk factors among stroke survivors. Interestingly, balance impairment (due to risk factors associated with stroke) has been shown to be the risk factor most associated with falling during the post-stroke rehabilitation phase (Campbell & Matthews, 2010). Therefore, it seems that balance needs to be improved during the post-stroke rehabilitation phase.

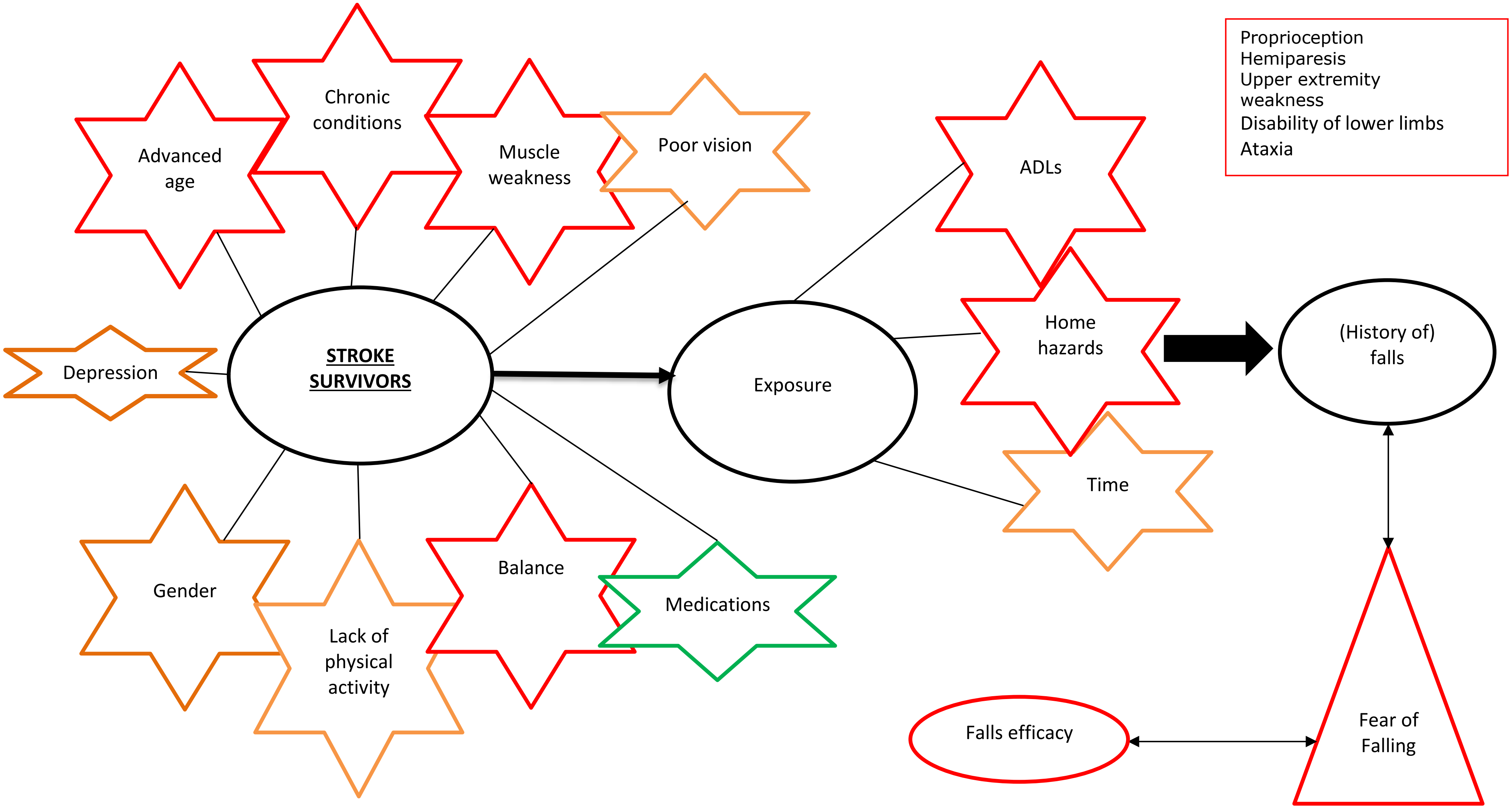


Figure 2 Fall risk factors for stroke survivors

Table 2 Fall risk factors associated with stroke

Fall risk factors associated with stroke	Comments	References
Hemiparesis	Sudden weakness on one side of the body; affects the ability to perform tasks due to deficient walking ability.	American Stroke Association (2016); Moreland et al. (2004); Salbach et al. (2004); Stroke Association (2014)
Upper extremity weakness	Arm raising may disturb balance resulting in displacement of the centre of mass with respect to the base of support.	Lamontagne et al. (2003)
Disability of lower limbs	Stroke survivors prefer to load more weight onto the non-paretic limb which is unable to compensate for the paretic limb.	Danells et al. (2013); Genthon et al. (2007); Kluding and Gajewski (2009); Mansfield et al. (2013)
Spasticity	Muscle tone is changed, developing into stiffness, making limb movement difficult.	Esquenazi, (2004); Soyuer and Öztürk, (2006); Stroke Association (2013); Tyson et al. (2008); Urban et al. (2010)
Proprioception	The sensorimotor system plays a part in maintaining stability. Damage to this causes loss of 'position sense.'	Bohannon, (2007); Carey (1995); Chu, Hornby and Schmit (2015); Jerosch and Prymka (1996); Niessen et al. (2008)
Ataxia	Leads to the inability to coordinate limbs.	National Stroke Association (2006)
Time	The probability of falling persists up to an excess of six months, which can be up to 12 months.	Forster and Young (1997); Jaylayondeja et al. (2014)

Cho, Yu, & Rhee (2015), Lamb et al. (2013), and Schmid et al. (2015) all agree that exposure to performing ADLs such as dressing, toileting, showering and performing household chores have been linked to balance impairment. Mackintosh, Goldie and Hill (2008) noted that performing ADLs involves complex movements such as stooping and kneeling, which may encourage a loss of balance and lead to a fall. Hence, stroke survivors who fall whilst performing ADLs may develop a fear of performing these activities again, and avoid ADLs (Jalayondeja et al., 2014). Thus, incorporating an exercise programme which improves the performance of ADLs may reduce falls in stroke survivors.

Once a fall has occurred, the risk of falling again is increased further due to a fear of falling. Fear of falling is further made problematic through time because it has been reported that fear of falling one month after stroke onset is the best predictor that a person is at high-risk of falling within five months after stroke onset (Jalayondeja et al., 2014). Although few studies have investigated fear of falling among stroke survivors in the community, with most recruiting participants from rehabilitation centres (Shinkel-Ivy, Inness & Mansfield, 2016) or hospital (Batchelor, Williams, Wijeratne, Said & Petty, 2015) these studies found that 32 to 38 per cent of stroke survivors reduced the frequency of ADLs because of fear of falling. A pilot study exploring fear of falling among ten stroke survivors found that the reason why stroke survivors who had a fear of falling without a history of falls is because fear of falling led them to become more conscious about falls risk (Schmid et al., 2015). However, the population used by the authors were independently mobile, and therefore were not at high-risk of falls. The authors acknowledge this and recommended future studies to only include stroke survivors with a Berg Balance score below 46. Participants were asked one question, requiring a yes/no response relating to fear of falling, which was, 'are you worried about falls?' This question is limited because fear of falling may not be always present, and participants may have given their answer based on that moment in time. Schinkel-Ivy et al. (2016) also used this single question as an outcome measure in their observational study of 208 participants with or without stroke. The authors found that 40 per cent (84 out of 208) of participants reported a fear of falling and suggested that fear of falling was related to balance confidence and depression. However, there was no difference between the experimental and control group. The answers obtained by Schinkel-Ivy et al. (2016) were achieved following the performance of three tasks, which may have increased confidence and reduced fear of falling, thus affecting the results. The question of how fear of falling among stroke survivors can be reduced needs to be addressed to reduce falls. Preventing falls as early as possible or getting fallers active in exercise may prevent a fear of falling and thus reduce falls. Hence, fear is a risk factor for falls and falls increase fear.

It has been discussed above that depression may be associated with fear of falling. Sheeran et al. (2004) found that geriatric patients with depression were nearly three times more likely to have a fall. Similarly, studies have demonstrated that depression, in the general population aged above 64 years, is a risk factor for falls (Friedman et al., 2002; Kojima et al., 2015; Kvelde et al., 2013; Sjösten et al., 2008; Turcu et al., 2004), as well as in stroke survivors (Sinyor et al., 1986). An exercise programme may therefore add an additional benefit of helping post-stroke depression, which may help to reduce falls.

To conclude, falls are multifactorial (Gillespie et al., 2012) and people with long-term conditions having four or more risk factors. However, home hazards as a fall risk factor are not very modifiable in practice through healthcare. If the impact of other modifiable factors, such as balance impairment, are reduced through exercise, people may be able to negotiate the home hazards better. Stroke survivors may experience balance impairment in more debilitating ways than the general population due to additional falls risk factors associated with stroke. If an exercise programme designed to reduce risk factors associated with falling is implemented, a proportion of falls may be prevented. The question now to ask is which exercise is the most suitable to address this problem.

1.5. Exercise after stroke

The term exercise has been used interchangeably with the term physical activity. Physical activity is defined as "any bodily movement produced by skeletal muscles that results in energy expenditure," and is related to movements that people perform (Caspersen, Powell & Christenson, 1985). Exercise is a subcategory of physical activity and can be defined as "planned repetitive physical activity structured to improve and maintain physical fitness" (Stedman, 2011, p.594). Being physically fit is defined as "the ability to carry out daily tasks with vigour and alertness, without undue fatigue and with ample energy leisure-time pursuits and to meet unforeseen emergencies" (Caspersen et al., 1985). For the purpose of this section, the term exercise shall be used to cover a range of physical activity that can be classed as exercise.

National guidelines support the evidence that exercise can be effective in improving physical fitness and function after stroke (Saunders, Grieg, Mead, & Young, 2009). In fact, the National Clinical Guidelines for Stroke state that all stroke patients should participate in aerobic training unless there are contraindications unrelated to stroke (RCP, 2016.) Further, it is recommended that aerobic exercise is incorporated into usual rehabilitation for stroke and should start immediately following discharge from physiotherapy (RCP, 2016). Moreover, exercise needs to be extended after stroke rehabilitation ends and become a lifelong activity (Scottish Intercollegiate Guidelines Network [SIGN], 2008). The RCP (2016) agree by advising all stroke patients to "take regular exercise as far as they are able: the aim should be to achieve moderate physical activity (sufficient to become slightly breathless) for 20-30 minutes each day." Additionally, the National Stroke Strategy states that "rehabilitation – support to regain well-being – requires rehabilitation specialists and continuing support from a wide range of community-based services such as exercises classes" (DH, 2008).

One concern with exercise after stroke is the risk of falling during exercise. However, the Falls Management Exercise (FaME) study showed that an exercise programme can be safely and effectively delivered to older people at risk of falls (Skelton, Dinan, Campbell & Rutherford, 2005). Before an exercise programme can be implemented, it is necessary to identify any barriers to exercise and put strategies in place to avoid any issues (Gordon et al., 2004).

It is recommended that, wherever possible, exercise after stroke rehabilitation should be delivered in a group rather than in individual sessions. Carin-Levy, Kendall, Young & Mead (2009) and Reed, Harrington, Duggan, & Wood (2010) found that stroke survivors are in favour of the social aspect of group exercise, and recommended that before each session, the exercise provider interacts with the stroke survivors and facilitates the social interaction between them. The authors recommended having social interaction at the end of each sessions along with refreshments being provided.

As discussed in the previous section, some falls risk factors are modifiable through exercise, such as balance impairment, muscle weakness, fear of falling, lack of physical activity, performing ADLs, falls efficacy and depression. Which exercise is the most suitable for stroke survivors to address the above-mentioned fall risk factors in order to improve balance and reduce falls? Table 3 below shows exercises used with stroke survivors, highlighting how they address falls risk factors. This table will be used to guide the following discussion aimed at determining which exercise is most suitable for this study.

Table 3 Exercises for stroke survivors and fall risk factors they address

Exercise	Outcomes	Fall risk factors addressed (see Fig. 2)	Comment	References
Aerobic exercise	-Functional balance -Fitness levels -Aerobic capacity -Cognition -Walking distance -Motor function	-Balance -Lack of physical activity -Muscle weakness	-Aerobic capacity increased. -Functional balance improved. -Cognition improved. -Motor function improved. -Walking distance improved.	An & Shaughnessy (2011); English et al. (2007); Meek et al. (2003); Quaney, Boyd & McDowd (2009); Saunders et al. (2004); Stoller et al. (2012); Tang et al. (2013); Weil (2017); Wist et al. (2016)
Repetitive task training	-Upper and Lower limbs -Walking -Walking speed -Walking distance -Functional gain -Balance -Strength	-Balance -Muscle weakness -Lack of physical activity -Hemiparesis	Most studies did not focus on balance. Training benefits were lost once exercise stopped. Improvements in walking speed and distance. Improved balance (non-significant) and strength.	English et Hilier (2010); Hesse et al. (2013); French et al. (2009); French et al. (2016); Weavers et al. (2009)
Strength training	Muscle weakness	-Muscle weakness -Lack of physical activity	Did not mention relationship between muscle weakness and balance. Improved upper and limb strength. Spasticity did not increase with exercise.	Ada et al. (2006); Bandura (1989); Bobath (1990); Engardt et al. (1995); Forster and Young (1995); Karatas et al. (2004); Morris et al. (2004); Mosby (2009); Sharp and Brouwer (1997); Weiss et al. (2000); Winstein et al. (1989)
Balance training	-Improved agility -Improve stability of gait -Asymmetrical weight-bearing -Weight-shifting exercises -Develops	-Muscle weakness -Proprioception -Balance efficacy -Lack of physical activity	Not enough evidence of optimum dose and frequency to prevent falls. Weight-shifting exercises used for static balance not dynamic balance. Improvement in balance self-efficacy.	Batchelor et al. (2012); Cabanas-Valdés et al. (2013); Mosby (2009); Tang et al. (2015)

	core muscle strength, ankle strength -Proprioception		Positive effects in reducing falls.	
Yoga	-Mindfulness -Mobility -Balance -Post-stroke -Fatigue -Quality of life	-Depression -Balance -Lack of physical activity	Focused on stress-relief and the changing of mind-sets. Balance was a minor focus.	Bastille and Gill-Body (2004); Chan and Woollacott (2007); Garrett, Immink and Hillier (2011); Grossman, Niemann, Schmidt and Walach (2004); Hofer et al. (2012); Johansson, Bjuhr and Ronnback (2012); John, Khanna and Kotwal (2010); Lazaradou et al. (2013); Lynton, Kligler and Shiflett (2007); McEwen, Polatajko, Huijbregts and Ryan (2009); Schmid et al. (2012); Yogapratap (2009); van Puymbroeck, Schmid, Miller and Schalk (2012)
Tai Chi	-Balance -Blood pressure	-Balance -Proprioception -Depression -Muscle weakness -Hemiparesis -Lack of physical activity -Fear of falling	Inexpensive. Need to be translated into the community. Mobility issues and transport cause a barrier. Improves quality of life. Associated with better balance, improved mood. It is safe for stroke survivors. More research is needed among stroke survivors.	Au-Yeung et al. (2012); Hempel et al. (2014); Liu et al. (2018); Stevens, Voukelatos and Ehrenreich (2013); Taylor-Piliae and Haskell (2007); Li et al., 2018b); Liu et al. (2019); Lyu et al. (2018); Taylor-Piliae et al. (2014); Wang et al. (2010); Wu et al. (2018); Yoshinaga and Cai (2013); Zhang et al. (2015)

1.5.1. Aerobic exercise

Aerobic exercise typically involves fast walking or running or requires the use of equipment such as treadmills and cycle ergometers. Despite evidence which shows machine-based aerobic exercise improves balance (Globas et al., 2012; Sauvage et al., 1992), the machines required to perform this exercise are very expensive and are not able to be used by stroke survivors at home. Therefore, machine-based aerobic exercise is not the most suitable exercise for this study.

1.5.2. Repetitive task training

Repetitive task training involves 'the active practice of task-specific motor activities' and is 'a component of current therapy approaches in stroke rehabilitation' (French, Moore, Pohlig & Reisman, 2016). According to Hesse et al. (2013), 'task-specific therapy can enable hemiplegic patients to practice walking repetitively, in contrast to conventional treatment in which tone-inhibiting manoeuvres and gait preparatory tasks during sitting and standing dominate'. Task-orientated circuit training was used in most studies, which is not suitable for performance in stroke survivors' homes. Although studies which included balance improvement as an outcome showed an improvement in balance, albeit insignificant, most studies did not focus on balance improvement (Hesse et al., 2013). Additionally, training effects stopped once the performance of the exercise stopped.

1.5.3. Strength training

Muscle strengthening exercises used in physiotherapy include repetitions of individually-prescribed exercises aiming to alleviate the effects of atrophy (Gray et al., 2012). A meta-analysis by Wist, Clivaz and Sattelmayer (2016) suggests that lower limb muscle strengthening among stroke survivors improves the strength in the lower limbs and balance. However the stroke survivors in the studies analysed approximately nine months post-stroke, rather than at the point of discharge from hospital. This may not be the optimal time because it is possible that during the nine months without exercise, deconditioning of the muscles has taken place. An exercise programme involving muscle strengthening may benefit stroke survivors to help improve balance.

Strength training aims to improve muscular strength by introducing resistance, thus stimulating the development of muscle strength, and has been researched because limb weakness is a frequent source of impairment and disability among stroke survivors (Mosby, 2009). Some researchers argue that strength training can improve muscle strength without increasing spasticity (Morris, Dodd & Morris, 2004). Therefore, if achievable, strength training may be good for stroke survivors. Hence, there may be a role for strength training early after stroke (Ada, Dorsch & Canning, 2006).

1.5.4. Balance training

Balance training includes exercises to improve one's agility and stability of gait (Mosby, 2009). There is moderate evidence that balance may be improved among stroke survivors following individual balance training, with two to three times weekly sessions recommended in the acute phase (Lubetsky-Vilnai, Anat & Kartin; 2010). Mansfield et al. (2018) showed that despite balance training having the potential to reduce falls, ongoing training is required to maintain the benefits.

Cheng et al. (2001) showed that symmetrical body-weight training in stroke survivors improved particpants' sit-to-stand performance, with body-weight being distributed more symmetrically in both legs, leading to a decreased number of falls. Stroke fallers were also reported by Cheng et al. (1998) to put less weight on their paretic limb than the non-fallers during sit-to-stand manoeuvre, and Liu et al. (2016) found in a pilot study that stroke survivors given sit-to-stand training reported an improvement in weight-bearing symmetry during sit-to-stand manoeuvre.

1.5.5. Yoga

Yoga is the adoption of specific body postures combined with breathing practices and meditation, aimed to calm the mind (Yogapratap, 2009). Most studies focus on mindfulness and stress-relief rather than on balance – although, balance was found to improve in some studies in a systematic review by Lazaridou and Tzika (2013). It is unclear to what extent balance did improve and which falls risk factors were addressed to gain optimum prevention of falls (Lazaridou et al., 2013). Despite Yoga showing a potential to improve balance in the general population (Ni et al., 2014; Saravanakumar, Higgins, van der Riet, Marquez & Sibbritt., 2015), there is not enough high-quality evidence to comment on the benefits and safety of Yoga in stroke rehabilitation (Lawrence et al., 2017).

1.5.6. Tai Chi

Most falls among high risk older adults occur at home whilst performing tasks such as cleaning, opening or closing doors, bathing, and getting in and out of cars (Stevens, Mahoney & Ehrenreich, 2014); these tasks involve leaning in different directions and moving the arms, which may cause the individual to lose their balance. Therefore, it is important that potential fallers maintain their balance through mindfulness of their posture and arm position whilst performing tasks. Tai Chi is a branch of Chinese martial arts that involves slow repetitive gentle movements (Liao, 2017). It involves mindfulness and awareness of where the body is in relation to the environment. Importantly, mindfulness and awareness are present during weight shifting and stepping. Thus, Tai

Chi may be more plausible than Yoga and other alternative exercises. There is no definitive reason as to why Tai Chi may be more plausible, but it seems that Tai Chi has the potential to improve balance and reduce falls in stroke survivors by maintaining an awareness of where the body is in relation to the environment and being aware of each movement (Jimenéz-Martin, Meléndez-Ortega, Albers & Schofield, 2013). Thus, the most plausible mechanism of action for an improvement in balance is proprioception. Some studies have shown potential for Tai Chi to improve balance and reduce falls among stroke survivors, but the evidence is limited (Li et al., 2018b; Lyu et al., 2018; Wu et al., 2018). As well as proprioception, Tai Chi might address a further five of the modifiable fall risk factors for stroke presented in Figure 2 and Table 3 (muscle weakness, lack of physical activity, balance, fear of falling, and depression). There is some existing evidence on each of these factors. According to the evidence presented in Table 3, Tai Chi may improve balance in stroke survivors (Li et al., 2018b; Lyu et al., 2018; Wu et al., 2018).

Yoshinaga and Cai (2013) suggest that the mechanisms through which balance improves among stroke survivors practising Tai Chi are by strengthening the core of the body and symmetrical distribution of the centre of gravity which in turn improves muscle strength. Some researchers suggest that Tai Chi may improve balance in stroke survivors through improvement of proprioception (Ding, 2012; Zhang et al., 2015). Previous studies have shown that physical activity is an important part of stroke rehabilitation to reduce disabilities, as well as promoting spontaneous neural functional recovery and regaining brain function in cerebral apoplexy. Thus, effective interventions for improving physical function are needed (Wu et al., 2018). Tai Chi is a form of physical activity which has been shown to improve physical function, incorporating the performance of ADLs, strength improvement, flexibility, co-ordination and balance all in one workout (Lyu et al., 2018). Evidence also suggests that depression may be improved in stroke survivors following Tai Chi Taylor-Piliae and Haskell, 2007; Wang et al., 2010; Zhang et al., 2015). Few studies have explored fear of falling and falls among stroke survivors following Tai Chi. However, recent meta-analyses have been conducted on Tai Chi and falls (Winser, Tsang, Krishnamurthy & Kannan, 2018; Liu et al., 2019). Despite the evidence for Tai Chi and falls among stroke survivors being limited, this area deserves further study. Therefore, the current study will explore fall reduction as a primary outcome with balance improvement as a secondary outcome, with additional outcomes for depression and fear of falling.

Another reason why Tai Chi would be appealing for this study is because it is inexpensive and does not require specialist equipment but does require specialist instruction. It is also an exercise that can be practised at home. Therefore, Tai Chi seems to be the most appropriate exercise of all those common types itemised in Table 3.

There is a variety of different exercises that may address the needs of stroke survivors during rehabilitation: aerobic exercise, repetitive task training, strength training, balance training, Yoga and Tai Chi. Although the above exercises address some of the modifiable falls risk factors among stroke survivors, they have limitations and characteristics (e.g. they require specialist equipment or not capable of being practiced at home) that make them unsuitable for stroke survivors. In principle, Tai Chi addresses most, if not all, modifiable falls risk factors among stroke survivors. Limited research on Tai Chi amongst stroke survivors is promising, with the additional benefit of being low-cost without requiring any specialist equipment. After reviewing what exercises are available for stroke survivors, it has been concluded that Tai Chi appears to be the most suitable exercise for this study.

Reflections

Stroke is a leading cause of disability (RCN, 2016), and there is an increasing demand on NHS services from the increasing number of stroke survivors. Disability is not just a health problem but also a medical one (WHO, 2018a). Activity limitation is one factor affecting the ability of stroke survivors to perform ADLs. Additionally, stroke survivors experience a lack of involvement in social activities, such as leisure. A barrier to activities such as leisure has been found to be lack of transportation and social provision, posing a problem when wanting to offer an exercise programme to stroke survivors. Balance impairment among stroke survivors is often the reason for barriers to activities, and is a major falls risk factor, which is linked to other modifiable falls risk factors. Stroke survivors are prone to having four or more of these falls risk factors. Therefore, an exercise programme for stroke survivors should address as many of these falls risk factors as possible to gain optimum falls prevention. There is a variety of possible exercises available for stroke survivors, but many are not suitable for a variety of reasons. Tai Chi addresses many, if not all, modifiable falls risk factors, and has the additional appeal of being inexpensive without requiring specialist equipment. Therefore, a literature review will be conducted in Chapter 2 to establish what evidence there is to support Tai Chi as an exercise, targeting fall prevention for stroke survivors, as well as to establish any gaps in evidence.

Chapter 2 – Tai Chi Literature Review

2.1. Introduction

The aim of this literature review is to understand the evidence regarding Tai Chi for reducing falls as well as improving balance and quality of life in stroke survivors. The literature discussed in this review is non-exhaustive because of time restrictions. However, the articles included are central and pivotal to the field of Tai Chi regarding falls, balance and stroke. Identified are the empirical, theoretical and methodological insights associated with the effect of Tai Chi on falls and balance, which, in turn, have a potential impact on quality of life.

2.2. The search strategy

The data collection process began with an electronic search of the academic databases PubMed, Medline, Pedro, PsycInfo, BioMedCentral and Cochrane.

The date of each search, databases searched, key words, key word combinations used, along with the number of records resulting from each search can be found in the search strategy tables in Appendix 1. The keywords used for the search were: 'stroke,' 'cerebrovascular,' 'tai chi,' 'taiji,' 'tai ji,' 't'ai chi,' 'fall*,' 'balance' and 'quality of life.'

A total of 17,826 studies was retrieved using the above key words over various searches between 2015 and 2018. To strategically manage this large volume of literature, 'linked full text' or 'linked free text' was applied to the search. Additionally, inclusion and exclusion criteria were applied. Studies included in the literature review were included if they met the following criteria:

- the article is from a peer-reviewed journal
- the article was available
- participants were based in the community
- Tai Chi was the intervention
- falls, balance or quality of life were outcomes
- the population had a degree of balance impairment
- usual care was normal daily activities or usual therapy
- articles were in English
- articles with the most comprehensive reporting were used if multiple articles of one study

Studies were excluded if:

- the population did not have a degree of balance deficit (cancer, chronic heart failure, relatively healthy, COPD, fibromyalgia)
- the control group was another intervention (unless exercise was stretching, breathing or usual physiotherapy)
- the purpose of the study was stroke prevention
- the general elderly population used was relatively healthy
- upper limb improvement was the focus of the study

Subsequently, relevant studies were identified if they were relevant and suitable to the topic. This was done by screening the title for a combination of the following terms: 'tai chi', 'stroke', 'fall*', 'balance' and 'quality of life'.

Evidence sources are ranked on a hierarchy of evidence according to the strength of the evidence they provide. The hierarchy of evidence is graded from the highest level (one) to the lowest (seven) (Burns, Rohrich & Chung, 2011). The higher up on the hierarchy, the more likely the evidence will provide reliable answers to the research question (Melynk & Fineout-Overholt, 2011). However, the appropriate hierarchy level of evidence depends on the nature of inquiry (Polit & Beck, 2017). Level two evidence are the best choice to find out the efficacy of an intervention (in this case Tai Chi) because they involve RCTs which include randomisation, and thus an ability to control bias. However, there are poorly conducted RCTs (Burns et al., 2011). Even stronger evidence are summaries of the best current randomized controlled trials, known as systematic reviews (level one on the hierarchy of evidence). Systematic reviews are conducted by carefully synthesising multiple studies, the strongest being a synthesis of RCTs (Polit & Beck, 2017). Meta-analysis is also at the top of the hierarchy but integrate quantitative findings statistically rather than narratively (Polit & Beck, 2017).

Evidence sources become less reliable the further down the hierarchy they are (Polit & Beck, 2017). However, should there be a lack of systematic reviews and RCTs on which to base decisions on treatments, evidence from qualitative studies, despite being lower down on the hierarchy of evidence, should be considered when making clinical decisions (Melynk & Fineout-Overholt, 2011). Therefore, articles high on the hierarchy of evidence were searched. Searching for articles high on the hierarchy of evidence also removes the high volume of literature retrieved during the search because the search excludes newspaper articles, books and reports.

The highest quality evidence should be critically appraised before implementing evidence-based practice in healthcare settings (Polit & Beck, 2017). However, due to the low amount of evidence high on the hierarchy, evidence in the middle of the hierarchy or not included on the hierarchy at all will be included in the review (Melynk & Fineout-Overholt, 2011). Therefore, also included in this review are pilot studies for prospective RCTs (not graded on the hierarchy of evidence). These are included because they represent a fundamental phase of the research process, and inform the researcher of the feasibility of an approach intended to be used in a larger scale study, such as recruitment, randomization, retention, methods and the implementation of the intervention (Leon, Davis & Kraemer, 2011). Other evidence used in the literature review are one quasi-experimental study (level three on the hierarchy of evidence), intervention designs (ungraded on the hierarchy), cross-sectional studies (ungraded on the hierarchy), and one qualitative study (Level six on the hierarchy of evidence) (Polit & Beck, 2017).

Evidence collated was synthesised to identify:

- the main methodologies and outcome measures used and how they differ
- methodological strengths and weaknesses
- how Tai Chi has been applied as an intervention (intensity/duration, setting, style, delivery, home practice)
- any adverse effects or barriers to Tai Chi
- the most appropriate time to start Tai Chi following a stroke
- the methods of analysis (it is necessary to evaluate the research methods used in the past and to establish the best method to utilise for a future study)
- the findings, integrate and generalise them, thus drawing conclusions
- recommendations for further research

The potentially relevant studies were separated from the irrelevant studies by reading the titles. If titles hinted at containing the above concepts but did not contain the keywords, the abstracts were read to determine if the articles were relevant or not. Once articles were retrieved from the above databases, reference lists found in the articles were searched to find further relevant articles. In turn, the references from those articles were searched until a point of saturation was reached.

In total, 345 relevant articles were identified by title, dating from 1996 to 2019. After reading the abstracts, 254 of these articles were eliminated because they did not meet the inclusion/exclusion criteria listed above. Therefore, a total of 67 articles were included in this literature review. Figure 3 presents the PRISMA diagram for the search:

PRISMA 2009 Flow Diagram

Systematic Search for “Tai Chi” using

Medline, PubMed, BioMed Central, PEDro and PsychInfo

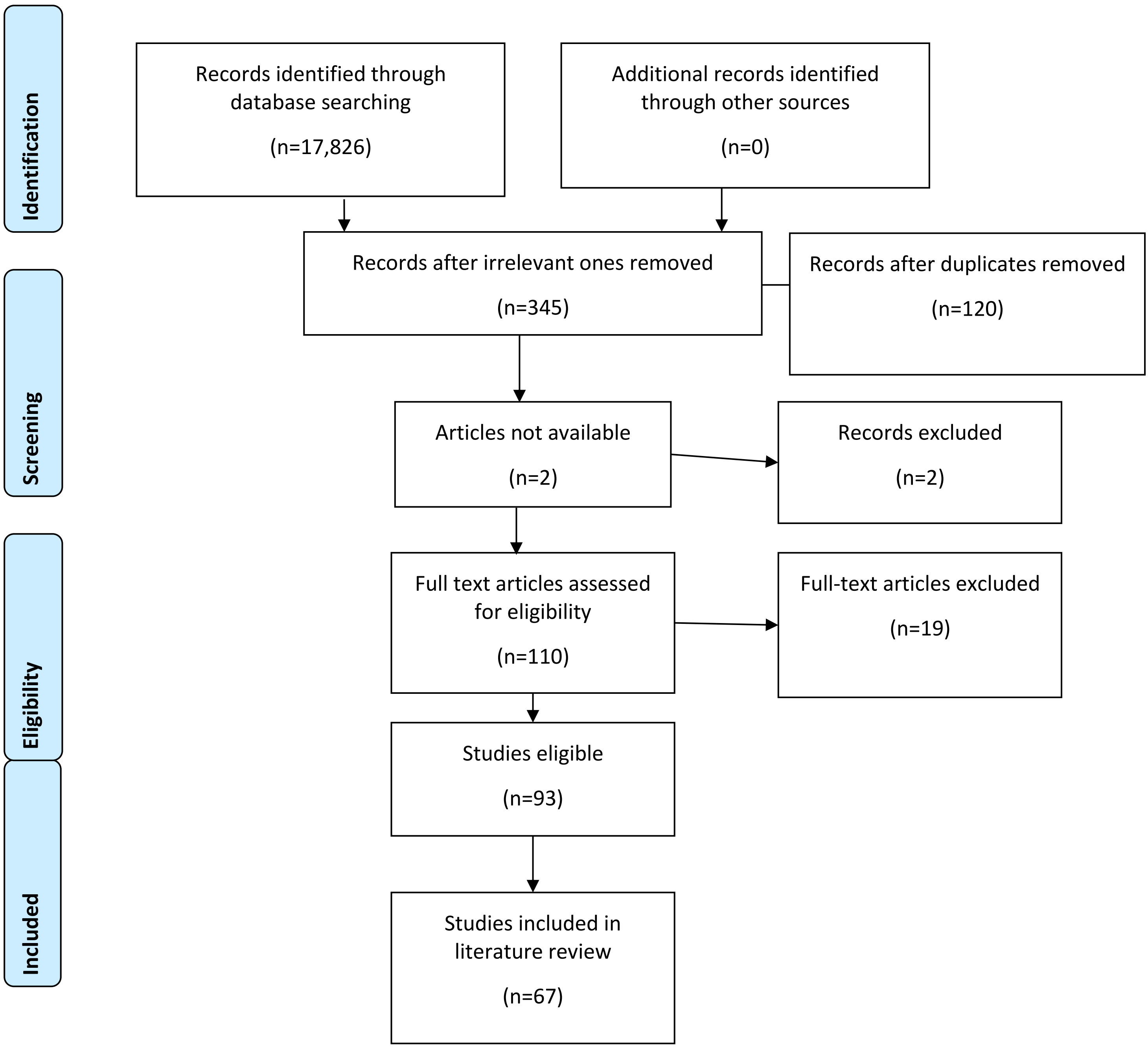


Figure 3 PRISMA 2009 flow diagram

Once all the relevant articles were identified for the review, articles were critically appraised. Li et al. (2012) conducted a systematic review on the quality of reporting RCTs in Tai Chi interventions. The authors found sub-optimal reporting quality. Similarly, Zhang et al. (2015) reported that the quality of existing studies is below standard and do not meet CONSORT guidelines. The least reported items were details of the Tai Chi intervention, method of randomisation and blinding, recruitment criteria, and sample size determination. According to the authors, the intervention should be described clearly and concisely to facilitate comparison and its relocation by other researchers. It was found that stroke studies failed to describe clearly the Tai Chi intervention or style. Therefore, each RCT was critically appraised using the CONSORT statement. Other designs were appraised using the Critical Appraisal Skills Programme [CASP].

In summary, specific key words and key word combinations were searched in various databases to yield articles within the higher end of the hierarchy of evidence. These papers are central and pivotal to the empirical and methodological insights into the impact of Tai Chi on falls, balance and quality of life in stroke survivors.

2.3. Limitations of the search

The Allied and Complementary Medicine Database [AMED] provides a collection of scientific, technical and medical information, including international papers. Some papers are even unique to this database. While it would be a valuable database to access for the purpose of this literature review, unfortunately neither the University of Huddersfield nor the NHS databases available at the hospital could offer access to AMED. The limitation of not having access to the AMED database was partially overcome by some of the retrieved reviews having included AMED as well as Chinese databases in their searches.

Another limitation of the literature review in this thesis is the inclusion of only English-language papers, which introduces language bias (Morrison, Polisena, Husereau & Moulton, 2012; Rasmussen & Montgomery, 2018). Tai Chi has been practised in China for thousands of years. Thus, it is not surprising that China conducts a lot of research around this exercise. Hence, it is expected that there are numerous inaccessible studies regarding Tai Chi in the Chinese databases. The researcher made attempts to contact the many Chinese students based at the University of Huddersfield regarding access to Chinese databases and the willingness to help translate any papers retrieved. However, this was to no avail. Rasmussen and Montgomery (2018) suggest that the exclusion of non-English studies in reviews is because of lack of resources, thus risking the exclusion of key data and resulting in language bias.

It has been argued that many researchers working in non-English speaking countries publish their research in local journals (Dickersin, Scherer & LeFevre, 1994) but are more likely to report positive findings in English-speaking journals (Egger et al., 1997). More studies are being published in the English language by international researchers, diminishing the extent and effects of language bias, especially German-language RCTs (Galandi, Schwarzer & Antes, 2006). The potential impact of non-English studies being published may be minimal as far as meta-analyses are concerned (Higgins & Green, 2011). However, it is uncertain to what extent language bias is introduced for systematic reviews (Higgins & Green, 2011).

The search approach was to include meta-analyses and systematic reviews but, so as not to rely entirely on reviews, original studies were included in the present review. Meta-analyses may contain a small number of poor-quality studies or studies with an outcome favourable to the reviewers, introducing publication bias. This is particularly so when the analyst is not an expert and only reports the overall outcome rather than considering heterogeneity. Similarly, research with negative results does not always get published, and is left out of reviews. Therefore, caution is needed when considering the reliability of results because the review can only be as good as the papers it is analysing (Mallett, Hagen-|Zanker, Slater, & Duvendack, 2012).

To reduce language bias, meta-analyses and systematic reviews included in the current literature review include articles retrieved from the AMED and Chinese databases. There may be, however, some risks and limitations of relying on review articles as a primary source, such as the reliance upon the reviewers' limited language skills rather than the support of professional translators due to a lack of resources (Rasmussen & Montgomery, 2018). It may be that the Google Translate service was used in some systematic reviews. A 2012 study assessing the accuracy of Google Translate when used for translating non-English studies concludes that caution was needed using this service for this purpose (Jackson et al., 2019). Despite a recent update which included improved accuracy (Jackson et al., 2019), there may still be some inaccuracies when using Google Translate for non-English studies.

Another limitation of systematic reviews is subjectivity during the screening process by different reviewers; multiple reviewers may interpret the inclusion criteria slightly differently (Mallett et al., 2012). Another limitation of systematic reviews relates to the difficulty of reviewing studies which involve complex interventions and make them difficult to analyse (Mallett et al., 2012). Thus, recommendations cannot be made, and reviewers may assert that more research is needed.

To increase the confidence in the accuracy of the review papers used in the current thesis, the CASP tool for systematic reviews was utilised for each review so that satisfaction could be achieved in terms of being reliable by fulfilling the CASP criteria, such as including RCTs, including non-English RCTs, offering reasons for the variation in results, results being similar from study to study, and the papers having multiple independent reviewers.

2.4. Findings from the search

Previous literature which have focused on relatively independent people were not included in the current review. Although Tai Chi seems to be effective in reducing falls in the general elderly population, there are still some questions that need answering before deciding whether it would be an effective exercise to reduce falls and improve balance in stroke survivors. Thus, Tai Chi studies were searched if they included falls, balance and stroke according to the above inclusion and exclusion criteria. Table 4 presents the results of the search.

Table 4 Results of the search

TAI CHI STUDIES				
Type of study	**Falls**	**Balance**	**QoL**	**Stroke**
Meta-analyses	Liu et al. (2019); Lomas-Vega, Obrero-Gaitán, Ortega and Del-Pino-Casado (2017)	Liu et al. (2019); Wu et al. (2018); Yan et al. (2018); Zou et al. (2018a)	Wang et al. (2015)	Li et al. (2017); Wang et al. (2015); Wu et al. (2018); Yan et al. (2018); Zou et al. (2018a)
Meta-analysis and systematic reviews	Huang, Feng, Li and Lv (2016); Winser et al. (2018)	Chen et al. (2015); Huang and Liu (2014); Ni et al. (2014); Winser et al. (2018); Yang et al. (2014)		Chen et al. (2015); García-Rudolph, Pinsach, Salleras and Tormos (2019); Ge et al. (2017); Lyu et al. (2018); Winser et al. (2018)
Systematic reviews		Ćwiękała-Lewis, Gallek and Taylor-Piliae (2016); Jiménez-Martin,	Ćwiękała-Lewis et al. (2017); Lee, Pittler and Ernst (2007); Li,	

		Meléndez-Ortega, Albers and Schofield (2013); Maciaszek and Osiński (2010)	Yuan and Zhang (2014); Toh et al. (2013)	
RCTs	Gao et al. (2014); Hosseini et al. (2019); Hwang et al. (2016); Li, Harmer, Fisher and McAuley (2004); Li et al. (2018); Logghe et al. (2009); Mortazavi et al. (2018); Taylor et al. (2012); Taylor-Piliae et al. (2014a); Tousignant et al. (2013); Wolf et al. (2003)	Au-Yeung et al. (2009); Gao et al. (2014); Hosseini et al. (2018); Hwang et al. (2016); Kim et al. (2015); Li et al. (2004); Li et al. (2012); Logghe et al. (2009); Zeng et al. (2014)	Kim et al. (2015); Liao and Tan (2019); Tajik et al. (2018); Taylor-Piliae et al. (2014a)	Au-Yeung et al. (2009); Chan and Tsang (2018); Kim et al. (2015); Taylor-Piliae et al. (2014a); Wang et al. (2010), Xie et al. (2018)
Cross-sectional studies		Hakim et al. (2010)		
Pre-test/post-test	Gallant et al. (2017)	Burschka et al. (2014); Hain, Fuller, Weil and Kotsias (1999)		
Pilot studies		Hackney and Earhart (2008); Hart et al. (2004); Pan et al. (2017)	Hart et al. (2004)	Chan and Tsang (2017); Hart et al. (2004); Pan et al. (2017); Taylor-Piliae and Coull (2012)
Qualitative studies		Desrochers et al. (2017)		Desrochers et al. (2017)
Literature reviews		Choi et al. (2013); Ding (2012)	Fetherston and Wei (2011)	Chen (2018); Ding (2012); Fetherston and Wei (2011); Lan, Chen, Wong & Lai

				(2013); Wahbeh, Elsas & Oken (2008); Yoshinaga and Cai (2013); Zhang et al. (2015)	
Protocols	Zhong et al. (2019)	Tao et al. (2015); Tousignant et al. (2014); Zhong et al. (2019)		Tao et al. (2015); Tousignant et al. (2014); Yang et al. (2018); Zhang et al. (2014)	
TOTAL	17	33	11	32	93
Total without duplicates	67				

The aims of the studies reviewed can be found in the synthesis tables in Appendix 2, along with outcome measures used, sample size, details of the intervention and statistical tests.

Strength of the evidence

All studies included in the reviews retrieved from the databases are listed in Table 5. Lomas-Vega, Obrero-Gaitńan, Molina-Ortega and Del-Pino-Casado, (2017) felt that there was a need for a review focussing on fall prevention in older adults and conducted a meta-analysis, which included ten RCTs.

Table 5 Table to show the studies included in the reviews retrieved from the literature search

Studies included in the meta-analyses, systematic reviews and literature reviews	
Meta-analyses	
Chen et al. (2015)	Au-Yeung et al. (2009); Hart et al. (204); Taylor-Piliae et al. (2014); Xie et al. (2008); Yang et al. (2013); Zhou et al. (2013)
Huang, Feng, Lee and Lv. (2016)	Chyu et al. (2010); Day et al. (2015); Faber et al. (2006); Gao et al. (2014); Li et al. (2005); Li et al. (2012); Taylor-Piliae and Coull (2011); Taylor-Piliae et al. (2014); Tousignant et al. (2013); Voukelatos et al. (2007); Woo et al. (2007); Wolf et al. (2003); Zeng et al. (2009)
Huang and Liu (2014)	Gao et al. (2014); Li et al. (2005); Li et al. (2007); Quigley et al. (2014); Taylor et al. (2012); Tousignant et al. (2012)
Li et al. (2017)	Au-Yeung et al. (2009); Fu et al. (2016); Gao et al. (2012); Kim et al. (2015); Liu et al. (2009); Taylor-Piliae and Coull (2012); Miu et al. (2014); Taylor-Piliae e al. (2014); Yang et al. (2013); Xu et al. (2014); Xie (2008); Yang et al. (2016); Zheng et al. (2015); Zhou et al. (2010); Zhou et al. (2013); Zhou et al. (2015)
Li, Wang, Liang & Zhang (2018)	Au-Yeung et al. (2009); Hart et al. (2004); Kim et al. (2015); Taylor-Piliae and Coull (2012); Taylor-Piliae et al. (2014)
Liu et al. (2019)	Choi et al. (2013); Gao et al. (2014); Hackney and Earhart (2008); Li et al. (2012); Zhu et al. (2011)
Lomas-Vega et al. (2017)	Faber et al. (2006); Logghe et al. (2009); Taylor et al. (2012); Tousignant et al. (2013); Woo et al. (2007); Voukelatos et al. (2007)
Lyu et al. (2018)	Au-Yeung et al. (2009); Hart et al. (2004); Kim et al. (2015); Li et al. (2011); Liu et al. (2009); Miu et al. (2014); Taylor-Pilae and Coull. (2011); Taylor-Piliae et al. (2014); Wang et al. (2010); Xie et al. (2008); Zhou et al. (2013); Yang et al. (2013)
Ni et al. (2014)	Choi et al. (2013); Gladfelter et al. (2011); Hackney (2008;2009); Li et al. (2011); Li et al. (2012); Li et al. (2013); Nocera et al. (2013); Zhu et al. (2011)
Wang et al. (2015)	An et al. (2008); Barrow et al. (2007); Blake et al. (2009); Cai et al. (2010); Chen et al. (2008); Chen et al. (2013); Cheung et al. (2005); Chyu et al. (2010); Fang et al. (2014); Fransen et al. (2007); Gemmell et al. (2006); Guan et al. (2012); Haak et al. (2008); Hart et al. (2004); Ji et al. (2012); Lam et al. (2008); Lee et al. (2009); Li et al. (2010); Li et al. (2012); Li et al. (2013); Liu et al. (2012); Meng et al. (2014); Ng et al. (2011); Park et al. (2014); Putiri et al. (20120; Rendant et al. (2011); Robins et al. (2013); Shen et al. (2010); Singh-Grewal et al. (2007); Skoglund et al. (2011); Sprod et al. (2012); Stephens et al. (2008); Sun et al. (2014); Taylor-Piliae and Coull (2012); Trott et al. (2009); Tsang et al. (2003); Tsang et al. (2007); Wang et al. (2008); Wang et al. (2009); Wang et al. (2010); Wang et al. (2012); Wang et al. (2013); Wang et al. (2014); Wayne et al. (2012); Wei et al.

	(2014); Wenneberg et al. (2004); Wu et al. (1999); Wu (2012); Yang et al. (2005); Yeh et al. (2010); Yeh et al. (2011); Yeh et al. (2013); Zhou et al. (2014)
Wu et al. (2018)	Huang et al. (2016); Kim et al. (2011); Taylor-Piliae and Coull (2012), Taylor-Piliae et al. (2014); Zhou et al. (2010)
Yang et al. (2014)	Amano et al. (2013); Choi et al. (2013); Cheon et al. (2013); Gao et al. (2014); Hackney (2008); Li (2011)
Zou et al. (2018)	Kim et al. (201); Schmid et al. (2012); Taylor-Piliae et al. (2014); Yang et al (2013); Zhang et al. (2017); Zhou et al. (2015)
Meta-analyses and systematic reviews	
Chen et al. (2015)	Au-Yeung et al. (2009); Bai et al. (2011); Hart et al. (2004); Jia et al. (2008); Taylor-Piliae et al. (2014); Zhang et al. (2013); Zhou et al. (2013); Yang et al. (2013); Xie et al. (2008)
García-Rudolph et al. (2019)	2 Tai Chi papers=Lyu et al. (2018a) and Lyu et al. (2018b)
Ge et al. (2017)	Au-Yeung et al. (2009); Bai et al. (2011); Cai et al. (2011); Fu et al. (2016); Gao et al. (2012); Guo et al. (2013); Huang et al. (2016); Jia et al. (2008); Jiao et al. (2011); Kim et al. (2015); Li et al. (2011); Li et al. (2012); Liu et al. (2009); Taylor-Piliae and Coull (2012); Taylor-Piliae et al. (2014); Wang et al. (2014); Wang et al. (2016); Yang et al. (2013); Yang et al. (2016); Xie et al. (2008); Xu et al. (2014); Zhang et al. (2013); Zhang et al. (2015); Zhang et al. (2016); Zheng et al. (2013); Zheng et al. (2015); Zhou et al. (2010); Zhou et al. (2013); Zhou et al. (2015)
Lyu et al. (2018)	Au-Yeung et al. (2009); Fu and Zhang (2016); Hart et al. (2004); Huang et al. (2016); Kim et al. (2015); Li et al. (2011); Liu et al. (2009); Miu et al. (2014); Taylor-Piliae and Coull (2012); Taylor-Piliae et al. (2014); Wang et al. (2010); Wang et al. (2016); Xie et al. (2008); Yang et al. (2013); Yang et al. (2016); Yu et al. (2015); Zhao et al. (2017); Zheng et al. (2015); Zhou et al. (2013); Zhou et al. (2015)
Winser et al. (2018)	Au-Yeung et al. (2009); Choi et al. (2013); Gao et al. (2014); Hackney and Earhart (2008); Kim et al. (2015); Li et al. (2012); Taylor-Piliae et al. (2014); Zhang et al. (2015); Zhu et al. (2011)
Systematic Reviews	
Ćwiękała-Lewis et al. (2017)	Amano et al. (2013); Cheon et al. (2013); Choi et al. (2013); Gao et al. (2014); Hackney and Earhart (2008;2009); Kim et al. (2011); Kim et al. (2014); Li et al. (2007); Li et al. (2012; 2014); Nocera et al. (2013)
Jiménez-Martin et al. (2017)	(no years stated for most papers reviewed) Gatts and Woollacott; Hackney and Earhart; Lelard et al.; Li et al.; Ramachandran et al.; Taylor and Coull; Taylor-Piliae et al. (2014); Taylor et al.; Voukelatos et al.; Wolfson et al.; Woo et al.; Xu et al.; Yan et al.; Zhang et al.
Lee, Pittler and Ernst (2007)	No authors cited

Li, Yuan and Zhang (2014)	Barrow et al. (2007); Caminiti et al. (2011); Chan et al. (2010); Wang and Liu (2013); Yeh et al. (2008; 2010; 2011; 2013)
	Kirsteins et al. (1991); Lee et al. (2005;2006); Wang et al. (2005)
Li et al. (2018)	Au-Yeung et al. (2009); Hart et al. (2004); Kim et al. (2015); Taylor-Piliae and Coull (2011); Taylor-Piliae et al. (2014)
Toh (2013)	Amano et al. (2013); Hackney and Earhart (2008); Hackney and Earhart (2009); Kim et al. (2011); Kluding and McGinnis (2006); Li et al. (2007); Li et al. (2012); Venglar et al. (2005)
Maciaszek and Osínski (2010)	Choi et al. (2005); Faber et al. (2006); Li et al. (2004); Li et al. (2007); Nnodim et al. (2006); Tsang et al. (204); Tsang and Hui-Chan (2003); Wolf et al. (2003); Wong et al. (2001); Woo et al. (2007)
Literature Reviews	
Ding (2012)	unclear
Lan et al. (2013)	Au-Yeung et al. (2009); Barrow et al. (2007); Caminiti et al. (2011); Hart et al. (2004); Redwine et al. (2012); Taylor-Piliae and Coull (2012); Wang et al. (2010); Yeh et al. (2004; 2008; 2011; 2013)
Yoshinaga and Cai (2013)	26 studies (11 in English, 15 in Chinese)
Zhang et al. (2015)	unclear

In the meta-analysis by Huang, Feng, Li & Lv, (2016) who aimed to review the preventive effect of Tai Chi on falls, eighteen RCTs were included. Among them was one RCT which included a focus on fall prevention which did not find any significant effects of Tai Chi among the experimental group (Logghe et al., 2009). Other studies in the meta-analysis which evaluated falls which found positive results were by Li et al. (2004), Tousignant et al. (2013), Hwang et al. (2016) and Taylor-Piliae et al. (2014a).

2.4.1. Tai chi and falls

Heterogeneity

Most meta-analyses reviewed in this thesis concluded that heterogeneity was moderate or high, suggesting the studies contain a diversity of different interventions and outcome measures; if different studies contain diverse interventions and outcome measures, it is difficult to compare methodologies and results. For example, finding out the optimum dose of Tai Chi would not be possible. This diversity of study characteristics is referred to as 'heterogeneity'. Very low heterogeneity was found in the results of individual studies in the review by Lomas-Vega et al. (2017), whereas heterogeneity was found to be moderate to high in the reviews by Huang et al. (2016) and Liu et al. (2019). Huang et al. (2016), therefore, conducted a sub-group analysis to evaluate the estimated effect in subgroups according to the above variations. A meta-analysis by Winser, Tsang, Krishnamurthy and Kannan (2018) found that heterogeneity existed in the style, forms, frequency and duration of Tai Chi. None of the authors found it possible to recommend an optimum duration frequency and intensity of Tai Chi.

Sensitivity analysis

To determine how robust an assessment of studies is, the sensitivity of the output to which results are affected by change in methods is analysed. A sensitivity analysis was conducted by Huang et al. (2016) and Lomas-Vega et al. (2017). Lomas-Vega et al. (2017) conducted a sensitivity analysis to assess the contribution of the studies to the pooled estimate in each meta-analysis, and to assess the differences in the results of the sub-group analysis.

Sensitivity analysis did not show any major influence on the primary meta-analysis results (Lomas-Vega et., 2017). Huang et al. (2016) conducted a sensitivity analysis according to sample size and co-morbidity. Any arbitrary characteristics such as Tai Chi dose and missing data were, therefore, accounted for when producing findings. Winser et al. (2018) did not perform a sensitivity analysis because meta-analyses were only performed on two to four studies.

Randomization

Randomized controlled trials are high on the hierarchy of evidence in which people are randomly allocated to receive one of several interventions. Random allocation means that chance alone played a part as to which group participants are assigned to. Following randomisation, participants are likely to be similar across groups at the start of the comparison (baseline). The impact of the intervention may then be isolated and quantified whilst minimising the effects from other factors that could influence the outcomes (Jadad and Enkin, 2007).

Without randomization, the number and characteristics of the participants allocated to each group will differ at any point in the study. To minimise this, block randomization may be used. This helps keep the numbers of participants in all study groups as close as possible. It also ensures that the same number of participants will be allocated to the study groups within each block (Jadad and Elkin, 2007). Another reliable method of randomization is the use of random number tables. Random number tables contain a series of numbers which occur equally often and are arranged in a random way (Jadad and Elkin, 2007). This method was adopted by Gao et al. (2014). Li et al. (2004) and Wolf et al. (2003) did not report on their method of randomization. Therefore, the design quality of the latter studies is difficult to evaluate. It is important to report on allocation method because it would not be possible to determine if the researcher used an appropriate method to generate random sequences of allocation.

Allocation concealment

Blinding participants is not possible in the TCAS study due to the nature of exercise interventions. However, most studies used a single-blinded approach where the researcher was blinded. This may be difficult in the current study, however, because there is only one researcher conducting the whole study. When meta-analyses report high bias in Tai Chi studies, caution may be necessary because if the high bias is in relation to blinding, the bias level may be overestimated. For example, Winser et al. (2018) reported that 80 per cent of studies reviewed failed to report allocation concealment. This failure to report may be because it is impossible to do. Nevertheless, CONSORT guidelines on reporting studies suggest that inability to conceal allocation should be reported.

Intention-to-treat approach

RCTs often find that participants are non-compliant or do not complete certain aspects of the study. To avoid bias, it is better to report any deviations from random allocation and missing data as highlighted in the Consolidating Standards of Reporting Trials (CONSORT) guidelines on the reporting of RCTs (Gupta, 2011). Most randomized controlled studies in the current review stated that an intention-to-treat approach was used. which includes every participant who is randomized but ignores non-compliance, withdrawal and anything that happens after randomization (Hwang et al., 2016; Li et al., 2004; Logghe et al., 2009; Wolf et al., 2003). However, one meta-analysis by Winser et al. (2018) reported that 60 per cent of studies reviewed failed to conduct an intention-to-treat analysis.

Population and setting

In order to generalise study results to the stroke population, stroke survivors are required to be the target population. However, there is currently little Tai Chi research which has included stroke survivors. Therefore, populations with balance deficits have been included in the current review. All meta-analyses and systematic reviews included participants with varying risks of falling. Lomas-Vega et al. (2017) did not state the level of fall risk among participants. It is difficult to generalise results to the TCAS study if participants in previous studies are relatively independently mobile. Winser et al. (2018) searched for papers which included participants with neurological conditions, including stroke. Also included in the meta-analysis by Winser et al. (2018) were Chinese studies. The inclusion of Chinese studies is advantageous because Tai Chi is practised widely in China, with most of the population having good knowledge of its principles. However, as Tai Chi is practiced everyday by many Chinese in parks and other public places, participants based in China may be more accepting and compliant with practice than UK participants, and thus may be a limitation for UK studies where Tai Chi is less part of the culture. Additionally, results of the study by Winser et al. (2018) cannot be generalizable to UK stroke survivors during the early rehabilitation phase because participants in the study by Winser et al. (2018) were in the sub-acute or chronic phase.

Intervention

Tai Chi can take months to memorize and learn well enough to have a therapeutic effect. Balance-disordered patients may develop stress and fear if they are being told to learn a relatively complex sequence of movements (Wayne and Fuerst, 2013). Therefore, researchers have modified the Tai Chi programme by using a minimal amount of movements taken from the original Tai Chi form (Wolf et al., 2003). However, what is unclear in some studies is the actual movements performed. The choice in movements may influence results because a modified Tai Chi programme which contains movements focused on balance may produce different results to a modified Tai Chi programme which does not focus on balance. For example, a Tai Chi programme designed for reducing pain in arthritis may not benefit stroke survivors. Li et al. (2004) and Taylor-Piliae et al. (2014a) included 10-minute warm-ups and cool-downs but did not explain the format. Logghe et al. (2009) and Tousignant et al. (2013) included warm-ups and cool-downs but did not mention for how long or what format they took. It is mentioned by Taylor-Piliae et al. (2014a) that rest periods were regularly offered to avoid the stroke-related fatigue. Taylor et al. (2012) explain that their seven-minute warm-up and cool-down consisted of walking.

As well as adapting the Tai Chi movements, the Tai Chi programme needs to be adapted to the individual (Tousignant et al., 2013). Tai Chi was adapted to each participant at the beginning of the intervention in the study by Tousignant et al. (2013) by the Tai Chi instructor and therapist. Individual adjustments were made in the gradient of difficulty over time. Taylor et al. (2012) modified the Tai Chi programme but did not give details of how and why. Li et al. (2014) and Taylor-Piliae et al. (2014a) do not mention adapting and modifying their Tai Chi programme but taught some of the programme as seated exercises, as did Taylor et al. (2012).

Most studies retrieved in the current literature review modified Tai Chi. However, some apply a set of activities that is more a form of Qigong because the movements are easy to learn and are simple and repeatable compared to the traditional Tai Chi sequences. Adapting Qigong may be preferred because learning the traditional Tai Chi sequences takes a long time (Jahnke, Larkey & Rogers, 2010). The authors warn that many studies refer to using a practice called Tai Chi, but this may be in name only because they do not report if their study incorporates Qigong. For example, Tousignant et al. (2013) used a series of eight movements from an exercise stemming from Tai Chi called Ba-Duan-Jin, but still referred to their exercise programme as Tai Chi. Nevertheless, Jahnke et al. (2010) suggested that both Qigong and Tai Chi produce a wide range of health benefits. It was concluded that a Tai Chi programme would be better suited if it included Qigong exercises.

To be effective in reducing falls, exercise should be focus on improving balance, becoming progressively more challenging and intensity to be at least 50 hours is required (Stevens, Voukelatos & Ehrenreich, 2014). Stevens et al. (2014) stated if studies failed to achieve a significant reduction in falls following Tai Chi, it may have been because participants did not receive the sufficient dose. Interestingly, despite many studies exploring Tai Chi as a fall prevention exercise, Stevens et al. (2014) suggest that effectiveness of the intervention depends partly on the health status of participants and did not recommend Tai Chi for those at high-risk of falls.

The Tai Chi instructor

It is important to know the optimum level of instructor support required to maintain safety in people with balance impairments. Stroke survivors would be potentially at high-risk of falling during the class and would need close supervision. In classes with many potential fallers, it is necessary to know the appropriate ratio of participants to supervisors/instructors. Most studies did not report the number of participants per class. Therefore, it is difficult to know the optimum class size to maintain safety with adequate supervision. Most studies used multiple Tai Chi instructors (Hwang et al., 2016; Li et al., 2004; Logghe et al., 2009; Taylor et al., 2012; Wolf et al., 2003). However, it is not clear if the multiple instructors were used in different locations or in the same location at the same time. Where this was the case, all instructors in each of the studies standardised the teaching by using one protocol. Three studies used one Tai Chi instructor (Gao et al., 2014; Taylor-Piliae et al., 2014a; Tousignant et al., 2013). Tai Chi was given to two to four participants at one time in the study by Tousignant et al. (2013) so that potential fallers can be well-supervised. Logghe et al. (2009) included larger Tai Chi group sizes, ranging from seven to 14 participants at one time. However, the participants appeared to be less challenged with balance (Logghe et al., 2009). Taylor et al. (2012) delivered Tai Chi in a group setting in the community with up to 15 participants were in the class per one instructor. It is expected the maximum number will be less in people who are less mobile and prone to falls.

Location of Tai Chi classes

Stroke survivors are not allowed to drive for at least one month following diagnosis (Stroke Association, 2018). For this reason, Hwang et al. (2016) delivered Tai Chi individually in people's homes. This may not be possible in the current study due to limited time and resources. Additionally, conducting Tai Chi in the participants' homes loses the social interaction from being part of a group; participating in group-based exercise may bring social influences which may help to explain the falls reduction in all groups in the study by Taylor et al. (2012).

Follow-up

It is not known if Tai Chi would have lasting effects on stroke survivors. Therefore, follow-up assessments were conducted in some studies. Gao et al. (2014) and Li et al. (2004) followed participants up after six months, whereas Hwang et al. (2016) and Tousignant et al. (2013) followed participants up after 12 months. During the 48-week study, Wolf et al. (2003) followed participants up every four months. Taylor et al. (2012) followed participants up after 11 and 17 months. Due to the limited time of a PhD, long-term follow-up as long as the above-mentioned studies in the current study is not possible.

Home practice
Tai Chi movements taught in class may be done at home as a supplement to physiotherapy. Additionally, participants may continue to practice this after the Tai Chi classes have ended. Therefore, evidence about the effectiveness of Tai Chi home practice on reducing falls needs to be evaluated. Logghe et al. (2009) recommend participants in the intervention group to practice Tai Chi twice a week at home for 15 minutes but did not report on how much home practice was done. Gallant, Tartaglia, Hardman & Burke (2017) recommend home practice 45 minutes per week using a DVD of the eight forms used, step-by-step. The authors report that adherence to home practice was high but did not specify how much was practiced. Hwang et al. (2016) included home practice where participants were encouraged to record the amount of home practice adhered to each day. However, Hwang et al. (2016) do not report how much was practised and whether this practice had any impact on the outcomes. It is, therefore, difficult to draw any inclusions about the optimum amount of home practice to make a positive change.

Control group
Studies with control groups who practise balance training are not the best to evaluate the effect of Tai Chi compared with how stroke survivors would be. Therefore, studies which have implemented another balance training intervention as the control group, have been excluded. Control groups in the studies reviewed by Huang et al. (2016) included usual care, stretching or other low-level exercises, education or standard lifestyle modification. Lomas-Vega et al. (2017) included studies with comparison groups that did usual care or other therapies different from Tai Chi.

Two studies had usual care as the control group (Gao et al. 2014; Taylor-Piliae et al. 2014a). However, Taylor-Piliae et al. (2014a) had a third group which was an alternate exercise group to Tai Chi. This group received the same amount of exercise as the Tai Chi group. This third group consisted of 'Silver Sneakers', a national fitness programme for older adults offering different types of group exercise such as aerobics, Yoga etc. However, Taylor-Piliae et al. (2014a) do not mention whether Silver Sneakers included Tai Chi. The usual care groups did not receive the same amount of input from the researcher but were telephoned weekly to inquire about their health status. However, the researchers did not inquire about frequency of any exercise they may have undertaken after being given contact details of community-based physical activity (Taylor-Piliae et al., 2014a). Gao et al. (2014) also included a usual care group as a control. Hwang et al. (2016) used two interventions to compare whether Tai Chi was better than lower extremity training. This alternative exercise was delivered by a physical therapist and exercises consisted of stretching, muscle strengthening and balance training that is similar to community rehabilitation. Hwang et al. (2016) recognise that exercises performed in the exercise control group may have increased the risk of falling according to exercise type, which may affect the estimate of the effects of Tai Chi on falls. It is difficult to compare a Tai Chi group to an alternative balance training exercise because the activity level in the alternative exercise group may be more than what is usual. Therefore, it would not be generalizable to stroke survivors performing light exercise as part of a physiotherapy programme.

Adherence

Adherence to the intervention was good in all three randomised controlled trials with 85 per cent overall for prescribed sessions (Taylor-Piliae et al., 2014a). Adherence was highest in the usual care group (93 per cent) who received less intervention time than the other two groups, followed by the Tai Chi group (82 per cent) and Silver Sneakers (81 per cent). Adherence to the study by Hwang et al. (2016) was better in the Tai Chi group at six months but not at 18 months. Three participants dropped out six months with eighteen dropping out at 18 months, whereas eight participants dropped out of the control group at six months and sixteen dropping out at 18 months.

Health problems (Logghe et al., 2009; Tousignant et al., 2013; Wolf et al., 2003), transportation issues (Gao et al., 2014; Logghe et al., 2009) and lack of interest (Gao et al., 2014) were the main reasons for dropping out of the study. Taylor-Piliae et al. (2014a) acknowledge that high adherence to Tai Chi was due to developing solutions to transportation problems. Out of 152 participants, 24 did not finish Tai Chi and 26 did not finish the conventional physiotherapy (Tousignant et al., 2013). Interestingly, one study reports 25 out of 138 participants dropped out after randomisation before starting the first lesson (Logghe et al., 2009). Similarly, 24 out of 311 participants withdrew immediately after randomisation in the study by Wolf et al. (2003). Li et al. (2004) do not report on the drop-out rate. One evaluation of a programme intervention found in those participants who self-reported as being of fair or poor health, they were more likely to drop out or have spotty attendance (Gallant et al., 2017). This concerned the authors because it is this group (at the highest risk of falling) which may benefit the most from Tai Chi. Gallant et al. (2017) thus recommend the identification of strategies to successfully recruit and retain individuals most at risk of falling. Taylor et al. (2012) suggest that group exercise may be beneficial for adherence and self-efficacy.

Effectiveness of Tai Chi on falls

Liu et al. (2019) conducted a meta-analysis and found moderate to high quality evidence that Tai Chi may be a good intervention to prevent falls and improve balance in patients with Parkinson's disease. However, the authors warn that results may not be generalizable to UK participants because the population was American or Asian. Overall, Lomas-Vega et al. (2017) found high-quality evidence in five studies reviewed (Hwang et al., 2016; Li et al., 2004; Saravanakumar et al., 2014; Voukelatos, Cumming, Lord & Rissel, 2007; Wolf et al., 1996) that Tai Chi provides a significant falls risk reduction in the short-term (less than 12 months) and a risk reduction at 13 per cent in the long-term (Faber, Bosscher, Chin & van Wieringen, 2006; Hwang et al., 2016; Logghe et al., 2009; Taylor et al., 2012; Tousignant et al., 2013; Woo, Hong, Lau & Lynn, 2007). Li et al. (2004) report that an improvement in balance was required to decrease the risk of falls. Improved slope scores for functional balance measures were shown to be predictive of non-fallers among Tai Chi participants (CI 0.07-0.96, p=<0.04). At six months, a significant reduction (p=<0.001) in falls risk was found in those who showed improvements in functional balance in the Tai Chi group. Similarly, Logghe et al. (2009) suggest that lack of improvement in balance was the explanation for a lack of reduction in falls, and further conclude that Tai Chi may not be effective for those at high-risk of falls living at home. Wolf et al. (2003) acknowledge that some fallers in their study fell multiple times. The Tai Chi group had a significantly lower risk of falls than the control group from month four to 12 (RR=0.54, CI=0.36-0.81) but there was no significant difference between groups for falls. This suggests that those who are at low risk of falls are as likely to fall as those who are at high risk of falls because there was no difference in falls between the groups. However, Logghe et al. (2009) found that there were more falls in the Tai Chi group than in the control group at 12 months (115 versus 90), but there were more fallers in the control group.

Lomas-Vega et al. (2017) found a medium protective effect (falls risk reduction of 43 per cent) in the short-term compared to the control groups in five high quality studies (Hwang et al., 2016; Li et al., 2004; Saravanakumar et al., 2014; Voukelatos et al., 2007; Wolf et al., 1996), and a small protective effect in the long-term (Faber et al., 2006; Hwang et al., 2016; Logghe et al., 2009; Taylor et al., 2012; Tousignant et al., 2013; Woo et al., 2007). In terms of falls that resulted in injury, Lomas-Vega et al. (2017) found a medium protective effect for the short-term (50 per cent reduction) and a small to medium protective effect in the long-term (28 per cent reduction) in the study by Hwang et al. (2016). Hwang et al. (2016) found that participants in the Tai Chi group were significantly less likely to experience an injurious fall (IRR=0.30 for six months and IRR=0.32 for 18 months. Hwang et al. (2016) found that the healthier the participants, the more effective Tai Chi was in reducing falls, suggesting that Tai Chi may only be suitable to able-bodied stroke survivors. However, Lomas-Vega et al. (2017) found that this evidence was of low quality. Therefore, Lomas-Vega et al. (2017) view this as a limitation of the meta-analysis by concluding that they could not make a firm conclusion about falls, resulting in injury. Based on the two articles at the top of the hierarchy of evidence (Huang et al. 2016; Lomas-Vega et al., 2017), the evidence to investigate the effect of Tai Chi for preventing falls in older adults remains controversial. However, it can be concluded that Tai Chi significantly reduces the number of fallers (Huang et al. 2016) and rate of falls (Huang et al.

2016; Lomas-Vega et al., 2017). Moreover, the preventive effect is likely to increase with exercise frequency (Huang et al., 2016).

Lomas-Vega et al. (2017) report that Tai Chi can reduce falls rates by almost half during the first year of follow-up. Moreover, this falls rate reduction may be extended to more than a year of follow-up (Lomas-Vega et al. (2017). Lomas-Vega et al. (2017) agree with Huang et al. (2016) who found that out of a total of 15 studies which included falls rates as an outcome measure. Huang et al. (2016) also found that the chance of falling was significantly lower in the Tai Chi group than the control group. Additionally, the effect size of the Tai Chi group seemed to increase with exercise frequency (from a RR of 0.05 for once a week to 0.36 for three times per week or more). However, Huang et al. (2016) acknowledge that in studies with a small sample size, the IRR was not significant. Three randomized controlled trials retrieved from the current literature search did not report any statistically significant effect on falls reduction (Logghe et al., 2009; Tousignant et al., 2013; Wolf et al., 2003). Tousignant et al. (2013) report that 29 out of 49 participants fell in the Tai Chi group compared to 35 out of 44 in the control group (RR:0.74, CI=0.56-0.98). However, the mean number of falls between all participants and within subgroups of each intervention group was not statistically different. Taylor et al. (2012) do not show a difference in fall rates between groups at baseline ($p=.13$) or over time ($p=.25$). Taylor et al. (2012) explain that this lack of difference may be because of the level of missing data between both Tai Chi groups. The authors further report that participants who reported having fallen were 1.43 (CI 0.94-2.17) times as likely to withdraw as those who had not ($p=.10$), but this was not significant. Taylor et al. (2012) do not report a significant difference between groups in falls reduction, despite measures of balance and strength improving over time in all groups. The authors acknowledge that the findings may be clearer had the control group refrained from an organised exercise programme. Participants did continue to exercise which may explain the continued falls reduction over the 12-month follow-up period. However, the authors did not record exercise type and duration that was continued.

A total of 29 (24 per cent) fall-related events resulted in injury according to Taylor-Piliae et al. (2014a). However, the authors do not clarify which groups received the most injurious falls. Nevertheless, Tai Chi participants had two thirds fewer falls (five falls) than the Silver Sneakers group (14 falls) and usual care group (15 falls). Post hoc test showed that the Tai Chi group had significantly fewer falls than the usual care group ($p=0.04$) but there was no significant difference between the Tai Chi group and Silver Sneakers group ($p=.11$) or between the Silver Sneakers group and usual care group ($p=.59$) (Taylor-Piliae et al., 2014a). Gao et al. (2014) showed that falls among the Tai Chi group significantly reduced at the six-month follow-up. Out of 39 participants in the control group, there were nineteen fallers, whereas in the Tai Chi group there were eight fallers out of 37 participants. It is not known from this study the exact number of falls per group. If fallers, in a particular group, experienced multiple falls, the overall fall rate may be higher that group. However, the authors calculated the average amount of falls in the Tai Chi group compared with the control group, with the result being significantly lower in the Tai Chi group ($p=<0.05$).

Li et al. (2018a) conducted an RCT and that found the Tai Chi group yielded the greatest reduction in falls, with both groups showing some improvement. However, it is unclear what the mechanisms of the falls were. Most of the participants targeted were women (92.1 per cent), and women are more likely to fall than men due to osteoporosis. The Tai Chi programme used is available for sale and includes many movements stroke survivors in the early phase of rehabilitation may find difficult to do. Researcher bias may be present in this study because it is in the researcher’s interest to sell the Tai Chi programme.

Limitations of the studies exploring fall prevention

The limitation of the two reviews by Huang et al. (2016) and Lomas-Vega et al. (2017) are that studies reviewed by the authors included relatively healthy older adults. The current literature review aims to find out the effects of Tai Chi on those at high-risk of falling. Huang et al. (2016) recognise this and recommended more research on the effective intensity and style of Tai Chi, along with assessing the effect of Tai Chi on falls in older adults with certain comorbidities such as stroke and Parkinson’s disease.

There has been little evidence focusing on the effects of Tai Chi and falling among the stroke population. Moreover, a stroke population on the point of discharge from hospital receiving community physiotherapy in the UK. One study involved stroke patients, but falls was not the primary focus, meaning the study was not designed to reduce falls (Taylor-Piliae et al., 2014a). The authors suggest that the number of fall-related events may have been underreported by participants because of recollection bias. Taylor-Piliae et al. (2014a) suggest collecting data on fear of falling to add potential insight on reasons for falling.

It seems that Tai Chi has been found to provide a significant reduction in falls. However, at the end of this literature review, it is difficult to recommend an optimum Tai Chi dose, as well as be sure of its adherence by stroke survivors.

2.4.2. Tai Chi and balance

Many studies and reviews have shown Tai Chi to be effective in improving balance in relatively healthy older people, but some studies who used the general healthy older population found no significant change in balance (Fong & Ng, 2006; Lelard, Doutrellot, David & Ahmadi, 2010; Woo et al., 2007) or no difference between groups (Lelard et al., 2010; Woo et al., 2007).

Randomization

A meta- analysis by Wu et al. (2018) found that three articles reviewed described the method of randomization. One study reviewed fail to mention their method of randomization (Hart, Kanner, Giboa-Mayo, Haroeh-Peer & Rozenthul-Sorokin, 2004). Au-Yeung, Hui-Chan & Tang, (2009) randomized participants with the aid of a computer program that treated gender and side of hemiplegia as stratification variables. Zeng et al. (2014) randomized their participants by using random number tables, where even numbers were allocated to the control group and odd numbers allocated to Tai Chi. Li et al. (2012) randomized participants using permuted-block randomization. Seven studies did not randomize participants (Burschka, Keune, Hofstadt-van Oy, Oschmann & Kuhn, 2014; Desrochers, Kairy, Pan, Corriveau & Tousignant, 2017; Hain, Fuller, Weil & Kotsias, 1999; Hakim, Kotroba, Teel, & Leininger, 2010; Kim, Kim & Lee, 2015; Li et al., 2007; Pan, Kairy, Corriveau & Tousignant, 2017). Hakim et al. (2010) comment that causation could, therefore, not be determined.

Nine of the nineteen studies reviewed by Chen et al. (2007) were not randomized, with Maciaszek and Osiński (2010) suggesting that studies without a control group were not reliable in terms of their results. The reviewers also questioned whether experimental and control groups were equal because some participants in studies were already experienced in Tai Chi at baseline (Tsang & Hui-Chan, 2005; Wong, Lin, Chou, Tang & Wong, 2001). Therefore, it was difficult for the reviewers to assume groups within studies were equivalent. Hakim et al. (2010) used a convenience sample, whereas Burschka et al. (2014) recruited via mail to patients who were or had been in out-patient care. Hackney and Earhart (2008) used simple random assignment which was performed by the first author by tossing a coin. Kim et al. (2015) acknowledge that they randomly allocated participants into one of two groups but did not mention which method they used. Maciaszek and Osiński (2010) question the reliability of some of the results generated from the studies they reviewed. Participants also volunteered and were categorized into groups, limiting the generalizability of the findings. Li et al. (2007) acknowledge that a pre-test/post-test design was susceptible to uncontrolled threats to both internal and external validity. For example, Li et al. (2007) could not be sure that improvements made were directly related to Tai Chi because other confounding factors such as maturation, testing effect or selection bias may have influenced the outcomes.

Hwang et al. (2016) comment that their study may be biased due to the volunteer effect which may restrict generalization of results to frail elderly people. Participants were enthusiastic and may have had high expectations of Tai Chi (Li et al., 2007). Zeng et al. (2014) comment that the Tai Chi group may have been influenced by positive effects from the group, such as receiving more attention from the Tai Chi instructor and social interactions. Li et al. (2012) recognize awareness of group allocation may have introduced biases in the results, and the authors suggest that those interested in participating may have had positive expectations about the benefits of Tai Chi.

Intervention

Optimal training duration and most effective period of exercise were not established from the review by Maciaszek and Osiński (2010). Studies reviewed varied in duration. For example, some studies recommended 12 months (Pereira, Oliveira, Silva, Souza & Vianna, 2008; Woo et al., 2007), whereas others recommended eight weeks (Zhang et al., 2006). Optimum intensity and frequency were also not established with the reviewers concluding that frequent training did not improve balance (Tsang et al, 2004). However, it is unclear whether participants included in the reviews by Jiménez-Martin et al. (2013) and Maciaszek and Osiński (2010) had balance impairments to begin with in order see an improvement. Hackney and Earhart (2010) recognise that Tai Chi duration was short with the authors suggesting longer training may increase benefit from Tai Chi.

Home practice

Three studies encouraged home practice (Au-Yeung et al., 2009; Choi et al., 2013; Zeng et al., 2014), where one encouraged home practice to be done outside in a park or in nature (Zeng et al., 2014). Choi et al. (2013) only recommend home practice once a week, whereas Au-Yeung et al. (2009) recommend three hours of home practice a week. Zeng et al. (2014) do not specify time. Burschka et al. (2014) specifically told participants not to practice at home because it would be unsupervised. Au-Yeung et al. (2009) encouraged home practice by offering a video clip of the lesson to be practiced. Home practice with a video and written materials was encouraged every day for 30 minutes. Hain et al. (1999) included home practice in their study but did not measure compliance. However, compliance with home practice was low, despite all participants continuing with Tai Chi after the study ended. The authors cite that the Tai Chi exercises may have been too difficult compared to the exercises given to the control group. Therefore, it is difficult to assess how this part of the programme contributed to the results. Adherence to home practice was advised by Zeng et al. (2014) who suggest a family member supervise this. The authors acknowledge that in China, families live together with their elderly to make this feasible. This supervisor may also have prevented any falls rather than the Tai Chi according to the authors.

Control group

Two studies offered stretching and breathing exercises to their control groups (Au-Yeung et al., 2009; Li et al., 2012). It is acknowledged by Li et al. (2012) that the control group participated in low-level exercise. The authors suggest that by using a non-exercise control group, the net gain of Tai Chi training can be gauged. Li et al. (2012) offered a third group resistance training which included muscle training important for balance, whereas Zeng et al. (2014) used strength and hip ROM training. This training included bilateral lower-extremity strength training. The control groups in the studies by Li et al. (2012) and Zeng et al. (2014) cannot be compared to community physiotherapy because stroke survivors would not be receiving such intense training as part of their rehabilitation. Therefore, it cannot be confirmed if Tai Chi can supplement rehabilitation by comparing with such a control group.

Hakim et al. (2010) included two control groups; one that practised Yoga and one that did not engage in any exercise programme. However, intensity and duration of Yoga is not mentioned by the authors. Kim et al. (2015) involved general physiotherapy with both the Tai Chi group and the control group, suggesting that Tai Chi may be a supplement to the physiotherapy already being received. Hackney and Earhart (2008) do not include a control group in their study, and Choi et al. (2013) offered no exercise to their control group.

Adherence

Overall, adherence to Tai Chi among all studies was good. Out of 195 participants, 176 completed the study (Li et al., 2012). Five participants dropped out of Tai Chi and 11 dropped out of the control group (unrelated to the study) in Zeng's study. Zeng et al. (2014) commented that due to 40 per cent of participants dropping out, the sample size was reduced greatly. In contrast, Au-Yeung et al. (2009) acknowledge that the Tai Chi group had lower compliance than the control group. The authors suggest this was because the control group exercises were easier to learn and practice at home. To improve adherence to Tai Chi, Au-Yeung et al. (2009) recommend forming Tai Chi groups in convenient community venues.

Hakim et al. (2010) do not mention adherence but participants had voluntarily enrolled in Tai Chi or Yoga prior to taking part in the study, as well as not seeming to have any chronic medical conditions. Therefore, adherence was good in the Tai Chi group (76.1 per cent) and Yoga group (54.5 per cent). Only 30 per cent completed in the no exercise group. Hackney and Earhart (2008) required their participants to attend at least 20 sessions over 13 weeks. Four participants dropped out of Tai Chi (two for transportation reasons, one thought Tai Chi was not challenging, one was hospitalised). Three dropped out in the usual care group but no reason was given. Kim et al. (2015) and Burshka et al. (2014) do not mention attendance or drop-out rates.

Effectiveness of Tai Chi on balance

Jiménez-Martin et al. (2013) found that studies evaluated two types of balance: static and dynamic. Thirteen studies of the 27 reviewed by Jiménez-Martin et al. (2013) showed that

Tai Chi caused significant improvements in static balance. Kim et al. (2015) comment that improved static balance was due to improvement in proprioception of the trunk and lower limb. Further, control of muscle and joints was enhanced with Tai Chi training, even though it was subtle. Repetitive weight-shifting to the paralysed side had a significant effect on the asymmetrical posture of stroke survivors. The authors conclude that combining Tai Chi with general physiotherapy was more effective for improving static balance of stroke survivors.

Most studies and reviews retrieved from the databases found that balance improved in the Tai Chi groups compared to the controls within the populations investigated (Burschka et al., 2014; Hackney & Earhart, 2008; Hain, Fuller, Weil & Kotsias, 1999; Hakim et al., 2010; Kim et al., 2015). However, Wu et al. (2018) conducted a meta-analysis and found that despite an improvement in balance among the Tai Chi group using the BBS, there was unexplained statistical heterogeneity observed, which may be related to differences among studies in the study population, different types of Tai Chi, intensity and duration. Therefore, the authors advised caution when accepting the results. Results in the meta-analysis by Wu et al. (2018) reached high heterogeneity and low reliability. The authors acknowledged that this low quality of evidence was due to lack of information on random sequence generation, allocation concealment and the blinding of outcome assessors.

Limitations

Only short-term effects of Tai Chi on balance were evaluated by Wu et al. (2018). The authors recommend long-term effects to be assessed, particularly after long-term use of medication. Maciaszek and Osiński (2010) and Yang, Li, Gong, Zhu & Hao (2014) agree that the follow-up effects of Tai Chi should be done on those with Parkinson's disease.

Chen et al. (2015) recognise that according to the Cochrane Collaboration recommendations, all studies included in their review were of low quality with a high bias risk. Out of the three studies they reviewed which implemented Tai Chi, only one was clear about the style of Tai Chi used (Yang). Jiménez-Martinez al. (2013) acknowledge the difficulty in performing a meta-analysis due to the different Tai Chi styles, outcome measures and sample sizes. Subgroup analyses are recommended by Maciaszek and Osiński (2010) to determine the effectiveness of interventions in people with different characteristics.

Improvements in balance may not directly relate to a reduction in falls. Therefore, a direct measure of the number of falls should be included (Maciaszek and Osiński, 2010).
Hain et al. (1999) suggest that Tai Chi may be useful for balance rehabilitation but stated an appreciable risk of falls may be present, especially in a class of ten participants, if close supervision is not given.

2.4.3. Tai Chi and quality of life [QoL]

Quality of life is a broad-ranging concept which comes from measures of a person's perceived physical, psychological state, personal beliefs, social relationships and relationship to the individual's environment (Jahnke et al., 2010). Due its large scope encompassing numerous subcategories, articles with the term 'quality of life' will be reviewed.

Strength of the evidence (systematic reviews)

Lee, Pittler and Ernst (2007) emphasise the methodological quality of the randomized controlled trials was low because there were no reports of blinding and randomization method. Toh et al. (2013) acknowledge that their review may be open to publication bias due to limiting the articles retrieved to English-only. Two independent reviewers were used in the study by Li et al. (2014). Lee et al. (2007) and Li et al. (2014) acknowledge that heterogeneity prevented a meta-analysis due to the heterogeneity of study designs and outcome measures. Lee et al. (2007) found the quality of all RCTs reviewed to be low, with none reporting details on randomization, blinding and allocation (Kirsteins, Dietz & Hwang, 1991; Lee, 2005; Lee & Jeong, 2006; Wang et al., 2005). Cwiękała-Lewis et al. (2017) found the articles retrieved to be of medium quality with QI scores ranging from 19-30 (the highest score is 32 representing the highest quality).

Strength of the evidence (other studies)

Li et al. (2014) question the quality of the studies reviewed and note that studies by Galantino et al. (2005) and Barrow et al. (2007) had high selection and performance bias due to lack of reporting allocation concealment and blinding of participants and care providers. Li et al. (2014) suggest that self-reporting may have had dramatically different responses.

Intervention

Li et al. (2009) report that in RCTs, only 23 per cent provided adequate details of the type of intervention used. Within the studies reviewed in the current literature review, there are inconsistencies with the type of intervention used. Full details of the Tai Chi programme are rarely reported. Frequency and duration of Tai Chi also varied considerably across all studies. However, all studies offered Tai Chi for at least one hour. Sessions varied by being between one to five times a week, lasting from one to 24 weeks. Most studies preferred a 12-week programme (Ćwiękała-Lewis, Fallek & Taylor-Piliae, 2017; Li et al., 2014; Toh et al., 2014). Ćwiękała-Lewis et al. (2017) conclude that this greatly varied Tai Chi dose affected reported study outcomes, limiting the generalizability of reported results. Fetherston and Wei. (2011) found a great variation in style, making it difficult to make recommendations, whereas Rogers, Larkey and Keller (2009) also cite inconsistencies in the duration and intensity of Tai Chi. The authors, therefore, found it difficult to know exactly what level of practice might be needed to achieve any results.

Outcome measures

Rogers et al. (2009) found a lack of consistent outcome measures, with different scales being used to measure the same variable, making it difficult to compare or recommend an outcome measure. Li et al. (2014) comment that all objective outcome measures resulted in inconsistent results and suggested that a qualitative approach would be better suited to find out quality of life.

Effectiveness of Tai Chi on QoL

Li et al. (2014) found clinical benefits of Tai Chi in participants with arthritis and fibromyalgia (Lee et al., 2009; Wang et al., 2010). Most studies (18/21) reviewed by Li et al. (2014), found that Tai Chi significantly improved QoL in terms of their health, with three studies showing no significant improvement. Fetherston and Wei (2011) found that QoL and self-esteem can be significantly reduced in people with chronic conditions due to decreased physical, psychological and social functioning. Fetherston and Wei (2011) suggested that improvements in self-esteem, physical self-worth, physical condition, sport competence, body attractiveness and physical strength have capacity to enhance self-efficacy and improve quality of life by giving people a feeling of control over their bodies and surrounding environment. The authors recognize the importance of social support for individual health and community well-being in relation to public health. Hart et al. (2004) found a significant improvement in general and social functioning defined by the Duke Health Profile compared with controls. Toh et al. (2013) report that there was an increase in confidence to achieve functional independence, along with a self-perceived improvement of balance. Ćwiękała-Lewis et al., 2017 found that out of six studies reviewed, four reported significant improvements in one or more aspect of well-being ($p<0.05$) compared with controls (Cheon et al., 2013; Choi et al., 2013; Li et al., 2014; Nocera et al., 2013). However, only 64 per cent were randomized controlled trials. The remaining two studies (Hackney & Earhart, 2008; Li et al. 2007) found no-significance in results ($p<0.05$).

Kim et al. (2015) found that combined Tai Chi and physiotherapy showed an improvement in QoL in stroke survivors, but this improvement was not significant. Kim et al. (2015) suggest that this non-significant improvement was done by influencing mental and physical factors. The authors further suggest that lack of significant improvement may be due to limited social interactions due to a long hospital stay, disability categories with role limitations owing to physical health, social functioning and emotional problems. The control group did not show any significant changes in quality of life because of relatively little functional improvement and no intervention programme to improve this (Kim et al., 2015).

Taylor-Piliae et al. (2014a) found that there were no significant changes in perceived physical health for any of the groups, but all groups had significant improvements in mental health.

Lee et al. (2007) found only one randomized controlled trial by Wang et al. (2005) which evaluated the effect on Tai Chi on QoL but found no intergroup (Tai Chi versus education and stretching exercises) differences using the Sf-36 questionnaire ($p=0.01$).

2.4.4. Tai Chi and stroke

Ding (2012) excluded observational studies, case series and case reports. Trials in which there was a comparison between a treatment group receiving Tai Chi as a main intervention or comparison group that received an alternative form of intervention or no treatment were included in Ding's review. Li et al. (2017) included 17 RCTS, and Chen et al. (2015) included nine RCTs.

The Cochrane Handbook for Systematic Reviews of Interventions can be used to assess the risk of bias (Chen et al., 2015). Ding (2012) assessed the quality of studies using the Jadad score (the higher the score, the higher the methodological quality), and assessed publication bias by means of funnel plot and Egger's test of asymmetry. The authors cited publication bias as a limitation because Tai Chi is popular in Japan and Korea, but relevant studies may have been omitted due to language barriers. Additionally, databases in these countries may not be searched. However, Ding (2012) did include Chinese literature. Ding (2012) do not mention how many reviewers were involved but commented that the methodological quality of the trials reviewed was moderate. Chen et al. (2015) and Li et al. (2017) involved two independent reviewers. Disagreements between these reviewers were resolved through discussion. If a consensus was not reached, a third reviewer was consulted. Chen et al. (2015) and Li et al. (2017) were blind to the study objectives and outcomes. Yoshinaga and Cai (2013) and Zhang et al. (2015) do not mention how they assessed the quality of the evidence. Li et al. (2018b) found that in their review, every article had a high risk of bias. This was because five were unclear regarding allocation concealment, the blinding of participants, and outcome assessments.

The prospective single-blind RCT by Wang et al. (2010) does not mention their method of randomization. Taylor-Piliae & Coull (2011) used simple randomization with allocation concealment by drawing a slip of paper from a non-transparent container. Participants were handed an opaque, sealed envelope matching the slip of paper, and told to open them when they returned home. The authors comment that this method was used to reduce dropouts related to group assignment. Taylor-Piliae & Coull (2011) comment that it is possible the use of simple randomization may have led to imbalanced group sizes and recommended block randomization in future to mitigate potential selection bias. Hart et al. (2004) randomly divided participants into two groups of nine. Base-line tests were conducted by a physiotherapist who was blinded to group allocation. Tousignant et al. (2013) aim to use block randomization of sizes two and four done by computer with a system of numbered, sealed envelopes, and Tao et al. (2015) aim to randomize participants by producing random allocation sequence by an independent statistician. Blinded outcome assessors will be included in the study by Tao et al. (2015). Li et al. (2017) found that out of eighteen studies, only five revealed that the allocation concealment was only eight describing assessor blinding.

Target population

The target population in the current review have been recruited at the point of discharge from hospital and were entered into the study once they got home because stroke rehabilitation has been recommended to start as early as possible when vital signs are stable (NICE, 2008). However, many existing studies do not involve stroke survivors so early after stroke onset. All of the participants included in the studies had a stroke diagnosis, but time post-stroke varied from at least three months (Au-Yeung et al., 2009; Hart et al., 2004; Tao et al., 2015; Taylor-Piliae & Coull, 2011) and less than six months (Li et al., 2012). According to Zhang et al. (2015), studies which are at least three-months post-stroke cannot be regarded as assessment of the overall effect of Tai Chi for stroke rehabilitation because there is insufficient evidence of the effects of Tai Chi within the first three months. The authors suggest this lack of evidence is because researchers wanted to make sure that participants were ambulatory. Therefore, the level of balance impairment used in these studies is brought into question because results may not be generalisable to stroke survivors who are immediately discharged from hospital. Therefore, the authors recommend future studies to include varying degrees of disability to better appraise the comprehensive effects of Tai Chi for stroke rehabilitation (Zhang et al., 2015). Pan et al. (2017) required participants to have been diagnosed at least six months before the study but did not state the earliest time from onset. Tousignant et al. (2014) aim to recruit stroke survivors immediately after discharge from hospital to supplement their community rehabilitation. However, the Tai Chi will be delivered at home, rather than as group practice.

Intervention

Each Tai Chi class lasted at least one hour in all studies, and took place between four and 12 weeks, between once and five times a week (Hart et al., 2009; Pan et al., 2017; Tao et al., 2015; Taylor-Piliae & Coull. 2011; Taylor-Piliae et al., 2014a; Tousignant et al., 2014; Wang et al., 2010; Yoshinaga & Cai, 2013). Hart et al. (2004) and Wang (2010) acknowledge that study duration was short. Wang et al. (2010) suggest that this short study duration may be the reason why there was no significance between groups. Similarly, Hart et al. (2004) suggest that a short study duration may have contributed to a lack of improvement in balance. Zhang et al. (2015) report that most studies with a short duration lacked long-term outcomes; thereby current results are limited to the immediate effects of Tai Chi.

Home practice

Kim et al. (2015) did not include home practice in their Tai Chi programme. In the study by Pan et al. (2017), home practice was encouraged on days without sessions and during the follow-up period of nine to 12 weeks.

The Tai Chi instructor

Kim et al. (2015) sought advice from professors of Tai Chi-related departments and a doctor of rehabilitation medicine regarding the programme. This programme was led by an experienced researcher and research assistant, but the authors are not clear about who delivered the Tai Chi. In the study by Pan et al. (2017), a clinician delivered Tai Chi. Tousignant et al. (2014) aim to recruit a physiotherapist to deliver Tai Chi.

Location of Tai Chi classes

Desrochers et al. (2017), Hart et al. (2004), Kim et al. (2015) and Tao et al. (2015) do not mention where the Tai Chi took place. Pan et al. (2017) delivered their Tai Chi programme in a research centre. Tousignant et al. (2014) aim to deliver their Tai Chi programme at home and via telerehabilitation.

The control group

Most studies used a control group consisting of usual care (Taylor-Piliae & Coull, 2011; Taylor-Piliae et al., 2014a), rehabilitation (Kim et al., 2015; Tousignant et al., 2014; Wang et al., 2010; Zhang et al., 2014) or low-level exercise such as stretching and breathing (Au-Yeung et al., 2009). Two studies used an exercise intervention as a third group (Taylor-Piliae & Coull, 2011; Taylor-Piliae et al., 2014a), and one used balance training (Tao et al., 2015).

Adherence

In the study by Pan et al. (2017), all eleven participants took part in all 16 sessions of Tai Chi over two months and practiced at home, with three-months follow-up with self-practice increasing significantly over the three months. The authors concluded that Tai Chi was a good way of integrating various skills learned during rehabilitation. Participants expressed a desire to continue practicing Tai Chi (Desrochers et al., 2017). Recruitment and retention in intervention studies remains a challenge for researchers (Taylor-Piliae & Coull, 2011). However, adherence was high with Taylor-Piliae and Coull (2011) stating this high leve of adherence may be due to the high proportion of college-educated participants in the study (82 per cent, n=23). Retention was also high (89 per cent, n=25) in the study by Taylor and Coull (2011). The authors suggest high retention was due to a tracking method during recruitment, providing personalised feedback, using the same location for all aspects of the study (assessments, intervention), personal attention and encouragement, monitoring attendance, a charismatic Tai Chi instructor, incentives and good communication. Despite high retention, three people dropped out of the study who were in the experimental group, but the reason was not related to Tai Chi (Taylor-Piliae & Coull 2011).

Effectiveness of Tai Chi on stroke survivors

Many Tai Chi exercises involve the arm and calf muscles which help strengthen the core of the body and the symmetrical distribution of the centre of gravity. This leads to stability when walking, as well as reduced muscle atrophy and maintenance of muscle strength (Yoshinaga and Cai, 2013). According to Yoshinaga and Cai (2013), Tai Chi is an excellent exercise for rehabilitating stroke patients because of the above benefits, including improving equilibrium and balance.

Taylor-Piliae and Coull (2011) agree that Tai Chi is safe and feasible for community-based stroke rehabilitation with no adverse effects. Taylor-Piliae et al. (2014a) found balance improved in stroke survivors but this was only achieved after several weeks of Tai Chi practice. It seems that Tai Chi is similar to conventional stroke rehabilitation because it contains the required deep breathing and relaxation of the body and mind, aiming to achieve a better recovery (Zhang et al., 2015). However, these findings by Zhang et al. (2015) may not be generalisable to other countries because stroke rehabilitation programmes will vary. For example, the relaxation component mentioned by the authors may not be present in stroke rehabilitation programmes elsewhere.

Tai Chi may benefit stroke survivors with upper limb impairment. Desrochers et al. (2017) report perceived physical, functional and psychological benefits from Tai Chi, whereas participants in the study by Pan et al. (2017) felt they had improvements in their arms with better flexibility and control in the paretic arm. ADLs were also perceived to have improved. Overall, there was a significant improvement in nearly all outcome measures over time, except for WMFT grip and MAL QOM scale. The authors suggest this lack of significance may be because the measures tested hand function which may not have improved as much as the arm. Improvements on outcome measures persisted or increased at follow-up.

Xie et al. (2018) conducted an RCT using Tai Chi Yunshou exercises among stroke survivors at least three months post-stroke. It is unclear what Yunshou entails but the authors explain that it is 'wave hands in the clouds.' A UK participant would find this difficult to understand. Additionally, 'wave the hands like clouds' if done in the classical Tai Chi way is very difficult to perform, especially for a stroke survivor. It is possible that participants in this Chinese study already have gained some foundation in Tai Chi. Both showed improved balance, but the Tai Chi group showed greater improvement in fear of falling, depression and motor function.

Li et al. (2018b) conducted a meta-analysis on Tai Chi and stroke survivors and did not find any high-quality research due to low frequency and low intensity of the intervention affecting the outcomes. Pooled analysis did not show a significant improvement in the Tai Chi group. Interestingly, the studies deemed low quality are the same studies found in other meta-analyses regarding stroke and Tai Chi (Au-Yeung et al., 2009; Hart et al., 2004; Kim et al., 2015; Taylor-Piliae & Coull, 2011; Taylor-Piliae et al., 2014a). Lyu et al. (2018) acknowledges the difficulty in blinding participants and assessors but found that nine studies reviewed in their meta-analysis had blinding of outcome assessors. Lyu et al. (2018) found that stroke survivors receiving Tai Chi as rehabilitation recovered better compared with therapy only or without therapy. Due to incomplete reporting of the random allocation sequence and allocation concealment, there was a strong risk of bias found, as well as large heterogeneity among studies. Despite the inability to blind, Ge et al. (2017) judged all studies as low risk of bias in terms of blinding method. However, the authors did find publication bias and statistical heterogeneity due to different types of Tai Chi, length and duration.

Limitations

Zhang et al. (2015) suggest that those studies with long-term outcomes are few and have small sample sizes, thereby lacking statistical significance. Ding (2012) also comment that larger sample sizes are needed. Wang et al. (2010) conclude that Tai Chi could be a useful non-pharmacological approach, along with rehabilitation for maintaining cognitive function and improving quality of life. Despite positive outcomes, study quality was poor in some cases, affecting the strength of the evidence. Fetherston and Wei (2011) suggest that studies only looked at the short-term effects rather than long-term, and that follow-up assessments are needed to see if any improvements made are maintained.

Overall, reviewers found it difficult to recommend an optimum dose of Tai Chi due to high heterogeneity, and outcome measures also varied greatly. Therefore, reviewers are unable to recommend the most appropriate outcome measure. Time post-stroke also varied, with only two recruiting from the point of discharge from hospital. However, one of these studies used a home-based Tai Chi programme, whereas the other only focused on the upper limb. Zhang et al. (2015) assert that any assessment of Tai Chi on stroke survivors at least three-months post-stroke cannot be regarded for the impact of rehabilitation because research needs to focus on those below three months of stroke onset.

Although there has been a lot of research about Tai Chi and its effect on balance and falls reduction, little has been done involving stroke survivors. One interesting point raised in this Chapter was that most Tai Chi research that has been done with stroke survivors did not use stroke survivors who have just returned home from hospital. Further, many studies have not used a Tai Chi programme modified for stroke survivors; it is difficult to rely on study results from a Tai Chi exercise programme for stroke survivors if the exercises within that programme are not suitably designed for the study outcomes, e.g. improving balance and reducing falls among stroke survivors after discharge from a stroke unit. Research that has previously used modified Tai Chi programmes for stroke do not describe in detail the Tai Chi programme used so that it can be replicated by others. Therefore, the Tai Chi programme developed for this study will be replicable and modified for the needs of stroke survivors, i.e. targeting the modifiable fall risk factors for stroke survivors, as discussed in Chapter 1.

Another interesting point raised in this Chapter was the lack of importance given to home practice in Tai Chi studies which included it as part of their programme. Further, few studies included home practice as a component of their Tai Chi programme, making it difficult to conclude if home practice is beneficial for stroke survivors. In order that contributions to this gap in research knowledge are made, the Tai Chi exercise programme developed for this study will include home practice as an essential part of the Tai Chi programme.
For the purposes of this thesis, the modified Tai Chi programme for stroke will be referred to as Tai Chi After Stroke [TCAS].

The proposed study aims to determine whether a bespoke Tai Chi programme for stroke survivors is feasible for and acceptable by stroke survivors entitled to community therapy services at the point of discharge from hospital in the UK. Further, the proposed study will provide data to inform a future RCT.

Chapter 3 – Designing a Tai Chi Programme

3.1. Introduction

It has been established in Chapter 2 that Tai Chi, as a supplement to community physiotherapy, has the potential to improve balance and reduce falls in stroke survivors recently discharged from hospital. The purpose of this chapter is to first expound the Tai Chi exercise programme by describing how the Tai Chi programme was developed; from the seed of an idea to its germination into a replicable exercise programme. Secondly, to fully understand the journey of developing a Tai Chi exercise programme for stroke survivors. Obstacles, which may become potential barriers, encountered along the path of its development will be discussed, as well as how these obstacles were overcome; understanding these obstacles is vital to the replication of designing a bespoke exercise programme for stroke survivors. Such barriers include finding a Tai Chi instructor, cost of a Tai Chi instructor, transport, and finding a suitable venue. Finally, justification for each exercise included within the Tai Chi exercise programme will be discussed.

One advantage for the researcher in developing Tai Chi as a therapeutic exercise for stroke survivors is having the experience of two-years practice; the seed of the idea that Tai Chi may benefit stroke survivors was planted during a Tai Chi class at a local leisure centre, attended by the researcher. The slow gentle movements of Tai Chi may appeal to those with a 'fear' of exercise, such as stroke patients returning home from hospital.

According to researchers at Harvard Medical School, Tai Chi is 'a mind-body exercise rooted in multiple Asian traditions, including martial arts, traditional Chinese medicine, and philosophy, comprising of gentle, slow and relaxed movements based on the principles of Yin and Yang (Wayne & Fuerst, 2013). Wayne and Fuerst (2013) explain further that 'Tai' means 'great' and 'Chi' means 'most ultimate' and is often translated together as 'supreme ultimate' (Wayne & Fuerst, 2013).

Tai Chi is an effective form of martial arts for fighting and defeating opponents (Swain & Lightfoot, 2015) and has roots in Taoism (a branch of Chinese philosophy) (Posadzki & Jacques, 2009). It may not be surprising, therefore, if it is mistakenly perceived to be made up of non-direct and non-specific coordinated strikes. A false perception of Tai Chi may lead to some potential participants expressing disinterest. Therefore, it is important to clarify to potential participants what Tai Chi is.

Participants may want to know the origins of Tai Chi, so some knowledge about its history should be known by the researcher. Originally developed in China by Wangting Chen in the 18the century AD (Swain & Lightfoot, 2015), Tai Chi was used to train ancient Chinese soldiers to protect wealthy government leaders (Wayne & Fuerst, 2013). Through martial arts training, Tai Chi has integrated martial arts, Chinese folk and medicine, breathing and meditative techniques to maintain health and well-being (Yang, Li, Gong, Zhu & Hao, 2014). Tai Chi has gained popularity in the West as a therapeutic exercise with examples found in hospitals, leisure centres and schools (Wayne & Fuerst, 2013). Locally, Tai Chi is offered to cardiac rehabilitation patients at a local West Yorkshire NHS Trust, but stroke survivors do not have access to such an exercise following discharge from hospital.

Since its development, Tai Chi has evolved into five different styles: Chen (the oldest), Yang, Wu, Hao and Sun, named after their founders. Yang et al. (2014) found that Yang style is the most widely practised due to various reasons in the 19th century and its promotion by the Chinese government since the establishment of the People's Republic of China. Table 6 presents the styles used in Tai Chi studies with stroke survivors.

Table 6 Tai Chi styles used in stroke studies

Tai Chi style	Studies
Yang	Taylor-Piliae et al. (2011; 2012; 2014); Wang et al. (2010); Zhou et al. (2010); Pang et al. (2017)
Sun	Au-Yeung et al. (2009)
Chen	Pang et al. (2017)
Wu	Nil
No mention	Hart et al. (2004); Zhou et al. (2010); Kim et al. (2017)

Each style has its own choreographed sequence of movements, known as a 'form' (Wayne and Fuerst, 2013). However, these sequential movements can take a long time to learn, resulting in modified/shorter versions (Lan, Chen, Lai & Wong, 2013). Highlighted in Table 7 are stroke studies using Tai Chi as an intervention and whether or not they modified Tai Chi.

Table 7 How previous Tai Chi studies have modified Tai Chi for stroke survivors

Practised a full form	Modified movements	Modified a form but not for stroke	Did not mention if modified	Did not mention if full form practised	References
X	X	X	YES	YES	Hart et al. (2004)
YES (full 24-posture short form)	X	X	X	X	Taylor-Piliae et al. (2011; 2012; 2014a)
YES (24-short form)	X	YES (for arthritis)	X	X	Au-Yeung et al. (2009)
X	X	X	YES	YES	Wang et al. (2010)
X	X	X	YES	YES	Zhou et al. (2010)
X	X	YES (8 forms from different styles)	X	X	Pan et al. (2017)
X	YES (10 movements)	X	X	YES	Kim et al. (2017)
X	YES	X	X	X	Zhang et al. (2015)

Without details of the Tai Chi programme, it is difficult to comment how movements and forms were modified. Au-Yeung et al. (2009) report that their participants found memorising sequences of movement difficult which prevented them participating in home practice.

3.2. The principles of Tai Chi

All Tai Chi masters and practitioners follow a set of principles (Yang et al., 2014), set out in Chinese classical texts, such as 'the Tai Chi classics' by Chengfu (2005). Few studies have commented on whether the adoption of Tai Chi principles was included in their studies. However, Wang et al. (2010) educated their participants about the Tai Chi principles, with Pang et al. (2017) recommending two principles in particular: 1) practising whilst being relaxed and 2) using whole body co-ordination. If certain Tai Chi principles are adhered to, Tai Chi may be performed more accurately. It has already been discussed in Chapter 2 that participants had to complete a form by a certain time frame in some studies, thus prompting the instructor to move participants on quicker before they are ready.

Briefly, the general principles of Tai Chi according to most Tai Chi instructors are:

- relax the shoulders and sink the elbows to release tension in the shoulders
- align the spine with the head and maintain an upright stance
- the waist moves first, and the hands follow
- bend the knees slightly so they are not locked
- maintain breathing pattern

3.3. The challenges encountered designing a bespoke Tai Chi programme for stroke survivors

3.3.1. Choosing a suitable Tai Chi instructor

As discussed above, choosing which style of Tai Chi to use for stroke survivors needs careful consideration. However, finding a Tai Chi instructor specialising in the desired style may not be possible due to a lack of instructors in the area. Previous studies have not explained why they used a certain Tai Chi style. Therefore, it may be that previous studies used a certain Tai Chi style because it was the only one available, or it was convenient. Taylor-Piliae et al. (2014a) acknowledged that Yang style is the most popular one practised in the West, suggesting it may have been the only option. Thus, one advantage of using Yang style among western studies is the ability to compare results across studies.
The Tai Chi instructor at the researcher’s gym who specialised in Yang style was approached. The researcher designed the TCAS programme before approaching the instructor, so that he could see what was desired from the study. The instructor then offered his expert advice without diverting from the research question. This first draft of the exercises designed for TCAS can be found in Appendix 3.

It has become clear from the above discussion that self-efficacy, transport issues and significant others may play an essential role in adherence, attendance and retention of participants. Taylor-Piliae et al. (2011) suggest that a charismatic Tai Chi instructor is essential in maintaining adherence to their Tai Chi programme for stroke survivors.

According to Yang et al. (2014), Tai Chi instructors include qualitative components such as imagination, philosophy, encouragement and the Tai Chi principles which may make or break the success of the Tai Chi programme. Therefore, utilising one Tai Chi instructor may help participants talk about issues regarding adherence, attendance and retention, so that the researcher and instructor can work through these issues to avoid participants dropping out of the study.

3.3.2. Designing appropriate exercises for stroke survivors with varying levels of impairment

There are numerous things to weave into the designing of a Tai Chi programme for stroke survivors. This section will discuss things to consider, such as the safety of participants, ways to improve attendance and adherence, and communication. Justification for the inclusion of each exercise in both the class and home practice shall also be discussed. It will be made clear which exercises were initially included by the researcher and how the final version of the TCAS programme was developed following collaboration with the Tai Chi instructor. A number of pertinent aspects related to safety, attendance/retention and communication were considered during the development of TCAS:

1) What is in place for fatigued participants?
2) Is there a need for special clothing?
3) What can be done to maximise attendance and adherence?
4) Which exercises should be included?
5) How long and frequent should Tai Chi classes be?
6) Are these exercises to be included the most appropriate?
7) Should the programme include a ‘warm up’ or ‘cool down’?
8) Why is each exercise included in the study?
9) What exercises would be better suited for home practice?
10) What should be included and omitted from the home practice DVD and booklet?
11) How long should home practice be?

3.3.3. Ensuring the safety of participants

Safety of stroke survivors whilst taking part in exercise is important to consider, particularly because this population is at high-risk of falls. Aspects of safety to consider are fatigue, ratio of instructors per participants, clothing and footwear. This section will discuss concerns regarding safety and how they were addressed.

Stroke survivors experience fatigue, so they are encouraged to not only rest as part of the programme’s schedule, but to also rest whenever needed. As well as placing chairs near participants during exercises in the TCAS, study chairs were laid out along the length of the sports hall where participants were stepping, so they could have intervals of rest whenever they required. Whilst resting, participants were able to observe other participants practising their movements.

Stroke survivors who are assessed as being at risk of falling require supervision during the intervention. Therefore, it is important that there are enough people to monitor the participants during the intervention. Previous studies have used small groups. For example, Au-Yeung et al. (2009) used a class of between two and five participants, and Taylor-Piliae and Coull (2011) used a class of a maximum of six participants. The safest ratio of instructor versus participant was sought from a local physiotherapist to be implemented in the TCAS study. The physiotherapist advised an instructor/participant ratio of two supervisors per twelve participants to ensure the safety of participants.

Clothing is important when practising Tai Chi because if unsuitable clothing is worn, the full range of movement required may not be possible. Additionally, not being able to move easily may result in loss of balance because participants have adopted an incorrect movement or position. There is no specific Tai Chi clothing, but most Tai Chi instructors agree that casual clothing is ideal for Tai Chi (Docherty, 2014). Therefore, loose clothing is recommended for the TCAS programme so that participants may move freely: participants do not need to purchase any clothing specifically for Tai Chi and should be able to find suitable clothing in their wardrobe.

As well as clothing, suitable footwear is also important for practising Tai Chi safely. Shoes chosen by many older people may increase their risk of falling, by impairing their ability to walk and keep their balance (Ramstrand, Theusen, Nielsen, Brandborg & Rusaw, 2010). Therefore, participants of the TCAS study were encouraged to wear shoes as suggested above.

In line with an emergency procedure by Taylor-Piliae et al. (2014a), an emergency procedure for TCAS was verbally agreed between the researcher, hospital matron and ward staff. The emergency buzzer available in the sports hall could not be used because this would encourage ward staff to leave their patients. Therefore, a trained nurse would be present during the classes who would be qualified to deal with medical urgencies, such as falls. Should an adverse event happen, the incident would be dealt with as an out-of-hospital situation, where the participant would be treated by the researcher or taken to the Emergency Room.

A sense of safety among participants is important for the maintenance of attendance, adherence and retention. However, safety is not the only factor for ensuring the continuation of the exercise programme. Other factors involved include catching up after participants fail to attend, not being able to get to the venue, participants' feelings of not being able to do it, and feeling isolated. This section will discuss each of these points related to attendance, adherence and retention.

3.3.4. Designing exercises which stroke survivors can easily remember

Participants may miss classes due to outpatient follow-up appointments and family commitments. Being unable to attend certain classes, may make participants feel Tai Chi is not worth pursuing because they may forget what they have already learned or may not be able to catch up. Participants of TCAS join a rolling programme. By its nature, a rolling programme includes participants who are more ‘advanced’. The TCAS programme has, therefore, being designed to be flexible so that participants may drop in and out of classes without impeding on their progression. Participants may catch up easily because exercises are repeated in each class, to a point where participants become familiar with them. Repetition of exercises not only increases familiarity but also helps to practice each movement with greater accuracy. This accuracy in practising exercises enables participants to move onto more challenging exercises. Thus, feeling able to re-join a class at any time without difficulty may increase adherence.

3.3.5. Involving significant others

None of the Tai Chi studies involving stroke survivors in Chapter 2 mentioned the inclusion of significant others. Brooks, McCluskey, King & Burton (2013) suggest that the inclusion of significant others should be considered carefully when designing rehabilitation programmes. For example, the authors showed that significant others may support optimal functioning in people with back pain. It may be that significant others (spouse, partners, close family members) may support stroke survivors’ attendance and adherence to Tai Chi. For this to occur, it is important that significant others do not perceive stroke disability as an obstacle to recovery, otherwise significant others may have a negative impact on attending Tai Chi classes. It is thought that self-management strategies are most effective when involving significant others, especially with more burden placed on healthcare due to the current ageing population; being involved in the recovery process may enable significant others to be able to encourage optimal functioning (McCluskey, de Vries, Reneman, Brooks & Brouwer, 2015). In terms of the TCAS study, participants’ significant others may, therefore, become involved in the Tai Chi classes, enabling them to help participants with the home practice component of the intervention, thereby increasing adherence.

Significant others may provide a solution for transport issues if stroke survivors are unable to drive. It is known that lack of transportation is a barrier to exercise participation for stroke survivors (Taylor-Piliae, Boros & Coull, 2014b). However, adherence of significant others is required for this to be possible. Barriers which may cause a problem for significant others is the accessibility of parking. Using a hospital as the venue means high parking costs with limited availability of parking spaces. Additionally, significant others may find timing an issue because hospital car parks require payment by the hour, which may result in participants leaving classes early to avoid the payment of an extra hour.

3.3.6. Communication difficulties

Communication difficulties due to stroke may have a significant impact on participating in a Tai Chi exercise programme. Improved communication may develop through camaraderie. To enable camaraderie in the TCAS study, refreshments were made available with time to socialise at the end of each class. This also encouraged participants to share plans regarding missing sessions due to appointments or holidays within a comfortable setting.

Communication is also important during the intervention (Taylor-Piliae et al., 2014b). Impaired memory may prolong the mastery of exercises due to recall difficulties. Similarly, impaired comprehension may prolong the mastery of exercises due to an inability to understand instructions. These difficulties in communication may lead to a lack of self-efficacy which may encourage the participant to drop out. Therefore, it is essential that the researcher and Tai Chi instructor possess effective communication skills. Excellent two-way communication skills are required for the correct adoption of each exercise. Clear instruction from the Tai Chi instructor on how to practise each exercise is required, with minimal word prompts. Where certain postures may be complex to describe in simple terms, analogies, common in Tai Chi classes, were used. For example, the concept of 'central alignment', the instructor may use commonly used analogies such as, "imagine there is a thread attached to the top of your head, connected to the sky, keeping you aligned" and "imagine there is a thread all the way down from your head, down the centre of your body, and is rooted firmly in the ground." Participants will also be given time and encouragement to ask questions at any time.

3.4. The Tai Chi after stroke [TCAS] programme

3.4.1. The first draft

This section will discuss the first draft of the class exercises for the TCAS programme before amendments were made following the collaboration with the Tai Chi instructor (see Appendix 3). The following discussion includes each individual exercise for both the classes and home practice, along with the justification for its inclusion. Additionally, justification for duration and intensity shall also be given attention.

The first draft of the TCAS programme was split into six parts:

1) Beginning meditation
2) Joint-loosening exercises
3) Leg-strengthening exercises
4) Tai Chi stepping (walking like a cat)
5) The Tai Chi movements
6) Closing meditation

1. Beginning meditation (sitting)

According to ancient tradition, mindfulness is important; meditation practice in the form of mindfulness-led breathing can improve psychological capacities and cognitive performance (Lee, 2018). Lee (2018) suggests that mindfulness-led breathing with accordant body postures of Tai Chi may affect the emotions in a positive way, reducing fear and inducing a relaxed state. According to one Tai Chi instructor, 'one exhales more strongly when one is angry, whereas when one is calm, exhalation and inhalation are equal' Yang (2010). Participants involved in the TCAS programme may need to control their breathing pattern because of worry and stress associated with life changes following stroke. In a study exploring the effect of Tai Chi on preventing falls in the general elderly, it was suggested that by meditating at the beginning of the class, obtrusive thoughts, fears or anxieties which may distract the practitioner from focusing on Tai Chi movements, are avoided (Bartimole & Fristad, 2017).

Meditation leads to a deep awareness of the present moment through calming the mind, resulting in positive physical and emotional effects (Wright, 2007), including improving confidence, quality of life and motivation (Posadzki & Jacques, 2009). Meditation through mindful breathing exercises may help to reduce reactivity to repetitive thoughts and is used as a stress-management approach (Feldman, Greeson & Senville, 2010). According to Tappan (2002), who conducted a study on rehabilitation for balance and attention impairment in people with an intracranial bleed, a lack of awareness of the present moment may lead to loss of balance. It is not known if Tai Chi studies involving stroke survivors utilised meditation as part of their intervention, though four studies included what the authors called a 'warm up' (Kim et al., 2015; Pan et al., 2017; Taylor-Piliae at al., 2014a; Wang et al., 2010). By including meditation at the beginning of the TCAS programme, stroke survivors may be able to control their breathing and thus acquire a calm mind without any distractive thoughts which could lead to a loss of balance whilst practising Tai Chi.

2. Joint-loosening exercises

Many Tai Chi instructors recommend relaxing the joints as part of a warm-up before practising Tai Chi (Galante, 1980). Wu (2012) found that 15 minutes of repeated dynamic ankle joint exercise with weight-loading in whilst stationary may reduce ankle spasticity and improve walking ability. Loosening certain joints, such as the ankles, wrists, head, neck, shoulders and elbows exercises will, therefore, be included in the TCAS programme before practising Tai Chi.

3. Leg-strengthening exercises

Before starting any Tai Chi exercise, including stepping, practitioners should adopt a safe stance to avoid loss of balance. Wu (2012) suggested in a paper about the biomechanical characteristics of stepping in older Tai Chi practitioners, that by keeping the head forward as opposed to looking down to see where the feet are going, maintains balance. Wu (2012) further suggests that by keeping the head upright and gaze straight ahead, any mental distraction will be minimised, which is important because mental distractions have been found to have a direct impact on postural stability and balance on healthy older adults (Wu, 2012).

A semi-squat position is encouraged whilst performing the continuous, curved and spiral body movements that are characteristic of Tai Chi; during this semi-squat position, body weight is evenly distributed between the fore-foot and the rear-foot, and a large medial-lateral displacement of the foot centre of pressure (Lan, Chen, Lai & Wong, 2013). Older participants may not be able to maintain a semi-squat position, so Lan et al. (2013) recommend a higher posture should participants have muscle weakness (Lan et al., 2013).

For those who may benefit from more advanced rooting exercises, single-leg rooting (bearing weight on one leg whilst raising the foot lightly off the floor) may be used as an advanced strengthening exercise. Single-leg dynamic balance exercise may improve dynamic stability rapidly. Single-leg rooting was, therefore, included in the first draft of the TCAS programme included.

4. Tai Chi stepping (walking like a cat)

Tai Chi may be beneficial in improving stepping in stroke survivors; it has been shown that those who practise Tai Chi long-term step better than non-Tai Chi practitioners (Wu, 2012). The author suggested this was because Tai Chi practitioners demonstrated a faster stepping time due to the shorter preparation time to lift the stepping leg. Wu (2012) continues by suggesting that a faster stepping time is biomechanically and functionally important to reduce falls upon postural disturbance. Pavlol, Owings, Foley & Grabiner (2001) who examined the mechanics leading to a fall from an induced trip in older adults, agree with

Wu (2012), suggesting further that delayed stepping was significantly associated with falls during walking.

It has been suggested in a study by Hausdorff, Edelberg, Mitchell, Goldberger and Wei, (1997) that step time, step length and step width are associated with falls in the general elderly. Tai Chi (and specifically Tai Chi stepping) is an exercise which may control step time, length, and width due to its light agile movements. According to Gatts and Woollacott (2007), who analysed how Tai Chi may improve balance in impaired older people, the only way a fall can be avoided is by placing the foot down safely. Further, after examining the characteristics of foot movements in Tai Chi, it was found that continuously shifting the centre of gravity challenges the practitioner's balancing ability whilst the foot is firmly on the ground (Chau & Mao, 2006.) It has been shown that on placing the heel on the floor, healthy older people have a flatter foot position, thus reducing the risk of falls (Gatts & Woollacott, 2007.) In Tai Chi stepping in the TCAS study, weight is shifted from one leg to another, then lifting the empty leg to step and when placing the foot down, the heel touches the floor first.

5. Tai Chi movements

Stroke survivors with hemiplegia experience difficulties with balance, because the paretic arm experiences a feeling of heaviness, causing the stroke survivor to lean to the affected side. Seated practice of the arm movements will help gain some spatial awareness and maintain balance when incorporating them into the Tai Chi stepping. Therefore, whilst seated, participants are encouraged to familiarise themselves with the Tai Chi movements by looking at the body part being exercised so that they are mindful of what that body part is doing in relation to the rest of the body. Once they have mastered one movement, they may move onto the next one, which is more challenging. Upper limb movements will be introduced only when participants have gained mastery in stepping without arm movements. This is because by introducing arm movements, balance is challenged even further. As participants progress in stepping and moving the upper limbs whilst maintaining the centre of gravity the lower limb muscles become stronger because the muscles are being activated (Chau & Mao, 2006). Following 'preparation', there are eight Tai Chi movements included in the TCAS which are described in Table 8, along with justification for their inclusion.

6. Closing meditation (seated)

The Tai Chi class ends with meditation. As discussed previously, meditation aims to calm the mind. At the end of the class, meditation aims to rest the body before returning to daily activities because stroke survivors are likely to be fatigued.

Table 8 Justification for including Tai Chi movements in the first draft of TCAS classes

Movement	Description	Justification	Reference
Preparation	The practitioner adopts a shoulder-width stance, bends the knees slightly and adopts an upright stance.	The practitioner requires the body to be relaxed and balanced before beginning an exercise.	
Beginning	Also known as 'heaven and earth', this movement involves raising the hands to the chest level whist keeping the elbows relaxed.	This exercise releases tension in the fingers and hands.	
Holding the Ball	One palm faces up whilst the other faces down with a gap large enough to fit a ball. Palms rotate so that the palm facing up becomes faced down, and vice versa.	This exercise helps practitioners become aware of where the arms are in relation to the body and environment	
Parting the Wild Horse's Mane	This movement flows from 'holding the ball'. One foot is placed forward with the heel touching the floor first. Two arms and one leg move at the same time. Whilst stepping, the arms cross each other, like scissors. As the foot is firmly rooted on the ground, the arms uncross so that the right hand is facing up at chest level. The left hand is facing down.	This exercise is a more advanced movement which involves spreading the arms to maintain balance.	Pang et al. (2017)
Turning the Wheel	With knees slightly bent, the centre of gravity is lowered then raised whilst moving both hands in a rowing motion.	The arms are closer to the body and are not spread, making balance more challenging, especially if one limb is heavier than the other due to stroke.	
Cloud Hands	Start as in 'holding a ball'. Step with the right foot shifting weight onto the right leg. Lower the left hand and raise the right hand. The upper arm extends along to the right, so that the	Slow movements with arms spread to maintain balance.	Pang et al. (2017)

	lower hand can rise. This is repeated for the other side.		
Repulse Monkey	This movement involves stepping backwards whilst pushing each palm of the hand away from the body separately.	An advanced exercise. The arm movements are broad which may help maintain balance.	Pang et al., (2017)
White Crane Spreads its Wings	The right hand is forward with the left hand parallel. The left hand faces the right elbow. The right heel is turned 90 degrees. The foot is rooted to the floor and weight is shifted to the right leg. The left leg is 'empty' of weight. The left leg steps forward whilst the right hand moves in front at chest level with the palm facing out. The left hand moves down to the side.	This exercise helps the stroke survivor 'spread' the arms to the sides, practising balance control.	
Brush Knee	The right foot faces forward, in 'bow stance'. The left hand is in front of the right shoulder and the right hand is by the right thigh. Weight is shifted onto the right foot. The left footsteps forward. Once the foot is firmly rooted, the left lowers down by the side and the right hand is raised in front of the chest, with the hand pushing out.	The is challenges balance by not placing arms by the sides but challenging the stroke survivor to place one arm in front of the chest.	Pang et al. (2017)

3.4.2. The amended Tai Chi programme following consultation with the Tai Chi instructor

This section highlights the changes made to the first draft of the TCAS programme following discussion between the researcher and the Tai Chi instructor: four Tai Chi movements in the first draft were omitted and two others were added to the final movements included. An extra component, Qigong was also added. The final version of the TCAS programme can be found in Appendix 4.

1. Beginning meditation (sitting)

No changes were made to this section of the programme.

2. Joint-loosening exercises

The elbow exercises mentioned in the previous section were omitted because it was decided that the elbows would be relaxed if the shoulders were relaxed, thus there was no need to include this exercise. In its place, head and neck loosening exercises were introduced because it may be beneficial to relax these areas to help maintain central body alignment. Loosening the neck may help to relax the shoulders down, thus elbows will be lowered. Additionally, exercises to loosen the hand joints were included in preparation for upper limb movements.

3. Leg-strengthening exercises

As mentioned above, a semi-squat position (whilst adopting a high posture) is encouraged which helps to strengthen the leg muscles (Lan et al., 2013). Leg-strengthening occurs because bending the knees can place a large load on the muscles of lower extremities (Tsang & Hui-Chan, 2005.) This semi-squat position is often known as 'sinking,' a concept adopted by Tai Chi practitioners. An additional leg strengthening exercise was added to replace the movement 'turning the wheel'. Rather than practise 'turning the wheel', the instructor thought it better to practise the sinking and rising aspect of this form behind a chair without the arm movements.

4. Qigong exercises

According to a practitioner of Qigong, Tai Chi consists of sequential forms, whereas within the practice of Qigong are individual exercises (Zhang, 2000), hence Qigong may be viewed as being warm-up exercises. Following discussion with the Tai Chi instructor, it became clear that it is common practise to incorporate Qigong exercises into any Tai Chi practice to allow for the smoothness and controlling of Tai Chi movements.

Qigong exercises chosen for TCAS involve seated and standing exercises. Practising movement whilst seated before standing is important because the ability of each participant can be assessed within safe parameters. The Qigong exercises chosen by the instructor involve arm movements, encouraging the participant to gain spatial awareness. To help gain spatial awareness, participants are encouraged to look at their hands during the movements. Looking at the hands also helps to control the movements.

5. <u>Balance-training exercises</u>

Tai Chi includes weight-shifting, which help participants' 'limits of stability'. Limits of stability are the points at which the centre of gravity approaches the limits of the base of support, requiring a correction strategy to return the centre of mass to the base of support. To help participants recognise their own limit of stability, the concept of an imaginary balance line was introduced by the instructor, which is numbered from one (on the left), two (the middle) and three (on the right), depicted in Figure 4 (permission to use these photographs has been given by Richard Morley). This line is imagined by the participant during a parallel stance. Weight is shifted from position two to one, from position one to two, from position two to three, then from position three to two. Participants pause once they reach each position to gain insight into their limits of stability. It is stressed that participants should not move out of the imaginary line's range, or they may lose their balance.

As weight is shifted from one leg to another, participants are encouraged to imagine another line going down the centre of the body, representing the centre of gravity, depicted in Figure 4. As weight is shifted, this centre of gravity line should remain in the centre to maintain central alignment and balance. An upright stance is essential for the body to maintain balance, another principle of Tai Chi. To maintain body balance in Tai Chi, participants align their spines vertically without leaning forwards, backwards or sideways (Galante, 1980) with the head held upright whilst facing forwards (Chengfu, 2005). If the head is too far forward, it may cause the participant to lean forward, resulting in loss of balance. By maintain the centre of gravity, weight-shifting becomes a smooth movement. To practise smooth movements, participants are encouraged to shift along the imaginary balance line without pausing, should they become confident in their limits of stability. Following this, single-leg rooting may be practised. However, participants were encouraged to lift only the heel as opposed to the whole foot because lifting the whole foot may prove to be too difficult.

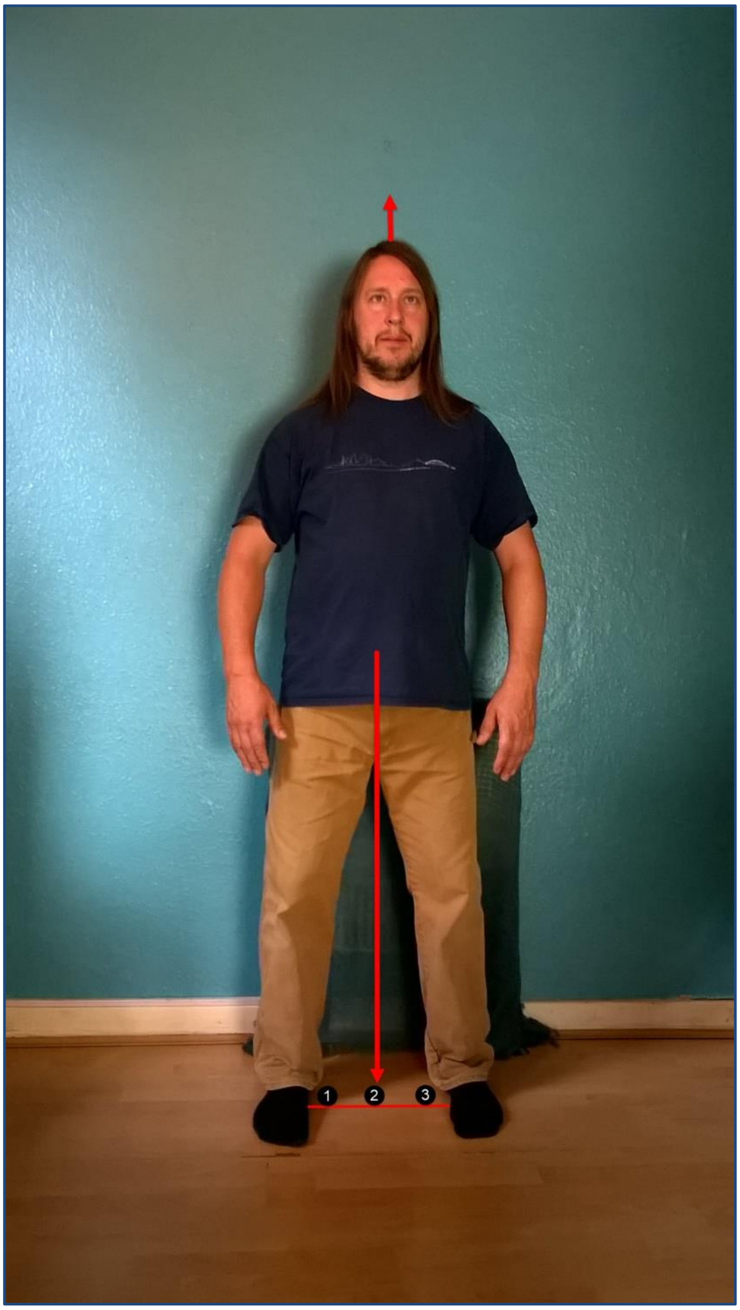


Figure 4 Centre of gravity during parallel stance

Once participants have achieved the aims of the weight-shifting exercises in the parallel stance, weight-shifting may then be practised in the bow stance (see Figure 5). A bow stance is where the practitioner places one foot forward so that the knee and toes are lined up perpendicularly and the leg supports 60 per cent of the body's weight (Yang, 2010.)

Figure 5 Centre of gravity during bow stance

Participants mirror the instructor so that the exercises are practised in group synchrony. Weight-shifting in the bow stance prepares the participant for the Tai Chi stepping by positioning the foot in the stepping position. Participants are thus able to give an indication as to whether they can move on to this stage in the programme.

6. Tai Chi movements

It was the original intention of the researcher to create a 'form' for stroke survivors by amalgamating different Tai Chi movements. However, on reflection, it was concluded that stroke survivors may find this too difficult. Therefore, the TCAS programme was confined to individual movements. The final draft of the Tai Chi programme focusses on integrating the movements with Tai Chi stepping.

Four movements included in the first draft of the programme were omitted. These are presented in Table 9, along with justification for the omissions.

Table 9 Tai Chi movements omitted from the TCAS programme

Movement omitted to the TCAS programme	Justification
Turning the wheel	This movement was incorporated into the leg strengthening section of the programme. Mastery of the practise of rising and sinking was needed before introducing arm movements.
Parting the Wild Horse's Mane	This was too complicated for stroke survivors recently discharged from hospital. Given the 12-week timeframe, it was decided that this is too short to be able to advance to more complex movements.
Cloud Hands	This exercise is not conducive to mix with stepping because it involves stepping to the side.
Repulse Monkey	Stepping backwards is very advanced and may be practised following completion of the final programme. However, the short time frame makes it unlikely that this advanced level of the programme would be reached by participants.

Movements added to the programme are presented in Table 10.

Table 10 Tai Chi movements added to the final Tai Chi exercise programme

Movements added to the TCAS programme	Description	Justification
Play guitar	Both arms are raised, shoulder-width.	This exercise helps participants understand their limits of stability in preparation for more challenging exercises.
Single whip	Arms are moved out to the side whilst stepping.	This exercise is more advanced and challenges balance further than 'play guitar' due to the wider arm movements.

3.4.3. Duration and intensity

There is no recommended duration and intensity to gain any benefits of Tai Chi (Zhang et al., 2015). Table 11 presents the intensity and duration of Tai Chi in previous studies. Most studies presented in Table 11 suggested that stroke survivors can tolerate a Tai Chi class well for a period between 40 and 60 minutes, with rest periods. As discussed in Chapter 2, twice a week for twelve weeks seems sufficient to gain health benefits in stroke survivors. Therefore, the TCAS study will have a Tai Chi intensity of one hour, twice a week for a duration of 12 weeks.

Table 11 Duration and intensity of previous Tai Chi exercise programmes

Duration and Intensity of Previous Tai Chi Exercise Programmes		
Number of minutes	60	Au-Yeung et al. (2009); Hart et al. (2004); Taylor-Piliae and Coull (2011)
	50	Wang et al. (2010)
	40	Kim et al. (2017); Pang et al. (2017)
Frequency per week	Once	Au-Yeung et al. (2009); Wang et al. (2010)
	Twice	Hart et al. (2004); Kim et al. (2017); Pang et al. (2017); Taylor-Piliae and Coull (2011)
	Three times	Fei et al. (2008)
	Six times	Zhibo et al. (2013); Zugang et al. (2013)
Number of weeks	Two	Fei et al. (2008)
	Four	Zhibo et al. (2013); Zhou et al. (2010)
	Six	Kim et al. (2017); Zugang et al. (2013)
	Eight	Pang et al. (2017)
	Twelve	Au-Yeung et al. (2009); Taylor-Piliae and Coull (2011); Wang et al. (2010);
Warm up/cooldown included	Yes	Kim et al. (2017); Pang et al. (2017); Taylor-Piliae et al. (2014); Wang et al. (2010)

3.4.4. Home practice

Locally, community therapy for stroke is carried out in patients' homes, where the physiotherapist spends an hour per visit. However, according to a local physiotherapist, contact time with patients is much less than this due to time travelling and filling out paperwork. A booklet is given to the patients who are encouraged to engage in self-practice every day. An example of an experimental group's rehabilitation booklet is found in Appendix 5.

Home practice of exercise programmes are beneficial: based on RCTs, continued rehabilitation at home from hospital reduces dependency (Fearon & Langhorne, 2012). Further, a systematic review reporting on the adherence to unsupervised home-based rehabilitation exercise programmes reported that patient adherence was generally high, with home-based interventions achieving improved physical fitness in patients with lung cancer (Driessen et al., 2017). Another systematic review found equivalent or better outcomes for mild to moderate stroke patients, with significant improvements over time in mental health also reported (Fisher et al., 2016). However, patient adherence to such exercise problems is often poor, particularly in patients with low confidence levels who refrain from activities (Picha & Howell, 2017). The authors suggested that adherence is low in those with poor social support and those without positive feedback and recommended encouraging self-efficacy to address the issue of low adherence rates to home practice. Home-based exercise programmes are recommended to optimise adherence to rehabilitation (Driessen et al., 2017).

Tai Chi as a low-impact, low-intensity therapeutic exercise was used as a home-based intervention in a study by Brismée et al. (2006) who offered a home video. The authors included an intervention consisting of six weeks of classes followed by six weeks of home practice. It seems that adherence was good because participants had experienced supervised classes beforehand. There are few Tai Chi studies involving stroke survivors where home practice is recommended. Only four Tai Chi studies involving stroke survivors included in Chapter 2 offered home practice as part of the intervention (Au-Yeung et al., 2009; Pan et al. 2017; Taylor-Piliae et al., 2011; Taylor-Piliae et al., 2014a). Taylor-Piliae et al., 2011; 2014a) offered a workbook and CD, and Pan et al., (2017) offered video clips and pictures. Pan et al. (2017) did not offer any supplementary material to practise at home but were encouraged to do so for ten minutes a day. Home practice materials were chosen by the researcher for the TCAS study to encourage adherence to home practice, as well as acting as guidance. Below, it will be discussed how a home practice booklet and DVD were developed.

3.4.5. The home practice booklet

The booklet was designed by the researcher and can be found in Appendix 6. The booklet was given to five members of a local Tai Chi club to review for legibility and clarity. Overall, members did not find any problems with the booklet. However, the following recommendations were made:

- two out of five members suggested more colour. The original colour was blue and was perceived as being too clinical.
- a larger font was also recommended by two members.
- one member recommended including breathing patterns, such as abdominal breathing, but it was decided that participants may find the focus on breathing a distraction from the movements. However, a 'tips for movement' section was included at the back of the booklet, which includes a brief tip for breathing.
- one member suggested that somebody new to Tai Chi may not understand certain terminology. Therefore, a glossary of terms was included at the back of the booklet.

Members did not find any problems with the exercises chosen for home practice. Included in the home practice booklet were four balance exercises, and a rooting practice exercise, which were included in the classes. There were photographs of the instructor demonstrating the exercises. Beside the photographs were detailed descriptions of how to perform each exercise at both beginner and advanced level. Exercises involved standing in the rooting position and shifting weight from one leg to the other in both parallel and bow stances, as taught in class. Home-based exercises included raising the heel from the floor and lifting the whole foot for more advanced participants. A glossary, as well as a section on Tai Chi principles and movement were also included. A red line depicting the centre of gravity were added to the photographs to clarify the importance of maintaining the centre of gravity (see Appendix 6). The four balance exercises included in the home practice exercise were chosen because they were suitable to be practised with a chair for safety, but also because home practice exercises focused on leg-strengthening and weight-shifting which prepares participants for stepping, the main exercise which challenges balance. Practising the home-based exercises regularly aims to improve stability, enabling quicker progression.
The recommended practise time was 15 minutes per day, as shown at the beginning. However, each of the home practice exercises has a two-minute prompt, adding up to only 10 minutes in total. Participants are informed during the class that for the remaining five minutes of home practice, focus should be on those exercises which pose most difficulty. If participants find the home practices too easy, the participant may freely choose exercises from the booklet for the remaining five minutes.

Home exercises focus on leg strengthening and maintaining the centre of gravity. The layout of the booklet is as follows:

- Participants are reminded to adopt the main Tai Chi principles to gain maximum stability.
- There is a preliminary exercise for rooting practice because, as discussed previously, it is important to establish stability before movement.
- The first two exercises involve weight-shifting both in parallel and bow stances and are practised in class.
- Exercises two and three are more challenging and prepare the participants for stepping.
- Exercise four is practised without a chair and introduces arm movements.
- A glossary is included to clarify any terms which are unclear.
- Tips for movements are included to achieve maximum stability.
- Contact details are provided if participants have any concerns.

3.4.6. The home practice DVD

Utilising a home-based DVD as part of a physical activity programme has been found to be suitable and supportive in some studies (Khalil et al., 2012; McAuley et al., 2013; Moffitt & Mohr, 2015). Combined with group exercise, improvements in balance have been found in the general population (McAuley et al., 2013), as well as high rates of adherence (Khalil et al., 2012; McAuley et al., 2013; Moffitt & Mohr, 2015). The DVD has been particularly effective in Huntington's disease patients with a low motivation for exercise (Khalil et al., 2012), as well as increase physical activity in the general population (Moffitt & Mohr, 2015).

A DVD was included in the Tai Chi programme to encourage adherence to home practice in case participants forgot how to carry out the exercises. Au-Yeung et al. (2009) included a complex Tai Chi form in their home practice programme and found adherence to be poor because of a reported inability to remember the exercises taught in class. Therefore, the exercises included in the TCAS DVD were taught in class, as well as mirroring the exercises contained in the home practice booklet. The Tai Chi instructor was given a copy of the home practice booklet and asked to create a DVD based on its contents. The DVD is included as an attachment to this thesis. Balance principles are introduced on a slide at the beginning of the DVD. On the DVD, the instructor demonstrates each exercise for the recommended time (two minutes per exercise), thus avoiding the need to use a stopwatch whilst practising alongside the DVD. Exercises in the DVD were intended to be followed in order, so that participants progress onto the next one. Hence, there is no interactive menu on the DVD to prevent participants from skipping exercises.

3.4.7. The home practice diary

Participants in the experimental group were asked to complete a home practice diary to indicate whether they had practised at least 15 minutes off home practice on days they did not come to Tai Chi. An example of a home practice diary is presented in Appendix 7. It was not known how burdensome filling out the diary would be. Therefore, the diary consisted of a 'yes' or 'no' response, along with space for optional comments.

3.5. Implementation of the TCA classes

A Tai Chi package has been developed for stroke survivors receiving rehabilitation following discharge from hospital aiming to reduce falls and improve balance. Home practice aimed to increase intensity and encourage progress, as well as for stroke survivors to take control over their own recovery at home. The package is split into two components: group classes and home practice. Group classes were one-hour long and were offered twice a week for 12 weeks. The finalised programme for the group practice which was delivered throughout the study is presented fully in Appendix 4. Home practice was encouraged to be at least 15 minutes on days when Tai Chi was not practiced. Materials for the home practice were a booklet and a DVD.

Details about the adherence and attendance to the TCAS programme will be discussed in Chapters 5 and 6. Tai Chi classes were held in a sports hall based at the hospital where recruitment took place, every Tuesday and Thursday at 12.00. Each class lasted one hour where participants collectively practised seated and standing exercises before adjourning to their individually paced stepping exercises. There was no need to change any of the exercises prescribed in the final programme. Participants expressed during classes that they were happy with the familiarity of the same routine, enabling them to progress. Details of changes to the home practice exercises were made by the participants, however, and will be discussed in Chapter 6.

Chapter 4 - Methodology

4.1. Introduction

The purpose of this chapter is to justify the theoretical framework chosen, along with the chosen study design and methods.

4.2. Philosophical framework

A philosophical framework helps to 'understand the researcher's perceptions of truth, reality and knowledge; through its use, the beliefs and values that guide the research design, collection and analysis of data are demonstrated' (Ryan, 2018). There are two ways of viewing research philosophy:

1) *Ontology.* Ontology refers to what there is to know and the nature of existence; what can be known as real and what someone believes to be factual, e.g. believing that a world exists outside the influence of the researcher and is yet to be discovered (Bryman, 2008).
2) *Epistemology.* Epistemology is the study of the foundations of science (Quine, 1971) and refers to how the researcher comes to that knowledge (Ryan, 2018), how knowledge is created and what can be known (Creswell, 2014). Epistemology determines a proper method of evaluation of determining truth from falsehood.

Quantitative research focuses on quantification in the collection and analysis of data (Bryman, 2008). Research using this paradigm is deductive (testing of theory) in nature and is concerned with the epistemological framework of 'positivism', and the ontological position of 'objectivism' (Bryman, 2008) both of which are discussed below.

4.2.1. Positivism

The epistemological framework which fits within the quantitative paradigm is positivism. Positivism justifies the methods of the natural sciences to the study of social reality (Bryman, 2008), and has become the standard philosophical view of natural science (Robson, 2015). Epistemologically, the world exists outside of the researcher's perspective, and this world exists separately from the researcher (Bryman, 2008).

Positivism purports that science can only be conducted in an objective way and truth cannot be confirmed by the senses (Bryman, 2008). Objectivism is thus the ontological position of the quantitative paradigm that relates to there being only one version of what is real, free from researcher bias (Ryan, 2018). From this ontological point of view, positivists believe that facts may be proven correct by testing hypotheses and using deductive reasoning, and that reality is the same for everybody (Bryman, 2008). Bryman (2008) highlights that positivists believe that only knowledge confirmed by the sciences is true knowledge. This knowledge is gained after testing a hypothesis to prove a theory correct.

The 'researcher's role is to be an explorer of universal realities and the verifier of theories or hypotheses in the search for unbiased universal truths' (Kelly, Dowling & Millar, 2018, p.10), which is why hypothesis testing is widely used in healthcare: it draws conclusions about the nature of populations and to produce statistically significant findings (Daniel, 1999).

Positivism has been criticised by some researchers for generating knowledge which is the absolute truth; the problem lies with the positivist suppositions lacking experience (Creswell, 2014). Whilst positivists believe there is only one truth based on objectivity and measurable accounts of reality, it is difficult to obtain measurable accounts of reality when the complexity of a situation is not understood (Williams, Rycroft-Malone & Burton, 2017). Another criticism of positivism is that it does not use real-life settings, but controlled laboratories that are easily manipulated (Bowen et al., 2009). In this way, the studies will reflect the realities of community and practice settings and will determine whether interventions are truly acceptable or not (Bowen et al., 2009).

4.2.2. Post-positivism

Post-positivists recognise that all observation is fallible and revisable (Trochim, Marcus, Mâsse, Moser & Weld, 2006). Post-positivists assert that one study alone is not enough to draw firm conclusions; confidence in the conclusion is gained when multiple related studies produce a similar result (Robson, 2015). From an ontological point of view, it is believed by post-positivists that 'there is a reality, but it can only be known imperfectly and probabilistically in part because of the researcher's limitations' (Robson, 2015).

Post-positivists acknowledge unobserved phenomena as well as observed phenomena (Creswell, 2014), and the use of quantitative and some qualitative methods is strongly supported within a post-positivist philosophical framework (Kelly et al., 2018).
Karl Popper, a prominent philosopher of post-positivism, suggested that if a theory is observably testable, it is falsifiable (Robson, 2015). In other words, we should never assume that the truth has been found because the next observation may show this truth to be false. Rather than make theories fit the facts, Popper asserts that facts derive from theories (Robson, 2015). By finding weaknesses and flaws of theories, theories can be refuted rather than supported, and better theories can be generated (Barnhart, 1996). Further, a hypothesis, if shown not to be false, has just not been falsified yet, suggesting that knowledge is provisional (McNamee, 2005).

Realism is based on the assertion that there exists an objective world independent of our knowledge, beliefs, theories or descriptions concerning it (McEvoy & Richards, 2006). It can be argued that positivists are realists because it is believed that there is an external reality separate from the mind (Robson, 2015). Realism asserts that:

'there is a real world that exists independently of our perceptions, our thoughts, feelings and attitudes' (Searle, 1999). However, to increase confidence in their assertions about reality, post-positivists require 'detailed prescriptions for research procedures' by generating hypotheses to obtain clear unambiguous answers whilst maintaining control over the research situation (Robson, 2015). Robson (2015) argues that in a real-life setting, objectivity may be difficult to achieve due to emotional involvement.

4.2.3. Philosophical framework for the qualitative paradigm

Qualitative research focuses on words rather than quantification in the collection and analysis of data (Bryman, 2008). Qualitative research is informed by various epistemological views and not all qualitative researchers share the same epistemological view (Soini, Kronqvist & Huber, 2011). Research using this paradigm is inductive (generation of theory) in nature (Bryman, 2008). Qualitative researchers using interviews often take an 'interpretivist' approach where reality needs to be interpreted to understand the underlying meaning of what happens. Participants' perceptions of balance improvement and falls reduction were also explored within various contacts, interactions and settings. Any relationships between participants and the Tai Chi programme will be determined.

The epistemological framework which fits within the qualitative paradigm is interpretivism. Interpretivism holds that the focus of the social sciences (people and their institutions) is different from that of the natural sciences and requires a different research method that reflects the distinctness of humans as against the natural order (Bryman, 2008). Understanding of human behaviour through empathy is the recommended method, rather than with the forces deemed to act on it; understanding through empathy requires the interpretive understanding of social action to gain an explanation of its cause and effect (Bryman, 2008).

Constructivism, one of the ontological positions commonly used amongst qualitative researchers, relates to social phenomena and their meanings which are continually being accomplished (Bryman, 2008). The researcher acquires a subjective meaning of social action, suggesting a strategy is required to respect the differences between people and the objects of the natural sciences (Bryman, 2008).

4.2.4. Adopting a multimethods approach

The TCAS study has adopted a multimethod approach, using more than one method of data collection in order to answer the research questions (quantitative and qualitative). For example, the quantitative element of the study is exploring to what extent participants complete the outcome measure, as well as the promise of Tai Chi as an effective intervention for a future RCT, whereas the qualitative element is exploring participants' perceptions of the acceptability, practicality, demand, implementation and integration of the Tai Chi programme, as well as outcome measures.

Although each paradigm is separate, the combining of the two is a planned and deliberate synthesis aiming to improve knowledge around the topic under investigation (Brewer & Hunter, 1989). A multimethod approach offers an alternative to mixed methods. It involves different methods for separate purposes within the same study and may only include one paradigm (quantitative only or qualitative only) or both paradigms (quantitative and qualitative) (Morse, 2003). Therefore, a multimethod approach was taken for the TCAS study, using both quantitative and qualitative paradigms involving separate methods. The multimethod approach has been adopted to overcome each paradigm's weaknesses and limitations by combing the two approaches together in the same study (Brewer & Hunter, 1989). This means that two theoretical frameworks will be adopted; a positivist approach will be adopted for the quantitative component, whereas the theoretical framework for the qualitative element is discussed below.

It was the aim of the researcher to obtain the opinions of the participants so that these views can be considered when designing a future study. There are many qualitative approaches which were considered for the TCAS study, including case studies, focus groups, grounded theory, and phenomenology. However, the latter approaches were not the most suitable to answer the research questions of the current feasibility study. Case studies involve single individuals which would not be representative of the whole experimental group (Bryman, 2012); future intervention changes would rely on one individual. Focus groups seemed to be a favourable approach but was rejected for the purposes of the current study because this approach would bring out group dynamics where meanings become socially constructed (Denzin & Lincoln, 2005). Additionally, those who are quiet may not speak up and let individuals dominate the conversation. People may also be less likely to differ in opinion if the majority agreed in opinion. Grounded theory was not chosen because the aim of the study is not to develop a theory, but simply just to gain participants' opinions about the intervention. Phenomenology was found not to be suitable because this approach focuses on interpretations (Denzin & Lincoln, 2005); the TCAS study is not looking for interpretations, but merely accepting what participants say. Thus, the most appropriate approach was a naturalistic one because participants can give their opinions and these opinions can be accepted as they are. Table 12 highlights the strengths and weaknesses of different qualitative approaches.

Table 12 Strengths and weaknesses of some qualitative approaches

Strengths and Weaknesses of Some Qualitative Approaches		
Qualitative Approach	**Strengths**	**Weaknesses**
Case studies	• Detailed and intensive analysis of a single case (Bryman, 2012). • Each participant's opinion is obtained (Bryman, 2012).	• A single case study would not represent the whole group (Bryman, 2012).
Focus groups	• Focusses on group dynamics (Denzin & Lincoln, 2005.) • Meanings are constructed within groups are largely socially constructed (Denzin & Lincoln, 2005).	• The TCAS study requires each participant's opinion. • Conversation may be dominated by certain people, leaving some without a voice. • Some participants may agree out of fear of disagreeing with the majority.
Grounded theory	• Data is gathered then analysed to develop a theory (Silverman, 2016).	• The TCAS study is not aiming to develop a theory but aiming to obtain participants' opinions. • The TCAS study is looking for opinions not behaviours.
Phenomenology	• How individuals make sense of the world without pre-conceptions of the researcher of that world is obtained (Denzin & Lincoln, 2005).	• The researcher is providing interpretation of others' interpretations (Denzin & Lincoln, 2005). • The TCAS study is not aiming to obtain interpretations, but to accept what participants say
Naturalism	• Data is obtained within a natural environment (Bryman, 2012). • Participants feel at ease to talk (Bryman, 2012). • Each participants' opinions can be obtained.	

The social world from the points of view of research participants was examined in the TCAS study. Silverman (2016) suggests that interviewing is useful for this. Further, interviews can identify culturally embedded normative explanations because they are representative of 'ways in which people organize views of themselves, of others, and of their social worlds' (Silverman, 2016; page 56). Contexts and situations in which phenomena about the Tai Chi programme can emerge from interviews, as well as knowledge about the cultural frames participants use to make sense of their experiences (Silverman, 2016). Herbert Blumer believed that social research should take a 'naturalistic approach' and rely on fieldwork to gain the perspectives of participants and to see reality from their point of view (Silverman, 2016). The naturalistic approach allows participants to feel comfortable and competent enough to talk back during the interview, providing insight into the meanings of their social worlds (Silverman, 2016). This naturalistic approach has been called 'interactionism' and its principles include:

- relating symbols and interaction, showing how meanings arise in the context of behaviour.
- taking the participant's point of view.
- studying the situated character of interaction.
- analysing processes instead of structures, avoiding the determinism of predicting behaviour from class, gender, race, age etc.
- generalising from descriptions to theories (Silverman, 2016).

A naturalistic approach has thus been adopted for the qualitative component of the TCAS study. Bryman (2012) defines naturalism as a style of research seeking to minimalize the intrusion of artificial methods of data collection, such as 'natural conversations.' The interviews at 12 weeks took place following the participants' final Tai Chi class, a natural uncontrolled environment in line with the natural flow of events. For example, participants were interviewed after the participant's final Tai Chi class had ended whilst waiting for transport home. Thus, participants were going about their normal activities, maintaining the natural flow of events. However, Bryman (2012) argues that even when the interviewing style is more of a conversational kind, interviewees still need to be taken away from their activities. Nevertheless, TCAS participants were not engaged in any activity except for waiting for transport. Thus, interviews were like chatting informally about an event they had just attended. In this way, Bryman (2012) asserts that perspectives of participants are more likely to surface where otherwise participants would have kept quiet.

To gain understanding of participants views would clarify certain issues that the quantitative approach is unable to do. There are critiques of the quantitative approach which are presented in Table 13. Similarly, some critiques of the qualitative approach are also shown in Table 13.

Table 13 Critique of quantitative and qualitative research paradigms (adapted from Bryman, 2008)

Critique against the quantitative paradigm	Critique against the qualitative paradigm
Does not distinguish people and social situations from the world of nature. Interpretation of people's views are not considered.	May be too subjective.
Fixed choice answers are used so that questions are interpreted the same, in terms of the question.	It is difficult to replicate.
It is difficult to show how the concern effects a person's daily life from measurement tools.	The importance of an issue may not be viewed as important by somebody else.
The relationship between variables does not show how they connect to everyday life of people.	Interpretation is influenced by the researcher.
	It cannot be generalised to other settings because it involves few cases.
	It is difficult to tell how conclusions were made: generalisations can be made to the theory but not the population.

4.3. Research design considerations

4.3.1. Randomized controlled trials

A randomized controlled trial is so-called because they randomly allocate participants to one of two or more groups, i.e. the intervention being tested, no intervention or usual care (O'Gorman et al., 2013). They test the efficacy of a new intervention and may produce statistically significant results (Whitehead, Sully & Campbell, 2014). Some people argue that a trial conducted properly is one of the highest levels of evidence second only to systematic reviews in the hierarchy of evidence in terms of quantitative studies (O'Gorman et al., 2013). Where a new intervention may be potentially better than current treatment, randomized controlled trials are preferred and have been labelled the 'gold standard', although this is debatable (Cartwright, 2007; Denzin & Lincoln, 2011; Scriven, 2008). It is argued that RCTs as a gold standard is based on deductive assumptions requiring rigorous internal validity standards; RCTs can be difficult to conduct, expensive and may not necessarily be the most suitable research design to answer a research question (Christ, 2014).

An intervention may be compared against the other groups to be able to test a hypothesis, such as whether the new intervention being tested is more effective than no intervention or the current treatment. The trial starts with a 'null hypothesis' (no difference between groups). Testing the null hypothesis is deductive in nature, ensuring the truth of conclusions is irrefutable (Wilkinson, 2013). It is the purpose of the randomised controlled trial to accept or reject this null hypothesis. This rejection of a null hypothesis is borne out of the epistemological framework supporting Popper's falsification theory of testing the null hypothesis. Should the null hypothesis be rejected, an alternative hypothesis is accepted (Gorman et al., 2013).

Two RCTs have been conducted on Tai Chi and its effect on stroke survivors. The key issue with an RCT and the TCAS study is numbers of participants; large numbers are required for results to be significant. Obtaining large numbers will require the involvement of multiple sites and a longer amount of time than the one provided for a PhD study. Large numbers of participants and multiple sites require a large amount of funding. Moreover, many public funding bodies expect substantial amount of work done prior to the bid in return for a substantial sum of money to support this work (Whitehead et al., 2014). Funding bodies want to support research which has an intervention worthy of testing for efficacy (Bowen et al., 2009). The question remains how the researcher can show the funding bodies that a research study is worthy of funding.

Work required to show its worthiness takes the form of a preliminary trial, thereby facing issues relevant to feasibility and addressing them before an RCT takes place. The UK Medical Research Council [MRC] (2008) guidance on designing and evaluating complex interventions strongly recommended a feasibility or pilot study prior to the main study so that feasibility issues are identified and managed. Whitehead et al. (2014) suggest that researchers are encouraged to publish this preliminary work in advance of the main study. Issues of feasibility have not yet been addressed with regards to the TCAS study because it involves a UK population and a bespoke Tai Chi programme for stroke survivors which has not yet been used. It is for this reason that a preliminary study is required before shaping TCAS into an RCT design. Table 14 presents why the need for a preliminary study is indicated:

Table 14 Indications for the need of a preliminary study

Indications for a Preliminary Study
• There are few previous studies which have utilised a bespoke Tai Chi programme for stroke as an intervention.
• There are few studies which have utilised Tai Chi as an intervention among UK stroke survivors receiving community rehabilitation at the point of discharge.
• Previous studies had positive outcomes but in different settings and stages of stroke to the one of interest.
• UK stroke survivors receiving community rehabilitation at the point of discharge have been shown by government health guidelines to need suitable exercise to prevent falls.

4.3.2. Pilot and feasibility studies

The terms pilot and feasibility have been used interchangeably and inconsistently, leading to confusion about their purpose (Whitehead et al., 2014). The MRC guidance does not provide an explicit definition of a pilot or feasibility study. The UK National Institute for Health Research [NIHR] offer the following as definitions:

Feasibility studies, are:
'pieces of research done before a main study to answer the question, can this study be done? They are used to estimate important parameters that are needed to design the main study' (NIHR, 2017).

Pilot studies are:
'a smaller version of the main study used to test if the components of the main study can all work together' (NIHR, 2017).

The UK NICE agree with the above definition of a pilot study being a small-scale version of the main study and add that problems or areas of concern need to be highlighted and amended before the main study can be conducted. In contrast, the MRC highlighted in their guidance that pilot and feasibility studies are not necessarily a scale model of the main-stage evaluation but agree that the aim is to address any uncertainties encountered by researchers.

The definitions of both pilot and feasibility studies often lead to confusion about what the difference is between these types of studies. Thabane et al. (2010) suggest that pilot studies are synonymous with feasibility studies and further suggest that feasibility should be the main emphasis of pilot studies. It is not surprising that the differences between definitions lead to lack of clarity. Thus, lack of clarity may lead to confusion when reporting and conducting pilot and feasibility studies.

Whitehead et al. (2014) found from a review of literature that features what distinguishes a pilot study from a feasibility study. Pilot studies have:

- stricter study methodology (more likely to mimic the main study design).
- an intention for further work (crucial for pilot studies because the study may be seen as underpowered trial deemed unethical with limited scientific use).
- a smaller version of the main study.
- a focus on trial processes.

The authors further suggest that all pilot studies are feasibility studies but not all feasibility studies are pilot studies.

The definitions of pilot and feasibility studies were re-evaluated by Eldridge et al. (2016). The authors felt this was necessary due to the weaknesses in the quality of reporting and conducting these studies. Based on the 2010 CONSORT statement, the authors administered a Delphi survey to obtain consensus on checklist items for inclusion in a reporting guideline. It was decided by the authors that feasibility is an umbrella term, with all studies conducted in preparation for a main study being categorized as feasibility studies. Consequently, three types of feasibility studies emerged, according to Eldridge et al. (2016):

1. randomized pilot studies (the future RCT, or parts of it, including the randomization of participants, is piloted on a smaller scale to see if it can be done. This type of study may also be referred to as a randomized feasibility study).
2. non-randomized pilot studies (the same as a randomized pilot study but without the randomization of participants).
3. other feasibility studies (where researchers attempt to answer the research question about whether some element of the future trial can be done but do not implement the intervention).

Throughout this thesis, the design shall be referred to as a feasibility study. Feasibility studies are exploratory in nature (Shanyinde, Pickering & Weatherall, 2011), and aim not to address efficacy but rather 'to carefully examine the success of procedures and react to unanticipated problems to get the best possible design for the next trial' (Shanyinde et al., 2011).

The NIHR suggest that certain parameters need to be estimated to design the main study. These parameters are presented in Table 15.

Table 15 NIHR estimated parameters for the design of an RCT

Estimated Parameters for designing an RCT (Shanyinde, Pickering and Weatherall (2011)
• Standard deviation for the outcome measure, needed to estimate sample size.
• Willingness of participants to be randomized.
• Evaluating the recruitment process.
• Number of eligible patients.
• Characteristics of the proposed outcome measure.
• Response rates to questionnaires, adherence/compliance rates.
• Time required to collect and analyse data.
• Determining consent rates.
• Examining the acceptability of the intervention.

Bowen et al. (2009) proposes that there are eight areas of focus of the intervention that feasibility studies need to be addressed:

1. **Acceptability:** how do both individual participants and the researcher react (suitability, attractiveness) to the intervention? Are participants happy with the home practice resources?
2. **Demand:** is Tai Chi likely to be used by stroke survivors? Are they willing to continue with Tai Chi after the study has finished?
3. **Implementation:** to what extent and in what manner is the intervention able to be fully implemented as proposed?
4. **Practicality:** are participants able to get to the venue? what is the cost of implementing Tai Chi? what is the most suitable venue? how committed are the instructor and participants? Are participants able to carry out the intervention exercises?
5. **Adaptation:** does the Tai Chi programme deviate from the protocol? If so, why? Actual adaptations to the programme need to be documented. Do the exercises and home practice resources need modification?
6. **Integration:** are there any changes that occur within the social lives of the participants, such as hospital appointments, starting to drive again, holidays, family commitments etc?
7. **Expansion:** is there any potential success of Tai Chi for stroke survivors at the point of discharge receiving rehabilitation in the UK?
8. **Limited-efficacy testing:** does Tai Chi show promise as an effective intervention for stroke survivors?

4.3.3. Chosen research methodology

The TCAS study included both quantitative and qualitative approaches and will thus adopt a multi methods approach with a quantitative priority where greater emphasis is placed on the quantitative methods and the qualitative methods are used in a secondary role. The first phase of the study is concerned with the collection and analysis of quantitative data, e.g. number of falls. This method is used to explore the suitability of the outcome measures for a future RCT. The TCAS study is a feasibility study where the second phase obtained participants' opinions and experiences of the intervention, logistics and outcome measures. As previously mentioned, the TCAS study has included both quantitative and qualitative components, which are separate from each other in terms of outcomes. Table 6 highlights the critique of both quantitative and qualitative approaches.

Tai Chi was offered to participants who were randomized into the intervention group in this preliminary study. Therefore, the design chosen for this study is a randomized pilot study under the umbrella term, feasibility study. Four pilot studies have been conducted on Tai Chi with stroke survivors. Such studies have aimed to explore feasibility issues but have not used the study population or Tai Chi programme used in the TCAS study.

All of the above eight areas of focus have been embedded within the design of the TCAS study. It is important to note that feasibility studies are not designed or intended to compare treatment groups in terms of statistically significant differences between groups on outcome measures. Rather, they aim to bring maximum benefit to the main trial (Whitehead et al., 2014). However, Bowen et al. (2009) suggest that feasibility studies do allow some comparison if randomization into an intervention or control group is used. With this suggestion in mind, groups in the TCAS study have been compared, despite the results not being statistically significant and will be discussed in Chapter 7.

Results from the TCAS study are not statistically significant because a meaningful effect size estimate for planning the main study is not possible in feasibility studies due to the small sample size. If effect size is calculated in a feasibility study, it should not be assessed for statistical significance. Instead of effect size, Whitehead et al. (2014) suggest the use of clinical experience to define a 'clinically meaningful effect'. In other words, any significant difference of outcome measures between groups may be identified to define stroke survivor's improvements in a practical way.

In short, a preliminary study is required before conducting an RCT to find out if the RCT is worth investing in practically, ethically and economically. The 2008 MRC guidelines encourage this preliminary study to ensure any issues are identified and managed in the preliminary study. The modified Tai Chi programme used in the TCAS study has not been tested for its feasibility and acceptance by stroke survivors. Further, it is not known if a stroke population at the point of discharge will accept the study. Therefore, a randomized pilot study under the umbrella term 'feasibility study' has been conducted according to the parameters suggested by the NIHR which include the willingness to be randomized, estimation of sample size, number of eligible participants, suitability of outcome measures and evaluation of the recruitment process.

The Consolidated Standards of Reporting Trials [CONSORT] 2010 statement is a guideline on how to report randomized controlled trials to a high-quality standard with improved transparency (Eldridge et al., 2010). Due to weaknesses in reporting pilot and feasibility studies, as well as reporting their conduct, an extension to this statement has been added for randomized pilot and feasibility studies. This extension provides a 26-item checklist of information to include when reporting such types of study. Presented in Table 16 is the CONSORT 2010 checklist for the reporting of the TCAS study, along with reference to the page numbers in this thesis where the information can be found. Included in the checklist are details to inform other researchers who may want to replicate the study, such as the intervention, study design (as well as changes to the study design), participation location, identification and recruitment (as well as sample size and randomization), outcomes and results.

Table 16 CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title.	Cover page, 3
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials).	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial.	16-53; 54-87
	2b	Specific objectives or research questions for pilot trial.	87
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio.	122-123
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons.	243-245
Participants	4a	Eligibility criteria for participants.	139-141; 161
	4b	Settings and locations where the data were collected.	142
	4c	How participants were identified and consented.	143; 149-151; 156-158; 161
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.	88-112; Appendices 4,5,6,7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed.	136-138
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons.	n/a
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial.	251
Sample size	7a	Rationale for numbers in the pilot trial.	144-146
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	n/a
Randomisation:			

Sequence generation	8a	Method used to generate the random allocation sequence.	146; 151-152; 158
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size).	151-152
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned.	151-152
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions.	151-152
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	151-152
	11b	If relevant, description of the similarity of interventions.	n/a
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative.	163-206; 209-229
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective.	160
	13b	For each group, losses and exclusions after randomisation, together with reasons.	160
Recruitment	14a	Dates defining the periods of recruitment and follow-up.	157
	14b	Why the pilot trial ended or was stopped.	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group.	Appendix 34
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group.	Appendix 34
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group.	251-259
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial.	164-205
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms).	n/a
	19a	If relevant, other important unintended consequences.	n/a
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility.	267-268
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies.	267-268
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence.	231-259
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments.	231-259

Other information			
Registration	23	Registration number for pilot trial and name of trial registry.	Appendix 22
Protocol	24	Where the pilot trial protocol can be accessed, if available.	Appendix 22
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders.	Appendix 39
	26	Ethical approval or approval by research review committee, confirmed with reference number.	Appendices 23, 25

This section is concerned with developing the research protocol, along with the research methods chosen in order to answer the research question.

4.4. Outcome measures

4.4.1. Qualitative outcome measures

Outcome measure for fall rates

The primary outcome measure of TCAS is quantitative: the number of falls using a falls calendar (see Appendix 8). Fall rates have not been widely used among Tai Chi studies because the primary outcome was not fall-related. Generally, however, when measuring falls, the calendar method is the most commonly used (Li et al., 2004; Logghe et al., 2009; Taylor et al., 2012; Taylor-Piliae et al., 2014a; Tousignant et al., 2013), along with telephone calls to reduce self-reporting bias (Logghe et al., 2009; Taylor et al., 2012; Tousignant et al., 2013). A systematic review of methods of measuring falls in randomised controlled fall prevention trials by Hauer, Lamb, Jorstad, Todd & Becker (2006) found eight primary collection methods: prospective registration, calendar, prospective registration, patient diary, prospective registration, postcard, recall, face to face interview, recall, postal questionnaire, recall, telephone, nursing home fall records and hospital fall or health records. Routine health records have limited quality and availability in different settings. In the community, they have little significance because only less than 20 per cent of falls are reported by patients (Hauer et al. 2016). According to Hauer et al. (2016), prospective systems are superior, with falls diaries leading to an increased number of reported falls. However, the authors found the three systems of prospective reporting to be difficult to determine, and may be under or over reported, often having a back-up retrospective recall, such as telephone calls. Thus, the authors acknowledge that retrospective recall may introduce retrospective recall error into the data. Fall calendars with follow-up telephone calls for non-responders have been chosen as the method to record the number of falls in this study, thus minimising data error. Additionally, fall rates are the most direct measure to assess whether the number of falls is reducing, and obtaining fall rates from records is not suitable for TCAS because this study is exploring the number of falls following discharge from hospital during the intervention period.

Outcome measure for balance

To assess balance improvement as an outcome, numerous measures for balance have been developed (See Table 17). Because the TCAS study focuses on dynamic balance (maintaining balance whilst in motion), balance assessment tools measuring this type of balance were evaluated. Dynamic balance assessment tools evaluated included the BBS, Dynamic Gait Index, EquiTest, Limit of Stability Test, Romberg Test of Balance, Timed-Up-And-Go Test [TUG] and the Short Physical Performance Battery [SPPB].

The SPPB is a brief performance battery designed for older adults to assess balance, gait speed and lower body strength (Guralnik et al., 1994). It involves aspects which are not being investigated by the TCAS study, e.g. gait and lower body strength.

The EquiTest and Limit of Stability Test [LoS] measure balance through computed dynamic posturography, which is expensive technical equipment. This equipment also requires special training, thus making these tests unsuitable for this study due to limited financial resources.

The Romberg Test and The Dynamic Gait Index focus on aspects other than balance caused by limb weakness. For example, the Romberg Test is used to investigate the cause of loss of motor coordination and is used more in conjunction with the vestibular system and vision rather than limb weakness. The Dynamic Gait Index assesses gait, balance and fall risk. However, in stroke it has moderate responsiveness in depicting change at two months and five months after treatment. The Limits of Stability Test requires the use of force plates which are not available for the TCAS study.

The Timed-Up-And-Go [TUG] test, a tool used to assess a person's mobility based on timing sitting to standing and walking, can be used as a simple measure of balance comparable to the BBS (Bennie et al., 2003). However, most studies in Table 15 have used TUG for general mobility. Although the TUG only takes five minutes, lessening the burden on participants compared with the BBS taking fifteen minutes to perform, the BBS is already in use as part of a routine assessment in the local community where the TCAS study is located. Harada, Chiu & Damron-Rodriguez, (1995) found that the BBS was a more valid measurement of balance than other clinical laboratory balance tests, and Stevenson and Garland (1996) found the BBS to have excellent reliability in elderly stroke survivors.

The TCAS study adopted the BBS (see Appendix 9), a 14-item/five-point ordinal scale which takes approximately 25 minutes and is easy to administer, requiring minimal equipment such as a step, stopwatch, ruler and a chair (Stevenson, 2001). The scale aims to quantitatively assess balance and risk for falls in older people living in the community by performing tasks which are graded from zero to four. The total possible score adds up to 56 with higher scores reflecting better balance. The BBS can predict falls in the elderly by demonstrating scores less than 45 out of 56 (Bogle, Thorbahn & Newton, 1996). As well as assessing both dynamic and static aspects of balance (Blum & Korner-Bitensky, 2008), the BBS is also useful as a screening tool to identify if stroke survivors require physical therapy (Stevenson, 2001). Physiotherapists based at the study site use the BBS to assess stroke survivors who have been referred to community physiotherapy. Therefore, it would be easy to obtain a baseline BBS score for the Tai Chi study, but the purposes of a study, a measure needs to be also adequate at examining the effectiveness of an intervention. Berg, Wood-Dauphinee, Williams, and Gayton (1989) designed the scale to provide a means to determine change in balance ability over time, and, indeed the BBS has been administered before and after the intervention (Stevenson, 2001). It has been shown that the BBS has been responsive to change in stroke survivors at two, six and12 weeks post-onset (Wood-Dauphinee et al., 1999), with moderate to excellent sensitivity to change in the early post-stroke period (Blum & Korner-Bitensky, 2008). Establishing change and whether an intervention may be effective or not is more difficult than predicting falls and assessing balance. It is not clear how much change in score is needed to claim that an intervention has been effective, and what constitutes an improvement in balance may vary between assessors. Therefore, some agreement is required. Stevenson (2001) suggests that the clinical interpretation of the before and after Berg Balance scores requires a change score of five BBS points or more to be 90 per cent confident that an individual's BBS performance has changed when assessed by two different raters. For example, an initial Berg Balance score of 40 would have to increase to 46 to show an effect in the intervention. However, Blum and Korner-Bitensky (2008) suggest exercising caution when measuring change in stroke survivors who have mild balance impairment but did not state why. It is likely that stroke survivors with mild balance impairment may not improve balance because they may not show an improvement in balance because there is limited scope for improvement. A minimum change score of five was considered when analysing data from the BBS in this study to conclude that genuine change has occurred in participants.

One consideration with the BBS used with stroke survivors is the performance of the final two tasks where standing on one leg and standing in tandem are required. Stroke survivors with hemiparesis may find these tasks challenging. Kwong (2015) found that selecting the paretic leg as the primary weight-bearing leg in these two tasks resulted in significantly lower BBS scores in stroke survivors. The author suggests standardising the chosen leg for these two tasks. Therefore, in Kwong's study, all participants were instructed to weight bear on the non-paretic leg to reduce the risk of falling. This means that the BBS score may potentially be even lower if the paretic leg was used.

Despite strong psychometric properties for assessing balance, previous studies with stroke survivors have demonstrated large floor and ceiling effects post-stroke (Blum & Korner-Bitensky, 2008). The authors thus recommended the use of other balance measures in conjunction with the BBS to address this, so possible additional measures were considered.

Only one stroke study discussed in Chapter 2 has used the BBS to measure dynamic balance; outcome measures varied greatly among studies, making it difficult to conclude which is the most appropriate.

Excellent between- and within-rater reliability for the BBS has been reported by Berg, Wood-Dauphinee and Williams (1995), as well as excellent test-retest and interrater reliability among chronic stroke (Blum & Korner-Bitensky, 2008). Interrater reliability was established for the TCAS, the results of which can be found in Appendix 10. For the TCAS study, baseline assessments were conducted by the community physiotherapists and 12-week BBS scores were conducted by the researcher. The researcher did not conduct the initial BBS because to do so would introduce researcher bias when the researcher conducts the 12-week scores. Additionally, both assessors need to be achieving the same results when calculating the scores. Therefore, it is important that both assessors at baseline and 12-weeks are assessing using the same parameters. In order to gain inter-rater reliability for the BBS, the researcher was taught how to perform the BBS by a senior physiotherapist based at the hospital. We performed three BBS tests on the same three patients without seeing what each other had scored. When the scores were compared, it was found that scores were similar. The setting and equipment used was the same equipment for the same 12-week assessments. The letter to confirm inter-rater reliability has been established is found in Appendix 11.

Table 17 Quantitative outcome measures related to balance used in previous Tai Chi stroke studies

Outcome measure		Purpose	Reference
Berg Balance Scale		Dynamic balance	Hart et al. (2004)
Gateview		Static balance	Kim et al. (2015)
Sensory Organization Test		Static balance	Au-Yeung et al. (2009)
Dynamic Gait Index		Dynamic balance	Kim et al. (2015)
EquiTest		Dynamic balance	Au-Yeung et al. (2009)
Limit of Stability Test		Dynamic balance	Au-Yeung et al. (2009)
Romberg Test of Balance		Dynamic balance	Hart et al. (2004)
10min Walking Test		Gait	Kim et al. (2015)
2min Step Test		Aerobic endurance	Taylor-Piliae et al. (2014)
Timed-up-And-Go Test [TUG]		Gait	Kim et al. (2015)
		Mobility	Au-Yeung et al. (2009)
		Mobility	Hart et al. (2004)
Emory Fractional Ambulation Profile [EFAP]		Gait	Hart et al. (2004)
Short Physical Performance Battery [SPPB]		Balance, gait speed, lower-body strength	Taylor-Piliae et al. (2014)

<u>Outcome measure used for fear of falling</u>

Few Tai Chi research studies involving stroke survivors have included self-efficacy as part of their outcome measures. Four popular outcome measures used by researchers for this are the Activities-Specific Balance Confidence Scale [ABC], the FES, the Modified Falls Efficacy Scale [MFES] and the CONFbal Scale. The ABC and CONFbal Scale focus on confidence in performing an activity without losing one's balance. The TCAS study's primary outcome is falls. Therefore, confidence in performing an activity without falling would be more suitable to the study's aims.

The FES is a reliable and validated ten-item questionnaire intended to be used for community and hospital patients with brain injury, multiple sclerosis, spinal cord injury, stroke and the general elderly (Dewan & MacDermid, 2014). The FES assesses fear of falling, recommended for older people living in the community and is a self-reported questionnaire which requires individuals to rate from one to ten how confident they are at performing certain activities without falling, regardless of whether they perform these activities (Dewan & MacDermid, 2014). Total scores range from ten (most confident) to 100 (least confident and greatest fear of falling). There is also a modified version of the FES with an additional four tasks. Due to the nature of a feasibility study, it was deemed unnecessary to expect participants to perform these four extra tasks. Therefore, the original 10-point FES was used in the TCAS study (see Appendix 12).

<u>Outcome measure used for depression</u>

There are many tests available to measure depression, such as the Beck Depression Inventory, the Patient Health Questionnaire (PH2 and PH9), the GDS, the Zung Self-Rating Depression Scale, the Center for Epidemiological Studies Depression Scale [CES-D], the General Health Questionnaire, the Hospital Anxiety and Depression Scale [HADs] and the Hamilton Depression Rating Scale.

The 20-question CES-D was designed to measure the severity of depressive symptoms in the general population and is widely used in research as a screening instrument and has been used in the Tai Chi study by Taylor-Piliae et al. (2014a). However, it's robustness and suitability of the commonly used four-factor 20-item CES-D model has been called into question. Carleton et al. (2013) investigated this and concluded that results should be interpreted with caution. For example, item 17, for example used crying as a severity of depression and this could not be accurately interpreted as a sign of depression.
The Hospital Anxiety and Depression Scale [HADS] was developed to detect states of depression who were treated for clinical problems (Zigmond & Snaith, 1983) but has been used among non-hospital-based patients with success (McDowell, 2006). It was not originally designed to be a clinical diagnostic tool (Whelan-Goodinson, Ponsford & Schönberger, 2009) and has been found to perform as well as the Beck Depression Inventory and the General Health Questionnaire instruments (Mykletun & Stordal, 2001).

The Beck Depression Inventory is a 21-question multiple choice self-report tool designed to measure severity of depression, whereas the GDS is a 30-item self-report 'yes' or 'no' tool, aimed at older people to diagnose depression. Out of these two depression tools, the GDS was preferred because questions only required circling a 'yes' or 'no' to one response, as opposed to choosing one of four responses. The GDS scores result in a categorisation into normal, medium or severely depressed, and this should suffice for the TCAS study.

The Geriatric Depression Scale [GDS] has been shown to be useful in younger stroke survivors as well as older stroke survivors with minor depression and has demonstrated internal consistency and test-retest reliability (Sivrioglu et al., 2009). The GDS is a self-rating 30-item screening tool for depression developed for use in geriatric patients. Questions refer to how one felt over the last week and can detect changes over time. There is also a shorter 15-item GDS but Chau and Mao (2006) found that although it was suitable to detect post-stroke depression, the 30-item version had stronger psychometric characteristics in the stroke population. The GDS has been validated against the Hamilton Rating Scale for Depression and the Zung Self-Rating Depression Scale and was found to have a 92 per cent sensitivity and an 89 per cent specificity when evaluated against diagnostic criteria (Yesavage & Brink, 1983). The GDS was the chosen measurement tool for depression in the TCAS study because it has a 'yes' or 'no' answering system and can detect changes over time (see Appendix 13).

<u>Outcome measure for quality of life [QoL]</u>

The 11- item Patient Health Questionnaire asks questions relating to the last four weeks which stroke survivors may find difficult to recall. Similarly, the 12-item General Health Questionnaire requires recall over the last few weeks.

To measure QoL, there are numerous measuring tools, such as the SF 36, SF 12, Quality of Life Scale [Qols], WHOQoL-BREF, EuroQol, HRQoL, and the Duke Health Profile. The QoLs is designed for chronic conditions, intended for group assessment as opposed to individual patient assessment (Buckhardt & Anderson, 2003) and would be a good tool to use for the TCAS study. Another suitable tool is the HRQoL. The HRQoL is a four-item questionnaire with good retest reliability, validity and responsiveness (Yin, Njai, Barker, Siegel & Liao, 2016). An alternative tool to use is the Duke Health Profile, as used by Hart et al. (2004). This tool is a 17-item questionnaire which assesses six health measures and four dysfunction measures. According to Vahedi (2010), the WHOQoL-BREF could be further improved with more research needed to increase measurement precision at the high-end of the scale. Though moderately reliable, Vahedi (2010) suggested this tool be used to assess moderate levels of quality of life.

The SF 12 questionnaire is a shorter version of the SF 36 questionnaire. The SF 36 questionnaire is a generic measure of health status that has been validated in stroke survivors and includes both physical and mental component summaries, known as PCS and MCS respectively (Pickard, Johnson, Penn, Lau & Noseworthy, 1999). The average time to fill in the SF 36 by the general population has been known to be 10 to 12 minutes but takes longer for stroke survivors; researchers using the SF 36 have found it to be burdensome for stroke survivors, resulting in missing data (Pickard et al., 1999). By using the SF 12, missing data would be less problematic and thus increase the efficiency of the study. It is also quicker to complete, with the general population completing in two minutes. It is expected that stroke survivors would take longer but this is still far less time-consuming than the SF 36 (Pickard et al., 1999).

One disadvantage of using the SF 12 is the less-precise estimate of individual health and inability to calculate summary scores when one item has not been answered. Pickard et al. (1999) suggest that the SF 12 may not be suited to evaluate changes over time because it only includes one third of the items contained in the SF 36. The authors analysed the SF 12 and SF 36 to determine the extent to which the summary scores of the SF 12 replicate the SF 36. Strong agreement was found between the two questionnaires, affirming that the SF 12 replicates the SF 36 summary scores without substantial loss of information. However, other measures in conjunction with the SF 12 were recommended by the authors.
No previous stroke studies as discussed in Chapter 2 have used the SF 12. The choice of outcome measure for QoL vary, making it difficult to conclude about the most appropriate one. The SF 12 was chosen for the TCAS study because of the little time it takes for stroke survivors to fill it in. It has been argued by some researchers that adopting a qualitative approach would explore QoL more accurately. Therefore, quality of life will also be addressed by conducting an interview which will explore participants' perceptions of QoL to enrich the data from the SF 12.

Initially, the EuroQOL questionnaire was considered, but after assessing its suitability compared with the SF 12, it was decided that this questionnaire is better utilised as part of the economic appraisal of health programmes and their incorporation into health technology assessments (see Appendix 14).

The Falls Efficacy Scale, Geriatric Depression Scale and the SF 12 were piloted using nine elderly Tai Chi practitioners who attended a local Tai Chi class. Nobody expressed any difficulties with reading or understanding the questionnaires.

4.4.2. Qualitative interviews

The aim of this qualitative element is to gain participants' experiences, feelings, thoughts, values and perceptions, through empathic understanding, of how well the study was undertaken, as well as any improvements or changes needed in the Tai Chi programme. If any falls or drop-outs are reported, the qualitative component of the study enables deeper insight into why the fall or drop-out occurred. Burke-Johnson and Onwuegbuzie (2014) suggested that the subjective knower is the only source of reality. By adopting a qualitive approach, the subjective reality of the participant's experience of the world can be understood (Polit & Beck, 2017). Polit and Beck (2017) agree with Robson (2015), suggesting that results from a qualitative approach reflect on the participants, settings and tone of environment at that moment in time.

There are numerous ways to obtain qualitative data such as focus groups and individual interviews. Focus groups were not the method of choice for TCAS because they may be led by dominant participants and lead to participants to agree with the majority (Bryman, 2008). Individual interviews were conducted in the TCAS study as opposed to in a group to obtain individuals' opinions on each item in the interview schedule. Semi-structured interviews were chosen as opposed to structured interviews because of the opportunity they give to the researcher to ask questions which may arise from respondents' replies. Additionally, semi-structured interviews allow the interviewer to change the sequence of questioning. Participants' experiences and perceptions were obtained to gain empathic understanding about the study in general, as well as the Tai Chi programme. Reasons for missing classes and understanding the reasons behind unexpected falls were discussed. An interview template was produced as a guide to ensure all areas of inquiry were covered, as well as guide the interview's content should participants choose to go off on a tangent. This template can be found in Appendix 15 (words highlighted in yellow are corrections required by the REC).

4.5. How the different activities and data sources within the TCAS study address the research questions

Activities and data sources included in the TCAS study are the outcome measures, interviews and Tai Chi programme. It is important to articulate how these different activities and data sources address the research questions posed in section 4.3.2. This is presented in Table 18 as a list of research questions in relation to the seven areas of focus for a feasibility study recommended by Bowen et al. (2009), along with the corresponding activity and data source. In order to answer the research questions in terms of feasibility, the conduction of the Tai Chi programme is essential because six of the areas of focussed cannot be addressed without it. For example, it cannot be established if the programme needs changing or if participants are able to attend or practice the exercises unless they have a go. Future studies will investigate the efficacy of the intervention. Therefore, it is necessary to find out if the outcome measures chosen are the most suitable. To find out if participants can complete the outcome measures and to assess their suitability, participants need to fill them out as part of the feasibility. To explore the level of difficulty participants found the Tai Chi programme and completing the outcome measures, interviews are required to find out participants' opinions.

Table 18 The TCAS research questions and how the chosen activities and data sources answer the different areas of focus for feasibility studies

How the different activities and data sources included in the TCAS study answer the research questions		
Feasibility Study Area of Focus	**Research Question**	**Activity or Data Source**
Acceptability	How do both individual participants and the researcher react (suitability, attractiveness) to the intervention?	Interviews, Tai Chi programme, outcome measures
	Are participants happy with the home practice resources?	Interviews, Tai Chi programme
Demand	Is Tai Chi likely to be used by stroke survivors?	Interviews, Tai Chi programme
	Are stroke survivors willing to continue with Tai Chi after the study has ended?	Interviews
Implementation	To what extent and in what manner is the intervention able to be fully implemented as proposed?	Tai Chi programme, outcome measures
Practicality	Are participants able to get to the venue?	Tai Chi programme
	What is the cost of implementing Tai Chi?	Tai Chi programme
	What is the most suitable venue?	Tai Chi programme
	How committed are the instructor and participants?	Tai Chi programme
	Are participants able to carry out the intervention exercises?	Tai Chi programme, interviews, outcome measures
Adaptation	Does the Tai Chi programme deviate from the protocol? If so, why?	Tai Chi programme
	Do the exercises and home practice resources need modification?	Tai Chi programme, interviews
Integration	Are there any changes that occur within the social lives of the participants, such as hospital appointments, starting to drive again, holidays, family commitments etc?	Tai Chi programme, interviews
Expansion	Is there any potential success of Tai Chi for stroke survivors at the point of discharge receiving rehabilitation in the UK?	Interviews, outcome measures
Limited-efficacy testing	Does Tai Chi show promise as an effective intervention for stroke survivors?	Outcome measures

4.6. Applications of the chosen methods to the TCAS study

Inclusion and exclusion criteria

Patients with a diagnosis of stroke, at any age, on the stroke unit at Pinderfields General Hospital were identified as potential participants, whose eligibility was determined according to inclusion/exclusion criteria presented in Table 19 and Table 20.

Table 19 Inclusion criteria for the TCAS study

Inclusion Criteria	Rationale for the inclusion criteria
The patient has been diagnosed with stroke in the early rehabilitation phase.	The study aims to evaluate the feasibility of Tai Chi among stroke survivors. Therefore, a diagnosis of stroke is required. However, in some cases, a confirmed diagnosis is not always made by a CT scan or MRI. In such cases, the patient is treated clinically as a stroke. This means that the patient displays clinical features of a stroke, but these features have not been picked up radiographically. It may be that somebody who is being treated clinically as a stroke may be discharged at short notice once the stroke consultant has decided that the patient is not a stroke. This may cause a problem in recruiting because such a patient may have been offered community therapy services before the consultant's decision to discharge the patient from stroke services. Therefore, it is possible that the researcher may approach this patient for the Tai Chi study without realising they are not a stroke.
It is the patient's first stroke.	Many patients admitted to hospital with a stroke have had a previous stroke resulting in limb impairment. Should the patient be recruited into the study, the previous stroke would contribute to balance impairment. There may be residual weakness from a previous stroke – this previous weakness will already have been managed to its potential. Hence, any new weakness in such a patient would be difficult to determine an improvement because the previous weakness would act as a confounder. The aim of the study is to find the feasibility of Tai Chi in people with a new stroke.
Patients are receiving standard stroke rehabilitation post-discharge from hospital.	The study aims to assess the feasibility of Tai Chi among stroke survivors who have been discharged home from hospital because little research has

	been done at this early phase. Those patients who go home receiving community therapy services, namely physiotherapy, will be recruited because the referral to community physiotherapy suggests that this subgroup of stroke patients require physical improvement. The remaining stroke survivors would be either too independent or too severe to gain any beneficial effect from Tai Chi.
The participant has a Berg Balance Scale score between 30 and 45.	If an individual has a score below 30, the individual would be severely impaired. Above a score of 45, the individual would have no impairment. A score between 30 and 45 places the participant within the 'at risk' category for falls.
Participants can access the intervention venue.	Stroke survivors are not able to drive for at least four weeks after stroke onset. This increases the difficulty of recruiting this population. Therefore, significant others may be able to help in this area. Additionally, the local NHS Trust has a shuttlebus service running from each of the three hospital sites.
Participants can mobilise at least six metres with or without aids.	If participants are not able to mobilise six metres, it is doubtful that they will be able to practise the Tai Chi exercises. The ability to walk six metres has been identified by the fact that the patient has been referred to community physiotherapy. If the patient is unable to walk six metres, they are referred to the neurology community therapy services as opposed to stroke.
The participant can give informed consent.	If patients do not have capacity to consent, then it can be argued that as well as being unethical to recruit them into the study, patients will not understand what they are being asked to do. Despite family being able to consent on their behalf, it is important that participants understand the Tai Chi movements to avoid any injury during class.
Participants are willing to adhere to the procedures of the study.	If participants do not adhere to the programme, it may indicate a flaw in its design which would require evaluation.

To be clear who was excluded from the study, exclusion criteria was also created, as presented in Table 20.

Table 20 Exclusion criteria for the TCAS study

Exclusion criteria	Rationale for exclusion criteria
Cognitive impairment.	For participant safety.
Severe visual impairment	Participants will be unable to physically take part.
Uncontrolled hypertension, angina or diabetes.	For participant safety.
Dementia.	For participant safety.
Already practising Tai Chi, Yoga, dance or any other balance-training exercise.	Although stroke survivors practising Tai Chi already will be unlikely, one of the aims of the study is whether Tai Chi would be accepted by stroke survivors without prior experience, and whether it can be taught to this population.
Involved in a falls-prevention programme.	To avoid confounding factors and overburdening.
Unmanageable incontinence.	For participant safety and dignity.
Already participating in a research study.	To avoid confounding factors and overburdening.
Uncontrolled epilepsy.	For participant safety.
Unable to understand English.	The questionnaires/outcomes instruments exist in (and are validated in) English, and this PhD project has no funds for translation and cross-cultural adaptation/validation.
Unable to mobilise 6m with or without aids.	See Table 19
The BBS score is outside the range of 30-45.	See Table 19.
Unwilling to adhere to the procedures of the study.	See Table 19.
Unable to give consent.	See Table 19.
In the post-rehabilitation phase.	Th study aims to explore Tai Chi among stroke survivors in the early intervention phase whilst receiving rehabilitation.
Patients have a previous stroke.	See Table 19.
Not going home with community therapy services.	See Table 19.

It is important to note that the TCAS study is one of the few Tai Chi studies to include stroke survivors who are about to be discharged from hospital. From the stroke studies discussed in Chapter 2, previous studies have included participants who are at least three - months post-stroke (Taylor-Piliae & Coull, 2011; Taylor-Piliae et al., 2014a), at least six-months post-stroke (Au-Yeung et al., 2009; Pan et al., 2017), and at least 27-months post-stroke (Hart et al., 2004). Only two stroke studies discussed in Chapter 2 have included stroke survivors who are about to be discharged from hospital (Kim et al., 2015; Wang et al., 2010;). However, the aims and outcomes were not focused on falls. Wang et al. (2010) focused on the psychological effects of Tai Chi and Pan et al. (2017) focused on upper limb movement. Additionally, the Tai Chi programmes used in the latter two studies may not have been designed for balance.

Stroke survivors who have severe balance impairment are referred to the neuro team rather than the stroke team. Therefore, it was unlikely that the TCAS study would accidently recruit stroke survivors who were too impaired to participate. However, because the TCAS programme had not been tested, a 'safe range' was put in place as part of the eligibility criteria. Therefore, the local community therapy services were visited by the researcher to gain their expert advice regarding the BBS range most common for those discharged with their services. It was decided that in order to be eligible for the TCAS study, potential participants were required to have a BBS score between 30 and 45. The community physiotherapists suggested this range because from their experience, most referrals had a BBS score within this range. However, it was decided by the researcher to omit this eligibility requirement for two reasons. Firstly, the baseline BBS score was required prior to discharge from hospital as fulfilment of the eligibility criteria. However, it was not possible to obtain prior to discharge, because this assessment was done following discharge in the community. Secondly, using a limited BBS range as part of the inclusion criteria of the study excluded those stroke survivors who were referred to community therapy services with a BBS score outside of the required range. Thus, anybody who was referred to community therapy services in need of further rehabilitation might also benefit from Tai Chi. In other words, anybody who was eligible for community therapy services was also eligible for the TCAS study.

Location of the intervention

The location of the study was Wakefield because it is where the researcher was based. Coincidently, Wakefield is an area with a high number of stroke patients. The general hospital in this area also includes patients from three other towns within Mid Yorkshire Hospitals NHS Trust, which may explain the high number of stroke admissions. This is advantageous for the researcher because stroke survivors can be recruited from one NHS Trust. Another advantage of using Wakefield is that the researcher is a nurse on the stroke unit in Wakefield, enabling east access to patients, staff and medical records.

Piloting the identification of potential participants

After a six-month scoping exercise on the hyper-acute stroke unit at Pinderfields Hospital, it was found that there were five potential participants per month (see Appendix 16). A ten-month period producing five participants a month was deemed sufficient enough to achieve the required 50 participants. There were 101 potential participants on the targeted stroke unit between March and August 2015. This number has been obtained from a scoping exercise at the stroke unit over six months to be used for recruitment. These figures include those patients sent to further rehabilitation hospitals and those sent directly home with community rehabilitation services. It is believed that potential participants are likely to find the notion of the Tai Chi classes attractive. Thus, it is also believed that the patient population for this study will be enough to recruit the necessary numbers because a scoping exercise on the hyper acute stroke unit at Pinderfields Hospital found that there were five potential participants per month, giving a total of 50 potential participants over ten months. To account for refusals, 50 potential participants were excluded from the count.

Identification of eligible participants

Potential participants were identified initially by looking on the nursing handover sheet for stroke patients. The stroke unit receives patients without a stroke as well as with a stroke. Therefore, looking through the handover daily would exclude the patients without a stroke. Once stroke patients were identified on the handover, the patients' medical notes were read to find out if they met the inclusion and exclusion criteria. The patients' physiotherapy notes were also read for any indication that the patient will be discharged with community physiotherapy (see Appendix 17 for general criteria to be referred). If it was still unclear from the notes, the physiotherapist would be directly asked if the patient would be going home with community physiotherapy. In some circumstances, the physiotherapists were unsure and would regard certain patients as 'potentials.' Once eligibility was clarified, the patient was approached with a verbal explanation of the nature and purpose of the study. For those patients who were 'potentials' for receiving community physiotherapy, they too were given a verbal explanation of the study, but it was added 'should the patient become eligible.' Additionally, nursing staff were also asked to identify eligible participants, but most of the time they were not made aware of the referral to community physiotherapy. A screening log was used to document eligibility (see Appendix 18).

Barriers to the identification process

One barrier to the identification process on the stroke unit was the presence of various ongoing research trials. It was agreed between the researcher and the stroke research team based on the ward that the researcher would not take potential participants that were eligible for their trials. This became an issue to recruitment because most of the patients eligible for the Tai Chi study were also eligible for one of the stroke research team's studies. The issue of potential participants being in somebody else's trial was not anticipated during the piloted scoping exercise, and initially became a major problem for recruiting in the Tai Chi study. Although the research team offered to help identify participants for the Tai Chi study, the Tai Chi study was at the bottom of the list. This meant that although a potential participant had been identified, the researcher was unable to approach the participant until they had been seen by the stroke research team. The researcher thus relied on participants eligible for the other stroke trials to refuse to participate. However, this increased the chance of refusal into the Tai Chi study because unwillingness to participate in a study had already been evident.

Sampling

Quantitative sampling

The selection of an appropriate method of sampling depends on the aim of the study. Convenience sampling is frequently used in quantitative studies (Etikan, Musa, & Alkassim, 2006) and is a type of non-random sampling where potential participants meet the inclusion and exclusion criteria of the study, such as geographical location, proximity, availability and willingness to participate. However, convenience sampling is not necessarily representative of the population, but may be satisfactory for determining the suitability of an intervention as part of a feasibility study (Bell, Whitehead, & Julious, 2017). Convenience sampling is often chosen because recruitment difficulties are a major issue in the UK, where 45 per cent of publicly funded trials fail to reach the target sample size (Bell et al., 2017). Further, a convenience sample used at the beginning of a project may offer information on the trends and results expected from a random sample. The approach of the study may thus need to be modified before embarking upon a more expensive sampling procedure (Bell et al., 2017).

Feasibility studies do not need to randomize participants into comparison groups because the aim of the feasibility study is not to evaluate the outcome of interest (Arain, Campbell, Cooper & Lancaster, 2010) or to make any statistical claims (Ochoa (2017). However, it can be argued that if a feasibility study aims to inform a future RCT, then the willingness of participants to be randomized should be part of the feasibility question (Marshall, 1996). One of the aims of the proposed study is to inform a future RCT. Therefore, random sampling has been utilised. Two advantages of using the random selection procedure are that both groups will be of approximately equal size, and (assuming sufficient numbers) the results may be generalisable to the target population (Marshall, 1996).

Recommended sample sizes for feasibility studies range between 24 and 50 (Julious, 2005; Lancaster, Dodd & Williamson, 2004; Sim & Lewis, 2012), but do not account for the future trial (Bell et al., 2017). A statistician based at the University of Huddersfield was consulted regarding the sample size for the TCAS study. Sample size is important in this feasibility study to be able to estimate parameters such as a standard deviation, which will be used in a sample size calculation for a full-scale trial (Hooper, 2016), and it was decided that in order to achieve sufficient data to inform sample size calculations for a future trial, 20 complete data sets per group should be sufficient, giving a total of 40 participants. However, in order to consider possible dropouts, 50 participants (25 per group) were recruited in anticipation of incomplete data sets. In order to ensure that 50 participants were feasible to attain prior to recruitment in the TCAs study, a six-month scoping exercise took place within the location where TCAS participants would be recruited (the stroke unit at Pinderfields Hospital). Potentially five stroke survivors per month were possible participants for the study, following the deliberate exclusion of alternate potential participants, anticipating unwillingness to participate. It was therefore decided that a ten-month recruitment period was required in order to achieve 50 participants. The proposed sample size is somewhat larger than previous studies in order to ensure sufficient data to inform a future trial. Taylor-Piliae and Coull (2011) recruited 28 participants in total in their pilot study (16 in the experimental group and 12 in the control group). In a pilot study conducted by Hart et al. (2004), 18 participants were recruited (nine per group).

Recruiting from a venue where the researcher works and, therefore, develops relationships with the patients is an important consideration for future recruiting. Within clinical situations, coercion may occur more easily (Patel, Doku, & Tennakoon, 2003), due to a therapy versus therapist effect where patients may view participating in the study as being part of their treatment or feel they have an obligation to participate, particularly if a good relationship has developed between the researcher as a nurse and the patient. Those who refuse to participate once they have been contacted tend to differ from those who do not agree to participate. Saying 'yes' out of obligation and feeling they owe something back may have been a reason why many participants changed their minds about participating once they are away from the clinical environment. Stroke survivors approached for the study may have felt safe once they arrived at home, thus contributing to changing their mind. Personality clashes may also result in the patient not wanting to take part in the study. As a result, selection bias may be introduced associated with non-response (Patel et al., 2003). Selection bias, which is a distortion in a measure of association due to a sample selection that does not reflect the target population accurately, can arise because the researcher used incorrect procedures for selecting a sample population, thus influencing continued participation (Alexander, Lopes, Ricchetti-Masterson, & Yeatts, 2013).

French and Stavropoulou (2016) carried out a qualitative study to find out specialist nurses' perceptions of inviting patients to participate in clinical research studies. Potential researcher bias arose with the possibility of participants offering socially desirable responses. Additionally, the nurse as researcher and recruiter may not invite a patient because of anticipated negative impacts on the research. Similarly, recruiting only those who may produce positive impacts, such as the need to feel included and those who may benefit from it more. The authors suggested that incorrect assumptions regarding the patients' wishes may be made, making the researcher cautious about inviting them. A patient who is disliked by the nurse as researcher and recruiter may not be approached which may potentially be detrimental to the study.

The supportive role established by the researcher as a nurse with the patient may make the nurse feel more comfortable inviting the patient at a time when the patient is recovering from a major illness resulting in disability and life-change (French and Stavropoulou, 2016). The authors add that the supportive role established may enable researchers to obtain reasons for declining to participate, as well as enhance recruitment, although this may be at the expense of tension for the patient.

<u>Qualitative sampling</u>

Sample size recommendations in qualitative studies vary due to the consideration of different factors. Qualitative interviews differ from a quantitative approach in that qualitative interviews look at depth as opposed to breadth. Mason (2010) suggests that the guiding principle should be the concept of saturation. Since the TCAS study has 12 experimental group participants and all 12 participants took part in the interviews, it could be argued that saturation has been reached in the TCAS study. Mason (2010) further adds that sample sizes for qualitive studies can range between five and 60 participants.

Random sampling is inappropriate for qualitative studies because it is not best suited to developing an understanding of complex issues related to human behaviour (Marshall, 1996). Additionally, Marshall (1996) proposes that small sample sizes would introduce large sampling error which in turn would introduce bias. According to Marshall (1996), convenience sampling aims to obtain knowledge from those that are willing, available and nearby. However, this sampling method was not suitable for selecting interviewees in the TCAS study because experience of the Tai Chi programme as an intervention was required. Thus, only participants in the experimental group receiving Tai Chi were suitable for qualitative interviews. Purposive sampling does not require a set number of participants; it is the researcher who decides what needs to be known and who finds the participants who are willing to provide this information by virtue of knowledge and experience in a reflective manner (Marshall, 1996). The sampling method used in the qualitative component of the TCAS study was, therefore, purposive sampling because the experimental group possessed the knowledge and experience required to answer the research question regarding the feasibility of the intervention.

4.7. Sharing the research idea among stroke survivors and clinicians prior to the study commencing

A local Stroke Association was visited by the researcher in order to gain insight as to whether stroke survivors would be interested in taking part in the Tai Chi study. Most members expressed disappointment that they would not get the opportunity to take part and asked if there was a chance of offering it to them. Thus, the nature of the study was discussed so that members were aware that the safety and feasibility of the Tai Chi has not yet been established. The uncertainty of its safety and feasibility was also the reason why hospital-based stroke survivors were not approached to practice the programme, as well as the potential burden placed without gaining official consent from the REC or hospital Trust.

One member of the Stroke Association expressed how she felt abandoned once she had been discharged from community therapy services. All members, as well as the Stroke Association staff, found the idea of offering Tai Chi to stroke survivors at the point of discharge welcoming, but one member commented on how difficult it would be to get to the venue, despite getting to the Stroke Association. The problem with liaising with Stroke Association members was that the interaction was only with stroke survivors who had access to transport and excluded those without.

As well as the local Stroke Association, the community therapists were also visited to gain their opinions about the Tai Chi study. The idea of the study was presented to all physiotherapists at work that day around a table, where each physiotherapist was invited to comment. The senior physiotherapist was confident that enough participants would be recruited. Overall, the reaction of the community physiotherapists was positive and welcoming. The community therapists agreed to forward the initial BBS scores via email after being informed in advance from whom the scores were required. Only one physiotherapist thought that there would be a potential problem which would make the study difficult to conduct, and that was logistics. None of the physiotherapy team could think of a solution regarding how participants would get to the venue. Therefore, logistics became part of the feasibility of the study. Overall, both the Stroke Association and the community physiotherapists thought that the TCAS study would be worthwhile with a potential benefit to stroke survivors.

4.8. Development of additional material prior to obtaining ethical approval

The Patient information sheet [PIS]

Various stakeholder engagement activities were conducted in order to involve patients and clinicians in the study design. One such activity was piloting the Patient Information Sheet [PIS] (see Appendix 19) amongst members of a local Stroke Association. It was deemed a burden to pilot it with stroke survivors who were currently in hospital. The PIS was, therefore, reviewed by five members of the Service User Review Panel [SURP] which is a part of the Stroke Association, via emails. Similar themes appeared among the PPI reviews:

1. <u>Terminology</u>

The information sheet was quite complicated and difficult for a member of the public to understand, with terminology too difficult to understand, such as 'significant other' and 'adherence'. To remedy this, terminology was explained to potential participants verbally whilst going through the PIS with them. Opportunity for questions was also given.

2. <u>Visual appearance</u>

It was suggested by the review panel that the font size should be larger, and at least size 14. One reviewer suggested adding the Stroke Association's imprimatur to the PIS. However, the Stroke Association has no relation to the study, so by doing so would be misleading to participants. Similarly, it was suggested that the PIS should be in the same format, font and colour as the information issued by the Stroke Association. Again, this would mislead participants into thinking the study is associated with the Stroke Association.

3. <u>Transportation issues</u>

Issues with transportation costs came up frequently, with reviewers wanting transport costs for those in the Tai Chi group reimbursed. Time taken from home to hospital was also an issue for some due to post-stroke fatigue. Certain members of the review panel were concerned that participants would be too tired to participate in Tai Chi by the time they arrived at the class. Finding out if Tai Chi is acceptable among stroke survivors at the early rehabilitation phase is part if the study's aim. It is not known if participants will be too fatigued to participate or not.

Piloting the questionnaires and home practice materials

The aims of piloting the questionnaires and the home practice booklet were to make sure the language was legible, clear and easy to understand. I was unable to give the documents to stroke survivors without obtaining the relevant permissions. Therefore, these documents were given to members of a local Tai Chi group who were aged above 65 years. Future material to be piloted may be sent to members of the Stroke Association where the PIS was piloted. It was not known at this time that such a group was available to provide such feedback.

Comments made by the Tai Chi group included:

- The home practice booklet was too clinical in appearance.
- The colour blue was not warm or friendly enough.
- Larger font was preferred for the home practice booklet.
- The history of Tai Chi could be included in the home practice booklet.

The colour of the home practice booklet was thus changed from blue to orange and larger font was applied. History about Tai Chi was not included because it was thought by the researcher that a stroke survivor may struggle to cope with too much writing. If a patient expressed an interest in the study, a PIS was given to them. The PIS helps the patient to make an informed decision by covering all aspects of the trial relevant to making this decision. This was given to them as soon as possible since identification to be able to give them enough time to decide. Additionally, the stroke unit discharges patient's home or to inpatient rehabilitation as soon as patients are medically fit. Therefore, there is a high chance that patients may be missed. To avoid this, patients were shown contact details on the back of the PIS in case they left the ward before expressing a willingness to participate.

Obtaining informed consent

Participants signed the consent form after they were given time to read the PIS, and the opportunity to ask questions. Informed consent is: 'a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written signed and dated Informed Consent Form' according to The International Conference on Harmonisation for Good Clinical Practice [ICH GCP], 1.28 (European Medicines Agency, 2016).

The purpose and nature of the study was briefly introduced verbally to the participant before giving the PIS. Where family members were present, they were involved. However, this posed a problem with some participants where family members either pushed the patient into consenting or persuaded the patient not to take part. When this occurred, time was given to the patient to discuss further with family members. Before

YAS were involved, patients felt they had no choice but to decline where family expressed there were transportation issues.

The researcher was clear and specific that participants may not get the Tai Chi group. Before gaining consent, potential participants were asked if they fully understood what was involved. Despite this, one participant who was randomised into the usual care group thought she was in the Tai Chi group. Patients' needs need to be considered when gaining informed consent. Stroke survivors have recently received bad news, so their need for information and understanding may need reinforcing. Before signing the consent form, verbal agreement was obtained from the patient. Some participants struggled to sign due to upper limb weakness but managed to write to the best of their ability.

Family members were also involved in the consent process, and both family and patient were given time to think and ask questions. Opportunity to ask questions was given to check that the study information was understood by the patient, as well as what was involved and what they were asked to do. Before written consent was obtained, verbal agreement to proceed was gained from the participant. The randomisation process was needed to be stressed beforehand, because patients were talking as if they were going to be in the Tai Chi group. Therefore, it was clearly stated that they may not get the intervention.

Caution with phrasing verbal information was needed when approaching stroke patients because they had only recently received their stroke diagnosis. Patients may well have been feeling quite emotional, as well as experiencing post-stroke fatigue. These factors may have played a part in certain patients' unwillingness to even talk about the study. It may be that stroke survivors will have found processing information difficult on top of everything else they were dealing with. Therefore, a gentle, non-threatening approach was used. For example, some patients thought that the Tai Chi study was compulsory as part of their care. Therefore, the voluntary nature of the study was emphasised repeatedly to avoid causing unnecessary distress to patients who were already emotionally challenged.

The requirement of voluntary consent recognises that eligible patients may not want to take part. Reasons why patients did not want to take part was collected, but it was stressed to them that they did not have to disclose a reason. Where patients who declined to take part explained why they were not interested, this was documented anonymously with the patient's verbal permission.

Once patients agreed to take part in the study, Consent Form 1 (see Appendix 20) was given. Patients were given time to read each statement and signed their initials in the boxes provided, along with date and signature. It was found that many participants were unable to write their initials due to limb weakness, therefore, they tried their best to initial the boxes as clearly as they could. A copy of the consent form was given to the participant, and where possible in the patients' notes. A copy of the consent form was also kept in the researcher's site file. Those in the experimental group were invited to take part in a follow-up interview. Consent was obtained separately using Consent Form 2 (see Appendix 21).

The study protocol

The study protocol (see Appendix 22) was formulated in adherence with the GCP guidelines (European Medicines Agency, 2016), and gives details of the location, sponsor and primary investigator. The study protocol defines the study's aims and objectives clearly, as well as giving a rationale and background information. The target population was described with the selection criteria for inclusion and exclusion. From the above methodology, the study design, i.e. a feasibility study to inform a future RCT, was described along with a detailed information about the study procedures. Ethical considerations, such as safety issues, obtaining informed consent, confidentiality and record maintenance were also included in the protocol. Finally, details of how both quantitative and qualitative data collected were analysed was explained.

Random allocation sequence, allocation concealment and blinding

Block randomization was used in the TCAS study as recommended by the University of Huddersfield statistician. Participants were randomized into one of two groups: Tai Chi with usual care or usual care alone. To do this, eight envelopes were offered to the first participant, the content of which was unknown to the participant and researcher. Four of the envelopes offered contained a piece of paper labelled, 'Tai Chi' whilst the remaining four envelopes contained a piece of paper labelled, 'usual care.' The content of the envelopes was not written by the researcher but by different hospital staff available at the time (away from the presence of the researcher and participant) in order to avoid researcher bias. Group allocation was determined through getting the first participant to choose an envelope after shuffling them. The next seven participants continued to choose from the remaining envelopes, after shuffling.

Due to long periods of non-recruitment at the start of the study, because of a lack of transport and ongoing ward-based research studies, some envelopes got mislaid, and the process had to start from the beginning. This may have resulted in bias regarding the number of participants per group, despite the allocation assignment being concealed by both researcher and participant until after it was revealed by opening the envelope. Blinding was impossible after allocation assignment because of the nature of the exercise intervention, as discussed in Chapter 2 regarding previous studies.

The process of ethical approval

There are various ethical considerations to follow before conducting a research study. Ethical approval was required from the School Research Ethics Panel [SREP] associated with the University of Huddersfield, and the Research Ethics Committee [REC] and MHRA.

The highest standards in conducting just, righteous and ethical research are expected by the Department of Health, who has set out national standards in the Research Governance Framework (2005). The Research Governance Framework (DH, 2005) contains research guidelines covering issues such as ethics, science, information, health, safety and employment, finance and intellectual property, which every research practitioner within health and social care should adhere to. The framework highlights the ethical responsibilities and accountability associated with patients' best interests and evidence-based practice.

In order for the research to be ethical, consideration should be given to whether the principles of beneficence, respect for persons and justice have been applied (Thompson, Melia & Boyd, 2005). The duty of beneficence includes the prior assessment of potential risks to participants, as well as potential benefits. Should the risks outweigh the benefits, the research is deemed unethical. Participants in the current study have been made aware of any risks and benefits, as well as the fully informed nature of the research so that they may give informed consent to take part in the study. Currently, there are no known health risks from Tai Chi because it is a non-invasive intervention, but other risks, such as falling during practice, may be controlled by due vigilance during the study. The research may also benefit the NHS on a wider scale in terms of advancing knowledge and skills in practical, theoretical, professional or clinical spheres (Polit and Beck, 2017).

Respect for persons was applied to the current study by respecting the participants' autonomy by allowing freedom and encouraging participation on a voluntary basis without fear, coercion, prejudice or bias from the researcher. Participants were initially approached whilst on the stroke unit once they were deemed eligible via the exclusion and inclusion criteria. They were kindly invited to think about participating in the study after being verbally informed about the nature of the study and its purpose. If participants expressed an interest to participate, they were given a participant information sheet [PIS] which informed them of the nature of the study, its design, randomisation procedure, purpose and potential risks and benefits (see Appendix 19). Prior to giving the PIS to participants, it was submitted to the Stroke Association, where stroke survivors in the association assessed it and made recommendations. Such recommendations included including a larger font. The PIS was also jargon-free and given to participants so that enough time was available to make an informed decision. Certain recommendations by the stroke survivors in the Stroke Association made some recommendations that were not achievable due to limited resources, such as increasing the voucher value for completing the study.

The ethical principle of justice requires that participants should not be discriminated against or abused, and that the research should benefit the general population. Treatment should not be compromised should participants drop out or be randomised into a certain group (Thompson et al., 2005). Anonymity and confidentiality and data was respected and protected according to the Data Protection Act 1998 and by following protocols. Identities were made anonymous by using identity codes and pseudonyms. Unless participants posed a threat to themselves or others, identity was not disclosed to anybody other than the researcher. All data was kept locked in a locked cupboard within a locked compartment and only accessed by the researcher. Participants were made aware verbally and via the PIS that all relevant data is retained securely.

In 1964, the Declaration of Helsinki included the validity and integrity of research data. In the UK, the Department of Health introduced the Research Governance Framework for Health and Social Care (2005), applying to all research involving patients, and not just clinical trials. This framework stressed that 'whatever the context, the interests of research participants come first. Those responsible must be satisfied they have taken all responsible steps to protect the dignity, rights, safety and wellbeing of participants' (DH, 2005). Other standards which apply to the Tai Chi study are:

- The Data Protection Act (1998).
- The Freedom of Information Act (2000).
- The Mental Capacity Act (2005).
- Professional accountability.

After presenting the study's protocol, including the consent forms and data collection documents, ethical approval was obtained on 4th September 2015 by the School Research Ethics Panel [SREP] to perform the Tai Chi after stroke study (see Appendix

23). Along with approval, it was confirmed by the University that indemnity for the study was covered by the insurance policy held by the University because the study falls within the normal range of research activity. Following SREP approval, approval from the Research Ethics Committee [REC] was sought via the IRAS system (see Appendix 24); the Leeds West REC gave a favourable opinion on 15th July 2016 (see Appendix 25).

The Research Governance Framework for Health and Social Care (DH, 2005) includes the principles of Good Clinical Practice [GCP]. GCP is 'an international ethical scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects' (European Medicines Agency, 2016); by adhering to GCP guidelines, public assurance that rights, safety and well-being of participants are protected.

One aspect of GCP is producing a protocol of the study written within the GCP standards (see Appendix 26). This protocol has been supplied to the site where the study has been delivered. The R&D department at the site considered the feasibility of delivering the study before agreeing to undertake the work. Aspects of feasibility included the safety of participants, the capacity to collect data within the window and to determine the number of participants within the timescale provided.

Research is central to the NHS because good patient care is evidence-based which can only be achieved through research. Practice based on uncertainties or experience is more unreliable. In order to conduct research within the NHS, I was required to undergo training in Good Clinical Practice [GCP] (see Appendix 26). This training included an understanding of the importance of clinical research to patients, health professionals, the NHS and wider society. The main purpose of the GCP training was to demonstrate an understanding of GCP principles and their application to practice. By following the GCP principles at each stage of the defined pathway, patients would be protected as well as ensuring high quality data.

GCP training enlightened me on how to store the research data. An investigator site file was maintained throughout the study and will be archived when the study is complete. Inside this file is every relevant piece of information collected relating to the study.
All documents required were approved by the MHRA but authorisation from the ward manager of the unit where participants will be recruited was needed, as well as the stroke Consultant, Clinical Lead for Stroke and all other participating sites, such as the physiotherapy department where the study took place and the community therapy

services, MY Therapy and Locala. These permissions were obtained and, subsequently, approval was granted on 20th September by the MHRA.

Recruitment could not start until confirmation of Capacity and Capability was also obtained. This was approved on 12th December 2016, when the recruitment process started. This start date was dependent on the Occupational Health Authorisation (see Appendix 27), as well as a criminal record check (see Appendix 28), and insurance for the Tai Chi instructor (Appendices 29, 30 and 31), which was obtained. Additionally, the Tai Chi instructor obtained an access letter (see Appendix 32), enabling him to teach Tai Chi on the hospital grounds. To meet the national target of recruiting the first patient into the study within 30 days of this permission letter, the first patient had to be recruited by 11 January 2017. This was achieved, with the first patient being recruited on 1st January 2017.

Proof of competence to conduct clinical research
In order to carry out clinical research to an international ethical and scientific quality standard, IHC Good Clinical Practice [GCP] training was completed by the researcher. The IHC GCP states that:

'Investigators should be qualified by education, training and experience to assume responsibility for the proper conduct of the trial, should meet all the qualifications specified by applicable regulatory requirement(s), and should provide evidence of such qualifications.' Documentation of all stages of the research process is recommended in the GCP training so that the sequence of events can be tracked. The Code (Nursing and Midwifery Council [NMC], 2018) states that all patient records should be completed at the time or as soon as possible after the event, accurately without any falsification. Such documentation should be kept securely. Additionally, The Code advises that data and research findings should be collected, treated and stored appropriately.

Overall, ethical approval has been sought and gained from the SREP, REC and MHRA in accordance with the Research Governance Framework (2005) and the Declaration of Helsinki (1964) to ensure the dignity, rights, safety and wellbeing of participants (DH, 2005). To further ensure the safety and wellbeing of all those involved in the TCAS study, the researcher has received GCP training. The REC reference for the study is 16/YH/0130. The IRAS project ID is 171300.

Chapter 5 – Quantitative Data

5.1. Introduction

This section will present how the study population was selected using the eligibility criteria described above, as well as the proportion of those identified, who consented, withdrew and participated. Reasons for non-eligibility, refusal to participate and withdrawal from the study will be discussed. Descriptive statistics about participants will also be presented, along with comparisons where appropriate.

5.2 Recruitment

A control group was included so that issues with recruitment may be addressed so that they can be resolved in a future RCT. Additionally, a comparison could be made with the experimental group in order to look for trends which may indicate some possible effect if repeated in a future larger trial.

5.2.1. Identification of participants

The Sentinel Stroke National Audit Programme [SSNAP] was searched for the total number of stroke admissions to the stroke unit where recruitment took place at Pinderfields Hospital, part of Mid Yorkshire Hospitals NHS Trust between January 2017 and October 2017. SSNAP is a database where stroke staff based at the hospital record data regarding stroke care and procedures. According to SSNAP, a total of 688 stroke patients were admitted to the local stroke unit between January 2017 and October 2017. It must be noted that these figures reflect only those stroke patients who were recorded into the database; some patients may have been missed due to time pressures and staff shortages.

Out of these 688 stroke patients, 326 were referred to community therapy services, following their in-patient treatment, making them potentially eligible for the TCAS study. However, not all stroke survivors potentially eligible for the study based on the community therapy services criteria (see Appendix 17) were able to participate. Sixty-nine out of 326 stroke survivors referred to community therapy services were not able to participate in the study for reasons given in Table 21. A further 143 were missed by the researcher because there was only one researcher, as well as time restrictions and rapid patient turn-over. There was also an unknown number of stroke survivors who were ostensibly discharged to community therapy services but were referred to neurology rather than stroke for severe impairment or were simply missed by the researcher. A total of 114 stroke survivors was identified by the researcher as being potentially eligible.

Table 21 Reasons for non-eligibility for the TCAS study

Reasons for non-eligibility	Number of non-eligible stroke survivors with community therapy services
Culture misunderstandings (according to SSNAP 31 in total between Jan-Oct 2017).	15
Medical issues.	18
Lacks capacity.	17
No longer eligible for community therapy.	1
No longer treated as a stroke.	2
Transport issues.	4
Participation in research study.	2
Discharged to care home.	1
Too independent.	9

Further criteria were introduced so that participants could engage in the intervention. These criteria have been discussed in Chapter 4 and are discussed above and presented in the study protocol found in Appendix 22.

The process of identification began by reading the nursing handover to find out the presence and mobility of stroke survivors on the ward. Medical records were then read, alongside the inclusion and exclusion criteria, to mark patients as potentially eligible. The ward-based physiotherapists were asked about their potential for community therapy services, and their medical notes were looked at for physiotherapy updates. Where it was not certain if a patient would be referred for community therapy, they were informed that their participation would depend on receiving a referral. Recruitment started in December 2015 and ended in October 2016. A six-month extension period for recruiting was needed in order to meet the target recruitment figures. The letter to confirm this is presented in Appendix 33. The study ended in January 2017.

5.2.2. Informing participants of the study

Out of 114 stroke patients identified, 58 declined and 56 accepted to participate. Out of the 58 who declined, 43 declined without receiving a PIS, after having a verbal explanation of the purpose and nature of the study. A further 15 accepted a PIS but still declined to participate. Reasons for declining are found in Table 22.

Recruitment for the TCAS study started in December 2016 and ended in October 2017, with the study itself ending in January 2018. A six-month extension period for recruitment was granted by the University of Huddersfield in order to meet the target recruitment figures.

Table 22 Reasons for declining without consenting, categorized by reason

Reason for Declining	Number declined with PIS	Number declined without PIS
Transport issues.	2	21
Not interested.	5	18
Family commitments.	1	3
Medical issues.	1	0
Doing other exercise.	2	1
Discharged.	4	0
TOTAL	15	43

Obtaining consent

Fifty-six participants accepted the PIS and gave informed consent. Six of those who signed the consent form were not randomised. Reasons why six people were not randomised was due to: wanting to choose their own group (n=4) or being no longer interested (n=2).

Randomisation

The remaining 50 stroke patients were randomised as discussed above; 28 into the experimental group and 22 into the control group.

Participation

The baseline questionnaire was expected to be completed by both groups on the ward prior to discharge. If this was not done, the experimental group were encouraged to return it before the first Tai Chi class, and the control group were encouraged to post it. Retention through to baseline assessment of those who were randomised, was poorer in the experimental group with 13 people dropping out before completion of the baseline questionnaire, compared with 10 people in the control group. This resulted in a total of 15 people in the experimental group and 12 people in the control group who took part in the TCAS study. Reasons for dropping out of the study before baseline are presented in Table 22.

Non-completion of the baseline questionnaire whilst on the ward occurred due to absence at the bedside, significant others taking the documents home, failure to fill out the questionnaires and being discharged before completion. Those people who failed to complete the baseline questionnaire whilst on the ward either completed it after they were discharged home or decided not to continue with the study. Table 23 presents reasons for not wanting to continue with the study. Reasons were obtained through telephone calls.

Table 23 Reasons for declining before baseline and after signing the consent form

Reasons why participants dropped out before taking the baseline questionnaire		
Reason for dropping out	**Number of participants**	
	Tai Chi group	*Control group*
No longer interested.	2	6
No response.	5	3
Medical issues.	4	0
Relocated.	1	1
Other commitments.	1	0
TOTAL	13	10

One participant in the experimental group and three in the control group were lost to follow-up at 12-weeks and did not provide follow-up data. Most people said they were no longer interested in the study when asked why they did not want to participate, with the remaining reasons being unwell or no response to telephone calls. Reasons are given in Table 24. Thus, of the 50 participants randomised, there was a total of 23 participants who completed the study, 14 in the experimental group and nine in the control group. Reasons for being lost to follow-up at 12 weeks are presented in Table 24. Figure 6 presents a CONSORT diagram of the recruitment process.

Table 24 Reasons for being lost to follow-up

Reasons why participants were lost to the 12-week follow-up		
Reason	*Tai Chi group*	*Control group*
No longer interested.	1	1
Not answering telephone calls.	0	1
Falls.	0	1
TOTAL	1	3

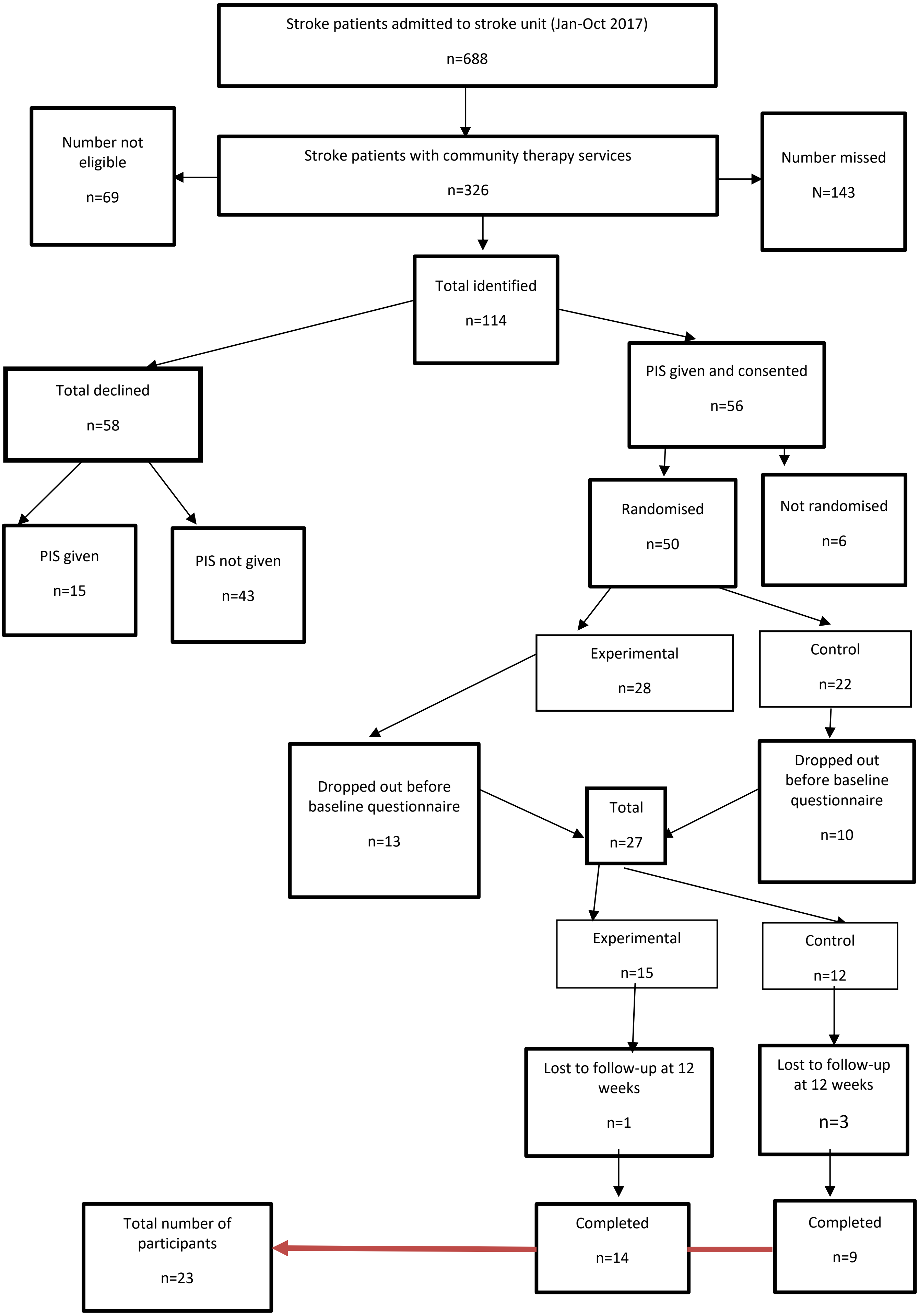


Figure 6 CONSORT diagram of the recruitment process

5.2.3. Eligibility of participants

The key eligibility criterion was 'discharged home with community therapy services.' However, not all stroke survivors eligible for the study based on this key criterion were able to participate. Out of a total of 688 stroke patients admitted to a local acute stroke unit during a 10-month recruitment period, 326 were eligible for community therapy services. Sixty-nine were not approached because they did not meet the inclusion and exclusion criteria, described in Chapter 4. Reasons for non-eligibility despite going home with community therapy services are presented in Table 25. In addition, there were an unknown number of stroke survivors who were either ostensibly discharged to community therapy services but were referred to the neurology department for severe impairment or were simply missed by the researcher.

Table 25 Reasons for patient non-eligibility despite going home with community therapy services

Reasons for non-eligibility	Number of non-eligible stroke survivors
Cultural differences/poor English.	31
Uncontrolled co-morbidities.	9
Problematic mental health issues.	5
Cognitive impairment.	4
Inability to access venue.	4
Severe visual impairment.	3
Poor feet condition.	2
Already in a research study.	2
Chronic leg wound.	2
Below-knee amputee.	1
Back problems.	1
Discharged to a residential home.	1

The total number of eligible stroke survivors identified for the TCAS study was 114.

5.2.4. Obtaining consent and randomization

Out of 114 eligible stroke survivors, a total of 50 people gave their informed written consent. Four stroke survivors expressed an interest but were not randomized because they wanted to choose their group allocation (Tai Chi n=2; usual care n=2). One person who gave consent was no longer eligible due to a diagnosis that was found not to be a stroke. Out of the 50 participants, 28 were randomized into the experimental group and 22 were randomized into the control group.

5.3 Characteristics of the participants

Community-dwelling stroke survivors referred to community therapy services at the point of discharge were eligible to take part in the TCAS study.

5.3.1. Age

The demographic and clinical characteristics of the participants are shown in Appendix 34. The age range for participants in the TCAS study is between 51 and 88 years. The age range between groups was not significantly different, with a mean age of 72.50 years in the experimental group and 72.56 years in the control group. The mean age of women was 74.07 years, whereas the mean age of men was 71.19 years.

5.3.2. Sex

The majority of TCAS participants were male (n=16). However, there were equal numbers of both males and females in the experimental group (males: n=7, females: n=7). The control group contained more males (n=9) than females (n=7).

5.3.3 Type of stroke

In the TCAS study, only one participant was diagnosed with having a haemorrhagic stroke and was randomised into the experimental group. All other participants, including those who did not complete follow-up assessments, received a diagnosis of ischaemic stroke (n=29).

5.3.4 Type of impairment

Over one-third of participants in the TCAS study (38 per cent) had left sided dual-limb weakness (n=13), with six being in the experimental group and four in the control group. The second highest impairment was right-sided dual-limb weakness (n=7), with four in the experimental group and three in the control group. Only three people had a single limb impairment, with one experimental group participant having upper arm weakness and two control group participants having only single-leg weakness. One person in the experimental group had a visual deficit, but this was mild, enabling the participant to take part. Interestingly, 25 per cent of participants reported no deficit (experimental group n=1; control group n=4).

5.3.5 Dropouts

Following randomisation, 13 participants from the experimental group and 10 from the control group (a total of 23 participants out of 50) failed to complete the baseline questionnaire and can be considered to have dropped out. This reduced the total number of participants to 27 (15 in the experimental group and 12 in the control group). Most people who dropped out failed to give a reason why. The baseline questionnaire was expected to be completed by the experimental group either on the ward or at home before attending the first Tai Chi class. Control group participants were encouraged to complete baseline assessments on the ward before discharge. The initial BBS score was collected by the community physiotherapists within 24 hours of the participant returning home.

Non-completion of the baseline questionnaire whilst on the ward occurred due to absence at the bedside, significant others taking the documents home, failure to fill out the questionnaires and being discharged before completion. Those people who failed to complete the baseline questionnaire whilst on the ward either completed it after they were discharged home or decided not to continue with the study.

5.3.6 Loss to follow-up

The remaining 27 participants in the TCAS study completed the baseline assessment (Tai Chi n=15; control group n=12). One of the 15 participants in the experimental group were lost to follow-up, compared with three participants from the control group (see Table 26). Some participants said that they did not want to continue with the study when telephoned to collect their first falls diary. One participant in the control group experienced two hospital admissions due to falling during the study (see Appendix 34). Finally, a total of 23 participants completed the TCAS study at 12-weeks, with all 14 participants in the experimental group participating in the interviews.

Table 26 Reasons why participants were lost to follow-up

Reasons why participants were lost to follow-up		
Reasons	*Experimental*	*Control*
No longer interested.	*1*	1
Not answering phone.	0	1
Falls.	0	1
TOTAL	1	3

While this feasibility study does not include a formal power calculation, the Institute for Digital Research and Education (IDRE) (2013) suggests that a rough estimate of the effect size and variability in the outcome measures used should be provided, so that a power calculation may be made to determine the sample size for a future study (based on the outcome measure concerned). The quantitative data provided should allow for this to be done.

5.4. Outcome measures

5.4.1. Number of falls

During the 12-week intervention, there was a total of seven falls. Experimental group participants had fewer falls (n=1) than the control group (n=6). In terms of fallers, there were more in the control group (n=3) than the experimental group (n=1), with two fallers in the control group experiencing multiple falls. Despite the apparent difference between groups, a statistical analysis was not considered appropriate due to the small numbers. However, falls will be later discussed in relation to the other outcome measures.

5.4.2. Berg Balance Scale [BBS]

Baseline scores were obtained from the community physiotherapists via emails once participants were assessed following discharge from hospital. Most scores were available by the physiotherapists unless the community physiotherapist discharged the patient soon after referral. For all participants in the TCAS study, the baseline range for the Berg Balance Scale is between 26 and 55, with a range of 26 and 55 for the experimental group and 32 and 54 in the control group. Cut-off scores for all quantitative outcome measures are presented in Appendix 35.

Table 27 presents the mean scores with standard deviations in brackets at baseline and 12 weeks for the BBS in both groups. Following the 12-week intervention, both groups improved on the BBS. However, the experimental group were at medium risk of falls at baseline, whereas the control group were at low risk. This difference between groups was calculated and is presented in Table 27. Calculations were made to find out how much improvement each group made. A statistician was consulted (see Appendix 36) who advised that the sign of the difference (positive or negative) is not important because it is determined by which group is considered first; what is important is the magnitude of the difference. However, it is acknowledged by the researcher that although performing a subtraction on group means may give a measure of effect of group differences, this alone does not constitute a statistical test of group differences. A significance test such as an independent t-test on the group difference calculated is required. The independent t-test calculated through SPSS would also produce a confidence interval for the group difference. Further, the significance test to be performed would be to calculate the difference between the experimental group and control group in terms of their 12-week scores. Table 27 shows that the experimental group made a greater improvement (6.25 ± -6.19) than the control group (1.62 ±-2.609) How much this was due to the intervention was calculated by subtracting the baseline/12-week difference of both groups (4.63 ± 8.799). Therefore, the BBS was able to show an improvement in balance, and thus appears to be a sensitive instrument to measure changes in balance ability (and falls risk).

Table 27 Berg Balance Scale means with Standard Deviations

BERG BALANCE SCALE						
Group	**N° of Participants at Baseline**	**Baseline Mean (SD)**	**N° of Participants at 12 weeks**	**12-Weeks Mean (SD)**	**Change Scores**	**Effect Size (Cohen's d)**
Experimental	13	43.54 (10.883)	14	49.79 (4.693)	6.25	0.745783
Control (n=10)	10	46.50 (8.898)	8	48.12 (6.289)	1.62	0.21026
Group Difference		-2.96		1.66	4.63	

Individual scores presented in Appendix 35 show that, overall, there were no participants classed as a high falls risk (score 0-20), with most participants being at low risk of falls (score 41-56; n=15). The remaining participants were at medium risk of falls (21-40; n=7). Four participants in the experimental group were at medium risk of falls compared with three in the control group.

Most of the seven participants with a BBS below 40, indicating medium risk of falls, had dual limb weakness. Those who did not have dual limb weakness had single-leg weakness or problems with the vestibular system. Those with no limb deficit at all were at low risk of falls, with three participants in each group having the same BBS score at 12 weeks as at baseline.

It can be seen in Appendix 34 that the one faller in the experimental group and one faller in the control group who were at low risk of falls at baseline, with another faller in the control group at medium risk. The baseline BBS was not available for the remaining faller, but they were at medium risk of falls at 12 weeks. Due to the small sample size and low number of falls in the TCAS study, it is difficult to find trends among the baseline BBS and falls. Two fallers were at medium risk of falls at baseline, suggesting that the BBS is a good predictor of falls. With a larger sample size, it may be that scoring low on the BBS, may be an indicator for future falls, which means that the BBS is suitable for detecting changes over time in terms of falls risk among stroke survivors practising Tai Chi. Therefore, the BBS may be used as a proxy for falls, which in turn, may be used as a proxy for independent living, suggesting there is some clinical meaningfulness.

At 12-weeks, the range for the BBS for all TCAS participants was between 38 and 55. Mean BBS scores for both groups were not significantly different; it was expected that both groups would improve because both received community therapy services, and the natural variation of community therapy alone is towards improving. Overall, by 12 weeks, there were more participants (n=20) at low risk of falls than at baseline (n=16). However, individual scores (see Appendix 34 show that more participants in the experimental group (n=9) improved than the control group (n=3). This study cannot conclude this improvement was due to the intervention due to the small sample size.

5.4.3. Geriatric Depression Scale [GDS]

Table 28 presents the mean scores of the GDS with standard deviations in brackets at baseline and 12 weeks for both groups; normal levels of depression are represented by a score between 0 to 9, whereas mild levels of depression are indicated with a score between 10 to 19, and severe levels of depression are indicated with a score between 20 and 30. There was a large difference between groups at baseline (8.14), with the experimental group showing a higher level of depression than the control group. It is, therefore, not surprising that the control group appears to have lower levels of depression at 12 weeks. Change scores show that the experimental group made greater improvements than the control group (experimental group = 3.64 ± 1.855; the control group = -2.5 ± 2.92). Despite the small changes in both groups, the control group seemed to have got more depressed while the experimental group improved. Thus, the change in depression over time seems inconsistent between groups.

Table 28 Geriatric Depression Scale Means with Standard Deviations

GERIATRIC DEPRESSION SCALE						
Group	**N° of Participants at Baseline**	**Baseline Mean (SD)**	**N° of Participants at 12 Weeks**	**12-Weeks Mean (SD)**	**Change Scores**	**Effect Size (Cohen's d)**
Experimental	14	13.64 (9.410)	14	10.00 (7.555)	3.64	0.426576
Control	12	5.50 (4.034)	9	8.00 (5.148)	-2.5	0.54058
Group difference		8.14		2.00	6.14	

Individual scores presented in Appendix 34 show that the baseline range for the Geriatric Depression Scale was between zero and 30 for all participants, with a range between two and 24 in the experimental group and between 0 and 10 in the control group. Overall, four participants were classed as having severe depression at baseline, whereas there were none in the control group. This may explain the mean baseline score for the experimental group being lower than the control group. This inconsistency between groups remained at 12 weeks.

At 12-weeks, the range for the Geriatric Depression Scale for all TCAS participants was less than at baseline, with a range between 0 and 23 in the experimental group, and 1 and 16 in the control group, suggesting that there was a greater level of depression among the experimental group than the control group at 12 weeks. The experimental group showed greater improvement because there was less room for the control group to improve. Further, despite both groups improving, they were only small improvements. This study has shown that depression levels between groups were inconsistent, and that any improvements in depression levels are not significantly different between groups. Thus, this may explain the mean group difference.

5.4.4. Tinetti Falls Efficacy Scale [FES]

The scoring system of the FES suggests that a score of 70 or more indicates that a person has a fear of falling, suggesting that anybody with a score below 70 does not have a fear of falling (Tinetti et al., 1990). While those over 70 have a clearly identifiable fear of falling, those with lower scores may still have concerns over certain ADLs, which may inhibit them from participating in these activities. Table 25 presents the mean scores with standard deviations in brackets for the FES at baseline and 12 weeks for both groups. The mean baseline scores for both groups show that overall, none of the groups had a fear of falling at baseline, meaning it is unlikely a fear of falling will be presented at 12 weeks.

Despite the FES having a cut-off score of 70 for determining the presence of a fear of falling, changes below the score of 70 were still made, with the experimental group presenting greater changes than the control group; the experimental group had a baseline mean of 41.93 ± 9.829, indicative of an absence of a fear of falling. However, although participants remained without a fear of falling at 12 weeks, the mean score reduced considerably to 22.14 ± 17.853, with a difference of 19.79 ± 11.976. The control group demonstrated a similar reduction at 12 weeks, with a difference of 12.81 ± -4.088 (see Table 29). This may mean there is a potential to have some degree of fear which may indicate how close a participant is to having a fear of falling. It may be that the range of scores below 70 has some clinical meaningfulness in terms of fear of falling.

Table 29 Falls Efficacy Scale Means with Standard Deviations

FALLS EFFICACY SCALE						
Group	**N° of Participants at Baseline**	**Baseline Mean (SD)**	**N° of Participants at 12 Weeks**	**12-Weeks Mean (SD)**	**Change Scores**	**Effect Size (Cohen's d)**
Experimental	14	41.93 (29.829)	14	22.14 (17.853)	19.79	0.805077
Control	12	44.92 (32.018)	9	32.11 (36.106)	12.81	0.375404
Group difference		-2.98		-9.96	6.98	

After the 12-week intervention, the overall range was between 10 and 100. The experimental FES scores ranged between 10 and 80, whereas, the control group ranged between 10 and 100, suggesting that the control group had higher levels of fear of falling. with two participants scoring as having a fear of falling. More experimental group participants scored lower at 12 weeks than at baseline. It is expected that if participants do not have a fear of falling (score=<70) at baseline, it is unlikely that they would have a fear of falling at 12 weeks. However, changes may be clinically meaningful because of improvements indicated by decreased scores. Although the FES is a good tool to detect a fear of falling, it suggests it is only significant with a score above 70. This outcome measure was successful in outlying those with a fear of falling but did not seem to be a predictor of falls.

5.4.5. SF 12 (physical composite scores [PCS])

The physical and mental composite scores are computed using the scores of twelve questions which range from 0 to 100: zero indicates the lowest level of health and 100 indicates the highest level. Scores below 45 indicate the presence of impaired functioning, and scores less than 40 indicate significant impairment. Scores between 40 and 44 are below average (Ware et al., 2010).

Table 30 presents the mean scores with standard deviations in brackets for the SF 12 [PCS]. Despite the control group performing better than the experimental group at 12 weeks, the experimental group had significant functional impairment at baseline (38.43 ± 9.378), whereas the control group had impaired functioning (41.54 ± 9.913), suggesting that experimental group participants were more impaired than the control group at baseline. Therefore, a calculation was made to find out how much each group improved. The calculations show that the experimental group (2.43 ± 0.636) made an improvement but the control group was essentially unchanged (-0.32 ± 4.138). Therefore, there is some indication that the intervention may have an effect on the PCS.

Table 30 SF 12 [PCS] means with Standard Deviations

SF 12 [PCS]						
Group	**N° of Participants at Baseline**	**Baseline Mean (SD)**	**N° of Participants at 12 Weeks**	**12-Weeks Mean (SD)**	**Change Scores**	**Effect Size (Cohen's d)**
Experimental	14	38.43 (9.378)	14	40.86 (10.014)	2.43	0.250484
Control	13	41.54 (9.913)	9	41.22 (14.051)	-0.32	0.233566
Group difference	1	-3.11		0.36	2.75	

Individual scores (see Appendix 34) that for all participants in the TCAS study, the baseline PCS ranges from 19 to 58. The baseline PCS for the experimental group is from 19 to 51, whereas the control group is from 20 to 58. Overall, four participants scored between 40 and 44, indicating they were below average, with two participants from each group scoring within this range. Fourteen participants scored below 40, indicating significant impaired functioning: eight in the experimental group and six in the control group, with one participant from each group scoring 20 or less. It is interesting to note that most participants were below average at baseline. Overall, nine participants scored above 44; four in the experimental group and five in the control group, suggesting that they were average for impaired functioning. Both groups had two participants scoring between 40 and 44, indicating they were below average in functional impairment.

After the 12-week intervention, the overall range for the physical component of the SF 12 varied between 18 and 59; with a range of 19 to 53 in the experimental group and 18 and 59 in the control group. More experimental group participants improved than the controls at 12 weeks (experimental group: n=8; control group: n=4). Individual scores show that the experimental group perceive themselves to be more physically impaired than the controls, and further perceived themselves to have improved more than the controls at 12 weeks. This suggests that the more physically impaired participants perceive themselves to be, the more likely they are to perceive an improvement after the intervention. It is difficult to conclude whether the perceived improvements are due to the intervention because the control group had less room to show any change.

5.4.6. SF 12 (mental composite scores [MCS])

The scoring system for the SF 12 [MCS] is the same as the PCS. Table 31 presents the mean scores with standard deviations in brackets for both groups at baseline and at 12 weeks. Mean 12-week scores show that there was no significant difference between the groups (-0.6 ± -0.747). Baseline mean scores show that experimental group participants were below average (44.36 ± 9.353), whereas control group participants were average (51.23 ± 8.197). Therefore, comparing baseline with 12 weeks, it appears that, despite being a small change, the control group performed worse at 12 weeks than at baseline (-2.34), whereas the experimental group showed an improvement at 12 weeks (3.96). These findings suggest that the intervention may have had an impact on mental well-being, but a larger sample size is needed to confirm this.

Table 31 SF 12 [MCS] means with Standard Deviations

SF 12 [MCS]						
Group	**N° of Participants at Baseline**	**Baseline Mean (SD)**	**N° of Participants at 12 Weeks**	**12-Weeks Mean (SD)**	**Change Scores**	**Effect Size (Cohen's d)**
Experimental	14	44.36 (9.353)	14	48.29 (11.330)	3.93	0.378298
Control	13	51.23 (8.197)	9	48.89 (12.077)	-2.34	0.226723
Group difference		-6.87		-0.6	6.27	

At 12 weeks, the range of the mental component of the SF 12 was between 26 and 71, with a range of 26 and 65 in the experimental group and 33 and 71 in the control group. Generally, the experimental group improved, but the control group had less room for change. However, individual scores show that some participants in the control group had below average scores at 12 weeks compared with average at baseline, suggesting they got worse. A larger study may confirm whether the intervention had an impact on the mental well-being of stroke survivors using the SF 12 questionnaire.

5.4.7. Potential associations between outcome measures

Regression analysis 'attempts to predict or estimate the value of a response (dependent) variable from the known value of one or more explanatory (independent) variables' (Lang & Secic, 2006). The aim of the analysis is to determine which variables are most strongly associated with the dependent variable. For example, to determine whether the BBS (independent/explanatory/X variable) is strongly associated with the FES (dependent/response/Y variable). It is unlikely to generate significant results, given the small sample size. Additionally, due to the small sample size, it is expected that there will be multiple outliers, highlighted as extreme values, thus having a disproportionate effect on the results of the analysis. However, individual data may present with some potential clinical meaningfulness, such as, in the case of the BBS and FES, whether balance scores as measured by the BBS are affected by fear of falling as measured by the FES. This in turn would suggest that the two outcome measures are not independent of each other.

SPSS was used to calculate the linear regression to show the impact of each independent variable on the dependent variable. The regression line is described by the equation:

$$Y=a+bX$$

Y represents the value of the response variable to be predicted, whereas a is the point at which the regression line crosses the axis, and b is the slope of the regression line. X is the explanatory variable used to predict the value of Y.

P-values have been calculated to determine the significance of the results; the p-value represents the probability that the results of the outcome measure occurred by chance ($p=<0.05$). As expected, due to the small sample size, results were not significant ($p=>0.05$).

Falls and the BBS at baseline

A regression analysis was not done for falls due to insufficient data.

Participants who fell in the control group had a low baseline BBS score (<40), indicative of being at medium risk of falls. However, one experimental group participant fell but was at low risk of falling at baseline.

Falls and the BBS at 12 weeks

The faller in the experimental group had a reduced BBS at 12 weeks, resulting in a shift from being low to medium risk of falls. The 12-week BBS score for two fallers in the control group was unavailable. The remaining faller had a missing baseline BBS score, but the 12-week BBS was indicative of medium falls risk.

Falls and the FES at baseline

Fallers from both groups who completed the baseline questionnaires did not have a fear of falling at baseline according to the FES.

Falls and the FES at 12 weeks

All fallers remained the same at 12 weeks as at baseline for fear of falling: two fallers, one from each group, remained without a fear of falling, whereas one faller in the control group maintained having a fear of falling. This study shows no potential association or trend between falls and fear of falling.

Falls and the SF 12 [PCS] at baseline

Interestingly, all participants from both groups who fell also scored as having significant functional impairment at baseline according to the SF 12 [PCS]. This may suggest that there is a possible association between the PCS and falling.

Falls and the SF 12 [PCS] at 12 weeks

At 12 weeks, all fallers remained with a perception of significant functional impairment with one control group participant seemingly becoming worse. These findings strengthen the baseline findings which may suggest a trend between falling and perceived functional impairment within the physical domain of the SF 12.

Falls and the SF 12 [MCS] at baseline

All fallers in both groups who completed the baseline questionnaires had an average score for mental wellbeing, which are similar to the results of the GDS which may suggest that mental wellbeing may not a predictor for falls in this study.

Falls and the SF 12 [MCS] at 12 weeks

Overall, two out of three fallers remained having an average score for the SF 12 [MCS] at 12 weeks. The remaining participant, who was from the control group, shifted from being average to below average. Therefore, it is difficult to find a trend between falls and the MCS.

The BBS and the FES at baseline

Simple regression analysis was used to examine the association between the BBS and FES at baseline, which could be used to assess whether these two outcome measures are independent of each other or whether there is a possible association between balance and fear of falling. The BBS is the independent variable looking for an association with the FES (see Table 32). Figure 7 presents a scatterplot between the association between the BBS and FES at baseline for the experimental group, whereas Figure 8 shows the association within the control group at baseline.

The coefficients for both groups are below 0, suggesting that there is no association between the two variables. All the assumptions were verified. The assumption of simple linear regression is that each of Y is independent of the other value of Y. The scatterplots in Figure 7 and Figure 8 present this assumption.

Table 32 Simple regression analyses of the BBS and FES at baseline

BBS and the FES				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	-1.266	-.459	.114
	Control	-1.168	-.292	.446

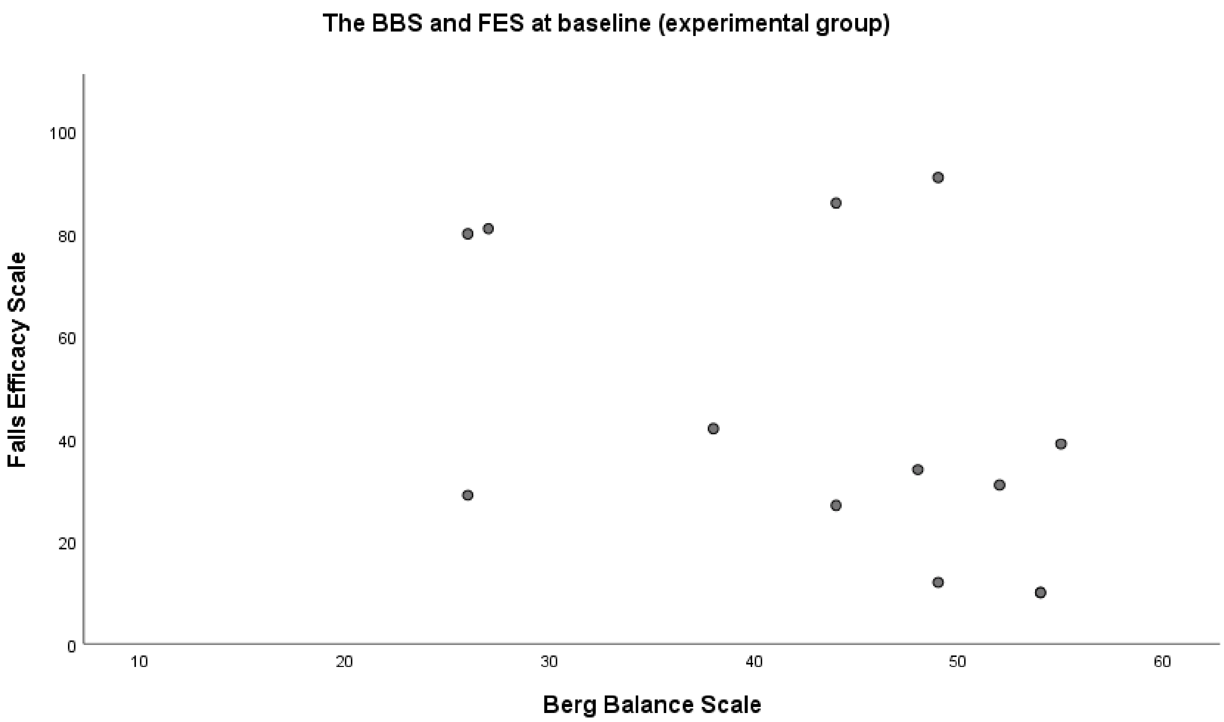


Figure 7 Scatterplot showing the association between the BBS and FES at baseline (experimental group)

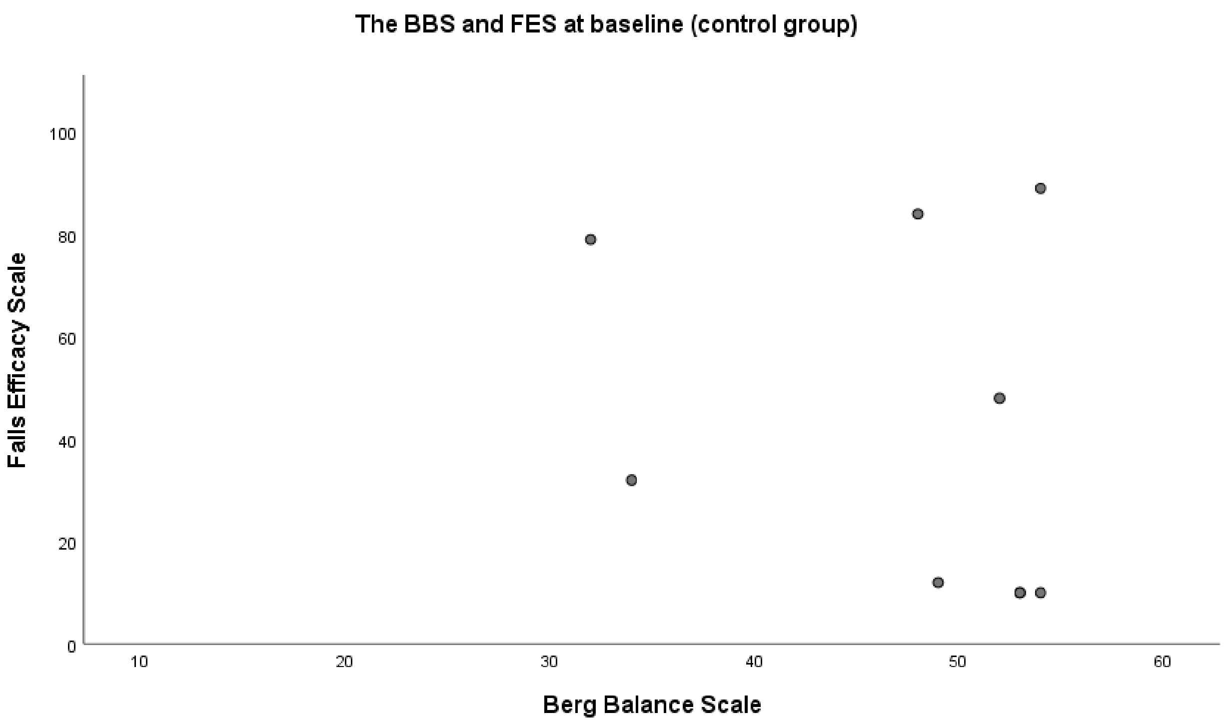


Figure 8 Scatterplot showing the association between the BBS and FES at baseline (control group)

It was expected that both groups would have similar scores at baseline because groups were randomized. Additionally, it was expected that if a participant had a high BBS score (being at low risk of falls), they would also score low on the FES (suggesting no fear of falling). Neither the experimental group nor control group analyses show a significant correlation (p >0.05). This is mirrored in the plots which show data points do not align themselves on a single line.

The BBS and FES at 12 weeks

The BBS is the independent variable looking for an association with the FES (see Table 33), suggesting that there is no association between the two variables. Figure 9 presents a scatterplot showing the association between the BBS and FES at 12 weeks for the experimental group, whereas Figure 10 shows the association within the control group at 12 weeks.

Table 33 Simple regression analyses of the BBS and FES at 12 weeks

BBS and the FES				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	-2.006	-.527	.053
	Control	-2.567	-.590	.124

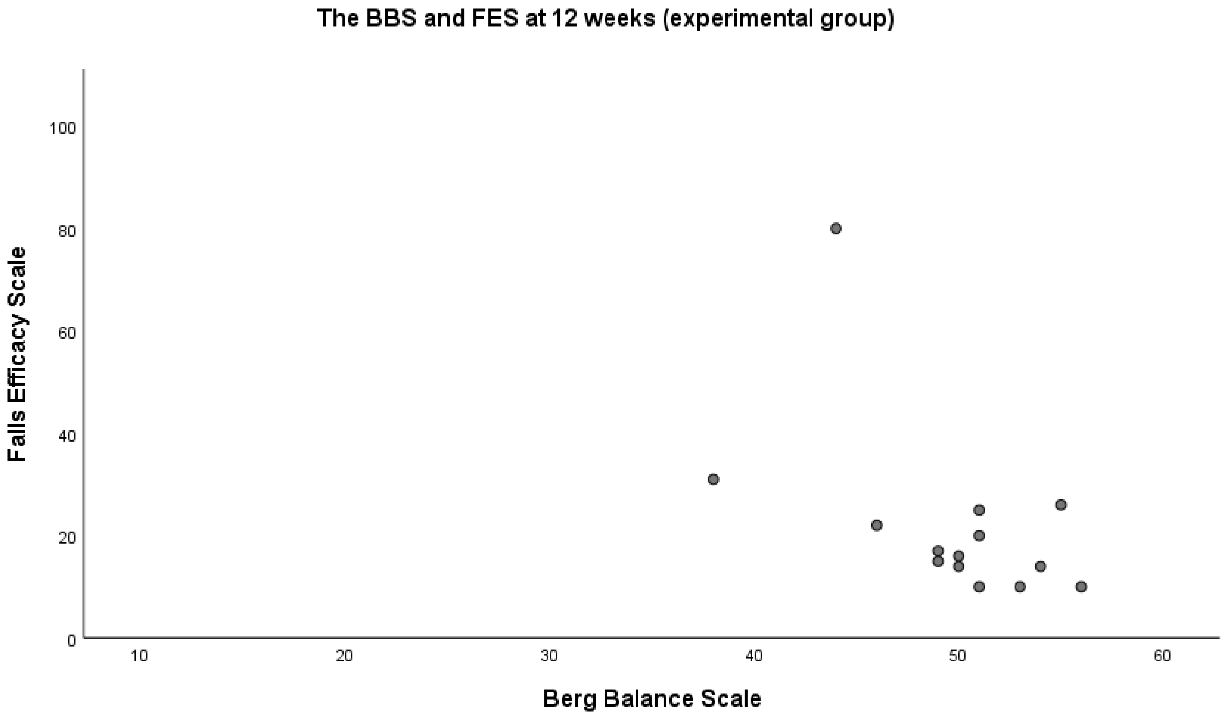


Figure 9 Scatterplot showing the association between the BBS and FES at 12 weeks (experimental group)

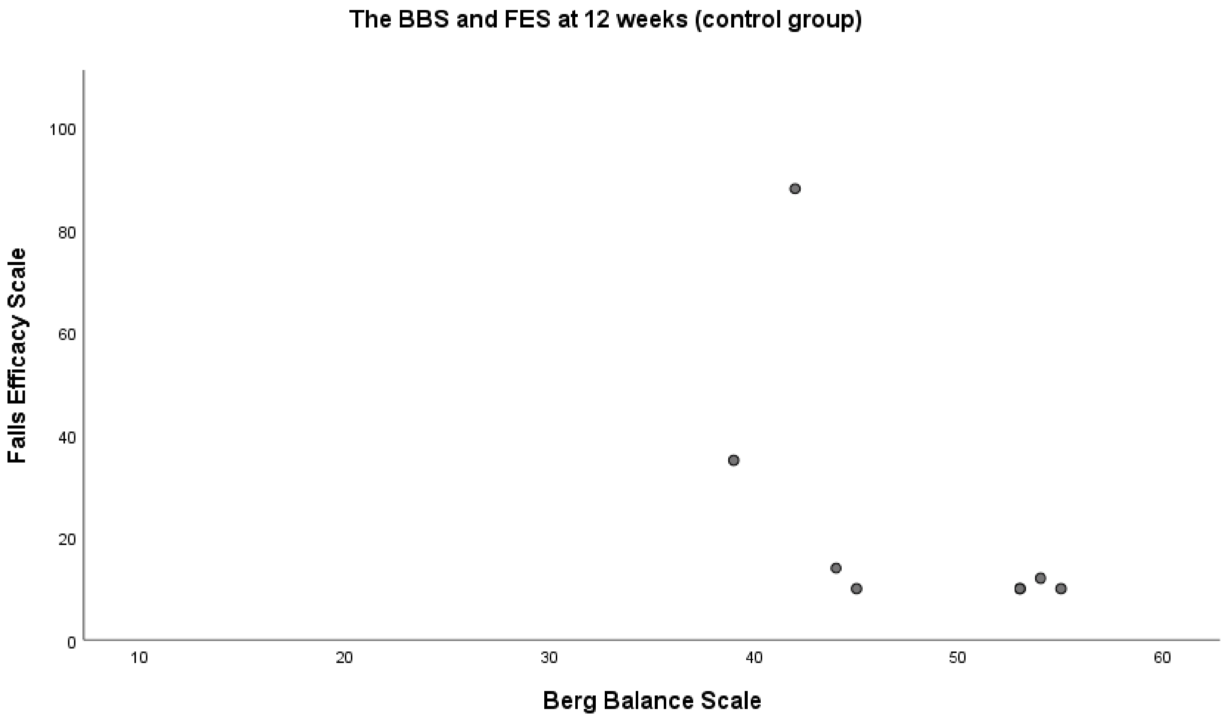


Figure 10 Scatterplot showing the association between the BBS and FES at 12 weeks (control group)

It was expected that at 12 weeks, both groups would improve their BBS and FES scores. As for the baseline, there was a trend for participants with a high BBS score to have a low FES score with the exception of some outliers, with a slightly stronger (but still not statistically significant) association between the BBS and FES. The experimental group showed more improvement in mean scores for both variables than the control group. Neither the experimental group nor control group analyses show a significant correlation ($p > 0.05$). This is mirrored in the plots which show data points do not align themselves on a single line.

The BBS and SF 12 [PCS] at baseline

The BBS is the independent variable looking for an association with the SF 12 [PCS] at baseline (see Table 34), suggesting that there is no association between the two variables. Figure 11 presents a scatterplot showing the association between the BBS and SF 12 [PCS] at baseline for the experimental group, whereas Figure 12 shows the association within the control group at baseline.

Table 34 Table Simple regression analyses of the BBS and SF 12 [PCS] at baseline

BBS and the SF 12 [PCS]				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	.101	.114	.711
	Control	.002	.002	.997

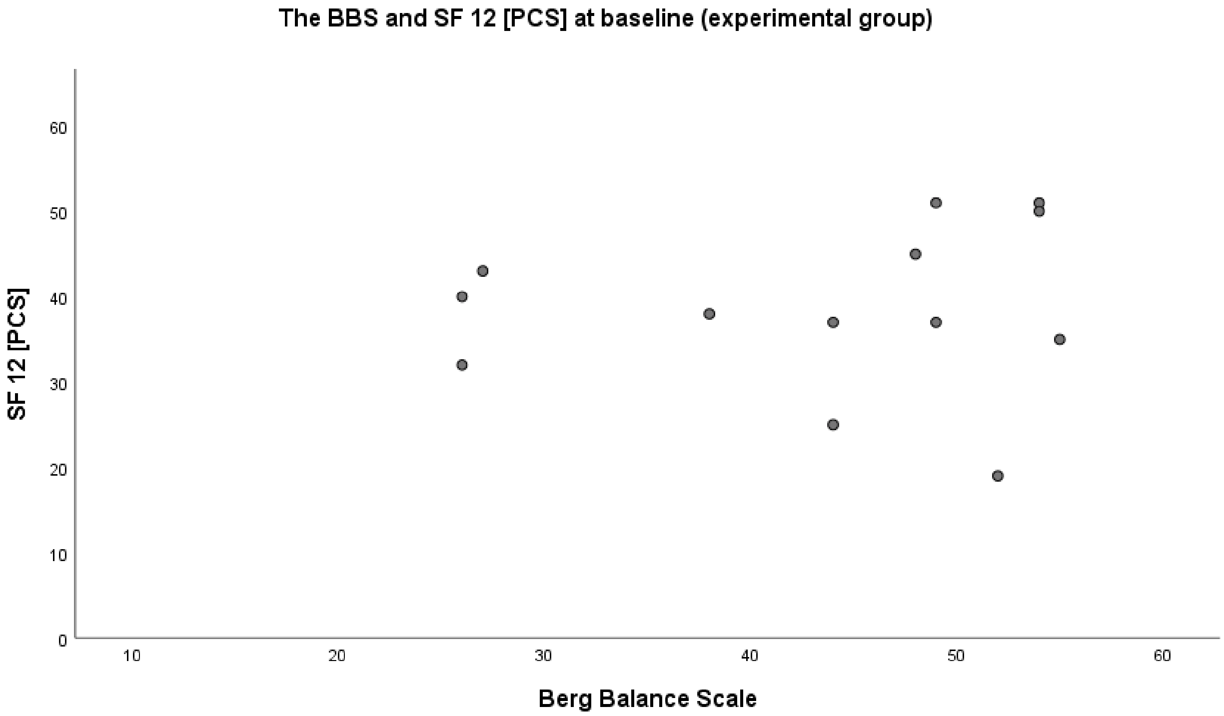


Figure 11 Scatterplot showing the association between the BBS and SF 12 [PCS] at baseline (experimental group)

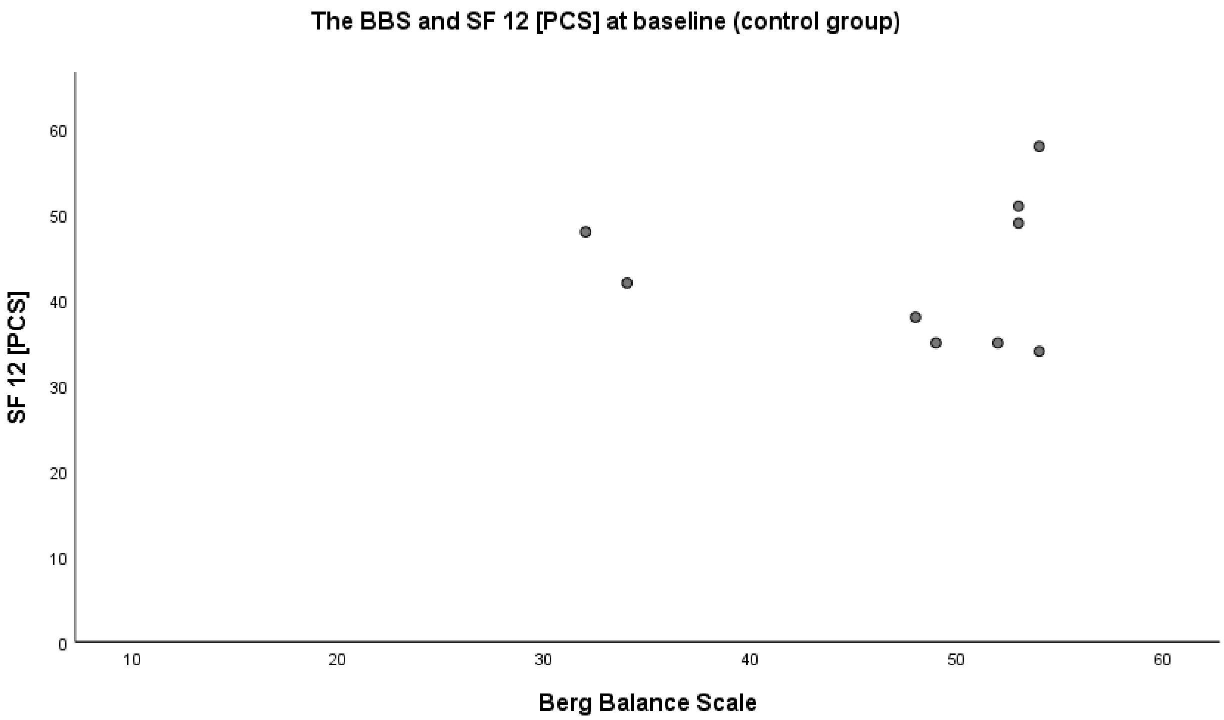


Figure 12 Scatterplot showing the association between the BBS and SF 12 [PCS] at baseline (control group)

It was expected that those with a high BBS would also score high on the SF 12 [PCS], indicating good balance is associated with good physical function. Whilst there is some semblance of clustering in the upper right quadrant, no clear association between the variables is apparent ($p > 0.05$).

<u>THE BBS and SF 12 [PCS] at 12 weeks</u>

The BBS is the independent variable looking for an association with the SF 12 [PCS] (see Table 35). Figure 13 presents a scatterplot between the association between the BBS and the SF 12 [PCS] at 12 weeks for the experimental group, whereas Figure 14 shows the association within the control group at 12 weeks.

Table 35 Simple regression analyses for the BBS and SF 12 [PCS] at 12 weeks

BBS and the SF 12 [PCS]				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	1.099	.515	.060
	Control	1.805	.963	.000

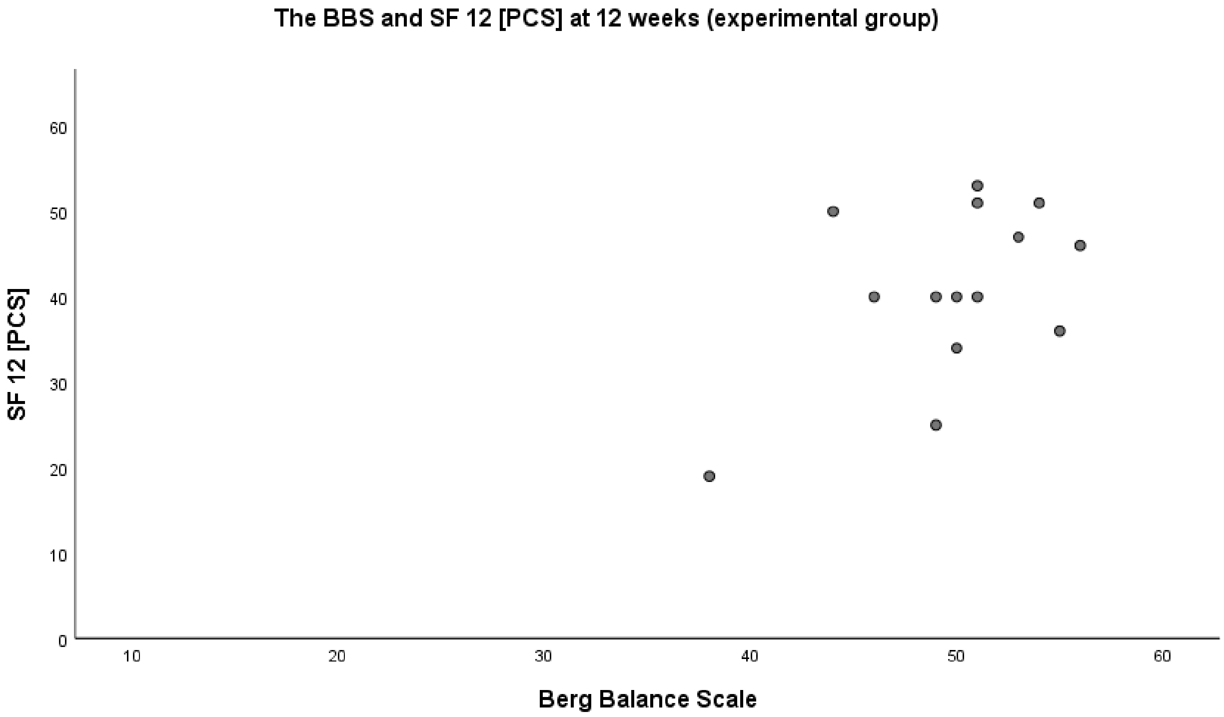


Figure 13 Scatterplot showing the association between the BBS and SF 12 [PCS] at 12 weeks (experimental group)

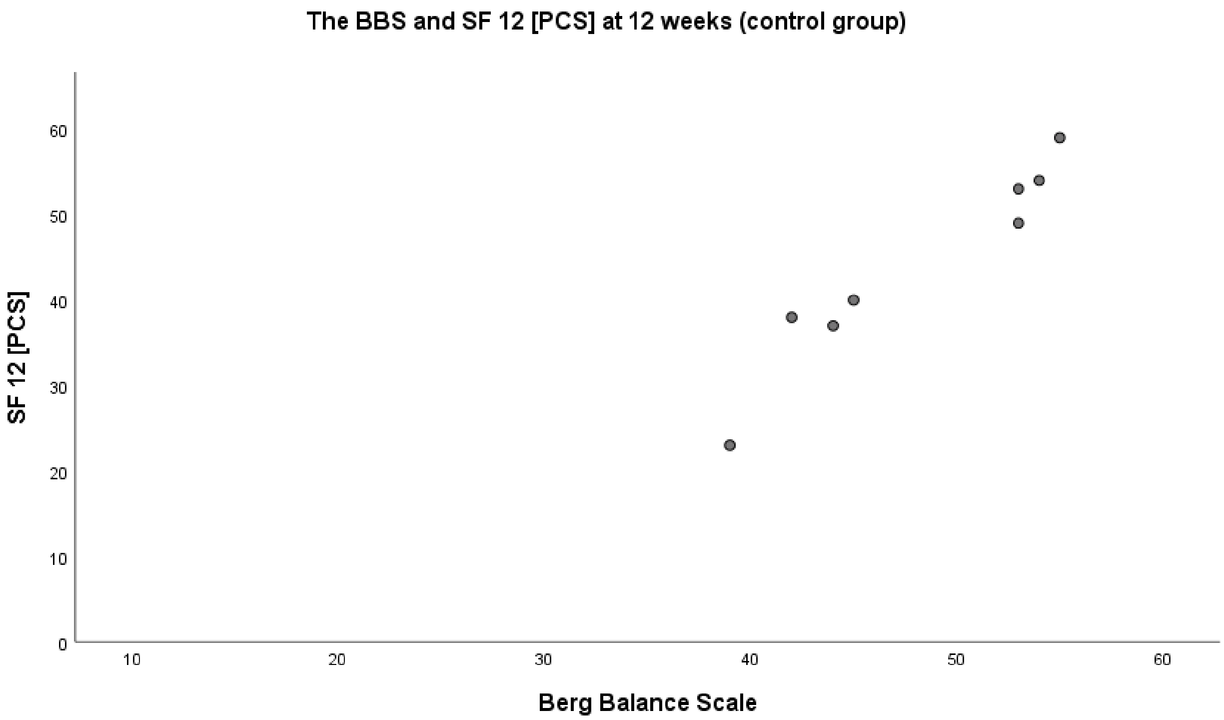


Figure 14 Scatterplot showing the association between the BBS and SF 12 [PCS] at 12 weeks (control group)

It was expected that at 12 weeks, both groups would improve on the BBS and FES. The plots at 12 weeks show a statistically significant association between the variables that was not apparent at baseline for the control group (p=0.000), with higher balance scores being associated with higher SF 12 [PCS] scores for both groups. Whist the experimental group appeared to improve on their mean scores over time, it is difficult to say whether this was due to the intervention because scores (whether measured by the BBS or the SF 12) may simply reflect a natural physical improvement expected among stroke survivors within the first six months following stroke onset.

The GDS and SF 12 [MCS] at baseline

The GDS is the independent variable looking for an association with the SF 12 [MCS] (see Table 36). Figure 15 presents a graphical depiction between the association between the GDS and SF 12 [MCS] at baseline for the experimental group, whereas Figure 16 shows the association within the control group at baseline.

Table 36 Simple regression analyses of the GDS and SF 12 [MCS] at baseline

GDS and SF 12 [MCS]				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	-.318	.272	.265
	Control	-.796	.613	.223

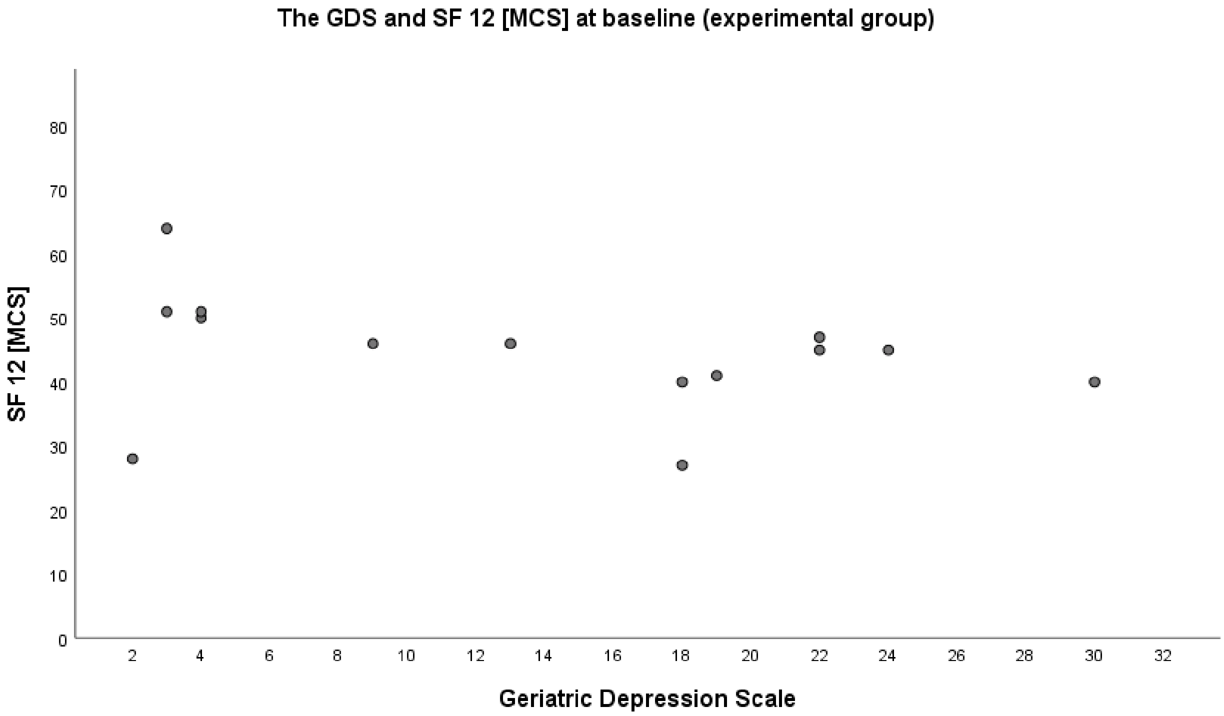


Figure 15 Scatterplot showing the association between the GDS and SF 12 [MCS] at baseline (experimental group)

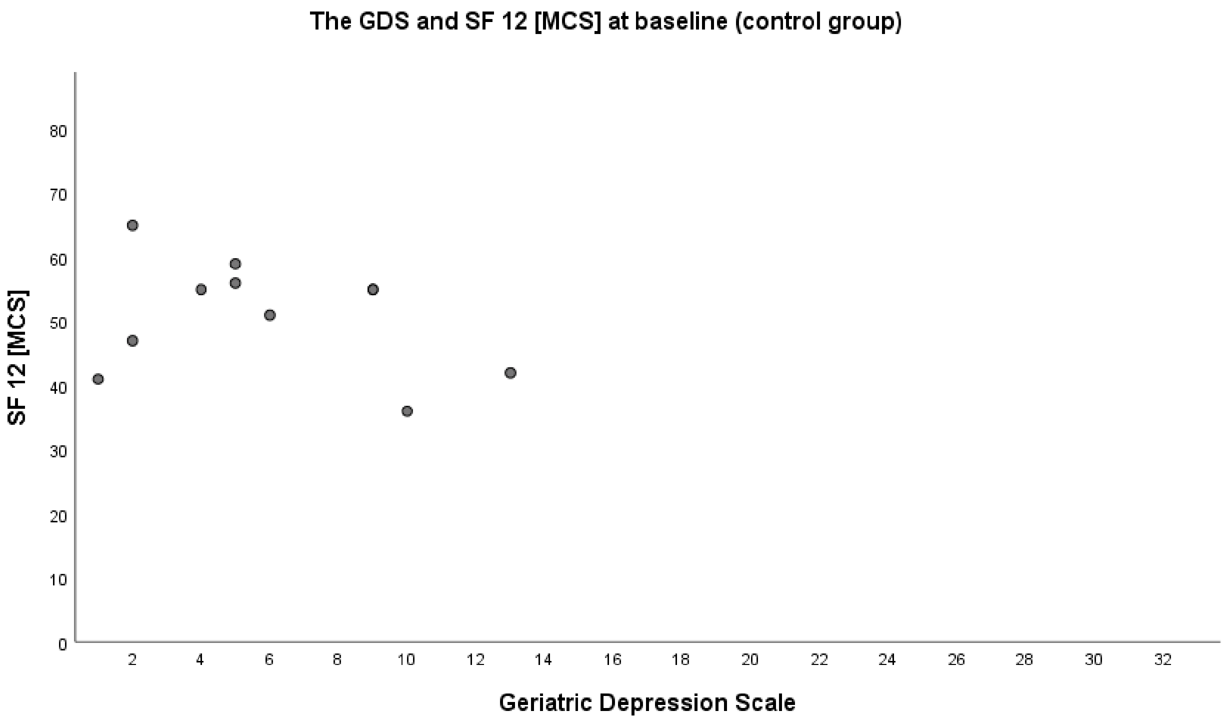


Figure 16 Scatterplot showing the association between the GDS and SF 12 [MCS] at baseline (control group)

It was expected that both groups would show similar results in the GDS and SF 12 [MCS] because they are measuring similar items. Neither the experimental group nor control group analyses show a significant correlation ($p > 0.05$). This is mirrored in the plots which show data points do not align themselves on a single line; regression lines would be somewhat flat with data points above and below. The plots seem to show a slight trend for lower SF 12 [MCS] scores being associated with higher GDS scores, but do not show a clear relationship, suggesting that they may be measuring different parameters.

The GDS and SF 12 [MCS] at 12 weeks

The GDS is the independent variable looking for an association with the SF 12 [MCS] (see Table 37). Figure 17 presents a graphical depiction between the association between the GDS and SF 12 [MCS] at 12 weeks for the experimental group, whereas Figure 18 shows the association within the control group at 12 weeks.

Table 37 Simple regression analyses for the GDS and SF 12 [MCS] at 12 weeks

GDS and SF 12 [MCS]				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	-1.243	-.829	.000
	Control	-.703	-.300	.434

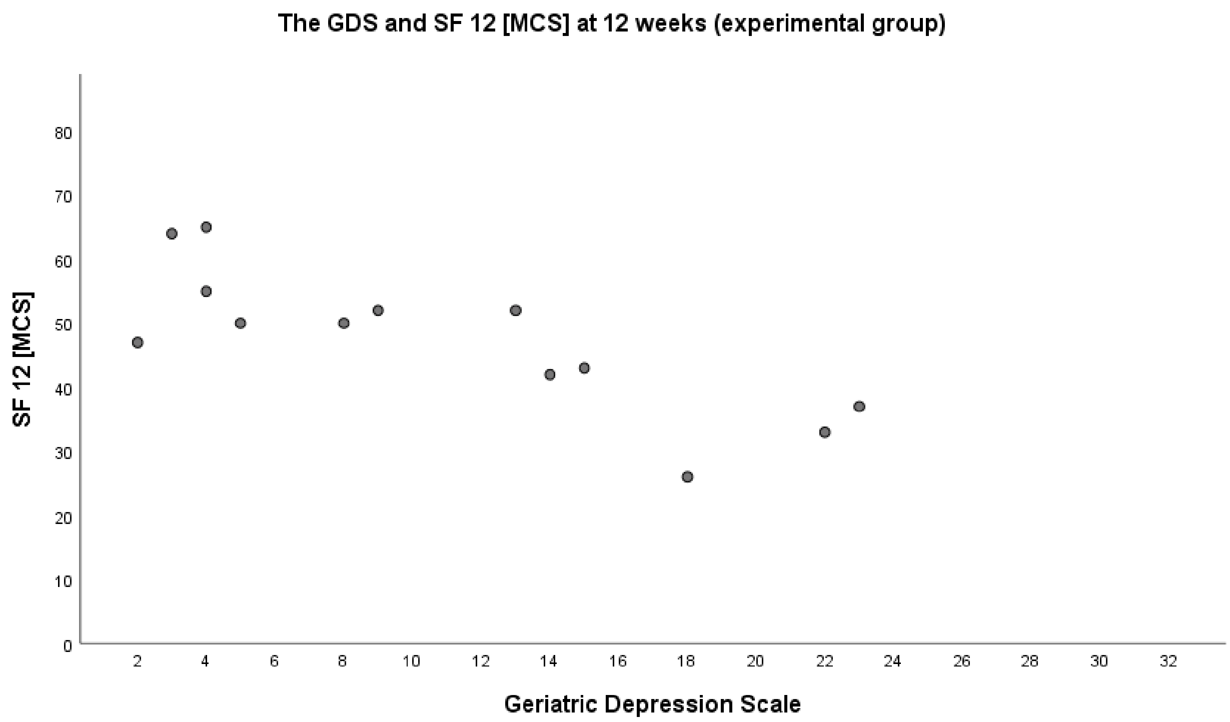


Figure 17 Scatterplot showing the association between the GDS and SF 12 [MCS] at 12 weeks (experimental group)

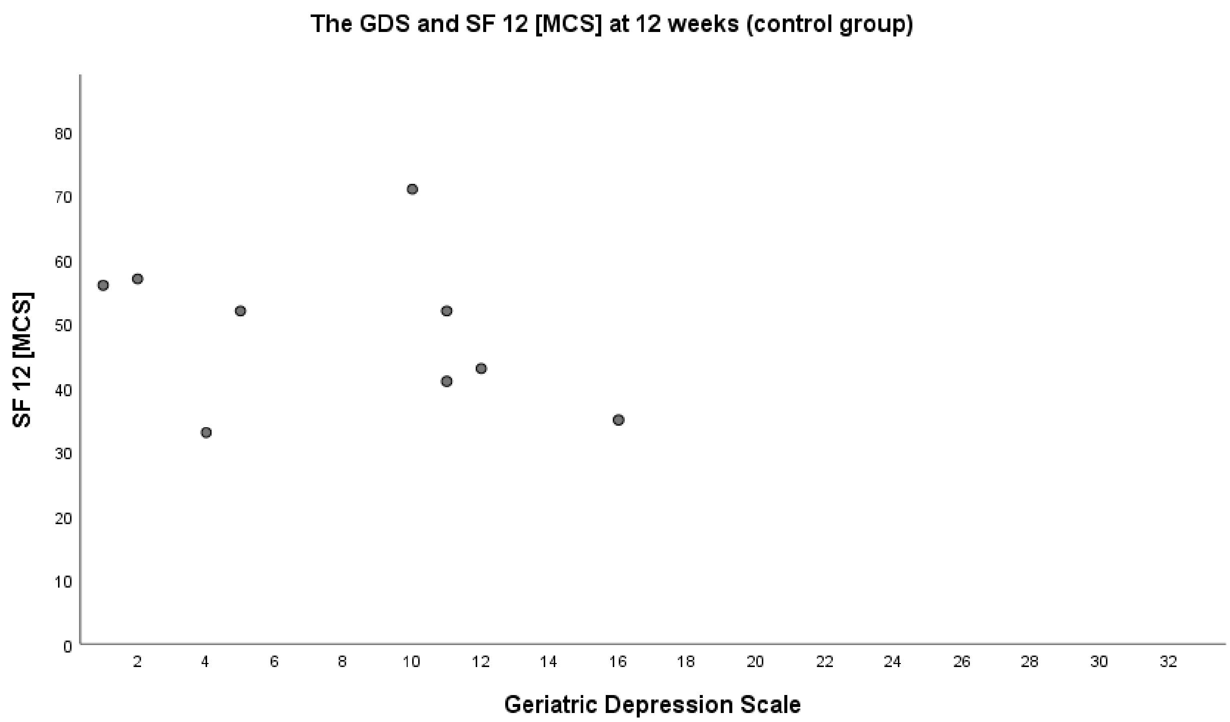


Figure 18 Scatterplot showing the association between the GDS and SF 12 [MCS] at 12 weeks (control group)

It was expected at 12 weeks that the GDS and SF 12 [MCS] would show similar results, suggesting an association between the outcome measures. Simple regression analyses show that at 12 weeks, there was a statistically significant association (p=0.000) between the variables that was not apparent at baseline, with similar scores for the GDS and SF 12 [MCS].

Reflections on the simple regression analyses

There is no clear association between the BBS and the FES either for the experimental or control groups. Distribution of data plots for the BBS and FES show that both variables are measuring different things, suggesting that the FES may be useful in a future trial to measure fear of falling. Using the FES as a secondary outcome measure may help predict future fallers.

In relation to the BBS and SF 12 [PCS], there is no clear association between variables either for the experimental or control groups. Twelve-week plots show the same general distribution of data points as seen at baseline. Despite the control group showing a stronger relationship, there is insufficient evidence to conclude that the variables are measuring the same thing. The BBS is a good indicator for balance changes over time, as well as being a predictor of falls (Li et al.,2004). Therefore, a future trial may want to include only the BBS as a primary outcome measure because it seems that the SF 12 [PCS] neither measures the primary outcome of the study, which is fall risk, nor the secondary outcome, balance changes over time. Had there been a correlation between the BBS and SF 12 [PCS], one of these outcome measures would have been assessed as being the most useful to be used in a future trial.

There is no convincing evidence from the regression analyses on the GDS and SF 12 for choosing one over the other; there is no clear association between variables either for the experimental or control groups. However, based on the responsiveness to change over time, ease of use and its ability to predict levels of depression (mild, moderate and severe) more clearly than the SF 12 [MCS], the GDS could be used in a future trial to assess depression over time.

Age and association with outcome measures

Age and the BBS at baseline

Age is the independent variable looking for an association with the BBS (see Table 38). Figure 19 presents a scatterplot showing the association between age and the BBS at baseline for the experimental group, whereas Figure 20 shows the association within the control group at baseline.

Table 38 Simple regression analyses for age and the BBS at baseline

Age and the BBS				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	.043	.288	.883
	Control	-.464	.278	.134

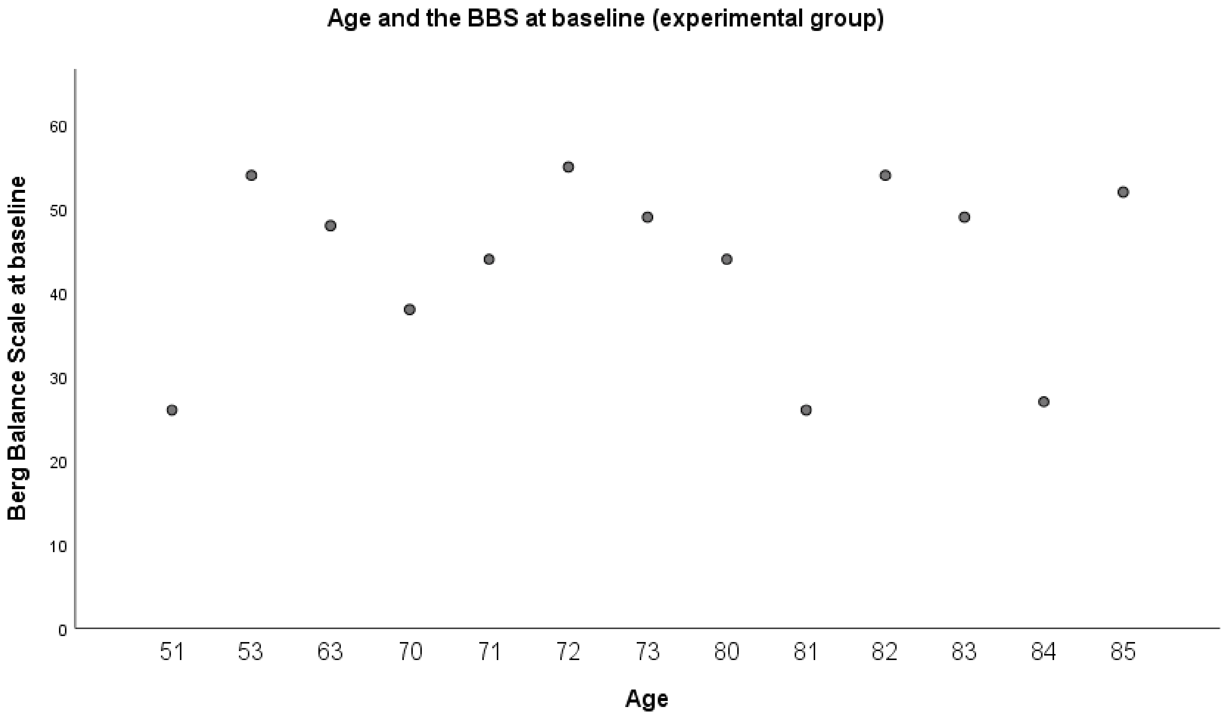


Figure 19 Scatterplot showing the association between age and the BBS at baseline (experimental group)

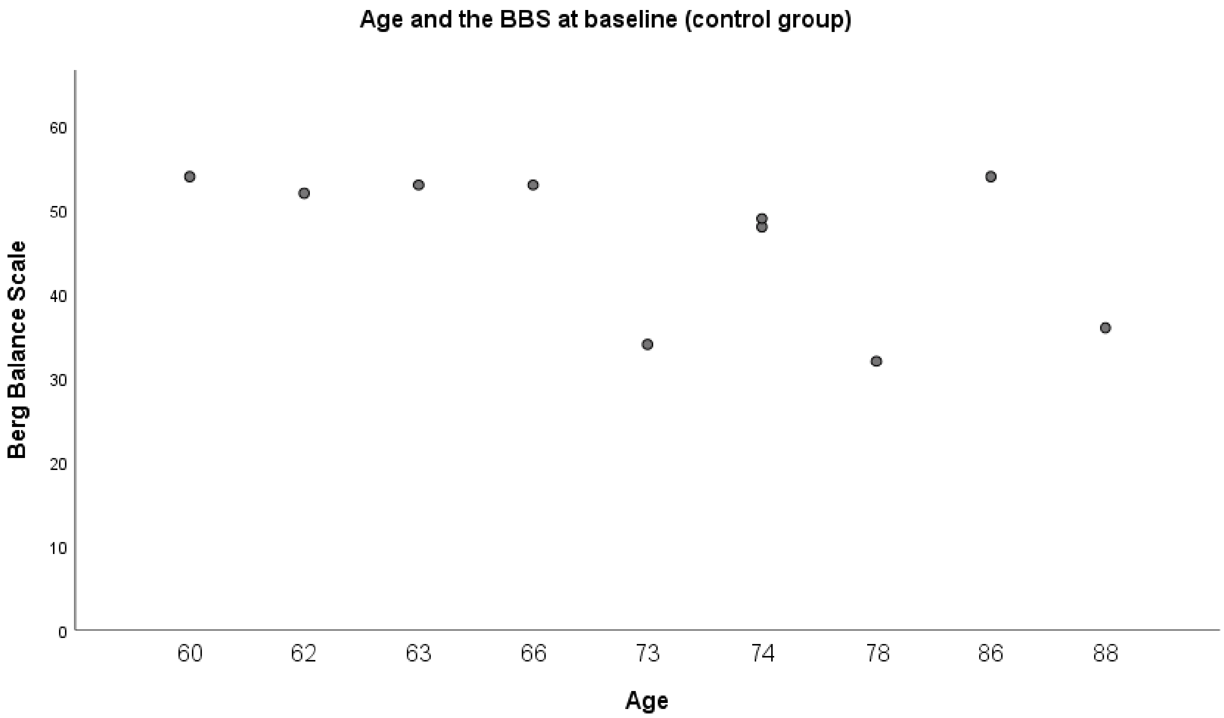


Figure 20 Scatterplot showing the association between age and the BBS at baseline (control group)

Age and the BBS at 12 weeks

Age is the independent variable looking for an association with the BBS (see Table 39). Figure 21 presents a scatterplot showing the association between age and the BBS at 12 weeks for the experimental group, whereas Figure 22 shows the association within the control group at 12 weeks.

Table 39 Simple regression analyses for age and the BBS at 12 weeks

Age and the BBS				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	-.207	-.487	.077
	Control	-.196	-.252	.547

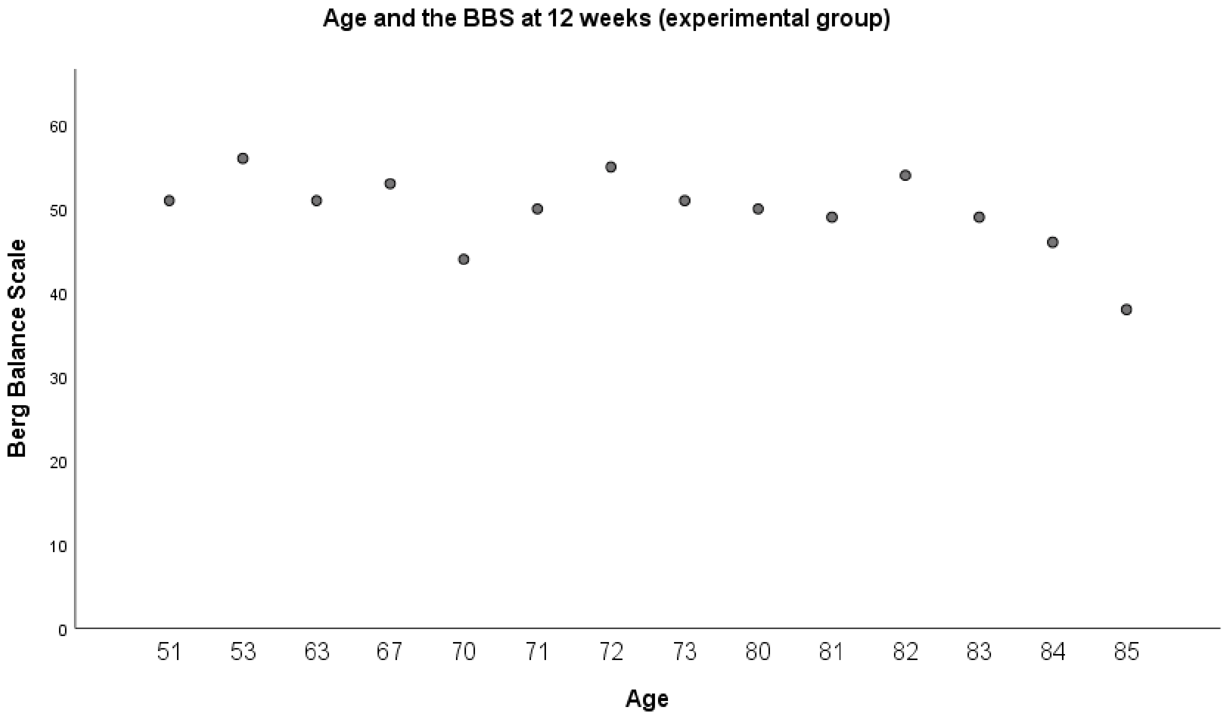


Figure 21 Scatterplot showing the association between age and the BBS at 12 weeks (experimental group)

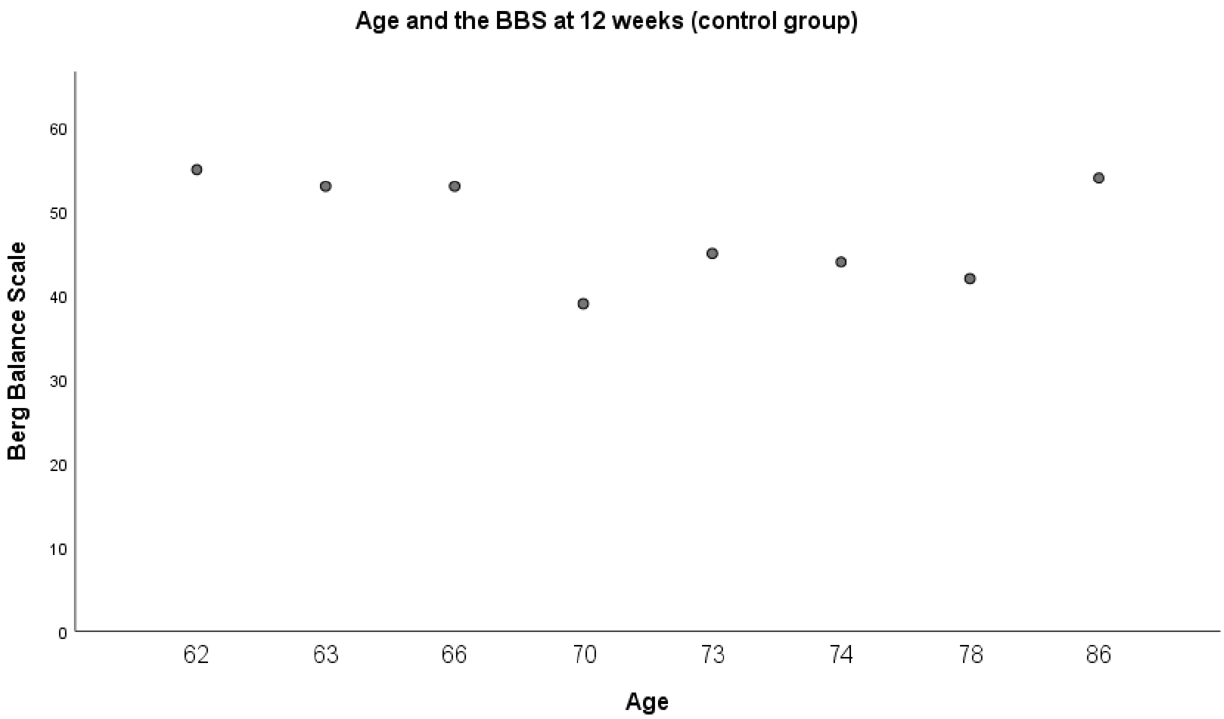


Figure 22 Scatterplot showing the association between age and the BBS at 12 weeks (control group)

Age and the GDS at baseline

Age is the independent variable looking for an association with the GDS (see Table 40). Figure 23 presents a scatterplot showing the association between age and the GDS at baseline for the experimental group, whereas Figure 24 shows the association within the control group at baseline.

Table 40 Simple regression analyses for age and the GDS at baseline

Age and the GDS				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	-.141	-.166	.571

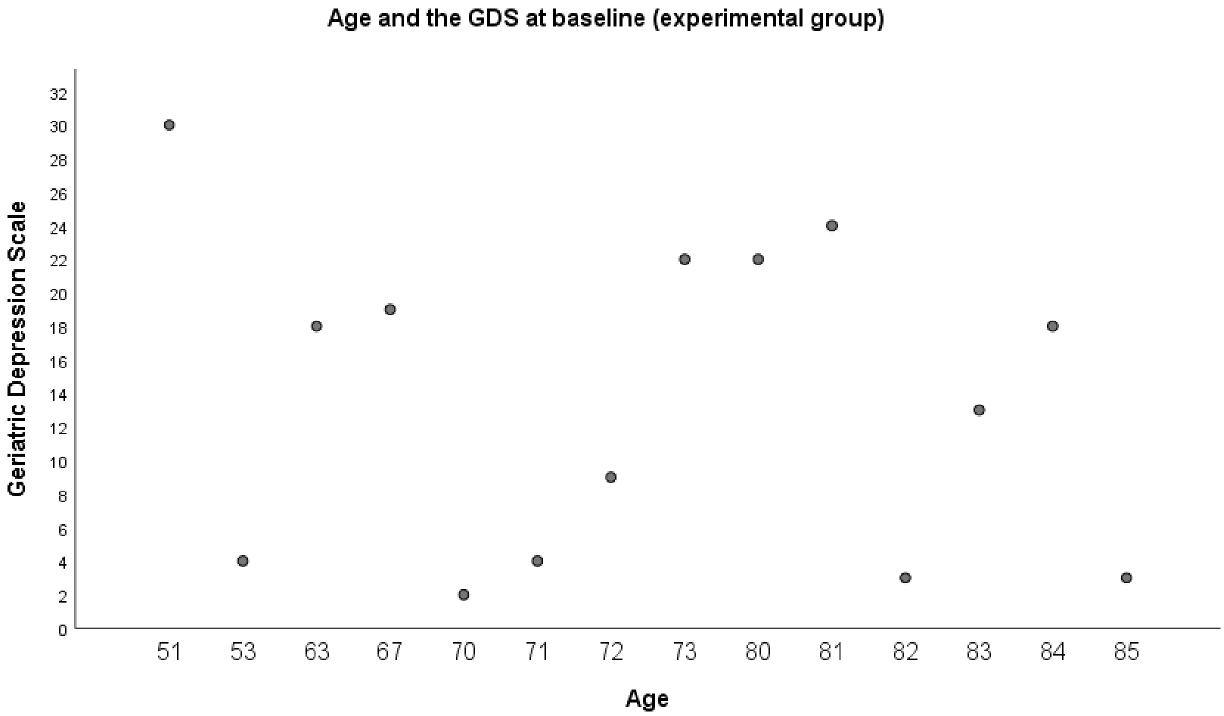


Figure 23 Scatterplot showing the association between age and the GDS at baseline (experimental group)

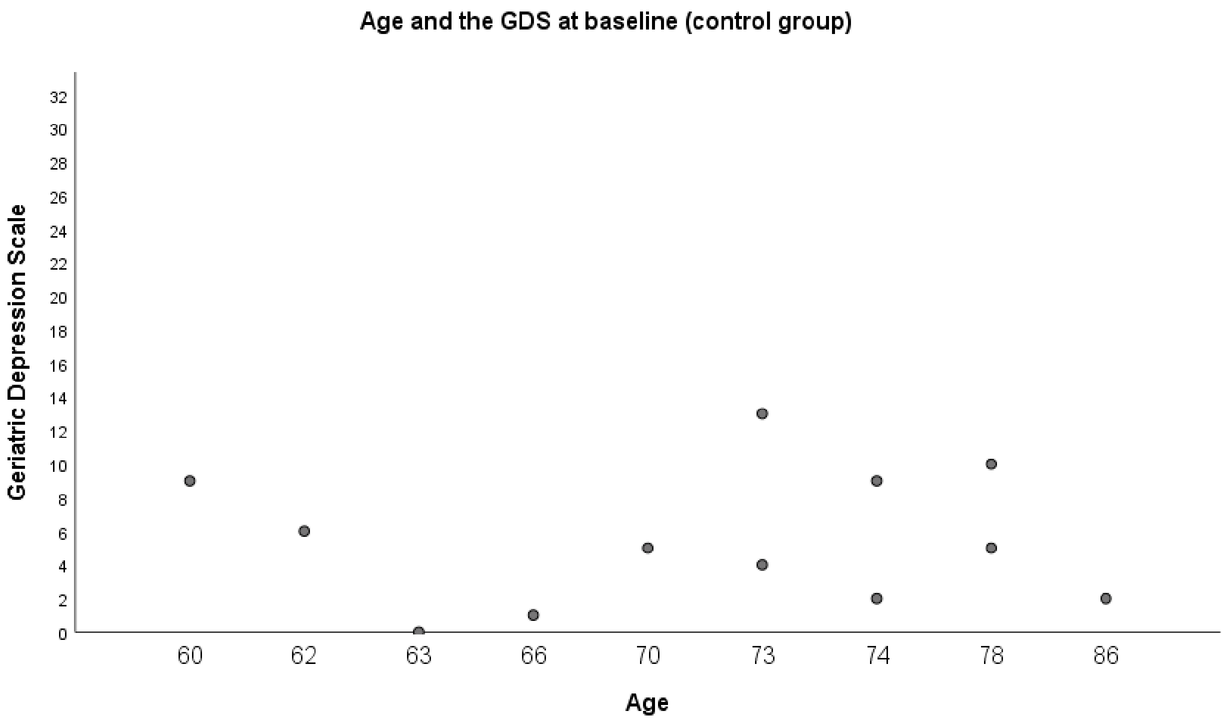


Figure 24 Scatterplot showing the association between age and the GDS at baseline (control group)

Age and the GDS at 12 weeks

Age is the independent variable looking for an association with the GDS (see Table 41). Figure 25 presents a scatterplot showing the association between age and the GDS at 12 weeks for the experimental group, whereas Figure 26 shows the association within the control group at 12 weeks.

Table 41 Simple regression analyses for age and the GDS at 12 weeks

Age and the GDS				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	-.059	-.086	.771
	Control	.481	.710	.032

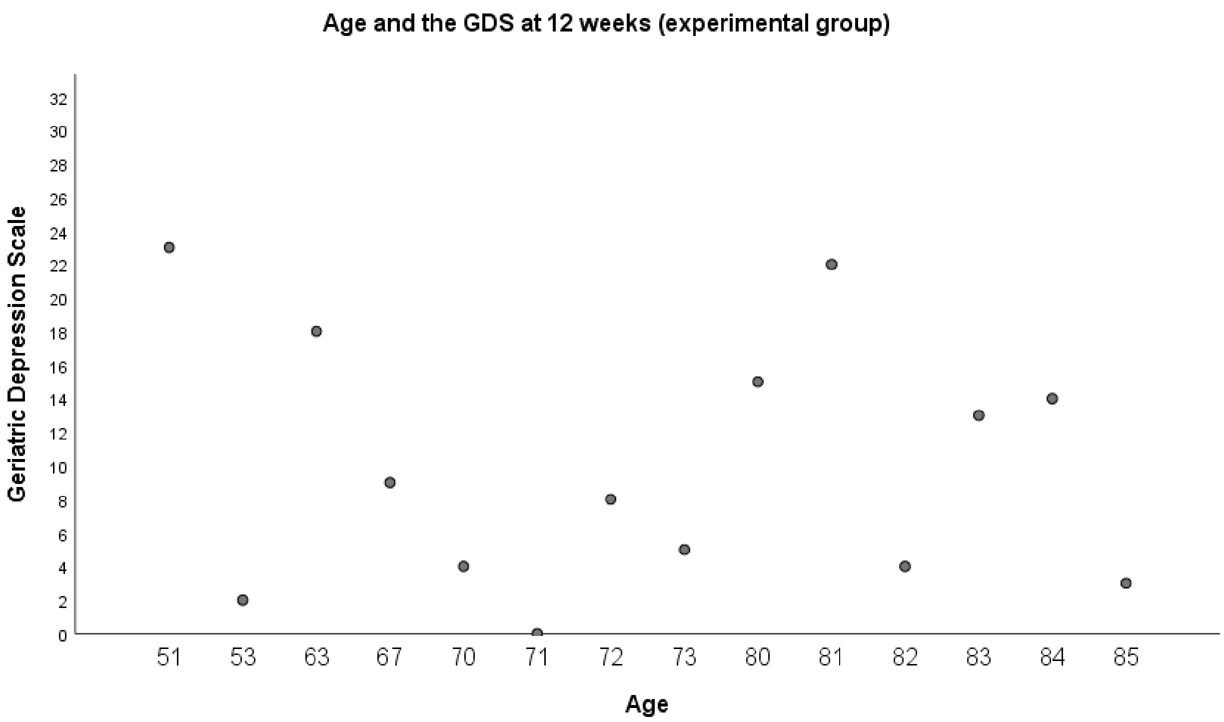


Figure 25 Scatterplot showing the association between age and the GDS at 12 weeks (experimental group)

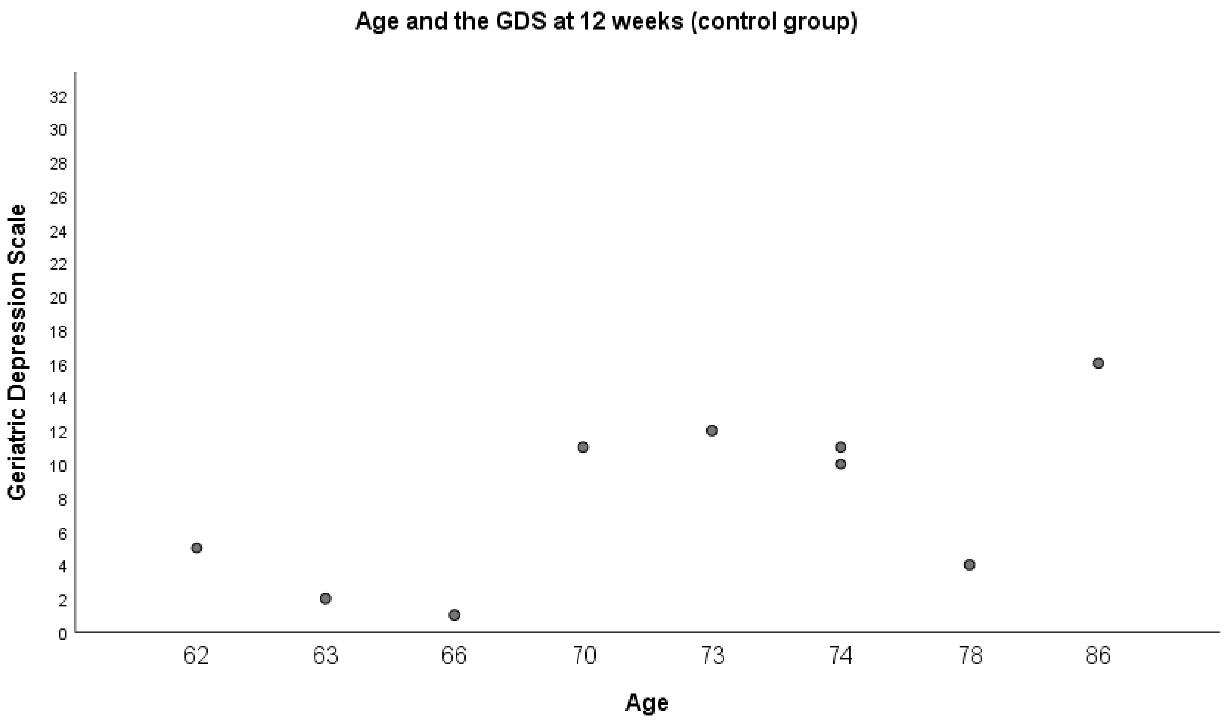


Figure 26 Scatterplot showing the association between age and the GDS at 12 weeks (control group)

Age and the FES at baseline

Age is the independent variable looking for an association with the FES (see Table 42). Figure 27 presents a scatterplot showing the association between age and the FES at baseline for the experimental group, whereas Figure 28 shows the association within the control group at baseline.

Table 42 Simple regression analyses for age and the FES at baseline

Age and the FES				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	1.454	.539	.047
	Control	-.146	-.035	.914

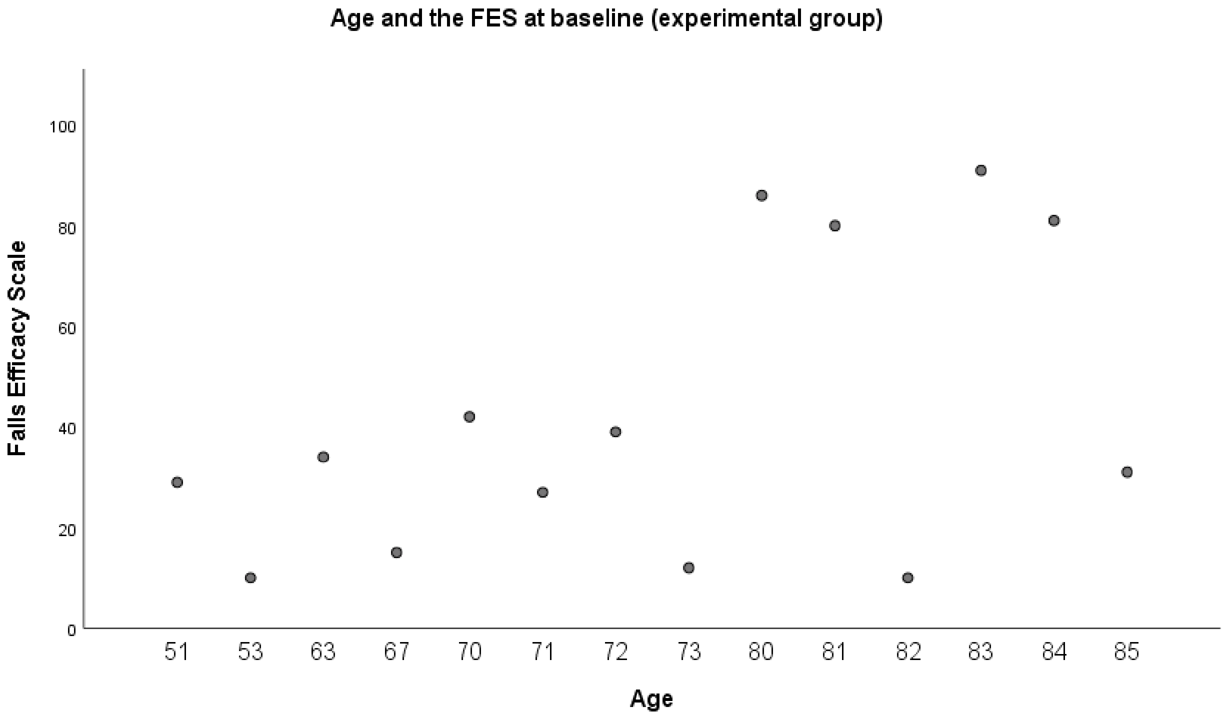


Figure 27 Scatterplot showing the association between age and the FES at baseline (experimental group)

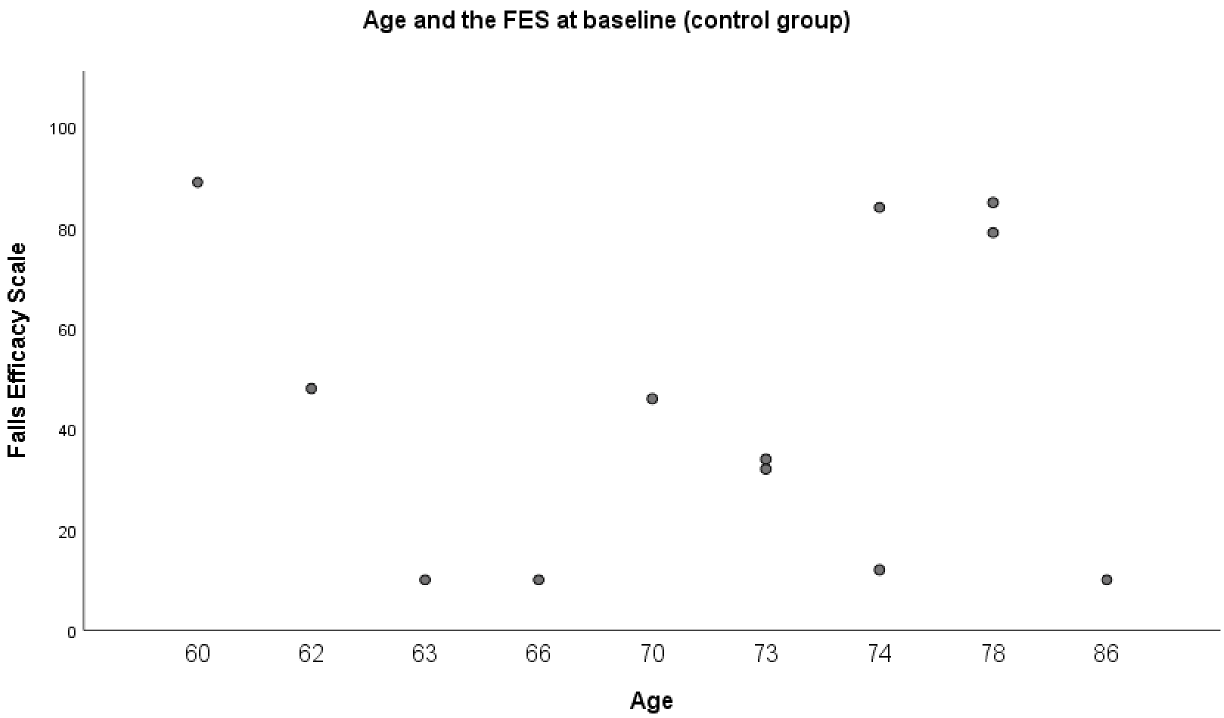


Figure 28 Scatterplot showing the association between age and the FES at baseline (control group)

Age and the FES at 12 weeks

Age is the independent variable looking for an association with the FES (see Table 43). Figure 29 presents a scatterplot showing the association between age and the FES at 12 weeks for the experimental group, whereas Figure 30 shows the association within the control group at 12 weeks.

Table 43 Simple regression analyses for age and the FES at 12 weeks

Age and the FES				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	.020	.012	.967
	Control	1.469	.309	.418

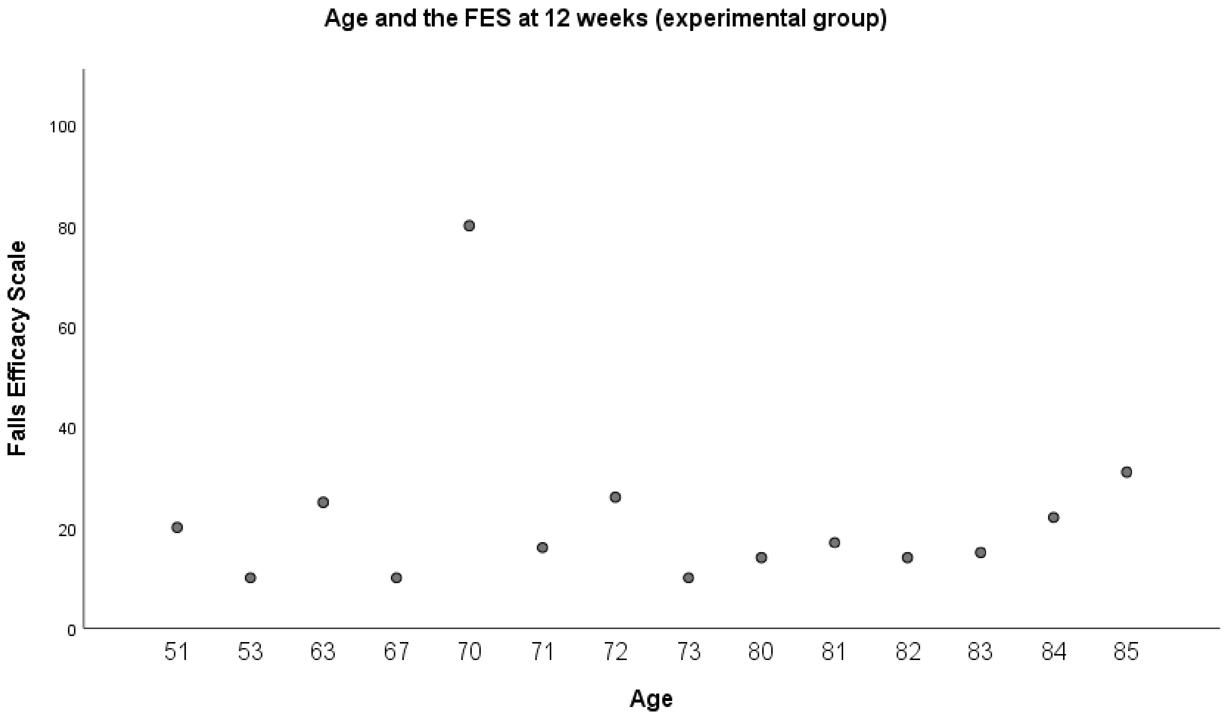


Figure 29 Scatterplot showing the association between age and the FES at 12 weeks (experimental group)

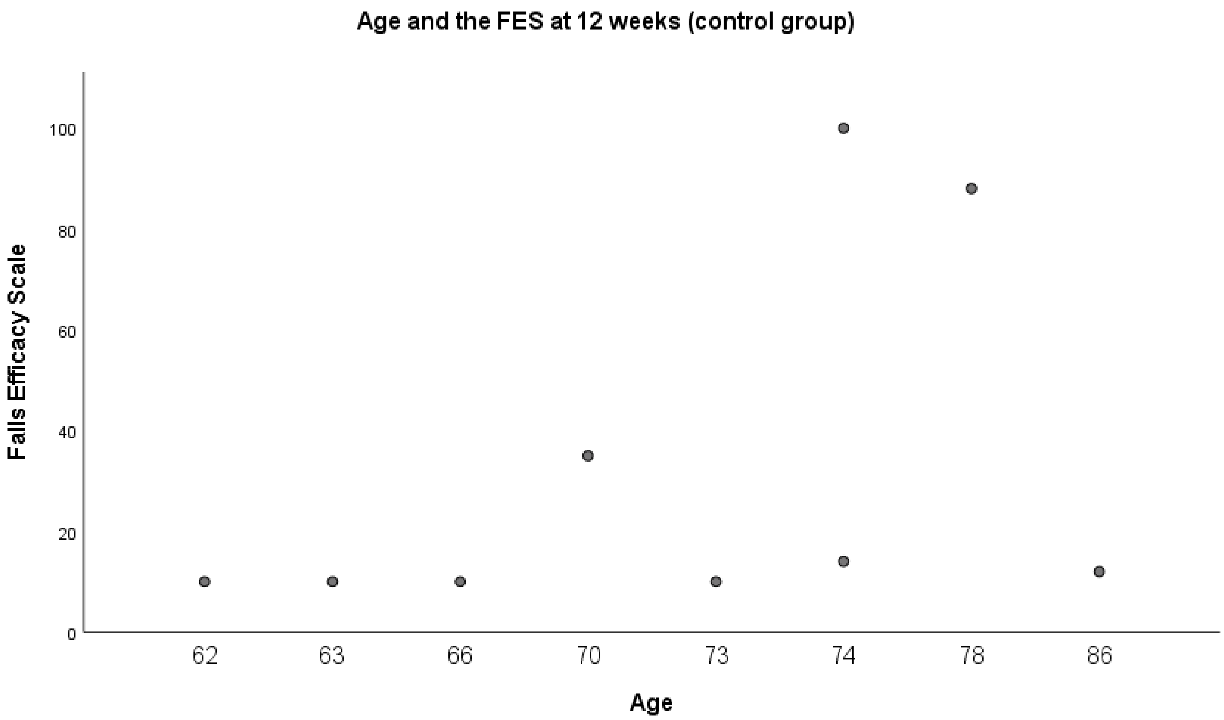


Figure 30 Scatterplot showing the association between age and the FES at 12 weeks (control group)

Age and SF 12 [PCS] at baseline

Age is the independent variable looking for an association with the SF 12 [PCS] (see Table 44). Figure 31 presents a scatterplot showing the association between age and the SF 12 [PCS] at baseline for the experimental group, whereas Figure 32 shows the association within the control group at baseline.

Table 44 Simple regression analyses of age and the SF 12 [PCS] at baseline

Age and SF 12 [PCS]				
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	-.184	-.771	.455
	Control	.269	.733	.479

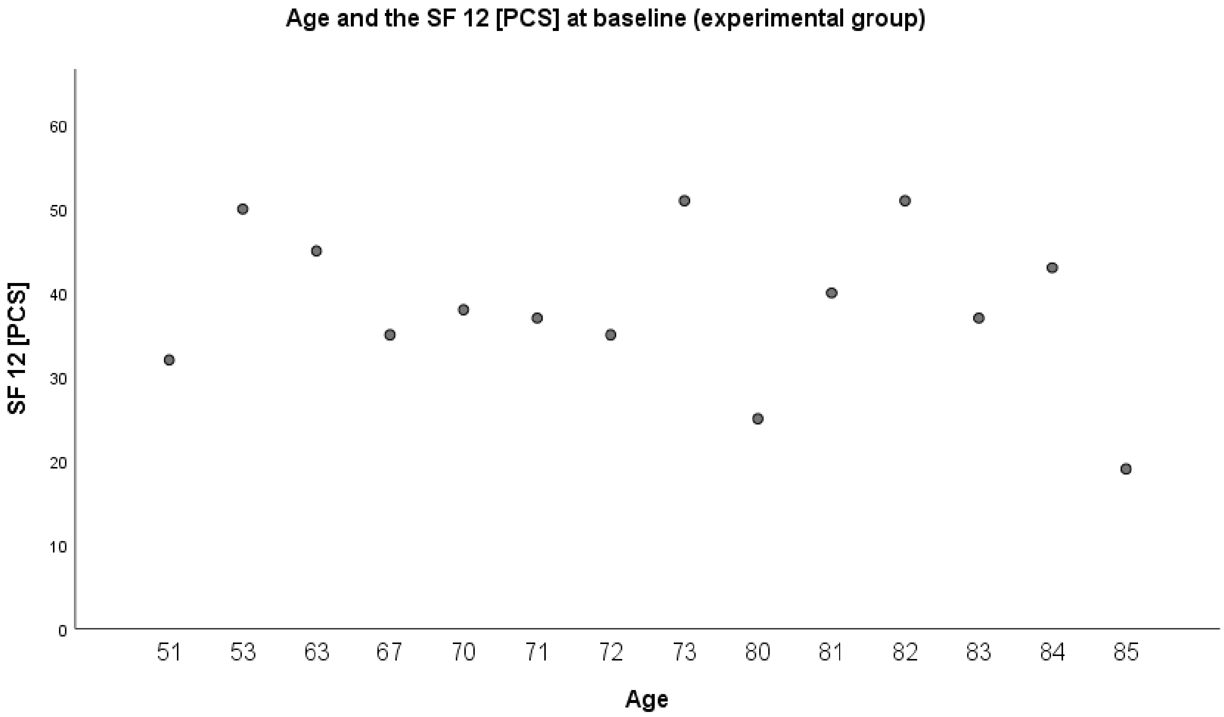


Figure 31 Scatterplot showing the association between age and the SF 12 [PCS] at baseline (experimental group)

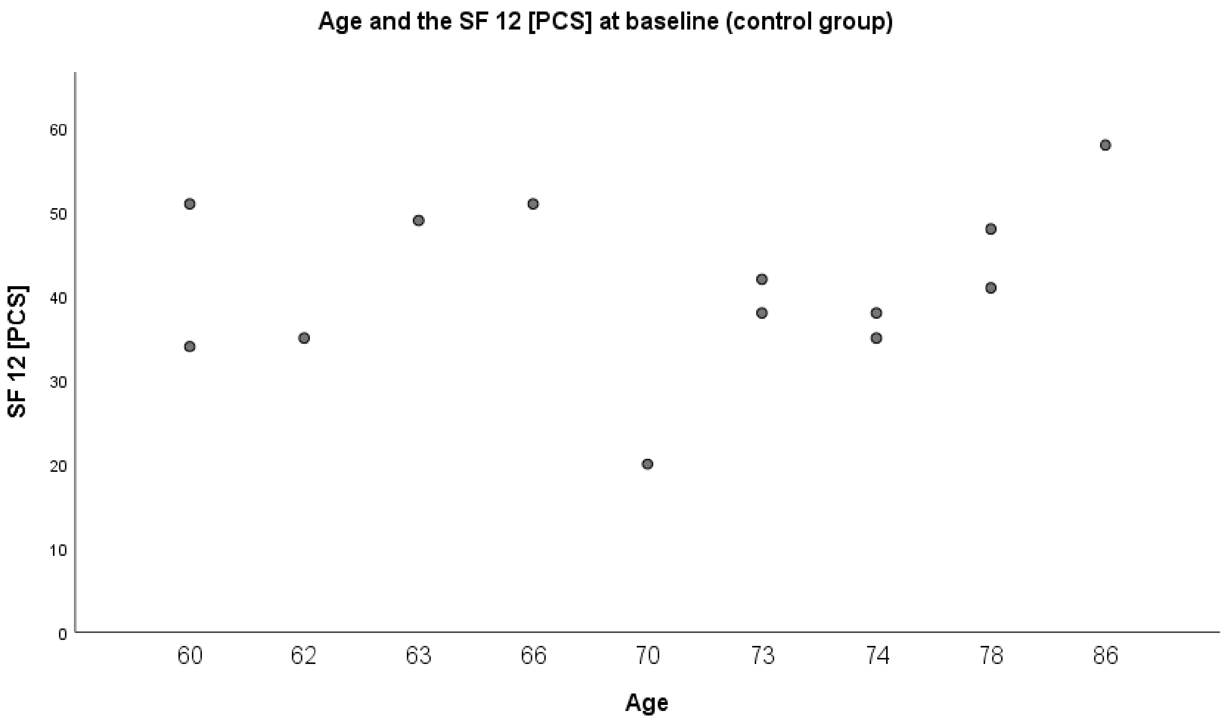


Figure 32 Scatterplot showing the association between age and the SF 12 [PCS] at baseline (control group)

Age and the SF 12 [PCS] at 12 weeks

Age is the independent variable looking for an association with the SF 12 [PCS] (see Table 45). Figure 33 presents a scatterplot showing between the association between age and the SF 12 [PCS] at 12 weeks for the experimental group, whereas Figure 34 shows the association within the control group at 12 weeks.

Table 45 Simple regression analyses for age and the SF 12 [PCS] at 12 weeks

		Age and the SF 12 [PCS]		
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	.465	-.513	.060
	Control	-.387	-.209	.589

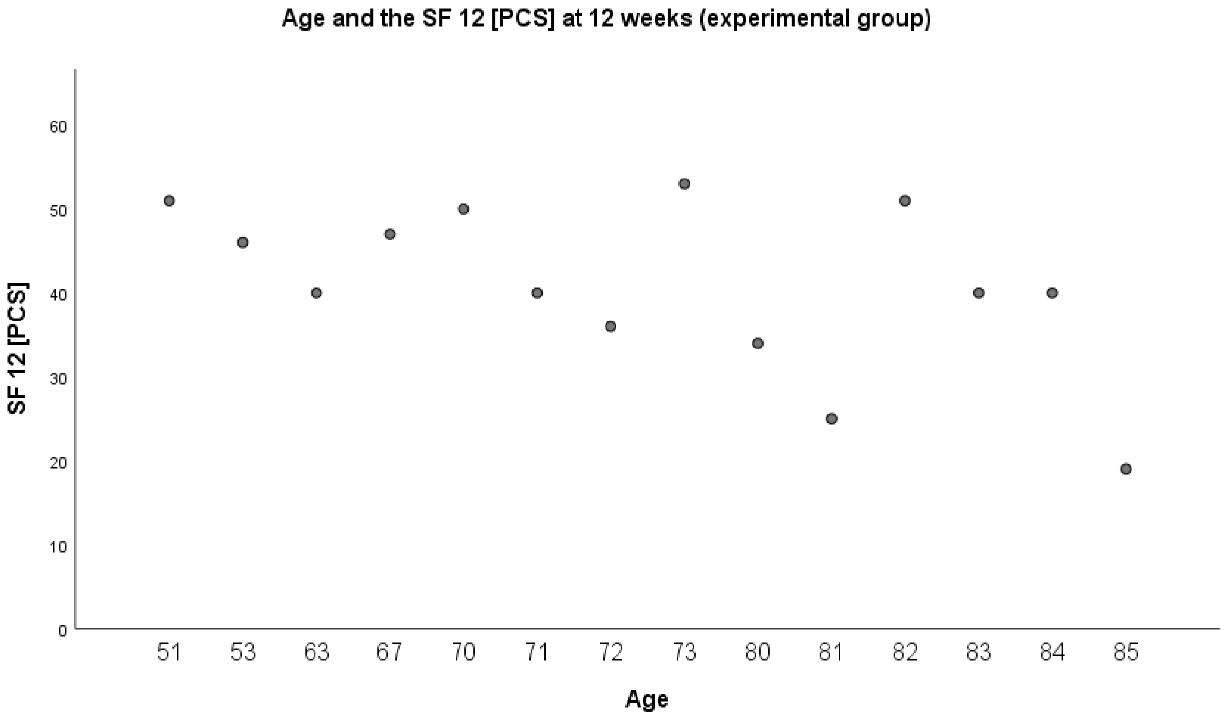


Figure 33 Scatterplot showing the association between age and the SF 12 [PCS] at 12 weeks (experimental group)

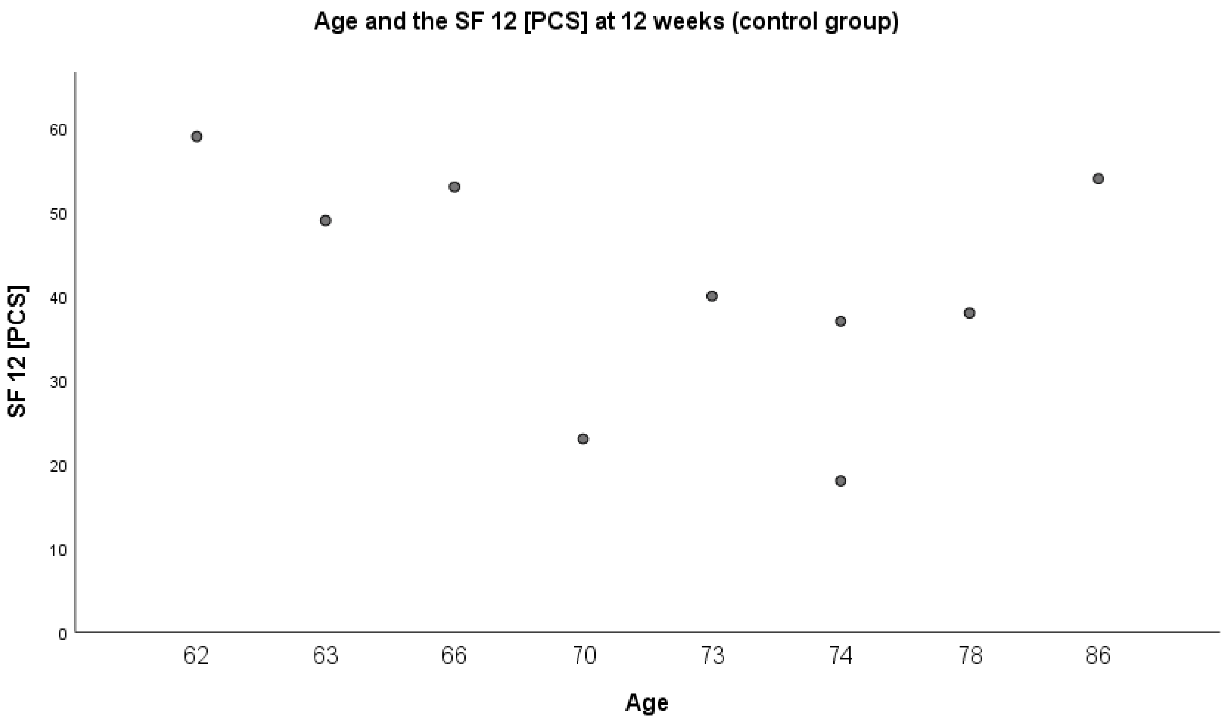


Figure 34 Scatterplot showing the association between age and the SF 12 [PCS] at 12 weeks (control group)

Age and SF 12 [MCS] at baseline

Age is the independent variable looking for an association with the SF 12 [MCS] (see Table 46). Figure 35 presents a scatterplot showing the association between age and the SF-12 [MCS] at baseline for the experimental group, whereas Figure 36 shows the association within the control group at baseline.

Table 46 Simple regression analyses for age and the SF 12 [MCS] at baseline

		Age and the SF 12 [MCS]		
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
Baseline				
	Experimental	.293	.347	.224
	Control	-.088	-.085	.782

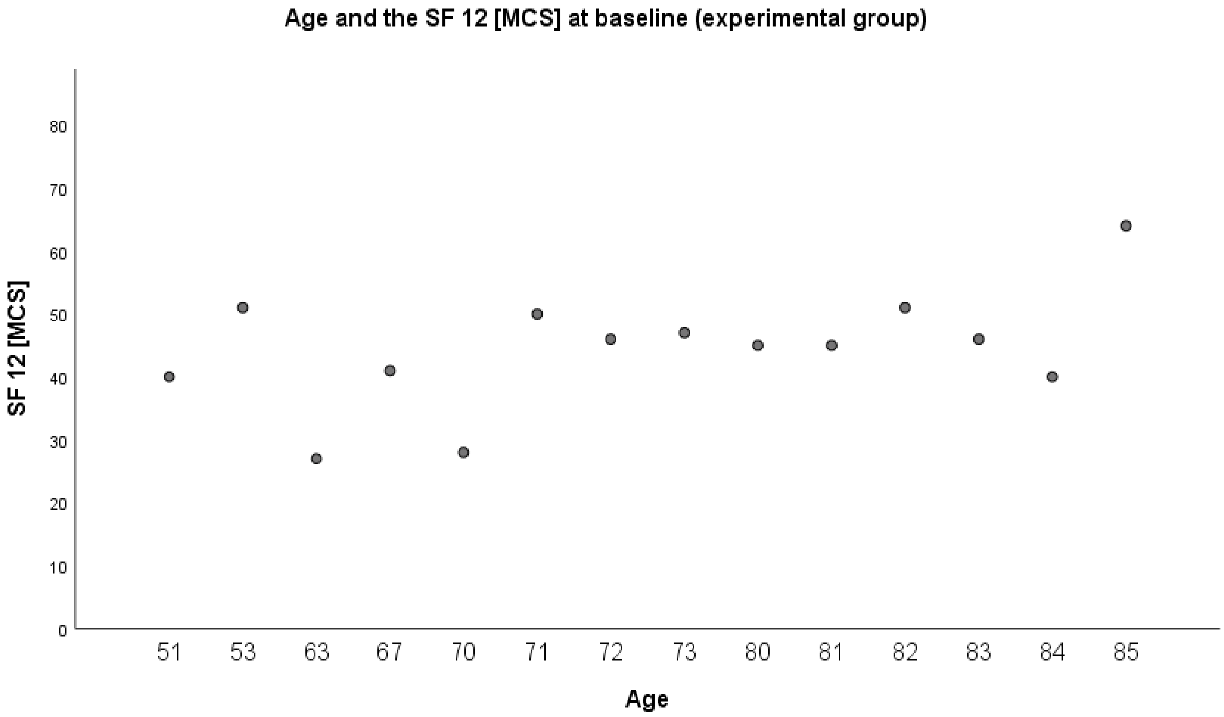


Figure 35 Scatterplot showing the association between age and the SF 12 [MCS] at baseline (experimental group)

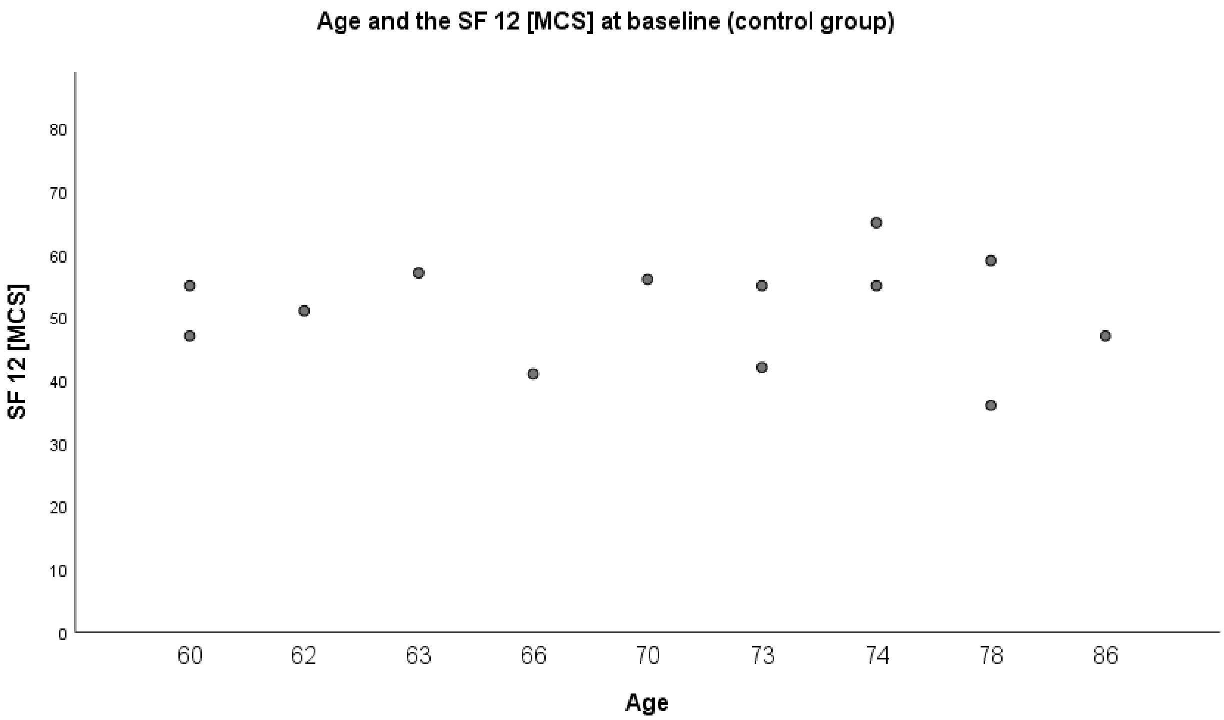


Figure 36 Scatterplot showing the association between age and the SF 12 [MCS] at baseline (control group)

Age and SF 12 [MCS] at 12 weeks

Age is the independent variable looking for an association with the SF 12 [MCS] (see Table 47). Figure 37 presents a scatterplot showing the association between age and the SF 12 [MCS] at 12 weeks for the experimental group, whereas Figure 38 shows the association within the control group at 12 weeks.

Table 47 Simple regression analyses for age and the SF 12 [MCS] at 12 weeks

		Age and the SF 12 [MCS]		
	Group	**Unstandardized Coefficients**	**Standardized Coefficients**	**P-value**
12 weeks				
	Experimental	.288	.281	.331
	Control	-.815	-.513	.158

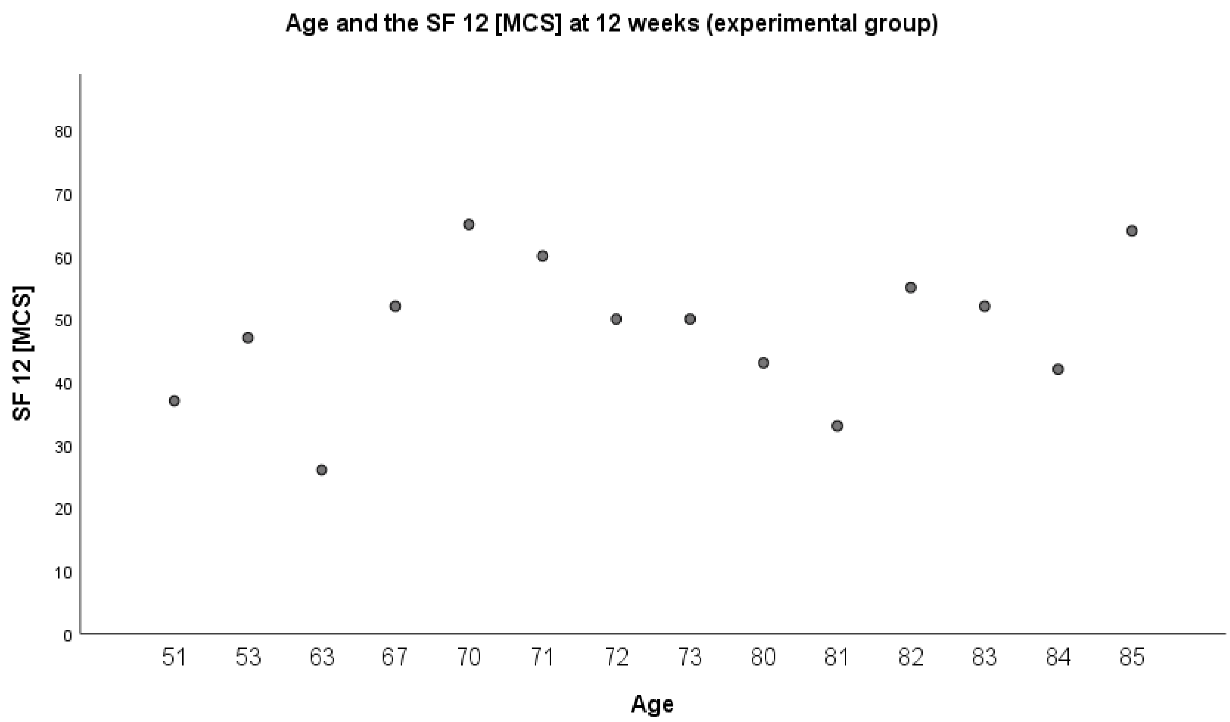


Figure 37 Scatterplot showing the association between age and the SF-12(MCS) at 12 weeks (experimental group)

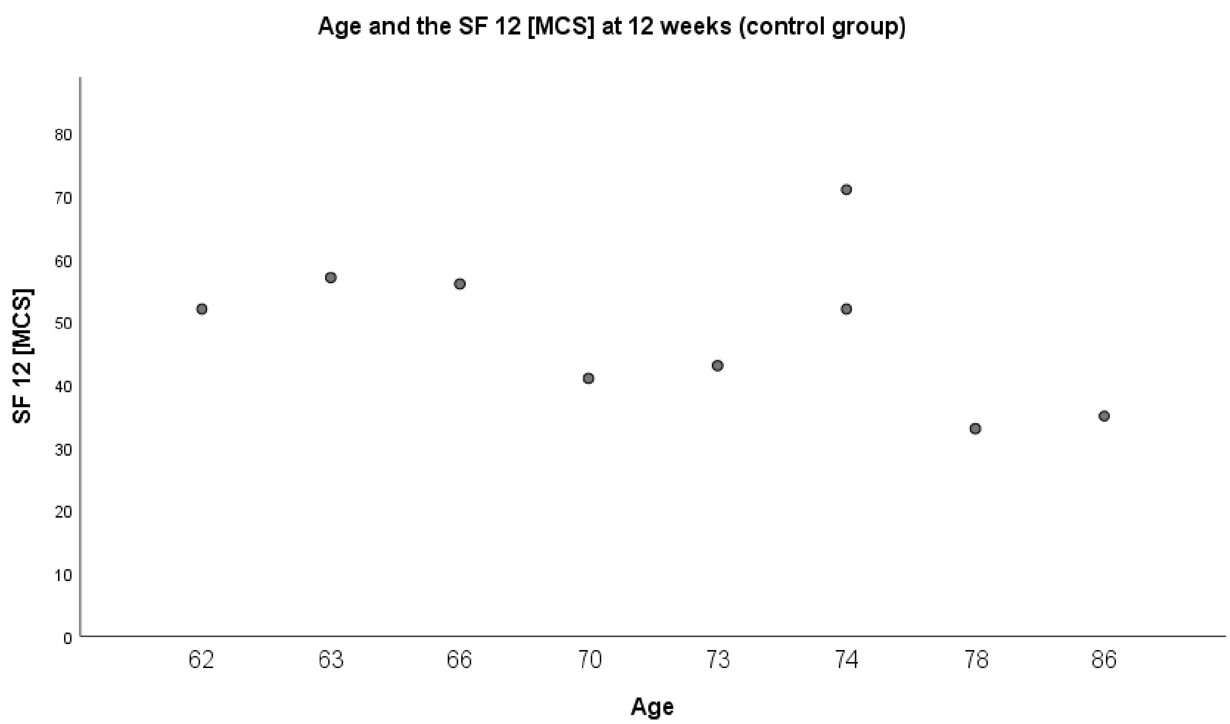


Figure 38 Scatterplot showing the association between age and the SF-12(MCS) at 12 weeks (control group)

Reflections on the simple regression analyses with age

Overall, in terms of age and the outcome measures, there does not appear to be any consistent associations between them, suggesting that age does not need to be considered when analysing the outcome measures explored. From the regression analyses, it seems that Tai Chi is feasible for older people because age does not have a significant influence on outcomes.

5.5. Acceptability of the TCAS programme to intervention participants

5.5.1. Number of Tai Chi classes attended

Out of a total of 24 classes, the number of classes attended by the 14 experimental group participants varied. Only three participants attended all 24 classes, with one participant attending 23 classes, two attending 21 classes, and two attending 20 classes. The remaining participants attended between one to seventeen classes. Reasons for this will be discussed in further detail in the discussion chapter.

The average attendance of participants in the Tai Chi exercise class was 18 out of 24 sessions. Reasons for non-attendance are highlighted in Table 48. The most popular reasons for non-attendance were attending outpatient appointments and going on holiday. In total, 14 participants attended at least part of the 12-week Tai Chi programme. The greatest number of classes possible to attend was 24, two classes per week.

Table 48 Reasons for non-attendance of Tai Chi

Reasons for non-attendance of Tai Chi		
Reason	**Number of participants**	**Number of classes**
At a medical appointment.	9	9
Going on holiday.	5	9
Having a medical investigation.	3	3
Not feeling grea.t	2	2
Ambulance transport was late.	2	2
Had a 'blackout.'	1	23
No transport.	1	24
Side effects from medications.	1	1
Has grandchildren every Tuesday.	1	14
Awaiting x-ray results.	1	1
Having somebody coming to visit.	1	1
The heat (weather) was too much.	1	1
Taking a friend out.	1	1
Was not ready in time for when ambulance turned up.	1	1
Upset stomach	1	1
Bank holiday trip.	1	1
Family commitments.	1	1
Awaiting therapy.	1	1
Transport failed to turn up.	1	1

None of the reasons for non-attendance of Tai Chi was due to the Tai Chi itself. Most non-attendance was due to the recent discharge from hospital. Most of the reasons cited included having a follow-up appointment related to the stroke (n=9) and going on holiday to help with stroke recovery (n=5).

5.5.2. Adherence to home practice

Home practice was adhered to very well by the experimental group with 86 per cent of participants practising at least fifteen minutes per day. Only two participants (14 per cent) admitted to not practising Tai Chi at home. Out of 14 participants, 13 said that they practised home exercises with 12 completing the home practice diary. Out of the 12 completed home practice diaries, one contained comments without documentation evident in any home practice diary on minutes practiced. Acceptability of the home practice resources will be reported in Chapter Seven. Prompting was needed in each class to remind participants to bring their completed forms. Out of all participants who attended Tai Chi, thirteen required multiple reminders to complete the home practice diaries.

5.5.3. Attendance of significant others

In the TCAS study, out of 14 participants in the Tai Chi group, seven significant others attended the Tai Chi. However, only two significant others attended all classes with the participant. Reasons why significant others did not attend all classes included: the ambulance not receiving a booking for the significant other (n=1), arguing with the participant and deciding to sit in the car (n=1), work commitments (n=3).

During the TCAS study, half of participants (n=7) brought along a significant other to classes. Reasons why half did not bring a significant other and how well accepted the significant others were into the class will be discussed in the qualitative analysis and discussion chapters.

5.5.4. Reliance on the Yorkshire Ambulance Service [YAS]

Out of fourteen experimental group participants, eight (57 per cent) relied on hospital transport to reach the venue. Six participants (43 per cent) were brought to the venue by a significant other. Thus, most participants in the experimental group could not have made it to the classes without the support of the Yorkshire Ambulance Service [YAS].

Chapter 6 – Qualitative Data

6.1. Introduction

This study aimed to recruit as many experimental group participants as possible to take part in a semi-structured interview following the 12-week intervention. Interviews were structured in order to gain insight into how participants experienced the intervention, as well as exploring their opinions to establish the acceptability and feasibility of the Tai Chi programme. Anybody who was randomised into the experimental group and participated in at least one Tai Chi class was eligible to be interviewed.

All experimental group participants who completed the 12-week intervention agreed to be interviewed. Hence, fourteen semi-structured interviews were audio-recorded, transcribed in full and analysed (for interview excerpts see Appendix 37). The interview topic guide was used to guide the researcher to explore the experiences of the Tai Chi programme before, during and after attending, as well as influences on attending and absenteeism (see Appendix 15).

Data analysis was conducted by using the framework method. The framework method was developed by two researchers for the Qualitative Research Unit at the National Centre for Social Research in the United Kingdom (Gale, Heath, Cameron, Rashid & Redwood, 2013). The framework method is not aligned with any epistemological approach in particular. This method of qualitative data analysis is widely used in health research and is commonly used for the analysis of semi-structured interviews (Gale et al., 2013).

The framework method was chosen for the TCAS study so that data could be compared and contrasted across individual interviewees, as well as within individual interviewees. The seven stages of the framework method explained by Gale et al. (2013) is described below in relation to the application of the proposed study.

<u>Stage 1: Transcription</u>

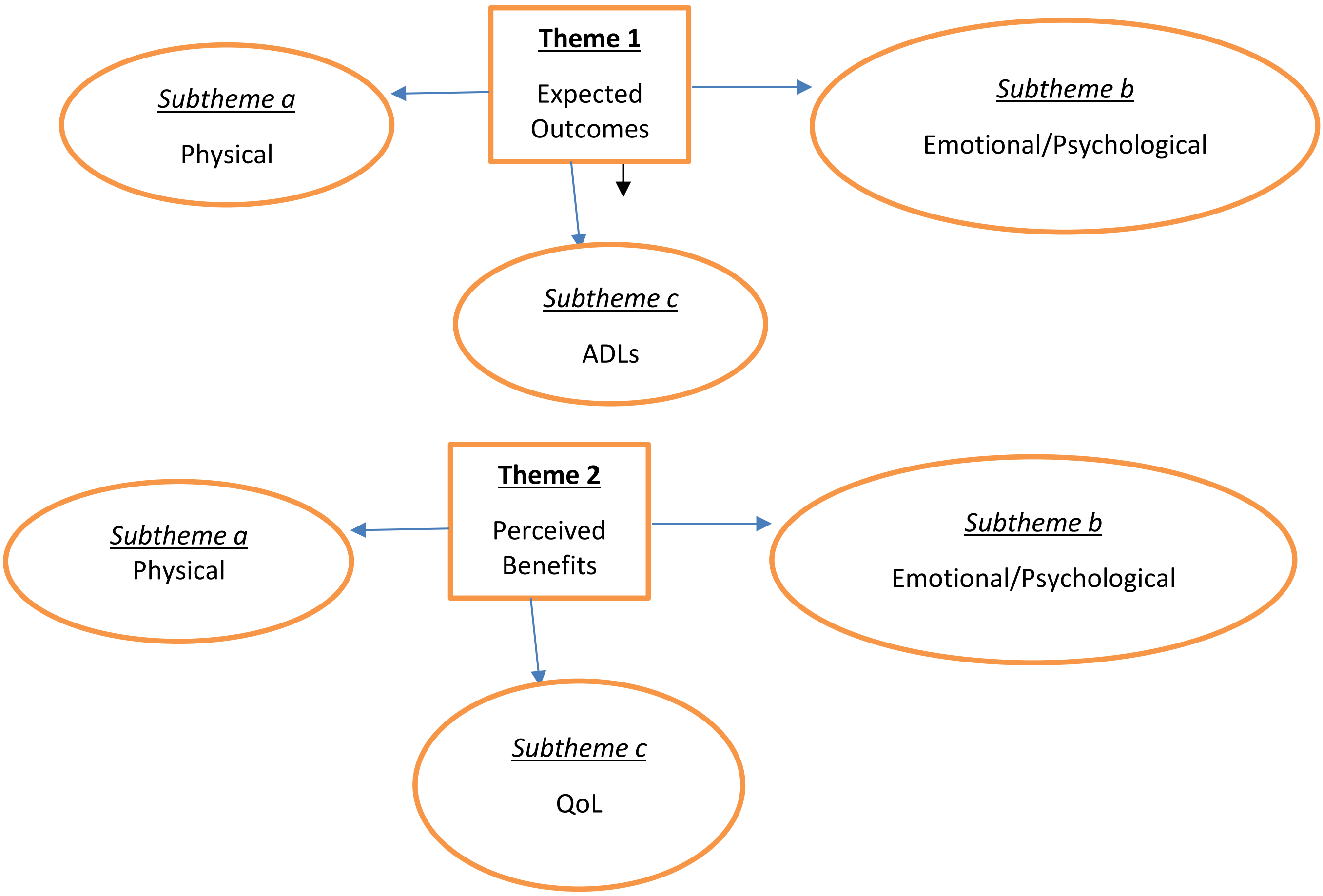
Audio recordings of each of the 14 interviews were transcribed verbatim. Margins and space between each line were formatted within the transcript to allow for notes to be made.

<u>Stage 2: Familiarisation with the interview</u>

Audio recordings were listened to by the researcher a few times to become familiarised with intonation, mood, content and context of the interview. Transcripts were then read through for the same purpose. Notes were taken within the margins regarding any thoughts or impressions.

Stage: 3 Coding

Each line of the individual transcript was then read whilst placing paraphrases (themes) next to the passages interpreted as being important. Going through the data line by line was carried out to increase the chance of the researcher noticing things which were said that would otherwise not have been as clear. Themes were applied for behaviours, incidents, values or emotions. All data was classified to be compared with other parts of the data set. The excerpts from the transcripts below show examples of data, highlighted in yellow, which were classified as belonging to the theme, 'perceived benefits.' A spider diagram was created where subthemes were placed around the themes, forming a working analytical framework (see Figure 39). The first few transcripts were analysed for themes and subthemes by a second person who was qualified in qualitative research analysis (PhD supervisor). The second data analyst was important so that the researcher's perspective alone was not dominant.



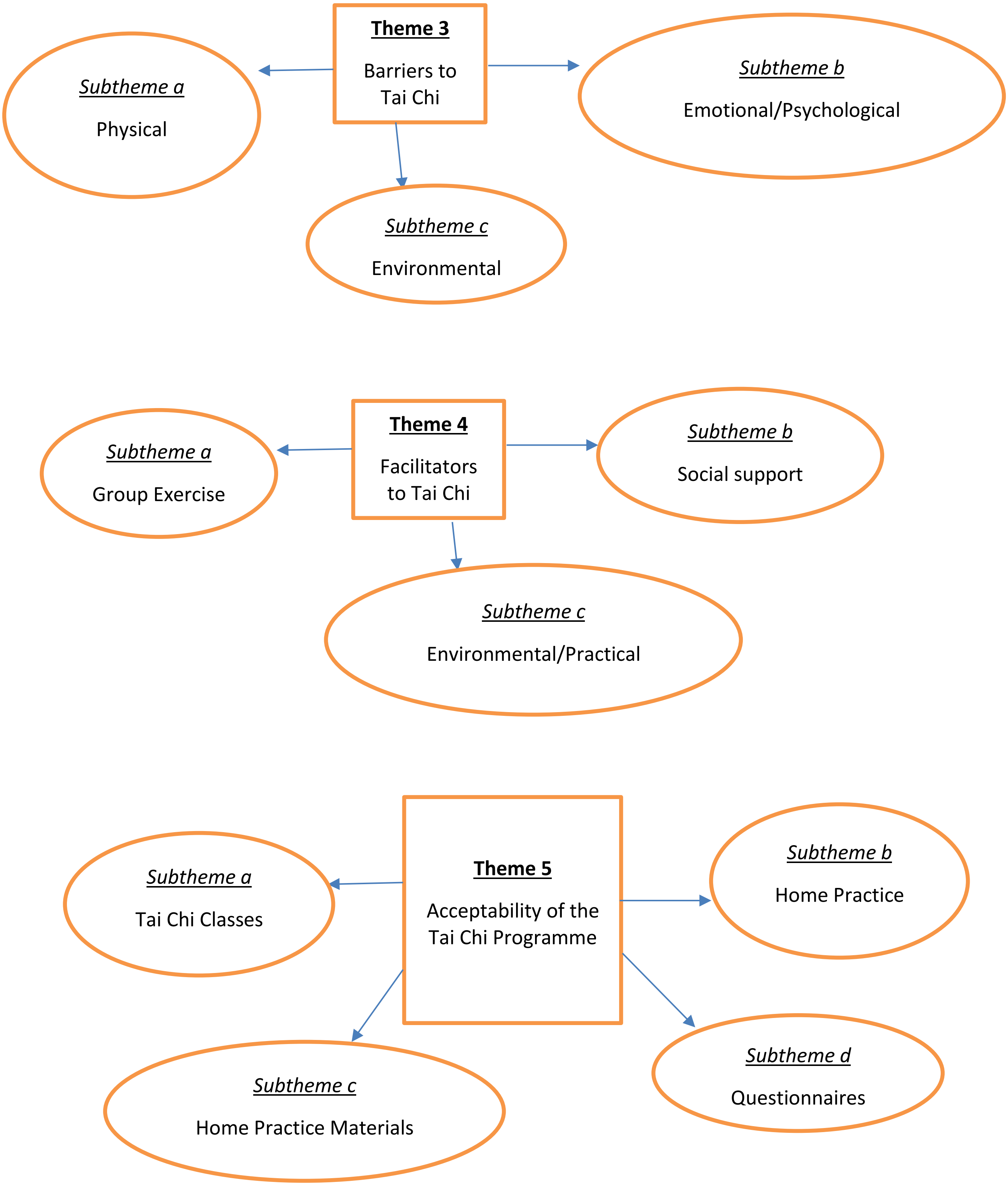


Figure 39 Spider diagrams created to show the development of themes and subthemes

Stage 4: Developing a working analytical framework

The PhD supervisor and researcher (PhD student) met thereafter to compare the themes and subthemes applied to the first few transcripts during stage 3 to find out if the themes identified were the same, similar or different, as well as to come to an agreement on the themes. Agreement was then made regarding the set of themes and subthemes which were applied by the researcher to all subsequent transcripts.

Stage 5: Applying the analytical framework

All subsequent transcripts were then indexed using the themes and subthemes.

Stage 6: Charting data into the framework matrix

Charting the data into the framework matrix (see Appendix 38) allows the researcher to describe the data using participants' own subjective frames and expressions before interpretation begins (Gale et al., 2013). A matrix was produced which featured rows, columns and cells of summarised data so that data could be analysed by individual interviewee. The data was charted into the matrix and included references to interesting quotations, along with the transcript ID, page number and line reference.

Stage 7: Interpreting the data

Following the charting of the data, connections between themes to explore relationships or causality were mapped and reasons for certain phenomena. Additionally, areas which did not function well with the Tai Chi programme were also identified.

Overall, five themes were identified from the qualitative interviews following the framework method of analysis (subthemes are depicted in brackets): expected outcomes (physical, emotional/psychological, ADLs), perceived benefits (physical, emotional/psychological, QoL), barriers to Tai Chi (physical, emotional/psychological, environmental), facilitators to Tai Chi (group practice, social support, environmental/practical) and acceptability of the Tai Chi programme (Tai Chi classes, home practice, home practice materials, questionnaires). Two pages of transcript from two interviews have been included in Appendix 37 to highlight how the analysis took place. Themes have been colour coded for the purpose of explaining how the framework method was carried out. In bold brackets next to each highlighted test is the corresponding subtheme.

6.2. Expected outcomes

Expected outcomes can be defined as being whatever participants expect from the Tai Chi classes before attending their first class. The analysis identified three subthemes for expected outcomes which were (i) physical, (ii) psychological/emotional and (iii) ADLs.

(i) Physical

Severity of limb impairment partly determined participants' expectations. Those who perceived their mobility to be normal either did not mention any expected physical outcomes from the intervention, but one participant said, 'my wife thought it would help me.' Another participant who perceived his mobility to be normal wanted to practice Tai Chi because he 'needed to do some sort of exercise but nothing too strenuous'. In contrast, those with some degree of impairment expected positive physical outcomes. Participants with limb impairment reflected on how they used to be prior to their stroke and expected the intervention to help regain some of this independence. For example, participants expressed that they 'just want to get back to normal, like I used to be.' Getting back to normal included 'getting walking again', 'getting to the shops' and 'getting back on track' after losing some balance ability:

> Because it wa' just getting me out of the house and getting me limbs working again, 'cos I had an hour you doing things and different things whereas I dint wi' them. They want err…there that long enough, really. You know, it wa' just a matter of erm…quarter of an hour or so, that wa' all. So really, it dint do a lot of good. (PR, p.1, lines 43-46)

One participant's expected physical outcomes were based on a relative's previous experience practising Tai Chi after recovering from an illness:

> It was err…to do with my brother really because he had Guillain-Barré Syndrome which is basically a virus that attacks the whole nervous system and he couldn't err…feed himself or anything like that when he was poorly. And somebody recommended Tai Chi and he went to Tai Chi and he still goes to Tai Chi and he's a normal person now, so that's what attracted me to it. (JM, p.1, lines 4-8)

Another expected physical outcome was a general improvement related to physical health; participants viewed Tai Chi as a positive interaction with improving health. Participants with these expectations were willing to try anything which had the potential to 'do some good', 'do better for myself' and that was 'helpful for health':

> I don't know, you saw me in 'hospital and I just thought it might be something, have a go, you know, you just don't know what to do when you've err…when you first have a stroke an' all that. You're pretty shocked, you don't know what to do, do you? So, I thought, well, I'll have a go at anything, really. Try an' help, you know. (NM, p.1, lines 2-5)

Likewise, those participants who did not know what to expect from Tai Chi agreed to take part assuming it may be beneficial or not do anything:

> Err…I didn't know what to expect to be quite honest, I ant a clue, you know, ermm, when they say physio, you think right I'll work on this arm and go pumping iron or something, you know what I mean, it's not really, no. But yeah, it wa' alright, I've enjoyed it. (NM, p.1, lines 38-41)

Nobody expected any negative physical outcomes from Tai Chi. 'Getting back to normal' may have influenced the attendance of some participants and improving health may have been a motivating factor for others.

(ii) Emotional/Psychological

Participants expected positive outcomes on their emotional and psychological wellbeing. Some participants who were in the experimental group were experiencing depression. It is interesting to note that those participants who were feeling low in mood also lived alone and did not bring any significant others to the classes. This was documented in a diary which the researcher completed during each class. Participants feeling low in mood were also those with impairment resulting in a reduction in balance ability, as well as confidence. Thus, many participants had low confidence to exercise, affected by depression and low confidence levels:

> I wanted to get moving again. I felt that it wa' 'end o' line for me. I mean, err (sighs)…the way I felt…I felt so depressed to be quite truthful. [] I just felt I wa', you know, 'end o' line sort o' thing. I can't explain it how you felt, but I just dint feel well. [] And I just want to get walking and getting out to 'shops which I haven't been to 'shops yet. (BG, p.3, lines 98-106)

(iii) Activities of Daily Living [ADLs]

As discussed above, 'Getting back to normal' was represented as an expected outcome under the subtheme 'physical'. However, physical improvement was also associated with the performance of ADLs. Thus, 'getting back to normal' was perceived as carrying out a normal daily routine. Outdoor ADLs seemed to pose a difficulty for most participants. Participants mentioned that they were unable to leave home due to being 'scared of falling' and having a 'fear of open spaces':

> [] I've had the experience of being little and open spaces were unnerving is the word. I can use err…basically like car parks and supermarkets…the open space, it just used to unnerve me and I got giddy then but never to the point of falling over. (JM, p.1-2, lines 41-44)

The purpose of leaving home for most participants was to 'get walking again' and to 'go to the shops'. Hoping to regain ADLs may, therefore, may have contributed to the motivation to attend Tai Chi classes.

6.3. Perceived benefits

Perceived benefits have been defined as benefits experienced by participants following the 12-week intervention. The analysis identified three subthemes for expected outcomes which were (i) physical, (ii) psychological/emotional and (iii) Quality of Life [QoL].

(i) <u>Physical</u>

Severity of limb impairment determined how participants perceived benefits of Tai Chi, with participants acknowledging that severity of limb impairment played a part in the extent of improvement by expressing that 'it depends how bad you are before you start.' Participants who perceived their mobility as normal or had dense upper limb weakness did not perceive to have gained any physical benefit, whereas those participants with mild upper limb weakness experienced some improvement in upper limb function:

> My movements. Erm…before Tai Chi, the movements were erratic. I couldn't hold things without having to force myself to let go, but now I'm more aware of my left hand and my left arm. I'll actually do what I want it to do, whereas before Tai Chi, my left hand decided to do what it wanted to do. (JM, p.1, lines 36-39)

"Ermm..as I say, I think it's more for a well-being thing rather than erm…trying to overcome injury sort of thing, you know..err..I just..I don't know."

(NM, p2, lines 79-80)

Participants who wanted to 'get back to normal' found that some degree of normality was achieved but not in its entirety:

> I just want to thank Liz and Richard for helping me so much and I appreciate it very much. An' I thank them from the bottom of my heart. It's really done me good. An' I'm so grateful that they've helped me to get back to normal nearly. I'm not there yet, I know I' m not, but they've helped me immensely. An' I'm so grateful. (BG, p.7, lines 178-181)

Balance improvement was perceived by some participants who compared their ability at 12 weeks to the beginning of the intervention. Despite receiving community therapy, participants who perceived an improvement in balance ability at 12 weeks also perceived Tai Chi to have been the major contributing factor to this improvement:

> I felt the Tai Chi for me was the main…the main thing to get me better and to erm…for my walking and everything. I relied more on the Tai Chi than the books, although I did the books up and down them steps at home and erm…but yeah, for me, the Tai Chi was the main thing.
>
> (AM, p.4, lines 102-105)

These perceived improvements may have contributed to the ongoing attendance to classes as well as the high response to home practice.

(ii) <u>Emotional/Psychological</u>

Many participants commented that at the start of the intervention, Tai Chi left them feeling tired, resulting in them falling asleep when they arrived home. Towards the end of the intervention, these participants noticed that they no longer fell asleep following Tai Chi classes and that they experienced increased energy levels and became more motivated to exercise:

> At the beginning, I'd go home and I'd sit down and I'd fall asleep and I'd be asleep for couple of hours, but now it gives me energy, it wants me to go out and about, not to sit on the settee and fall asleep. I've got more energy now. (JM, p.2, lines 72-74)

Participants who reported that they were depressed prior to the intervention said that they felt more like their old self towards the end, with increased confidence levels, especially in terms of fear of falling. Reduced experience of fear of falling included a perception of balance improvement and ability to walk safely:

> [] I was really depressed, but when I started coming and doing Tai Chi, and then there were other people there 'same as me, it bucked me up and made me feel better that I want on my own [laughs]. [] But err…at first, I felt that wa' it. But now, I feel me old self again. (PR, p.3, lines 99-105)

These experiences have enhanced participants' experience of participation in the study through enjoyment and improved confidence levels, which may suggest that Tai Chi improves confidence and reduces a fear of falling in stroke survivors.

(iii) Quality of Life [OoL]

From the accounts of experimental group participants, quality of life appears to have improved in most participants. Many participants reported that they incorporated the Tai Chi stepping exercises into their everyday walking whilst performing ADLs. Whilst walking, participants commented that they were more conscious of their movements in relation to their balance, resulting in increased cautiousness, which may explain why there were fewer falls in this group:

> I walk more carefully than I did before, definitely. [] More conscious of when I'm walking, yeah, definitely, yeah. Otherwise, it's silly not to. You know, just be careful all 'time, really. An' try not to do things that you can't do, you know. But err…I'm careful, yeah. And nothing's happened so far, so hopefully, that's it. (PR, p.7, lines 287-292)

Social benefits were reported by participants who found that 'getting out of the house' resulted in 'meeting people in class' and talking to new people who became good friends:

> Yeah, an', you know, you can…you can say, 'I did so and so yesterday,' and I want right good…it happened an' you get their opinion, don't you? I mean, it's nice to have somebody's opinion that's in 'same boat as you.
> (BC, p.6, lines 154-157)

Establishing good relationships with other group members may, therefore, have been a motivating factor on attendance.

It was observed by the researcher that increased quality of life may be detrimental to some stroke survivors in terms of them dropping out of Tai Chi classes, but in terms of the stroke survivor improving, it was positive. For example, due to an improvement in confidence levels, one participant started to drive again. This enabled the participant's family to force pressure upon this individual to carry out ADLs associated with driving. It was assumed by the participant's family that she was back to her normal self both physically and mentally. However, during the interview, the participant broke down because she did not perceive herself to be completely back to normal. Due to her family commitments, her attendance dropped, which upset the participant. As a result, this participant wished that she hadn't started to drive again:

> (crying)…And then I thought I wished I hadn't started driving 'car…yeah, so when I started driving initially, that was…you can't wait to drive but then…it was easier coming in the transport and somebody picking you up an' taking you back. Although the days were a bit longer, but you really appreciate the ambulance staff coming along and transporting you, so…
>
> (AM, p.5, lines 132-136)

> Ermm…no, I've wanted to come back really, but it was just that, yeah, your life does get back to normal, then, of course, once you're driving and people erm…so you've appointments and you've got to…so it…it does the driving part did affect it really, so…it was a lot easier with the transport. (AM, p.6, lines 152-155)

A future study may benefit from being aware of potential non-attenders due to a perceived improvement during the intervention.

6.4. Barriers to Tai Chi

Barriers to Tai Chi have been defined as barriers which may hinder or prevent participation in Tai Chi or participation in the study. The researcher identified three subthemes for expected outcomes which were (i) physical, (ii) psychological/emotional and (iii) environmental.

(i) Physical

Those participants who perceived themselves as not needing the intervention admitted to not practising Tai Chi at home and were less likely to have a high attendance rate. Therefore, a perception of not needing the intervention is a barrier to practising Tai Chi, but also leads to the question whether the intervention is suitable for these participants.

Many stroke survivors have co-morbidities which may prevent them from taking part in exercise. Indeed, some participants found participating in Tai Chi difficult as a result of having a hip replacement and complications from diabetes. Pain and numbness due to these co-morbidities led the participants to feel that they could have done better:

"Well, I think if it hadn't been for my hip, I'd have been well away. But I haven't…but as soon as I try and put weight on this hip [points to hip], I know I'm going to wobble."

(BB, p.2, lines 26-29)

Despite having co-morbidities, a potential barrier to practising Tai Chi, these participants still perceived some benefit and continued to attend classes. These perceived benefits may be mentioned in discussion with future potential participants with co-morbidities to help encourage them to participate in a future study.

(ii) Emotional/Psychological

Potential barriers to participation in the study may have been due to lack of confidence and a fear of falling. Participants with these characteristics have commented that before their first Tai Chi class, they felt scared to fall and did not feel safe. Despite low confidence levels, they still attended classes:

"Well, I wasn't very confident 'cos I wasn't balancing properly. And I was frightened of falling." (BG, p.1, lines 24-25)

It is important to be sensitive to the mental wellbeing as well as physical for Tai Chi to be accepted by stroke survivors. One participant found coordination difficult which made her emotional during the class and expressed that 'the worst part was I got to a stage where emotions sort of kicked in and that was hard for me.' Without the correct emotional support, such participants may stop attending classes. This participant reduced her attendance. Therefore, emotional instability may be a barrier to participation.

(iii) Environmental

Some participants were delayed in starting the intervention due to waiting for community therapy services. For example, one participant did not want to attend a class out of fear of missing the therapist delivering equipment because they did not give a delivery date. When the equipment was delivered, the therapist spent a few mornings with the patient to make sure she was safe when taking a shower without supervision:

> Oh well, I couln’t get in ‘shower to start with, I had to wait for somebody coming and bringing me the err…buffets…and then somebody had to come an’ fix the err…handle on ‘outside the shower so I could get in the shower. And then sit on the buffet…and then there wa’ somebody in wi’ me all the time at the beginning. (PR, p.2, lines 87-90)

Another participant fell prior to discharge. Despite this fall not affecting her discharge, the participant wanted to wait a few weeks before attending her first class. Interestingly, this participant failed to remember the reason why she did not attend straight away and admitted that due to this delay she did not start the intervention at her worst.

Barriers to Tai Chi participation included attending medical appointments, going on holiday and family visits following their stay in hospital. These barriers affected most experimental group participants in this study. This leads to the question of whether the intervention was given too early; one participant believed this was so, whereas the remaining participants did not comment on this.

Unmanageable conditions are included in the study’s exclusion criteria, but some participants may experience issues with their medications, thus representing a barrier to exercise participation. Some participants perceived their medications to be a cause of feeling tired and light-headed, saying ‘it’s probably the tablets.’ Nevertheless, they experienced improved confidence with balance. However, this was a perception made by participants; it is common for stroke survivors to feel tired with an acute stroke. Significant others may hinder the participation of Tai Chi. It was found during the interviews that some participants found the inclusion of their significant other in the class as a hindrance rather than a support. Some significant others did not want to be in the class and either stopped bringing the participant to the class or waited in the car. Minor disputes may also have resulted in the non-attendance of significant others:

> He’s daft. He’s err…he’d have been better off dropping me off and then coming back for me. [] Or going to ‘café and then coming when I…I could go an’ look for him or sumat like that. [] ‘Cos it want up to him. You know, he didn’t…he didn’t want to do it. (EJ, p.2, lines 27-33)

The major barrier to Tai Chi was transport. Despite the availability of the shuttlebus system, none of the fourteen experimental group participants used this service. Many participants found it difficult to reach the shuttlebus, with some having to take multiple buses to get there:

> ‘Cos like this…if I go from ’bus here, I can get a bus from ‘bottom o’ road to Wakefield and then I’ve got together one from there to Stanley Royd and walk over, you know, it’s…I got ‘bus.. I don’t do buses. An’ I got ‘bus at end of this road ‘other day and I went seven… [] …seven bus stops I went to. Two pounds sixty. Two pounds sixty! For seven bus stops, so I says to ‘woman that wa’ driving, which part o’ ‘bus ‘ave I bought? (laughs)….Jesus (PB, p.9, lines 379- 386)

Because stroke survivors are not allowed to drive for at least four weeks, participants relied on significant others to escort them to the venue by car. Those participants who were brought to Tai Chi by a significant other, commented that hospital parking was expensive and that it was sometimes difficult to find somewhere to park, stating ‘it’s too dear. We used to have to park across ‘road!’.

To remedy this problem, the Yorkshire Ambulance Service [YAS] was contacted in April 2017, who were willing to offer transport to the participants. The utilisation of YAS also brought a potential barrier to the attendance of Tai Chi. Participants were required to wait up to two hours before the class began, as well as two hours after the class ended. This resulted in a one-hour intervention to become a day out, as observed by the participants where ‘you feel as if it’s like a day out for you, a morning out type, you know, from ‘four walls, you know.’ Despite the long waits, participants continued to attend, recognising that the intervention brought benefits which outweighed the waiting times for transport where participants felt ‘it’s beneficial’ and ‘worth the wait’. Had participants not perceived any benefit from attending, they could have stopped attending the classes. The fact that all participants who used the YAS service continued to attend classes, strengthens the value in the intervention as perceived by participants.

6.5. Facilitators to Tai Chi

Facilitators to Tai Chi are people or circumstances which help participants participate in Tai Chi classes. The analysis identified three subthemes for expected outcomes which were (i) group exercise, (ii) social support and (iii) environmental/practical.

(i) Group Exercise

Observing other stroke survivors and perceiving them as being ‘in the same boat’ led to a feeling of being part of a group. Additionally, this perceived sense of belonging put stroke survivors at ease during the classes with one participant saying ‘well, we’re all in ‘same…stage as me, want they? So, you know, …errr…I didn’t feel as much of a nuisance'. Because participants were at 'the same stage' as each other in their stroke journey, stories of how they improved could be shared and they were able to encourage each other. Participants felt supported by somebody being there who understands their condition.

Meeting others made participants who lived alone feel better and these participants viewed the intervention days as 'a day out':

"It's like I say, the group, there's a bit of comradeship, you…you…you all get on…you can talk and 'experience that you've had, they'll tell you about what they've done and what you've done, yeah." (RG, p.5, lines 139-141)

Practising together enabled participants to copy each other if they did not understand the instructor or if the instructor was unavailable. Comparisons to others led to gaining insight into how other stroke survivors were coping with the intervention and helped to put their own progress into perspective, which may have motivated attendance:

> Erm…well, I don't mind either way, it's nice to be with other people and err…I think you can assess your own progress when you see other people, yeah. [] …but I don't make it obvious. I sort of look through the corner of my eye.
>
> (JO, p.2, lines 45-49)

Those who perceived their mobility to be normal were less likely to feel part of a group and were also less likely to attend classes. One participant started classes with only him in the class, and noticed a difference when others joined by remarking, 'You know, so I enjoyed it but last time I went when there were them other folk up there it wa' slow, you know. Instead o' getting straight on wi' it, it wa' just show and it I didn't like it.'

Such participants felt that the presence of those with greater limb impairment hindered their progress, and that the pace of the class became too slow. This may suggest that this modified Tai Chi programme is not a suitable for those who do not perceive to have any limb dysfunction.

(ii) <u>Social Support</u>
Support influenced the adherence to Tai Chi classes for most participants. Findings from the interviews showed that social support was categorised into three: fellow participants,

significant others and the researcher/instructor. Those who lived alone found that meeting others led to enjoyment of the intervention:

> Err…just to communicate and talk to people because when you live on your own, it's funny, you've nobody there, only when they come visiting, whereas if you…it's a day out in a sense. I know it's to make me feel better, but it makes me feel better 'cos I'm going to see people. And talk to people. An' I've met some nice people. (PR, p.3, lines 119-122)

Participants supported each other with their progress which served to reassure and increase their confidence. However, these participants did not mind their significant others abstaining from attendance, commenting that they were 'used to going on their own' and had 'been managing quite well without anyone.' Reasons for the non-attendance of significant others was mainly work-related for their offspring, with spouses being unable to drive.

Seven of the fourteen participants interviews brought along a significant other. These participants spoke of how they enjoyed their presence and felt supported. Significant others often commented if they thought their loved ones were not performing a movement correctly. Additionally, participants were able to copy the movements of the significant others who joined in with the intervention:

> It helped me to begin with because I copied 'cos I couldn't comprehend what was being said to me and I had to literally copy everything that was done so I used to watch him 'cos Richard would be with somebody else, so.. (JM, p.1, lines 13-15)

However, it was observed by the researcher that this was not always welcome by participants and often served as a distraction. For example, not all comments were accepted, and one participant had a disagreement, leading to the exclusion of the significant other in the class. One significant other did not enjoy being in the class and started work two weeks into the study, so was not willing to bring the participant to any future classes. Nevertheless, participants generally felt that their significant others were also 'getting some sort of benefit' from joining in with the intervention and home practice which put them at ease. Thus, involvement of significant others may have contributed to the high response to home practice.

(iii) Environmental/Practical

The involvement of YAS became a type of social support for participants using this service because ambulance drivers got to know the participants well, and participants found them 'pleasant' and 'nice'. Participants enjoyed chatting to the drivers and found this a comfort on their journey to and from the venue. YAS was a major support because without their help, seven out of the fourteen experimental group participants would not have been able to attend.

6.6. Acceptability of the TCAS Programme

Acceptability of the Tai Chi programme was determined by the experiences and opinions of participants during the 12-week intervention. The analysis identified four subthemes for expected outcomes which were (i) Tai Chi classes, (ii) home practice, (iii) home practice materials and (iv) questionnaires.

(i) Tai Chi Classes

Participants found the characteristics of the Tai Chi instructor to be important. Due to the older age of most participants, many had hearing difficulties and found it essential that the instructor spoke clearly and loudly. Some participants found the TCAS instructor 'too softly spoken', despite being able to understand him. This may explain why some participants felt the need to copy others. Despite being softly spoken, participant found the instructor to be encouraging. Offering encouragement, motivated participants to keep going, contributing to their adherence.

Participants spoke of feeling supervised by the researcher and an experienced instructor, which contributed to a sense of security and confidence in performing the movements:

> Liz and Richard know what they're doing an' they're there to advise you an'…and tell you what to do. An' I think that's better to have somebody with you who knows 'cos they don't just stand, that they walk with you and they do the exercises with you. An' they can see how you're doing, whether you're making it any better or not, but…in my case, they've done well for me. An' I can't thank 'em enough for the help and advice they've given me. (BG, p.8, lines 184-189)

Monitoring was important to participants, knowing that 'somebody is there' to assist how to perform movements correctly, as well as give individual attention and encouragement:

> The encouragement that he gives you, and he's there if you've messed up. And show you the right way to do it, yeah. Absolutely wonderful, yeah. Can't fault him in any way, shape or form. I wasn't being detrimental to him when I said I couldn't comprehend what he said. That was me not comprehending what he was telling me to do because if anybody had told me to do anything, I'd just stare blankly at them and try and work out what they wanted me to do. JM, p.2, lines 51-56)

As well as encouraging, participants found the Tai Chi instructor approachable, and found it comfortable to take rest periods at their own disposable without fear of ridicule. Participants were encouraged by the instructor to practise Tai Chi at their own pace and at their own individual levels.

Chairs were made available so that participants could sit down whenever they wanted, increasing their confidence to step further distances. Participants found stepping and the other TCAS exercises easy to learn and beneficial. Further, they were easy to memorise. Remembering exercises and being able to practise them reduced anxiety and increased motivation to practise.

The ease of practising and ability to practise at a slow and steady pace led those who perceived their mobility to be normal to find the Tai Chi classes too slow and repetitive. One participant requested a full demonstration of the programme in its entirety so that he had some sort of goal to focus on. Thus, when asked if he thought the length, frequency and duration was adequate, he replied 'it should be shorter, unless progress was being made'. In contrast, the remaining participants wanted the classes to run for longer than 12 weeks and were happy with the length and frequency. One participant desired more flexibility with the days allocated so that classes did not take place on the same days every week, but another preferred having set days allocated to Tai Chi to help establish a routine:

> Err…the best part of it was erm…just initially for me was knowing every Thur…Tuesday and Thursday that you were going somewhere and that got you up an' made you get sorted, whereas when you just come out of hospital, you lose your confidence and err…so being able to come on a Tuesday an' a Thursday was great. (AM, p.4, lines 117-120)

All participants, including those who found the pace too slow and repetitive, said they would take part in a similar study again. Further, many participants said they would carry on with Tai Chi after the study ended, provided that the classes were nearby and at a suitable level to their needs.

(ii) Home Practice

Participants who perceived their mobility as being normal did not take part in home practice and did not experience any benefit to do so. These findings suggest that this Tai Chi programme may not be suitable for those with normal limb function. The remaining participants took part in home practice for more than 15 minutes on at least alternate days, with many incorporating the movements into their ADLs, such as watching television, making a cup of tea, and walking in the garden:

> I incorporate it into everyday life like watching TV, holding cups. I do the walk all the time. I go out in the garden, I go out and make a cup o' tea. It's the walk that's…I want to do that more than I want to do the arm movements. And holding the ball. I've…I still have difficulty remembering which way it's supposed to go around, but I practice and persevere, so.
>
> (JM, p.3, lines 118-121)

Participants added their own exercises to their home practice regime, with seated exercises taught in class being particularly popular. Participants reported how easy it was to memorise exercises taught in class and added the stepping exercises into their daily routine, remembering foot placements taught in class. These findings suggest that the original home practice regime was rejected by participants in favour of their own personal ones, made up from what they had learned. Many participants said they will continue with the home practice exercises after the study ended:

> Oh, I shall continue now, definitely, yeah…definitely. That is a must is that, yeah. I think you've got to keep yourself moving, you know. You sit down too long, I think. [] Exercises we do when we're sat down, I do that as well, you know, all 'time. (PR, p.5, lines 211-220)

(iii) Home Practice Materials

Participants were given a home practice booklet and DVD (see Appendix X for the booklet). The DVD mimicked the exercises shown in the booklet. Most participants said that they did not have access to a DVD player or, if they had one, did not know how to work it. Those that did watch the DVD, found the instructions confusing:

> Make the DVD with more precise movement because you think your DVD has stopped. And it's not, it's the slight movements and you can't really…they're not really defined on the CD I've got. [] Err…when Richard's got his back to you, it doesn't look like he's moving. [] There's no real definition, whereas here, I can physically see him moving, but on the DVD, whether it's…it looks like it's paused and you're fast-forwarding then you've lost it, so you have to go back and it's…it's the small movement that he makes, they're not defined on the CD. Pronounced, yeah. But it may be the DVD I've got. It may have been paused for a few minutes, you know what I mean, so… (JM, p.3-4, lines 131-135)

The booklet was better received, but participants reported that the booklet was only useful initially, and that it was only read once. Participants explained that this was because the exercises taught in class were easy to remember, rendering the booklet unnecessary:

> Err…at the beginning it was down to the DVD and booklet, and I was following those in a mirror. And now, there's a couple that I miss out sometimes, the sitting up err…the sitting-standing, where it does your hips. Sometimes, I forget that and that comes in at the last, but it's basically from memory. (JM, p.3, lines 113-116)

Instead of using the home practice materials, participants devised their own personal home practice regimes based on what they remembered in class. This may explain why most participants practised at least 15 minutes on days when they did not attend Tai Chi. These findings suggest that the booklet was too simple and that all exercises taught in class should be included in the booklet. Because participants could remember the exercises, it is possible a DVD is not required, unless it is for reference purposes only.

(iv) <u>Questionnaires</u>

Overall, participants found the questionnaires easy to understand and complete, and 'everything wa' laid out what you'd to do and how to fill it in, so, yeah, so from that point of view it wa' perfect, yeah'. However, some participants found the scoring system on the FES confusing, reversing the meaning of the scale, and one found one of the questions on the GDS to be 'ambiguous'. One participant found the questionnaires to be 'a bit long-winded' but were easy to understand and complete.

Qualitative interviews answer questions about experience, meaning and perspective from the participant's viewpoint (Hammarberg, Kirkman & de Lacey, 2016). This has been shown in the above interview excerpts (see Appendix 36) within the five themes and subthemes. Aspects of the study, which could otherwise not be attained through other research methods, were the feelings of participants after taking part in the intervention. The intricate understanding by stroke survivors of the intervention was gained, along with participants' beliefs, attitudes and concepts regarding the Tai Chi programme. Positive outcomes (physical and emotional) were both expected and perceived by participants, motivating them to adhere to the intervention.

It is evident that the qualitative interviews have contributed well to the acceptability of the Tai Chi intervention in the TCAS study, with participants demonstrating a willingness and ability to engage in the intervention. For example, it is interesting to observe that participants were fatigued at the start of the 12-week intervention following Tai Chi classes, and that this fatigue was replaced by energy later in the intervention period. Thus, the acceptance of the intervention shows promise of Tai Chi being a suitable exercise for stroke survivors at the point of discharge when fatigue is at its worst.

Qualitative interviews gave insight into how group exercise was accepted by participants. On the whole, group exercise was highly regarded by participants because it gave them opportunities for social interaction, encouragement by others and to compare progress by observing others.

Participants in the experimental group who found the intervention too slow or easy were drawn out through the interviews, as well as those who perceived or did not perceive any benefit. It was interesting to observe that those who perceived most benefit had more severe weakness. Thus, insight was gained into diversity, adding important information useful to know in a future study.

By interviewing, the researcher gained insight into participants initial beliefs about the study, with most believing it would only take a couple of hours out of their day. Due to perceived benefits, participants were willing to wait hours for transport and viewed the intervention as a day out, establishing acceptance of the intervention.

Fidelity of the Tai Chi intervention was explored in terms of the intervention being delivered as it was supposed to be. Participants continued to practice Tai Chi at home whilst performing ADLS, as well as continuing to practice once the study had ended. Some participants requested YouTube video clips of all the exercises so they could continue with Tai Chi once the study had ended because they were not confident in practising correctly. Information about nearby active Tai Chi classes was also requested by participants once they completed the study. Therefore, fidelity of the home practice materials could be improved by a video including the whole TCAS programme where participants are able to choose the desired exercise from a menu.

Insight into the use of the home practice DVD was gained where very few participants watched it and found it confusing. Participants also requested more information (the whole programme) to be included in both the DVD and the booklet so that they may choose which exercises to practice, as well as being able to continue after the study ended. Interviews provided insight into which parts of the home practice element was adhered to. Interviews suggested that participants followed the booklet initially but found the programme easy to memorise so decided to choose their own exercises to practice from memory.

Chapter 7 – Discussion

A feasibility study was conducted between January 2017 to January 2018 in preparation for a future RCT aiming to investigate whether a bespoke Tai Chi programme specifically for stroke survivors referred to community therapy services at the point of discharge can reduce falls rates and improve balance. The current study is explorative in nature and aims to assess the feasibility of conducting an RCT of the programme for stroke survivors. A preliminary study is needed before an RCT to evaluate the feasibility and acceptability of programme. One of the aims of the study was, therefore, to assess the acceptability and adherence to the programme, which included home practice exercises, as well exploring the suitability and acceptability of the home practice booklet and DVD. Suitability of the duration and intensity if the TCAS programme was also evaluated, as well as the suitability of the outcome measures. Funding to carry out the study was obtained from The Malcolm Tillotson Fund and West Riding Masonic Charities Limited (see Appendix 39).

The study had two arms, an experimental group which received the intervention as well as community rehabilitation (usual care), and a control group which received community rehabilitation alone. Fourteen participants who were randomised into the Tai Chi programme attended one-hour classes, twice a week for 12 weeks, and completed all questionnaires. The experimental group also took part in an interview following the intervention to gain insight into participants' perceptions and opinions of the programme. Nine participants who were randomised into the control group completed the 12-week questionnaires. Quantitative data was analysed using SPSS, whereas qualitative data was analysed using a framework analysis.

Running an RCT, however, even a feasibility one, is fraught with problems and pitfalls. The Numerous problems and pitfalls were encountered during the construction and development of the TCAS study and its materials. This section will discuss what worked and issues faced, along with how these issues were overcome by reporting on the eight areas of focus for feasibility studies as proposed by Bowen et al. (2009): acceptability, demand, implementation, practicality, adaption, integration, expansion and limited-efficacy testing. The various activities and data sources used to answer the research questions presented in Table 17 have already being presented. Table 49 shows to what extent the results of these activities and data sources are worthwhile approaches and if they are workable in a future trial. Suggestions are also included as to how a future trial may be conducted as a result of these findings.

7.1. Acceptability

One of the aims of the study is the acceptability of the Tai Chi programme. Aspects of the study explored for its acceptability include whether participants would withdraw from the study, retention rates and the participants' perspectives which of the Tai Chi programme.

All experimental group participants remained in the study, with two out of 14 people only participating in the home practice element due to blood pressure problems and lack of transport. These participants commented that engaging in the home practice was beneficial and found that attending at least one class was helpful to enable them to practice at home. Home practice practised by those who attended classes had high adherence rates, as well as perceived benefits due to the additional practice. Participants commented that the DVD and booklet were useful initially but due to being able to remember the exercises taught in class, many participants abandoned the home practice materials in favour of practicing class-based exercises. This suggests that the TCAS programme is suitable as a home-based exercise following some introductory classes. Participants empowering themselves and taking control over what they practise suggests that they perceive certain exercises as more beneficial for their personal needs. In contrast, Au-Yeung et al. (2009) found their experimental group to have lower compliance with home practice than the control group, possibly due to the complexity of memorising complex Tai Chi forms. The TCAS programme thus shows promise as a home-based therapeutic exercise for stroke recovery. However, Tai Chi may not be suitable for all stroke survivors.

Some participants, however, did not perceive any benefit from the intervention because the exercises were too easy and commented that they would like more advanced exercises. A future trial may, therefore, benefit from offering a separate more advanced version of the programme, together with professional home practice materials. Offering a more advanced version may improve recruitment among those who feel they do not need the intervention. Indeed, Michelet, Lund and Sveen (2014) found that participants who perceived themselves to have got better following discharge felt they did not need the intervention being offered.

Some participants had co-morbidities such as diabetes (resulting in foot problems) and arthritic hip; these participants found it difficult to practice Tai Chi to the best of their ability. Nevertheless, despite complaining about these ailments, participants continued to engage in the classes, with the participant with diabetes commenting that her foot numbness had improved as the class went along. Although co-morbidity may be seen (by the person) as reason to decline participation in the study, there is evidence suggesting that people with certain co-morbidities should be encouraged to participate because of additional benefits. For instance, a feasibility study on Tai Chi conducted by Cavegn and Riskowski

(2015) showed that ankle proprioception increased, and plantar pressure distribution in the forefoot decreased in participants with somatosensation and Type 2 diabetes. The authors concluded that Tai Chi may positively affect lower extremity health. Further, a meta-analysis found that Tai Chi may be beneficial for improving arthritic symptoms and physical function in osteoarthritis and suggested that aspects of the Tai Chi to be part of the rehabilitation programme for patients with arthritis.

7.2. Demand

The TCAS study aimed to evaluate the demand for the intervention and question if stroke survivors were likely to use the programme. This was done by monitoring the adherence to classes, as well as willingness to continue once the study had ended.

Recruitment numbers did not reach the anticipated target in the TCAS study. However, only one third of trials held by the Medical Research Council [MRC] and Health Technology Assessment Programmes [HTAP] recruited the required number of participants by the time the study ended (Campbell et al., 2007). There was a delay to the implementation of the study because of the ethics procedure as discussed in Chapter 4, thus reducing the amount of time available to recruit. Early recruitment rates were also slower than expected in the current study, mainly due to logistical issues such as unavailability of transport and distance due to only one venue with three recruitment sites. Campbell et al. (2007) identified 41 per cent of studies having delays to the start of recruitment. According to the authors, 63 per cent of studies held by the MRC and HTAP had slower than expected early participant recruitment.

Recruiting on a busy stroke unit was challenging because stroke survivors were occupied with either protected mealtimes, doctors, nurses, or therapists. Often, stroke survivors were absent from the bedside due to being in the cafeteria with family, being with therapists or at an investigation. Seeing patients at set times of day when they are present on the ward may remedy this, such as seeing patients on an evening. Time restrictions on the researcher's part due to being present in the Tai Chi class or travelling to another site meant that sometimes stroke survivors were missed or delayed in the recruitment process. Additionally, a stroke unit has a fast patient turn-around, so that a patient can be unexpectedly moved to a different ward or be discharged home.

Hunter et al. (1987) believed that a failure to recruit in studies was possibly due to the selection and recruitment process. Brintnall-Karabelas et al. (2011) suggested that the study protocol was a major issue for non-participation. Indeed, it was observed by the researcher that many stroke survivors were going home with community therapy who did not meet the inclusion criteria in the protocol, thus excluding this population from the study. Additionally, the researcher found it difficult to use the initial BBS score as part of the inclusion criteria because this was not made available until after participants were discharged home. However, being eligible does not guarantee that the stroke survivor will participate. Despite the general public expecting innovations in medical treatments, most eligible individuals decline to participate in research studies (Brintnall-Karabelas et al., 2011). Studies rely on people's willingness to participate and so recruitment targets can be a challenge (Locock & Smith, 2011). Therefore, it is important that the reasons for non-participation are understood so that those at risk from dropping out can be identified, which is useful in recruiting and retaining participants in stroke rehabilitation programmes, as well as contributing to less biased samples (Michelet et al., 2014).

Most stroke survivors who were approached for the study declined to take part because they did not feel they needed it, or the venue was too far away. Additionally, it became apparent there was a reluctance to participate unless there was some personal gain to be had. Because it would be improper to state that there would be a benefit from participation in the TCAS study, another inducement was used. Therefore, a monetary incentive of £10 was offered to all TCAS participants who completed all questionnaires. However, Stroke Association members who read the PIS deemed £10 not to be enough. Given the limited resources of the resources, this was not achievable. The feeling that £10 was not enough was reflected in experimental group participants who offered the money back to the researcher. Previous Tai Chi studies do not mention whether a monetary incentive was offered. However, Taylor-Piliae et al. (2014b) recommended gift cards but did not mention the value. Monetary incentives are commonplace in medical research and seem to have a positive impact on response rates (Head, 2009). However, there may be the potential for monetary incentives to be exploitive and coercive, where the power lies with the researcher (Head, 2009). A future trial may consider offering a greater monetary incentive to increase recruitment and adherence rates. Organizations such as the Stroke Association may be approached to endorse the study. The inclusion of such organizations may also give confidence to potential participants to take part whilst knowing the study is supported by a trustworthy organization with their best interests at heart.

As well as a monetary incentive, a change in the study design's approach may encourage more people to take part in the study without feeling coerced into doing so. Clinical equipoise provides the ethical basis for research which assigns participants to different treatment arms with the uncertainty regarding their comparative therapeutic benefits (Freedman, 1987). Should the researcher subsequently discover that one treatment has superior therapeutic benefit, the researcher is obliged to offer that treatment to the group that did not receive it (Freedman, 1987). Given that the feasibility study suggests that Tai Chi is acceptable and may yield benefit, a wait-list design may be appropriate in a full-scale trial where home practice materials can be offered to the control group (assuming evidence of effectiveness) even if the actual classes cannot be offered.

While Taylor-Piliae et al. (2014a) and Chan and Tsang (2018) gave trial materials to their control group to promote recruitment, the TCAS study could not offer this at recruitment (which might have aided recruitment) because it was not known at that time whether the programme and materials were safe and acceptable. However, TCAS home practice can, in principle, now be offered to the control group in a trial, so a wait list design is recommended. A wait list is a group of participants who do not receive the intervention initially but are on a list awaiting intervention at a later time: they act as an untreated control group but go on to receive treatment at a later time. Having a wait list control group ensures that all participants eventually receive the intervention, whilst allowing for the control of experimental variables (Jewell, 2011).

The inclusion of stroke survivors being discharged to care homes (who would otherwise be eligible for the study) may increase recruitment rates in a future trial. Further, by collaborating with care homes, the intervention may be delivered at these residences.

Another strategy to improve recruitment, is to encourage potential participants through the ethical principle of altruism. Altruistic motivations are commonly held in research participants, with a sense of connection to community (Carrera, Brown, Brody & Morel, 2018). Participants in the TCAS study felt a sense of belonging to a community whilst participating in Tai Chi classes. Interviews showed that participants liked that other participants were 'in the same boat' as themselves. The sense of belonging to a community may be promoted when recruiting in a future trial; those who do not participate because they find no benefit may choose to take part not for themselves but for the benefit of others in their community.

The TCAS study has shown that it is likely that Tai Chi is likely to be used by stroke survivors. For example, after the study ended, one participant continued to attend the classes but was no longer part of the study. A further two participants requested video clips of the whole sequence of exercises taught so that they could continue to practice. Another participant asked for information about local classes and purchased a book and DVD to practice at home when the study ended. The request for resources to continue after the study has ended suggests that the home practice materials are inadequate to enable independent long-term practice after the study has ended, and that professional and more informative material is needed for a future trial. It would be a good idea to include the complete modified Tai Chi programme (including more advanced exercises) within the home practice resources. An interactive DVD menu is also recommended to enable flexibility with the home practice exercises. Further indication that Tai Chi is likely to be used by stroke survivors is that some participants wanted to continue with the intervention after the study had ended is the demand by some participants for the intervention to be more than 12 weeks.

Non-compliance with completing the study was found in the control group. In order to increase compliance among the control group, a future study may adopt an adaptive design, enabling flexibility where sample size, the intervention, methods etc. can be modified after the start of the study (Pallmann et al., 2018). Additionally, Pallmann et al. (2018) recommend subgroup selection to characterise patients who are most likely to benefit from the intervention, along with involving stakeholders (such as, in this case, the Stroke Association) to improve compliance through giving participants additional peace of mind. This feasibility study may suggest the best approach for a subsequent full-scale trial would be to a adopt an adaptive design.

7.3. Implementation

The study protocol was adhered to, with the exception of making minor amendments to the inclusion criteria which is discussed in the adaptation section. The protocol required a PIS to be given to every potential participant, but the PIS was often not read by the potential participant who either left it on their bedside table or gave it to a significant other who took it home. The length of the PIS may have discouraged stroke survivors from reading it. Patients are expected to read large amounts, despite being approved by the REC. Some stroke survivors agreed to take part in the study following discussion without reading the PIS. Despite this, these individuals were encouraged to read the PIS and were given time to reflect and discuss with their family. Some participants had the PIS read to them by significant others, thereby depending on the significant others' interpretation. Lack of reading the PIS may lead to misunderstandings about the purpose and nature of the study as well as what is expected from the participant. Few studies have reported on whether the PIS was read by the potential participants.

Health literacy is 'the ability of individuals to access, understand and use information to promote health' (WHO, 1998). Older stroke survivors are at risk of low health literacy (Hoffmann & McKenna, 2006), which is why the PIS was adapted appropriately to the needs of stroke survivors. Reading ability has been shown to be a predictor of difficulty understanding written information (Weiss, Reed & Kligman, 1995). The length of the PIS may have discouraged participants from reading the PIS correctly. If stroke survivors did not read the PIS correctly, it may have resulted in not enough information being given. For this reason, Locock and Smith (2011) recommend more emphasis on face-to-face discussion at the recruitment stage. It is possible that there was not enough face-to-face discussion in the TCAS study. However, caution is needed during face-to-face information given due to 'therapeutic misconception', where people misunderstand the purpose of the study to be therapeutic (Locock & Smith, 2011). Locock and Smith (2011) highlight that promises of personal benefit should be during face-to-face information giving. The same principle should apply to written information. Indeed, the UK National Research Ethics Service guidance notes emphatically state 'it is important not to exaggerate the possible benefits' and suggests as a model formula, 'we cannot promise the study will help you but the information we get from this study will help improve the treatment of people with (stroke).'

A future trial may need to place more emphasis on face-to-face discussion and add some perceived benefit for all participants. For example, the PIS may include quotes from the positive experiences experienced by the TCAS participants. Another benefit a Tai Chi study may offer stroke survivors is social support. If stroke survivors felt a need for the social support offered, they may be willing to participate (Michelet et al., 2014). Home visits may be appealing to those in the control group because TCAS participants in this group required regular prompting to post falls calendars and questionnaires. Additionally, the control group found it burdensome travelling to the hospital to perform the BBS. Older stroke survivors living at home may benefit from a home-based method of collecting data, thus enabling recruitment in those unwilling to participate due to transport and mobility issues (Michelet et al., 2014).

Reading the PIS is important to obtain informed consent, but by doing so may encourage stroke survivors to take part in the study. Following the positive response of the intervention offered, future recruitment may be done through making changes to the PIS which includes positive reports from previous participants.

Participants were randomised into the experimental group or control group by using block randomisation. Participants were offered eight envelopes and had to choose one. Some participants found shuffling the envelopes and selecting one difficult due to upper limb weakness. In this case the participant informed the researcher which envelope they would like to choose, and the researcher took the envelope out of the pile. It may be better in a future trial to place the envelopes on a table to make it easier for participants with upper limb weakness to select one. Additionally, due to slow recruitment rates, envelopes were kept in a locker based on the ward and were subsequently removed by cleaning staff. Therefore, envelopes should be kept with the researcher at all times.

Many stroke survivors interested in the TCAS study were willing to be randomised, with only four people wanting to choose their own group. Few Tai Chi studies report on the willingness to be randomised. In a pilot study by Taylor-Piliae and Coull (2011), three out of 69 people refused randomization. In the follow-up RCT, 22 out of 393 stroke survivors refused randomisation (Taylor-Piliae et al., 2014a). The number of stroke survivors not willing to be randomised is, therefore, relatively low in these studies. Thus, it can be deduced that refusing to be randomised is unlikely to be a major problem for a future trial.

Having an imbalanced sample size is a potential problem with small clinical trials using simple randomization methods, with the preference of block randomization to achieve balance (Kang, Ragan, & Park, 2008). Therefore, block randomization was performed in this study. Despite using a valid randomisation procedure, due to the involvement of small numbers and slow period of recruitment, the randomisation process did not result in equal groups. Small numbers may have led to the imbalanced group sizes in this feasibility study. It was not always possible to use the same batch of eight envelopes per eight participants due to them getting damaged or being left at one site. Yelland et al. (2015) recommend researchers to accept randomisation errors, despite the possibility of introducing an imbalance in the number of participants. One TCAS participant was randomised and later became ineligible for the study. The participant in question was treated clinically as a stroke patient without any diagnosis confirmed by imaging. According to Yelland et al. (2015), eligibility should be confirmed before randomisation takes place. Therefore, a future study may want to consider including a stroke diagnosis confirmed by CT or MRI of the head strictly as part of the inclusion/exclusion criteria. It is recommended that if an ineligible participant is found to be in the study, they should cease to receive the treatment. The TCAS participant was aware she was not a stroke survivor and requested to leave the study. Strict adherence to the study protocol is thus recommended through the employment of a second member of staff to ensure that there are no errors in treatment allocation. Few studies have reported randomisation errors which may be because it is not a recommendation of the CONSORT statement (Moher et al., 2010). Nevertheless, randomization errors in this study have been reported. Envelopes were stored in a locker on the ward but were removed by staff, resulting in lost and damaged envelopes. In future, envelopes should be carried with the researcher at all times and kept in a waterproof wallet.

Although all experimental group participants completed the study, some were delayed in attending their first class. Some participants expressed a fear at the start of the study due to feeling unsafe because of stroke-related limb weakness, which reduced their confidence to walk. These feelings may delay or put the participant off from attending the Tai Chi class. For example, one participant fell prior to discharge and did not want to attend Tai Chi until she felt more confident, whereas another participant said she was one week late coming to Tai Chi because she was waiting for the occupational therapist delivering bathroom equipment and she was worried she may miss them if she came to class. The participant admitted that she did not join the study at her worst state. A six-week joining period was therefore, introduced to the TCAS study, where participants were able to delay attending their first Tai Chi class by six weeks in order for them to adjust from being in hospital. A future study may benefit by offering the first Tai Chi class(es) to participants whilst they are still hospital in-patients to give them the confidence to start Tai Chi classes whilst still adjusting to being back at home. By introducing Tai Chi classes prior to discharge, other patients may become interested in participating in the study with those already taking part recounting their experiences. Participants may be more inclined to attend Tai Chi sooner than six weeks after discharge.

Commitment of the Tai Chi instructor and researcher were needed to keep the classes running throughout the study’s duration. Despite running beyond the agreed study duration due to an extension on the recruitment period (six months), the Tai Chi instructor was willing to continue with the study. There was no back-up instructor or researcher in case of illness in the current study due to lack of funding. Fortunately, absenteeism on the part of the Tai Chi instructor and researcher did not cause a problem to the running of the classes. However, the Tai Chi instructor was absent for two weeks to go on holiday and the researcher missed one class due to illness, causing disruption to the study. Thus, limited resources highlighted a factor that needs to be taken into account for a future trial; sufficient numbers of skilled personnel need to be available to ensure there are no breaks in the process due to illness and holidays, etc., as well as to maintain safety using the appropriate ratio of instructors to participants. A future study may wish to take absenteeism into account in order to maintain progression throughout the study. Some studies have used multiple Tai Chi instructors, but due to the limited resources of the TCAS study, only one Tai Chi instructor was available. To keep TCAS participants focused on attending Tai Chi classes, participants were encouraged to carry on attending the classes to practice their home-based exercises under the supervision of the researcher (less than six participants attended).

Practice of the home-based exercises were recorded in diaries which were completed by all experimental group participants. Diaries are a common method of charting aspects of people’s behaviour (Bryman, 2012). The purpose of the home practice diaries in the TCAS study is to find out if experimental participants practised at least 15 minutes of home-based Tai Chi. Diaries are, therefore, the most practical and appropriate method to be used. Although diaries are a trustworthy, effective, useful and insightful method of data collection if they are completed properly, participants often fail to do this (Bedwell et al., 2010). In the TCAS study, space was made in the diaries so that participants could add comments regarding the home practice, but this was optional in order to avoid over-burdening because diaries place a great deal of responsibility on the participant (Bryman, 2012). Leaving the comments section as optional also aimed to encourage the participants to complete the diaries. Most participants did not fill these sections out. If they did, the information provided was irrelevant. In retrospect, it would have been beneficial to have given participants guidelines on what to write in the comments section of the diaries to gain further insight into the exact duration and frequency of home practice, as well as types of exercise chosen by participants. Knowing the exact number of minutes practised may have helped to inform a future trial about the minimum amount of home practice. Additionally, guidance would have avoided the collection of irrelevant data.

Diaries are time situated and provide insight into events as they occur (Bedwell et al., 2011). However, the accuracy of the data gathered from the home practice diaries may be called into question because it is not known if diaries are filled out as soon as the event occurs or days afterwards, leading to memory recall problems (Bryman, 2012). Thus, the time the entries are written is important for accuracy (Hall, 2008). It is not possible for the researcher to tell that what participants recorded is what actually happened; how does the researcher know the home practice was really adhered to? According to Hall (2008), participants may deceive themselves. Additionally, diaries can suffer from a process of attrition, where participants have had enough of completing them, and are prone to become less committed to keeping god time with record keeping Bryman (2012). If the collected data is incorrect, it throws doubt over the fidelity of the home practice exercises and whether these exercises are doable in a larger scale trial. Although TCAS participants completed the diaries, it was unknown when they were completed. Participants were reminded to bring them to the class at the end of the month, but many forgot to do so. A future trial may benefit from using a daily text messaging service to act as a reminder to complete the home practice diary.

Another challenge faced with the use of diaries is the ability to write; many stroke survivors find writing difficult. Data may, therefore, be skewed towards those able to write easily. Participants in the TCAS study did not find a problem completing the diaries. However, the optional comments section was often omitted by most participants. It is not known if participants who provide the optional comments are doing so because they think they have to, thus writing anything to please the researcher (Hall, 2008). Indeed, Robson (2011) suggests participants may change their behaviour to be shown in a good light, limiting the usefulness of the diaries. Hence, Robson (2011) recommends a second data collection method to cross-check with diary entries. That was done in the TCAS study with semi-structured interviews conducted to gain extra information, making it possible to determine if participants were likely to be telling the truth. That said, the researcher has to assume that the participant's truth is the participant's truth. Truth telling was encouraged by adopting an apparent honest and open relationship between the participants and the researcher.

Due to time restrictions, some participants were not able to complete the baseline questionnaires before discharge. Therefore, they completed at home and either handed them in before the start of the first Tai Chi class or posted them as soon as possible. Because the control group needed prompting by telephone calls, the baseline questionnaires were often delayed in the control group. This makes the regular home visits more appealing in order to collect data more promptly.

Returning the falls calendars and questionnaires was challenging, particularly with the control group. It may be that the experimental group had an advantage over the control group which explains the higher response rate in the experimental group. The experimental group received more attention from the researcher and were able to be reminded to hand the falls calendars and questionnaires in. The control group were telephoned if they did not post them on time. These telephone calls may have been seen by the control group as nuisance calls or putting pressure on them, resulting in failure to complete the data collection instruments. However, weekly telephone to the control group, which did not receive any exercise by the researcher, were part of the protocol in the study by Taylor-Piliae et al. (2014a), who received a lower drop-out rate in this group. The control group in the TCAS study did not receive any input other than being chased via a telephone call, not regarding their welfare but regarding their failure to post the required calendars and questionnaires. As previously mentioned, contacting participants with regards to focussing on their welfare may help with adherence rates. Additionally, home visits once a week for social support may have developed a rapport, like the rapport developed in the experimental group, which may lead to a higher response rate among the control group.

Another advantage that the experimental group had over the control group was having the opportunity to ask the researcher questions regarding the questionnaires. To avoid researcher bias, the researcher did not answer questions regarding what participants should put if they were undecided, nor did she answer questions which would show the researcher's influence. If participants did not understand the order of a scale, this was explained as was written on the questionnaires. However, despite regular contact with the researcher, confusion was still evident regarding the questionnaires.

Timing of filling out the baseline questionnaires is important because most participants completed these whilst still being an inpatient at the hospital. Being in hospital may have affected their perceptions of their overall health, where participants are lower in mood due to being in hospital. Additionally, if participants filled out the baseline questionnaires before being discharge by the hospital physiotherapists, they may also perceive their balance to be worse than when they get discharged because they have not reached discharge potential. Thus, those participants filling out the baseline questionnaires at home after discharge from hospital, may have more positive perceptions of their health. This leads to the question if filling out the baseline assessments should be done at home rather than hospital before discharge.

Challenges obtaining the 12-week questionnaires were mainly in the control group who required regular prompting to post them. Some participants returned the questionnaires at the same time as performing the 12-week BBS. The 100 per cent successful response rate within the experimental group may be due to the time of completion, which was after the final class whilst waiting for transport prior to their interviews.

Because stroke survivors were recruited whilst still in hospital and attended the Tai Chi classes within six weeks of discharge, it is difficult to conclude whether any perceived benefits of Tai Chi were due to spontaneous recovery from stroke (Cramer, 2008; Lamola, Fanciullacci, Rossi & Chisari, 2014). It is usual for some degree of spontaneous behavioural recovery in the weeks to months following a stroke with most occurring within the first three months after stroke onset (Cramer, 2008). However, a pilot study by Hart et al. (2009) recommended an intervention period longer than 12 weeks in order to notice improvements in balance. Should the intervention period in a future study be longer than 12 weeks, a future study, therefore, may need to lengthen the duration of Tai Chi with the 12-week follow-up being the mid-study assessment with a 24-week intervention period or longer. Alternatively, a mid-study follow-up in a 12-week study would be six weeks. Obtaining a mid-study assessment would make it easy to compare the rate of improvement. There is evidence to suggest that introducing Tai Chi as an adjunct to community rehabilitation is more effective in improving balance and quality of life than rehabilitation alone. Kim et al. (2015) suggested combining therapeutic Tai Chi with general physical therapy was more effective for improving static balance in stroke survivors. Au-Yeung et al. (2009) suggested combining Tai Chi with rehabilitation so that stroke survivors will be able to continue with their own rehabilitation anytime, anywhere, and that this should be an important goal in stroke rehabilitation. Therefore, a future study may want to place emphasis on empowering the stroke survivor to take control of their own rehabilitation when discussing the benefits of Tai Chi during the recruitment period.

7.4. Practicality

This feasibility study explored how practical it was to implement Tai Chi, e.g. how easy it was for participants to get to the venue, whether it was feasible to employ an experienced instructor and to see how far both the participants and instructor were willing to continue.

In this feasibility study, various strategies have been implemented in the TCAS study to provide adequate safety for participants, such as having a suitable venue and small class sizes (class sizes varied between one and five participants). All aspects of the study were conducted at a local NHS Trust within three sites, providing easy, convenient access and familiarity with the setting. The hospital sports hall was used following permission from the physiotherapists and was readily accessible except for one class which was moved to a smaller gymnasium within the hospital because the physiotherapists required the sports hall. The sports hall was a good venue to host Tai Chi classes because an easy-access toilet was nearby, preventing participants breaking away from class for longer than was necessary. Additionally, tea-making facilities were available whilst participants were waiting for the class to start; some participants arrived at classes as early as one and half hours before the class was due to start.

A maximum number of 12 participants with two supervisors was recommended by the physiotherapists, but there were not adequate recruitment numbers to fill the sports hall to its maximum capacity. It was also observed by both the researcher and Tai Chi instructor that more than five unsteady participants may be difficult to handle if the instructor and researcher (a registered nurse) were watching over participant's foot placements. One solution to this difficulty is to hire more supervisory staff, such as nurses or physiotherapists. During all classes, all participants practised Tai Chi with a chair behind them to allow for rest periods or to practise exercise whilst seated. One advantage of conducting the research on a hospital site was the near-by presence of an automated defibrillator and the Emergency Department should an adverse event occur.

It was not practical for stroke survivors to get to the venue because they or their significant others could not drive, or their significant others had work commitments. Hence, transport was a major pitfall in recruiting and attending. For this reason, the shuttlebus service was recommended to participants. Despite shuttlebus information being given, none of the participants were willing to use this service because they struggled to get to the shuttlebus.

In contrast, a pilot study by Taylor-Piliae and Coull (2011) provided a list with local transportation services to assist with their transportation issues and found that this improved their adherence rates. TCAS participants differed from those of Taylor-Piliae and Coull because TCAS participants were relatively independent. Additionally, participants in the study by Taylor-Piliae and Coull were six months post-stroke and would have adjusted to going outside and resuming their activities prior to stroke.

To resolve the issue of transport, the local ambulance service was used. However, the use of hospital-based transport meant waiting for up to two hours for the ambulance to arrive. This long waiting time could have deterred participants from continuing to participate. Nevertheless, participants remained in the study even when they realised that what was meant to have been a one-hour exercise class turned out to be a day out due to the waiting times for ambulance transport. As a result, participants committed themselves for the whole day, avoiding making plans on Tai Chi days, thus contributing to class attendance. Many of the participants commented that if it wasn't for the ambulance, they would not be able to make it to the classes. Despite waiting up to four hours, participants continued to attend and took the waiting as part of the routine. Waiting to be taken home encouraged social interaction and a sense of belonging to a group who have had similar experiences.

Overall, Tai Chi was a relatively inexpensive intervention for the TCAS study with the only expense being the Tai Chi instructor. However, it did cost a lot of time on the part of the researcher, instructor, physiotherapist and ambulance driver. A future study may be more expensive because if classes are held more locally using multiple sites, it may be that venues outside of the hospital need to be hired should the hospital venues not be available. Additionally, transport may become an additional cost as well as the employment of multiple Tai Chi instructors.

7.5. Adaptation

Adaptation aims to look at whether the study deviated from the protocol, and if any adaptions to the intervention were made.

Obtaining consent before patients were discharged became a challenge because some stroke survivors were frequently absent from their bedsides, discharged unexpectedly, wanted more time to think about it or had not read the PIS yet because they were too busy. Frequently, the researcher was unable to catch the stroke survivor before discharge because of work commitments, attending the Tai Chi class or being at one particular site (recruitment took place over three sites). Stroke survivors are often discharged from the local stroke unit on the same day that they have been discharged from the hospital physiotherapists and referred into the community. Hence, it was known if patients were eligible for community therapy until they were discharged. There is little research that talks about the difficulties of obtaining informed consent from patients at the point of discharge. A future study may benefit from approaching potential participants as soon as possible, before being referred to community therapy services. The input of the physiotherapists may be useful in this case, where physiotherapists may also be involved in the identification of eligible people and the giving of the PIS form. Hospital physiotherapists were willing to help in the identification of patients who were eligible for community therapy by making a list of eligible patients. However, due to a busy work schedule, this list was not compiled. Rather, physiotherapists found it easier to give on the spot information face to face. The involvement of including the physiotherapists in the identification process saved a lot of the researcher's time, as well as reducing the amount of missed potential participants.

Once participants attended the Tai Chi classes, it was found that two one-hour classes of Tai Chi per week for a duration of 12 weeks, using the DH (2011) recommended national physical activity guidelines (recommended weekly activity of moderate-intensity should be >150 minutes), was acceptable and tolerated in stroke survivors at the point of discharge from hospital. In order that participants to complete the study in future, a duration of 24 weeks is recommended. Only participants who were relatively independent thought the classes were too long due to boredom but added if the classes were more advanced, one hour, twice a week would be adequate. Most participants practised home practice exercises willingly and perceived benefit from doing so. This perceived benefit seemed to have motivated the participants to engage in home practice.

In hindsight, the TCAS study would have benefitted from a six-week assessment, as well as baseline and 12-weeks. This is important, given that not all participants in the TCAS study attended all classes; if changes in the TCAS study occurred after a certain number of weeks, it may indicate that only one class per week is necessary. In addition to a six-week assessment, a six month and 12-month follow-up (or longer) would be beneficial to investigate the long-term effects of the TCAS programme, if any, and would also show better or more sustained effects.

The TCAS study used Qigong exercises combined with modified Yang-style movements, a style modified in previous Tai Chi studies among stroke survivors. Although there were no changes to the Tai Chi programme, the Tai Chi instructor did comment that he was surprised at how long it took participants to perform each exercise well enough to move onto the next. Therefore, rather than individual exercises changing, it was length of time devoted to those exercises. The Tai Chi programme was flexible so that exercises could be tailored to the individuals in the class. For example, if a participant was ready to move onto a hand movement that nobody else in the class was doing, all participants were able to join in with the seated version of this exercise. Tai Chi stepping combined with hand movements was practised on an individual level.

Participants incorporated Tai Chi into their everyday activities, such as walking to from one room to another and practising exercises whilst watching TV. Incorporating the TCAS exercises into ADLs, gives the exercise a sense of purpose. Anderson, Wojcik, Winett and Williams (2006) recommended physical activity interventions to focus on increasing self-regulatory behaviours and incorporating them into everyday activities. Negative expected outcomes may be decreased if practice of the intervention is scheduled into their daily life with practice and reinforcement. Broderick et al. (2015) found that 'older adults perceive exercise as incidental to more purposeful activities rather than endpoints itself.' The authors further suggested that exercise was perceived as being a by-product of purposeful activities. A future study may, therefore, benefit from incorporating Tai Chi into everyday activities as part of the home practice routine to increase adherence.

7.6. Integration

The current study observed how significant others may integrate into the intervention. The presence of family members made it easier when approaching participants because they were able to help explain to the stroke survivor the purpose and nature of the study whilst helping them read the PIS. However, in some cases, significant others wanted to take over the decision-making process by either persuading the stroke survivor not to participate or to make them participate. This made obtaining consent difficult if the participant expressed that they did not want to participate, but their significant other is making them. In this situation, the researcher spoke to the stroke survivor alone to find out what they wanted. If the stroke survivor expressed that they did not want to participate, their decision was honoured.

As well as being involved in the decision-making process, significant others were invited to play a role in attending Tai Chi classes and home practice. Rackow, Scholz and Hornung (2015) found that those receiving rehabilitation who exercised with significant others, increased their exercise frequency. Further, the greater the number of significant others who exercised regularly, the more likely the participants were to achieve the recommended levels of physical activity. Indeed, Darlow and Xu (2010) observed that significant others' exercise habits were associated with one's own. Moreover, exercising as a group seems to be beneficial for emotional support through encouragement and comforting, as well as social support, thus promoting better self-regulation, particularly self-efficacy. Yeh, Chan, Wayne and Conboy (2016) found that Tai Chi group participants reported an increase in social support among heart failure patients. The authors reported a strong sense of community, feeling part of a group, sense of belonging and comfort was found among participants. Gallant et al. (2017) also reported some social benefits of practising Tai Chi among older people. Interestingly, Hwang et al. (2016) avoided social support among stroke survivors in their study because it may affect the results of their study. These findings are similar to Tai Chi participants in TCAS, who expressed they felt good that there were other people in 'the same boat.' Thus, including significant others may increase exercise adherence (Osuka et al., 2017).

Approximately half of all experimental group participants brought along a significant other to class who offered support during classes. However, the Tai Chi instructor found significant others to be a hindrance because they interfered with the participants' concentration by telling them they were doing it wrong and how they should be practising it. Although, this may appear a positive thing, the Tai Chi instructor commented that the significant other was not demonstrating moves correctly, thus leading to confusion on the participants' part. Nevertheless, significant others were found to be partners with home practice and were encouraging their partners to continue.

Despite the support of significant others, family commitments were often the reason for non-attendance. Classes were also missed due to holidays and appointments. However, these are circumstances that can occur at any time and are an accepted issue in any trial regarding participants to be in a particular place at a particular time. In common with other studies, (Au-Yeung et al., 2009; Ding, 2012; Ge et al., 2017; Kim et al., 2015; Li et al., 2017; Zhang et al., 2015; Yoshinaga and Cai, 2013) the idea of TCAS was to incorporate Tai Chi as part of early stroke rehabilitation, thus some problems with early attendance were unavoidable. One aspect of TCAS that helped overcome any missed classes was the inclusion of a home practice element.

Family commitments increased following the perceived improvement in mobility, enabling one participant to start driving again. The participant's family placed an increased demand on the participant, reducing class attendance. As a result of the increased family commitments, the participant became emotional during a class. Therefore, the emotional wellbeing of participants needs to be considered. The Tai Chi instructor needs to be made aware of this complication of stroke and thus adopt a compassionate approach. A compassionate approach gave the tearful participant confidence to carry on with the class rather than drop out. However, despite giving this participant confidence to carry on, their attendance decreased, nevertheless. An increase in confidence overall encouraged the tearful participant to start driving again, leading to demanding family commitments.

7.7. Expansion

Expansion aims to find if there is any potential success of Tai Chi for stroke survivors at the point of discharge receiving community therapy services, and whether it can be brought to a wider population.

The non-engagement of black, Asian and minority ethnic [BAME] groups has been found to be a limitation of the study. South Asians, in particular, make up a large proportion of stroke survivors locally, where many of the older people do not have a good command of English. It is, therefore, not surprising that many stroke survivors were ineligible for the study due to not being able to speak English, reducing the number of potential participants. The absence of a language barrier as part of the inclusion/exclusion criterion has been mentioned in previous studies, suggesting that there were no language barriers since there were no mention of interpreters involved in the study. Kerry et al. (2018) investigated the failure to include ethnic populations in exercise studies and found that including these populations tends to involve increasing costs. For example, the involvement of an interpreter and translator may be required. It was found by Quay, Frimer, Janssen and Lamers (2018) that in those patients who did not speak English, many were not approached or there was a lack of translated materials (Quay et al., 2018). The present study did not have enough resources to employ an interpreter or to translate trial materials. However, in future, in a location where many stroke survivors are South Asian, it would be wise to invest in interpreters/translators to represent the whole community, making results more generalisable. However, that, while necessary, may not be sufficient to increase participation rates in this community.

South Asians are under-represented in health research generally, according to a systematic review by Quay et al. (2018). This issue is further made difficult because the researcher in the current study found that South Asians who were eligible and spoke English were not interested in participating in the study. Kerry et al. (2018) found that reasons why this population is generally under-represented in research were participant-related, logistical, cultural or general disinterest; South Asian patients were less likely to participate because of insufficient time and perceiving themselves as physically active. Because Rimmer, Wang and Smith (2008) reported lack of time as a reason not to participate in exercise, time was not a significant barrier among stroke survivors. Thus, questioning whether the barrier is a cultural issue rather than one related to lack of time.

Quay et al. (2018) found that participant-related reasons why eligible South Asians did not participate in research included being labelled with a health condition, mistrust of research, and fear of being reported to immigration. Transport and family-commitments also played a major role in non-participation, with decisional hierarchies within families often creating a barrier. Religious or cultural conflicts were found to be an issue by the authors. This is interesting because it may be that Tai Chi could be regarded as a practice from another religion. Despite its roots in Taoism, it may be necessary to sensitively highlight in the informed consent face-to-face discussion that the Tai Chi exercise programme would not impinge on any religious beliefs.

Disinterest in study participation was found to stem from a feeling of not belonging to the society that would benefit from the research, as well as not perceiving any personal benefit (Quay et al., 2018). Strategies suggested by Quay et al. (2018) for a future study to include this population include liaising with key community figures and developing community partnerships, offering personal benefits, such as financial incentives and health benefits, utilising a multi-lingual research assistant who may aid in interpreting and translating.

A future study may address the issue of non-engagement of BAME communities by organizing coordinated involvement with key community figures and developing community partnerships. This may be done in places of worship acting as therapeutic landscapes, where religious sites are associated with healing (Tomalin, Sadgrove & Summers, 2019). Therapeutic landscapes also include therapeutic spaces and networks, where therapeutic spaces may carry out therapeutic or health-related activities and therapeutic networks may enable BAME communities to gain support and care (Tomalin, Sadgrove & Summers, 2019). Thus, Tai Chi may be delivered in places of worship as a healing therapy. There is existing precedent for this: it is not unusual for community Tai Chi classes to be conducted in church halls. Gender differences may be addressed through the employment of a female Tai Chi instructor, enabling separate classes for men and women.

Future studies may benefit from collaborating with local organizations as well as community groups. A local example is the Leeds-based 'Touchstone' organization which aims to increase the number of people from BAME communities who are able to access appropriate and timely care through their faith. Interpreters from such organizations may be willing to get involved for those who do not speak English, thus increasing recruitment rates by involving more participants from BAME communities.

7.8. Limited efficacy-testing

Although it is still unknown if the TCAS programme improves balance and reduces falls among stroke survivors at point of discharge from hospital, it has shown better insight into Tai Chi being a promising exercise for stroke recovery in terms of improving balance. Observation has shown that participants were reluctant to let go of their walking aids at the beginning of the study, but after two weeks, participants let go of them and were walking with confidence by the end of the programme. BBS scores show promise with more improvement in balance among the experimental group than the control group. However, a large sample size is required to generate significant and generalisable results. A future study would thus require to be multi-centred with multiple Tai Chi instructors and researchers. The inadequacy of the outcome measures was examined by the level of difficulty experienced by the participants completing them, as well as adequacy in answering the research question for an RCT: what is the effect of Tai Chi on the number of falls and balance among stroke survivors at the point of discharge?

The number of falls in the current study was few, given the small sample size; there were fewer falls in the experimental group (n-1) than the control group (n=6). Due to participants experiencing multiple falls, it was difficult to determine the clinical meaningfulness based on this outcome measure alone. For example, if a study reports a high frequency of falls, the results are not clinically meaningful if one participant was involved in all fall incidents reported. Thus, to gain insight into how meaningful the results were in a clinical context, the number of fallers was analysed.

Interestingly, Gao et al. (2014) used the number of fallers rather than fall rates as an outcome measure for falls in a study involving people with Parkinson's disease. The authors found that the experimental group had significantly fewer fallers than the control group: out of 37 experimental group participants, eight fell compared with 19 out of 39 in the control group. Despite the finding that the experimental had fewer falls and fallers than the control group in the TCAS study, there was not enough falls data to analyse in order to find an indication of the potential value of using fall rates as an outcome measure in a future study. Interestingly, participants who fell in the TCAS study were more likely to not attend classes; the faller in the experimental group ceased to attend the intervention but agreed to remain in the study and perform home practice exercises. Similarly, Taylor et al. (2012) found no difference between groups for fall rates and suggested that those who fell during their intervention were more likely to withdraw than non-fallers. Overall, to gain more insight into clinical meaningfulness, the number of fallers rather than fall rates may be a more suitable outcome measure to investigate the effectiveness of Tai Chi in reducing falls in stroke survivors in a future study.

The BBS has been shown to be effective in detecting improvements in balance function among stroke survivors following a Tai Chi intervention (Zou et al., 2018). Additionally, the BBS has shown to be a predictor of fallers in the general population following Tai Chi practice (Li et al., 2004). Obtaining the initial BBS from community physiotherapists was successful via regular communication via email and telephone. Those BBS scores that were unavailable was because the participants were either not seen by community therapists, despite their referral at the point of discharge, or the participants were discharged from the community following the first visit. The BBS was obtained from the experimental group following their final class. Unfortunately obtaining the BBS from the control group was a challenge because participants were reluctant to return to the venue just for this purpose. Reasons given were due to schedule and transport issues. This may explain the loss to follow-up in some control group participants. Therefore, home visits may be more beneficial in a future trial to perform the BBS and collect fall calendars and questionnaires. One alternative to home visits is to use the FES as the primary outcome measure, with fear of falling being the primary outcome instead of balance because it is difficult to say whether balance improved due to a physical improvement or whether it was due to an increase in activity due to an increase in confidence as measured by the FES. Further recommendations for a future trial are presented in Table 49 and are further discussed in Chapter 8.

Table 49 Suggestions for conducting a future trial (based on the areas of focus for feasibility studies proposed by Bowen et al., 2009)

Results of the activities and data sources with suggestions for a future trial			
Feasibility Study Area of Focus	**Activity or Data Source**	**Is it worthwhile?**	**Suggestions for a future trial**
Acceptability	Interviews, Tai Chi programme, outcome measures	• Interviews found out that participants accepted the Tai Chi instructor and enjoyed the study. All experimental group participants continued to remain in the study until the end, with most completing the home practice. However, the DVD was not used by most participants and the home practice booklet was only used at the beginning for reference. All experimental group participants were willing to participate in the 12-week interview. • Despite having co-morbidities, participants were able to practise the exercises. • None of the participants used the shuttlebus service because it was difficult to get to.	• Modifications are required for the home practice DVD and booklet, such as making it more professional with an interactive menu so that it is appealing to participants with more challenging exercises. More advanced exercises may be offered to those with less impairment. • A DVD containing the full programme as opposed to the home practice materials are recommended to enable participants to continue once the study has ended. • The shuttlebus service is not recommended in a future trial.
Demand	Interviews, Tai Chi programme	• Many stroke survivors did not agree to participate. Venue, transport and the feeling of not needing the exercise were included as reasons why stroke survivors did not participate. • Those with good balance found the exercises to be too slow and simple, and felt held back by those with more impairment. • Most experimental group participants wanted to continue with Tai Chi after the study ended, asking for video clips of the full programme so they could continue at home.	• Many relatively independent stroke survivors who felt they did not need Tai Chi and declined returned to hospital with a second stroke which severely disabled them so they were unable to walk. None of the experimental group have had a further stroke. • A future study may benefit from explaining that despite the feeling they do not need the exercise, it may reduce the chance of having a further

			stroke. This may increase recruitment rates. - To increase recruitment rates, it is recommended that a wait-list design is adopted where Tai Chi is offered to the control group at the end of the intervention period. - An incentive in the form of a voucher of appropriate value is also recommended to aid recruitment and completion of the study. More than the offered £10 was recommended by a Stroke Association member; it would be beneficial for the study if organisations such as the Stroke Association could become involved to endorse the study. - A full demonstration of all exercises at the beginning may help participants work out their progress in relation to the end-goal, enabling them to focus more on moving forward. - In a future study, participants' experiences gained from the interviews can be expressed in the PIS to encourage future potential participants to take part. - Additionally, including more advanced exercises may also motivate those with minor impairments to enjoy the classes.

			• It is also recommended that the full programme be presented in the home practice DVD and booklet so that participants may continue with the programme after the study has ended. • Home practice materials should be professionally made with the DVD having an interactive menu.
Implementation	Tai Chi programme, outcome measures	• On a busy stroke unit, it is easy to miss potential participants due to a quick patient turnaround. • The PIS form was understood by participants, but most stroke survivors who were approached did not want to participate. • Randomisation was stifled due to slow recruitment response. • Overall, the TCAS programme was able to be fully implemented. However, participants did not complete all of the exercises contained in the programme because it took longer than expected for them to progress. • The Tai Chi instructor was absent due to holidays and the researcher was absent for one day due to sickness. • The adherence to the home practice diaries was successful. However, the number of minutes and type of exercise was not recorded. The number of minutes practised would have been useful to find out to see if 15 minutes as a minimum amount of time could be extended. Recall bias may be involved with this method, as well as the researcher having to assume the truth had	• Multiple researchers are recommended in a future trial in order to avoid missing potential participants. • The positive experiences of the TCAS participants may be included in the PIS, along with more emphasis on face to face discussion during the recruitment stage. • Envelopes should be securely stored during times of non-recruitment. • In a future trial, an extra instructor would be required in case of illness or personal appointments. • Home practice diaries should be more specific than just a comments section in a future trial. Details about the exact number of minutes practiced, as well as type of exercise chosen would be useful to obtain, as well as offering guidance on how to complete this section.

		been told. Semi-structured interviews gave the researcher deeper insight into the diaries, as well as developing an honest and open relationship with participants. - Control group participants needed prompting to return the questionnaires and falls diaries. - Timing was often difficult for control group participants because participants were often reluctant to return to hospital just to perform the BBS. Timing was also dependent on the availability of control participants. - Participants found it difficult to reach the venue due to disability and significant others either not being able to drive or having to work. - The hospital sports hall was an ideal venue because of the easy access to first aid, handy location of a rest room, and suitable environment to practise Tai Chi. - The TCAS programme deviated during the classes because the full programme was not achieved by most participants. Interviews found out that participants took their time to progress because they did not know how many exercises were available to complete. Many participants wanted to complete the full range of exercises after the study finished but were unable due to the limited number of exercises contained in the home practice resources. This limited number was initially used because it was not known whether stroke survivors would be able to do the exercises. Therefore, caution was given.	- Home visits for the control group are recommended in order to maintain contact with participants, as well as motivate them to remain in the study. This also allows for more the return of questionnaires and falls diaries more promptly, as well as increasing the accuracy in the reporting of falls, where the researcher can collect falls data weekly rather than monthly. - Starting the Tai Chi classes whilst participants are still in hospital may be an option for a future study to not only encourage other stroke survivors to participate but also to ensure a smooth transition from home to hospital and encourage participants to attend as soon as possible. Participants may also tell of their experiences to other potential participants who may then want to take part. - To be successful, a future trial would benefit from being a multi-centre trial, obtaining financial resources from funding bodies and employing multiple researchers to recruit and collect and analyse data. Collaboration with the Stroke Association is recommended which may help fund the study

		- The TCAS study only employed one researcher and one hospital trust. A future study would not be successful with only one researcher, venue and hospital Trust because larger recruitment numbers are required.	and give confidence to potential participants in the study because the study is backed by a trustworthy organization. - Including stroke survivors discharged to care homes who would be otherwise eligible for the study is recommended. Delivery of the intervention may take place in such homes.
Practicality	Tai Chi programme, interviews, outcome measures	- Participants were committed to attending and were willing to wait up to two hours for transport, totalling four hours per Tai Chi day. The long waiting time may have deterred participants from continuing with the study. Participants expressed how they called the days of the study a 'Tai Chi' day and were willing to commit to the whole day, making it a 'day out.' Participants were able to carry out the exercises at their own pace, resting when appropriate. The study was inexpensive and feasible but costly in time. - Although the physiotherapists recommended a maximum of 12 participants with two supervisors, it was found that six was more suitable for stroke survivors practising Tai Chi. - One difficulty faced was after consenting, some participants were discharged before completing the baseline assessments. - Some participants suggested more flexible days so that if they missed a day, they could catch up.	- A future study may want to make the Tai Chi class a social event as well as therapy for stroke recovery because of the hospital waiting times. - Refreshments are recommended as many stroke survivors are diabetic and will need feeding if transport takes a long time. - In order to be a multicentre trial, a future study will need financial assistance to cover the cost of instructors, mini-bus hire, printing and refreshments, as well as other administrative tasks. - A rolling programme with a ratio of six participants per two supervisors is recommended for a future trial. - If experimental group participants are discharged, it is recommended that they return the baseline questionnaires before they start their first class, so the results are not

			affected by attending a social event. - The help of the local ambulance service to transport participants to and from the venue would also be a consideration if classes were hospital-based. If classes were held in the community, a mini-bus service would be recommended. - Having venues closer to home may help with transportation issues or ease off the feeling of having to travel far. - A future study may benefit from having multiple Tai Chi venues, one in each town linked to the hospital Trust, possibly based at each town's hospital. - The involvement of the ward-based physiotherapists is recommended to help save the researcher's time and to avoid missing some patients.

Adaptation	Tai Chi programme, interviews	- Home practice resources were not used efficiently because they were deemed too basic. Instead, participants chose which exercises they wanted to do at home from memory, incorporating Tai Chi exercises into their everyday activities. - Some participants were unable to join the Tai Chi class straight away because they needed to adjust to being back at home. - Part of the inclusion criteria was changed because it was not feasible to use a range for the BBS. - During the identification process, asking the physiotherapists which patients were eligible to go home with community therapy was found to make identifying participants easier. - Frequency and duration were found to be acceptable, with some participants wanting longer. Classes were one hour in duration with a frequency of twice a week for 12 weeks. - It was difficult to pinpoint which week of the programme participants started to experience benefits without a mid-study assessment. Additionally, it would have been interesting to find out if participants still perceived any benefits, as well as observing any changes to their balance scores after the study had ended. - Some experimental group participants were reluctant to attend Tai Chi classes straight away. As a result, a six-week window was offered to allow participants to become adjusted at home following discharge.	- A future trial would benefit by including Tai Chi stepping as part of home practice. - Anybody going home with community therapy services should be eligible for a future study. - A future study is recommended to introduce the Tai Chi classes whilst participants are still on the stroke unit to encourage early commencement of the intervention. - In a future trial, involving the multi-disciplinary team to help identify participants would be beneficial. - A future study would benefit from extending the number of weeks to 24, so that participants may complete the programme but also have better and more sustained effects. - A six-week assessment, mid-way through the study is recommended to find out how soon changes are being made, as well as a six-month (and 12-month) follow-up to see if any improvements remain, get better or get worse.
Integration	Tai Chi programme, interviews	- Interviews and the Tai Chi programme helped gain insight into the changes in the	- A future study would benefit from introducing a 'catch up

		social lives of participants in relation to attendance. Such changes included medical appointments, inability to drive, stopping work, family commitments and holidays. The Tai Chi programme was useful in finding out that not everybody could attend set days throughout the week. - Significant others were encouraged to participate but not as part of the study. Some participants found this helpful, but others found it a hindrance. Some participants were not able to invite significant others but did not mind because they were used to doing things alone and did not want to bother their significant other.	day' or days to enable missed classes to be caught up, so that participants may participate in the full number of classes required. The future involvement of significant others may require further information given to the significant others regarding what is an what is not expected of them, so they are not felt to be hindering participants' progress, for example, leave the correcting to the instructor.
Expansion	Interviews, outcome measures	- It is feasible to conduct the TCAS study on a larger scale with success based on the data obtained from conducting the Tai Chi programme, outcome measures and interviews. - BAME groups (particularly South Asians), were not represented in the TCAS study due to non-engagement. The TCAS study was limited in terms of interpreting resources.	- Using places of worship and engaging with BAME community leaders and local organizations such as 'Touchstone' may increase recruitment rates and include these communities in exercise research.
Limited-efficacy testing	Outcome measures	- Although it cannot be definitely determined, the TCAS study has shown better insight into Tai Chi as a promising exercise in the recovery of stroke survivors in terms of improving balance and reducing falls. Interviews have shown that participants' balance has improved, along with confidence levels to perform ADLs without losing their balance. BBS scores also show the potential to improve balance in a future	- The number of fallers would be a more suitable primary outcome than number of falls. - A future study may want to consider collecting data on the number of falls and the BBS. - A future trial would benefit using the FES and GDS as secondary outcome measures in relation to the number of fallers.

		study, though they are insignificant in this feasibility study. - Fall rates as the primary outcome measure was not feasible to gain clinical meaningfulness due to the small numbers in the TCAS study.	- A multicentre study is recommended in future in order to be able to recruit large numbers needed for an RCT.

Chapter 8 – Summary, Conclusion and Recommendations

Stroke is a leading cause of disability (RCP, 2016) with increasing age associated with poorer outcomes (Seshadri et al., 2016). There are approximately 1.2 million stroke survivors in the UK (Stroke Association, 2018), posing an economic burden onto the NHS (Hisham & Bayraktutan, 2013). Additionally, it has been reported that 90 per cent of UK stroke survivors receive community therapy services (Stroke Association, 2018).
Due to stroke-related impairment, there is a high incidence of falling, reducing confidence in ADLs (RCP, 2016). Exercise programmes have been shown to reduce falling in the general population (Gillespie et al., 2012), with Tai Chi being recommended for those at high risk of falling (DH, 2011). This randomized controlled feasibility study sought to explore if Tai Chi as an early intervention is feasible among stroke survivors as an adjunct to community rehabilitation in the UK setting, and to determine the feasibility of conducting a randomized controlled trial among this population and setting. The current study provides data to inform potential future studies to explore the effectiveness of Tai Chi in reducing falls and improve balance among stroke survivors at the point of discharge receiving rehabilitation.

Participants for the current feasibility study were randomized into two groups: Tai Chi with usual care or usual care alone. Twenty-three participants were randomized, 14 into the experimental group (Tai Chi with usual community care) and 9 into the control group (usual community care alone). A bespoke 12-week Tai Chi programme, specifically for stroke survivors (which included two one-hour classes per week with home practice materials) was designed by the researcher and an experienced Tai Chi instructor for the experimental group with the intention of empowering stroke survivors to take control over their own rehabilitation at home. Primary outcomes were quantitative and included fall counts and the BBS to measure falls risk and balance. Secondary outcomes were the GDS for depression, the FES for fear of falling and the SF-12 for QoL and were completed by participants at baseline and 12 weeks. All fourteen participants in the experimental group consented to a 12-week interview to explore participants' perceptions and opinions about the intervention. Quantitative data was analysed using SPSS, whereas qualitative data was analysed using a framework analysis. Eight areas of focus of this feasibility study were addressed as proposed by Bowen et al. (2009): acceptability, demand, implementation, practicality, adaption, integration, expansion and limited-efficacy testing.

Acceptability

Tai Chi is an ancient Chinese exercise which is characterised by slow gentle movements which may be appealing to TCAS participants. Prior to the study, it was not known how stroke survivors would react to the TCAS programme and if participants would be happy with the home practice resources. It appears that this is one of the first studies to apply a modified Tai Chi exercise programme among stroke survivors at the point of discharge to inform a future RCT investigating its effects on balance and falls. Interviews showed that the TCAS programme was accepted and enjoyed by most participants; the intervention was adhered to by all fourteen experimental group participants, with two people choosing to continue being in the study by practising the prescribed intervention exercises at home.

Home practice has the potential to empower participants to take control of their own stroke recovery at home. Home-based exercises were practised by most participants who also perceived some benefit from practising at home. Although the home practice booklet and DVD were used by participants at the start of the study, many admitted to not using them once they had remembered what was taught in class, with the DVD not been used except by one participant. The simplicity of the exercises together with the ability to memorise easily may have contributed to the good adherence to home practice, as well as continued attendance. A professional home practice booklet and DVD with interactive menu is recommended for a future study which includes the whole TCAS programme which aims at different levels of ability.

Demand

Despite recruiting 56 participants, many randomized participants failed to actually enter the study due to changing their minds about participating. Although experimental group participants completed the study, some found the pace too slow, repetitive and basic for their level of impairment, leading them to request more challenging exercises. An end-goal seemed to be missing for some participants who wanted the Tai Chi instructor to demonstrate the full set of TCAS exercises at the beginning of the class. A future trial would, therefore, benefit from participants receiving this demonstration to allow for goal setting. Additionally, demonstration of the full programme of class exercises may also enable participants to monitor their own progress and motivate them to work towards their goal. Overall, the Tai Chi practise achieved by participants showed that the TCAS exercises were safe and doable by participants, with participants confirming this in the interviews. Further, the quantitative data shows that the TCAS programme has the potential to be beneficial for all ages.

Once the intervention had ended, some experimental group participants wanted to continue with Tai Chi and requested video clips as a reference tool for future home practice. Future participants would, therefore, benefit from a professionally made booklet and DVD containing the whole modified TCAS programme with the DVD including an interactive menu. For those who do not complete all the exercises shown in the demonstration, they may be given the opportunity to do so using the modified DVD.

An incentive of a £10 voucher was used on completion of the study. Participants were indifferent to this, with some offering to give it back. Feedback from members of the Stroke Association included the suggestion of a higher sum than £10. Thus, a future study may want to consider more than £10 as an incentive to complete the study.

Implementation

The TCAS programme explored to what extent and in what manner the intervention was able to be fully implemented. Overall, participants were willing to be randomized; only two potential participants wanted to choose their group so were no longer eligible for the study.

As far as the intervention is concerned, the programme was implemented according to the protocol but not all exercises prescribed within the programme were delivered; participants did not have enough time to complete all prescribed exercises. An extension of the study duration would enable participants to complete all exercises in the study.

Overall, delivering the programme was successful in terms of the Tai Chi instructor's commitment to continue to deliver the TCAS programme until the end of the study period. The extension for the recruitment period may have caused a potential problem in this respect because the instructor may not have been happy to be involved in the study for longer than was originally agreed. However, the programme was disrupted on two occasions when the instructor missed one week to go on holiday and the researcher missed one day due to sickness. Nevertheless, the Tai Chi instructor's absence did not prevent participants continuing with their practice; participants were encouraged to come to the Tai Chi venue nevertheless and practise the home practice exercises with the researcher. On the day the researcher was absent, participants practised at home. In view of any potential disruption to the running of the classes, a future trial would benefit from a cover instructor(s).

In this study, approximately half of those approached during the recruitment process were not interested in taking part, with many citing travel issues and not needing the intervention as reasons for non-participation. As well as losing potential participants due to disinterest, many potential participants were missed because recruitment took place on three hospital sites. Thus, it was extremely difficult, if not impossible, for one researcher to get in touch with them all. A future RCT would be multi-centre in nature and would face this latter issue with only one researcher. Therefore, multiple researchers and Tai Chi instructors would be essential to the successful recruitment of an adequate sample size for a larger trial. In such a future large-scale study, organizations such as the Stroke Association are recommended to become involved in order to increase recruitment rates. Recruitment rates may be improved with the help of the Stroke Association because stroke survivors would feel confident that the study is being backed by a trustworthy organisation. Another recruitment strategy to adopt in a future trial would be to include stroke patients being discharged to care homes who would otherwise be eligible for the study. Collaboration with care homes may result in delivering the TCAS programme in the care homes.

When recruiting from hospital, it is recommended that the intervention starts whilst participants are still inpatients to encourage ongoing participation following discharge. Additionally, delivering the start of the programme as an inpatient may also encourage other patients to take part because current participants are able to tell them of their experiences. A further recommendation to aid recruitment is to adopt a wait list design where the control group is offered the intervention at the end of the study. This way, participants who decline participation because they wanted to be in the Tai Chi group are more likely to agree to take part. Additionally, potential participants may be informed about the potential of Tai Chi to prevent stroke and reduce stroke risk as found by some researchers (Lauche et al., 2017), as well as reminding them of the benefit to fellow stroke survivors.

It was difficult to establish the exact length of time practiced from the home practice diary because it only required circling 'yes' or 'no' if more than 15 minutes was practised. Many participants reported practising at least 15 minutes but did not mention how much longer they practised for. This would have been interesting to find out because it may be that the minimum duration of home practise could be extended in a future trial. As well as omitting the total number of minutes for home practice, the type of exercises practised by participants was not included in the home practice diary. Interviews showed that the Tai Chi walking was the most popular exercise chosen for home practice. Participants were not encouraged to add this information to avoid over-burdening. Thus, more specific guidance on what to write in the comments section of the home practice diary is recommended for a future trial, such as exact number of minutes and type of exercises practised.

To encourage retention and obtain data more promptly, weekly home visits among the control group may be considered for a future trial. Alternatively, a simpler solution may be to use a text messaging service to give participants daily reminders to return the diaries and questionnaires.

Practicality

The current feasibility study sought to explore any potential obstacles for conducting the study, such as the inability to obtain funding to pay the Tai Chi instructor, unavailability of a suitable venue, lack of commitment on the part of the Tai Chi instructor to complete the study, and unsuitability of the Tai Chi exercises. Another potential obstacle was being unable to find transport for participants. Fortunately, all of these practicality issues were resolved by finding funding from two sources; the Malcolm Tillotson Fund based at the University of Huddersfield and West Riding Masonic Charities. Overall, the delivery of the intervention was inexpensive, but was costly regards to time.

Finding a suitable venue for the Tai Chi classes was a challenge. This challenge was resolved through discussion with the spinal injury physiotherapy department based at Pinderfields Hospital who obtained approval for the researcher to carry out the intervention in the department's sports hall. Half of the experimental group did not have transport to get to the sport's hall and without the help of the YAS, would not have been able to attend. Participants were required to wait up to two hours for transport, a requirement which could have deterred them from attending the classes. Despite the long wait for transport, participants perceived the intervention to be beneficial and, therefore, worth the wait. Indeed, participants committed the whole day to the study and accepted the waiting times as part of their 'day out'. A future trial would benefit from using the ambulance service if the intervention is hospital-based on the grounds of the intervention being part of the participant's stroke recovery. Otherwise, it is recommended to hire one mini-bus per intervention site.

Although all experimental participants completed the study, many participants did not complete the total number of Tai Chi classes (24) over a 12-week period due to family commitments, appointments, etc. All participants found 12 weeks to be suitable, with some participants wanting a longer duration. Despite the frequency of classes being twice a week, most participants did not attend both weekly classes. Classes were on set days (Tuesdays and Thursdays), making it difficult to attend for those with commitments on those days. A future trial would benefit by offering catch-up days for those who miss classes.

Despite the TCAS exercises being safe for stroke survivors, the recommended 12 to two (participant to supervisor) ratio was regarded as being unsafe by both the researcher and Tai Chi instructor. Hence, a ratio of six to two (participant to instructor) is recommended in a future trial.

<u>Adaptation</u>

Deviations from the protocol were noted, along with modifications needed to the Tai Chi exercises and home practice resources. Due to slow recruitment rates, changes to the inclusion criteria were made, such as altering the BBS score criterion. Thus, the BBS eligibility range changed to anybody eligible for community therapy services. In a future trial, it is recommended not to have a BBS range as an inclusion criterion because it makes sense that all stroke survivors who are eligible for stroke community therapy would also be suitable for TCAS. The slow recruitment rate led to the application of a four-month extension of the recruitment period, which was obtained to increase the number of participants in the study.

As previously mentioned, participants took it upon themselves to adapt the home practice exercises by choosing for themselves exercises they deemed to be most beneficial. Choosing their own home practice routine may have contributed to the high adherence to home practice.

It was expected that participants attended classes at least one week following discharge. Due to many participants not being able to attend all classes for various reasons, a window of six weeks was offered to give participants time to adjust to being back at home before starting the intervention. This enabled those who consented to be still eligible and improve retention rates. Strategies used to encourage retention in the experimental group were offering encouragement and personal attention.

Originally, the physiotherapists were not involved in the identification of eligible participants. During the recruitment process, a strategy was adopted by the researcher which included asking the ward-based physiotherapists which patients were eligible for community therapy services. This strategy saved the researcher’s time in identifying eligible stroke survivors and avoided missing some participants. Involving the physiotherapists in the study is recommended in terms of recruitment, venue and instructing in a multicentre study.

A future study would be advised to conduct mid-intervention (six weeks or longer) and post-intervention (six months and twelve months or longer) assessments to establish at what point improvements are made, if any, and if these improvements last after the study has ended. An additional recommendation would be adapting the study duration of 12 weeks to a duration of 24 weeks or longer with a frequency of twice per week, along with additional catch-up classes.

Integration

Significant others' involvement in the classes, as part of the TCAS study, enabled stroke survivors to practice Tai Chi with their family members at home, thus enabling the involvement of significant others with their rehabilitation. Practising the TCAS programme at home empowered participants to take control of their rehabilitation, making rehabilitation enjoyable and part of their daily routine. Most participants incorporated the movements and exercises into their ADLS, such as walking from room to room using the stepping taught in class, watching TV and making a cup of tea. Findings suggest that the TCAS programme may be suitable as a rehabilitation exercise which participants can engage in with significant others following discharge from community therapy services.

The TCAS study found that although significant others are encouraged to attend Tai Chi classes, guidelines to what their role is within the study are needed. These guidelines would avoid unnecessary interference and make the significant other aware of their role in the recovery of their family member.

Expansion

BAME groups were under-represented in the TCAS study due to the limited resources of the researcher. It is recommended that in order to involve BAME groups in future trials, collaborating with community leaders and organisations such as Touchstone should be encouraged, as well as suggesting places of worship being venues for TCAS on a therapeutic level. Further, BAME groups may be more inclined to participate if materials were in the target language of the individual. Additionally, to help bridge the language barrier gap, interpreters and translators would be a useful asset to a future trial.

Limited-efficacy testing

Adequacy of the outcome measures was examined in the current study. Although falls as an outcome measure was not useful in the current feasibility study, it may be in a larger longer study. Alternatively, the number of fallers may be a better choice because most fallers in the TCAS study experienced multiple falls. However, the BBS has shown to be a useful potential primary outcome measure due to being sensitive to changes over time, as well as being a falls predictor (Li et al., 2004). Overall, the number of fallers may be optimal for clinical and economic reasons. A future trial should collect data on falls, fallers and the BBS, but the number of fallers is recommended as the primary outcome measure. A future trial may want to consider the effect of fear of falling and depression in relation to fallers. In which case, the FES would be a useful secondary outcome measure for fear of falling with the GDS useful to measure depression over time.

Limitations of the study

The present study has some limitations. The current study is a partial fulfilment of a PhD. Therefore, there were time restrictions and lack of resources, contributing to the failure to achieve the target recruitment rate. As a result of limited time and resources, the sample size of this study was small, unable to justify running hypothesis testing statistical procedures.

Due to the small sample size, results obtained from the population used may not be representative of the true local stroke population. Additionally, the lack of participants from local ethnic communities means that these populations are unrepresented in this study.

Another limitation of this study was that there was little room among some participants to detect any change because there were some participants who were classed as being a low falls risk with a high level of physical function at baseline. Although investigating any effects of Tai Chi was not the aim of the current study, having little room for an effect is an important consideration in a future RCT, particularly because some participants were referred to community therapy services and were not seen because the community therapists deemed them not to need input following the first home visit. If a future trial wanted to be pragmatic, and inclusive to test Tai Chi on a wide population of stroke survivors, it needs to be accepted that there will be some participants with little room to show large improvements on the primary outcome measure (BBS) – a possible solution is to recognise that that would impact on the sample size by increasing it.

There was a lack of mid-study testing in this study to establish at what point stroke survivors start to show any change. For example, by having a mid-study follow-up assessment, it may be that only one Tai Chi class per week was needed. Alternatively, participants who only attended classes once a week may have perceived less benefit than those who attended classes twice a week. Unfortunately, the study intended to carry out a six-month follow-up but due to time restrictions imposed, this was not completed. This study would have benefited from exploring to what extent TCAS participants continued to practise the home practice, and if any perceived or actual benefit was maintained.

In view of the limitations presented in this study, more large-scale, multi-centre RCTs are recommended using the modified TCAS programme among stroke survivors at the point of discharge. Future studies would benefit from introducing mid-intervention assessments on outcome measures, as well long-term follow-ups to assess the maintenance of any effect and continued practice of the intervention.

To conclude, results of this study support the idea that a bespoke 12-week Tai Chi programme for stroke survivors is feasible as an adjunct to rehabilitation. Further, participants are empowered to take control over their own recovery from stroke at home. The primary outcome should be the number of fallers, with data collected on the number of falls and the BBS. Secondary outcomes should be the FES to investigate the effect of fear of falling and the GDS to explore the effect of depression on the number of fallers. With participants wanting to continue for longer than 12 weeks, a future trial may want to consider extending the intervention duration to 24 weeks or longer. Moreover, extending the intervention to 24 weeks or more may lead to better or more sustained effects. To encourage the practice of Tai Chi once the study ends, more challenging exercises should be included in a professionally made home practice booklet and accompanying DVD. To help recruitment, a wait-list design is recommended, as well as offering the first class(es) in hospital before participants are discharged.

Table to show the literature search for the periods between 2014 and 2019.

Date Searched	Database	Keywords	Inclusion/Exclusion Criteria	Articles Retrieved	Articles Relevant	Authors
11/10/14	CINAHL	“tai chi” OR “taiji” AND stroke	Incl: peer-reviewed, foreign, abstract, linked full text	1	1	Taylor-Piliae et al. (2014)
11/10/14	CINAHL	“tai chi” OR “taiji” AND stroke AND balance AND fall*	Inc: peer-reviewed, foreign, linked full text, abstract	20	1	Faber et al. (2006)
11/10/14	CINAHL	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND “chi gong” OR “qi gong” OR “chi kung” AND stroke	Incl: peer-reviewed, foreign, linked full text, abstract	1	1	Taylor-Piliae et al. (2014)
11/10/14	CINAHL	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND “chi gong” OR “qi gong” OR “chi kung” AND balance AND fall*	Incl: peer-reviewed, abstract, linked full text, foreign	8	0	
12/10/14	CINAHL	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND effectiveness AND “fall reduction”	Incl: linked full text, abstract, English language, peer-reviewed, research articles	83	2	Faber et al. (2006); Taylor-Piliae et al. (2014)
14/10/14	CINAHL	“tai chi” AND slip* OR trip*	No filters	2	0	
27/10/14	CINAHL	“tai chi” AND neurorehab*	none	0	0	
27/10/14	CINAHL	“tai chi” AND neuro*	none	65	1	Au-Yeung et al. (2009)

11/10/14	PubMed	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND stroke	Incl: abstract, full text	16	6	Au-Yeung et al. (2009); Ding (2012); Hart et al. (2004); Li et al. (2012) Taylor-Piliae and Coull (2012); Taylor-Piliae et al. (2014)
11/10/14	PubMed	“tai chi” OR “taiji” AND stroke	Incl: abstract, full text	17	5	Au-Yeung et al. (2009); Hart et al. (2004); Taylor-Piliae et al. (2014); Tousignant et al. (2014); Li et al. (2012)
11/10/14	PubMed	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND stroke AND balance AND fall*	Incl: abstract, full text	3	2	Li et al (2012); Taylor-Piliae et al. (2014)
11/10/14	PubMed	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND “chi gong” OR “qi gong” OR “chi kung” AND balance AND fall*	Incl: abstract, full text	93	8	Faber et al. (2006); Li et al. (2004); Li et al. (2012); Maciaszek and Osinski (2012); Taylor et al. (2011); Taylor-Piliae et al. (2014); Tousignant et al. (2013); Wolf et al. (2003)
11/10/14	PubMed	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND “chi	Incl: abstract, full text	6	0	

		gong" OR "qi gong" OR "chi kung" AND balance AND fall* AND stroke				
11/10/14	PubMed	"tai chi" OR "tai chi chuan" OR "taiji" OR "taiji chuan" AND "chi gong" OR "qi gong" OR "chi kung" AND balance AND fall*	Incl: abstract, full text	6	0	
12/10/14	PubMed	"tai chi" OR "tai chi chuan" OR "taiji" OR "taiji chuan" AND "motor functions"	all	1	0	
12/01/14	PubMed	"tai chi" OR "tai chi chuan" OR "taiji" OR "taiji chuan" AND "falls reduction"	all	3	0	
12/10/14	PubMed	"tai chi" OR "tai chi chuan" OR "taiji" OR "taiji chuan" AND "reducing falls"	all	12	1	Taylor et al. (2012)
14/10/14	PubMed	"tai chi" AND cerebral	none	20	1	Wang et al. (2010)
14/10/14	PubMed	"tai chi" AND post-stroke	none	2	2	Taylor-Piliae et al. (2011); Tousignant et al. (2014)
14/10/14	PubMed	"tai chi" AND infarct*	none	6	0	
14/10/14	PubMed	"tai chi" AND slip* OR trip*	none	7	0	
27/10/14	PubMed	"tai chi" AND neurorehab*	none	3	1	Au-Yeung et al. (2009)
27/10/14	PubMed	"tai chi" AND neuro*	none	3	0	
12/10/14	Medline	"tai chi" AND stroke	all	17	6	Au-Yeung et al. (2009);

						Ding (2012); Hart et al. (2004); Taylor-Piliae and Coull (2011); Tousignant et al. (2014)
12/10/12	Medline	"tai chi" AND balance AND falls	Linked full text, abstract,	29	1	Taylor-Piliae et al. (2014)
14/10/14	Medline	"tai chi" AND post-stroke	none	2	2	Taylor-Piliae and Coull (2012); Tousignant et al. (2014)
14/10/14	Medline	"tai chi" AND infarct*	none	6	0	
14/10/14	Medline	"tai chi" AND slip* OR trip*	none	1	0	
27/10/14	Medline	"tai chi" AND neurorehab*	none	1	0	
27/10/14	Medline	"tai chi" AND neuro*	none	18	0	
11/10/14	Cochrane Library	"tai chi" OR "tai chi chuan" OR "taiji" OR "taiji chuan" AND balance AND fall*	all	1	0	
11/10/14	Cochrane Library	"tai chi" AND stroke	Cochrane reviews	2	0	
11/10/14	Cochrane Library	"tai chi" AND balance AND fall*	Cochrane reviews	2	0	
14/10/14	Cochrane Library	"tai chi" cerebral	all	1	1	Wang et al. (2010)
14/10/14	Cochrane Library	"tai chi" AND infarct*	all	2		
14/10/14	Cochrane Library	"tai chi" AND post-stroke	all	1	1	Tousignant et al. (2014)
14/10/14	Cochrane Library	"tai chi" AND stroke	Incl: peer-reviewed	10	2	Hart et al. (2004); Taylor-Piliae et al. (2014)
14/10/14	Cochrane Library	"tai chi" AND stroke AND falls AND balance	Incl: peer-reviewed	1	0	

12/10/14	PEDro	"tai chi" AND stroke		6	6	Au-Yeung et al. (2009); Ding (2012); Hart et al. (2004); Li et al. (2012); Taylor-Piliae and Coull (2011); Taylor-Piliae et al. (2014)
12/10/14	PEDro	"tai chi" AND balance AND falls		63	6	Gao et al. (2014); Li et al. (2004); Ni et al. (2014); Maciaszek and Osinski (2010); Taylor et al. (2012); Wolf et al. (2003);
14/10/14	PEDro	"tai chi" AND cerebral	none	1	1	Wang et al. (2010)
14/10/14	PEDro	"tai chi" AND post-stroke	none	2	2	Taylor-Piliae and Coull (2012); Taylor-Piliae et al. (2014)
14/10/14	PEDro	"tai chi" AND infarct*	none	1	0	
14/10/14	PEDro	"tai chi" AND slip* OR trip*	none	2	0	
27/10/14	PEDro	"tai chi" AND neurorehab*	none	1	1	Au-Yeung et al. (2009)
27/10/14	PEDro	"tai chi" AND neuro*	none	42	11	Au-Yeung et al. (2009); Choi et al. (2013); Ding (2012); Gao et al. (2014); Hackney and Earhart (2008); Hart et al. (2004); Jimenez-Martin et al.

						(2013); Ni et al. (2014); Taylor-Piliae et al. (2014); Toh et al. (2013); Wang et al. (2010)
12/10/14	ScienceDirect	“tai chi” OR “tai chi chuan” OR “taiji” OR “taiji chuan” AND balance AND falls	Filters: tai chi/ fall prevention (topic); journal (content type)	183	2	Jimenez-Martin et al. (2013); Taylor-Piliae et al. (2014)
27/10/14	ScienceDirect	“tai chi” AND neurorehab*	Journal (content type), filters: tai chi	14	2	Hackney and Earhart (2008); Taylor-Piliae et al. (2014);
27/10/14	ScienceDirect	“tai chi” AND neuro*	Journal (content type), filters: tai chi	19	2	Ni et al. (2014); Taylor-Piliae et al. (2014)
27/10/14	ScienceDirect	“tai chi” AND neuro*	Journal (content type), filters: tai chi, 2012, 2013	35	1	Jimenez-Martin et al. (2013)
14/10/14	PsycInfo	“tai chi” AND stroke	Incl: peer-reviewed journals, aged 65+, all languages, all populations, systematic reviews, qualitative/quantitative studies, meta-analyses, empirical study, interview, literature review, follow up study, longitudinal study	4	4	Au-Yeung et al. (2009); Li et al. (2012); Taylor-Piliae et al. (2012); Yoshinaga and Cai (2013)
14/10/14	PsycInfo	“tai chi” AND stroke AND balance AND fall*	Incl: peer-reviewed journals, aged 65+, all languages, all populations, systematic reviews,	1	1	Li et al. (2012)

			qualitative/quantitative studies, meta-analyses, empirical study, interview, literature review, follow up study, longitudinal study			
14/10/14	PsycInfo	"tai chi" AND balance AND fall*	Incl: peer-reviewed journals, aged 65+, all languages, all populations, systematic reviews, qualitative/quantitative studies, meta-analyses, empirical study, interview, literature review, follow up study, longitudinal study	27	3	Lee, Pittler and Ernst (2007); Fetherston and Wei (2010); Huang et al. (2010); Hakim et al. (2010); Li et al. (2012)
14/10/14	PsycInfo	"tai chi" AND cerebral	Peer-reviewed journals	3	0	
14/10/14	PsycInfo	"tai chi" AND post-stroke	Peer-reviewed journals	1	1	Taylor-Piliae et al. (2011)
27/10/14	PsycInfo	"tai chi" AND neurorehab*	Peer-reviewed journals	1	1	Au-Yeung et al. (2009)
27/10/14	PsycInfo	"tai chi" AND neuro*	Peer-reviewed journals	36	4	Au-Yeung et al. (2009); Li et al. (2012); Taylor-Piliae and Coull (2011); Wang et al (2010);
14/10/14	Zetoc	"tai chi" AND stroke	journals	7	5	Ding (2012); Hart et al. (2004); Taylor-Piliae and Coull (2011); Taylor-Piliae et al.

						(2014); Tousignant et al. (2014)
14/10/14	Zetoc	“tai chi” AND balance AND fall*	journals	63	7	Gao et al. (2014); Huang et al. (2010); Ni et al. (2014); Logghe et al. (2009); Tousignant et al. (2013); Wolf et al. (2003)
12/01/15	CINAHL	“tai chi” AND “Parkinson’s disease”		15	1	Gao et al. (2014)
12/01/15	PEDro	“tai chi” AND “Parkinson’s disease”		12	3	Choi et al. (2013); Gao et al. (2014); Ni et al. (2014); Toh et al. (2013)
12/01/15	Medline	“tai chi” AND “Parkinson’s disease”		29	3	Choi et al. (2013); Gao et al. (2014); Ni et al. (2014)
12/01/15	PubMed	“tai chi” AND Parkinson’s disease”		29	2	Choi et al. (2013); Gao et al. (2014)
12/01/15	PsycInfo	“tai chi” AND “Parkinson’s disease”		11	1	Gao et al. (2014)
12/01/15	Cochrane Library	“tai chi” AND “Parkinson’s disease”		1	0	
12/01/15	Google Scholar	“tai chi” AND “Parkinson’s disease”		Too many	0	
12/01/15	CINAHL	“tai chi” AND “multiple sclerosis”		2,050		
12/01/15	CINAHL	“tai chi” AND “multiple sclerosis” AND fall*		41	0	
12/01/15	PEDro	“tai chi” AND “multiple sclerosis” OR “MS”		1	0	
12/01/15	Medline	“tai chi” AND “multiple sclerosis”		0	0	

12/01/15	PubMed	"tai chi" AND "multiple sclerosis"		8	1	Burschka et al. (2014)
12/01/15	PsycInfo	"tai chi" AND "multiple sclerosis"		2	0	
12/01/15	Google Scholar	"tai chi" AND "multiple sclerosis"		1	0	
12/01/15	Cochrane Library	"tai chi" AND "multiple sclerosis"		1	0	
12/01/15	CINAHL	"tai chi" AND neurological		125	3	Faber et al. (2006); Ni et al. (2014); Taylor-Piliae et al. (2014)
12/01/15	PEDro	"tai chi" AND neuro*		44	6	Gao et al. (2014); Hackney and Earhart (2008); Hart et al. (2004); Jimenez-Martin et al. (2013); Taylor-Piliae et al. (2014)
12/01/15	PEDro	"tai chi" AND neurological		5	0	
12/01/15	Medline	"tai chi" AND neuro*		17	1	Ni et al. (2014)
12/01/15	Medline	"tai chi" AND neurological Subheading 'balance'		21	3	Hackney and Earhart (2008); Ni et al. (2014); Taylor-Piliae et al. (2014)
12/01/15	PubMed	"tai chi" AND neuro*		1	0	
12/01/15	PubMed	"tai chi" AND neurological		9	2	Burschka et al. (2014); Wang et al. (2010)
12/01/15	PsycInfo	"tai chi" AND neurological		19	2	Taylor-Piliae and Coull (2011); Wang et al. (2010)

12/01/15	Cochrane Library	"tai chi" AND neurological		4	0	
15/01/15	PubMed	"tai chi" AND depression		79	2	Burschka et al. (2014); Wolf et al. (2003)
15/01/15	PsycInfo	"tai chi" AND depression		58	1	Wang et al. (2010)
15/01/15	Medline	"tai chi" AND depression	Linked full text	20	1	Taylor-Piliae et al. (2014)
15/01/15	CINAHL	"tai chi" AND depression	Linked full text	17	1	Taylor-Piliae et al. (2014)
15/01/15	CINAHL	"tai chi" AND depression	Abstract available	52	1	Wolf et al. (2003)
15/01/15	Cochrane Library	"tai chi" AND depression		7	0	
15/01/15	PEDro	"tai chi" AND depression		38	2	Taylor-Piliae et al. (2014); Wang et al. (2010)
15/01/15	CINAHL	"tai chi" AND adherence		30	2	Taylor-Piliae et al. (2014); Wolf et al. (2003)
15/01/15	PubMed	"tai chi" AND adherence		40	2	Taylor-Piliae and Coull (2011); Taylor-Piliae et al (2014)
23/02/15	CINAHL	stroke AND rehab* AND exercise	linked full text, abstract, academic journals	272	1	Taylor-Piliae et al. (2014)
23/02/15	CINAHL	stroke AND (self-manage* OR self-care)	linked full text, abstract, limit to: academia, source type: journals	48	0	

23/02/15	Medline	stroke AND rehab* AND exercise	linked full text, abstract, academic journals	553	1	Taylor-Piliae et al. (2014)
23/02/15	Medline	stroke AND rehab* AND exercise AND "lower limb"	linked full text, abstract, academic journals	30	0	
23/02/15	Medline	stroke AND (self-manage* OR self-care) AND "lower limb"	abstract, full text, 5 years, humans	20	0	
23/02/15	PubMed	stroke AND (self-manage* OR self-care)		59	0	
23/02/15	PsycInfo	stroke AND rehab* AND exercise		355	0	
23/02/15	PsycInfo	stroke AND rehab* AND exercise AND "lower limb"		13	1	Au-Yeung et al. (2004)
23/02/15	PsycInfo	stroke AND (self-manage* OR self-care)		219	0	
23/02/15	Cochrane	stroke AND exercise		41	0	
23/02/15	Cochrane	stroke AND (self-manage* OR self-care)		6	0	
23/02/15	CINAHL Medline, PubMed, PsycInfo	stroke AND "tai chi"		2 added new	2	Kim et al. (2015); Zhang et al. (2014)
17/03/15	CINAHL	"tai chi" AND "blood pressure"		70	0	
17/03/15	CINAHL	"tai chi" AND sleep		50	0	
17/03/15	Medline	"tai chi" AND "blood pressure"		70	0	
17/03/15	Medline	"tai chi" AND sleep		49	1	Wang et al. (2010)

17/03/15	PubMed	"tai chi" AND "blood pressure"		70	2	Zheng et al. (2015); Yeh et al. (2008)
17/03/15	PubMed	"tai chi" AND sleep		50	0	
17/03/15	PsycInfo	"tai chi" AND "blood pressure"		24	0	
17/03/15	PsychInfo	"tai chi" AND sleep		25	0	
17/03/15	Cochrane	"tai chi" AND "blood pressure"		2	0	
17/03/15	Cochrane	"tai chi" AND sleep		3	0	

Date of Search	Database	Keywords Used	N° References Found	Filters Used	N° References Found	N° Relevant	Authors of Relevant Articles
13/11/17	Medline	(stroke OR balance OR fall*) AND “tai chi”	451	Linked Free Text	105	1	Ćwiękała-Lewis, Galleck and Taylor-Piliae (2017)
19/12/17	Medline	(“quality of life” OR QoL) NOT (stroke OR balance OR fall*) AND “tai chi”	216	Linked Free Text	51	0	
15/11/17	PubMed	(stroke OR balance OR fall*) AND “tai chi”	434	Linked Full Text	123	2	Hwang et al. (2016); Pan, Kairy, Corriveau and Tousignant (2017)
19/12/17	PubMed	(“quality of life” OR QoL) NOT (stroke OR balance OR fall*) AND “tai chi”	216	Linked Full Text	50	1	Tao et al. (2016)
15/11/17	BioMedCentral	(stroke OR balance OR fall*) AND “tai chi”	259	n/a	259	0	
15/11/17	PEDro	stroke AND “tai chi”	11	n/a	11	0	
15/11/17	PEDro	fall*AND “tai chi” f	114	n/a	114	1	
15/11/17	PEDro	balance AND “tai chi”	144	n/a	144	1	Huang and Liu (2015)
19/12/17	PEDro	“tai chi” AND “quality of life”	112	n/a	112	4	Savaranakumar et al. (2014); Tao et al. (2015); Yeh, Chan, Wayne and Conboy (2016)
15/11/17	Cochrane	(stroke OR balance OR fall*) AND “tai chi”	12	n/a	12	0	
15/11/17	PsycInfo	(stroke OR balance OR fall*	15	n/a	15	0	

		OR “quality of life) AND “tai chi”					
19/12/17	PsycInfo	“tai chi2 AND fall*	80	n/a	80	1	Lomas-Vega et al. (2017)
19/12/17	PEDro	“tai chi” AND “quality of life”	112	n/a	112	3	Savavanakumar et al. (2014); Tao et al. (2015); Yeh, Chan, Wayne and Conboy (2016)

Exclusion Criteria

- If Tai Chi and falls, stroke or balance are not in the title, the abstract was read
- Not elderly with a balance deficit
- Not healthy elderly
- Not young or middle aged focused
- Not single sex
- Not comparing Tai Chi with other form of exercise
- Not foreign language
- Unavailable
- Not elderly with cognitive issues

Date of search	Database	Keywords	N° found	N° relevant	N° repeated	N° unavailable	Total n°	Authors
01/03/17	PsycINFO	"tai chi" AND fall*	88	5	1	0	38	Gao et al. (2014); Hain et al. (1999); Hakim et al. (2010); Huang et al. (2010); Li, Fisher, Harmer & McAuley (2004); Logghe et al. (2009); Tousignant et al. (2013)
01/03/17	PEDro	"tai chi" AND fall*	107	2	3	0	83	del-Pino-Casado, Obrero-Gaitan & Comas-Vega (2016); Faber et al. (2006)
04/03/17	PubMed	"tai chi" AND fall*	161	0	64	0	37	

Date	**Database**	**Key Words**	**Articles Retrieved**	**Articles Relevant**	**Authors (not repeated)**
16/09/18	Summon	"tai chi" AND stroke	2000 (peer reviewed, articles only=506)	12 (2 protocols, one about sleep, two at risk of stroke)	Chan et al. (2017); Chan and Tsang. (2018); Gallant et al. (2017); Lauche et al. (2017); Li et al. (2017); Li et al. (2018); Lyu et al. (2018); Norouzian et al. (2017); Wu et al. (2018); Xie et al. (2018); Xu et al. (2017); Yang et al. (2018); Zhang et al. (2015)

Date of Search	**Database**	**Keywords Used**	**N° References Found**	**Filters Used**	**N° Relevant**	**N° Repeats**	**N° unavailable**	**Total N° Included**	**Authors of Relevant Articles**
23/05/19	Medline	"tai chi" AND cerebral	6		4	4		0	0
23/05/19	CINAHL	"tai chi" AND stroke	40		17	15	2	0	0
23/05/19	PEDro	"tai chi" AND stroke	22		14	12	1	1	Chen (2018)
23/05/19	PubMed	"tai chi" AND cerebral	69		1	1	0	0	0
23/05/19	PsycINF0	"tai chi" AND cerebral	4		1	1	0	0	0

23/05/ 19	Summon	"tai chi" AND cerebral	861		57	57	0	0	0
23/05/ 19	PubMed	"tai cji" AND stroke	57		27	24	1	4	García-Rudolph et al. (2019); Yang et al. (2018); Zheng et al. (2019)
23/05/ 19	Medline	"tai chi" AND stroke	57		26	18	1	7	Lyu et al. (2018); Wahbeh et al. (2008); Winser et al. (2018); Zhang et al. (2016); Zheng et al. (2017); Zhong et al. (2019); Zou et al. (2018)
03/07/ 19	PubMed	("tai chi chuan" OR taiji) OR ("t'ai chi" AND stroke OR infarct)	60		26	26	0	0	0
03/07/ 19	PsycInfo	("tai chi chuan" OR taiji) OR ("t'ai chi" AND stroke OR infarct)	0		0	0	0	0	0
03/07/ 10	Medline	("tai chi chuan" OR taiji) OR ("t'ai chi" AND stroke OR infarct)	14		3	3	0	0	0
03/07/ 19	CINAHL	("tai chi chuan" OR taiji) OR ("t'ai chi"	12		3	1	0	2	Kressig (2001); Lan et al. (2013)

		AND stroke OR infarct)							
03/07/19	PubMed	("tai chi" OR "t'ai chi" ORtaiji) AND "quality of life"	54		0	0	0	0	0
03/07/19	CINAHL, PsycInfo, PEDro	("tai chi chuan" OR taiji) OR ("t'ai chi" AND stroke OR infarct)	0	Linked full text Academic journals	0	0	0	0	0
03/07/19	Medline	("tai chi chuan" OR taiji) OR ("t'ai chi" AND stroke OR infarct)	88		2	0	0	2	Liao and Tan (2019); Tajik et al. (2018)
03/07/19	CINAHL	("tai chi" OR "t'ai chi" OR taiji") AND balance	64		0	0	0	0	0
03/07/19	Medline	("tai chi" OR "t'ai chi" OR taiji") AND balance	37		2	2	0	0	0
03/07/19	PubMed	("tai chi" OR "t'ai chi" OR taiji") AND balance	48	Last 5 years Ful text	9	7	0	3	Li et al. (2018); Liu et al., (2019); Wu et al. (2018)

03/05/19	PEDro	("tai chi" OR "t'ai chi" OR taiji") AND balance	0		0	0	0	0	0
03/05/19	PsycInfo	("tai chi" OR "t'ai chi" OR taiji") AND balance	26		1	1	0	0	0
03/05/19	CINAHL	("tai chi" OR "t'ai chi" OR taiji") AND fall*	238		2	1	0	0	0
03/05/19	Medline	("tai chi" OR "t'ai chi" OR taiji") AND fall*	67		2	1	0	1	Hosseini et al. (2018)
03/05/19	PubMed	("tai chi" OR "t'ai chi" OR taiji") AND fall*	227		6	4	0	1	Liu et al. (2019)
03/05/19	PsycInfo	("tai chi" OR "t'ai chi" OR taiji") AND fall*	16		6	3	2	1	Huang et al. (2010)
03/05/19	PEDro	("tai chi" OR "t'ai chi" OR taiji") AND fall*	132		2	0	2	0	0

07/06/ 19	Athens database: Journal 'Stroke'	"tai chi"	5		1	0	1	0	0
07/06/ 19	Athens database: All Sage journals	"tai chi" AND stroke	285		4	0	4	0	0
07/06/ 19	Athens database: Hindawi journals	"tai chi" AND stroke	62		1	0	0	1	Chan and Tsang (2017)
07/06/ 19	Athens database: Journal of Stroke	"tai chi"	890		34	34	0	0	0

<u>Tables to describe literature retrieved which include Tai Chi and stroke (meta-analyses)</u>

Table 1 description of literature retrieved with search terms Tai Chi and stroke (meta-analysis)

2017 Li, Y., Zhang, Y., Cui, C., Liu, Y., Lei, M., Liu, T., Meng, L., & Jin, C.	The effect of Tai Chi exercise on motor function and sleep quality in patients with stroke: a meta-analysis
<u>Description:</u> Tai Chi and stroke.	➢ <u>Background</u>: Globally, approximately 15m people have a stroke each year, being the first leading cause of death in China. Prevalence of stroke continues to increase. Exercise can help with disability caused by stroke, in particular, Tai Chi due to its slow relaxing movements. ➢ <u>Participants:</u> 18 community-dwelling first-stroke survivors, aged 45-64, randomly divided into 2 matched groups of 9 participants each (16 men/ 2 women). Ten participants had right hemiparesis, eight had left hemiparesis. Participants were 27 months after stroke onset. Participants identified from records and examined by a physician. ➢ 2 independent reviewers. ➢ 17 RCTs analysed, 9 studies used to compare balance function between Tai Chi and control group. ➢ <u>Databases searched:</u> PubMed, Web of Science, Cochrane Library, EMBASE, AMED, CBM, CNKI, Wanfang and VIP. ➢ <u>Inclusion criteria</u>: English or Chinese language. Had a stroke less than 6 months.

	➢ Intervention: included groups with conventional therapy, including usual care) ➢ Data analysis: Chi-square tests, means. ➢ Outcome measures: BBS, TUG, Ability of daily activities, Barthel Index, Modified Barthel Index, Trunk Impairment Scale, S-F36, GQOL-74, Pittsburgh Sleep Quality Index. ➢ Outcomes: TC helps with balance function and ability of ADLs. ➢ Recommendations: More rigorous study designs are needed.
Critique ➢ Heterogeneity was high. ➢ Lack of studies including long-term effects of Tai Chi.	

Table 2 description of literature retrieved with search terms Tai Chi and stroke (meta-analysis)

2018 Li, M.S., Wang, W., Liu, G.L., & Zhang, Y.	Effects of Tai Chi on balance and gait in stroke survivors: a systematic meta-analysis of randomized controlled trials
Description: Tai Chi, stroke, balance and gait.	➢ Background: stroke survivors often experience poor physical functioning and significantly decreased QoL. Poor gait and balance are correlated with an increased risk of falling, one of the most common complications during stroke rehabilitation. Therefore, effective interventions are needed for improving physical functioning and QoL among stroke survivors. Physical therapy increases physical function and reduces fall rates whilst improving QoL among stroke survivors. Tai Chi is in line with stroke rehabilitation programmes in China that encourage patients to relax and stay calm to achieve better recovery. ➢ Aim: to evaluate the effectiveness of Tai Chi on stroke rehabilitation to help make evidence-based decisions on the use of Tai Chi among stroke patients. ➢ Method: a meta-analysis of systematic reviews ➢ 2 independent reviewers involved. ➢ Databases searched: PubMed, EMBASE, Cochrane Library. ➢ Search terms: tai chi, taiji, stroke, cerebral apoplexy, acute cerebral accident, cerebral infarction. ➢ Inclusion criteria: RCTs only, adult stroke survivors, Tai Chi (all types) is the intervention, no language constraints.

	➢ No definition of a fall mentioned. The control group received usual care. The outcome was balance and gait after stroke. ➢ 5 RCTs chosen (China, South Korea, Israel and USA). ➢ Intervention: Sun style (1), Yang style (2) and not documented (2). ➢ Outcome measures: TUG, SPBB, fall rates, 2-minute step test, SF-36, CESDS, PSQI. ➢ Outcomes: Fall incidence was two thirds lower in the Tai Chi group. All groups showed an improvement in balance and gait after stroke except for one which showed no improvement in Tai Chi but did in the control group. There was no significant difference in dynamic standing balance ➢ between the Tai Chi and control group. ➢ Conclusion: Tai Chi has benefits on gait in the short term but larger RCTS are required to determine beneficial effects with regards to standing balance and gait. ➢ Recommendations: low intensity and frequency affected outcomes. Therefore, there needs to be increased frequency and intensity to detect clearer differences.
Critique ➢ It is unclear what is meant by 'dynamic standing.' ➢ None of the studies used the BBS. ➢ Low heterogeneity.	

➢ More focus was on standing balance than dynamic balance.

Table 3 description of literature retrieved with search terms Tai Chi and stroke (meta-analysis)

2018 Wu, S., Chen, J., Wang, S., Jiang, M., Wang, X., & Wen, Y.	Effect of Tai Chi exercise on balance function of stroke patients: a meta-analysis
Description: Tai Chi, stroke and balance.	➢ Background: Stroke has high rates of morbidity, mortality and relapse with approximately 2 million new strokes in China annually. About 70-80% are left with disability, affecting QoL and causing a huge economic burden on families and society. Burden in China has been increasing over the last 2 decades. Balance dysfunction caused by proprioception disorder is common in stroke, affecting the ability to walk, decreasing QoL. Rehabilitation aims to maximise stroke recovery and help patients regain freedom of movement as fully as possible. Physical therapy promotes spontaneous neural functional recovery and regains brain function in patients with cerebral apoplexy to promote the process of functional recovery. Effective interventions for increasing physical function and QoL among stroke survivors are critically needed. Most of the stroke population globally are not sufficiently active to gain major health benefits of physical activity. Tai Chi is an ancient Chinese form of physical activity. Evidence is growing suggesting Tai Chi improves balance and QoL as well as reducing falls. ➢ Method: a meta-analysis.

	➢ Aim: to evaluate the effectiveness of Tai Chi as a supportive therapy for stroke rehabilitation. ➢ 2 independent reviewers involved. ➢ Databases searched: PubMed, Cochrane Library, Wanfang. ➢ Search terms: tai chi, tai ji, tai chi chuan, stroke, cerebral apoplexy, balance, equilibrium, posture control. ➢ Inclusion criteria: no time or language restrictions. All RCTs. Tai Chi is the main intervention. The control group received general physical therapy or some other intervention. ➢ 6 studies chosen (China, Korea, USA). ➢ Intervention: Tai Chi. ➢ Outcome measures: BBS, SPPB, fall rates, FRT, DGI. ➢ Outcomes: The SPPB did not show improvements in balance. BBS scores were significantly higher with Tai Chi than controls. This was also the case with the FRT and DGI. Standing balance with falls was significantly affected by Tai Chi. ➢ Conclusion: Tai Chi improves balance efficiency by increasing the BBS score and reducing fall rates. Additionally, the FRT and DGI were significantly higher in the Tai Chi group. However, unexplained heterogeneity was observed in the BBS scores which may be related to differences among studies in the study population,

	different Tai Chi types and intensity and duration of Tai Chi. ➢ Recommendations: more rigorous RCTs with larger sample sizes and longer duration to determine if effective in stroke rehabilitation.
Critique ➢ Dynamic balance was not examined.	

Table 4 description of literature retrieved with search terms Tai Chi and stroke (meta-analysis)

2018 Zou, L., Yeung, A., Li, C., Chiou, S.Y., Zeng, N., Tzeng, H.M., Wang, L., Ren, Z., Dean, T., & Thomas, G.A.	Effects of mind-body movements on balance function in stroke survivors: a meta-analysis of randomized controlled trials
<u>Description:</u> Tai Chi and its' effects on balance among stroke survivors.	➢ <u>Background</u>: Approximately 15m people worldwide have a stroke each year, resulting in physical impairment and economic burden on health services. According to the Centers for Disease Control and Prevention, 67% of stroke survivors need input to help with balance control. Mind-body movements such at Tai Chi, Qigong and Yoga are recommended by some studies. ➢ 2 independent reviewers with a third for discussion. ➢ 17 RCTs analysed, 9 studies used to compare balance function between Tai Chi and control group. ➢ <u>Databases searched:</u> PubMed, Web of Science, Cochrane Library, EMBASE, AMED, CBM, CNKI, Wangfang and VIP. ➢ <u>Inclusion criteria</u>: RCTs, English or Chinese language, usage of at least Yoga, Tai Chi or Qigong as the primary intervention, at least 15 stroke survivors. ➢ <u>Exclusion criteria</u>: controlled trials without randomisation, cross-sectional studies, case reports and reviews. ➢ <u>Intervention:</u> Yoga, Tai Chi or Qigong as the primary intervention. ➢ <u>Outcome measures</u>: BBS, functional reach test, Timed Balance Test. ➢ <u>Outcomes:</u> It is not known if the results of this study can be generalised to different countries.

	➢ Results: Study designs had significant weaknesses and outcomes varied in different countries. Publication may result if only studies with positive findings are published. ➢ Recommendations: More robust study designs are needed.
Critique ➢ This paper does not just include Tai Chi. ➢ It is unknown if these findings can be generalised to the UK.	

Tables to describe literature retrieved which include Tai Chi and stroke (systematic review with meta-analysis)

Table 1 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2015 Chen, B.L., Guo, J.B., Liu, M.S., Li, X., Zou, J., Chen, X., Zhang, L.L., Yue, Y.S., Wnang, X.Q.	Effect of traditional Chinese exercise on gait and balance for stroke: a systematic review and meta-analysis
Description: Tai Chi, stroke and balance.	➢ Background: Stroke has high disability rates, reducing a person's independence. Balance is a major problem in stroke, affecting one's walking ability and quality of life. Proprioception also decreases after a stroke. As a complication of these things, falling is common and is one of the biggest problems during rehabilitation. There are different opinions as to whether Chinese exercise has benefits for stroke survivors. ➢ Method: a systematic review and meta-analysis to determine the effect of Chinese exercise for stroke survivors. ➢ 2 independent reviewers involved. ➢ Databases searched: PubMed, EMBASE, Cochrane Library, CINAHL, Web of Science and CNKI using the search terms, traditional Chinese exercise, and randomized controlled trials. ➢ Inclusion criteria: RCTs only, stroke survivors, impaired physical function. ➢ No definition of falls mentioned. ➢ 9 RCTs chosen (6 exploring Tai Chi).

	➢ <u>Intervention:</u> not mentioned. ➢ <u>Outcome measures:</u> BBS, FCA, gait parameters, SPPB, 2min step test, Limit of Stability Test, Sensory Organization Test, TUG, standing on one leg. ➢ <u>Outcomes:</u> Chinese exercise may be more effective in improving balance in the short-term. The BBS indicates better balance than other tools. ➢ <u>Recommendations</u>: to investigate Tai Chi style and to explore the effects of Tai Chi in stroke and Parkinson's disease. Larger sample sizes are needed.
<u>Critique</u> ➢ Small number of studies reviewed. ➢ Exercise other than Tai Chi included – six out of nine articles explored Tai Chi. ➢ Difficult to establish the effect of Tai Chi alone.	

Table 2 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2017 Ge, L., Zheng, Q.X., Liao, Y.T., Tan, J.Y., Xie, Q.L., & Rask, M.	Effects of traditional Chinese exercises on the rehabilitation of limb function among stroke patients: a systematic review and meta-analysis
Description: Chinese exercises and stroke rehabilitation.	➢ Background: Stroke is the second major cause of death in the world and is the leading cause of disability and functional impairment, reducing the ability to perform ADLs. Chinese exercise, such as Qigong, Tai Chi, Baduanjin, Yijinjing, Wuqinxi, Liuzijue, and Daoyin, is gentle and appealing to stroke survivors. ➢ Country: China. ➢ 2 independent reviewers with a third for disputes. ➢ 31 RCT (4 in English, 27 in Chinese). ➢ Databases searched: PubMed, Cochrane Library, Web of Science, EMBASE, Science Direct, PsycINFO, CINAHL, AMED, VIP, CNKI, CBM, Wanfang using the terms Qigong, Tai Chi, Baduanjin, Yijinjing, Wuqinxi, Liuzijue, Daoyin, stroke, apoplexy, cerebral infarction, cerebral haemorrhage and cerebral vascular accident. ➢ Inclusion criteria: English or Chinese language. RCTs, diagnosed with stroke via CT or MRI, the above exercises were the intervention and the control group received routine rehabilitation or similar exercise. ➢ Data analysis: Chi-square tests, standardized mean difference.

	➢ <u>Outcome measures</u>: Fugl-Meyer assessment, BBS, TUG, SPBB, 2min step test, ADL assessment, NIHSS. ➢ <u>Outcomes:</u> No conclusion could be made on the positive effects on physical function. Tai Chi seemed to have more effect on the rehabilitation of limb function compared with other Chinese exercises. ➢ <u>Recommendations</u>: Larger samples are needed with multi-centre RCTs to verify the efficacy of Chinese exercises on the rehabilitation of limb function among stroke survivors.
<u>Critique</u> ➢ Heterogeneity was high. ➢ It is not clear how Tai Chi compared with other Chinese exercises.	

Table 3 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2019 García-Rudolph, A., Sánchez-Pinsach, D., Salleras, E.O., &, Tormos, J.M.	Subacute stroke physical rehabilitation evidence in activities of daily living outcomes
<u>Description:</u> Physical rehabilitation, stroke and ADLs.	➢ <u>Background</u>: Stroke is a leading cause of disability globally. Physical therapy is primary to the restoring of and maintaining ADLs. ➢ <u>Method: a</u> systematic review of meta-analyses. ➢ <u>Aim:</u> to systematically evaluate existing evidence from published systematic reviews and meta-analyses of rehabilitation interventions in ADLs for stroke patients. ➢ 2 independent reviewers involved. ➢ <u>Databases searched:</u> Medline, Cochrane Library, Web of Science, Scopus, Google Scholar. ➢ <u>Inclusion criteria:</u> meta-analyses of RCTs in the subacute phase (1-6 months after stroke onset). ➢ 30 RCTs chosen (only one exploring Tai Chi). ➢ <u>Intervention:</u> Robotics, acupuncture, virtual reality, Tai Chi, repetitive tasks, hydrotherapy, mirror therapy. ➢ Outcome measures: varied. ➢ <u>Outcomes:</u> Outcomes are highly variable between stroke survivors. Genetic variation may influence individual's capacity for brain plasticity. Tai Chi showed large SMD values and large numbers of participants, but also the highest values of heterogeneity, as with acupuncture. Tai

	Chi as a therapy has been applied to stroke research over ten years. ➢ Recommendations: to analyse the excess significance bias, and to conduct subgroup analysis considering age and age differences.
Critique ➢ Only one Tai Chi study was reviewed. ➢ High heterogeneity so unable to make a conclusion about Tai Chi. ➢ Despite only reviewing one Tai Chi study, subacute stroke was examined rather than acute stroke (less than one month after stroke onset) which is what the TCAS study is exploring. Chronic stroke is being more than six months post-stroke. ➢ The type of rehabilitation to be examined is not specified in the inclusion criteria.	

Table 4 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2018 Lyu, D., Lyu, X., Zhang, Y., Ren, Y., Yang, F., Zhou, L., Zhou, Y., & Li, Z.	Tai Chi for stroke rehabilitation: a systematic review and meta-analysis of randomized controlled trials
Description: Tai Chi, stroke and rehabilitation.	➢ Background: Stroke is a major cause of poor health in China, along with disability. Stroke is the second largest number of disability-adjusted life years lost. The number of new onset stroke cases, post-stroke disability and stroke-related death has risen between 1990-2010. This number is expected to rise over the next 20 years as the population ages and lifestyles change (Giroud et al., 2014). Quality of life is reduced and the economic burden on health services increases. Current proven rehabilitation techniques widely used need one-to-one therapy, and some countries are unable to afford this. Tai Chi may have a positive effect on stroke rehabilitation. ➢ Aim: Recent clinical findings not included in previous reviews are to be included in this review. ➢ Country: China. ➢ Method: a systematic review and meta-analysis. ➢ 2 independent reviewers involved. ➢ Databases searched: (three English, four Chinese) Medline, EMBASE, Cochrane Library, CNKI, CBM, VIP, Wanfang, ICTRP. ➢ Inclusion criteria: RCTs only. Participants were confirmed strokes via imaging. Both types of stroke included. All ages

	included. Meta-analysis only done when no less than two studies with similar study designs reported the same outcome indicators. ➢ 14 RCTs chosen for meta-analysis and 21 for systematic review. ➢ Intervention: all types of Tai Chi with or without rehabilitation therapy. The control group only received one conventional rehabilitation treatment. ➢ Outcome measures: BBS, FRT, DGI, TIS. ➢ Outcomes: Using the BBS, two studies reported balance improvement after Tai Chi but there was no significant difference between groups. One study reported an improvement in balance in the control group but not the Tai Chi group. Eight studies showed significant differences both within and between groups for balance. There were no significant differences between Tai Chi and therapy and the control groups with therapy using the SS-QoL. It was reported that the Tai Chi group improved with ADLs consistently compared with rehabilitation therapy. ➢ Recommendations: Methodological quality of RCTs needs to be improved with a rigorous design. Research of a modified Tai Chi programme for stroke is needed. Different Tai Chi styles need exploring. Tai Chi combined with conventional rehabilitation therapy or alone is needed.

Critique

- Quality of studies was low.
- Blinding was not possible.
- From the SF-36 results, Tai Chi was recommended but there was inconsistency with the sub-categories.
- Huge heterogeneity.

Table 5 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2018 Winser, S.J., Tsang, W.W.N., Krishnamurthy, K., & Kannan, P.	Does Tai Chi improve balance and reduce falls incidence in neurological disorders? A systematic review and meta-analysis
Description: Tai Chi, neurological disorders, reducing falls incidence and improving balance.	➢ Background: Falls are common in people with neurological disorders. Tai Chi may improve balance and reduce falls incidence by strengthening muscles of the knee and ankle and promote even weight distribution and increase awareness of the body and movement. ➢ Method: a systematic review and meta-analysis. ➢ 2 independent reviewers involved. ➢ Aim: to determine whether Tai Chi improves balance and reduces falls incidence compared to control conditions of either active treatment or no treatment in people with neurological disorders (including stroke). ➢ Databases searched: AMED, EMBASE, Web of Science, Scopus, EBSCO, Medline. ➢ Search terms: constructed with four themes which uncluded neurological disorders, intervention, outcome measures and study type. ➢ Inclusion criteria: participants had a neurological disorder. Tai Chi was the intervention. Balance was assessed using the Berg or TUG. Number of falls was the outcome measure. All RCTs. Thesis and non-English publications were included.

	➢ 20 studies chosen (10 systematic reviews: 9 English, 1 Chinese; 1 thesis;9 journaled publications) exploring Tai Chi). ➢ <u>Intervention:</u> Parkinson's disease (x3 Yang 24-form, x2 Yang short-form, x1 6-movement with 8-form Tai Chi, x1 style not reported); stroke (x1 10-form Tai Chi, x1 Yang 24-form, x1 short-form Sun style). ➢ <u>Outcome measures:</u> BBS, number of falls, TUG. ➢ <u>Outcomes:</u> In stroke, balance using the TUG in Tai Chi group was not significant. There was a statistically significant effect of Tai Chi compared with active therapies after 12 weeks for number of falls. ➢ <u>Recommendations</u>: well-designed RCTs are needed to determine whether Tai Chi can improve balance and reduce fall risk in other neurological conditions such as MS, spinal injuries or traumatic brain injury.
<u>Critique</u> ➢ Tai Chi style is not clear in some studies reviewed. ➢ BBS not used in stroke studies. However, there was no significant effect of Tai Chi for balance measured with the BBS among Parkinson's disease participants, contradicting the findings of Yang et al. (2014). ➢ By including studies published in the Chinese language, most of the studies published have been included. ➢ Tai Chi is already popular and well-known in Chinese and Hong Kong regions. It is unclear if stroke survivors in the UK would accept Tai Chi as part of their rehabilitation.	

Table 6 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2018 Yan, G.Y., Wang, W., Liu, G.L., & Zhang, Y.	Effects of Tai Chi on balance and gait in stroke survivors: a systematic meta-analysis of randomized controlled trials
Description: Tai Chi for stroke rehabilitation.	➢ Background: Poor physical functioning and reduced quality of life are common among stroke survivors. Poor gait and balance have been associated with falls. Exercise has been shown to improve physical functioning, reduce falls and improve quality of life. Further, many studies recommend Tai Chi to improve balance due to its ability to increase muscle strength and control balance. ➢ Study design: a systematic review on the effects of Tai Chi on rehabilitation in stroke survivors, followed by a meta-analysis of findings. ➢ Databases searched: PubMed, EMBASE, and Cochrane Library using the search terms: tai chi or Taiji and stroke or cerebral apoplexy or acute cerebral accident or cerebral infarction. ➢ 9 RCTs analysed. ➢ 2 reviewers involved with a third to solve disputes. ➢ Inclusion criteria: RCTs only, stroke survivors practising Tai Chi, usual care as the control, all types of Tai Chi, outcomes of balance and gait. ➢ Intervention: all types of Tai Chi. The control group included groups with usual care.

	➢ Data analysis: standardized mean differences and confidence intervals. ➢ Outcome measures: gait view, FRT, DGI, SF-36, TUG, SOT, COG, RTB, BBT, EFAP, DHP, SPBB, PSQI, ESDS. ➢ Results: Most studies, except for one, reported improvement in better balance and gait. One RCT reported the Tai Chi group to have two thirds fewer falls than the control group and alternative exercise group. ➢ Outcomes: Tai Chi has beneficial effects on gait in the short-term for stroke survivors. ➢ Recommendations: More rigorous studies with larger samples and long-term follow-up are needed.
Critique ➢ Lack of studies including long-term effects of Tai Chi. ➢ Did not conclude if Tai Chi was beneficial for balance.	

Table 7 description of literature retrieved with search terms Tai Chi and stroke (systematic review with meta-analysis)

2018 Yang, F., Lyu, D., Yan, R., Wang, Y., Li, Z., Zou, Y., & Zhang, Y.	Effect of Tai Chi for post-stroke mental disorders and sleep disorders
<u>Description:</u> Tai Chi and stroke.	➢ <u>Background:</u> Stroke is the second largest cause of death and one of the leading causes of disability. This may continue until 2030. Over the past decades, the number of new onsets and survivors has been great and is increasing. Therefore, it poses a challenge for governments and a large medical burden. China bears the heaviest stroke burden in the world. Anxiety and depression are high among stroke survivors, with less sleep duration and daytime sleepiness. Apathy and social inactivity are also common in stroke. ➢ <u>Aim:</u> to conduct a systematic review and meta-analysis to determine the therapeutic efficacy of Tai Chi for poststroke anxiety and depression. ➢ <u>Method:</u> protocol for a systematic review and meta-analysis. ➢ 2 independent reviewers. ➢ <u>Databases:</u> Medline, EMBASE, Cochrane Library, CNKI, CBLD, CSTPD, Wanfang. ➢ <u>Inclusion criteria:</u> RCTs only. Both types of stroke, confirmed via imaging. All types and frequency of Tai Chi. Tai Chi combined with or not with conventional rehabilitation.

	➢ Outcome measures: Hamilton Anxiety Scale, Generic QoL Inventory-74, CESDS, PSQI, mental health component of the SF-36, adherence and adverse events.
Critique ➢ Includes Chinese databases so will have a wider insight to the Chinese literature unavailable for this thesis.	

Tables to describe literature retrieved which include Tai Chi and Stroke (narrative reviews)

Table 1 description of literature retrieved with search terms Tai Chi and stroke (narrative review)

2012 Ding, M.	Tai Chi for stroke rehabilitation
Description: Tai Chi and stroke rehabilitation.	➢ Background: Stroke is the third leading cause of death in China and renders many with physical disabilities. Rehabilitation aims to maximise recovery and enable functional independence and reintegrate into the community. Physical activity is important for reducing disabilities among stroke survivors. Tai Chi is low impact with moderate intensity which may promote physical health such as better balance and improved mood. ➢ Method: a literature review to summarize and critically evaluate clinical trials which aim to investigate the effectiveness of Tai Chi as an adjunct to stroke rehabilitation. ➢ Databases searched: PubMed, EMBASE, CINAHL, AMED, China Knowledge Infrastructure, Chinese Medical Database, Taiwan Academic Online, Cochrane Library using the search terms: Tai Chi, Taiji or Tai Chi Chuan and stroke or cerebrovascular accident. ➢ Inclusion criteria: All prospective controlled clinical trials investigating stroke survivors were included. English or Chinese language were included. Tai Chi was the main

	treatment group, where the control group received alternative treatment or no treatment at all. ➢ 5 RCTs (4 in English and 1 in Chinese). ➢ Tai Chi style: not mentioned. ➢ Outcome measures: Limit of Stability Test, Sensory Organisation Test, Duke Health Profile, Romberg Test, standing on one leg, walking speed, SPPB, CESDS, Pittsburgh Quality Sleep Index, Global Sleep Quality, general health questionnaire, BBS, Hamilton Anxiety Meter ➢ Outcomes: Tai Chi may improve balance, quality of life and mental health in stroke survivors. ➢ Recommendations: more rigorous RCTs are needed to determine the effectiveness of Tai Chi in stroke rehabilitation.
Critique ➢ Small number of studies reviewed. ➢ No meta-analysis performed due to the heterogeneity of the study conditions and outcome measures.	

Table 2 description of literature retrieved with search terms Tai Chi and stroke (narrative review)

2013 Lan, C., Chen, S.Y., Wong, M.K., & Lai, J.S.	Tai Chi Chuan exercise for patients with cardiovascular disease
<u>Description:</u> Tai Chi and stroke rehabilitation.	➢ <u>Background</u>: Exercise has been shown to be good for cardiovascular [CVD] health. China has seen a decline in physical activity with increasing death rates from CVD between 1990 and 2009. Non-rigorous exercise training is a central focus of health promotion in China and is the core component of rehabilitation for CVD patients. Hypertension is a major risk factor for stroke. About 54% of strokes are attributed to hypertension worldwide. Therefore, lowering the blood pressure may reduce CVD morbidity and mortality. Aerobic exercise has been known to lower resting blood pressure in hypertensives. Tai Chi is of moderate intensity and may be good for lowering blood pressure. Tai Chi may also improve balance and muscular strength and is safe and effective for stroke survivors. Tai Chi is easily accessible, of low cost and is easily implemented in the community. ➢ <u>Method:</u> a literature review. ➢ <u>Aim:</u> to provide an overview of Tai Chi benefits on CVD health and introduce the potential application of Tai Chi for CVD patients. ➢ <u>Outcomes:</u> Tai Chi has been shown to increase aerobic capacity, though more recent studies argue that the Tai Chi in most studies requires at least 12 weeks, 5 to 6 times per

	week, in order for there to be and improvements made. Other studies have shown Tai Chi to increase psychological wellbeing (mood, anxiety, sleep quality, depression, insomnia, anger and tension). Tai Chi may be an alternative exercise programme to current rehabilitation with standing balance improving after 12 weeks. ➢ <u>Recommendations</u>: Large-scale RCTs using standardised protocols are recommended.
<u>Critique</u> ➢ This paper is out of date.	

Table 3 description of literature retrieved with search terms Tai Chi and stroke (narrative review)

2008 Wahbeh, H., Elsas, S.M., & Oken, B.S.	Mind-body interventions: applications in neurology
<u>Description:</u> Mind-body interventions in neurology.	➢ <u>Background</u>: Relaxation techniques are helpful for disorders where psychological stress is a factor. Tai Chi is discussed in this review along with Yoga, hypnosis, biofeedback, visual imagery and meditation. Tai Chi poses a low physical and emotional risk. Tai Chi is of low cost and allows patients to take a more active role in their treatment. Interactions between the CNS and the endocrine, immune and peripheral autonomic nervous systems provide a mechanism by which mind-body medicine may be influencing health. Tai Chi and Qigong incorporate body movement, breath, and attentional training to improve disease symptoms and mental health. In contrast to Yoga, Tai Chi contain body movement as a critical component. Tai Chi includes slow body positions that flow from one to the next continuously and promote posture, flexibility, relaxation, well-being, and mental concentration. Tai Chi is externally focused and can provide self-defence, whereas Qigong is internally focused. ➢ <u>Method</u>: a literature review. ➢ <u>Aim:</u> to offer a clinical overview of mind-body interventions and their applications in neurology. ➢ <u>Databases searched</u>: Medline, PsycInfo.

	➢ Search terms: mind-body, relaxation techniques, biofeedback, hypnosis, meditation, tai chi, yoga, breathing exercises, relaxation techniques and dementia or Alzheimer disease, pain, headache, epilepsy, multiple sclerosis, Parkinson's disease [PD], carpal tunnel syndrome, peripheral neuropathy, attention deficit-hyperactivity disorder [ADHD], stroke. ➢ Outcomes: There are some studies regarding risk factors and people at risk of stroke rather than those who already have had a stroke in mind-body research. Blood pressure is a stroke risk factor and meditation or breathing exercises may reduce blood pressure, and changes have been noted in carotid artery intimal thickness which may cause stroke. Due to varying outcome measures, small numbers and poor design, heterogeneity limited the results.
Critique ➢ Rather than focusing on those with a stroke, this paper focuses on stroke risk factors and stroke prevention. However, this review is old and a lot of research on stroke survivors and mind-body techniques has been researched since then.	

Table 4 description of literature retrieved with search terms Tai Chi and stroke (narrative review)

2013 Yoshinaga, S., & Cai, D.	Tai Chi Quan and stroke prevention and rehabilitation
Description: Tai Chi and stroke rehabilitation.	➢ Background: Stroke is a major cause of disability globally. Tai Chi has been shown to improve balance and prevent falls in the elderly. ➢ Method: a literature review which discusses the potential for Tai Chi as part of stroke rehabilitation. ➢ Databases searched: not mentioned. ➢ Inclusion criteria: not mentioned. ➢ Intervention: no details mentioned. ➢ Outcomes: As far as rehabilitation and depression are concerned, Tai Chi impacts arousal mechanisms followed by improvement of sleep as a result of depression. Tai Chi is excellent for stroke rehabilitation due to involving the arms and calf muscles. Tai Chi strengthens muscles and is a slow exercise. Tai Chi is effective in improving balance, improving walking ability. ➢ Recommendations: no recommendations made.
Critique ➢ Little detail of the search strategy. ➢ Little detail of Tai Chi as an intervention, such as Tai Chi type, duration and intensity. ➢ Little detail on the characteristics of participants involved in the studies reviewed. ➢ Little detail about Tai Chi impact on depression itself.	

Table 5 description of literature retrieved with search terms Tai Chi and stroke (narrative review)

2015 Zhang, Y., Ning, Y., Liu, H., Zhou, L., Zou, Y., & Li, Z.	Current trends in Tai Chi for stroke rehabilitation
Description: Tai Chi, stroke and balance.	➢ Background: Stroke is the second most common cause of death globally, impacting on quality of life and the economy of the healthcare systems. Tai Chi is widely practised in China and has been shown to relax the mind, improve balance, strength and coordination. Symptoms of fibromyalgia and Parkinson's disease are also known to have improved according to some studies. ➢ Method: a literature review to summarize the potential benefits of Tai Chi for stroke rehabilitation. ➢ Databases searched: Cochrane Library, PubMed, EMBASE, Chinese Biomedical Database, Wanfang Database and China National Knowledge Infrastructure. ➢ Inclusion criteria: most studies included stroke survivors 3-6 months post-stroke, not in the rehabilitation phase. ➢ Tai Chi style: Yang, Chen and Sun styles used. Movements varied, along with intensity and duration. ➢ Outcomes: Overall assessment could not be done regarding Tai Chi and its suitability for stroke rehabilitation due to all participants being at least 3 months post-stroke. ➢ Recommendations: studies are need which include patients of varying degrees of disability to evaluate effectively the effect of Tai Chi on stroke rehabilitation.
Critique	

- Number of studies not mentioned.
- Inclusion criteria not mentioned.
- Many studies restricted stroke survivors who experienced difficulty walking.

Tables to describe literature retrieved which include Tai Chi and stroke (randomized controlled trials)

Table 1 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2009 Au-Yeung, As.S.Y., Hui-Chuan, C.W. Y., & Tang, J.C.S.	Short-form Tai Chi improves standing balance of people with chronic stroke
Description: Tai Chi and stroke.	➢ Background: stroke population experience difficulties in tasks requiring balance. Balance can increase fall risk due to associations with ambulatory dysfunction. Supervision required by healthcare workers for exercise progression, so self-practice not feasible. Long-term Tai Chi can reduce fall risk and improve standing balance. ➢ Method: RCT. ➢ Participants: 136 participants from 20 local community/day care centres. 62 randomised into CG, 74 into IG. Mean age 60+ ➢ Country: Hong Kong. ➢ Duration: 1 hour, weekly for 12 weeks with 3 hours self-practice. ➢ Intervention: Tai Chi group did short -form Sun style, CG did general breathing and stretching exercises, mobilizing of muscles and joints, memory and reasoning exercises. ➢ Inclusion criteria: stroke post 6 months, hemiplegia, ability to walk at least 6m with/without aids.

	➢ <u>Exclusion criteria</u>: severe cognitive impairment (Mini-Mental State Examination score <23), prior TC experience, involvement in other rehab programs. ➢ Randomized via computer program – gender and side of hemiplegia as variables. ➢ 18 dropped out Tai Chi group, 10 dropped out of CG (22 before end-program evaluation). ➢ Participants in Tai Chi group recorded self-practice in a diary. ➢ <u>Outcome measures</u>: Motricity Index, Composite Spasticity Score, Barthel Index. ➢ More males than females: 33:22 (CG), 33:26 (TC) ➢ Baseline, mid-program, end-program, 6-week follow up. ➢ <u>Outcomes</u>: measured by Equitest, Limit of Stability Test, Sensory Organization Test, Timed Up & Go Test. Tai Chi group showed greater COG excursion amplitude in leaning forward, backward and to non-affected sides. Also, faster reaction times towards the non-affected side. Tai Chi group also demonstrated better reliance on vestibular integration for balance control at end-program. Improvements noticed as early as 6 weeks in Tai Chi group. Tai Chi group performed head-and-eye movements and frequents changes of head-and-body orientation, improving visual and vestibular systems for balance control.

	➢ <u>Recommendations</u>: Recommendations: to introduce Tai Chi early on in stroke rehabilitation. To set up Tai Chi groups after the study in convenient venues. A further prospective study of a larger group is recommended.

<u>Critique</u>

- Title is a positive statement rather than a question.
- Tai Chi program was designed for people with arthritis, not balance.
- Tai Chi group were younger yet higher drop-out rate.
- No mention of why some refused follow-up.
- No mention why people dropped out.
- Tai Chi group taught in groups of 2-5.
- No power calculation.
- P-values mentioned with significance.
- Population from Hong Kong – more adherence to Tai Chi as follows their culture of Ying-Yang etc.
- Performance Bias: No mention of blinding in researchers and physio.
- Can computer algorithms be truly random?
- Neither group improved significantly on Timed Up&Go – acknowledged by author.
- Produced specific standing balance improvements in people with chronic stroke.
- Some participants were affected in mobility function at the time they joined this study.
- Improvements of voluntary weight-shifting (continuous weight-shifting movements during exercise) not single-leg balance in Tai Chi group.
- No focus on balance in the control group.
- Informed consent, ethics given.
- T-test and chi-square tests done.

- Qualified physiotherapist taught the Tai Chi.
- Tai Chi group had extra time, so input of both groups not equal. Also, the Tai Chi group could refer to a video clip of group practice and pictures of the Tai Chi forms.
- Could have resulted in better integration of the visual and vestibular systems for balance control.
- Tai Chi exercises focussed on weight-shifting exercises for standing balance control, rather than speed, therefore no change in Timed Up & Go Test.
- Each participant was given 1 practice trial for each battery before data recording.
- A trained rater was blinded to do the Timed Up & Go Test.
- SPSS used – chi-square tests for categorical data.
- Intention to treat principles applied.
- Control group had 1 educational talk about stroke prevention with exercise diary.
- Tai Chi group had lower compliance in self-practice than control group – Tai Chi form was difficult to remember; control group exercises were easier to remember.
- Not clear if the improved balance would reduce falls in stroke as reduced ability to maintain standing ability has been shown to predict multiple falls in people after stroke.

Table 2 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2018 Chan, W.N., & Tsang, W.N.	The effect of Tai Chi training on the dual-tasking performance of stroke survivors: a randomized controlled trial
<u>Description:</u> Tai Chi and stroke survivors' performance of dual tasking.	➢ <u>Background:</u> Turning has been one of the most frequent acts that leads to falling among stroke survivors. Whilst turning, if an additional cognitive task is added, this could further put stroke survivors at risk of falling. Tai Chi encourages correct posture positioning, weight shifting between legs with a changing base of support, turning in different directions and maintaining spacial awareness. Movements need to be memorized and the next movement needs to be planned whilst maintain balance. ➢ <u>Method:</u> an assessor-blinded 3-group RCT with a one-month follow-up. ➢ Ethical approval obtained from the Ethics Committee of the Hong Kong Polytechnic University with informed written consent. ➢ <u>Duration:</u> 12 weeks, with Tai Chi lasting 60mins twice a week. ➢ <u>Intervention:</u> Tai Chi, conventional exercise and control group. ➢ <u>Tai Chi style</u>: Yang. ➢ <u>Participants:</u> 88 community-dwelling stroke survivors aged 50 years or above were enrolled but 47 participated. At least 6 months post-stroke.

	➢ <u>Outcome measures:</u> auditory swoop test, a turning-while walking test, a dual-task condition combining two tests, BBS, TUG. ➢ <u>Inclusion:</u> at least 6 months post-stroke, able to walk 5m indoors without physical support. Understand Cantonese. ➢ <u>Exclusion:</u> those with a neurological condition other than stroke, severe visual or hearing impairments, cognitive impairment. ➢ <u>Data Analysis:</u> ANOVA, Chi-square tests, Bonferroni adjustments. ➢ <u>Outcome:</u> Tai Chi group had fewer falls, most occurring due to trips/slips and speed. Better perceived mental health after 12 weeks. ➢ <u>Result:</u> No significance between groups at baseline. Tai Chi group showed improvement in dual-tasking in the auditory swoop test and improved their average turning-while-walking times. No significant change was found in the single-tasking condition in the Tai Chi group. The other two groups showed no significant change in dual tasking. The conventional exercise and control groups improved in the auditory swoop test for single tasking. The conventional exercise group showed a reduction in turning-while-walking time at follow-up.

	➢ <u>Outcome:</u> Tai Chi shows no superior effect on dual task training among stroke survivors compared with conventional exercise. However, this study shows the potential for Tai Chi to improve dual tasking performance in stroke survivors. ➢ <u>Recommendations:</u> Studies with a larger sample size are recommended with a longer follow-up period and more training. More severely disabled stroke survivors should be included in future studies.
<u>Critique</u> ➢ Stroke survivors were relatively independently mobile. ➢ Participants were not on the point of discharge. ➢ Small sample size. ➢ Participants were members of a self-help group, meaning participants were more likely to react positively to the intervention, resulting potential selection bias. ➢ Results cannot be generalised to stroke survivors with more severe disability. ➢ The control group was not restricted to other types of physical activity which may explain the improvement made in this group.	

Table 3 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2018 Chen, T.	Effects of martial arts on recovery of motor function and nerve excitability of stroke patients
Description: Martial arts and stroke.	➢ Background: Stroke, also known as apoplexy, is common among the middle-aged and elderly. Its motor dysfunction is one of the most common problems of patients, which affect their ADLs and QoL. According to the 2012 Stroke Index in China, 70 million stroke survivors lacked assistance. The number of stroke deaths in China was ranked the highest globally in 2010. Studies have shown that traditional martial arts can effectively improve the motor function and sensory nerves of middle-aged and elderly people. Moreover, traditional martial arts can be implemented in stroke rehabilitation. Tai Chi is one such martial art. Tuo Wanliang's research shows that stroke survivors can be improved by meridian adjustment, yin-yang balance and other factors. ➢ Method: method is unclear. There is a control and experimental group but no mention of a randomisation procedure having taken place - ? an RCT. ➢ Duration: 6 months. ➢ Participants: Chinese stroke survivors with mild to chronic stroke. ➢ Outcome measures: BBS, TUG, standing on one foot, DFTT on the index finger.

	- Intervention: Tai Chi versus traditional rehabilitation. - Inclusion: confirmed stroke via imaging, has a Rankin score below 3 points, blood pressure is stable (100-160/60-100mm Hg), no neurological dysfunction if had a previous stroke, more than 3 months post-stroke, no serious organ disease. - Ethics approval obtained, written informed consent obtained. - Outcome: The Tai Chi group scored higher at 6 months with the Berg than at baseline with significant differences before and after. In contrast, the control group scored lower than baseline. There were no significant differences at baseline but there were significant differences between groups after 6 months ($p<0.05$). - Conclusion: Six months of Tai Chi can significantly improve standing on one foot but there wrre no significant improvements in the control group. It is not clear from this study whether Tai Chi improves balance among stroke survivors. However, this study suggests that Tai Chi is superior to traditional rehabilitation. - Recommendations: further exploration of the neuroplasticity of stroke survivors in Tai Chi exercise.
Critique	

- Mild to chronic stroke may not have much balance deficit compared to acute strokes. Hence results may not be generalisable to UK patients with acute stroke.

Table 4 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2015 Kim, H.Y., Kim, Y.L., & Lee, S.M.	Effects of therapeutic Tai Chi on balance, gait, and quality of life in chronic stroke patients
<u>Description:</u> Tai Chi and its effects on stroke survivors in terms of balance and quality of life.	➢ <u>Background</u>: Compared with the general population, postural perturbations of a standing position increased two-fold in hemiplegic stroke survivors. The ability to adjust the centre of gravity whilst maintaining balance is decreased. Balance training has been reported to increase physical activity capacity and reduce the risk of falls in stroke survivors. Healthcare systems have been finding it difficult to provide services for stroke survivors. Tai Chi heals tired muscles and relaxes them and has been known to improve mental and physical post-stroke aspects, e.g. depression and quality of life. ➢ <u>Method:</u> An RCT to investigate the effect of Tai Chi on balance, gait and QoL of stroke survivors. ➢ <u>Participants</u>: 22 stroke patients in South Korea were randomly divided into two groups (physical therapy with Tai Chi and physical therapy alone. Average age of 63 yrears. ➢ <u>Inclusion criteria</u>: ability to walk 10m independently, scores on independent tests. ➢ <u>Exclusion criteria</u>: cognitive impairment, co-morbidities affecting walking. ➢ <u>Duration</u>: Six weeks, one-hour classes twice a week.

	➢ Ethical approval sought from the Institutional Review Board of Sahmyook University. ➢ Tai Chi style: not stated. ➢ Outcome measures: Gaitview, functional reach test, TUG, SF-36. ➢ Data analysis: SPSS using frequencies, paired t-test, independent two-sample t-test for between-group differences, Cronbach's α. ➢ Results: Tai Chi group showed greater improvement in FRT, DGI with the average change after treatment being statistically larger than the control group. In the 10m walking test, the Tai Chi group showed a significant reduction, but the control group did not. Tai Chi group showed a reduction in walking speed in TUG. Significant changes in the SF-36 among the Tai Chi and control groups, except for social functioning and role limitations. ➢ Outcomes: Tai Chi influences balance, gait and quality of life in stroke survivors. ➢ Recommendations: no recommendations made.
Critique ➢ Participants were independently mobile.	

Table 5 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2014 Taylor-Piliae, R.E., Hoke, T. M., Hepworth, J.T., Latt, L.D., Najafi, B., & Coull, B.M.	Effect of Tai Chi on physical function, fall rates and quality of life among older stroke survivors
<u>Description:</u> Tai Chi and stroke.	➢ <u>Background:</u> poor physical function leads to significantly decreased quality of life. Gait and balance are essential components of physical function, leading to increased falls. Effective interventions are needed for stroke. ➢ Studies state exercise leads to improved physical function, fewer falls and better quality of life in healthy older people. Effectiveness of Tai Chi in improving physical function has not been adequately studied. No studies on falls rates or quality of life. ➢ <u>Method:</u> single-blind, 3-group RCT. ➢ <u>Duration:</u> 12 weeks,1 hour, 3 times a week. 10 min warm-up, 40 min TCC, 10 min cool-down. Chairs nearby for rest periods. ➢ <u>Participants:</u> 145 community-dwelling stroke survivors from Arizona, USA, aged 50+, 3 months post-stroke. Recruited over 3 years from radio, newspaper ads, fliers, brochures at outpatient rehab, community centres and physician's offices. Randomly assigned – simple randomisation with allocation concealment. ➢ <u>Tai Chi style:</u> Yang style. ➢ <u>Outcome measures:</u> short physical performance battery (function), counting falls, 2-min step test, depression scale,

	Pittsburgh sleep quality index, medical outcomes study short form 36. Modified Rankin Scale used to screen for safety and eligibility. SPPB and mini-mental state exam done. ➢ Inclusion: all sexes, racial groups. Allowed canes and walkers. ➢ Exclusion: no disability, severe disability, long-term conditions. ➢ Ethics approval obtained, written informed consent obtained. ➢ Experienced Tai Chi teacher (30 years+). ➢ Definition of falls given. Definition of a near-fall given. ➢ Reasons for falling collected and if resulted in injury. ➢ Intention-to-treat analysis done. ➢ Data Analysis: T-tests and chi-square test used via SPSS. ➢ 14 withdrew as they didn't like their group assignment. ➢ Outcome: Tai Chi group had fewer falls, most occurring due to trips/slips and speed. Better perceived mental health after 12 weeks. ➢ Result: Tai Chi suitable for stroke survivors. Results were similar to Tousignant who used frail participants. Both groups improved balance, yet Tai Chi group had fewer falls. ➢ Recommendations: to focus on Tai Chi as a fall prevention strategy. To consider the impact of hemiparesis on the

	occurrence of falls when conducting exercise interventions. Observed improvements in physical function may have occurred due to learning effect (SPPB). Home safety assessments.

Critique

- Control group had weekly phone calls, therefore time given to each group not equal, but this is difficult to do. Given written materials and resources for taking part in a community-based physical activity therefore some will have done it, others won't so the group will have varied levels of activity. The group members will not be the same. Those participating may have improved or fallen more due to more activity.
- List of abbreviations given.
- Transport services info given to participants.
- Balanced numbers in each group. 14 withdrew – maybe they wanted to be in the Tai Chi group. Highlights a need to offer Tai Chi at the end to the control group for retention.
- Participants 'volunteered', so not truly random.
- Power calculation done may have underestimated the effect size – acknowledged by the author.
- Why did Tai Chi group have fewer falls if both groups improved balance? Is balance related to falls?
- Control group had fewer sessions, hence the better adherence rate?
- Does not go into qualitative detail about reasons for falling.
- Participant-reported falls rate the only method – may not be underreported due to recollection bias – acknowledged by the author.
- Interviewed weekly therefore more likely to have accurate recall.
- Not mentioned how participants were randomized.
- Bias could be introduced as monitored by instructor and study staff but were blinded to group assignment.
- No data about fear of falling reported.

➢ No home safety assessments done – acknowledged by the author.

Table 6 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2010 Wang, W., Sawada, M., Noriyama, Y., Arita, K., Ota, T., Sadamatsu, M., Kiyotou, R., Hirai, M., & Kishimoto, T.	Tai Chi exercise versus rehabilitation for the elderly with cerebral vascular disorder: a single-blinded randomized controlled trial
<u>Description:</u> Tai Chi and stroke (cognition).	➢ <u>Background:</u> Japanese study where stroke is the third most common cause of death. It is of major medical economic importance. Decreased quality of life follows, particularly cognitive function. ➢ Tai Chi is viewed as a way of life restoring health. Individuals learn control over some bodily functions. Tai Chi also calms the mind. ➢ Few studies focussing on cognition. ➢ <u>Method:</u> a single-blind, randomized controlled trial. ➢ <u>Purpose:</u> to evaluate the psychological effects of Tai Chi in stroke. ➢ <u>Participants:</u> aged 50+; 34 patients from a hospital outpatient clinic. Randomly assigned to receive Tai Chi or rehab. 17 in both groups. ➢ <u>Inclusion:</u> 50+ diagnosed with stroke by CT/MRI in the last 30 days. ➢ <u>Excluded:</u> past experience of Tai Chi or other complementary therapies including Yoga; mini-mental state exam score <20; participated in other trials in the last 30 days. ➢ Written informed consent obtained. ➢ <u>Tai Chi style:</u> Yang style.

	➢ <u>Duration:</u> 50 mins once a week for 12 weeks: 10 min warm-up and review of principles, 30 min Tai Chi and 10 min cool-down. ➢ CG group did non-resistance training (20mins) and used exercise machines (60 mins). ➢ <u>Outcome:</u> measured via stimulus test using electrodes. GHQ used to measure health-related quality of life, as well as the PSQI. Data collectors blinded to diagnoses. Four subscales: somatic symptoms, anxiety/insomnia/social dysfunction/severe depression. ➢ <u>Data Analysis:</u> ANOVA, t-tests. SPSS used. ➢ <u>Results:</u> no significant differences between the groups. Tai Chi has a positive effect on sleep. Tai Chi promotes general health.
<u>Critique</u> ➢ Looking for ways to reduce costs: Tai Chi just may be a cheaper option. ➢ Focusses on cognition. However, are these stroke survivors with dementia, or stroke survivors with cognitive impairment due to the stroke? ➢ Refers to Au-Yeung's paper which reported Tai Chi improves standing balance in chronic stroke. ➢ Method of randomization not mentioned. ➢ Small group. ➢ No mention of ethics approval. ➢ Control group received more input (80 mins) compared with 50 mins TCC group.	

- Mention a prior report with healthy elderly and state Tai Chi is good for depression in these people. The cognitive impairment varies in stroke – is this memory loss, depression or inability to speak or understand? The part of the brain affected changes certain cognitive areas e.g. frontal lobe causes change in behaviour.
- GHQ is self-reporting, could lead to bias.
- Data collector blind to diagnosis but doesn't state if blind to group allocation.
- Japanese version (validated) of GHQ used. Japanese culture and health different to western lifestyle so tool will not be generalizable to western societies.
- Title suggests dealing with stroke survivors yet results and discussion talk about people with dementia.
- No significant changes between groups, yet recommends Tai Chi over rehabilitation – for financial reasons?
- No mention of how much post-stroke participants are.

Table 7 description of literature retrieved with search terms Tai Chi and stroke (RCT)

2018 Xie, G., Rao, T., Lin, L., Lin, Z., Xiao, T., Yang, M., Xu, Y., Fan, J., Lin, S., Wu, J., Feng, X., Li, L., Tao, J., & Chen, L.	Effects of Tai Chi Yunshou exercise on community-based stroke patients: a cluster randomized controlled trial
<u>Description:</u> Tai Chi Yunshou and stroke.	➢ <u>Background</u>: Stroke is the second most common cause of death and is the third most common cause of disability worldwide, restricting ADLs. Therefore, interventions are needed to improve balance and functional mobility. Growing evidence suggests that Tai Chi may improve balance, fear of falling and QoL in the elderly. Safety of Tai Chi has already been demonstrated in stroke. Tai Chi can be practised anytime, anywhere without supervision or guidance. Tai Chi Yunshou movement is 'wave hands in the cloud.' ➢ <u>Aim</u>: to evaluate the effects of a 12-week Tai Chi Yunshou exercise programme on physical health and mental health on stroke. ➢ <u>Country</u>: China. ➢ <u>Method:</u> a cluster RCT. ➢ <u>Inclusion criteria:</u> aged 45-75 years, stroke diagnosed confirmed by imaging, first onset of stroke more than three months prior, has a balance dysfunction caused by stroke, able to walk 6m independent or assisted, willingness of patient or a legal guardian to consent, has capacity. ➢ <u>Exclusion criteria:</u> impaired vestibular function, existing disease after training, sensory aphasia, prior Tai Chi

	experience in the last 6 months, serious medical condition, participating in other research which would affect the results of this study. ➢ <u>Participants:</u> 250 randomized from the community; 125 in each group. Participants were randomized in a 1:1 ratio via the PLAN algorithm in the statistical software SASv8.2. The total number analysed was 112 in the Tai Chi group and 113 in the control group. The average age of participants was 60.9 in the Tai Chi group and 60.1 in the control group. Most participants were male (74.6%). ➢ <u>Intervention:</u> Tai Chi Yunshou movements (originated from the 24-short form normed by the General Administration of Sports of China), based on the principles of Tai Chi. Routine therapy continued (balance rehabilitation training) and both groups received education regarding health. 12 weeks of Tai Chi, x5 per week at 60 mins per session. ➢ The instructor was not involved in assessment of outcomes. The screeners, outcome evaluators and statisticians were blinded throughout the study. ➢ <u>Follow-up:</u> at 12 weeks via telephone or monthly home visits. ➢ <u>Outcome measures:</u> Chinese versions of the BBS (for static and dynamic balance), Modified Bartel Index, FES and SF-36. Also included were the single-leg stance test (for static

	balance), the Beck Depression Inventory (for depression), the Fugl-Meyer Assessment (for motor function) and TUG (for mobility). ➢ Data analysis: t-tests and Mann-Whitney tests for continuous variables. Pearson's chi-squared or Fisher's Exact tests for categorical variables to compare differences between groups. ➢ Outcomes: Five participants in the Tai Chi group dropped out before baseline compared with one in the control group. Eight Tai Chi participants dropped out during the study compared with 11 in the control group. Tai Chi had more positive effects on motor function, fear of falling and depression than the control balance rehabilitation training group. ➢ Conclusions: Both groups improved by the end of the 12 weeks. Both Tai Chi Yunshou and balance rehabilitation training are suitable community-based programmes that may be of benefit for stroke recovery and community reintegration. Tai Chi Yunshou was more effective in motor function, fear of falling, and depression than balance rehabilitation training over 12 weeks. ➢ Recommendations: More research using the Tai Chi Yunshou programme is recommended.
Critique	

- A better definition of Yunshou is needed for those unfamiliar with 'wave hands in the cloud.'
- The good adherence rate was credited by the authors due to the Tai Chi taking the form of a group exercise where encouragement was given as well as receiving social support and knowledge.
- Class sizes were small (a maximum of five per group so it can be supervised efficiently).
- Classes were instructed near participants' homes, thus encouraging adherence.
- To encourage adherence in the control group, weekly telephone follow-ups and monthly home visits were conducted.
- Those with severe arm weakness were encouraged to use their unaffected arm to aid the affected hand.
- No adverse effects were observed.
- The social interaction with the Tai Chi group may have contributed to improved depression.
- Not everyone adhered to training completion due to absence to attend GP appointments, health investigations, family dinners or other commitments conflicting with the training times. Nevertheless, the attendance rate was more than 75% in the Tai Chi group.
- No home practice was offered or reported if so.
- Five days a week may not be suitable for UK stroke survivors with no knowledge of Tai Chi at the early rehabilitation phase. Acceptability of Tai Chi is unclear.

Tables to describe literature retrieved which include Tai Chi and stroke (pilot studies)

Table 1 description of literature retrieved with search terms Tai Chi and stroke (pilot study)

2017 Chan, W.N., & Tsang, W.N.	Effect of Tai Chi training on dual-tasking performance that involves stepping down among stroke survivors: a pilot study
Description: Tai Chi and its effect on dual-task performance in stroke survivors.	➢ Background: Falling whilst descending stairs is problematic among stroke survivors who may find negotiating stairs difficult. It is considered to be one of the most difficult activities in their daily life due to impaired physical functioning. Descending stairs whilst having an additional cognitive task may add to this difficulty. Tai Chi has been shown to prevent falls in the general population and stroke survivors. ➢ Study design: a pilot study involving 3 groups which hypothesised the cognitive and physical task performance under single-tasking and dual-tasking conditions would be improved after Tai Chi, and that performance would be better than conventional exercise after the intervention period. ➢ Participants: 88 participants were recruited from patient self-help groups in Hong Kong. ➢ Inclusion criteria: aged 50 or more, diagnosed with stroke six months or more, able to perform stepping down without assistance, able to follow instructions in Cantonese.

	➢ <u>Intervention:</u> Tai Chi, conventional exercises using elastic bands and stretching and control group who received no intervention. ➢ <u>Exclusion criteria:</u> neurological disease other than stroke, severe visual or hearing impairment, cognitive impairment, major surgery in the last six months. ➢ Ethics approval gained with written informed consent. ➢ <u>Duration:</u> Two one-hour sessions per week for 12 weeks, limited to 10 participants per session. ➢ <u>Tai Chi style:</u> 12-form Yang style. ➢ Tai Chi taught by instructor with at least 30 years of experience. ➢ <u>Outcome measures:</u> an auditory swoop test, stepping down on a force plate which measured the sway of centre of pressure whilst stepping down, dual-tasking using a pressure sensor. ➢ <u>Data analysis</u>: SPSS used with ANOVA, Chi-square tests, Bonferroni adjustments. Intention-to-treat approach. ➢ <u>Outcome:</u> Tai Chi can better improve the cognition in dual-tasking conditions compared to conventional exercises. ➢ <u>Results:</u> Tai Chi group showed significant improvement in the auditory swoop test than the conventional group. ➢ <u>Recommendations:</u> Further studies are needed with a larger sample size with less able participants.

<u>Critique</u> ➢ Participants are based in Hong Kong where Tai Chi is widely practised. ➢ Participants are most likely to respond positively because they volunteered and were recruited from a self-help group. ➢ Results did not say if the Tai Chi group performed better than the control group. ➢ Patients were able to step down without assistance. ➢ Participants were at least 6 months post-stroke. ➢ Small sample size used.

Table 2 description of literature retrieved with search terms Tai Chi and stroke (pilot study)

2004 Hart, J., Kanner, H., Gilboa-Mayo, R., Haroeh-Peer, O., Rozenthul-Sorokin, N., & Eldar, R	Tai Chi Chuan practice in community-dwelling persons after stroke
Description: Tai Chi and stroke.	➢ Background: cost-effective rehabilitation; reports of falls reduction and useful in balance training in older people; no study using stroke population. ➢ Method: Pilot study of a Randomised Controlled Trial (RCT). ➢ Participants: 18 community-dwelling first-stroke survivors from Israel 27 months post-stroke on average, aged 45-64, randomly divided into 2 matched groups of 9 participants each (16 men/ 2 women). Ten had right hemiparesis, 8 had left hemiparesis. Participants were 27 months after stroke onset. Participants identified from records and examined by a physician. ➢ Inclusion criteria: intact visual acuity, residence within 1 hour's drive, willingness to participate in an afternoon group therapy session. ➢ Exclusion criteria: receptive aphasia, impaired joints. ➢ Intervention: intervention group (IG) received Tai Chi (TC); the control group (CG) received physiotherapy exercises focussing on balance. ➢ Duration: Both groups received 1 hour twice a week for 12 weeks. ➢ Outcome measures: Romberg's Test, Berg-Balance Test, Timed 'Up and Go' Test, Duke Health Profile.

	➢ <u>Outcomes:</u> IG showed improvement in social and general functioning and well-being. Control group showed improvement in balance and speed of walking. There is potential in Tai Chi practice in stroke, with no adverse effects. Relearning lost neuromuscular functions in patients with hemiparesis affects balance and ambulation.

<u>Critique</u>

- The control group focused on balance. Tai Chi group may not have focused on balance.
- Was 27 months too late to make a difference?
- <u>Selection Bias:</u> Does not mention type of records participants were recruited from. No method stated regarding method used for randomisation.
- No outcome clearly stated in the title.
- 9 is a small number of participants for an RCT but acknowledged by the author. No power calculation.
- Duration of study short, if longer may have improvement in balance – acknowledged by authors.
- Both groups were matched and balanced.
- No differences explaining confounding outcomes mentioned.
- <u>Detection Bias</u>: No mention of blinding of data collector. Insufficient information to judge.
- <u>Performance Bias:</u> Blinding not possible as the nature of the study makes this impossible. Physiotherapist carrying out the tests was blinded but bias may have been introduced when physio speaks to the participants. No mention if the researcher was blinded or present at classes, introducing observer bias. Does not mention if the researcher was blinded.
- Very short research paper, indicating a lot of information not included.
- No mention of dropouts or loss to follow-up.
- Focuses on outcomes, which are unclear in the title.

- No follow-up mid-study: were participants left alone?
- No mention of data collection.
- Results are not presented as a proportion of people experiencing an outcome.
- T-test done, which is appropriate but is it statistically significant? No mean or Standard Deviation (SD) mentioned. No C.Is reported. No p-values.
- Results were not precise enough to enable to make a conclusion due to small sample size and significance.
- Study population Israeli – may have a better transport system to travel.
- This is a pilot so could generate a further larger trial rather than apply results.
- Encourages further research and recommends longer than 12 weeks.
- Style of Tai Chi not mentioned, or what was practised. Does not state if study included Qi Gong exercises.
- No mention of ethical approval.
- No mention of informed consent.
- Used qualified Tai Chi instructor who followed guidelines of Emory University. How long practiced?
- SPSS used.

Table 3 description of literature retrieved with search terms Tai Chi and stroke (pilot study)

2017 Pan, S., Kairy, D., Corriveau, H., & Tousignant, M.	Adapted Tai Chi enhances upper limb motor control in chronic stroke patients: a pilot study
Description: Tai Chi and stroke survivors with upper limb impairment.	➢ Background: 85% of stroke survivors report upper limb impairment, a challenge for stroke rehabilitation. At 6 months post-stroke, ndividuals do not regain functional use of the arm and only 5-20% will fully recover arm function. Current treatment effects have been shown to be modest. Tai Chi has been shown to improve balance and prevent falls in older people. Some recent evidence has shown this to be the case among stroke survivors. Evidence on the upper limb is limited. ➢ Method: pilot study to explore adherence to Tai Chi and self-practice at home. ➢ Ethical approval gained from the CRIR with written informed consent. ➢ Duration: one-hour classes twice a week for 8 weeks with 10mins of home practice. ➢ Tai Chi style: Chen. ➢ Participants: 12 community-dwelling stroke survivors in Canada recruited with an average age of 60 years. Average stroke onset 22 months sago. ➢ Outcome measures: Fugl-Meyer Assessment, Wolf Motor Function Test, Modified Motor Activity Log, feedback questionnaire.

	➢ <u>Inclusion criteria:</u> stroke with upper limb weakness, at least 6 months post-stroke, upper limb recovery between stage 2 to 6 on the Chedoke-McMaster Arm Impairment Inventory, presence of upper limb dysfunction, able to follow instructions. ➢ <u>Exclusion criteria:</u> participating in an upper limb rehabilitation programme, uncontrolled medical problems, significant visual problems, severe aphasia. ➢ Ethics approval obtained, written informed consent obtained. ➢ <u>Data Analysis:</u> frequencies using SPSS to calculate extreme values, linear mixed models for repeated measures, statistical tests could not be performed to detect differences due to the small sample size. ➢ <u>Outcome:</u> Tai Chi group had fewer falls, most occurring due to trips/slips and speed. Better perceived mental health after 12 weeks. ➢ <u>Result:</u> All participants completed all 16 classes over 8 weeks. Self-practice was enabled after the first class. Self-practice time increased over the weeks. Shoulder pain did not interfere with movements. All subgroups (low, middle and high functioning) showed improvements. Severity of impairment determines the effect of Tai Chi with the middle functional group showing large improvements in all four

	variables, with the high and low functional groups having much smaller increases in the FMA-UL. The low function group did not show any improvements in the two MAL scales. ➢ Outcome: Tai Chi may be acceptable and effective for upper limb stroke rehabilitation with different upper limb impairment levels and balance. ➢ Recommendations: RCTs with larger sample_sizes are recommended.
Critique ➢ 6 months post-stroke so improvement may be minimal. ➢ Small sample size. ➢ No control group included as a comparison.	

Table 4 description of literature retrieved with search terms Tai Chi and stroke (pilot study)

2011 Taylor-Piliae, R.E., & Coull, B.M	Community-based Yang-style Tai Chi is safe and feasible in chronic stroke: a pilot study
Description: Tai Chi and stroke.	➢ Background: Community exercise programmes are costly; community-based exercise programmes for stroke survivors is needed; Tai Chi is cheaper, low-tech, low-impact, moderate-intensity, appealing to elderly; to test safety of Tai Chi in this population. ➢ Method: A prospective pilot study to examine the safety and feasibility of a 12-week Tai Chi intervention among stroke survivors in an outpatient rehabilitation facility. ➢ Participants: Aged >50. >3 months post stroke. 28 participants from Arizona, USA. ➢ Intervention: Control group allocated to usual care. ➢ Those attending/-ed outpatient rehabilitation at 4 rehab facilities were targeted for recruitment by placing study flyers, ads, brochures in these locations. ➢ Rehab staff aided in recruitment. ➢ Approval from Institutional Review Boards at the University of Arizona, HealthSouth and Carondelet Health Network in Tucson AZ. ➢ According to principles outlined in Declaration of Helsinki. ➢ Written informed consent obtained from all participants. ➢ Eligibility and safety screening prior to recruitment.

	➢ <u>Inclusion criteria</u>: Modified Rankin Scale (functional disability) score of 3 or less, Short Physical Performance Battery (balance, gait speed, lower body strength, mortality predictor) score of 3-9, Mini-Mental State Exam score of >18. ➢ <u>Exclusion criteria</u>: no disability (SPPB >9, or <3), severe disability (MRS >4), severe cognitive impairment (MME <18), serious medical condition that would interfere with study participation. ➢ Cohorts of 10-12 using simple randomization with allocation concealment. ➢ Participants drew a slip of paper from a non-transparent container and handed an opaque, sealed envelope matching the slip of paper. They opened the envelope when they returned home. ➢ A self-administered health survey posted and completed before baseline visit. ➢ <u>Duration</u>: 36 one-hour Tai Chi sessions throughout 12 weeks, CG had 12 weekly phone calls. 20min warm-ups with 30 mins Tai Chi, 10 min cool down. ➢ Data collected at baseline and at end of 12 weeks. ➢ Staff blinded to group assignment. ➢ Short form used in Tai Chi group.

	➢ Variables included were sleep difficulties and depressive symptoms using Pittsburgh Sleep Quality Index and the Center for Epidemiological Studies Depression scales. ➢ National physical activity guidelines for persons with physical disabilities were followed. ➢ Participants had a chair in close proximity to allow for rest periods. ➢ Canes and walkers allowed. ➢ Classes limited to 6 subjects per group for adequate supervision. ➢ Safety and correct foot placements monitored. ➢ Certified experienced Tai Chi instructor. ➢ Registered nurse experienced in exercise testing/supervision with CPR training in attendance in all sessions. ➢ Automated defibrillator at hand in rehab centre. ➢ Link given to participants: www.youtube.com/watch?v=FmtmVITG-8 ➢ 24-posture short-form, Yang style developed by Dr Pi-Lu Fei. ➢ On completion of 12 weeks, participants received a Tai Chi workbook and CD Rom of the taught form. ➢ Control group was given written materials and resources, e.g. www.silversneakers.com/ as well as weekly phone calls

	inquiring on health status with individual attention. After 12 weeks they were given the National Center on Physical Activity and Disability stroke survivors exercise DVD and booklet: www.ncpad.org ➢ Descriptive statistics collected, mean, SD, SE, inter-quartile percentage values. ➢ SPSS for Windows. ➢ Sample size calculated. ➢ Changes in balance, endurance and quality of life scores for Tai Chi. ➢ Changes in overall physical functioning, strength, gait in control group. ➢ Outcomes: Tai Chi is a safe, community-based exercise programme for stroke survivors. 52 subjects per group needed.

Critique

- Title is a positive statement rather than a question.
- American study where people pay health insurance – more focus on cost reduction rather than effectiveness?
- Only a pilot study with broad outcomes so would not rely on this to make changes to clinical practice.
- No falls occurred throughout the study.
- More than balance measured. Also focussing on endurance and quality of life – outcomes unclear in title.
- Sample size calculated to need 29 participants per group to detect statistical significance in balance, therefore adequate sample size.
- No mid-program data collection.

- Selection Bias: Subjects ‘selected’ their group to reduce dropouts related to group assignment, therefore was not truly random.
- Retention strategies in place, e.g. establishing a tracking method during recruitment, providing personal feedback, using the same location for all aspects of the study, personal attention and encouragement, monitoring attendance, utilizing a charismatic Tai Chi instructor, providing appropriate incentives, and maintaining good communication.
- More right-sided hemiparesis, co-morbidities, lower physical functioning and quality of life scores at baseline in Tai Chi group.
- Simple randomization may have led to imbalanced group sizes.
- Recommendations: use block randomisation, stratifying by age and stroke type to mitigate potential bias selection – acknowledged by the author.
- Single leg stand test advisable.
- It is feasible for a larger study to detect statistically significant group differences in physical functioning among stroke survivors (also quality of life).

Tables to describe literature retrieved which include Tai Chi and stroke (protocols)

Table 1 description of literature retrieved with search terms Tai Chi and stroke (protocols)

2015 Tao, J., Rao, T., Lin, L., Liu, W., Wu, Z., Zheng, G., Su, Y., Huang, J., Lin, Z., Wu, J., Fang, Y., & Chen, L.	Evaluation of Tai Chi Yunshou exercises on community-based stroke patients with balance dysfunction: a study protocol of a cluster randomized controlled trial
<u>Description:</u> Tai Chi and stroke.	➢ <u>Background:</u> Balance impairment affects stroke survivors' participation in ADLs. Further, balance impairment contributes considerably to multiple falls, which leads to a fear of falling, which in turn leads to a reduction in activities, promoting a sedentary lifestyle. An important goal in stroke rehabilitation is to improve balance and mobility. Tai Chi is an economical and effective programme for improving balance confidence in the general population. ➢ <u>Method:</u> protocol for a RCT. ➢ <u>Participants:</u> The study aims to recruit 25 participants. ➢ <u>Duration:</u> 12-weeks of one-hour classes five days in China. ➢ <u>Tai Chi style:</u> Yunshou, known as the 'mother form', and is the basic technology form of Tai Chi according to the authors. ➢ <u>Control group:</u> balance rehabilitation for the same duration and frequency as the experimental group. ➢ <u>Inclusion criteria:</u> diagnosis of stroke, at least 3 months post-stroke, aged 45-75, able to walk at least 6m with or without aids, able to consent.

	➢ Exclusion criteria: balance dysfunction not caused by stroke, vestibular problems, arthritis or other co-morbidities affecting walking, visual or hearing impairment, receptive aphasia, participated in Tai Chi over the last 6 months, severe complications of stroke, severe medical problems, participating in other research, cognitive impairment. ➢ Outcome measures: BBS, Fugl-Meyer motor function assessment, Modified Barthel Index, SF-36, Beck Depression Inventory, Modified FES, single-leg test, TUG, Gait Analysis Process, step test, vital capacity, blood pressure, heart rate, Prokin proprioception evaluation and training system, blood glucose and blood lipid tests.
Critique ➢ Five days a week may not be feasible for UK stroke survivors, especially on the point of discharge.	

Table 2 description of literature retrieved with search terms Tai Chi and stroke (protocols)

2014 Tousignant, M., Corriveau, H., Kairy, D., Berg, K., Dubois, M.F., Gosselin, S., Swartz, R.H., Boulanger, J.M., & Danells, C.	Tai Chi-based exercise program provided via telerehabilitation compared to home visits in a post-stroke population who have returned home without intensive rehabilitation: study protocol for a randomized, non-inferiority clinical trial
Description: Tai Chi and stroke.	➢ Background: balance and ambulation are the most important risk factors for stroke. 75% of those having a stroke fall within the first 6 months following discharge from hospital. Tai Chi and balance retraining can improve balance. Optimum treatment dose in stroke should be twice weekly. ➢ Method: protocol for an RCT to test the non-inferiority of Tai Chi via tele-rehab. ➢ Participants: 6 based on the Rankin classification score 2-3, aged 45+, balance problem score between 46-54 on Berg Balance Scale. Randomly assigned to tele-treatment or home visit via block randomization 2-4 via computer. Recruited during the hospitalisation period. Stratification based on the Rankin score. ➢ Ethics approval obtained. ➢ Duration: 45 mins twice a week for 8 weeks. Intervention immediately after discharge. ➢ Excluded: stroke in last 12 months other than the present one, severe hemiplegia, severe visual problems, uncontrolled medication problems, aphasia.

	➢ Outcome: balance and mobility measured with the community balance and mobility scale. Second outcomes are quality of life and cost-effectiveness. ➢ Test for QoL is the reintegration to normal living index. ➢ Test for stroke impairment done by national institute of health stroke score (NIHSS). ➢ 120 per group needed. ➢ Tests: t-test, chi-square test. ➢ Trial has not yet started, recruitment started 2013.

Critique

- Canadian study where only 10-15% stroke survivors receive rehabilitation. Not as many transferred to rehab units as in the UK, leading to more likely falls.
- Tai Chi program designed for diabetes rather than stroke specific.
- Can the instructor tell if the participant is doing it correctly via computer?
- Short duration.
- Caregiver present at tele-rehab, who may assist to prevent falls.
- Excludes those without high-speed internet.
- Participants are aged 45+
- Telecommunication applicable as Canada is large and people cannot access rehab services as easily in the UK.
- Larger trial currently in progress.
- The same program done at home – on an individual basis? = time consuming. Only 6 participants used. Not feasible for large numbers.
- Small group, not generalizable.

Table 3 description of literature retrieved with search terms Tai Chi and stroke (protocols)

2012 Zhang, X.C., Leung, A.W.N., Lin, Z.X. & Qin, Y.	Tai Chi for improving recovery after stroke (protocol)
<u>Description:</u> Tai Chi and stroke.	➢ <u>Background:</u> Stroke is a worldwide problem, being the third leading cause of death in developed countries and the second leading cause of death in developing countries. Stroke survivors experience disability after six months and lowers their quality of life. ➢ <u>Method:</u> protocol for a review. ➢ <u>Participants:</u> of any age with a diagnosis of stroke, no limit to time of stroke. ➢ <u>Databases to be searched:</u> CENTRAL, MEDLINE, EMBASE, CINAHL, AMED, PEDro, REHABDATA, CBM, CMCC, TCMonline, CMAC, Index to Taiwan Periodical Literature, Wanfang data. ➢ <u>Outcome measures:</u> Modified Rankin Scale, Care Dependency Scale, Functional Independence Measure, BBS, Barthel Index, Modified Barthel Index, Motor Assessment Scale, Wolf Motor Function Test, Fugl-Meyer Motor Assessment, Clinical Outcome Variables. Secondary outcomes include quality of life scales, depression, mental health scales and questionnaires. ➢ <u>Intervention:</u> Tai Chi or exercise incorporating Tai Chi principles. The control group will have no treatment, other exercise or conventional intervention.

	➢ Inclusion criteria: all RCTs and quasi-RCTs irrespective of language or publication status. ➢ Data analysis; sensitivity analysis, intention-to-treat analysis, case analysis, meta-analysis, assessment of heterogeneity.
Critique ➢ This protocol has been removed from the databases.	

Table 4 description of literature retrieved with search terms Tai Chi and stroke (protocols)

2014 Zhang, Y., Liu, H., Zhou, L., Chen, K., Jin, H., Zou, Y., & Li, Z.	Applying Tai Chi as a rehabilitation program for stroke patients in the recovery phase: a study protocol for a randomized controlled trial
<u>Description:</u> Tai Chi and stroke.	➢ <u>Background:</u> Stroke influences quality of life, with stroke burden set to increase in the next 20 years. 7m stroke survivors live in China with 70% having functional disabilities. Tai Chi is similar to Bobath therapy making it suitable to apply for stroke rehabilitation. ➢ <u>Method:</u> protocol for a two-arm RCT. ➢ <u>Participants:</u> 20 participants per group, meaning a total of 50 participants should be included. Stroke onset on average 2-24 weeks. ➢ Ethical approval was obtained by the Ethics Committee of Dongzhimen Hospital with the intention of receiving informed written consent. ➢ <u>Intervention:</u> Tai Chi and conventional therapy or conventional therapy alone. ➢ <u>Duration:</u> Five times per week, for 4 weeks for one hour. ➢ <u>Tai Chi style:</u> not mentioned. ➢ <u>Inclusion criteria:</u> confirmed stroke, aged 40-75 years, first stroke, between 2-20 weeks following stroke onset, lower limb weakness, able to walk >6m, able to follow commands, no experience with Tai Chi.

	➢ <u>Exclusion criteria:</u> received thrombolytic therapy or surgery, unstable medical condition, pregnant, participating in other research, severe co-morbidities. ➢ <u>Outcome measures:</u> Fugl-Meyer Assessment, Barthel Index, BBS, SSQLS, NIHSS, RSscan footscan gait system. ➢ <u>Data analysis:</u> unpaired two-sample t-tests, intention-to-treat analysis, demographics using SPSS.
<u>Critique</u> ➢ Five times a week may not be feasible for UK stroke survivors.	

Tables to describe literature retrieved which include Tai Chi and stroke (qualitative studies)

Table 1 description of literature retrieved with search terms Tai Chi and stroke (qualitative design)

2016 Desrochers, P., Kairy, D., Pan, S., Corriveau, H., & Tousignant, M.	Tai Chi for upper limb rehabilitation in stroke patients: the patient's perspective
<u>Description:</u> Tai Chi and stroke survivors with upper limb impairment. This study is reporting the pilot study conducted by Pan, S., Kairy, D., Corriveau, H., & Tousignant, M. (2017).	➢ <u>Background:</u> 85% of stroke survivors report upper limb impairment, a challenge for stroke rehabilitation. At 6 months post-stroke, individuals do not regain functional use of the arm and only 5-20% will fully recover arm function. Current treatment effects have been shown to be modest. Tai Chi has been shown to improve balance and prevent falls in older people. Some recent evidence has shown this to be the case among stroke survivors. Evidence on the upper limb is limited. ➢ <u>Method:</u> Semi-structured interviews using an interview guide based on the theory of planned behaviour (TPB). Thematic analysis was conducted. ➢ <u>Duration:</u> one-hour classes twice a week for 8 weeks with 10mins of home practice. ➢ <u>Tai Chi style:</u> Chen. ➢ <u>Participants:</u> 12 community-dwelling Canadian stroke survivors recruited with an average age of 60 years. ➢ <u>Inclusion criteria:</u> stroke with upper limb weakness, at least 6 months post-stroke, upper limb recovery between stage 2 to 6 on the Chedoke-McMaster Arm Impairment

	Inventory, presence of upper limb dysfunction, able to follow instructions. ➢ <u>Exclusion criteria:</u> participating in an upper limb rehabilitation programme, uncontrolled medical problems, significant visual problems, severe aphasia. ➢ Ethics approval obtained, written informed consent obtained. ➢ <u>Outcome:</u> Participants perceived physical, functional and psychological benefits, exceeding their expectations. ➢ <u>Recommendations:</u> This study can guide future studies on Tai Chi as an intervention to measure its benefits for stroke rehabilitation.
<u>Critique</u> ➢ Perceived benefits only. ➢ Confounding factors may play a role, such as the voluntary nature of participants.	

Tables to describe literature retrieved which include Tai Chi and falls (meta-analyses)

Table 1 description of literature retrieved with search terms Tai Chi and falls (meta-analysis)

2019 Liu, H.H., Yeh, N.C., Wu, Y.F., Yang, Y.R., Wang, R.Y., & Cheng, F.Y.	Effects of Tai Chi exercise on reducing falls and improving balance performance in Parkinson's disease: a meta-analysis
Description: Tai Chi and falls among Parkinson's disease.	➢ Background: Growing evidence shows exercise and physical therapy can improve performance of balance-related activities among Parkinson's disease patients. Tai Chi showed the TUG and BBS performance, as well as FRT improved after 12 to 24 weeks of Tai Chi. Tai Chi is a balance-based exercise that links slow and rhythmic movements together in a continuous sequence. Centre of gravity also moves with the movements of each foot. Practise involves lower limb control, lower limb strengthening and dynamic posture control. Different postures are maintained whilst keeping the centre of gravity within a changing base of support to challenge the balance control system. If Tai Chi can enhance the dynamic postural stability, it may be an effective way to reduce falls in Parkinson's patients. ➢ Method: A meta-analysis with 3 independent reviewers. 5 RCTs included (China, Korea, USA). ➢ Databases: PubMed, Cochrane Library, Medline, EMBASE, PEDro, CINAHL, SportDISCUS (EBSCO), Airiti Library, Trip.

	➢ Search terms: Parkinson's AND tai chi OR tai ji AND balance OR fall. ➢ Inclusion criteria: RCTs with Tai Chi and Parkinson's disease. ➢ Intervention: Tai Chi for 60 minutes, 2-3 times per week for 4-24 weeks. The comparison group has no intervention or stretching, resistance training and walking. ➢ Outcome measures: BBS, TUG, FRT. ➢ Outcome: Tai Chi groups had significantly less numbers of participants who fell compared with no intervention or other treatments. The BBS used in 3 studies found balance function was significantly improved in the Tai Chi group compared with no intervention and the walking group. The Tai Chi group performed better compared with other exercises or no exercise using the TUG and FRT. Improved functional mobility, however, was not significant. ➢ Conclusion: There is moderate to high quality evidence from RCTs that Tai Chi may be a good physical training strategy for preventing falls and improving balance in Parkinson's disease. ➢ Recommendations: to investigate the effects of Tai Chi and the precise intervention protocols for Parkinson's patients with different disease stages.

Critique

- If Tai Chi is beneficial for Parkinson's disease it may also be beneficial for stroke.
- Likewise, different phases of stroke should be investigated, such as the early rehabilitation phase whilst still in hospital.

Table 2 description of literature retrieved with search terms Tai Chi and falls (meta-analysis)

2017 Lomas-Vega, R., Obrero-Gaitán., Molina-Ortega., & Del Pino-Casado, R.	Tai Chi for risk of falls: a meta-analysis
Description: Tai Chi and risk of falls. Reviewers based in Spain.	➢ Background: Falls are the primary cause of traumatic death in the elderly, contributing to a substantial economic cost. As the number of falls is increasing in recent years, fall prevention is a major priority for healthcare policy worldwide. Tai Chi may prevent falls because it has been shown to be an effective exercise to improve balance control. Impaired balance and fear of falling are risk factors for falls. However, there is a lack of evidence about the effects of Tai Chi on the reduction of falls rates. ➢ Method: Meta-analysis with 2 independent reviewers. ➢ The PRISMA statement wasused to perform the review. Databases searched included PubMed, CINAHL, Scopus and PEDro. ➢ Analyzed the effectiveness of Tai Chi for falls prevention. ➢ No definition of falls mentioned. ➢ Keywords used were "tai chi", fall. ➢ 10 RCTs chosen. ➢ Tai Chi may prevent falls in those at-risk, especially in the short-term. Tai Chi may prevent injury from falling. Tai Chi may not influence the time of first fall. Falls rates may be half of those achieved by other interventions.

	➢ <u>Recommendations</u>: to investigate the effect of Tai Chi on injurious falls and time to first fall. ➢ Fall rates was the outcome measure. ➢ <u>Exclusion criteria</u>: RCTs only, analysing the effect of Tai Chi not combined with any other intervention, on incidence of falls, injurious falls or first time to fall, compared to usual care or other therapies different from Tai Chi. ➢ <u>Intervention:</u> Tai Chi style was not mentioned. ➢ <u>Outcome measures</u>: falls rates ➢ <u>Data Analysis:</u> Confidence intervals, mean differences. ➢ <u>Outcomes:</u> High-quality evidence showed a medium protective effect over the short term. ➢ <u>Recommendations</u>: more research is needed to investigate the effect of Tai Chi on injurious falls and first time to fall.
<u>Critique</u> ➢ 6 out of the 10 studies were used to evaluate the effectiveness of Tai Chi on reducing the incidence of falls long-term.	

Tables to describe literature retrieved which include Tai Chi and falls (systematic review and meta-analyses)

Table 1 description of literature retrieved with search terms Tai Chi and falls (systematic review with meta-analysis)

2016 Huang, Z.G., Feng, Y.H., Li, Y.H., & Lv, C.S.	Systematic review and meta-analysis: Tai Chi for preventing falls in older adults
<u>Description:</u> Tai Chi falls and older adults.	➢ <u>Background</u>: Falls are one of the major threats to the health of older adults. Falls increase with age and are associated with a decline in functional status. Fall-related injury is associated with the cause of death related to unintentional injury, being the 5th leading cause of death. Tai Chi has been shown to be effective in improving balance and may be beneficial to the elderly. However, the preventative effect of Tai Chi may vary with Tai Chi style, exercise dose, duration and follow-up time. ➢ <u>Method:</u> Systematic and meta-analytical review with 2 independent reviewers. ➢ 2 electronic databases searched for RCTs: Cochrane Library and MEDLINE, plus the MetaRegister of Controlled Trials and the WHO International Clinical Trials Registry Platform. ➢ The aim is to evaluate the effect of Tai Chi for preventing falls in older adults by updating the latest evidence. Further, to explore the association between the effectiveness and potential influential factors including Tai Chi frequency, total exercise time, follow-up time, fall risk and Tai Chi style. older adult aged 60 years +.

	➢ No definition of falls mentioned. ➢ Keywords used were "tai chi", falls, accidents, and "randomized controlled trial." ➢ 18 RCTs chosen. ➢ Tai Chi is effective for preventing falls in older adults which increases with exercise frequency. Yang style seems more effective that Sun style Tai Chi, though direct comparisons are lacking. ➢ <u>Recommendations</u>: to investigate the most effective intensity and style of Tai Chi and to assess the effect in older adults with certain co-morbidities, such as stroke. ➢ Rate of falls was the outcome measures. ➢ <u>Exclusion criteria</u>: aged over 60 years. ➢ <u>Intervention:</u> Yang and Sun styles used. ➢ <u>Outcome measures</u>: falls rates ➢ C.Is, mean differences. ➢ <u>Outcomes:</u> the number of fallers was lower in the twice per weeks group than once a week group, but the difference was not significant. ➢ Increase in Tai Chi frequency was associated with a significant increase in the preventive effect, in terms of numbers of fallers and falls rates. ➢ <u>Conclusion</u>: Overall, Tai Chi may effective in preventing falls in older adults.

	➢ Recommendations: to investigate Tai Chi style and to explore the effects of Tai Chi in stroke and Parkinson's disease.
Critique ➢ This review has not included more recent studies.	

Tables to describe literature retrieved which include Tai Chi and falls (randomized controlled trials)

Table 1 description of literature retrieved with search terms Tai Chi and falls (RCT)

2006 Faber, M.J., Bosscher, R.J., Paw, M.J.C.A., van Wieringen, P.C	Effects of exercise programs on falls and mobility in frail and pre-frail older adults: a multicenter randomized controlled trial
Description: Exercise programme and falls.	➢ Background: more intervention studies are needed in frail people (instability and risk of loss of function). Exercise interventions may be effective in preventing, delaying, or reversing the frailty process. Training results in improved muscular strength according to a systematic review. Physical exercise is effective in reducing falls in those high at risk of falling. Results are less conclusive in frail elderly. The degree of frailty plays a role in the effectiveness of exercise programmes that aim at fall prevention. ➢ Method: RCT. Ethical approval obtained. ➢ Participants: 278 from 15 care homes in Netherlands, block randomization. Single-blinded. ➢ Exclusion criteria: unable to walk 6m, cognitively impaired, medical contraindications. ➢ Intervention: group sizes of 12. Allowed to sit in a chair instead of standing for fatigue or poor balance control. ➢ Duration: 90 min session with a 30-minute social component. 20 weeks with 1 session a week for the first 4 weeks then twice weekly thereafter. 52-week follow-up. Frequency and duration were the same for both groups.

	➢ <u>Outcome measures:</u> Fall counts, POMA, GARS. ➢ <u>Data Analysis:</u> SPSS, p=>.05, SDs and means. ➢ <u>Outcomes:</u> falls (primary), mobility and physical function (secondary). 40 withdrew, 6 excluded as no reliable full data. Intervention should be challenging yet safe – difficult in a frail group. Study acknowledges it may be underpowered and could increase falls in the elderly frail. May be that elderly frail may prefer environmental modifications.
<u>Critique</u> ➢ Not Tai Chi itself used, but Tai Chi inspired exercises. ➢ 90 mins is deemed too long due to fatigue. ➢ Not intention-to-treat analysis.	

Table 2 description of literature retrieved with search terms Tai Chi and falls (RCT)

2014 Gao, Q., Leung, A., Yang, Y., Wei, Q., Guan, M.,Jia, C., & He, C.	Effects of Tai Chi on balance and fall prevention in Parkinson’s disease: a randomized controlled trial
<u>Description:</u> Tai Chi and balance and fall prevention in Parkinson’s disease.	➢ <u>Background:</u> Falls are a major problem among those with Parkinson’s disease in China, and could lead to decreased mobility, functional decline, depressive symptoms and decreased quality of life. Tai Chi is widely practised in China and is recommended for the elderly because it has been shown to increase muscle strength, and coordination with social benefits. ➢ <u>Method:</u> single-blinded RCT with 6 months’ follow-up. ➢ <u>Duration:</u> 12 weeks, 36 sessions for 60 mins. ➢ <u>Participants:</u> 76 community-dwelling Parkinson’s disease patients, aged over 40 years. Randomised by offering groups to alternate patients. ➢ <u>Tai Chi style:</u> 24-form Yang style. ➢ <u>Outcome measures:</u> BBS, Unified Parkinson’s Disease Rating Scale (UPDRS) III, Timed Up & Go [TUG] and falls incidence. ➢ <u>Inclusion:</u> diagnosis of idiopathic Parkinson’s disease, over 40 years old, independently mobile, fell at least once over the last 12 months. ➢ <u>Exclusion:</u> participants have a Mini-mental state examination score <24, had a serious medical problem

	such as heart failure and severe hypertension, could not endure moderate exercise for 60 mins. ➢ No definition of falls given. ➢ Reasons for falling collected in a notebook by participants. ➢ <u>Data Analysis:</u> means and standard deviations calculated with Chi-square test to analyse categorical data, independent t-test for continuous data, change scores. ➢ <u>Outcome:</u> Tai Chi group showed significantly greater improvement in the BBS than the control group, but there were no significant changes in the other tests. Falls incidence significantly decreased at the 6-month follow-up in the Tai Chi group. ➢ <u>Result:</u> 12 weeks of Tai Chi improved balance and decreased fall incidence in people with Parkinson's disease. Tai Chi could be an effective intervention for people with Parkinson's disease either at home or in the community. ➢ <u>Recommendations:</u> no recommendations were made.
<u>Critique</u> ➢ This study was conducted in China where Tai Chi is already widely accepted. ➢ All participants were independently mobile.	

Table 3 description of literature retrieved with search terms Tai Chi and falls (RCT)

2010 Huang, H.C., Liu, C.Y., Huang, Y.T., & Kernohan, W.G.	Community-based interventions to reduce falls among older adults in Taiwan – long time follow-up randomised controlled study
Description: Tai Chi to reduce falls among older adults in Tawian.	➢ Background: Falls are a major problem for older people with nearly one third of older people in the USA experiencing a fall. One tenth of falls in older people results in serious injury. Falls may be considered a consequence of weakening physical function. Falls and fear of falling also contribute to decreased mobility and increased functional dependence. Fall pose a huge economic burden on medical services. Exercise has been shown to reduce falls and improve balance among older people. Tai Chi is a low-impact exercise involving the use of large muscle groups of the body. Research has shown Tai Chi involves multiple exercise components including balance, strengthening and resistance exercises. ➢ Aim: to examine the effects of different interventions on fall prevention. ➢ Method: A 4-arm (Tai Chi, Tai Chi with education, education and control) RCT with 1.5 years follow-up. ➢ Duration: 5 months. ➢ Participants: From four villages in Taiwan. 184 participants. More males than females. ➢ Outcome measures: TUG, FRT. ➢ Inclusion criteria: Aged over 65 years.

	➢ <u>Data Analysis:</u> Chi-square, Fisher's Exact tests, t-tests to examine differences in demographics between the groups. McNemar test to evaluate the significance of any change in a proportion of two category data. ➢ <u>Outcome:</u> In total 163 participants completed. Tai Chi group and control had better gait and balance, as well as lower fear of falling than the Tai Chi with education group. Tai Chi group performed significantly better at TUG and FRT than baseline. Other groups did too but it was not mentioned if this was significant. Tai Chi with education improved on the FRT compared with baseline. The Tai Chi group was the only group with a non-significant reduction of falls. The Tai Chi group with education showed a significant reduction in falls. At 1.5 years, all 3 intervention groups, namely education, had statistically significant reduced risk of falling compared with the control. ➢ <u>Conclusion:</u> education combined with Tai Chi was likely to be more effective at reducing fall incidence compared with education alone, Tai Chi alone. All groups showed a significant reduction in risk of falls after 1.5 years. ➢ <u>Recommendations:</u> to identify the appropriate aspects of home-based rehabilitation following fracture treatment.
<u>Critique</u>	

- Taiwanese older people are more familiar with Tai Chi whereas UK stroke survivors may be more aware of the education. It is unclear if UK stroke survivors would accept Tai Chi for such a long period of time.
- The details of the education given were not clear.

Table 4 description of literature retrieved with search terms Tai Chi and falls (RCT)

2016 Hwang, H.F., Chen, S.J., Lee-Hsieh, J., Chien, D.K., Chen, C.Y., Lin, M.R.	Effect s of home-based Tai Chi and lower extremity training and self-practice on falls and functional outcomes in older fallers from the Emergency Department – a randomized controlled trial
Description: Tai Chi, falls, home-based practice and lower extremity training.	➢ Background: Developing cost-effective fall prevention interventions is challenging. Whether Tai Chi is a cost-effective therapeutic fall-prevention intervention is not known despite evidence showing it reduces falls and associated injuries. The effect of Tai Chi self-practice on reducing falls is rare in studies thus the ED has been targeted to identify those at high-risk of falls. ➢ Method: RCT. ➢ Duration: 18 months with a 12-month follow-up. Tai Chi sessions lasted 60 mins once a week for a 24-week period. ➢ Participants: 456 people aged 60 years and older who received fall-related medical attention in the ED at least 6 months before the study. ➢ Tai Chi style: Yang style. ➢ Outcome measures: falls incidence, Tinetti Balance Test, Tinetti Gait Test, FES, GDS, MMSE, grip strength. ➢ Inclusion: independently mobile, received medical treatment for a fall in the last 6 months. ➢ Exclusion: major unstable cardiopulmonary disease, cognitive impairment, contraindications to exercise.

	➢ Ethics approval obtained from the Taipai Medical University institutional review board and written consent obtained. ➢ Multiple instructors used. ➢ Control group received stretching, muscle strengthening and balance training exercises for the same time as experimental group. ➢ No definition of falls given. ➢ Reasons for falling collected by participants in diaries. ➢ <u>Data Analysis:</u> intention-to-treat approach, a proportional hazards model used to investigate the relationship between type and time to first fall. A logistic regression model was used to compare the effects of Tai Chi and the control group exercises and occurrences of fallers and recurrent fallers. Paired t-tests were used. ➢ 88 dropped out before baseline because they died, were hospitalised, moved or were discouraged by family for safety reasons or childcare reasons. ➢ <u>Outcome:</u> home-based Tai Chi may reduce falls and injurious falls in older people, and this can be maintained for at least a year. ➢ <u>Result:</u> participants who attended 20 or more sessions did not significantly differ from the other group. However, the Tai Chi group was significantly less likely to fall during the whole intervention period.

	➢ Recommendations: to confirm whether actively practising Tai Chi can reduce injurious falls and lead to cognitive differences between groups.
Critique ➢ A volunteer effect was present. ➢ Loss to follow-up may restrict the generalization of results to frail older people. ➢ Multiple instructors were used and differences between them may have resulted in performance bias.	

Table 5 description of literature retrieved with search terms Tai Chi and falls (RCT)

2004 Li, F., Harmer, P., Fisher, J., & Mcauley, E.	Tai Chi: improving functional balance and predicting subsequent falls in older persons
<u>Description:</u> Tai Chi and falls and balance.	➢ <u>Background:</u> increasing age leads to loss of functional balance, particularly in the frail. Loss of balance has been shown to be reversible through exercise training. Properly designed exercise programmes can improve balance and reduce risk of falling and falls rates according to studies. However, it is not evident from literature if improved balance through exercise is related to reduced fall frequency when the intervention is over. Less than 3 months of Tai Chi will show little improvement. The duration has to be 12 weeks or more. ➢ <u>Method</u>: RCT. ➢ <u>Participants:</u> aged 70+ based in USA using staggered recruitment protocol. Does not state where from or inclusion/exclusion criteria. ➢ <u>Intervention:</u> Tai Chi involving multidirectional weight shifting, awareness of body alignment, multi-segmental movement coordination (arms, legs, trunk). Synchronized breathing (aligned with each Tai Chi movement) was also emphasised. 5-10 min warm-up, 30 mins Tai Chi, 5-10 mins cool-down. Instruction covering new movements and reviewing movements learned in previous sessions also delivered. Background music included. Control group were

	given stretching control exercises without the lower-extremity strength- and balance-training benefits of Tai Chi. Intervention followed up with a 6-month post-intervention follow-up period. ➢ <u>Duration:</u> 26 weeks, 60 minute three times a week. ➢ <u>Tai Chi style:</u> Yang. ➢ <u>Outcome measures:</u> BBS, dynamic gait index, functional reach test, falls counts. ➢ <u>Data Analysis:</u> ANOVA for analysis of variance, ordinary least squares regression analysis, SPSS, means, SDs. ➢ <u>Outcomes:</u> reasonable to say fall occurrence in the post-intervention period is attributed to a sustained effect of Tai Chi. ➢ <u>Recommendations:</u> to investigate subgroups with different levels of physical functioning.
<u>Critique</u> ➢ Control group did not benefit from lower extremity strength- and balance- training effects in Tai Chi. ➢ Investigated effects after the intervention. ➢ Researcher not blind =experimenter bias. ➢ No laboratory-based balance measures which are more rigorous such as tests of limits of stability and sensory organization.	

Table 6 description of literature retrieved with search terms Tai Chi and falls (RCT)

2012 Li, F., Harmer, P., Fitzgerald, K., Eckstrom, E., Stock, R., Galver, J., Maddalozzo, G., & Batya, S.S.	Tai Chi and postural stability in patients with Parkinson's disease
<u>Description:</u> Tai Chi, balance, falls and Parkinson's disease.	➢ <u>Background:</u> Patients with Parkinson's disease experience an impairment with balance, particularly standing balance, leading to reduced functional ability and increased risk of falling. This instability leads to frequent falls. Tai Chi has been shown to improve strength, balance and physical function, and also to prevent falls in older adults. Few studies have explored Tai Chi and falls a a result of improvement in balance among People with Parkinson's disease. ➢ <u>Method</u>: RCT. ➢ <u>Participants:</u> aged between 40 and 85 from four cities in Oregon from local support groups and newspaper ads, and referrals from physiotherapists and neurologists. ➢ <u>Intervention:</u> Tai Chi involved an 8-form routine, performing weight-shifting exercises and controlled displacement of the centre of mass over the base of support, and lateral stepping. The control group received resistance training or stretching exercises. ➢ <u>Duration:</u> 24 weeks with classes 60 minutes long twice a week. ➢ <u>Tai Chi style:</u> not mentioned.

	➢ Outcome Measures: computerized dynamic posturography, computerized walkway to measure gait, functional reach test, TUG. ➢ Data Analysis: intention-to-treat analysis, Chi-square test, independent t-test to compare means paired t-test for within-group changes, negative binominal regression. ➢ Outcomes: Tai Chi is more effective than low-intensity, low-impact exercise programs in alleviating Parkinson's symptoms and improving functional ability. ➢ Results: Tai Chi group had mean increases in stride length, functional reach and knee extension, but decreases in TUG. No significant change was observed in the group with stretching exercises. Incidence of falls was lower in the Tai Chi group. ➢ Recommendations: no recommendations were made.
Critique ➢ A non-exercise group was not included.	

Table 7 description of literature retrieved with search terms Tai Chi and falls (RCT)

2018 Li, F., Harmer, P., Fitzgerald, K., Eckstrom, E., Akers, L., Chou, L.S., Pidgeon, D., Voit, J., & Winters-Stone, K.	Effectiveness of a therapeutic Tai Ji Quan intervention vs a multimodal exercise intervention to prevent falls among older adults at high risk of falling: a randomized controlled trial.
Description: Tai Chi, balance, falls.	➢ Background: In the USA, 28% of community-dwelling adults aged 65 years and over fall annually. This places a financial burden on medical services. Exercise can be a safe and effective way to reduce falls. Identifying the exercise intervention that is the most safe, effective and easily implementable. ➢ Aim: to determine the comparative effectiveness of two proven interventions, therapeutically tailored Tai Chi exercise and multimodal exercise. Compared with stretching exercise in reducing falls in older people at high risk of falling. ➢ Method: RCT. ➢ Intervention: Tai Chi or multimodal exercises (aerobic conditioning, strength, balance and flexibility activities) for 60 minutes, twice a week for 24 weeks. The Tai Chi programme was specifically created by the authors and is for sale. ➢ Inclusion criteria: 70 years or older, already fell in the last 12 months, impaired mobility present, able to walk 1 or 2 blocks with or without assistive devices, able to exercise, willing to be randomized.

	➢ Exclusion criteria: already exercising, cognitively impaired, has severe comorbidities. ➢ Participants: from the community living in 7 urban and suburban cities across 3 counties in Oregon. These counties were of moderate to high density for older people and high falls incidence. Were block randomized into blocks of 3 or 6. Mean age was 77.7 years with 92.1% females. ➢ Outcome measures: number of falls, FRT, TUG, SPBB. ➢ Data Analysis: intention-to-treat analysis, Fisher Exact test for categorical variables. SPSS used. ➢ Outcome: Attrition rate was 13% (lower than the anticipated 15%). Two participants fell in class and needed ED. Two fell in the stretching group and three fell in the multimodal group. ➢ Recommendations: recommend using the Tai Chi programme to improve balance.

Critique

- It is not clear if the participants chosen had balance impairment.
- Falls were self-reported. Self-reports are known to be subject to recall bias. To minimalize self-reporting bias, monthly telephone calls, confirmation during assessments, medical records were also used to ensure data accuracy.
- Reason for falling was unclear.
- The authors are selling the Tai Chi programme which could introduce researcher bias.
- Most participants were female who are more at risk of falling due to osteoporosis rather than balance impairment.

- This Tai Chi programme may not be suitable for balance caused by stroke symptoms.

Table 8 description of literature retrieved with search terms Tai Chi and falls (RCT)

2009 Logghe, I.H.J., Verhagen, A.P., Rademaker, A.C.H.J., Zeeuwe, P.E.M., Bierma-Zeinstra, S.M.A., Van Rossum, E., Faber, M.J., Van Haastregt, J.C.M., & Koes, B.W.	Lack of effect of Tai Chi Chuan in preventing falls in elderly people living at home: a randomized clinical trial
Description: Tai Chi and falls.	➢ Background: falls risk is related to disturbed balance, dizziness, decreased muscular strength, use of benzodiazepines and diuretics, changes in walking pattern, and age. Exercise training is reported to help prevent falls. Tai Chi is an integral part of traditional Chinese medicine. As well as fall risk reduction and balance improvement, other physical and psychological aspects are enhanced, such as mental wellbeing. ➢ Methodology: RCT, partially blinded. Ethically approved. A blinded research assistant screened for eligibility. Secondary outcomes based on balance, fear of falling, blood pressure, heart rate at rest, forced expiratory volume, physical activity, functional status. ➢ Participants: 138 Dutch participants in the Tai Chi group, 131 in control group, people aged 70+ years, community-dwelling, high risk of falls (1+ falls in the last year or had disturbed balance, mobility problems, dizziness, use of benzodiazepines or diuretics. Identified using medical files. GPs invited patients by mail and screened for eligibility via telephone. Computer-generated randomization list/pre-stratified block randomization.

	➢ <u>Intervention:</u> brochure about fall prevention in the home. Control group received usual care (they could use available services), intervention group received Tai Chi. Chi Gong exercises for warm-up/cool-down. Group sizes 7-14. 15 mins home practice encouraged. ➢ <u>Duration:</u> 1 hour twice a week for 13 weeks. ➢ <u>Tai Chi style:</u> Yang. ➢ <u>Outcome measures:</u> falls calendar, BBS, FES, Groningen Activity Restriction Scale (functional status), Physical Activity Scale, questionnaire to register use of walking devices, medication, use of healthcare services. ➢ <u>Data Analysis:</u> means, SDs, HRs, Anderson-Gill model, Mann-Whitney test, t test, SPSS. ➢ <u>Outcomes:</u> no differences between the groups for falls risk. No support that Tai Chi improves balance, physical activity, functional status, fear of falling. ➢ <u>Recommendations:</u> further analysis needed on secondary outcome measures to provide more insight into effects on physical and psychological functioning.
<u>Critique</u> ➢ Participants did not have a high falls risk because of impaired balance, but for other things. Maybe better to include those with impaired balance for a marked difference. ➢ Lack of balance improvement could be responsible for results. Less likely to occur if no balance impairment to start with.	

Table 9 description of literature retrieved with search terms Tai Chi and falls (RCT)

2012 Taylor, D., Hale, L., Schluter, P., Waters, D.L., Binns, E.E., McCracken, H., McPherson, K., & Wolf, S.L.	Effectiveness of Tai Chi as a community-based falls prevention intervention: a randomized controlled trial
Description: Tai Chi and falls.	➢ Background: a need to reduce falls in the elderly; evidence for effectiveness is inconclusive. ➢ Method: An RCT. ➢ Participants: 684 community-based adults aged 70+ with at least one falls risk factor. ➢ From 11 sites throughout New Zealand. ➢ Intervention: Three groups: Tai Chi doing once a week; Tai Chi doing twice a week; CG with low-level exercise program. Sun style Tai Chi, modified. ➢ Duration: 20 weeks long. 1-hour sessions. ➢ Instructor:participant ratio was 1:15. ➢ Data Analysis: Randomized using web-based, computer-generated blocked random number system by statistician. Sealed opaque envelope given with group allocation and opened at home. Contact number given. ➢ Experienced Tai Chi instructors. ➢ Falls recorded monthly plus 12 weeks after follow-up. ➢ Falls data collected at baseline and after 12 months. ➢ Balance, mobility and leg strength collected at baseline, 11 and 17 months. ➢ Physical activity data collected at baseline using the New Zealand Physical Activity Questionnaire Short-Form.

	➢ Ethics approval and written informed consent. ➢ Recruited from community via newspaper ads, local radio and television, posters, flyers in community centres, doctors' and physio offices, libraries, churches. Contacted recruiter by phone. ➢ <u>Inclusion criteria</u>: ages 65+, had at least one fall in last 12 months, at risk of falls. ➢ Medical clearance obtained. ➢ Calendars provided to record falls monthly. ➢ Reminder phone calls if not returned within 2 weeks. ➢ Not mention which group they were in and definition of fall clarified. ➢ Adverse event forms filled out at the end. ➢ <u>Outcome measures</u>: Timed Up & Go test (functional mobility), step test. ➢ Power calculations made. ➢ SEs and C.I.s, p-values, means, SDs, median attendance rates, IQR. ➢ Confounders of falls included sex, age, walking aids indoors/outdoors, living alone, with career, medical conditions, fall in last 12 months. ➢ STATA used. ➢ Analysed according to original signed groups.

	➢ <u>Exclusion criteria:</u> if unable to ambulate independently, chronic medical condition, severe cognitive impairment, did Tai Chi in last year, currently in rehab exercise program to improve strength and balance. ➢ Assessors blinded to group allocation. ➢ <u>Outcomes:</u> no statistically significant differences in reduction of falls between the Tai Chi groups and the control group. The total dose of Tai Chi is important. At least 50 hours of Tai Chi is required to be effective in reducing falls.
<u>Critique</u> ➢ Funded and supported by the Accident Compensation Corporation (ACC). Desirability bias as participants may be eager to give what the assessors want. Author acknowledges this. ➢ Not clear what exercise the CG did. ➢ Population type is not clear in the question. ➢ More females than males (females more prone to fractures, osteoporosis). ➢ Balanced groups, all accounted for. ➢ Intention to treat. ➢ Falls declined in all 3 groups so no marked difference. ➢ Not clear how many sessions a week the CG had. ➢ Inconclusive results – no differences in falls rates, strength or balance. ➢ Mainly seated exercises with stretching, low-level cardio-vascular exercise so not focussing on balance, hence the results? ➢ Author acknowledges no exercises specifically targeted at balance training were included. ➢ Instructors provided with a manual.	

- Recommendations: 50 hours needed to be effective. Author acknowledges less done in this study.
- New Zealand is hilly. More likely to practice outdoors as it is sunny.
- Tai Chi modified to this country including Maori population.

Table 10 description of literature retrieved with search terms Tai Chi and falls (RCT)

2013 Tousignant,M., Corriveau, H., Roy, P.M., Desrosiers, J., Dubuc, N., Hebert, R.	Efficacy of supervised Tai Chi exercises versus conventional physical therapy exercises in fall prevention for frail older adults: a randomized controlled trial
<u>Description:</u> Tai Chi and falls in frail older people.	➢ <u>Background:</u> Accidental falls are a major problem for older people in the West. Falls can affect quality of life, resulting in preventing people from going out of the home. Frail older people may benefit from an individual intervention rather than a group. Additionally, Tai Chi may seem to be a good alternative to regular physiotherapy as part of falls prevention. The study aims to compare the effectiveness of supervised Tai Chi against rehabilitation. ➢ <u>Method:</u> blinded RCT. Variables were balance, gait, fear of falling, functional autonomy, self-actualization, self-efficacy. The objective was to see which fall-related variable explained reducing falls rates. ➢ <u>Participants:</u> 152 (76 both groups) aged 65+ in a Canadian hospital day unit. Both men and women. Randomized by random number generator to Tai Chi or conventional physiotherapy programme. Sample was stratified according to BBS with a cut off of 36/56. Brown sealed envelopes given to participants with group allocation. Single blind (researchers blinded). ➢ Falls definition given.

	➢ Inclusion criteria: high risk for falls, BBS below 49, 1 fall in the last 6 months, multiple disabilities, mentally competent. Can use aids. ➢ Exclusion criteria: unfit for physical activities following medical assessments, cognitively or physically impaired to participate. ➢ Intervention: Tai Chi using the 8-form BA-DUAN-JIN, a Tai Chi sequence involving turning, weight-shifting, leg bending and extension, single-leg standing and various arm movements. Warm up, principles explained to participants, as well as body awareness, relaxation and breathing. Movements were adapted to participants' condition and to ensure safety. Group session of 2-4 participants with an instructor with 20 years of experience. Assisted with a physio helping to adapt the movements to their abilities. Physiotherapy programme included weight transfer, strengthening and walking exercises. One-to-one adapted to each participant. ➢ Duration: 60 minutes twice a week for 15 weeks (30 hours). ➢ Outcome measures: falls incidence. ➢ Data Analysis: Mann Whitney U test, independent t-test.

	➢ Results: Faller status was in favour of the Tai Chi group, but there was no significant difference between groups for fall severity. ➢ Outcome: Supervised Tai Chi as part of a rehabilitation program seemed to be more effective than conventional physiotherapy for frail older people.
Critique ➢ Informed consent and ethical approval gained. ➢ 24 withdrew from the Tai Chi group, 26 withdrew from the control group (mainly illness). ➢ Result may be because frail people with multiple conditions in a day hospital – acknowledged by the author. ➢ The study focussed on balance, and medical conditions may cause loss of functional autonomy. ➢ 15 weeks was a burden for participants in both groups – therefore this time may be too long for stroke patients due to fatigue. ➢ Study was done at one site, assuring data validity. ➢ All instruments used have been proven to be valid and reliable. = good internal validity.	

Table 11 description of literature retrieved with search terms Tai Chi and falls (RCT)

2003 Wolf, S.L., Sattin, R.W., Kutner, M., O'Grady, M., Greenspan, A.I., & Gregor, R.J.	Intense Tai Chi exercise training and fall occurrences in older, transitionally frail adults: a randomized, controlled trial
Description: Tai Chi and falls.	➢ Background: falls in the elderly is a major public health problem; studies have focussed on robust elderly; less robust transitioning to frailty need to be investigated. ➢ To determine if an intense Tai Chi programme could reduce risk of falls more than a wellness education programme. ➢ Participants: 48 participants, aged 70-97, randomized from 20 congregate living facilities in Atlanta. 144 to TC, 141 to WE. ➢ Duration/Intervention: Tai Chi for two sessions a week, starting at 60 mins progressing to 90 mins for 48 weeks. Warm-up and cool-down lasted between 10-50 mins. ➢ Outcome measures: depression scale, activities-specific balance confidence scale, falls efficacy scales (for fear of falling). Berg Balance test used for balance. ➢ RRs of falling were not statistically different between the groups. C.Is used. ➢ Evaluators blinded to intervention allocation, instructors blinded to outcome measures. ➢ Written consent gained and approval from the Emory University human investigation committee. ➢ Inclusion criteria: had to be 'transitionally frail', had to have fallen at least once in the last year.

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➢ <u>Exclusion criteria</u>: severe illness that would affect study, i.e. cardiopulmonary diseases, cognitive impairment (MMSE score <24), wheelchair-bound, terminal cancer or major orthopaedic conditions.
➢ Two instructors (grand master and his student).
➢ Falls is the primary outcome, definition included from FICSIT.
➢ Two forms filled out if fallen: date of fall, and checklist for type of fall with circumstances and extent of injury, if any. Submitted weekly and reviewed monthly. Phone calls made to clarify errors, or incomplete forms.
➢ Measurements taken every 4 months – quarterly follow-up.
➢ Intention-to-treat.
➢ No statistically significant reduction in falls risk.
➢ <u>Outcomes:</u> Reduction in falls risk may be clinically important but not statistically significant as study had the power to detect a 50% reduction in fall rate but not a 25% one. More fell in the education group than the Tai Chi group.
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<u>Critique</u>
➢ Not compared to standard therapy but another intervention. Therefore, the authors can’t say if Tai Chi is better than standard therapy from this study.
➢ Facilities not randomized – all residents were able to enrol.
➢ Goes on to talk about how level of education can affect falls risk, which is not relevant to the original outcomes.
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- More women in the study than men – may have a history of upper extremity fractures. More prone to injurious falls.
- Fear of falling may be difficult to measure as it is based on participant's perception.
- Definition of frailty may be imprecise.
- Drop-outs included those who missed more than 8 consecutive weeks. So, it is possible participants missed 7 weeks, which is a lot to catch up on. This could affect performance.
- Warm-up/ cool-down took most of the session sometimes, lasting as long as 50 mins – leaving only 10 mins for Tai Chi. Maybe duration not long enough? Also, length of Tai Chi inconsistent each session.
- Intensity based on ability of the group – maybe some would have benefitted for more intense Tai Chi? Perhaps held back by the majority?

Tables to describe literature retrieved which include Tai Chi and falls (protocols)

Table 1 description of literature retrieved with search terms Tai Chi and falls (protocol)

2019 Zhong, D., Xiao, Q., He, M., Li, Y., Ye, J., Zheg, H., Xia, L., Zhang, C., Liang, F., Li, J., & Jin, R.	Tai Chi for improving balance and reducing falls: a protocol of systematic review and meta-analysis
<u>Description:</u> Protocol for a systematic review and metanalysis on Tai Chi, falls and balance.	➢ <u>Background:</u> Falls are a major health problem and an economic burden to society. Tai Chi prevails in China and is becoming popular worldwide. Tai Chi may improve balance and promote limb function in stroke. ➢ <u>Method</u>: protocol for a systematic review and meta-analysis. ➢ <u>Inclusion criteria:</u> RCTs only, no restrictions on language or date. Participants are healthy or unhealthy. The comparator is usual care, other exercise or no treatment. ➢ <u>Outcome measures:</u> number of falls, fall rates, BBS, standing-walk test, single-legged test, other balance measurements. ➢ <u>Databases:</u> CBM, CNKI, WanFang, Chinese Science and Technology Periodical Database, PubMed, EMBASE, Web of Science, Cochrane Library. ➢ <u>Search terms:</u> tai chi, fall, balance, randomized controlled trial, RCT.
<u>Critique</u> ➢ What is healthy and what is unhealthy?	

Tables to describe literature retrieved which include Tai Chi and falls (pre-test, post-test studies)

Table 1 description of literature retrieved with search terms Tai Chi and falls (pre-test, post-test studies)

2017 Gallant, M.P., Tartaglia, M., Hardman, S., & Burke, K.	Using Tai Chi to reduce fall risk factors among older adults: an evaluation of a community-based implementation
Description: Tai Chi and falls among the elderly.	➢ Background: Falls represent a major problem among the elderly, resulting in reduced quality of life and independence. Falls pose a problem for the substantial cost to healthcare services. Tai Chi has been shown to improve fall-related outcomes among older adults. An evidence-based Tai Chi programme has been developed for older adults by Li et al. (2004) and has been used in this study to see if it is suitable for community-based older adults. ➢ Method: pre-test/post-test to evaluate a community-based implementation of the above-mentioned Tai Chi programme. ➢ Participants: 131 participants older people aged 49-97 years and above, living in the community. They were recruited from adverts and word-of-mouth. ➢ Inclusion criteria: living in the community in USA, could walk with ease with or without devices, targeted those age 65 years or above but accepted younger people.

	➢ Intervention: The 12-week version of the Tai Chi: Moving for Better Balance programme as developed by Li et al. (2004). ➢ Duration: Each class lasted one hour, twice a week. ➢ Outcome measures: self-reported falls rates, TUG, Activities-Specific Balance [ABC] Confidence Scale. ➢ Data Analysis: Chi-square test, two-tailed t-test, Wilcoxon signed rank test using SPSS. ➢ Results: Mean attendance was 70%. Participants reported being satisfied with the class. There were significant pre-post improvements in all outcome variables. Length of home practice time was unknown. However, there was no significant difference between number of falls at baseline and 12-weeks. ➢ Outcomes: The intervention used in this study appeared to be effective at reducing fall risk and was well-received by older adults.
Critique ➢ The TC programme was not devised for people with severe balance impairment, despite promising to improve balance. ➢ Participants were relatively mobile. ➢ There was no comparison group who did not receive the intervention.	

Tables to describe literature retrieved which include Tai Chi and balance (systematic reviews with meta-analyses)

Table 1 description of literature retrieved with search terms Tai Chi and balance (systematic review with meta-analysis)

2014 Huang, Y., & Liu, X.	Improvement of balance control ability and flexibility in the elderly Tai Chi Chuan (TCC) practitioners: a systematic review and meta-analysis
<u>Description:</u> Tai Chi's effect on balance in elderly Tai Chi practitioners (aged 77-80 years) in China.	➢ <u>Background</u>: The number of people aged above 60 years is set to increase by 2020. Falls can lead to death and disability. Balance ability deteriorates with age, increasing the risk of falls. Tai Chi has been widely practised in China for centuries and may improve the balance ability in older people. ➢ <u>Method</u>: Systematic review and meta-analysis. ➢ This meta-analysis aimed to evaluate the effect of Tai Chi on the balance control ability of older people. ➢ <u>Databases searched:</u> PubMed, EMBASE, Cochrane Library with key words balance or balance control, flexibility, tai chi or Tai Chi. ➢ <u>Inclusion criteria</u>: RCTs only, older adults aged 60 years or above, Tai Chi was the intervention, the control group did not have Tai Chi but other means or nothing, outcomes of studies were balance control and flexibility.

	➢ <u>Exclusion criteria</u>: studies language was not English, reviews, letters, or comments, no available data in the studies. ➢ Two investigators were involved. ➢ 14 RCTS reviewed. ➢ <u>Tai Chi style</u>: Yang and Sun. ➢ <u>Outcomes</u>: Tai Chi was found to be beneficial to improve balance control ability in older adults.
<u>Critique</u> ➢ The number of included studies was small.	

Table 2 description of literature retrieved with search terms Tai Chi and balance (systematic review with meta-analysis)

2014 Ni, X., Liu, S., Lu, F., Shi, X., & Guo, X.	Efficacy and safety of Tai Chi for Parkinson's disease: a systematic review and meta-analysis of randomized controlled trials
Description: Safety of Tai Chi among people with Parkinson's disease.	➢ Background: Parkinson's disease is a challenge for neurologists, with long-term side effects of Levodopa. There is more risk involved for this population because they experience insomnia, excessive daytime sleepiness and autonomic dysfunction. Tai Chi has shown potential to help with these symptoms. ➢ Method: systematic review and meta-analysis to identify whether Tai Chi safely benefits people with Parkinson's. ➢ Databases searched: PubMed, EMBASE, the Cochrane Library, the Chinese Biomedical Database, the China National Knowledge Infrastructure, VIP Journal Integration Platform, Wanfang Med Online and the Japan Medical Abstracts Society using the search terms: Tai Chi, Tai Ji, T'ai Chi, Taijiquan, Parkinson disease, Parkinson's disease, Primary Parkinsonism and Paralysis Agitans. ➢ Inclusion criteria: RCTs, diagnosed with Parkinson's. No other restrictions. ➢ 2 independent reviewers. ➢ Two authors were involved. ➢ 9 articles were reviewed.

	➢ Outcomes: Tai Chi was deemed safe in the early stages of Parkinson's patients on medications. ➢ Recommendations: Studies with larger sample sizes are needed. The feasibility of Tai Chi needs to be assessed for different medical situations.
Critique ➢ The safety of Tai Chi may not mean that Tai Chi is safe for stroke survivors. ➢ The number of articles reviewed was low.	

Table 3 description of literature retrieved with search terms Tai Chi and balance (systematic review with meta-analysis)

2014 Yang, Y., Li, X.Y., Zhu, Y.L., Hao, Y.L.	Tai Chi for improvement of motor function, balance and gait in Parkinson's disease: a systematic review and meta-analysis
<u>Description:</u> Tai Chi, balance in Parkinson's disease.	➢ <u>Background</u>: Rigidity, rest tremor and balance disruption are problems for people with Parkinson's. These symptoms lead to motor function disability and lower quality of life. Tai Chi gas been shown to improve balance and strength in the general population and may do the same in the target population in this study. ➢ <u>Method</u>: A systematic review and meta-analysis to evaluate the efficacy of Tai Chi for Parkinson's. ➢ Insufficient evidence. ➢ <u>Databases searched:</u> PubMed, EMBASE, Cochrane Library, China Knowledge Resource Integrated Database, Weipu Database for Chinese Technical Periodicals and Wan Fang Data using the search terms: Parkinson's disease, Parkinson, tai chi, taiji, and shadowboxing. ➢ <u>Inclusion criteria</u>: RCTs, non-randomized controlled trials, diagnosis of Parkinson's, can be compared to other therapies and drugs, language was English or Chinese. ➢ <u>Exclusion criteria</u>: outcomes of the first phase could not be extracted in the cross-over studies, the studies reported without detailed information. ➢ 2 independent reviewers.

	➢ 8 articles of which 7 were RCTS and 1 was a non-randomised controlled trial. ➢ <u>Outcomes</u>: Tai Chi has beneficial effects in improving motor function, balance and functional ability in Parkinson's patients. Compared with other active therapies, Tai Chi only showed better effects in improving balance as opposed to gait and motor function.
<u>Critique</u> ➢ Other therapies and drugs may be confounders when generalising to other populations. ➢ The number of articles reviewed was low.	

Tables to describe literature retrieved which include Tai Chi and balance (systematic reviews)

Table 1 description of literature retrieved with search terms Tai Chi and balance (systematic review)

2017 Ćwiękała-Lewis, K.J., Gallek, M., & Taylor-Piliae, R.E.	The effects of Tai Chi on physical function and well-being among persons with Parkinson's disease: a systematic review
<u>Description:</u> Tai Chi and physical function in people with Parkinson’s. Reviewers based in USA.	➢ <u>Background</u>: By the year 2030, 9 million people over the age of 50 will be living with Parkinson's disease. Tremor, stiff muscles and postural instability are symptoms of Parkinson's disease. Parkinson's has an impact on physical function which includes balance and overall well-being. Many Parkinson's patients also have depression and anxiety. Tai Chi is low cost, low tech, and low impact and maybe an adjective therapy for this population. ➢ <u>Method</u>: A systematic review to evaluate the effects of Tai Chi on physical function and well-being among those with Parkinson’s. ➢ <u>Databases searched:</u> PubMed, Cumulative Index to Nursing and Allied Health Literature [CINAHL], Web of Science, Cochrane Library, PsycINFO and EMBASE using the search terms: tai ji, tai chi, and Parkinson’s Disease. ➢ <u>Inclusion criteria</u>: RCTs. English language only, Parkinson’s patients, outcome was physical function or well-being. ➢ <u>Exclusion criteria</u>: abstracts, reviews, commentaries, case-reports, research methodology papers, re-analysis of data,

	meta-analysis, an overview, qualitative research, not-related to the topic. ➢ 2 independent reviewers. ➢ 12 articles reviewed representing 11 studies (7 RCTs, 4 quasi-experimental studies). ➢ Outcomes: Tai Chi is safe and should be considered as a complementary therapy to manage decline in physical function. Overall, Tai Chi participants had better balance though mixed results were reported. ➢ Recommendations: Larger sample sizes are needed with more rigorous study designs.
Critique ➢ Number of studies reviewed was low.	

Table 2 description of literature retrieved with search terms Tai Chi and balance (systematic review)

2013 Jimenez-Martin, P.J., Melendez-Ortega, A., Albers, U., & Schofield, D.	A review of Tai Chi Chuan and parameters related to balance
Description: Tai Chi and balance in the general population. Reviewers based in Spain.	➢ Background: deterioration of balance control in the elderly due to the degeneration of the brain function, proprioceptive and motor systems. Tai Chi has been practised since the 17th century in China. ➢ Method: systematic review of RCTs based on the quality of the research design on the effects of Tai Chi on balance. Between 1996-2012, English only. 27 RCTs selected from 397. Balance was analysed from a vestibular, proprioceptive or visual viewpoint. ➢ Databases: MedLine, PubMed, Scirus, Cochrane, Pascal, ScienceDirect, SportDiscuss, Science Citation Index, BIOSIS. ➢ Tai Chi style: Yang (18), Chen (1), Sun (1) and NG – Cantonese for Wu (1). ➢ Duration: 3weeks-4 years. 2-3 times per week. Sessions lasted 1 hour. ➢ Outcomes: no studies found of tai chi on the improvement of balance in individuals suffering from deteriorated brain function. Information on the specific parameters taken into account when designing the intervention protocols should be included. From the biomechanical viewpoint, research

	has been done on the characteristics of movement, weight distribution on the soles of the feet, the transfer of the centre of mass and the movement patterns for overcoming obstacles which help to better understand the causes which contribute to the positive effects of Tai Chi with regard to balance.
Critique ➢ Some more appropriate parameters and measurement tools may have been ignored as many articles were ignored.	

Table 3 description of literature retrieved with search terms Tai Chi and balance (systematic review)

2010 Maciaszek, J., & Osinski, W.	The effects of Tai Chi on body balance in elderly people – a review of studies from the early 21st century
Description: Tai Chi and balance in the general population. Reviewers based in Poland.	➢ Background: past studies show conflicting results; studies needed to integrate measures of balance with other psychological and cognitive measures; high-quality RCTs needed reporting short and long-term risks and benefits; generally accepted Tai Chi is effective and attractive to the elderly. ➢ Published from 2000 only. ➢ Participants: Aged 60+ ➢ Databases: Medline, SPORTDiscus and Academic Search Complete databases searched for randomized, non-randomized and observational studies evaluating effects of TC on body balance and fall prevention. ➢ Keywords: “body balance”, stability, elderly, old, training or posturography. ➢ Bibliographies of articles examined. Google search engine also used. ➢ Method: systematic review. ➢ English only were identified, full texts and abstracts. ➢ Two researchers. ➢ 9/19 studies not randomized.

	➢ Strategies used to measure body balance significantly impact the assessment of Tai Chi training. ➢ Standing on one leg is not an indicator of body balance in the elderly. ➢ Posturography is more precise in measuring balance. ➢ Differences in Tai Chi style and Tai Chi training of the instructor may affect results. ➢ 19 studies selected. ➢ Tai Chi improves body balance of the elderly. ➢ Effectiveness of Tai Chi with other training methods is unclear. ➢ Subgroup analyses are recommended to determine effectiveness of interventions in people with different characteristics (frail). ➢ Cognitive and physical elements and effects of adherence and encouragement as contributors to success should be considered. ➢ Need to explore the physiological and neurobiological mechanics of the observed changes by controlling for the characteristics of movement kinetics. ➢ Large numbers needed and reliable method of measuring postural stability using latest technology. ➢ Self-reported measures of functional ability (ADLs) good for qualitative studies.

	➢ Age, health status, physical fitness level before the start and sex differentiation are important factors. ➢ A variety of balance measures used as no standard measure available. ➢ Well-defined questions, adequate selection criteria, similar characteristics at baseline, valid statistical methods, accounted-for confounders, appropriate outcomes, adequate follow-up methods needed to accurately assess effects of Tai Chi. ➢ A direct measure of the number of falls to be included as improvements in balance may not directly relate to number of falls. ➢ Post-intervention surveys important to show maintenance of regular Tai Chi during follow-up period. This shows the acceptance and long-term feasibility of Tai Chi by the elderly. ➢ Survey includes fall and reasons behind it. ➢ <u>Outcomes:</u> no standard measure of body balance. Difficult for experimental and control groups to be equal. Tai Chi is a potential to be long-term acceptable programme.
<u>Critique</u> ➢ Not possible to divide results into male/female groups. ➢ Author wrote one of the articles reviewed – author bias?	

- Balance is difficult to measure as we do not know much about the biomechanical parameters of body balance – these parameters must be identified to accurately predict falls risk.

Tables to describe literature retrieved which include Tai Chi and balance (randomized controlled trials)

Table 1 description of literature retrieved with search terms Tai Chi and balance (RCT)

2013 Choi, H.J., Garber, C.E., Jun, T.W., Jin, Y.S., Chung, S.J., & Kang, H.J.	Therapeutic effects of Tai Chi in patients with Parkinson’s disease
Description: Tai Chi and Parkinson’s disease.	➢ Background: Parkinson's patients have problems with balance, postural stability and physical function in people at high risk of falls. Tai Chi can help to improve physical function and reduce falls in people with chronic diseases, including Parkinson's disease, as well as in old people. This study recognises that Tai Chi may have benefits which improves physical function, postural stability and quality of life. ➢ Method: RCT ➢ Duration: 12 weeks, three times a week, one hour per class with home-based activity once a week ➢ Participants: 22 participants with Parkinson’s from a day centre for Parkinson’s patients in South Korea. ➢ Tai Chi style: not indicated. ➢ Outcome measures: UPDRS, one-leg standing test. ➢ Inclusion: diagnosed with idiopathic Parkinson’s, Hoehn-Yahr stage 1 and 2, stable drug regimen. ➢ Exclusion: severe cognitive impairment, concomitant severe neurologic, cardiopulmonary, or orthopaedic

	disorders, specific contraindications to exercise, recently participated in a physiotherapy or rehabilitation programme. ➢ Ethics approval obtained, written informed consent obtained. ➢ Data analysis: means and standard deviations, ANOVA using SPSS. ➢ Outcome: Motor and non-motor symptoms were not improved but participants self-reported ADLs was enhanced by TC. ➢ Result: No significant main effects for any of the variables. ➢ Recommendations: further studies to identify the intensity, duration, and frequency of Tai Chi to attain optimal benefits.
Critique ➢ Small sample size.	

Table 2 description of literature retrieved with search terms Tai Chi and balance (RCT)

2014 Zeng, R., Lin, J., Wu, S., Chen, L., Chen, S., Gao, H., Zheng, Y., & Ma, H.	A randomized controlled trial: preoperative home-based combined Tai Chi and strength training (TCST) to improve balance and aerobic capacity in patients with total hip arthroplasty (THA)
<u>Description:</u> Home-based Tai Chi and hip arthroplasty, and balance.	➢ <u>Background:</u> Total hip arthroplasty has been recommended for people with hip arthritis to alleviate pain and improve quality of life. Reduced muscle strength and power of the lower extremities with reduced balance ability are risk factors for falls. These risk factors are also associated with increased limitations in activities. Exercise may improve balance ability. Tai Chi has been known to be beneficial for balance in patients with arthritis due to the slow gentle movement and weight-shifting, as well physical functioning and muscle strengthening. ➢ <u>Method:</u> single-blind RCT to evaluate the feasibility and preliminary effectiveness of a home-based Tai Chi programme in people with hip arthritis and TCST. ➢ <u>Duration:</u> 12 weeks, at least 5 times a week for 60 mins each. ➢ <u>Participants:</u> 81 Chinese participants aged 60-69 years. ➢ <u>Tai Chi style:</u> not indicated. ➢ <u>Outcome measures:</u> WOMAC, 6-minute walk test, TUG, a unipedal stance test, values of range of movement.

	➢ Inclusion: aged 60-69 years, diagnosed with end-stage hip osteoarthritis, posttraumatic arthritis or osteonecrosis, unilateral chronic hip pain and disability unresponsive to conservative treatment, informed consent, fit for anaesthesia, availability of a significant other. ➢ Exclusion: hip infection, contraindication to do exercise, neuromuscular disease (paralysis, Parkinson's), unable to walk more than 150m in 6 mins, exercised regularly, scheduled hip replacement. ➢ Ethics approval obtained, written informed consent obtained. ➢ Data analysis: means, standard deviations, ANOVA using SPSS. ➢ Outcome: Tai Chi may not take away the pain and drugs may still be needed. Adherence to Tai Chi was good. Tai Chi can effectively improve balance in this population. ➢ Result: Tai Chi participants significantly improved on the TUC, WMT and ROM but no obvious change in the WOMAC. ➢ Recommendations: further studies to identify the intensity, duration, and frequency of Tai Chi to attain optimal benefits.
Critique ➢ Low sample size.	

Tables to describe literature retrieved which include Tai Chi and balance (pilot studies)

Table 1 description of literature retrieved with search terms Tai Chi and balance (pilot study)

2008 Hackney, M.E., & Earhart, G.M.	Tai Chi improves balance and mobility in people with Parkinson disease
<u>Description:</u> Tai Chi, and balance in Parkinson's disease patients.	➢ <u>Background:</u> Strategies to improve balance may reduce falls. Tai Chi may be away of improving balance. ➢ <u>Method:</u> pilot study to quantify the effects of Tai Chi on functional mobility, gait and balance in Parkinson's disease. ➢ Ethical approval was sought along with written informed consent. ➢ <u>Participants:</u> At least 40 years old living in the community based in USA who could stand for 30 mins and walk independently for at least 3m. ➢ <u>Inclusion criteria:</u> diagnosed Parkinson's, independently mobile for 3m, able to stand for 30 minutes. ➢ <u>Exclusion criteria:</u> had a serious medical problem, neurological deficit other than Parkinson's, such as stroke. ➢ <u>Intervention:</u> 13 weeks with twice-weekly one-hour classes (to complete 20 lessons within 13 weeks). ➢ <u>Tai Chi style:</u> Yang (short form of Cheng Manching). ➢ <u>Outcome measures:</u> UPDRS, BBS, TUG GAITRite walkway, 6min walk test.

	➢ Data analysis: independent t-tests, Mann Whitney Rank Sum tests, a Boneferroni correlation for multiple tests. ➢ Results: Improvements in the BBS were significantly greater in the Tai Chi group. The Tai Chi group improved on the UPDRS, TUG and 6min walk test, while the control group showed little change. ➢ Outcomes: Tai Chi participants experienced improvements in gait, balance and functional mobility. ➢ Recommendations: groups should be stratified by age.
Critique ➢ The sample size is small.	

Tables to describe literature retrieved which include Tai Chi and balance (pre test, post-test studies)

Table 1 description of literature retrieved with search terms Tai Chi and balance (pre-test, post-test study)

2014 Burschka, J.M., Keune, P.M., Hofstadt-van Oy, U., Oschmann, P., & Kuhn, P.	Mindfulness-based interventions in multiple sclerosis: beneficial effects of Tai Chi on balance, coordination, fatigue and depression
Description: Tai Chi and its effect on MS regarding balance, coordination, fatigue and depression.	➢ Background: Balance impairment, fatigue and depression are common in MS. Tai Chi may be suitable because it challenges coordination and balance. ➢ Method: pre-test/post-test study. ➢ Duration: weekly 90-minute classes for six months. ➢ Participants: 32 participants with an average age of 43 years, based in Germany. ➢ Tai Chi style: Yang. ➢ Ethical approval and written informed consent obtained. ➢ Outcome measures: an established balance test and a coordination test. Self-reported QoL questionnaires (CESDS, FSMC, QLS). ➢ Inclusion criteria: not stated. ➢ Ethics approval obtained, written informed consent obtained. ➢ Data analysis: Saphiro-Wilk tests, ANOVA, two-sided t-tests. ➢ Outcome: Tai Chi may be therapeutic for those with MS.

	➢ Results: Tai Chi participants improved with coordination and life satisfaction, with depression scores significantly decreasing in this group. ➢ Recommendations: Further research is required with larger samples.
Critique ➢ The outcome measures for balance and coordination are not specified. ➢ Small sample size.	

Table 2 description of literature retrieved with search terms Tai Chi and balance (pre-test, post-test study)

1999 Hain, T.C., Fuller, L., Weil, L., & Kotsias, J.	Effects of Tai Chi on balance
Description: Tai Chi and balance in the general population.	➢ Background: Tai Chi largely consists of static and dynamic balancing tasks. The progressive nature of balance training is similar to the process of learning a Tai Chi form. ➢ Methods: unclear in description - ? pre-test, post-test design. Ethical approval gained. Informed consent given. ➢ Participants: 30 participants based in USA with self-perceived mild balance disorders, stable for at least 3 months recruited through newspaper ads. Independently mobile. Aged 20-76. ➢ Exclusion criteria: benign paroxysmal positional vertigo, ataxia (as would be unresponsive to training), severe medical conditions. ➢ Intervention: class size 10. All participants practised Tai Chi. Physiotherapy, instructor and 2 volunteer 'spotters'. Home practice encouraged every day for at least 30 mins. Videotape and written materials given, illustrating the exercises. Movements included: preparation (holding a ball), turning the wheel, brush knee and twist step, step back to repulse monkey, walking the circle, kick heel to left and right, part the wild horse's mane, closing (holding the ball). ➢ Duration: 8 weeks, once a week for one hour.

	- Outcome measures: measured before and after intervention. Romberg test, reach test, health survey, 2 disability questionnaires, moving platform posturography. - Data analysis: SPSS, analysis of variance, p<0.05. - Outcomes: significant improvements in balance. A structured programme needed, supervised by health care professionals. Supervision needed with participants with impaired balance. - Recommendations: what is the optimum duration of Tai Chi training? What is the optimum sequence of movements?

Critique

- Illustrations are difficult to understand and are only useful if taught by an instructor prior and this has been understood.
- Results only limited to people with mild balance impairment.
- Old paper. Many studies done since this.

Tables to describe literature retrieved which include Tai Chi and balance (cross-sectional designs)

Table 1 description of literature retrieved with search terms Tai Chi and balance (cross-sectional study)

2010 Hakim, R.M., Kotroba, E., Cours, J., Teel, S., & Leininger, P.M	A cross-sectional study of balance-related measures with older adults who participated in Tai Chi, Yoga, or no exercise
Description: Tai Chi, Yoga and balance in older adults.	➢ Background: there is a growing body of evidence supporting the use of Tai Chi to improve balance-related measures in older adults. Tai Chi's positive impact on balance is theorized to be the result of using slow movements that require the coordination of the entire body (Jancewicz, 2001). Yoga also requires studying. To investigate if results of Tai Chi are similar to that of yoga and those with no exercise. ➢ Method: cross-sectional study. Ethically approved. ➢ Participants: 52 older adults based in USA, aged 65+. A convenience sample: 21 in the Tai Chi group, 11 in Yoga group, 20 with no exercise. Independent community-dwellers. Recruited from Yoga and Tai Chi classes so already got experience. With at least 8 weeks experience. All were volunteers. ➢ Outcome measures: activities of balance confidence (ABC) self-assessment questionnaire. single-leg stance, multidirectional reach test, Fullerton Advanced Balance Scale, timed floor transfer.

	➢ Data analysis: means, SDs. ANOVA. ➢ Outcomes: Tai Chi demonstrated greater limits of stability. Tai Chi is effective to improve or maintain balance. It can also be practised from a chair. Limitation may have been that there were no resting periods so fatigue could have been an issue. Tai Chi and Yoga improve balance performance. ➢ Recommendations: groups should be stratified by age.
Critique ➢ A cross-sectional study so causation cannot be determined.	

Tables to describe literature retrieved which include Tai Chi and balance (pilot studies)

Table 1 description of literature retrieved with search terms Tai Chi and balance (pilot study)

2008 Hackney, M.E., & Earhart, G.M.	Tai Chi improves balance and mobility in people with Parkinson disease
Description: Tai Chi, and balance in Parkinson's disease patients.	➢ Background: Strategies to improve balance may reduce falls. Tai Chi may be away of improving balance. ➢ Method: pilot study to quantify the effects of Tai Chi on functional mobility, gait and balance in Parkinson's disease. ➢ Ethical approval was sought along with written informed consent. ➢ Participants: At least 40 years old living in the community based in USA who could stand for 30 mins and walk independently for at least 3m. ➢ Inclusion criteria: diagnosed Parkinson's, independently mobile for 3m, able to stand for 30 minutes. ➢ Exclusion criteria: had a serious medical problem, neurological deficit other than Parkinson's, such as stroke. ➢ Intervention: 13 weeks with twice-weekly one-hour classes (to complete 20 lessons within 13 weeks). ➢ Tai Chi style: Yang (short form of Cheng Manching). ➢ Outcome measures: UPDRS, BBS, TUG GAITRite walkway, 6min walk test.

	➢ Data analysis: independent t-tests, Mann Whitney Rank Sum tests, a Boneferroni correlation for multiple tests. ➢ Results: Improvements in the BBS were significantly greater in the Tai Chi group. The Tai Chi group improved on the UPDRS, TUG and 6min walk test, while the control group showed little change. ➢ Outcomes: Tai Chi participants experienced improvements in gait, balance and functional mobility. ➢ Recommendations: groups should be stratified by age.
Critique ➢ The sample size is small.	

Tai Chi Programme Information

General Programme Information

'Tai Chi After Stroke' [TCAS] is a programme of tai chi specifically aimed at people who have had a stroke with the aim to reduce falls risk and improve balance. It is designed by the researcher, derived from the Yang-style Cheng Man Ch'ing Form. Also included are Qi Gong exercises which start off easy, becoming harder, from seated to standing. The use of a chair is required for seating exercises, as well as being used as support for the one-legged standing exercises.

Programme Objectives

To reduce falls risk and improve balance and daily activities of living, as well as quality of life in people who have had a stroke receiving community rehabilitation.

Intended Target Population

The programme targets people of both genders aged above 18 receiving community rehabilitation following a stroke with a history of falls, impaired balance, or lower limb weakness. People are able to use sticks and zimmer frames. Participants are also invited to bring along a significant other to the sessions.

Instructor

Background requirement: experience of at least 20 years, BCCMA registered. Gold medallist in Push Hands.

Training: Programme objectives taught, stroke overview taught, programme evaluated.

Assistants

A registered nurse/researcher and a senior physiotherapist.

Training Protocol

Class practice: For the first 4 weeks, the class will be taught as a whole by the tai chi instructor. There are four parts to the programme: 1) warm-up, 2) Qi Gong exercises 3) The Form, 4) a brief cool-down. As participants in week 5 move forward with the instructor,

those that do not want to progress forward or are newly recruited will be split into a separate group for part 2 of the session and will be taught by the assistant.
Teaching emphasis: weight shifting, waist turning, foot rooting, control of the centre of gravity, upright posture, breathing.
Practice parameters: 60-minute sessions, twice a week for 12 weeks, including 10 minutes of daily home practice.

<u>Class Set-Up</u>
Space and equipment: the physiotherapy gym based at Pinderfields General Hospital, located next-door to the acute stroke unit. Armless, straight-backed chairs are provided, as well as hand rails.
Recommended class size: A ratio of 5:1 or 8:2 [participants/instructor and assistants].
Participant clothing: loose and comfortable with flat-soled shoes.
Materials: home-practice booklet, YouTube videos.

<u>Safety</u>
Home practice is only to be practiced in a safe environment, i.e. away from loose mats. Somebody may be present whilst practising. Flat soled shoes or no shoes are recommended. If participants feel unwell, they ar advised not to practice.

<u>Target Health Outcomes</u>
Recommended measures: Berg Balance Scale, POMA, Falls Efficacy Scale, Activities Specific Confidence Scale, Geriatric Depression Scale, EUROQOL, falls calendar, home-practice diary.
Expected outcomes: Consistent class attendance (at least 20 out of 40 to complete the trial), resulting in the ability to calculate a power for a randomised controlled trial.
Measured outcomes: functional balance, mobility, number of falls, quality of life, depression, confidence.

<u>Programme Costs</u>
Tai chi instructor: £25 per teaching session, £50 for assisting with photographed postures for the home-practice booklet.
Room: cleaning after use – free of charge.
Printing materials
Refreshments
Vouchers: £10 per participant.

Programme Structure and Implementation

Part One

Warm-up (5 mins) – sat in chair

1) Seated meditation

Part Two

Seated Qi Gong for balance (15 mins)

1) Shoulder circles
2) Row elbows
3) Circle wrists, hands then body
4) Heel extensions
5) Circle ankles

Part Three

Leg strengthening (5 mins)

1) Sit to stand
2) Standing hip abduction (behind chair)
3) Single leg rooting (stood behind chair)

Part Four

Cat walking (10 mins)

BREAK (5 mins)

Part Five

The Tai Chi Form (18 mins)

1) Preparation
2) Beginning form
3) Holding The ball
4) Turning the wheel
5) Parting the wild horse's mane
6) Cloud hands
7) Repulse monkey
8) White crane
9) Brush knee

Seated Alternative

1) Preparation
2) Beginning
3) Ward off
4) Cloud hands
5) White crane
6) Brush knee twist

Part Six

Cool-down (2 mins)

1) Standing or seated meditation

Parts covered weekly:

Weeks 1-2: parts 1-2

Weeks 3-4: parts 1-2

Weeks 5-6 parts 1-3

Weeks 7-8 parts 1-4

Weeks 9-12: parts 1-6

<u>Resources</u>

Seated Warm-ups:

YouTube channel: bodyhealthtaiji
Chair tai chi

Seated Qigong:

YouTube channel: Omega Institute

Roger Jahnke “Sitting Qigong”

Seated Tai Chi:

YouTube channel: Taichitastic’s channel

Tai chi in a chair ‘white crane spreads its wings’

Tai chi in a chair ‘cloud hands’

Tai chi in a chair ‘ward off’

Tai chi in a chair* ‘brush knee twist’ *spelt chiar

Tai Chi Form:

YouTube channel: yangfamilytaichi
Yang Family Tai Chi Step Back Repulse Monkey
Yang Family Tai Chi Cloud Hands

YouTube channel: Lucille Chun

Yang Style Tai Chi Repulse The Monkey Of Lucy Chun, Honolulu, Hawaii, Kilauea District Park

YouTube channel: expertvillage
Tai Chi Movements: Tai Chi: Part Wild Horse’s Mane

YouTube channel: fightingisyourfriend

Hold The Water Ball & Part The Horse’s Mane – Martial Tai Chi Applications

YouTube channel:	Tai Chi Nation
	Cloud Hands

Appendix 4 – The Tai Chi programme (final version used in the TCAS study)

1. <u>Beginning meditation (approx. 3 minutes)</u>

Participants are seated with their eyes closed, backs straight and face facing forwards. The Tai Chi instructor guides participants in a meditation which aims to focus the mind and eliminate any distractions or worries which participants may have brought to class by concentrating on breathing.

2. <u>Joint-loosening exercises (approx. 7 minutes)</u>

Head and neck loosening (seated or standing) (1 minute)

Participants move their heads from side to side slowly and gently, followed by moving the head up and down without straining the neck.

Circling the shoulders (seated or standing) (1 minute)

Participants move their left shoulder in a circular motion without moving the whole arm. The arm should follow the movement of the shoulder. This is then repeated with the right shoulder. Following this, both shoulders are circled, first backwards then forwards.

Circling the hips (standing) (1 minute)

Participants are stood behind a chair and may hold onto the chair or place their hands on their hips. The hips are then circled one way, then the other.

Wrist-loosening (seated or standing) (20 seconds)

The right hand is positioned in front of the participant, relaxed, along with the elbow. The hand is circled by turning the wrist in one direction followed by the opposite direction. Participants are encouraged to feel and see the hand movements. This exercise is repeated with the left hand.

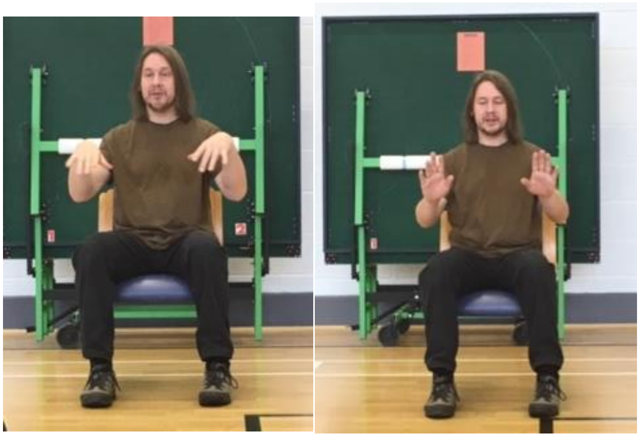
Seated leg-stretching (30 seconds)

Feet remain flat on the floor and the participant is in a seated position. The right foot is stretched forwards with the heel being pushed forwards and toes pointed inwards towards the patient. The foot is then brought back to its original position. This is repeated on the same leg, then is performed on the other.

Circling the ankles (seated) (30 seconds)
Both feet remain flat on the floor. The toes of one foot are lifted off the floor, with the heel remaining on the floor. The ankle is then circled in one direction, then in the opposite direction. This is repeated using the other foot.

Hand/arm movements (20 seconds)
Participants make a soft fist with a gap in the centre, keeping the hand at chest-height in front of them. The arm is extended forwards and the fist is opened out (like a flower) with the palm facing forwards. The fingers gently close again into a fist and the hand is brought inwards to the chest. The movement is then repeated, and then followed by the other hand.

Raising the Hands Up and Down (Heaven and Earth) (seated or standing) (1 minute)
The arms are raised up to the height of the shoulders, then lowered, keeping wrists, fingers and elbows relaxed. The hands are then raised up to chest height and then lowered with the fingers being the last to lower. This movement is repeated.



Arm stretches (seated) (1 minute)
Participants start this exercise with their palms on their laps. Participants are encouraged to be seated so as not to get tired from the previous standing exercise. Palms are lifted from the lap, faced down, and brought to the sides, stretched out. The hands are then brought inwards until arms are wrapped lightly around the body, as if giving yourself a hug. Hands the then become stretched out to the side again and the exercise is repeated.

3. Qigong exercises (approx. 5 minutes)

Floating the hands (seated) (1 minute)

Participants place their palms on their laps with shoulders relaxed. The hands are raised up to the height of the chest in a similar way to Heaven and Earth. Once the hands are at chest height, they are then moved out to the sides without stretching the arms too far backwards, like the previous arm stretching exercise. The hands are then brought back to the centre, palms facing. Once the hands are in front of the participant, the palms face down and are brought back to the lap. The exercise is repeated.

Diagonal arm raises (seated or stood) (1 minute 30 seconds)

The arms are held in front the abdomen, with hands relaxed. The waist turns to the right with the rest of the body following. Once the body is facing the corner, the hands are raised. The waist returns to the centre whilst the hands are lowered back in front of the abdomen. The movement is repeated to the left side.

Raise arms like a bird (seated) (1 minute)
Arms are by the sides, with shoulders relaxed. The hands remain by the sides and are raised upwards to shoulder-height, with the fingers following. The hands then float back down, with fingers following. The movement mimics as bird flapping its wings.

Hand pushes (seated) (1 minute)
The right hand is positioned above the right leg with the palm facing the participant and elbow relaxed. The left hand is relaxed above the left leg with the palm facing up. The right hand then scoops towards the participant so that this hand goes into the same position as the left hand with the palm facing up. The left hand now is positioned so that the left palm so it is facing out and is pushed forwards. This is repeated.

4. Leg-strengthening exercises (standing) (9 minutes)

Shifting weight in the parallel stance (4 minutes)

The participant is stood behind a chair for support throughout the leg-strengthening exercises. These exercises are in preparation for the Tai Chi walking. The patient stands with knees slightly bent, back straight, head up and facing forwards. Shoulders are positioned over the hips so that they are aligned. A parallel stance is adopted (feet shoulder-width apart). An imaginary line down the centre of the body is encouraged so that awareness of the centre of gravity is present. Weight is distributed equally on both legs (position 1). Weight from the left leg is then shifted onto the right, so that the left leg is 'empty', but the centre of alignment remains. The right leg is known as position 2 Participants are advised not to move further out of position 2. The weight is then shifted back to position 1. Weight is then shifted from the right leg (position 3) onto the left so that the right leg is empty. Participants are again advised not to shift weight beyond position 3. The weight from position 3 is then brought back to position 1 so that weight is evenly distributed between both legs. This exercise is repeated.

After these exercises, the participants are asked if they would like to sit down for a rest before continuing onto the next one.

Shifting weight in the bow stance (5 minutes)

The next exercise requires the adoption of a bow stance. The bow stance is adopted by beginning in the parallel stance. From here, the participant takes one step forwards with one of the legs.

This time weight is shifted onto the leg which is forward (position 3). The centre line (position 1) remains and participants move from position 3 to position 1. From position 1, weight is then shifted to the back leg (position 2). This exercise is repeated with the opposite leg forward after returning to the parallel stance. Participants stand behind a chair for support.




5. **<u>Balance training exercises (standing) (approx. 25 minutes)</u>**

Participants are now able to practice stepping using the balance training exercises. First, feet are together with knees slightly bent and back and head in alignment. They then use their left foot to step to the left. A parallel stance is then adopted with weight in both legs evenly distributed. Weight is shifted onto one leg so that they can step with the empty leg. A bow stance is then adopted by placing the empty leg forward. Weight is then shifted onto the forward leg so that the empty leg steps forward.
Once participants are confident with stepping, they may proceed to Tai Chi hand movements whilst stepping. Participants do not move their hands whilst stepping. Only after they have stepped and maintain their stability do they move their hands. For example, once they are stable after the step, they rotate the ball so that the right hand is over the left. The

ability of the participant to master one Tai Chi movement whilst stepping determines whether they progress onto the next, more challenging movement.

Before moving onto the next hand movement, the movements are practised first at the end of the Qigong exercises. Tai Chi hand movements incorporated into the programme:

a) Holding the ball

First, participants adopt a parallel stance then perform Heaven and Earth twice where the hands are raised up to the chest and back down. As the hands lower, the right hand goes over the left so both palms are facing each other, as if holding a ball. Weight is shifted from the left foot to the right foot and the left foot is used to step forwards. This is done whilst 'holding the ball'. Before stepping, the ball is rotated by moving the right hand, so the palms are facing up, and the left palm is facing down. The participant then steps with the right foot forward.

b) Play guitar

Both hands are lowered with palms facing each other. The participant steps forward with the right foot. Moving to the left, the left forearm is raised to shoulder-height with the right arm at chest height. Both arms are lowered back with palms facing each other. Then the participant steps with the right foot forwards. Moving to the right, the right hand goes up to shoulder height with the left hand at chest height. Both hands are lowered, and the exercise is repeated.

c) *White crane spreads its wings*

Both arms are by the participants' sides with armpits open. With shoulders and elbows relaxed, the right arm is raised, remaining at the side to the height of the forehead. The left arm remains to the side but faces downwards with the hand pointing to the floor. Participants step forwards with the right foot but do not move their arms whilst stepping. The right arm remains raised and the left arm remains out to the side. Once participants have stepped, the left arm raises to forehead-height and the right arm is lowered at the side. Without changing arm position, the participant steps forwards with the right foot. This movement is repeated.

d) Single whip

Participants step with the left foot forward with arms lowered and relaxed. Once the participant has stepped and has stability, the left arm is positioned in front of the body, remaining to the side whilst the right arm extends outwards to the side with the wrist relaxing downwards, with the wrist relaxed. Both arms lower until the arms are relaxed. Participants then step with the right foot forward with the arms lowered and relaxed. Once stability is maintained, the right arm is positioned in front of the body and the left arm goes out to the side.

e) Brush knee and push

The left arm is positioned in front of the chest, with the hand upright, and fingers relaxed. The right arm is positioned to the side of the left leg, without touching the leg. The right hand faces the floor. The participant pushes the left hand forward with the palm facing away from the participant. The participant steps with the left foot without changing arm position. Once the participant has stepped with the left foot forward, the right arm raises up to the same position as the left arm, and the left arm is lowered down to the side, pointing to the floor. The right hand then pushes forwards with the palm facing away from the participant. The left hand raises up and the right hand pushed forwards, with the palm facing away from the participant. Then the participant steps with the right foot forward, and the left hand is raised, and the right hand is lowered at the side and the left hand pushes forwards. This movement is repeated.

6. Closing meditation (2 minutes)

Closing meditation is like the meditation at the beginning.

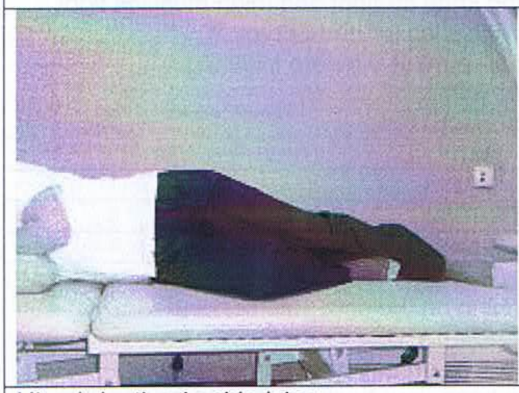
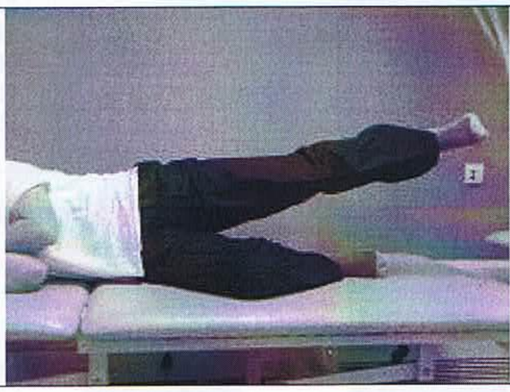
Appendix 5 ***An example of a rehabilitation booklet from community therapy services***

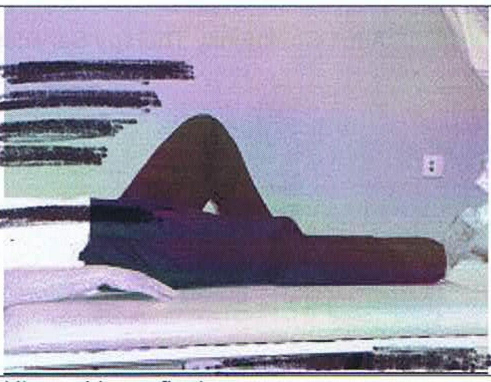
Locala
Community Partnerships

Adult Community Therapy Services
[redacted]

Telephone: [redacted]

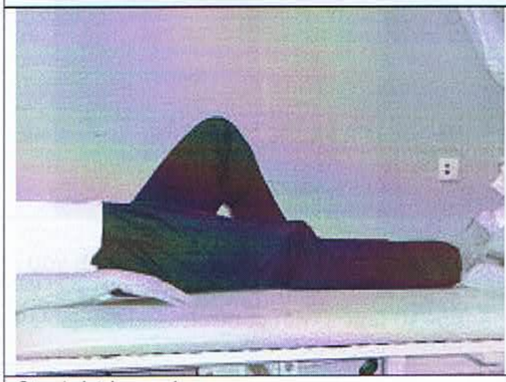
<u>Exercise Programme for</u> [redacted]
(provided by [redacted], Physiotherapist, March 2017)

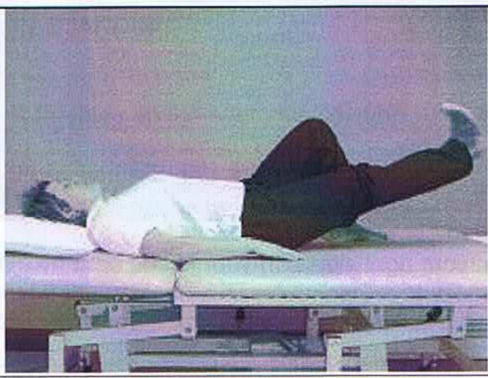
	
<u>'Clam'</u> Lay on your right side with your knees bent and ankles together. Keep your ankles together and raise your left knee off right knee.	Do not allow yourself to roll backwards as you raise the knee. Repeat 5- 10 times with control.
	
<u>Hip abduction in side lying</u> Lay on right side with left leg straight and right leg bent. Keeping left leg straight raise as high as you can with control.	Hold for count of 5 then slowly lower. Repeat 5 – 10 times with control.



Hip and knee flexion:
Lay on bed with one leg straight and other leg bent.
Slowly bend the straight leg bringing knee up towards stomach as far as you can.

[redacted]
Slowly straighten leg to starting position.
Try to increase the knee bend with each rep.
Repeat 5 - 10 times with each leg.





Straight leg raise:
Lay on bed with one leg straight and other leg bent;
Tighten thigh muscles of straight leg by pushing back of knee into bed.

Keeping knee straight and thigh muscles tight slowly raise leg off bed approx 8".
Hold for count of 3 before lowering.
Repeat with opposite leg.
Repeat 5 - 10 times.

EXERCISES IN STANDING

'Marching on the spot' (hip flexion)

Hold lightly on to your support.
Try to keep your back as straight as possible.
Lift one leg in front of you with a bent knee, as high as possible and then slowly return to starting position.
Repeat with other leg as if 'marching'.
Repeat 10 times.

Mini squats

Hold lightly on to your support.
Bend both knees slightly, trying to keep your back straight and upright.
Remain in this position for count of 3.
Straighten your knees to return to starting position.
Repeat x 10 times.

Hip Extension In Standing

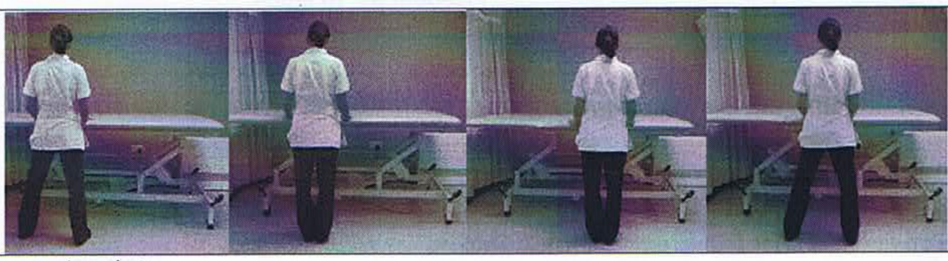
Stand tall, holding lightly to support.
Lift leg behind you, keeping knee straight.

Repeat 5 - 10 times, alternating between each leg.

Hip Abduction In Standing

Stand tall, holding lightly to support.
Lift leg up and out to the side, keeping toes facing forwards and knee straight.

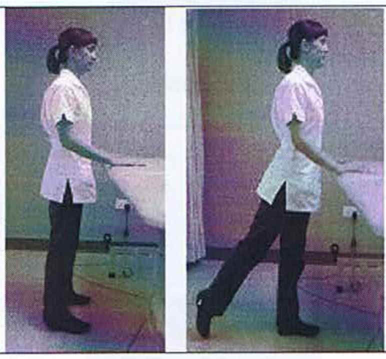
Repeat 5 - 10 times, alternating between each leg.



Sideways stepping
Stand tall holding lightly to your support (e.g. kitchen work surface).
Take steps sideways from one end to the other.
Repeat in opposite direction. Try to step as widely as you can each time.
Repeat 4 lengths.

Mini squats

Hold lightly on to your support.
Bend both knees slightly, trying to keep your back straight and upright.
Remain in this position for count of 3.
Straighten your knees to return to starting position.
Repeat x 10 times.



Hip Extension In Standing

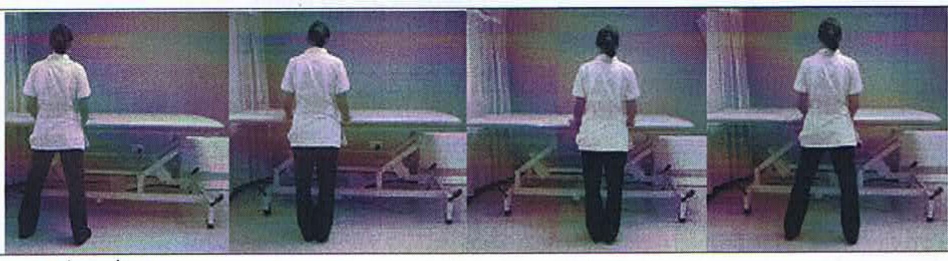
Stand tall, holding lightly to support.
Lift leg behind you, keeping knee straight.

Repeat 5 - 10 times, alternating between each leg.

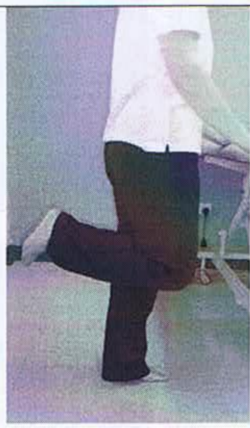
Hip Abduction In Standing

Stand tall, holding lightly to support.
Lift leg up and out to the side, keeping toes facing forwards and knee straight.

Repeat 5 - 10 times, alternating between each leg.



Sideways stepping
Stand tall holding lightly to your support (e.g. kitchen work surface).
Take steps sideways from one end to the other.
Repeat in opposite direction. Try to step as widely as you can each time.
Repeat 4 lengths.

	
<u>Heel raises</u> Stand with feet comfortably apart; Rest hands lightly on support if needed.	Push up through feet to lift heels off floor. Hold for count of 2. Slowly lower to starting position. Repeat 5 -10 times.
	
<u>Hamstring curl</u> Stand with feet comfortably apart; Rest hands lightly on support if needed.	Bend knee to lift heel towards your bottom. Hold for count of 2. Slowly lower to starting position. Repeat with other leg. Repeat 5 - 10 times.

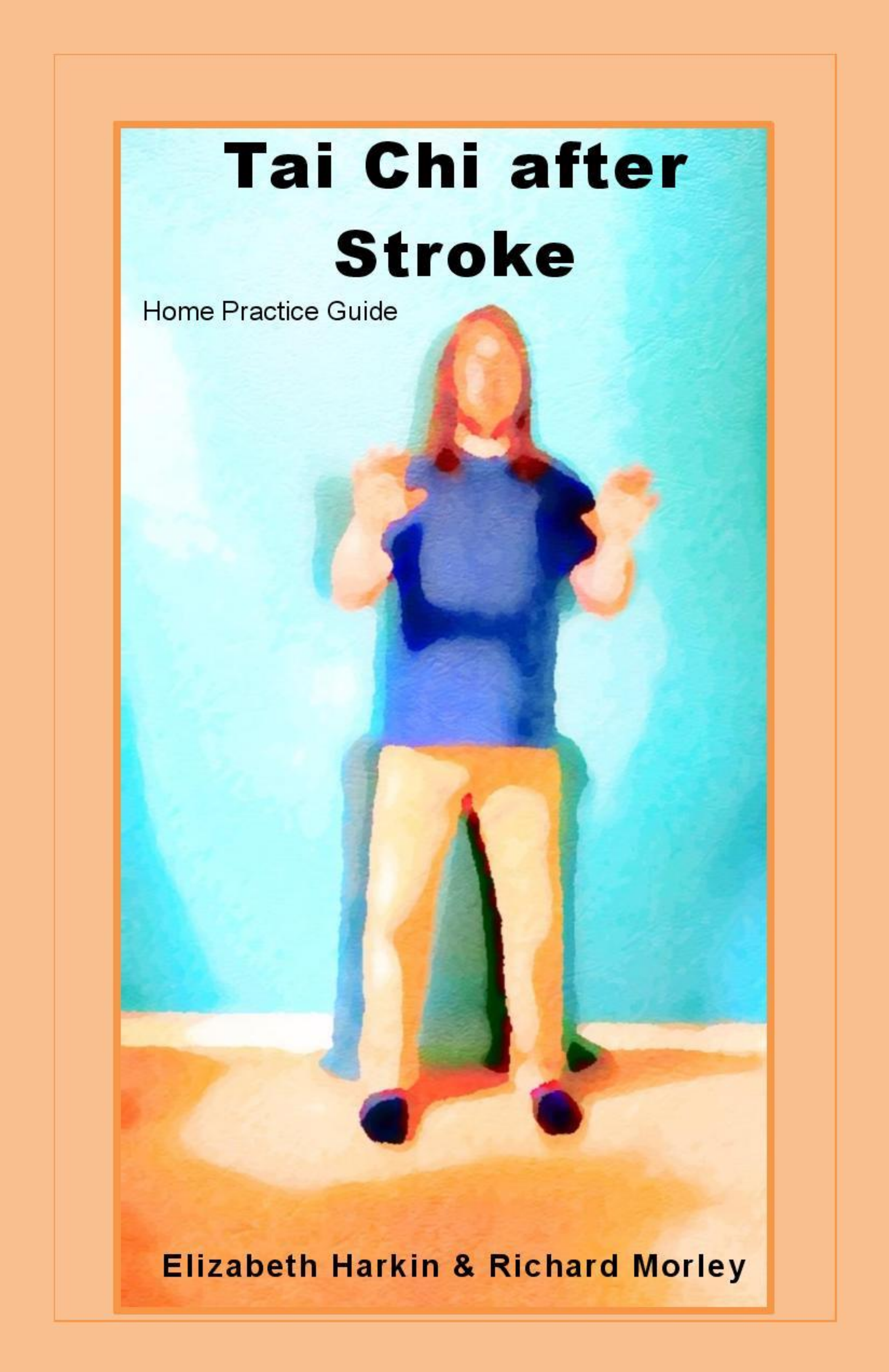

Tai Chi after Stroke
Home Practice Guide
Elizabeth Harkin & Richard Morley

Table of Contents

Balance Principles

- Head upright
- Relax shoulders - in line with hips
- Bend knees slightly.
- Shoulder-width stance.
- The centre line should land on number 2

(see pages 3 & 4)


1
2
3

4

Balance Exercises

(at least 15 minutes per day)

Rooting Practice **(2 minutes)**

(Beginner)

Take a shoulder-width stance.

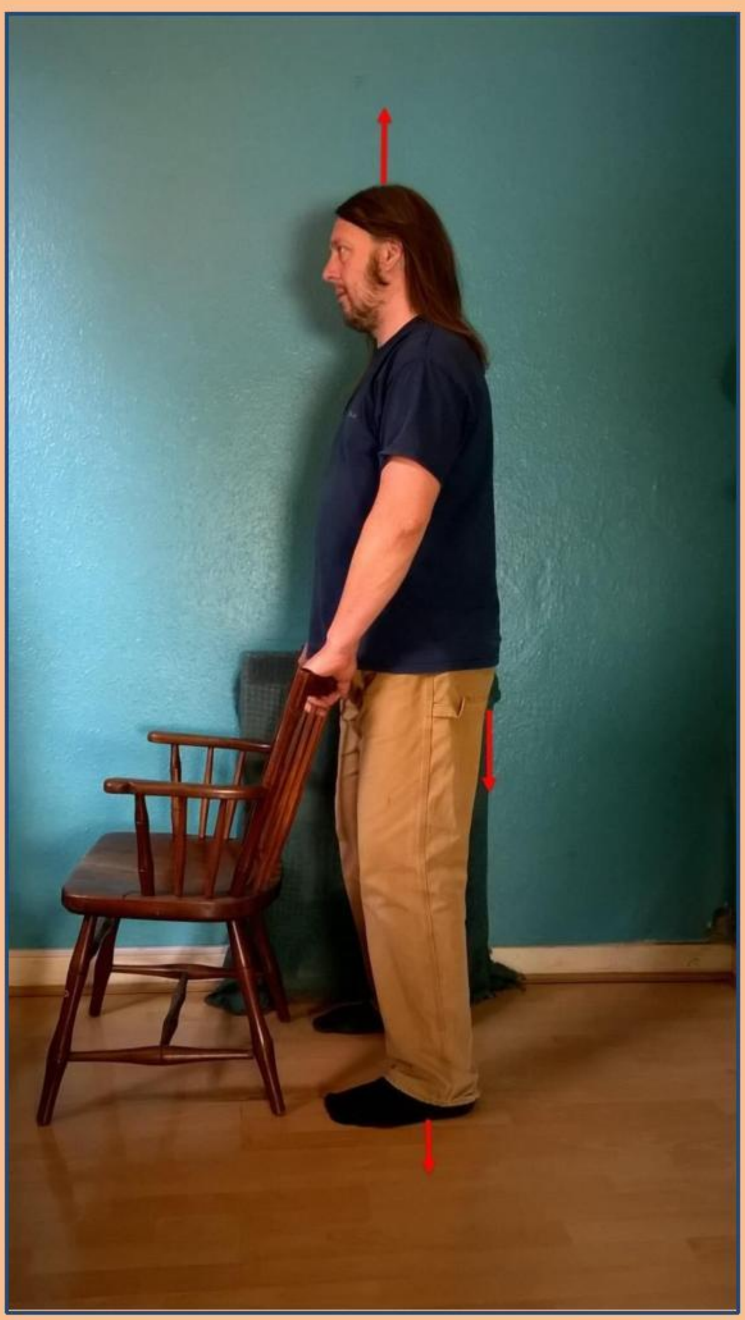
Hold the back of a chair with both hands. Sit down slightly.

Imagine your feet are relaxing and sinking into the ground.

Imagine your feet are growing roots that go deep into the ground and firmly anchor you there.

(see page 7)

(Advanced) Practice without a chair.



Balance Exercise 1 **(2 minutes)**

(Beginner)

Stand in a shoulder-width stance.

Hold the back of a chair.

Shift your centre from side to side along the balance line.

(Shift between 1,2,3, then move back 3,2,1.)

(Advanced)

When more confident, practice without the chair.

(see page 9)


1
2
3

Balance Exercise 2

(2 minutes)

<u>(Beginner)</u>

Stand in a bow stance with your right foot forward.

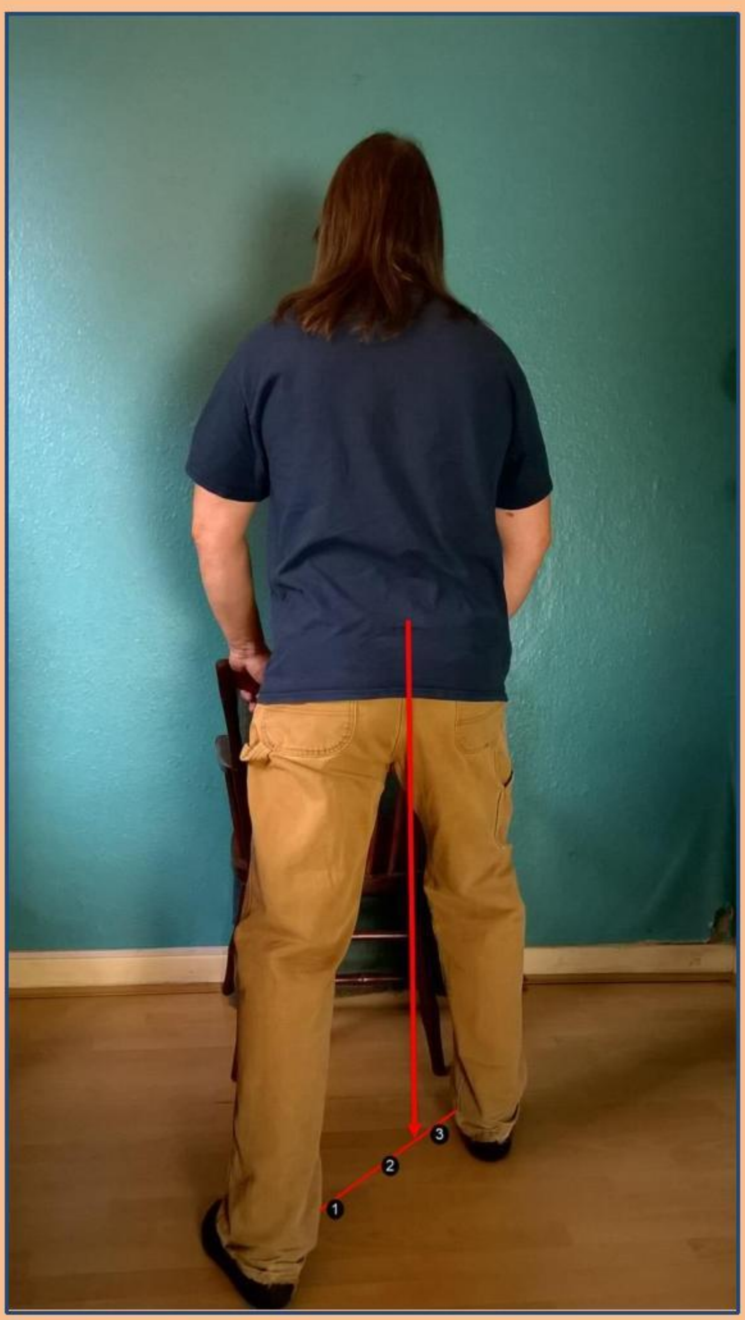
Shift your weight along the balance line.

Repeat with the left foot forward.

<u>(Advanced)</u>

When more confident, practice without the chair.

(see page 11)


1
2
3

Balance Exercise 3

(2 minutes)

<u>(Beginner)</u>

Shift your weight onto your right leg

Lift the left heel off the ground.

Repeat on the other foot.

(see page 13)

<u>(Advanced)</u> When your legs become

Balance Exercise 4

(2 minutes)

Beginner and Advanced

In a shoulder-width stance, raise and lower your arms in front of you.

Do not raise the elbows above the chest.

Be aware of the changes in balance as the hands raise.

Your weight will move backwards into your feet as the hands lift.

Keep the weight centered in the middle of your feet.

*this exercise can be done seated if unable to stand

(see pages 17 & 18)

18

Glossary

centre of gravity	the entire weight of the body is concentrated here
centre of gravity line	the line drawn in red down the centre of the body from head to toe
balance line	the red line drawn between both feet
bow stance	standing with one leg forward, the rear leg supports the rest of the weight. The knee of the rear leg is slightly bent. Knees are in line with toes

1,2,3 (in the pictures)	numbers along the balance line: **2** represents the centre of gravity **1 -3** represents the direction of the shift of centre of gravity.
shoulder-width stance	standing with feet shoulder-width apart

Tips for Movement

1) Posture	relax the shoulders and whole body, bend knees slightly - keep upright
2) Action	coordinate the body with breathing
3) Breath	breath deep and long through the nose
4) Concentration	be constantly aware of movements
5) Balance	maintain the centre of gravity
6) Diligent Practice	at least 15 minutes a day
7) Turning position	turn the waist whilst keeping the lower body rooted. The upper body and arms follow

Researcher Contact Details

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University of HUDDERSFIELD
Inspiring tomorrow's professionals

Dated 31st August 2016
V2.0

August 31st 2016 v2.0 (IRAS ID 171300)

University of HUDDERSFIELD

Home Practice Diary

Participant Identification:

Week # 5	Please circle Y or N			
Day	**Home Practice**	**Practised?**		**Notes (extra practice? problems?)**
Monday	15 mins	Y	N	
Tuesday	15 mins	Y	N	
Wednesday	15 mins	Y	N	
Thursday	15mins	Y	N	
Friday	15 mins	Y	N	
Saturday	15mins	Y	N	
Sunday	15 mins	Y	N	

Week # 6				
Day	**Home Practice**	**Practised?**		**Notes**
Monday	15 mins	Y	N	
Tuesday	15 mins	Y	N	
Wednesday	15 mins	Y	N	
Thursday	15 mins	Y	N	
Friday	15 mins	Y	N	
Saturday	15 mins	Y	N	
Sunday	15 mins	Y	N	

Week # 7				
Day	**Home Practice**	**Practised?**		**Notes**
Monday	15 mins	Y	N	
Tuesday	15 mins	Y	N	
Wednesday	15 mins	Y	N	
Thursday	15 mins	Y	N	
Friday	15 mins	Y	N	
Saturday	15 mins	Y	N	
Sunday	15 mins	Y	N	

Please turn over

Week # 8				
Day	**Home Practice**	**Practised?**		**Notes**
Monday	15 mins	Y	N	
Tuesday	15 mins	Y	N	
Wednesday	15 mins	Y	N	
Thursday	15 mins	Y	N	
Friday	15 mins	Y	N	
Saturday	15 mins	Y	N	
Sunday	15 mins	Y	N	

Feb 23 2016 v2.0

Patient Identification Number: Sheet number:
(IRAS ID 171300)

FALLS CALENDAR

A fall is when you come to rest on the ground, floor or other level. It does not include falling out of bed or a chair.

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January 2018

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Week 1	1 Falls: Reason:	2 Falls: Reason:	3 Falls: Reason:	4 Falls: Reason:	5 Falls: Reason:	6 Falls: Reason:	7 Falls: Reason:
Week 2	8 Falls: Reason:	9 Falls: Reason:	10 Falls: Reason:	11 Falls: Reason:	12 Falls: Reason:	13 Falls: Reason:	14 Falls: Reason:
Week 3	15 Falls: Reason:	16 Falls: Reason:	17 Falls: Reason:	18 Falls: Reason:	19 Falls: Reason:	20 Falls: Reason:	21 Falls: Reason:
Week 4	22 Falls: Reason:	23 Falls: Reason:	24 Falls: Reason:	25 Falls: Reason:	26 Falls: Reason:	27 Falls: Reason:	28 Falls: Reason:

Berg Balance Scale

The Berg Balance Scale (BBS) was developed to measure balance among older people with impairment in balance function by assessing the performance of functional tasks. It is a valid instrument used for evaluation of the effectiveness of interventions and for quantitative descriptions of function in clinical practice and research. The BBS has been evaluated in several reliability studies. *A recent study of the BBS, which was completed in Finland, indicates that a change of eight (8) BBS points is required to reveal a genuine change in function between two assessments among older people who are dependent in ADL and living in residential care facilities.*

Description:
14-item scale designed to measure balance of the older adult in a clinical setting.

Equipment needed: Ruler, two standard chairs (one with arm rests, one without), footstool or step, stopwatch or wristwatch, 15 ft walkway

Completion:
- **Time:** 15-20 minutes
- **Scoring:** A five-point scale, ranging from 0-4. "0" indicates the lowest level of function and "4" the highest level of function. Total Score = 56

Interpretation:
41-56 = low fall risk
21-40 = medium fall risk
0 –20 = high fall risk

A change of 8 points is required to reveal a genuine change in function between 2 assessments.

Berg Balance Scale

Name: ______________________________ Date: ________________

Location: ____________________________ Rater: ________________

ITEM DESCRIPTION	SCORE (0-4)
Sitting to standing	______
Standing unsupported	______
Sitting unsupported	______
Standing to sitting	______
Transfers	______
Standing with eyes closed	______
Standing with feet together	______
Reaching forward with outstretched arm	______
Retrieving object from floor	______
Turning to look behind	______
Turning 360 degrees	______
Placing alternate foot on stool	______
Standing with one foot in front	______
Standing on one foot	______

Total ______

GENERAL INSTRUCTIONS
Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches. Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

Berg Balance Scale

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

Berg Balance Scale continued…

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.
( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

Appendix 10 Inter-rater reliability results of the BBS

3rd March 2016 v2.0 Berg Balance Scale

Participant Identification Number: C **Date:** 01/03/17

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
) 4 able to stand without using hands and stabilize independently (
(3) able to stand independently using hands side of chair
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
) 4 able to stand safely for 2 minutes
(3) able to stand 2 minutes with supervision (
) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (
) 4 able to sit safely and securely for 2 minutes
(3) able to sit 2 minutes under supervision (
) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
(4) sits safely with minimal use of hands (
) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
(2) able to transfer with verbal cuing and/or supervision (
) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
) 4 able to stand 10 seconds safely
(3) able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
(3) able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together ( )
0 needs help to attain position and unable to hold for 15 seconds

Validated 1/3/17

ROBERTSON
CONSULTANT

1

Participant Identification Number: ____________ **Continued**

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches) (
) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet. ( )
4 able to pick up slipper safely and easily
(3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently ( )
1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)
(4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift (
) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction. ( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less (
2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing (
) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times. ( )
4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds (used box
10 secs) 2 able to complete 4 steps without aid with supervision
(1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds (
) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds (
1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on. (
) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds (
1 sec) 2 able to lift leg independently and hold ≥ 3 seconds
(1 tries to lift leg unable to hold 3 seconds but remains standing independently. ( )
0 unable to try of needs assist to prevent fall

(37) TOTAL SCORE (Maximum = 56)

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2

Participant Identification Number: C 1/3/17. **Continued**

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

26
(4) can reach forward confidently 25 cm (10 inches) (
) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet. ( )

29
4 able to pick up slipper safely and easily
(3) able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently ( )
1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)

33
(4) looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift (
) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction. ( ) 4 able to turn 360 degrees safely in 4 seconds or less

35
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less (
(2) able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing (
) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times. ( )

38
4 able to stand independently and safely and complete 8 steps in 20 seconds
(3) able to stand independently and complete 8 steps in > 20 seconds (
) 2 able to complete 4 steps without aid with supervision
(1) able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

10 seconds
holding a ① hand

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

41
( ) 4 able to place foot tandem independently and hold 30 seconds (
(3) able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds (
(1) needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on. (

42
) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds (
) 2 able to lift leg independently and hold ≥ 3 seconds
(1) tries to lift leg unable to hold 3 seconds but remains standing independently. ( )
0 unable to try of needs assist to prevent fall

(42) TOTAL SCORE (Maximum = 56)

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Running total

Participant Identification Number: C **Date:** 01/03/17

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
) 4 able to stand without using hands and stabilize independently (
3 (3) able to stand independently using hands
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
) 4 able to stand safely for 2 minutes
6 (3) able to stand 2 minutes with supervision (
) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (
(4) able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision (
10) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
14 (4) sits safely with minimal use of hands (
) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
16 (2) able to transfer with verbal cuing and/or supervision (
) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
) 4 able to stand 10 seconds safely
19 (3) able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
22 (3 able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together ( )
0 needs help to attain position and unable to hold for 15 seconds

Validated 1/3/17 [signature]
A Roberson
Consultant Physio

Participant Identification Number: A **Date:** 1/2/17 E stick

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
) 4 able to stand without using hands and stabilize independently (
) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

legs not on chair

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision (
) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL : back unsupported
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (
) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision (
) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
(4 sits safely with minimal use of hands (
) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
(4 able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision (
) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
(4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together ( )
0 needs help to attain position and unable to hold for 15 seconds

Participant Identification Number: ____________ **Continued**

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing (one way)
( ) 0 needs assistance while turning both ways

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.

( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

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Participant Identification Number: A **Date:** 1/2/17

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
( ) 4 able to stand without using hands and stabilize independently (
) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

Checked legs not on chair ✓

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
(4) able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision (
) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (
(4) able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision (
) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
(4) sits safely with minimal use of hands (
) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
(4) able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision (
) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
(4) able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together ( )
0 needs help to attain position and unable to hold for 15 seconds

Participant Identification Number: A **Date:** 1/2/17

SITTING TO STANDING

INSTRUCTIONS: Please stand up. Try not to use your hand for support. (

)4 able to stand without using hands and stabilize independently (Checked legs not on chair ✓

) 3 able to stand independently using hands

( ) 2 able to stand using hands after several tries (

) 1 needs minimal aid to stand or stabilize

( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED

INSTRUCTIONS: Please stand for two minutes without holding on. (

4 able to stand safely for 2 minutes

( ) 3 able to stand 2 minutes with supervision (

) 2 able to stand 30 seconds unsupported

( ) 1 needs several tries to stand 30 seconds unsupported (

) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL

INSTRUCTIONS: Please sit with arms folded for 2 minutes. (

4 able to sit safely and securely for 2 minutes

( ) 3 able to sit 2 minutes under supervision (

) 2 able to able to sit 30 seconds

( ) 1 able to sit 10 seconds

( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING

INSTRUCTIONS: Please sit down.

(4 sits safely with minimal use of hands (

) 3 controls descent by using hands

( ) 2 uses back of legs against chair to control descent (

) 1 sits independently but has uncontrolled descent (

) 0 needs assist to sit

TRANSFERS

INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.

(4 able to transfer safely with minor use of hands (

) 3 able to transfer safely definite need of hands

( ) 2 able to transfer with verbal cuing and/or supervision (

) 1 needs one person to assist

( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED

INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (

4 able to stand 10 seconds safely

( ) 3 able to stand 10 seconds with supervision (

) 2 able to stand 3 seconds

( ) 1 unable to keep eyes closed 3 seconds but stays safely (

) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER

INSTRUCTIONS: Place your feet together and stand without holding on.

( )4 able to place feet together independently and stand 1 minute safely

( ) 3 able to place feet together independently and stand 1 minute with supervision ( )

2 able to place feet together independently but unable to hold for 30 seconds

( ) 1 needs help to attain position but able to stand 15 seconds feet together ( )

0 needs help to attain position and unable to hold for 15 seconds

Participant Identification Number: A 1/2/17 **Continued**

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

(4) can reach forward confidently 25 cm (10 inches) (good instructions
) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet. ( )

4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently ( )
1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)

(4) looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift (
) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction. ( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less (
) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing (
0 needs assistance while turning

only did one way

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times. ( )
4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds (
2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

(4) able to place foot tandem independently and hold 30 seconds (
) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds (
) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on. (
) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds (
) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently. ( )
0 unable to try of needs assist to prevent fall

(46) TOTAL SCORE (Maximum = 56)

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Participant Identification Number: 8 **Date:** 1/2/17 ZZF

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
) 4 able to stand without using hands and stabilize independently (
(3) able to stand independently using hands
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision (
(2) able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
( ) unable to stand 30 seconds unsupported (· 20 secs

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (; feet flat
) 4 able to sit safely and securely for 2 minutes ; back supported
( ) 3 able to sit 2 minutes under supervision (
(2) able to able to sit 30 seconds 1m9.
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands (
(3) controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
((2) able to transfer with verbal cuing and/or supervision (If put hand down, needs assistance
) 1 needs one person to assist If not put hand on = 2
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
((1) unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
((1) needs help to attain position but able to stand 15 seconds feet together ( ) less than 15 secs ∴ 0
0 needs help to attain position and unable to hold for 15 seconds

Participant Identification Number: ____________ **Continued**

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING

INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently 25 cm (10 inches) (
) 3 can reach forward 12 cm (5 inches)
(2 can reach forward 5 cm (2 inches) yes, but needs supervision if does it further
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION

INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet. ( )
4 able to pick up slipper safely and easily
(3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently ( )
1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING

INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift (
) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning needs supervision
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES

INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction. ( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less (
) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing (
0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED

INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times. ( )
4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds (
) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT

INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds (
) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds (
) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG

INSTRUCTIONS: Stand on one leg as long as you can without holding on. (
) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds (
) 2 able to lift leg independently and hold ≥3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently. ( )
0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

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Participant Identification Number: B **Date:** 1/2/17 EZF

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
) 4 able to stand without using hands and stabilize independently (
3 able to stand independently using hands
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision (
2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
unable to stand 30 seconds unsupported 1· 20 secs

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (
) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision (
2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

! feet flat
! back supported
1m9.

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands (
3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
(2 able to transfer with verbal cuing and/or supervision (
) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

If put hand down, needs assistance
If not put hand on = 2

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
(1 unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
(1 needs help to attain position but able to stand 15 seconds feet together ( )
0 needs help to attain position and unable to hold for 15 seconds

less than 15 secs ∴ 0

Participant Identification Number: B **Date:** 1/2/17

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support. (
) 4 able to stand without using hands and stabilize independently (
3 able to stand independently using hands
( ) 2 able to stand using hands after several tries (
) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on. (
) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision (
2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported (
) 0 unable to stand 30 seconds unsupported

1m 20s

Make sure hands free in case of fall

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4. SITTING

WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes. (
) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision (
2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

– need to ensure back unsupported
1m 9s

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands (
3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent (
) 1 sits independently but has uncontrolled descent (
) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands (
) 3 able to transfer safely definite need of hands
2 able to transfer with verbal cuing and/or supervision (
1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds. (
) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision (
) 2 able to stand 3 seconds
(1 unable to keep eyes closed 3 seconds but stays safely (
) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision ( )
2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together ( )
0 needs help to attain position and unable to hold for 15 seconds

Participant Identification Number: B 1/2/17 **Continued**

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches) (
) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
(1) reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet. ( )
4 able to pick up slipper safely and easily
(3) able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm (1-2 inches) from slipper and keeps balance independently ( )
1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift (
) 2 turns sideways only but maintains balance
(1) needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction. ( ) 4
able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less (
) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing (
0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times. ( )
4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds (
) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
(0) needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds (
) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds (
) 1 needs help to step but can hold 15 seconds
(0) loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on. (
) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds (
) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently. ( )
0 unable to try of needs assist to prevent fall

(17) TOTAL SCORE (Maximum = 56)

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Appendix 11 Letter from the consultant physiotherapist to confirm the inter-rater reliability results of the BBS

Berg validation

Robertson Adrian

Sent: 01 March 2017 10:53

To: Harkin Elizabeth

Dear Liz

I feel from todays session you are able to consistently and reliably assess using Berg balance scale in a comparable way to a qualified and experienced physiotherapist.

Yours sincerely

Adrian

Falls Efficacy Scale 3 March 16 v2.0

Participant Identification Number:__
Date:_______________

On a scale from 1 to 10, with 1 being very confident and 10 being not confident at all, how confident are you that you do the following activities without falling? Please write a number between 1 and 10 in the spaces opposite the questions.

Activity:	**Score:** 1 = very confident 10 = not confident at all
Take a bath or shower	
Reach into cabinets or closets	
Walk around the house	
Prepare meals not requiring carrying heavy or hot objects	
Get in and out of bed	
Answer the door or telephone	
Get in and out of a chair	
Getting dressed and undressed	
Personal grooming (i.e. washing your face)	
Getting on and off of the toilet	
Total Score	

Depression Scale (Long Form) 16 May 16 v.2.0

Participant Identification Number: ______________________

Date:____________________

<u>Instructions:</u> Choose the best answer for how you felt over the past week.

Please circle the response (Yes or No) that best describes yourself.

No.	Question	Answer	Score
1.	Are you basically satisfied with your life?	YES / NO	
2.	Have you dropped many of your activities and interests?	YES / NO	
3.	Do you feel that your life is empty?	YES / NO	
4.	Do you often get bored?	YES / NO	
5.	Are you hopeful about the future?	YES / NO	
6.	Are you bothered by thoughts you can't get out of your head?	YES / NO	
7.	Are you in good spirits most of the time?	YES / NO	
8.	Are you afraid that something bad is going to happen to you?	YES / NO	
9.	Do you feel happy most of the time?	YES / NO	
10.	Do you often feel helpless?	YES / NO	
11.	Do you often get restless and fidgety?	YES / NO	
12.	Do you prefer to stay at home, rather than going out and doing new	YES / NO	
13.	Do you frequently worry about the future?	YES / NO	
14.	Do you feel you have more problems with memory than most?	YES / NO	
15.	Do you think it is wonderful to be alive now?	YES / NO	
16.	Do you often feel downhearted and blue?	YES / NO	
17.	Do you feel pretty worthless the way you are now?	YES / NO	
18.	Do you worry a lot about the past?	YES / NO	
19.	Do you find life very exciting?	YES / NO	
20.	Is it hard for you to get started on new projects?	YES / NO	

21.	Do you feel full of energy?	YES / NO	
22.	Do you feel that your situation is hopeless?	YES / NO	
23.	Do you think that most people are better off than you are?	YES / NO	
24.	Do you frequently get upset over little things?	YES / NO	
25.	Do you frequently feel like crying?	YES / NO	
26.	Do you have trouble concentrating?	YES / NO	
27.	Do you enjoy getting up in the morning?	YES / NO	
28.	Do you prefer to avoid social gatherings?	YES / NO	
29.	Is it easy for you to make decisions?	YES / NO	
30.	Is your mind as clear as it used to be?	YES / NO	
		TOTAL	

Patient Identification Number:___________ Date:______________

Your Health and Well-Being (SF-12) 3 March 16 v2.0

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. ***Thank you for completing this survey!***

For each of the following questions, please tick the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
a	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b	Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

3. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Were limited in the <u>kind</u> of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. **During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a <u>Accomplished less</u> than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did work or other activities <u>less carefully than usual</u>	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. **During the <u>past 4 weeks</u>, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

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INTERVIEW TOPIC GUIDE

1 Falls –	how often? Where? What doing? How? why didn't fall? trip? dizzy? weak? get hurt? get up? Help? doctor?
2 Quality of life –	mood, confidence, balance, impact of tai chi
3 Adherence –	why? Why not?
4 What was good about the intervention?	How felt before/after, benefits, home practice, able to do exercises?
5 What was bad about the intervention?	How felt before/after, improvements? home practice, not able to do exercises?
6 Reasons for participation –	motivation
7 What was the best part of the intervention? –	instructors, researcher, participants, intervention, home practice, assessments
8 What was the worst part of the intervention? -	instructors, researcher, participants, intervention, home practice, assessments

9 Would you continue with tai chi? – why? Why not?confident?	
10 Participation - would you participate again in a future study?	Were there any difficulties [transport, home/class practice]

MARCH 15	Recruit	Start	End
Week 1			
Week 2			
Week 3 16/03/15 [3-DDH; 1-PGI]	1,2,3		
Week 4 23/03/125 [4-DDH; 2-PGI]	4,5		
APRIL 15	Recruit	Start	End
Week 1 30/03/15 [3-DDH;2-PGI]	6,7		
Week 2 06/04/15 [3-DDH; 1-PGI]	8		
Week 3 13/04/15 [2-DDH; 2-PGI]	9,10	1,2,3,4,5	
Week 4 20/04/15 [1-DDH; 5-PGI]	11	6,7	
MAY 15	Recruit	Start	End
Week 1 27/04/15 [1-DDH; 3-PGI]		8	
Week 2 04/05/15 [4-DDH; 4-PGI]	12	9,10	
Week 3 11/05/15 [5-DDH; 2-PGI]	14,13	11	

Week 4 18/05/15 [5-DDH; 2-PGI]	15,16,17,18	12 [FULL IF 2 STAFF]	
JUNE 15	Recruit	Start	End
Week 1 01/06/15 [1-DDH; 1-PGI]		13,14	
Week 2		15,16,17,18	
Week 3			
Week 4			
JULY 15	Recruit	Start	End
Week 1			
Week 2			
Week 3 20/7/15 [2-DDH; 4-PGI]	19, 20 (13,14 if 12 per class)		1,2,3,4,5
Week 4 27/07/15 [3-DDH; 1-PGI]	21 (15 if 12 per class)	19, 20 (13,14 if 12 per class)	6,7
AUGUST 15	Recruit	Start	End
Week 1 03/08/15 [6-DDH; 1-PGI]	22 (16 if 12 per class)	21 (15 if 12 per class)	8
Week 2 10/8/15 [5-DDH; 3-PGI]	23, 24, 25, 26 (17,18,19,20 if 12 per class)	22 (16 if 12 per class)	9,10
Week 3 17/08/15 [3-DDH; 2-PGI]	27,28,29 (21,22,23 if 12 per class)	23,24,26,26 (17,18,19,20 if 12 per class)	11
Week 4 24/08/15 [2-DDH; 4-PGI]	30 (24 if 12 per class)	27,28,29 (21,22,23 if 12 per class)	12
SEPTEMBER 15	Recruit	Start	End

Week 1 31/08/15 [2-DDH]	31,32 (25,26 if 12 per class)	30 (24 if 12 per class)	13, 14
Week 2 07/09/15 [4-DDH; 2-PGI]		31,32 (25,26 if 12 per class)	15,16,17,18
Week 3 14/09/15			
Week 4			
OCTOBER 15	Recruit	Start	End
Week 1			
Week 2			
Week 3		13,14	
Week 4		15	19,20

NOVEMBER 15			
Week 1			16
Week 2			17,18,19,,20
Week 3			21,22,23
Week 4			24
December 15			
Week 1			25,26
Week 2			

Cheshire and Merseyside
Strategic Clinical Networks

Early Supported Discharge (in the context of Stroke Rehabilitation in the Community)

Gold Standard Framework

This document was produced with reference to national standards for best practice (e.g. NICE guidelines), a consensus document on stroke (Fisher et. al, 2011) and local expert opinion/benchmarking of ESD teams within Cheshire and Merseyside

Early supported discharge (ESD) teams should be commissioned as part of a whole pathway commissioning approach (National Stroke Strategy, 2007)

Stroke Rehabilitation	"People who have had strokes access high-quality rehabilitation and, with their carer, receive support from stroke-skilled services as soon as possible after they have a stroke, available in hospital, immediately after transfer from hospital and for as long as they need it" Quality Marker 10, Stroke Strategy
PART 1 – Models of Service Delivery	
Aim of Early Supported Discharge (ESD) Team	An ESD team should, according to needs and preferences of individual patients: • Facilitate earliest possible safe discharge from hospital, (wherever possible to the usual place of residence). • Provide high quality, stroke specialist multi-disciplinary rehabilitation; the initial frequency and intensity of therapy intervention must be at least equivalent to what would be provided on a stroke unit and be reduced gradually based on need. It should not result in a delay in care. • ESD is just one part of the patient pathway for a proportion (typically about 40%) of stroke patients. Locally, consideration should be given to how ESD fits within the entire pathway to ensure there is not a two tier system at the expense of non-ESD patients and to ensure smooth transition into longer term rehabilitation and support services.

	• An integrated approach with Social Care is essential and a joined up approach to commissioning may be needed to facilitate this.
Different models of ESD	The models may vary depending on what is provided across the whole pathway within a locality but all should provide the same level of quality. *In reach vs Outreach* Consideration of the local context and a whole pathway approach is key to ensuring the highest quality of rehabilitation for all patients. Outreach teams will need to work closely with community rehabilitation teams to ensure there are no excessive gaps when referring on. In contrast, in reach/community based teams should have a presence on the ward and be a key part of the
	discharge planning in order to facilitate the meeting of quality standards e.g. first contact within 24 hours of discharge, joint MDT care plan negotiated with patient/carers within 72 hours of referral to ESD team etc *5 or 7 day service* All ESD teams should offer at least a limited service at weekends to enable safe and timely discharge and respond to urgent needs. Therapy intervention at weekends should be available based on patient choice and if it is clinically appropriate. Analysis of capacity and demand should inform planning service delivery over 7 days that meets the required quality standards.

<u>Referral Criteria</u>	<u>ESD</u> • 18 years + • Registered with a GP or residents (by postcode) within a defined area • Clinical diagnosis of stroke (or subarachnoid haemorrhage if other suitable services are not available) • Under the care of a Stroke Consultant • Medically stable • Continence and nutrition plans in place and needs can be met • Risk assessment indicates patient is safe to be at home (taking into account home circumstances) • The discharge destination is a suitable environment in which to carry out rehabilitation • The patient is able to engage in rehabilitation and progress towards goals • Transfer independently or with one person/have a barthel score greater than 9 – for pure ESD provision. There is increasing evidence within established ESD teams that more complex patients can also benefit from ESD, e.g. those that transfer with two. Where an ESD pathway is part of a broader community rehabilitation team or accepts more complex patients as part of a whole pathway approach (different referral criteria) this will have implications for team composition and skill mix. Non – ESD Pathway for patients outside of ESD criteria There should be clear local guidance for pathways for non-ESD patients.
Length of time can access ESD pathway	Recommended range= between 6 and 16 weeks depending on the longer term rehabilitation and support services available. The ESD pathway should be a core component of a stroke rehabilitation and support pathway with access to stroke skilled staff for up to six months post stroke depending on need. Patients eligible for an ESD pathway will typically require the high intensity of input for up to 6 weeks. For patients that require further stroke specialist rehabilitation at a reduced intensity (including non-ESD patients) there should be appropriate pathways in place. e.g. ESD and non-ESD pathways provided by the same team (often community based) Managed transition from an ESD team (often outreach) to a community stroke or neuro team To ensure flow through these pathways it is important to for stroke

	rehabilitation teams to have clarity on other support services post the stroke specialist rehabilitation period (e.g. emotional support, life after stroke programmes, cardiac rehab etc.) including those provided by CCG funded voluntary sector providers. Opportunities to work in collaboration with these services and the voluntary workforce (e.g. carers, expert patients, volunteers) should be explored locally to ensure an integrated whole pathway approach A gold standard ESD team will work closely with acute staff and community teams and support services to ensure flow of patients along the entire pathway. Commissioners may need to consider how to address any blocks in the pathway or consider options for continued rehabilitation post ESD when required, potentially through a whole pathway approach.
Part 2 – Workforce and Skill Mix	

	Early supported discharge teams should: • Be multi-disciplinary • As a minimum should include dedicated physiotherapy, occupational therapy, speech and language therapy and access to psychological support in line with the sentinel stroke national audit programme/NICE guidelines • Have specialist knowledge in stroke care and rehabilitation • Be organised by a team coordinator – a Band 7 AHP with at least 5 years experience in neuro/stroke. Additional sessions should be allocated for this to ensure there is no negative impact on face to face time within one therapy discipline. For a **100 patient per year** caseload (note – these figures were based on providing a 5 day service and would need adjusting to provide a 7 day service): • 1.0 Physiotherapist (dedicated) • 1.0 Occupational Therapist (dedicated) • 0.5 Speech and Language Therapist (dedicated) • 0-0.5 Social Worker (consideration will need to be given to how to achieve an integrated model if there is not dedicated social worker time into the team) • 0-1.2 Nurse (more nursing input will be required for teams where increasingly complex patients are discharged earlier and supported by the team) • 0.1 Physician (teams that have this typically use the time to contribute to an MDT meeting) • 0.25 assistant (though many teams make greater use of assistant roles) • Access to Psychological support • Access to dietetics Based on a consensus (Fisher et. al., 2011) Improvements in access to psychological support by ESD patients need to be demonstrated over time in line with the national drive to improve access to psychological support.

	Skill Mix: • Services can be flexible and use judgement in the use of skill mix to ensure a high level of specialist knowledge and skills and adequate support for the range of grades within the team, e .g. assistant practitioners taking on extended roles where there is support available from qualified staff with specialist skills and experience, band 5 staff working jointly with a senior clinician until a level of competency is attained. • There are opportunities with the possibility of collaboration between stroke services and whole pathway, outcome based commissioning to think innovatively about these workforce issues, e.g. having an expert/consultant therapist across a larger geographical patch to focus on quality and improvement, ensuring a range of posts at different bands across the team, flexing staff across integrated pathways, coordinated approaches to recruiting and developing new graduates, e.g. rotational posts, maximising the skills of assistant practitioners. • Managers and commissioners should consider local geography and travelling distances and costs when agreeing staffing levels.
Part 3 – Measuring quality, performance and outcomes A gold standard ESD team should:	
Measurement and Improvement	• Have agreed local processes for collection of performance data • Will be registered with the Sentinel Stroke National Audit Programme (SSNAP) and input all required fields to SSNAP on a regular basis • Will own their own performance data and will work with senior managers and commissioners locally to drive improvements • Have a service improvement plan in place which addresses workforce, recruitment and retention issues; staff training and development; improvements in data collection and reporting, and quality of clinical care against NICE guidelines. • Audits itself against the NICE stroke rehabilitation guidelines and incorporates into service improvement plan to be shared with commissioners as required • Evidence that the service has contributed to work with all stakeholders to look at financial sustainability of all services across the whole stroke pathway, including consideration of unbundling of the stroke tariff

Quality of care and patient experience	<u>Quality Indicator</u> Measures collected through SSNAP can be looked at by Trust and CCG Local arrangements should be in place to ensure seamless transfer of care, e.g. joint discharge visits, joint discharge planning meetings Joint health and social care plan	<u>Measure</u> Submit data on all relevant measures and receive quarterly reports Agreed process developed jointly (ESD team(s) and acute team), 100% of transfers of care in line with local process 100% of patients with a personal copy

	developed jointly with families that supports seamless transfer from hospital (need a clear and regionally agreed and understood definition of this to ensure relevance to patients with different needs) Ensure patients are safe for discharge, e.g. equipment in place, training of carers completed, appropriate nutrition/continence plans in place Local arrangements in place to ensure integration with social care for those that need it All patients eligible for ESD are able to access it (typically around 40% depending on case mix) Visit at home within 24 hours of discharge by a relevant member of the specialist stroke rehabilitation team for assessment of patient-identified needs and the development of shared management plans Shared responsibility with the acute service to reduce or (for established ESD teams) maintain a low level of length of stay 100% patients have rehabilitation goals jointly agreed with patient/carer within 72hours of discharge - the patient and their family/carers should receive a copy of the goals which is appropriately formatted for their individual needs. Provide 45 minutes of therapy from each relevant stroke rehabilitation therapy (physiotherapy, occupational therapy and speech and language therapy) for a minimum of 5 days per	of a joint health and social care plan developed in collaboration with patients, carers and families Exception reporting of readmissions or incidents relating to unsafe discharge Potential measures: reduction in total number of visits from ESD and social care due to shared planning, exception reporting of delayed discharge due to delays in social care packages Report % and exception reporting of where patients are unable to access ESD Report on % achieved Exception reporting of delayed discharge due to capacity of ESD team Report on % achieved Measured by % of patients receiving 45 mins of each therapy, 5 days a week for first 2 weeks post discharge

	week to people who have the ability to participate, and where functional goals can be achieved. Intensity to be reduced gradually with a planned transition to longer term rehabilitation and support services. Mood screen completed within 6 weeks if not completed as an inpatient Increasing levels of access to psychological support when needed Patient experience measures agreed with local commissioners via a survey of all patients	Report on % achieved Referral rates and/or waiting times 100% patients receive a survey. To include questions about: • level of satisfaction with their involvement in the development of the joint health and social care plan • % of patients that report receiving a copy of this plan • Carer satisfaction with support and training prior to and during discharge
Outcomes	• Collect the nationally agreed outcome measures and submit these via the SSNAP audit (where possible this should the primary method for measuring outcomes used by commissioners) • 100% of patients should have a record of outcome measures within one week of arrival to the team that can be reviewed within an agreed timeframe. Changes over time to be reported. • Will have own local processes for measuring and reporting on outcomes agreed with commissioners as appropriate that include - Patient centred scale - Functional outcome measure - Patient satisfaction - Mood screen	

Key markers of quality longer term rehabilitation (ESD or broader community stroke/community neuro rehab teams) - % increases from baseline targets to be defined	Reduce dependency and enable patients to self-manage, e.g. by working in collaboration with third sector organisations • Increasing number of patients able to access psychological support • Increasing number of patients able to access return to work support if appropriate • A joined up whole pathway approach to reviews at 6weeks, 6 months and 12 months post stroke • There should be the flexibility for re-referral into stroke specialist rehabilitation services where it is clinically appropriate e.g. botox therapy for spasticity – re-referral rates to be reported to commissioners to identify gaps

A task and finish group produced the document at an initial meeting which was reviewed at a follow up meeting. The document was shared for wider consultation via a stroke therapist network meeting along with a group of patients/carers, a representative from the Stroke Association and a commissioner.

V5.0 dated 20th Sept 2016 (IRAS ID 171300)

University of HUDDERSFIELD
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Date:

SUITABILITY SCREENING QUESTIONNAIRE

All questions contained in this questionnaire are strictly confidential.

Participant Identification:	☐ M ☐ F	**Age:**
Doctor:		
Side of Weakness:	**Type of stroke:**	

PERSONAL HEALTH HISTORY

List any medical problems that other doctors have diagnosed

Recent hospitalizations

Year	Reason	Hospital

Understand English?	☐ Yes	☐ No

Please turn to next page

1

Medications		
Name	Dose	Frequency Taken

Allergies	
Name	Reaction

HEALTH HABITS AND PERSONAL SAFETY

ALL QUESTIONS CONTAINED IN THIS QUESTIONNAIRE ARE OPTIONAL AND WILL BE KEPT STRICTLY CONFIDENTIAL.			
Exercise	☐ Sedentary (No exercise)		
	☐ Mild exercise (i.e., climb stairs, walk 3 blocks, golf)		
	☐ Occasional vigorous exercise (i.e., work or recreation, less than 4x/week for 30 min.)		
	☐ Regular vigorous exercise (i.e., work or recreation 4x/week for 30 minutes)		
Tai Chi	Have been practicing tai chi in the last year?		
	☐ Yes	☐ No	
Mobility	Are you independently mobile	☐ Yes	☐ No
	Are you able to walk 6m with or without aids?	☐ Yes	☐ No
	Do you require assistance with mobility by: - a person?		

	☐ Yes			☐ No	
	Do you use a walking stick?	☐ Yes	☐ No		
	Do you use a zimmer frame?	☐ Yes	☐ No		
Berg Balance	Date assessed:				
	Score:				
Rehab	Have you been referred for community rehabilitation?			☐ Yes	☐ No
	☐ MYTherapy	☐ Locala			
	☐ prior DDH rehab	☐ prior PGI rehab			
Transport	Are you able to make your own way to Pinderfields Hospital?			☐ Yes	☐ No
	Have you got somebody who could take you to Pinderfields Hospital?			☐ Yes	☐ No
Significant Others (if in the tai chi intervention group)	Do you wish for a significant other to attend tai chi with you?			☐ Yes	☐ No
	If yes, do they agree?			☐ Yes	☐ No
	If attending alone, will you need any assistance?			☐ Yes	☐ No
	Please give details:			☐ Yes	☐ No
Personal Safety	Do you live alone?			☐ Yes	☐ No
	Do you have frequent falls?			☐ Yes	☐ No
	Do you have vision or hearing loss?			☐ Yes	☐ No
	Are you continent?			☐ Yes	☐ No
	Are you willing for the researcher to contact your significant other in case of emergency?			☐ Yes	☐ No

MENTAL HEALTH

Is stress a major problem for you?	☐ Yes	☐ No
Do you feel depressed?	☐ Yes	☐ No
Do you panic when stressed?	☐ Yes	☐ No
Are you afraid of falling?	☐ Yes	☐ No
Do you feel alone?	☐ Yes	☐ No
Do you have any cognitive impairment?	☐ Yes	☐ No
Have you been diagnosed with dementia?	☐ Yes	☐ No
Do you have trouble sleeping?	☐ Yes	☐ No
Are you on anti-depressants?	☐ Yes	☐ No

OTHER PROBLEMS

Check if you have, or have had, any symptoms in the following areas to a significant degree and briefly explain.

☐ Heart/Cardiac	☐ Cancer - in treatment	**Recent changes in:**
☐ Bladder	☐ Visual impairment	☐ Weight
☐ Bowel	☐ Angina	☐ Energy level
☐ Epilepsy	☐ Hip replacements	☐ Ability to sleep
☐ Terminal illness	☐ Blood Pressure	☐ Other pain/discomfort:
☐ Arthritis	☐ Osteoporosis	

Thank you for the completion of this form.

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The Mid Yorkshire Hospitals NHS
NHS Trust

Participant Information Sheet

Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors - a feasibility study.

You are invited to take part in some research. Before you make your decision, it is important for you to understand why the research needs to be done and what it will involve. Please take time to read the following information carefully. You may wish to seek further information from a member of the research team or talk to friends or family members about the study before deciding to take part.

Part 1 tells you the purpose of this research and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the research.

Take time to decide whether or not you wish to take part.

Part 1

What is the purpose and background of this research? Stroke survivors are at higher risk of falling. Regular physical activity improves mobility, reduces falls and increases quality of life.

Mobility and movement are important parts of stroke rehabilitation. However, this will stop, and stroke survivors no longer receive rehabilitation.

Exercise programmes may enhance rehabilitation for stroke survivors.

One possible exercise is tai chi. Tai chi is an ancient Chinese martial art. It is a gentle exercise, aiming to:

1. enhance balance and mobility
2. provide a general sense of wellbeing

The purpose of this research is to find out if stroke survivors leaving hospital are willing and able to follow a tai chi exercise programme. This research will prepare for further research.

Why me? You are invited to take part in this research because you have had a stroke and are leaving hospital. You will also be receiving community rehabilitation services at home.

Do I have to take part? No, it is up to you to decide whether or not to take part. If you decide to take part, you may withdraw at any time and without giving a reason. This would not affect the standard of rehabilitation you receive from community services.

What would taking part involve? We expect about 50 people who are leaving hospital and about to start community rehabilitation to take part in the research. If you agree to take part, you will be allocated to one of two groups: tai chi with usual care (the experimental group), or usual care alone (the control group). The tai chi group will attend exercise classes but the usual care group will not. Both groups will receive usual NHS community rehabilitation.

Once you agree to take part in the research, you will be asked to sign an informed consent form.

Your personal contact details and that of a friend, relative or carer will be required, as well as access to your medical records to obtain your:

*blood pressure * type of stroke *GP details *past medical history

If you agree to take part, you will be assessed for suitability on the ward. This includes a balance test, which takes about 20 minutes, and is part of your normal assessment.

You will be suitable for the research if your balance test score is between 30 and 45. We do not believe exercise will be helpful for people outside this range.

You will then be invited to complete three questionnaires, each taking about 5 minutes to complete, about your:

*quality of life *mood *confidence in daily activities

Following completion of the questionnaires, you will be allocated to one of two groups: tai chi with usual care, or usual care alone. We are hoping to get 25 participants per group.

Group Allocation

You will be assigned to usual treatment or to Tai Chi and usual treatment at random (like tossing a coin). Half of the participants will get usual treatment and half will also get Tai Chi. Neither you nor the researcher will know which treatment group you have been assigned to until a sealed envelope giving the information is opened at the beginning of the study.

Research Timeline

The research requires you to be involved for six months. Twelve of these weeks will be tai chi classes, if you are in the tai chi group.

Assessments will take place three times: before the research starts (baseline), at 12 weeks and at six months.

What will be involved?

Usual Care group*:* questionnaires will be self-completed in your own time and returned by stamped addressed envelopes at baseline, 12 weeks and six months. You will also do a balance test at these times. Each month, you will complete a falls diary. Falls diaries will be returned via a stamped address envelope.

Tai chi group*:* In addition to the tai chi classes, you will be given a home practice booklet and DVD to enable you to practise at least 15 minutes a day. This will also be supported with a private link to YouTube.

You may bring along a friend, relative or carer for support. However, no information will be collected from them.

Details of the tai chi times and dates will be given to you.

The tai chi exercise programme will be held in a physiotherapy gym at Pinderfields General Hospital.

You are encouraged to wear comfortable loose clothing with flat comfortable footwear.

One tai chi instructor and one researcher (registered nurse) will be present at the tai chi classes.

Self-completed questionnaires, balance tests and blood pressure will be recorded at baseline, 12 weeks and six months. You will also be asked to fill in diaries to record home practice and falls. If questionnaires are completed at home, they will be returned via a stamped address envelope.

Some participants will be invited to come for an interview. You will be asked:

- About your experiences of tai chi
- Changes you may feel after tai chi
- Falls
- Participation

Interviews will be recorded and written down. They may last for up to one hour. The information will be stored at the University of Huddersfield. After six years, it will be destroyed. Personal details will be destroyed when it is no longer needed.

Both groups: Throughout the research, you may also be contacted by telephone should you not attend tai chi classes or return questionnaires. Once you have completed all the required questionnaires, you will be given a £10 voucher.

The research will require you to make your own way to Pinderfields General Hospital. There are shuttle buses available at Pontefract, Dewsbury and Pinderfields hospitals, and a bus timetable will be given to you should you wish to take part.

You will be required to make your own way to these shuttle bus venues, and we cannot reimburse or compensate you for your transport costs.

What are the possible benefits of taking part? Although there is no guarantee of any specific treatment benefits, tai chi may offer additional benefits over community rehabilitation for stroke survivors. This might be seen as improvements in balance, mobility, and quality of life.

The usual care group enables the researcher to compare its results with the tai chi group. This will help the researcher to prepare for bigger research.

What are the possible disadvantages and risks of taking part? There are no significant risks or disadvantages resulting from participation in the research beyond those that may be experienced during usual community rehabilitation.

A registered nurse will be present in case of any adverse events. If there are any unexplained adverse events, the research will stop and you will be informed why.

Part 2

What if something goes wrong? If you wish to complain about any aspect of the research, the complaints procedure and related contacts will be given to you.

What if I don't want to carry on? Participation is entirely voluntary. You can withdraw from the research at any time without it affecting your usual care.

Will my taking part in this research be kept confidential? Information collected by the researcher will include:

- general personal information (for example your name, address, contact details, date of birth)
- health information (your past medical history and health condition)

If you agree to take part, you agree that any information about you recorded may be used for the research.

Information will be held on

- an encrypted computer
- paper records in an anonymised format using numbers rather than your name or other identifiable details

All information will be stored, used and reported in a way that none of the details of your specific health issues can be seen by others or traced back to you.

Relevant information may be seen by:

- the supervisors of the PhD researcher based at the University of Huddersfield
- the statistician based at the University of Huddersfield

All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Should you disclose things that may cause harm to yourself or others, this disclosure will be relayed to the appropriate authorities.

What will happen to the results of the research? The information and results from this research:

- will be used as part of a PhD thesis which will be made freely available
- may be published in medical journals
- may be published in scientific reports
- you will receive a report of the findings

Who is organising and funding the research? The research is organised and run by the University of Huddersfield as part of a research student's PhD. The PhD researcher is a registered nurse based at Pinderfields General Hospital, Wakefield.

How have patients and public contributed to this research? The Stroke Association Service User Review Panel [SURP], as well as local Stroke Association group have:

- been informed about the research
- expressed their opinions about the research

- contributed to this information sheet

Who has reviewed the research?

- Stanmore Research Ethics Committee
- Leeds West Research Ethics Committee
- School Research Ethics Panel [SREP] for the University of Huddersfield
- Two supervisors at the University of Huddersfield
- MidYorkshire Hospitals NHS Trust (R&D Department)

What if new information becomes available? Sometimes during the course of a research project, new information becomes available about what is being studied. If this happens, the researcher will discuss whether it affects the research.

Will my GP be informed? With your agreement, a letter will be sent to you GP to inform him/her that you will be participating in this research.

The informed consent process The researcher will discuss the risks and benefits of the research with you. You will then be given ample time and opportunity to ask questions about the research and discuss it with relatives and family members. Should you agree to take part in the research, you will provide voluntary consent by signing and dating the written informed consent document.

Information confidentiality and storage

Any and all information collected from your hospital records

* about your stroke *past medical history * blood pressure

will be anonymised and given a unique identifier.

This anonymised information will be entered onto a secure and password protected computer based at the University of Huddersfield.

It will not be possible for anyone viewing the information to be able to identify any individual participants.

Paper copies will be held at the University of Huddersfield by the researcher according to research archiving guidelines, following completion of the research.

Useful contacts for further information:

If you have any other questions or any concerns about the research or the way it has been carried out, you should contact:

Researcher: Elizabeth Harkin, Registered Nurse, Human and Health Sciences Research Building, Room HHRG/04, University of Huddersfield, Queensgate, Huddersfield, HD1 3DH.email: elizabeth.harkin@hud.ac.uk

For NHS complaints, contact the following for assistance:

Patient and Advice Liaison Service [PALS]
The Patient Liaison Manager
Trust HQ and Education Centre
Pinderfields Hospital
Aberford Road
Wakefield
WF1 4DG
telephone: 01924 542972 Mon – Fri: 8.30am – 5.00pm
email: pals@midyorks.nhs.uk

If you decide you would like to take part, please read and sign the consent form. You will be given a copy of this information sheet and the signed consent form to keep.

Thank you for taking the time to read this information sheet.

V3.0 dated 20th Sept 2016

The Mid Yorkshire Hospitals NHS
NHS Trust

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Participant Identification Number for this trial:

CONSENT FORM 1 (study)

Title of Project: **Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors – a feasibility study. (IRAS ID 171300)**

Name of Researcher: Elizabeth Harkin, School of Human & Health Sciences Research Building, Room HHRG/04, University of Huddersfield, Queensgate, Huddersfield, HD1 3DH. Email: elizabeth.harkin@hud.ac.uk

Please initial box

1. I confirm that I have read the information sheet dated 20/09/2016 (version 7.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the University of Huddersfield, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

5. I agree to my General Practitioner being informed of my participation in the study. ☐

6. I understand that the information held and maintained by MidYorkshire NHS Hospitals Trust and other NHS bodies (MyTherapy and Locala) may be used to help contact me or provide information about my health status. ☐

7. I agree to take part in the above study. ☐

____________________	____________________	____________________
Name of Participant	Date	Signature
____________________	____________________	____________________
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

v3.0 dated 20th Sept 2016

The Mid Yorkshire Hospitals NHS
NHS Trust

University of HUDDERSFIELD
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Participant Identification Number for this trial:

CONSENT FORM 2 (interview)

Title of Project: **Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors – a feasibility study. (IRAS ID 171300)**

Name of Researcher: Elizabeth Harkin, School of Human & Health Sciences Research Building, Room HHRG/04, University of Huddersfield, Queensgate, Huddersfield, HD1 3DH. Email: elizabeth.harkin@hud.ac.uk

Please initial box

1. I confirm that I have read the information sheet dated 20/09/2016 (version 7.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. I understand the types of questions I can expect to answer. I understand that the interview will be conducted at a place and time that is convenient to me, and that it will take approximately one hour of my time. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. I understand that, with my permission, this interview will be audio recorded and that any information I provide will be kept confidential, used for research purposes only. All interview notes and audio will be kept in a secured environment. ☐

3. I understand that relevant sections from the interview may be looked at by individuals from the University of Huddersfield, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data. ☐

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐

5. I agree to take part in a face to face interview. ☐

________________	________________	________________
Name of Participant	Date	Signature
________________	________________	________________
Name of Person taking consent	Date	Signature

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

PROTOCOL

Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors - a feasibility study.

1. Introduction

There has been a considerable increase in re-admission to hospital of older people as a result of falls, placing a substantial economic burden on the NHS (National Institute for Health and Care Excellence [NICE], 2013). Falling is multifactorial and not all falls can be prevented (Russell et al., 2010). However, the likelihood of a fall can be reduced if the risk factors are modifiable.

One subpopulation of older people with a high falls incidence is stroke survivors (Jørgensen, Engstad & Jacobsen, 2002). Factors associated with the risk of falling among stroke survivors include muscle weakness, balance impairment and loss of postural control (Ada, Canning & Low, 2003; Bensoussan et al., 2007; Doyle, Bennett, Fasoli & McKenna, 2010; Harling & Simpson, 2008). In order to improve muscle strength, balance and postural control, stroke survivors in the UK are referred to community physiotherapy (Dworzynski, Ritchie, Fenu, MacDermott & Playford (2013).

Rehabilitation interventions for stroke survivors which are delivered by physiotherapists have been recommended by NICE (2013) for at least 45 minutes, five times a week. However, in reality, according to local physiotherapists working for the community rehabilitation services, this does not happen as the 45 minutes includes time for travelling, assessing and paperwork, leaving very little time for actual physical rehabilitation. In order to make sure a minimum of 45 minutes is achieved, self-practice at home could supplement the physiotherapy.

In addition, according to local physiotherapists current community rehabilitation stops after about three weeks. This leaves stroke survivors vulnerable to falls, being at high risk of falling within the first six months (Forster & Young, 1995), and without any mobility input in the community (National Audit Office, 2010). The aim of community rehabilitation is to improve or maintain the ability to carry out activities, which are important to individuals' independence (The Mid Yorkshire Hospitals NHS Trust, 2011), to enable people to reach their optimal functioning irrespective of their circumstances or home environment, as well as to encourage clients to take an active role in managing their condition (Locala Community Partnerships, 2013). Anecdotally, stroke survivors at the local Stroke Association stated that they wish the physiotherapy had been longer and felt abandoned when it ended.

Tai Chi could be a solution to reducing falls in stroke survivors, as well as extending the duration of community rehabilitation. Tai Chi may promote the opportunity for self-practice at home, enabling stroke survivors to manage their own health. However, due to the different tai chi styles and the unknown acceptance of tai chi in the UK, it is necessary to assess the safety and feasibility of Tai Chi.

The safety and feasibility of Tai Chi has only been explored in one pilot study among stroke survivors (Taylor-Piliae & Coull, 2012). It is unknown whether tai chi would be adhered to by a UK population immediately discharged from hospital with a stroke, or whether stroke survivors will be able to do the exercises. Hart et al. (2004), encouragingly, tested for adverse effects in stroke survivors practising Tai Chi and showed that there were none. However, this was an Israeli study with participants more than 27 months post-stroke. Hart et al. (2004) recommended further research on the feasibility of Tai Chi with stroke survivors.

No previous studies have used Tai Chi as an intervention at the early stages of stroke rehabilitation, and it is not known whether recruitment would be successful, or if the questionnaires would be completed by UK-based participants following discharge from hospital. A feasibility study will be able to investigate these factors.

Little research has been done with regards to Tai Chi as home practice amongst stroke survivors. As far as home practice is concerned, a study protocol by Tousignant et al. (2014) is currently concentrating on tai chi used in tele-rehabilitation compared to home visits. However, this study is still in the recruitment phase and has not been completed at the time of writing this proposal. The author was contacted by myself in order to find out more information, but as of yet there has been no response. Au- Yeung, Hui-Chan and Tang (2009) conducted a RCT which involved Tai Chi home practice amongst stroke survivors. The study by these authors was conducted in Hong Kong where Tai Chi is already widely practised by older people and is part of the cultural background. However, the population used in this study were stroke survivors who were at least six months post-stroke. The Tai Chi used was also adapted for people with arthritis, rather than adapted for stroke survivors. This RCT also found that self-practice was only adhered to if the exercises were easily learned and practiced at home. Therefore, another reason for conducting a feasibility study is to see if the home exercise programme of Tai Chi is adhered to by stroke survivors and to find out if it is easily learned or not, so that it may be modified for a RCT.

The principles and values of feasibility studies have been outlined in several papers. According to Bowen et al. (2009), and Arain, Campbell, Cooper and Lancaster (2010), a feasibility study is conducted in order to help investigators prepare for formal testing of an intervention. It is necessary to conduct a feasibility study when the answer to a research question is not known in a new population in a new setting with new health outcomes (Bowen et al., 2009), and when there is a need to determine whether an intervention is appropriate for further testing. In essence, feasibility studies can identify potential problems to the successful conduct of a RCT, and determine any aspects of the research methods and protocols in need of modification, as well as how changes (in this study, balance and falls rates and quality of life) may occur.

A feasibility study is helpful when previous studies have shown positive outcomes but in a different setting and population than the one of interest. For instance, prior research covering Tai Chi did not take account of the UK's socio-cultural health beliefs, nor did studies involve stroke survivors who were recently discharged from hospital. Feasibility studies focus on estimating parameters for a full-scale study. The question is *will the study work*? This matters to the stakeholders of a full-scale RCT. Small-scale experiments can be used in feasibility studies to test the safety of the intervention (Tai Chi), and the optimal intervention intensity, frequency and duration acceptable to participants (as we cannot test the intensity, frequency and duration required for an intervention effect) before launching a full-scale trial requiring substantial funding. Although the present study is not testing to see how effective Tai Chi is for preventing falls, it is considered that positive trends in outcomes can suggest that an intervention is ready to be tested in a full-scale trial whose results will influence health practice (Bowen et al., 2009).

2. Background

2.1 Stroke and Falls

Falling amongst older people has been and still is of considerable public health importance and is consequently a high priority for health and healthcare costs (Department of Health [DH], 2001; NICE, 2013). A fall has been defined as 'inadvertently coming to rest on the ground, floor or other lower level, excluding intentional change in position to rest in furniture, wall or other objects' (World Health Organization [WHO], 2007; Forster & Young, 1995). This definition will be used in this research in order to establish a common interpretation.

One subpopulation within older people is stroke survivors. A study focussing on the perceptions of stroke survivors of their health status and goals for recovery from early post-stroke by Hartigan, O'Connell, McCarthy and O'Mahoney (2011) also showed that stroke survivors had an impairment of standing balance, leading to falls.

DH (2009) has indicated that tai chi has been promoted as a falls preventative exercise. Taylor-Piliae, Boros and Coull (2014) conducted a randomised controlled trial [RCT] following a pilot study in 2012, which showed that fall rates were an important indicator of balance control amongst stroke survivors in Arizona, USA via a 12-week Tai Chi intervention, resulting in fewer falls than usual care alone. However, decisions cannot be made on this study alone, and more research is needed because the target population is different to that in the proposed study. This study also focussed on stroke survivors three months post-stroke after the rehabilitation stage. Additionally, participants did not take part in home practice.

In a study by Jönsson, Lindgren, Hallström, Norving and Lindgren (2005), stroke survivors perceived their physical function to have deteriorated four months post-stroke. This finding is in agreement with DH (2008) which recognises that stroke survivors experience a high likelihood of falls within the first six months. *Within the first six months* could mean anytime between discharge from hospital and six months, suggesting that early intervention is required. The RCT study by Au-Yeung et al. (2009) also recommended further research earlier on in rehabilitation as Tai Chi practised earlier on in rehabilitation may have even greater functional and psychosocial implications. Additionally, the Royal College of Physicians (2012) states that stroke survivors are at risk of falling at all stages post-stroke.

Stroke is a leading cause of disability in the UK (Stroke Association, 2014). However, little research has been undertaken to evaluate interventions aimed at reducing falls in stroke survivors immediately discharged from hospital, and more research is needed (Royal College of Physicians, 2012).

2.2 Physical Activity and Stroke

The recent study involving stroke survivors six months post-stroke in Arizona has highlighted that regular physical activity improves physical function, reducing falls and increasing quality of life (Taylor-Piliae, Boros & Coull, 2014). Mobility and movement are considered to be important parts of stroke rehabilitation. NICE (2008) states that people with stroke should be mobilised as soon as possible. As an example of UK NHS practice, patients on the acute stroke ward at Pinderfields hospital are either referred to local specialist in-patient rehabilitation units, or discharged home with support from community rehabilitation services known as 'MyTherapy' and 'Locala.' These interventions end when these rehabilitation services are unable to make further improvements with the patients. Following discharge, clinical evidence of effective rehabilitative therapy interventions amongst stroke survivors are lacking and only 36 per cent of hospitals have such rehabilitation services due to funding (National Audit Office, 2010).

According to a survey conducted by the National Audit Office (2010) patients and carers suggested physiotherapy is needed for a longer time period than the current length. However, it was concluded by them that there is insufficient evidence to weigh up the relative benefits and costs for this longer term provision. Hopman and Verner (2003) conducted a qualitative study about the expectations of stroke survivors. They found that stroke survivors expressed a desire to be able to choose to participate in group exercise at the rehabilitation hospital because stroke survivors believed that this would increase their independence, usefulness, self-care and social life. A decline in health-related quality of life was believed by stroke survivors to result in a limited social life and unrealistic expectations of recovery after stroke.

One solution to the lack of participation of stroke survivors in group exercise is Tai Chi. Tai Chi could solve the problem of reducing falls, and lack of social inclusion and additional therapy following community rehabilitation, thus extending the rehabilitation period. NICE (2015) advises that stroke survivors should be encouraged to participate in physical activity such as building strength through increasing repetitions of body weight activities. This sort of activity is a component of Tai Chi.

2.3 Tai Chi and Falls

Systematic reviews (Harling & Simpson, 2008; Schleicher, Wedam & Wu, 2012; Wooton, 2010; Wu, 2002), state that Tai Chi in the general population may be one of the better exercises to prevent falls in the general older population. These reviews have also shown Tai Chi to have positive effects on balance function. However, participants with specific diseases such as stroke were excluded as part of their eligibility criteria. Therefore, the results may or may not apply to stroke survivors. Taylor-Piliae et al. (2014) conducted an RCT involving stroke survivors in Arizona more than three months post-stroke about Tai Chi and falls rates (Taylor-Piliae et al., 2014). This study showed that fall rates are an important indicator of balance control amongst US stroke survivors in the community because the study showed fewer falls with the Tai Chi intervention group compared with usual care and with a national fitness program for older adults. However, there are few studies in the UK regarding stroke and Tai Chi.

Au-Yeung et al. (2009) have noticed improvements in stroke survivors practising Tai Chi as early as six weeks with the arthritis Tai Chi programme, and this programme was shown to reduce the number of falls. No improvements were shown in single-leg stance, but exercises focussed on weight shifting rather than single-leg balance. The Tai Chi group did receive more input than the control group, which could have affected the results, despite not receiving home practice.

2.4 Tai Chi and Balance/Strength

Those most likely to benefit from tai chi classes are older people living in the community with recurrent falls and/or balance and gait deficits (NICE, 2013; 2015). In order to tackle the high incidence of falling in the older population, DH (2009) suggests focussing on improving strength and balance rather than falls in this population. In addition to DH (2009), NICE

(2013) is concerned about falls in older people and suggests fallers should be observed for balance deficits, as well as be considered for strength and balance interventions. NICE (2015) suggest that strength and balance training is most likely to benefit in terms of falls prevention in the general population.

According to Au-Yeung et al. (2009) who conducted a RCT to see if Tai Chi improves the standing balance of people with chronic stroke, balance deficits have been observed in a population more than six months post-stroke in Hong Kong, with standing balance being a risk factor for falls. Tai Chi is already widely practised in Hong Kong by older people and this may have influenced the acceptability of tai chi in this population. Additionally, the participants in this study were at least six months post-stroke. Therefore, these results cannot be generalised to a UK population recently discharged from hospital with a stroke.

Tai Chi is a low impact, low-speed exercise routine (Lan, Lai, & Chen, 2002) and has been shown to enhance physiological and psychological function, including balance in the general elderly population (Jahnke, Larkey, Rogers & Etnier, 2009). One component of the exercise routine involves transferring body weight from one leg to another (weight shifting) in a continuous sequence, turning the waist whilst the legs remain rooted in a fixed position, together with the incorporation of single-leg standing (Lan et al., 2002). It might reasonably be expected that this type of exercise could stimulate balance control and coordination. Indeed, it has been shown to increase control of voluntary weight-shifting and improve balance and decrease falls risk in stroke survivors (Taylor-Piliae & Coull, 2011).

2.5 Tai Chi and Reduction in Fear of Falling

A fall increases the likelihood of developing a fear of falling (Evitt & Quigley, 2004). This in turn could lead to avoidance of activity (Murphy, Dubin & Gill, 2003; Scheffer, Schuurmans, van Dik, van der Hooft & de Rooij, 2008). This can then lead to reduced mobility and balance (Gusi et al., 2012). The DH (2009) states that regular exercise can reduce fear of falling and fall risk in older people in the general population.

A study by Hartigan, O'Connell, McCarthy and O'Mahoney (2011) focussed on the perceptions of stroke survivors of their health status and goals for recovery from early post-stroke. It found that stroke survivors at this time felt anxious about falling and displayed anger and frustration at a non-functioning limb because their independence had reduced. Fear and anxiety were associated with their inability to adapt to these impairments. Returning to their pre-stroke life and regaining autonomy was important to them. Fear of falling in stroke survivors has been identified as a risk factor for falls, leading to a lack of confidence and increased falls risk (Royal College of Physicians, 2012).

Despite a lack of evidence of Tai Chi, stroke and fear of falling, tai chi has been shown to significantly increase confidence and mobility, enriching stroke survivors' social lives, as well as been considered to be useful as part of a fall reduction programme (Sattin, Easley, Wolf, Chen & Kutner, 2005).

NICE (2015) suggests that fear of falling affects older people's compliance with exercise and recommend fall prevention programmes to address barriers such as fear of falling. According to Zijlstra et al. (2007), home-based practice of Tai Chi reduces fear of falling in older people. Therefore, home-based practice would be beneficial as part of the Tai Chi programme. Moreover, fear of falling in stroke survivors has been identified as a risk factor for falls, leading to a lack of confidence and increased falls risk (Royal College of Physicians, 2012). However, it is not known if home practice of Tai Chi would benefit UK-based stroke survivors due to insufficient evidence.

2.6 Tai Chi and Blood Pressure

Friday and Sobel (1994) found that hypertension was associated with a higher risk of stroke recurrence, and this risk remains elevated for several years (Burn et al., 1993). Lai, Alter, Friday and Sobel (1994); Phillips, (1994); and Rashid, Leonardi-Bee & Bath, (2003) suggest that control of hypertension would bring the greatest chance of reducing risk of stroke recurrence after an ischaemic stroke.

Tai Chi has been shown to reduce blood pressure in people with hypertension (Lo, Yeh, Chang, Sung & Smith, 2012; Thornton, Sykes & Tang, 2004). Lo et al. (2012) suggested Tai Chi as an exercise programme for patients with hypertension in older people. There are currently known tai chi programmes administered by qualified physiotherapists within the local NHS hospitals for patients with cardiac problems. Tai Chi could thus provide an additional benefit for stroke survivors.

2.7 Tai Chi and Depression

An additional barrier to physical activity in stroke survivors is depression. Following a stroke, it is common for a person to develop depression due to reduced ability and social isolation, as well because of the part of the brain affected (National Institute of Mental Health [NIMH], 2015). One third of stroke patients develop post-stroke depression, which has a debilitating impact on participation in rehabilitation (Matsuzaki, Hashimoto, Yuki, Koyama & Hirata, 2015). Stroke patients who developed major depression prior to discharge from hospital were found to remain depressed after 12 weeks (Narushima & Robinson, 2002). Thus, it is possible that post-stroke depression can form an obstacle to early rehabilitation. Li et al., (2014) showed that long-term Tai Chi practice in the general population is independently related to a lower prevalence of depressive symptoms. Therefore, Tai Chi may elevate mood (Lo, Yeh, Chang, Sung & Smith, 2012).

2.8 Tai Chi, Stroke and Social Exclusion

Narushima and Robinson (2002) suggest that social interventions may help prevent or attenuate depression. According to Hare, Rogers, Lester, McManus and Mant (2006), social exclusion due to the physical consequences of stroke was experienced from community services by stroke survivors. Additionally, stroke survivors perceived their physical function to have deteriorated four months post-stroke in a study conducted by Jönsson, Lindgren, Hallstrom, Norrving and Lindgren (2005). Further, Carod-Artal, Egido, Gonzalez and de Seijas (2000) showed that a decrease in social activities was still evident one year post-stroke. Indeed, Tai Chi has been shown to be an appealing exercise programme and has been regarded as a self-regulated, enjoyable, and socially engaging activity (Li, Harmer, Fisher & Mcauley, 2004).

2.9 Tai Chi Style

The three main Tai Chi styles are: Yang, Wu and Chen. These styles vary in speed and pace of performance. However, numerous studies of tai chi and its effect on falls in the general population (Voukelatos, Cumming, Lord & Rissel, 2007; Wolf et al., 2003; Choi, Moon & Song, 2005), as well as studies of Tai Chi and its effect on balance (Li, Devault, & Van Oteghen, 2007; Li et al., 2008; Hart et al., 2004) have not actually specified the style involved.

The second most popular style amongst Tai Chi practitioners is Wu. This style is directly derived from the Yang style but utilises smaller, more compact movements. Due to this smaller frame training which requires more precision in movement, it may be more demanding initially for stroke survivors. It also involves leaning and stepping back off the heel which may lead to imbalance in a population with limb impairment not used to such exercises (Frantzis, 2003).

The third most popular style of Tai Chi is Chen, which Tai Chi comprises of lower postures and is more energetic, explosive and acrobatic than the other two styles (Frantzis, 2003). Physically demanding, Chen-style Tai Chi is also faster than the other two styles (Galante, 1981).

The most common style practised amongst Tai Chi practitioners is Yang (Taylor-Piliae et al., 2014). Yang-style Tai Chi is also widely available and practised worldwide, utilising medium to large movements (Frantzis, 2003). Its characteristics make it suitable for stroke survivors. Yang-style Tai Chi enables stroke survivors to concentrate their minds on correct postures when exercising (Ying-Hua & Yueh-Liang, 1991), as stroke survivors' brains process information slower which could lead to a lack of proprioception, causing balance problems (Barrett & John, 2014). Yang-style Tai Chi's slowness of movement may also be conducive for stroke survivors to have time to think about proprioception (Leung, Chan, Tsang, Tsang, & Jones, 2011; Wolf et al., 2003; Wooton, 2010).

2.9.1 Limitations of Recent Studies

There are no feasibility studies about the effect of Tai Chi on stroke survivors recently discharged from hospital in the UK. There is also insufficient research focussing on stroke survivors in the early stages of rehabilitation and Tai Chi home practice. Au-Yeung et al. (2009) focussed on stroke survivors six months post-stroke. Introducing Tai Chi early on in stroke rehabilitation was recommended, as well as continuing with the Tai Chi group after the end of the study, suggesting further improvements could be produced. Therefore, research involving Tai Chi in the early phases of stroke rehabilitation is needed.

Given that the Tai Chi programme in the study by Au-Yeung et al. (2009) was designed for people with arthritis, this programme may not be suitable for stroke survivors. Furthermore, modified Tai Chi programmes used in many studies are not widely accessible to other communities (Nnodim et al., 2006). Therefore, a modified programme of Tai Chi is needed for stroke survivors.

Other studies focussing on Tai Chi and its effect on balance and falls prevention were undertaken using populations without chronic illness, excluding stroke survivors, making it difficult to generalise the results to stroke survivors. More research was encouraged with more frail populations, such as those with stroke (Harling & Simpson, 2008; Li et al., 2008;

Lin, Hwang, Wang, Chang & Wolf, 2006; Low, Ang, Goh & Chew, 2009; Nnodim et al., 2006; Tsang & Hui-Chan, 2006; Voukelatos et al., 2007; Wolf et al., 2003; Wooton, 2010).

There is little research regarding cost-effective solutions to extending the duration of community rehabilitation by using Tai Chi and encouraging self-management. It is, therefore, unknown whether stroke survivors in the UK would accept and adhere to this type of exercise.

2.9.2 Summary

There is little evidence to show that physiotherapy prevents falls. NICE (2013; 2015) and DH (2010) recognise that despite current community rehabilitation provision, falls are a major problem, resulting in an economic burden of considerable public health importance. A substantial number of falls in older people has led to an increase in re-admission to hospital, costing the NHS a substantial amount of money.

After a stroke, people are at higher risk of falling following discharge from hospital (Forster & Young, 1995). Physiotherapy for stroke survivors has been recommended by NICE for at least 45 minutes five times a week (Dworzynski et al., 2013). However, this recommendation is not always being met (National Audit Office, 2010), and stroke survivors fall frequently within the first six months after stroke (Forster & Young, 1995). Home-practice of Tai Chi could be a solution in order to meet this minimum requirement.

NICE (2015) suggests that stroke survivors should be encouraged to take part in physical activity such as building strength. NICE (2013; 2015) also recommends strength and balance training for community dwellers with balance deficits and a history of falls. It has been indicated by DH (2009) that Tai Chi is beneficial and could prevent a first fall in older people. However, there is insufficient research focussing on stroke survivors in the early stages of stroke rehabilitation and Tai Chi. Au-Yeung et al. (2009) involved stroke survivors six months post-stroke, and Taylor-Piliae et al. (2014) involved stroke survivors three months post-stroke. Nevertheless, these two studies found improvements with fewer falls in the Tai Chi groups. Other studies (Voukelatos et al., 2007) have focussed on people without chronic illness or balance deficit.

Further research is needed using a UK population in the early stages of rehabilitation to assess whether Tai Chi will be acceptable and adhered to by this population. Therefore, the proposed study will be a feasibility study using a modified Tai Chi programme with home-practice for stroke survivors in the early rehabilitation phase, in order to evaluate its acceptance and adherence.

3. Aims

The overall aim of the proposed research is to conduct a feasibility study to inform a future RCT. The research is exploratory in nature in order to estimate parameters needed to design the main study. Such parameters include:

- The ability to identify the number of eligible participants in a typical NHS setting.

- The willingness of participants to be randomised.

- The ability to recruit suitable participants.

- To estimate the length of time required to do this.

- To see whether the dose used appears to have an effect.

- To calculate the power for a larger randomised controlled trial.

- To assess the suitability of the outcome measures.

- To assess adherence of participants to Tai Chi classes and the home practice.

- To estimate follow-up rates, compliance and adherence rates, and response rates to questionnaires.

- To assess whether or not Tai Chi would be acceptable amongst stroke survivors who have no experience of the exercise, and if Tai Chi can be taught to this population.

3.1 Objectives

The objective of this proposed study is to obtain data through the implementation of Tai Chi classes for stroke survivors receiving early rehabilitation to assess the feasibility and refine procedures for a future large randomised controlled trial.

3.2 Title

Exploring Tai Chi as an early intervention for stroke survivors to improve balance and reduce falls: a randomized feasibility study.

4. Methodology

4.1 Study Design

The proposed study is not intended as an RCT, rather the intention, as titled, is to conduct a feasibility study to collect material to inform a future RCT. An RCT was considered but deemed inappropriate due to insufficient evidence surrounding Tai Chi as an intervention at early discharge in the UK health system. There are several factors that should be explored before an RCT can be proposed. It is not known whether Tai Chi will be accepted by stroke survivors at a point shortly after being discharged from hospital, or whether participants would adhere to a programme of Tai Chi-exercise classes and home practice. Further, no previous studies have used Tai Chi as an early intervention as a part of rehabilitation, and nor has there been any investigation of home practice. The potential recruitment rate (to guide the timeframe of an RCT) is not known, as well as data on outcome measures (needed to calculate sample sizes). In order to estimate the sample size for a full-scale trial, it is necessary to obtain standard deviations of the outcome measures. Without knowing the estimated sample size, an RCT cannot be done properly (Arain et al., 2010). Also, there are no current data on compliance with follow-up and ability of this group of participants to complete the relevant questionnaires. A feasibility study will be able to investigate these factors prior to testing the intervention in a properly developed RCT.

This feasibility study will help to design a further confirmatory randomised controlled trial (Arain et al., 2010). This study has been designed in conjunction with the CONSORT statement, which implies the study will use eligibility criteria, outcome measures, statistical methods to compare groups, specified dates for recruitment and follow-up, and report appropriately (Arain et al., 2010).

Specialist statistical input to the design has been sought by consulting a statistician based at the University of Huddersfield because of the data analysis required at the end of the study, which is to estimate a parameter such as a standard deviation used in a sample size calculation for a full-scale trial (Hooper, 2016). Sample sizes between 24 and 50 have been recommended (Julious, 2005; Lancaster, Dodd & Williamson, 2004; & Sim & Lewis, 2012). For the purpose of this study, it was decided that in order to achieve sufficient data to inform sample size calculations for any subsequent full-scale trial, 20 complete data sets per group should be sufficient, giving a total of 40 participants. However, in order to take account of possible dropouts (resulting in incomplete data sets) 50 participants (25 per group) will be recruited.

The proposed sample size is somewhat larger than previous studies, with the intention of ensuring sufficient data to inform a future trial. Taylor-Piliae and Coull (2011) conducted a pilot study involving 28 participants in total with 16 in the Tai Chi group and 12 in the control group. Study drop-outs (n=3, 11%) were all in the Tai Chi group, but were not related to the intervention. In the pilot study conducted by Hart et al. (2009), 18 participants were recruited in total, with nine in the intervention group and nine in the control group. However, Hart et al. (2004) did not reveal their drop-out rate.

After a six-month scoping exercise on the hyper-acute stroke unit at Pinderfields Hospital, it was found that there were five potential participants per month. A ten-month period producing five participants a month should be sufficient to achieve the required 50 participants.

Participants do not have to be randomised to comparison groups in feasibility studies because they do not evaluate the outcome of interest (Arain et al., 2010). However, it has been advised by the Research Design Service that randomisation is preferred because it is necessary to assess the willingness of participants to take part in the alternative (non-preferred) treatment in order to avoid a biased sample.

Participants will be randomised into one of two groups: Tai Chi with usual care, or usual care alone. The first participant will be given a choice of eight sealed envelopes, the content of which will be unknown to the participant and to the researcher offering the envelopes. Four envelopes will contain a piece of paper labelled ‘Tai Chi group’, whilst the other four envelopes will contain a piece of paper labelled ‘control group’. The first participant will choose one of these envelopes, which will determine their group allocation. The next seven participants will continue to choose from the remaining envelopes. After this, the process will be repeated for the next eight participants. This method of block randomisation has been recommended by a statistician based at the University of Huddersfield.

As well as quantitative, there will be a qualitative element to the proposed study in the form of interviews. It is the intention of the researcher, who is trained to conduct interviews by the

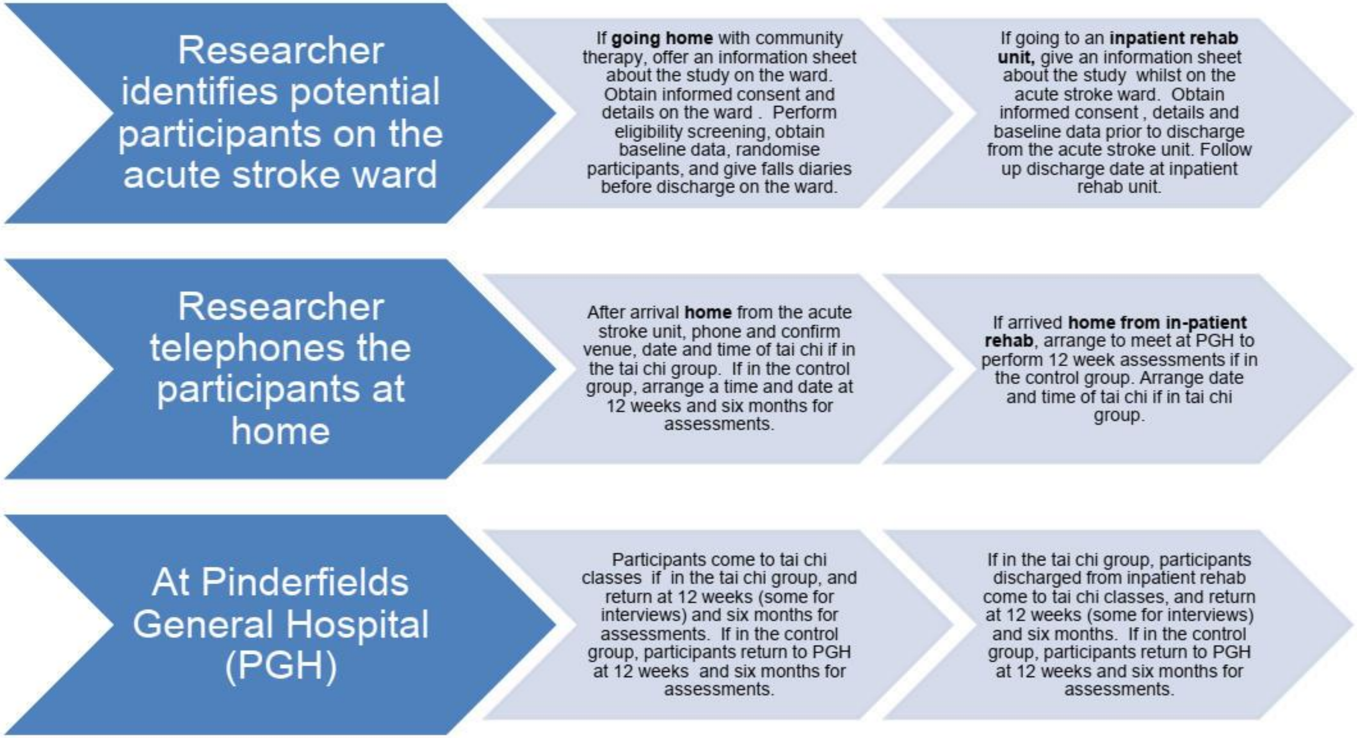
University, to obtain from the Tai Chi group consent from six participants to take part in a semi-structured interview as part of a process evaluation in order to understand the participants' perspectives about the acceptability of and adherence to tai chi, as well as any improvements, amendments, and adaptations.

4.2 Study Population and Setting

Patients with a diagnosis of stroke, at any age, on the stroke unit at Pinderfields General Hospital will be identified as being eligible according to pre-determined inclusion/exclusion criteria. There were 101 potential participants on the targeted stroke unit between March-August 2015. This number has been obtained from a scoping exercise at the stroke unit over six months to be used for recruitment. These figures include those patients sent to further rehabilitation hospitals and those sent directly home with community rehabilitation services. It is believed that potential participants are likely to find the notion of the tai chi classes attractive. Thus, it is also believed that the patient population for this study will be sufficient to recruit the necessary numbers because a scoping exercise on the hyper acute stroke unit at Pinderfields Hospital found that there were five potential participants per month, giving a total of 50 potential participants over ten months (to account for refusals, 50% of potential participants were excluded from the count).

The physiotherapy gym based at the local hospital will be used twice a week for one hour per Tai Chi class. This is located near to the stroke unit. A quiet room based at the hospital will be used to conduct interviews in private. In order for participants to get to these locations, a shuttle bus system is also in place to transport patients to the tai chi classes between Wakefield, Dewsbury and Pontefract. Participants will be encouraged to use this system as it will save participants time, effort and money should they live in a neighbouring town.

4.3 Recruitment



4.4 Eligibility Criteria

4.4.1. Inclusion Criteria

- Are diagnosed with stroke in the early rehabilitation phase.
- First stroke.
- Receiving standard stroke rehabilitation post-discharge from hospital.
- Berg Balance Scale score between 30 and 45. If an individual has a score below 30, the individual would be severely impaired. Above 45, the individual would have no impairment.
- Be able to access the intervention venue.
- Be able to mobilise at least six metres with or without aids.
- Able to give informed consent.
- Willing to adhere to procedures of the study.

4.4.2 Exclusion Criteria

- Cognitive impairment.
- Severe visual impairment.
- Uncontrolled hypertension, angina or diabetes.
- Dementia.
- Already practising Tai Chi, Yoga, dance or any other balance-training exercise. Although stroke survivors practising Tai Chi already will be unlikely, one of the aims of the study is whether or not Tai Chi would be accepted by stroke survivors without prior experience, and whether it can be taught to this population.
- Involved in a fall prevention programme.
- Unmanageable incontinence.
- Already participating in a research study – so as not to contaminate results or over-burden participants.
- Uncontrolled epilepsy.
- Unable to understand English. The questionnaires/outcomes instruments exist in (and are validated in) English, and this PhD project has no funds for translation and cross-cultural adaptation/validation.

4.5 Participant Identification and Recruitment

Approval has been gained from SREP for the study to continue and is being sought from the R&D department at the hospital. MyTherapy and Locala have approved of the contact with the participants and will be kept updated on the progression of the study. As the researcher and registered nurse at the NHS hospital acute stroke unit involved in the recruitment process, potential participants will be identified by myself at my place of work.

Whilst on the stroke unit, potential participants will be given an information sheet about the study. They will be informed about the study by myself and asked if they wish to participate. If they express an interest, informed consent (including informed consent to obtain personal details of themselves and significant others [a contact in case of emergency], as well as medical records for past medical history, type of stroke and blood pressure) will be obtained prior to discharge from hospital. Patients will be screened for eligibility by the researcher whilst still on the hyper-acute stroke ward, which will include taking part in the Berg Balance test. Should participants have a score which falls between 30 and 45, they will be eligible for the study. A score below 30 indicates that individuals are too severely impaired to participate in Tai Chi. A score above 45 indicates that individuals have no impairment. Should participants not be eligible, they will be informed straight away with the reason why. The Berg Balance Scale will be obtained via SystemOne (encrypted intranet hospital system) from the community rehabilitation services, if it is not obtained from the stroke unit.

After the eligibility screening, whilst still on the ward, participants will complete three questionnaires, given to them by the researcher (Falls Efficacy Scale, Geriatric Depression Scale and SF12 Questionnaire) as part of the baseline data. Whilst still on the ward, participants will be randomised into either the Tai Chi intervention group or the control group.

Those potential eligible participants who are discharged to inpatient rehabilitation units will be given an information sheet, and consent will be sought before discharge from the acute stroke unit. The researcher will obtain participants' Berg Balance scores before they are discharged home. These patients will be followed-up after discharge home from the inpatient rehabilitation ward. The physiotherapists on the rehabilitation wards will be consulted regarding their discharge dates.

4.6 Tai Chi Intervention Package

The novel experimental intervention for this feasibility trial comprises a package of group Tai Chi exercise classes along with guided individual practice as a self-management element.

The group exercise will be offered as a 12-week programme comprising one-hour Yang-style Tai Chi classes, twice weekly. These one-hour classes will be administered by a qualified Tai Chi instructor with indemnity insurance, and a gold medallist in *push hands* (a two-person Tai Chi training routine). Recent literature has stated that in order for benefits to be noticed, practising Tai Chi for a minimum of 12 weeks is recommended but it has not yet been established if this is true for stroke survivors (Hart et al., 2004; Au-Yeung et al., 2009; Taylor-Piliae et al., 2012; Li et al., 2008; Choi et al., 2005).

The programme of Tai Chi will be devised specifically for stroke survivors with a Berg Balance scale of 30-45, based on Tai Chi principles. The programme will encompass strength, balance and coordination with the aim of improving functional movement (Hamilton, 2009). During the Tai Chi intervention, participants will start seated and progress to standing. This will also give participants a sense of achievement. Exercises will start with relaxing joints in a flowing manner, calming the mind and relaxing the muscles incorporating the concepts of Tai Chi before participating in selected Tai Chi forms involving repetitive movements involving weight-shifting and trunk rotation exercises that aim to stimulate control.

Each Tai Chi form will be initiated from the hand, followed by the upper body, then the waist, and finally the hips, legs and feet (Lipka, 2014). Each session will start with joint relaxation in a flowing manner to calm the mind and relax the muscles before practising modified Tai Chi forms (National Qigong Association, 2014).

A significant other will be invited to come to the Tai Chi classes. However, they will not be a part of the study and no data will be collected from them. Significant others (who are covered by NHS indemnity at MidYorkshire NHS Hospitals Trust) will play a supporting role, improving adherence and attendance, as well as helping with home practice.

The guided individual practice involves participants performing Tai Chi exercises for at least 15 minutes per day. This individual practice will be expected, and participants will be asked to agree to this part of the package. To aid their self-management, a home-practice booklet and DVD will be developed to guide their practice (and adherence). The home-practice DVD has been designed by myself (having had two years of experience practising Tai Chi) and produced by the Tai Chi instructor. A home-practice information booklet will also be given to participants, which has been designed by myself with input from the Tai Chi instructor. With these materials and what was taught in class, participants will be encouraged to practise at home, recording adherence in a home-practice diary.

In order to encourage adherence to the Tai Chi until the end of the study, tea and coffee will be provided at the end of each Tai Chi session for a chance to allow the participants to socialise and encourage them to return. Peer support will help participants feel part of a group and encourage them to complete the programme and home practice.

On completion of the study, a £10 voucher will be given to all participants in both groups. This will act as a 'thank you' for their participation in the study rather than as coercion. Participants will be advised that they will be eligible for this on completion of the final questionnaire. In addition, those participants randomised into the control group will be given a copy of the Tai Chi home practice DVD and booklet to keep.

5. Data Collection

Data will be collected at baseline, 12 weeks and six months.

5.1 Primary Outcome Measures

1. <u>The Berg Balance Scale</u> (baseline, 12 weeks, six months) – an administered observational test

- The Berg Balance Scale [BBS], developed by Berg, Wood-Dauphine, Williams & Maki (1992), is a detailed grading scale and is designed to detect balance impairment.
- The test is administered by a trained operator. It requires participants to maintain their balance whilst attempting various tasks, e.g. reaching forward, retrieving an item off the floor, sitting to standing, standing to sitting, standing to sitting unsupported, standing with eyes closed. There are 14 items measuring balance, each with a five-point Likert scale.
- The BBS was found to be useful for predicting falls in stroke patients with a BBS score below 45 (Maeda, Kato & Shimada, 2009). The BBS ranges from 0-57 where the higher the score the less the impairment of balance. A score above 45/57 indicates an individual will have a low level of balance impairment, and therefore will not have the capacity for meaningful improvement on the BBS. A score below 30/57 indicates an individual is probably too severely impaired to perform the exercises. Therefore, eligible participants will have a baseline Berg Balance score between 30 and 45. A physiotherapist in the community informed me that this range fits a large enough proportion of the target population to make the intervention worthwhile. The BBS is easy to administer (taking about 20 minutes to complete), needing no specialist equipment. In addition, the interrater and intrarater reliability is strong (Bogle & Newton, 1996; Zwick, Rochelle, Choksi & Domowicz, 2000). Furthermore,

the BBS has the ability to identify community-dwelling people having recurrent or multiple falls compared to those who fell once (Noohu, Dey & Hussain, 2014).
- An added potential advantage for this study is that the tasks are similar to certain Tai Chi movements, thus offering some measure of context validity.

2. Falls Calendar (weekly for six months) – self-completed

- Number of falls recorded on a calendar, giving the reason why.
- Takes two minutes to complete.
- Will be collected monthly at each Tai Chi class. After 12 weeks, the falls calendar will continue monthly up to six months using S.A.Es.
- Falls calendars will be collected monthly by post for the control group. These will be sent by post using S.A.E.s which will include the calendar for the next month.

5.2 Secondary Outcome Measures

Various secondary outcomes will also be explored as Tai Chi may benefit stroke survivors in other ways which may be beneficial to explore in future that is not currently known.

Secondary outcome measures are:

1. The Falls Efficacy Scale (baseline, 12 weeks, six months) – self-completed questionnaire

- A score scale of one to ten with ten items about confidence in daily activities.
- Takes three to five minutes to complete.

2. SF-12 QUESTIONNAIRE (baseline, 12 weeks, six months) – self-completed questionnaire

- A quality of life questionnaire.
- Takes five minutes to complete.
- Participants will be required to answer questions regarding their health status on paper.

3. Geriatric Depression Scale (baseline, 12 weeks, six months) – self-completed questionnaire that will not be offered to participants as a geriatric scale

- Participants will be required to answer questions using yes/no responses relating to how they feel regarding their mood.
- Takes three to five minutes to complete.

4. Blood Pressure (baseline, 12 weeks [before the final Tai Chi session], six months = three readings) – this will be recorded according to The Royal Marsden Hospital Manual of Clinical Nursing Procedures.

5. Home Practice Diary (daily for 12 weeks) – self-completed diary

- Participants will record whether or not they practised Tai Chi for at least 15 minutes or not each day. A space for comments is provided.
- Takes a moment to complete each day.

- Will be collected monthly at the Tai Chi class, then sent to participants by post monthly with a S.A.E with a request to post the previous month's diary. This will maintain monthly communication up to the six-month questionnaires, enabling participants to continue to feel part of the study.

5.3 Other Questionnaires

- Six-Month Follow-Up Questionnaire (six months) – self-completed by post for the Tai Chi group only.

5.4 Interviews

Semi-structured interviews will then be conducted by myself, who has been trained by the University of Huddersfield to talk about participants' experiences of the intervention received, whether the amount of questionnaires given was burdensome, if the quality of questionnaires was reasonable, if they liked the experience and whether they would do it again. Only the Tai Chi group will be interviewed. Six participants in total will be interviewed, and each interview may last up to sixty minutes. Interviews will be ongoing and will be conducted at the point of each interviewee's 12-week period, as opposed to conducting all six interviews at the same time. There are few qualitative studies in this field (Choi et al., 2005) and more research is needed regarding fear of falling (Taylor-Piliae et al., 2014).

The interviews will be a part of the academic requirement to satisfy the examiners that I have learned about, and successfully used a broad range of research methods when answering a scientific question. Incorporating participants' lived experiences and methodological reflexivity into the research process will enhance the credibility of RCT research findings, thus maximising the validity of the RCT project by using mixed methods (Hesse-Biber, 2012). O'Cathain, Thomas, Drabble, Rudolph, and Hewison (2013) agree that researchers can increase the impact of generating evidence of effectiveness of health interventions by undertaking more work at the pre-trial stage. According to Levati et al. (2016), complex interventions at the pre-trial stage should be optimised, giving the participants a voice, in order to show an intervention effect.

The qualitative aspect of the study will address the quality of implementation, barriers to participation, and adoption by intended beneficiaries, because the quantitative aspect will only answer the attribute question without factual analysis. A mixture of both quantitative and qualitative data will determine what will work as well as how to make it work better (White, 2013). Additionally, a mixed methods approach will engage with the variety of questions relevant to the complexity of health care (O'Cathain, Murphy, & Nicholl, 2007).

Interviews will take place in a private room based on the stroke unit at the hospital, and:

- Will gain participant's perspectives on:
  - How they found the Tai Chi classes
  - How they felt beforehand
  - How they felt after participating in Tai Chi
  - How they found the home practice and home practice DVD and booklet
  - If participants were able to do the home practice and understand it
  - How confident they felt practising Tai Chi at home
  - If they did not do the home practice, the interview may find out why not.
- Will have an interview topic guide.

6. Analyses

- Data will be variously analysed by quantitative and qualitative methods (as appropriate) in order to provide relevant information to inform a future trial.
- Interviews will be analysed as participants complete their 12-week period, not altogether at the same time at the end of the study.
- Primary and secondary outcome measures will be scored and data entered into SPSS.
- Statistical support has been sought and is available from a statistician based at the University of Huddersfield.
- Falls diaries will be collected monthly, with telephone calls given to chase non-responders.
- In order to inform sample calculations for any further full-scale trial, population-specific variance parameters in the chosen outcome measures will be obtained (Arain et al., 2010).
- Interviews will be transcribed and analysed thematically. The timeline states that a period of seven months will be given for interviews to be conducted and analysed as each interviewee completes their 12 weeks. This will be whilst the participants are involved in the intervention.
- Electronic data will be stored on the University's k-drive for six years.

7. Ethical Considerations

The study will be conducted as recommended by the Medical Research Council (1998) which states the trial should be in accordance with the Declaration of Helsinki and consistent with Good Clinical Practice (GCP). The rights and safety of participants will be of most importance and will prevail over interests of science and society.

In order to conduct research using NHS patients, I require training in GCP (European Medicines Agency, 2015). As the lead investigator, I have been trained in GCP in order to understand and address ethical, legal and management issues involving NHS patients. The Trust's R&D department have approved the study to go ahead on condition that it has gained ethical approval from IRAS and has gone through the Trust's R&D ethics panel meeting, held once a month.

Ethical approval has also been sought from the University's School Research Ethics Panel (SREP). The local community therapy services, known as 'MyTherapy' (Wakefield and Pontefract) and 'Locala' (Dewsbury) have also given their consent to allow their patients to be involved in the study. Permission is required to use the SF-12 questionnaire and has being sought by myself.

The Nuremberg Code will be adhered to and information sheets will be given to potential participants by myself, highlighting the purpose of the study along with its risks and benefits at three stages – a) to obtain personal details and medical information relevant to the study, and b) to participate in the study, and c) to participate in the interview. Consent forms for each stage will then be signed, if in agreement by the participants.

The participants' comfort will be maintained throughout the study. All participants will be invited to bring a friend, carer or relative with them for supervision throughout the study. Significant others may participate in the Tai Chi class, but no data will be collected from them as part of the study, therefore consent will not be requested. Participants will be given time to think and discuss with family, friends and carers before making an informed decision.

In case of the need for psychological support, a list of support agencies will be given to all participants in both groups.

Participants will be reminded by myself in each Tai Chi session to complete the falls calendar and home practice diary. Should participants fail to turn up to session, one follow-up phone call will be made to ascertain why they didn't show and if they will be participating in future. Participants will not be pestered or pressurised. Information of participants who drop out will be included in the final data. Participants will be reassured the study is voluntary and that non-participation will not affect treatment.

Interviews will be specially structured in order to avoid researcher influence and bias. They will be structured in order to avoid discussion of sensitive topics in order to avoid discomfort participants will not be coerced into a certain view. Questionnaires will only contain information relevant to the study.

Confidentiality and anonymity will be maintained according to the Data Protection Act 1998, and subjects will be given identification codes. Consent forms and information sheets will not have participant identification codes. Consent forms require an identifiable signature. Should an identification code be added, this may make identifying the participant more likely. Information sheets used will be standard given to everybody. Therefore, no identification codes will be used on information sheets. Data will be stored for six years on the University's encrypted K drive, an area on a server. More than one copy will also be backed up on an encrypted USB. Only those requiring access will be authorised to view the data (myself, statistician and supervisors). Data collected on paper will be kept in a site file in a securely locked cupboard in a locked room. This will also have protection from the environment, such as damp, mould, fire, pests, etc). Any identifiable information will be kept separate from the study documents and paper copies will be kept at the Trust. I am going to contact the I.T. department at the hospital to obtain a dot.net account, enabling me to scan the paper documents to become electronic. On completion of the study, the site file will be archived. This will not be a single file, but a filing system containing every relevant piece of information I receive at site relating to my study. Electronic data will be electronically archived.

In order to try to minimise non-adherence, significant others will be invited to attend Tai Chi sessions and a £10 voucher given to each participant on completion of all questionnaires. Travel may be an issue for participants. If participants are unable to travel, an hourly shuttle bus is available at each hospital site which travels to and from the research site. Participants will be able to get to the hospital where they live and take the shuttle bus to the intervention site. Participants will be encouraged to practice Tai Chi at their own pace and will not be pressurised or harassed to do anything.

I am aware of different learning styles and that some participants may be anxious about their ability compared with other participants. Participants will not be pressurised into remembering exercises and will not be pressurised to move forward if not feeling ready. A DVD will be given to each participant to encourage home practice. There will also be the opportunity to socialise at the end of each session, with refreshments provided.

There is little evidence to guide how much therapy should be regarded as a minimum. Rehabilitation intensity is an area which requires urgent further research. The consensus agreed upon by the NICE Quality Standards Development Group was that 45 minutes five times a week is reasonable. This could be individual therapy or group therapy (Royal College of Physicians, 2012). However, on asking the physiotherapists based at a local hospital, this time includes reaching the patient and filling out paperwork, as well as getting back to base. The amount of active treatment is considerably less than 45 minutes in reality. Thus, a Tai Chi programme twice a week for 12 weeks will not be a burden on participants.

In addition, this suggests that the dose and effectiveness of rehabilitation may not be sufficient. Tai Chi is a pleasant and enjoyable activity with many potential benefits.

In order to comply with the needs and wishes of stroke survivors, I have spoken to members of the Stroke Association and have asked for their preferences and opinions about the study design. These comments have been taken into consideration for the study design, such as the involvement of significant others and the social time at the end of each session. Further discussion with these group members will take place throughout the study.

8. Health and Safety

After liaising with the stroke consultant on the stroke unit at a MidYorkshire hospital, there are no contra-indications as to why a stroke survivor is unable to practice Tai Chi. If anything, gentle exercise is encouraged.

Room temperature will be maintained at around 21 degrees for comfort and safety. During classes, there will be a 2:12 ratio of supervisors (Tai Chi instructor and researcher) versus participants. There will be no more than 12 participants per 2 supervisors in one class, but there may be less than 12 participants in some classes. There are no known ill-effects on health from Tai Chi exercising. Tai Chi will introduce a change of lifestyle for participants but this may be beneficial, which is why the study is being proposed.

The Helsinki Declaration will be adhered to in order to minimise risk and harm to participants. Therefore, risk assessments for safety will be carried out via the inclusion and exclusion criteria by myself (Resnik, 2011). Participants' GPs will be informed that their patients are involved in the study with the participants' consent. The crash call button in the hospital gym will be pressed in case of an emergency, as well as emergency contact numbers dialled. Chairs will placed next to the participants during tai chi in case they feel tired or want to sit down. I am a registered nurse working on the stroke unit, from which I hope to recruit, and will be able to identify any medical complications should they arise. I am trained in using the automated defibrillator available in the physiotherapy gym and able to perform basic life support. The Tai Chi instructor will be given a stroke information pack and be briefed as to what to do in case of emergency such as being aware of the call button and emergency phone number. Participants will be allowed to use their walking aids and will be monitored by two people (myself and the instructor) to avoid loss of balance or falling. There will be no more than 20 participants per session.

Because I will be including NHS patients, it is important that I record any safety incidents in order to ensure that any benefits of Tai Chi outweigh any risks. At every Tai Chi session and assessment, participants will be asked about their health and wellbeing, as well as any changes in medication which may increase their risk of falling. Any incidents will be reported in a timely manner and accurately according to the GCP protocol. This includes Adverse Events (AEs), Serious Adverse Events (SAEs), Adverse Reactions (ARs), Serious Adverse Reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs). These will be kept in the site file.

Should many participants want to do the interview at the same time, they will be invited to either wait in the hospital café or day room on the stroke ward. Interviews will take place in the interview room on the stroke ward, or the day room, physiotherapy room or occupational therapy room, depending on time of day. If times of the sessions change, participants will be given sufficient notice.

9. Resources

- One Tai Chi instructor to conduct the tai chi programme (paid for by the sponsor/researcher).
- Room to accommodate the Tai Chi programme (the hospital physiotherapy gym at Pinderfields General Hospital). One researcher to carry out and manage the study (myself).
- Room to accommodate interviews (quiet room on the hospital's stroke unit).
- One statistician (as quantitative data will be used such as standard deviations), available at the university.
- SPSS in order to input and analyse the quantitative data (available at the university).
- Measurement tools in order to measure outcomes (free and available).
- Indemnity insurance for the execution of the Tai Chi programme (acquired by the Tai Chi instructor).
- A DVD for participants to refer to for consolidation and home practice (produced by the Tai Chi instructor and paid for by the sponsor).
- Tea, coffee and biscuits at the end of each class (provided and paid for by the sponsor).
- Stamped self-addressed envelopes.
- All participants will receive a stroke information pack whilst on the ward as part of their care.

10. Timeline (see attached)

11. Dissemination

Participants will be informed of how the data will be used and will be offered a lay summary of the study results via post or email. Feedback on the progress of the study will be given to all those involved at regular intervals, including the community rehabilitation services and the Trust. Results will be disseminated via presentations, conferences, bulletins, Trust team briefings and management reports. Final results will be released to the general public via an appropriate journal to be peer reviewed and published.

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Appendix 23 Ethical approval from the School Research Ethics Panel [SREP]

University of
HUDDERSFIELD
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2013
THE AWARDS
AWARD WINNER
UNIVERSITY OF THE YEAR

6 October 2015

TO WHOM IT MAY CONCERN

Name: **Ms Elizabeth Harkin - University of Huddersfield**
Research Project Title: **"Exploring tai chi as an intervention with stroke survivors to reduce falls: is it feasible?"**
Reference: **SREP/2015/64**

Ms Elizabeth Harkin, the holder of this letter, is a PhD Student at the University of Huddersfield, where she is currently pursuing a doctorate on the above topic within the Centre for Applied Psychological and Health Research.

Ms Harkin's research has been through the School Research Ethics Panel (SREP) and her project was approved on 4 September 2015.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

If you require any further information in relation to this letter, please to not hesitate to contact me.

Yours faithfully

Prof Rachel Armitage
Chair, School Research Ethics Panel (SREP)
School of Human and Health Sciences
Direct Tel: +44 (0)1484 473854
Email: R.A.Armitage@hud.ac.uk

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Tai chi for stroke survivors version 2.0

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes and you have selected HRA Approval in question 4 above, your study will be processed through HRA Approval.

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (•) No

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before submitting other applications. If you have selected HRA Approval in question 4 above your study will be processed through HRA Approval. If not, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
I am a PhD student who is also a registered nurse on the stroke unit. I will be conducting the research.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Other clinical trial or investigation

NHS
Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Tai chi for stroke survivors version 2.0

Please complete these details after you have booked the REC application for review.

REC Name:
Yorkshire and the Humber - Leeds West

REC Reference Number:
16/YH/0130

Submission date:
08/03/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors - a feasibility study.

A2-1. Educational projects

Name and contact details of student(s):

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	DR	KIARA	LEWIS
Address	The University of Huddersfield		
	Queensgate		
	Huddersfield		
Post Code	HD1 3DH		
E-mail	kiara.lewis@hud.ac.uk		

Telephone	01484473218
Fax	

Academic supervisor 2

	Title	Forename/Initials	Surname
	Professor	Kim	Burton
Address	The University of Huddersfield		
	Queensgate		
	Huddersfield		
Post Code	HD1 3DH		
E-mail	a.k.burton2@hud.ac.uk		
Telephone	01484472460		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	**Academic supervisor(s)**

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Ms	Elizabeth	Harkin
Post	Registered Nurse		
Qualifications	BSc (Hons) Nursing Studies FIRST 2013 DipHE Nursing Studies (Adult) PASS 2008 PGCE (secondary) PASS 1996 BA (Hons) 2:ii 1995		
Employer	MidYorkshire Hospitals NHS Trust		
Work Address	Pinderfields Hospital		
	Aberford Road		
	Wakefield		
Post Code	WF1 4DG		
Work E-mail	elizabeth.harkin2@midyorks.nhs.uk		
* Personal E-mail	elizabethharkin123@btinternet.com		
Work Telephone	01924542005		
* Personal Telephone/Mobile	07860544546		
Fax	01924542001		

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Professor	Rachel	Armitage
Address	University of Huddersfield		
	Queensgate		
	Huddersfield		
Post Code	HD1 3DH		
E-mail	r.a.armitage@hud.ac.uk		
Telephone	01484473854		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	
Protocol Version:	3.0
Protocol Date:	23/02/2016
Funder's reference number:	
Project website:	

Registry reference number(s):
The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

There has been a considerable increase in stroke survivors being re-admitted to hospital as a result of falls, placing a substantial economic burden on the NHS (National Institute for Health and Care Excellence [NICE], 2013). People with stroke require rehabilitation to improve their functional mobility and are often referred to community therapy services. However, this rehabilitation stops once it is felt that the patient has reached their full potential. This is usually within the first six months, which is the period during which the patient is most at risk of falling. This suggests that falls prevention programmes for stroke survivors should be implemented at an early stage.

Physiotherapy for stroke survivors has been recommended by NICE for at least 45 minutes, five times a week. However, this includes travel and paperwork, leaving little time for rehabilitation. Self-practice at home could be an effective supplement to achieve this recommendation. Effective exercise programmes in the community are lacking (Department of Health, 2008).

According to the Department of Health (2010), exercise is required in order to prevent a first fall, and that this exercise could be tai chi.

It is unknown if tai chi would be acceptable amongst stroke survivors in the UK. Therefore, I propose a feasibility study of a programme of tai chi supplemented with home-practice for stroke survivors in the early rehabilitation phase. The intention is to collect the information necessary for a future randomised clinical trial. The study will evaluate such things as recruitment rates, data on outcome measures, acceptance, compliance and adherence. In addition, participants' experiences of the exercise will be assessed.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Issue 1: The researcher is not trained to carry out research on NHS patients.
Addressed by: I have attended a mandatory study day in Good Clinical Practice (GCP) in order to understand and address ethical, legal and management issues with research involving NHS patients. I am also a qualified registered nurse working on the stroke unit from which I recruit.

Issue 2: I will require approval to approach NHS patients whilst in hospital as well as involving them in research as NHS patients in the community.
Addressed by: Ethical approval has been sought from the university's School Research Ethics Panel [SREP] and approval from the MidYorkshire NHS Hospitals Trust is being sought via the R&D department. Consent has been given for me to use the NHS patients in my study by the community rehabilitation therapy services, MYTherapy and Locala. See attached emails.

Issue 3: Permission to use the measurement tools.
Addressed by: Permission to use the SF-12 questionnaire has been sought. Other tools have been investigated regarding permissions and they are free to use.

Issue 4: Reliability of the measurement tools.
Addressed by: Inter-rater reliability has been established between the researcher and a physiotherapist for the measurement tools.

Issue 5: Participants need to know the purpose, risks and benefits of the study before giving consent.
Addressed by:Information sheets will be provided regarding contact details, participating in the study, interviews and 6-month follow-up. An easy-to-read version will be made available if required. Participants will be given time to read and think before making decisions with no pressure and coercion from myself.

Issue 6: Ensuring the comfort of the patients in making an informed decision
Addressed by: Participants will be given time to read, think and discuss with family, friends and carers after being given patient information sheets about each aspect of the research – personal details and medical information, the study, and interview. Participants will be reassured that participation is voluntary and non-participation will not affect treatment. Questionnaires will only contain information relevant to the study. Interviews will be semi-structured

according to an interview topic guide. Conversation will only run according to these topics.

Issue 7: Tai chi instructor. He will require giving up some of his time and would therefore require payment. He should also be fully qualified.
Addressed by: The tai chi instructor is fully qualified with indemnity insurance. The rate at which the tai chi instructor will work at is reasonable. This is a feasibility study in order to work out the future cost.

Issue 8: Class size safety.
Addressed by: A ratio of 2:12 [assistants:participants] will be adhered to for safety.

Issue 9: Participants may feel harassed to complete the study.
Addressed by: If a participant fails to turn to a tai chi session, one follow-up call will be made to ascertain the reason and if the participant will continue to participate. They will not be pressurised beforehand to turn up to the tai chi. Participants will be gently reminded at each session to complete their falls calendar and home practice diaries.

Issue 10: Harm to participants throughout the study.
Addressed by: Risk assessments for safety have been carried out via the exclusion and inclusion criteria for study eligibility. Chairs will be placed next to the participants during tai chi in case they feel tired or want to sit down. I am a registered nurse working on the stroke ward and will be able to look out for any medical complications should they arise as I will be present in the tai chi sessions. I am competent in CPR and a defibrillator will be on site. An emergency call button as well as phone number are also available to alert the medical team. The tai chi instructor will be given a stroke information pack by myself from the stroke unit and be briefed as to what to do in case of emergency, such as be aware of the call button and phone number. Walking aids will be allowed during the tai chi. The ratio of instructors to participants will be 2:20. The stroke ward is also situated next door to the gym where the tai chi will be taking place. The Helsinki Declaration will be adhered to in order to minimise risk. Breathing will also be encouraged throughout the tai chi.

Issue 11: Confidentiality and anonymity.
Addressed by: Participants will be kept anonymous using identity codes. Electronic data will be stored on encrypted computers with passwords and paper data being stored in a locked cupboard in a locked room on the research site. Only those needing to know will be given access to data (myself and my supervisors). Data will be treated in compliance with the Data Protection Act. Naturally, participants will be required to sign on the consent forms, so in order to reduce the risk of personal identification from trial data forms (questionnaires), the consent forms will not include an identity code. Information sheets, being generic, do not require an identification code.

Issue 12: Approachability of the researcher.
Addressed by: I will maintain a friendly and approachable manner at all times, allowing for questions. My contact details will be given to participants to contact me.

Issue 13: Non-adherence to the study.
Addressed by: Participants will be not hassled to turn up to each session. A follow-up phone call will be made if they fail to turn up to a tai chi session or fail to produce a falls calendar or home practise diary each week to ascertain why this was. Significant others may participate in the tai chi class but no data will be collected from them as part of the study, therefore consent will not be requested for significant others. Participants will be invited to bring significant others to encourage them during the tai chi sessions and home practice. Shuttle buses are available between Pinderfields and Dewsbury hospitals free of charge to enable participants to reach the study location. A £10 voucher will also be offered to those completing the study. Participants will be encouraged to go at their own pace during the tai chi. If participants drop out, an intention-to-treat analysis will be performed and the participants will remain in the study.

Issue 14: The tai chi instructor may not understand their role in the study.
Addressed by: The programme of tai chi will be discussed with the instructor explaining the necessity of each component relating to the study outcomes. A tai chi instructor guide will be given to the instructor in order to help him focus on the study's objectives.

Issue 15: Participants may feel anxious taking part in tai chi.
Addressed by: Participants will be told the purpose of the tai chi and will be encouraged to practice at their own pace. Significant others will encourage them, and a DVD will be given containing the tai chi sequences to help them practice at home.

Issue 16: The study is not designed in accordance with stroke survivors' approval.
Addressed by: Discussion has taken place with members of the Stroke Association who have expressed their opinions and preferences following a talk about the study design. Their opinions and thoughts have been taken into account with the design of the study.

Issue 17: The physiotherapy gym may not be available at the same time each week. Should this be the case, participants will be informed in advance of the new time.

Issue 18: There may be a few people waiting for interviews. If this is the case, they will be asked if it is convenient to wait. If so, they will be invited to wait in the hospital café or stroke unit day room where there is a TV. If not, another time will be arranged, convenient for the participant.

Issue 19: It may be that there is no room available to conduct interviews. The interview room and day room are available on the stroke unit. In addition, if the interviews are after 16.00 hours, the physiotherapy or occupational therapy rooms may be used.

Issue 20: Patients are not fully informed about the study.
The patient information sheet will include:
• the study's purpose.
• potential risks.
• benefits.
• how participants were selected.
• Patient Advice and Liaison Service [PALS] contact details.
• the option to withdraw at any time without a reason, and that it will not interfere with their therapy. They will be informed that they can request for data to be removed from the study. A link will therefore be retained from any code used, tracing it back to the individual. This link will be kept confidential, and separate from the data.
• what will happen to the participants should they agree to take part.
• anonymity and confidentiality – the trust, location and participant identity will be anonymised. Confidentiality will be maintained for personal details of participants as well as keeping their identities anonymous by storing data on an encrypted computer and filing paper record in a locked cupboard.
• participants will be informed that they will not be identified in the final report and their opinions would remain confidential. They will be given the opportunity to ask questions. A contact name and number for any questions about the study or use of information will be given to participants. All questionnaires will be kept anonymous.
• how data will be used, stored and for how long.

Issue 21: Psychological support for participants.
A list of support agencies will be given to participants at the start of the study in case they wish to seek support regarding their stroke condition or the study.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- [ ] Case series/ case note review
- [ ] Case control
- [ ] Cohort observation
- [ ] Controlled trial without randomisation
- [ ] Cross-sectional study
- [ ] Database analysis
- [ ] Epidemiology
- [x] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [ ] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The overall aim of the proposed research is to conduct a feasibility study to inform a future randomised controlled trial. In order to design a main study, parameters will include the ability to identify the number of eligible participants in a typical NHS setting; the willingness of participants to take part; the ability to recruit suitable participants; to estimate the length of time required to do this; to calculate the power for a larger randomised controlled trial; to assess the suitability of the outcome measures; to assess adherence of participants of tai chi classes and the home practice; and to estimate follow-up rates, compliance, adherence rates and response rates to questionnaires.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

The objective of this proposed study is to obtain data through the implementation of tai chi classes for stroke survivors receiving early rehabilitation to assess the feasibility and refine procedures for a future (larger) randomised controlled trial. This includes assessing whether or not tai chi would be acceptable amongst stroke survivors who have no experience of the exercise, and if it can be taught in this population.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Falling amongst older people has become of considerable public health importance and is consequently a high priority for health and healthcare costs (DH, 2001; NICE, 2013). Systematic reviews (Harling & Simpson, 2008; Schleicher, Wedam & Wu, 2012; Wooton, 2010; Wu, 2002), state that tai chi in the general population may be one of the better exercises to prevent falls in the general older population.

One subpopulation within older people is stroke survivors. However, participants with specific diseases, such as stroke, were excluded as part of the eligibility criteria in the above systematic reviews. Therefore the results may or may not apply to stroke survivors. According to a randomised controlled trial by Au-Yeung, Hui-Chan & Tang (2009), balance deficits have been observed in a population more than six months post stroke, with impaired standing balance being a risk factor for falls. However, people in Hong Kong are already adapted to tai chi, and tai chi is already practised amongst a lot of older people. The acceptability and adherence rates cannot be generalised to a UK population where tai chi is not already a part of the country's heritage and way of life. In a study by Jönsson, Lindgren, Hallström, Norving & Lindgren (2005), stroke survivors perceived their physical function to have deteriorated 4 months post-stroke, suggesting that tai chi should be introduced in an early phase of stroke.

The DH (2007) recognises that stroke survivors experience a high likelihood of falls within the first 6 months. This suggest that stroke survivors are at high risk of falls between discharge from hospital and the recommended routine six-month follow up. One randomised controlled trial (RCT)about tai chi has been conducted involving stroke survivors and falls rates (Taylor-Piliae et al., 2014). This study showed that fall rates are an important indicator of balance control amongst US stroke survivors in the community because the study showed fewer falls with the tai chi intervention group. However, this RCT was conducted in Arizona, USA amongst stroke survivors more than three months post stroke. Therefore, the target population is different to that in the proposed study. There are no studies of tai chi involving the target population in the proposed study, which is UK-based and have been recently discharged from hospital, eligible for community rehabilitation.

The tai chi proposed is not meant as a replacement but a supplement to the community rehabilitation received. According to local hospital-based physiotherapists (who rotate from community to hospital), of their individual needs. Not all stroke survivors requiring community rehabilitation stroke rehabilitation in the community usually lasts for approximately three weeks following discharge from hospital. This period of time also differs from patient to patient, depending on the nature will have exactly the same impairment. Therefore, programmes of rehabilitation are tailored for individual need, meaning that patients will not be receiving the same rehabilitation exercise programme. There are different home-based practice exercise sheets which are given to patients to practice when they are alone. However, according to members of the local Stroke Association group, they do not do this very often. One of the reasons stated was the inability to understand the sheet. Therefore, patients receiving community rehabilitation in this group may not be receiving the optimum amount of physiotherapy as recommended by NICE.

NICE advises that stroke survivors needing community rehabilitation receive physiotherapy at least five times a week for 45 minutes. One reason why this recommendation by NICE is not being met is because the 45 minutes includes the physiotherapists' travelling time and administration of paperwork, according to local physiotherapists. Therefore, tai chi would act as a supplement to usual physiotherapy received, if given in this early stage of rehabilitation. Moreover, following discharge from the community rehabilitation team, stroke survivors may continue to benefit from tai chi. Once physiotherapists discharge stroke patients from community rehabilitation, they are not seen by physiotherapists again. Continuing with the tai chi classes would also abolish the sense of abandonment felt by stroke survivors, as expressed at the local Stroke Association.

Previous studies have followed stroke survivors for six months and have found that stroke survivors are at high risk of falling within the first six months after being diagnosed with a stroke (Forster & Young, 1995). This time period would start from diagnosis and end at six months, meaning that stroke survivors are also at high risk of falls during the early rehabilitation stage (Teasell, McRae, Foley & Bhardwaj, 2002). According to Weerdesteyn, de Niet, van Duijnhoven & Geurts, 2008), stroke survivors are at high risk of falls at all stages post-stroke.

A randomised controlled trial by Taylor-Piliae, Boros & Coull (2014) involving stroke survivors has highlighted that regular physical activity improves physical function, reducing falls and increasing quality of life. Mobility and movement are considered to be important parts of stroke rehabilitation. The DH (2009) has also indicated that tai chi has been promoted as a falls preventative exercise. However, little research has been undertaken to evaluate interventions aimed at reducing falls in stroke survivors in the UK, and more research is needed (Royal College of Physicians, 2012).

Tai chi is a low impact, low-speed exercise routine (Lan, Lai, & Chen, 2002) and has been shown to enhance physiological and psychological function, including balance in the general elderly population (Jahnke, Larkey, Rogers & Etnier, 2009). It might reasonably be expected that this type of exercise could stimulate balance control and coordination. Indeed, according to a pilot study, it has been shown to increase control of voluntary weight-shifting and improve balance and decrease falls risk in stroke survivors (Taylor-Piliae & Coull, 2011). This pilot study developed into a randomised controlled trial using the same population. However, this study population is different to the target population proposed in this study because participants were not recently discharged from hospital but were at least three months post-stroke. Additionally, the setting was in Tucson, Arizona where the weather is warmer which may make participants more motivated to leave their home. Moreover, participants in this study were not offered home practice (Taylor-Piliae, Hoke, Hepworth, Latt, Najafi & Coull, 2014).

The DH (2009) has indicated that tai chi is beneficial and could prevent a first fall in the general population (Wolf, et al., 1996). NICE (2015) advises that stroke survivors should be encouraged to participate in physical activity such as building strength through increasing repetitions of body weight activities, which is characteristic of tai chi. Au-Yeung et al. (2009) have noticed improvements in stroke survivors practising tai chi as early as six weeks with the arthritis tai chi programme, and this programme was shown to reduce the number of falls. This study, focusing on the Hong Kong population more than six months post-stroke, was a relatively late intervention and involved a tai chi programme designated as being for arthritis rather than being tailored for stroke survivors. Thus the findings cannot be generalised to UK stroke survivors receiving an early tai chi programme of classes and home exercise.

A fall increases the likelihood of developing a fear of falling (Evitt & Quigley, 2004). The DH (2009) states that regular exercise can reduce fear of falling and fall risk in older people in the general population. NICE (2015) suggests that fear of falling affects older people's compliance with exercise, and recommend fall prevention programmes to address barriers such as fear of falling. According to Zijlstra et al., (2007), home-based practice of tai chi reduces fear of falling in older people. Therefore, home-based practice may be beneficial as part of the tai chi programme. Moreover,fear of falling in stroke survivors has been identified as a risk factor for falls, leading to a lack of confidence and increased falls risk (Royal College of Physicians, 2012). However, it is not known if home practice of tai chi would benefit this population regarding falls prevention due to lack of evidence.

As well as fear of falling, another reason why stroke survivors might not engage in physical activity is high blood pressure. High blood pressure is a major cause of stroke and reducing blood pressure may prevent a further stroke (Phillips, 1994; Rashid, Leonardi-Bee & Bath, 2003). The risk of stroke recurrence is highest after the first stroke and remains elevated for several years (Burn et al.,1993). Lai, Alter, Friday & Sobel (1994) found that hypertension was associated with a higher risk of stroke recurrence. They suggest that control of hypertension would bring the greatest chance of reducing risk of stroke recurrence after an ischaemic stroke.

Tai chi has been shown to reduce blood pressure in outpatients with hypertension (Lo, Yeh, Chang, Sung & Smith, 2012; Thornton, Sykes & Tang, 2004). Lo et al. (2012) suggested tai chi as an exercise programme for patients with hypertension in older people. There are currently known tai chi programmes administered by qualified physiotherapists within the local NHS hospitals for patients with cardiac problems. Tai chi could thus provide an additional benefit for stroke survivors.

Another barrier to physical activity for stroke survivors is depression. Following a stroke, it is common for a person to develop depression due to reduced ability and social isolation, as well because of the part of the brain affected (National Institute of Mental Health [NIMH], 2015). One third of stroke patients develop post-stroke depression, which has a debilitating impact on participation in rehabilitation (Matsuzaki, Hashimoto, Yuki, Koyama & Hirata (2015).

Stroke patients who developed major depression prior to discharge from hospital were found to remain depressed after 12 weeks (Narushima & Robinson, 2002). Thus, it is possible that post-stroke depression can form an obstacle to early rehabilitation. Narushima and Robinson (2002) suggest that social interventions may help prevent or attenuate depression. Li et al., (2014) showed that long-term tai chi practice in the general population is independently related to a lower prevalence of depressive symptoms. Therefore, another potential benefit of tai chi is mood elevation (Lo, Yeh, Chang, Sung & Smith, 2012). The Arizona study conducted by Taylor-Piliae et al (2014) showed improvements in perceived mental health. It is not known if these results would be generalizable to the UK population as Vitamin D from the sun may have played a part in mood elevation. There is not enough research about the effects of tai chi on depression amongst stroke survivors to confirm the results from the Arizona study.

Due to the diversity of tai chi styles and the unknown acceptance of tai chi in the UK, it is necessary to assess the safety and feasibility of tai chi. The safety and feasibility of tai chi has only been established in one pilot study among stroke survivors amongst an Arizona-based population more than three months post stroke (Taylor-Piliae & Coull, 2012). Hart et al. (2004), however, tested for adverse effects in stroke survivors practising tai chi and showed that there were none. The paper was short with insufficient detail about the intervention. The population involved in this study was based in Israel, 27 months post-stroke. Therefore, it is not sufficient to rely on this result alone. Hart et al. (2004) recommended further research on the feasibility of tai chi with stroke survivors.

Other studies focussing on tai chi and its effect on balance and falls prevention were undertaken using populations without chronic illness, excluding stroke survivors, making it difficult to generalise the results to stroke survivors. More research was encouraged with more frail populations, such as those with stroke (Harling & Simpson, 2008; Li et al., 2008; Lin, Hwang, Wang, Chang & Wolf, 2006; Low, Ang, Goh & Chew, 2009; Nnodim et al., 2006; Tsang & Hui-Chan, 2006; Voukelatos et al., 2007; Wolf et al., 2003; Wooton, 2010). Therefore, research involving tai chi and its effect on balance and falls prevention in stroke survivors is needed.

No previous studies have used tai chi as an intervention in the early stages of stroke rehabilitation. Therefore, it is unknown whether stroke survivors in the UK would accept and adhere to this type of exercise. Therefore more research is needed.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

A RCT was considered but deemed inappropriate at this stage due to a shortage of evidence knowledge surrounding tai chi as an intervention at early discharge in the UK health system.

The principles and values of feasibility studies have been outlined in several papers. According to Bowen et al (2009) and Arain et al (2010), a feasibility study is conducted in order to help investigators prepare for formal testing of an intervention. It is necessary to conduct a feasibility study when the answer to a research question is not known in a new population in a new setting with new health outcomes (Bowen et al, 2009), and when there is a need to determine whether an intervention is appropriate for further testing. In essence, feasibility studies can identify potential problems to the successful conduct of a RCT, and determine any aspects of the research methods and protocols in need of modification, as well as how changes (in this study, balance and falls rates and quality of life) may occur.

A feasibility study is helpful when previous studies have shown positive outcomes but in a different setting and population than the one of interest. For instance, prior research covering tai chi did not take account of the UK's socio-cultural health beliefs, nor did studies involve stroke survivors who were recently discharged from hospital. Feasibility studies focus on estimating parameters for a full-scale study. The question is will the study work? This matters to the stakeholders of a full-scale RCT. Small-scale experiments can be used in feasibility studies to test the safety of the intervention (tai chi), and the optimal intervention intensity, frequency and duration acceptable to participants (as we cannot test the intensity, frequency and duration required for an intervention effect) before launching a full-scale trial requiring substantial funding. Although the present study is not testing to see how effective tai chi is for preventing falls, it is considered that positive trends in outcomes can suggest that an intervention is ready to be tested in a full-scale trial whose results will influence health practice (Bowen et al, 2009).

The proposed study is not intended as a RCT, rather the intention, as titled, is to conduct a feasibility study to collect material to inform a future RCT. There are several factors that should be explored before a RCT can be proposed. It is not known whether tai chi will be accepted by stroke survivors at a point shortly after being discharged from hospital, or whether participants would adhere to a programme of tai chi-exercise classes and home practice. Further, no previous studies have used tai chi as an early intervention as a part of rehabilitation, and nor has there been any investigation of home practice.

Additionally, the potential recruitment rate (to guide the timeframe of a RCT) is not known, as well as data on outcome measures (needed to calculate sample sizes). In order to estimate the sample size for a full-scale trial, it is necessary to obtain standard deviations of the outcome measures. For this reason, it is necessary to include the Berg Balance Scale and questionnaires, despite the feasibility study not looking at outcomes and results. Without knowing the estimated sample size, a RCT cannot be done properly (Arain et al, 2010). Also, there are no current data on compliance with follow-up and ability of this group of participants to complete the relevant questionnaires. A feasibility study will be able to investigate these factors prior to testing the intervention in a properly developed RCT. Additionally, I have been advised that a RCT is infeasible without substantial funding, and that funding will not be secured in the absence of a feasibility study.

While participants can be randomised to comparison groups in feasibility studies, it is not necessary since feasibility studies do not evaluate the outcome of interest (Arain et al, 2010). Because randomisation would introduce an additional level of complexity that could threaten the conduct of a feasibility study within the context of my PhD study, I have opted not to randomise participants. Observational cohorts within feasibility studies are not assigned randomly to treatment. Additionally, by having an observational cohort a practice-derived treatment hypothesis may be refined by conducting a feasibility study (Bowen et al, 2009).

Following hospital admission for a diagnosis of stroke, potential participants will be recruited if they are being discharged home with community rehabilitation, known locally as MyTherapy and Locala. Potential participants will be offered a place on the 12-week tai chi exercise programme that intends to improve their balance to reduce the likelihood of falling. Participants will be followed for six months. In addition a similar number of stroke survivors will be identified and offered to act as an observational cohort. Progress will be recorded through questionnaires (quantitative) and interviews (qualitative) in order to collect suitable data to inform a randomised controlled trial.

Whilst on the stroke unit, eligible potential participants will be informed about the study and asked if they wish to participate in the tai chi group. If they express an interest, an information sheet about the study/interview/personal details will be given and participants will be given one to two days to discuss this with significant others. This duration will be given because patients at the rehabilitation stage could be discharged at any time and the recruitment opportunity would be lost. Should they agree, consent will be obtained to obtain personal details of themselves and significant others (a contact in case of emergency) as well as medical records (past medical history, type of stroke and blood pressure). Participants will also be consenting to the study.

The balance of potential participants will be tested after they have been discharged from hospital as a final check that they are suitable for the study. Only people who have difficulties with their balance will be invited to join the study. This is because people without balance difficulties have no need for the exercise programme.
Following discharge, a visit to the hospital will be arranged in order to carry out baseline assessments. If participants at this stage do not wish to participate in the tai chi group, they will be offered the chance to take part in the observational cohort. The same inclusion and exclusion criteria will be used for both the intervention group and observational cohort. If potential participants are not eligible for the study via this criteria, they will be excluded from the study.

Those potential participants who are discharged to rehabilitation units will be given an information sheet about the study/interview/personal details and consent will be sought before discharge from hospital. A visit to the hospital will be arranged at a convenient time to perform baseline assessments.

Participants will be notified of the time and venue of the tai chi intervention when they are giving consent at the hospital. However, should the tai chi group be to full capacity, potential participants will be offered to be in the observational cohort only with an explanation that the tai chi group is full. As soon as participants end their 12 week intervention period, whether it be tai chi or usual care, more participants will be recruited in the same way as above in order to maintain the groups at full capacity.

Participants will also be invited to take part in an interview regarding their perceptions of the study. The interviews will only be one hour long and will not be in-depth. From these interviews, participants will express their opinions about the study design and their participation in order to make reasonable adjustments for a full-scale trial. Interviews will not need to be transcribed word for word and will take approximately six hours to transcribe. Up to ten participants will be interviewed, but this number may be reduced if the saturation is reached with a general consensus.

A 12-week programme comprising one-hour Yang-style tai chi classes, twice weekly, will be offered. These one-hour classes will be administered by a qualified tai chi instructor. The programme of tai chi will be devised specifically for stroke survivors with a Berg Balance scale of 30-45, and will be taken at baseline by the community therapy services, as well as by myself at 12 weeks and six months. The Berg Balance Score measures balance impairment. The above-mentioned range detects people with significantly impaired balance but are likely to be able to do the tai chi classes. The programme will encompass strength, balance and coordination with the aim of improving functional movement (Hamilton, 2009).

The inclusion criteria of this study states that potential participants should have a Berg Balance score between 30-45. Should the score fall below 30, the person will not be eligible for either the intervention group or the observational cohort. Below a score of 30 would mean the individual would not be able to stand and would, therefore, not be able to do tai chi. Above a score of 45 would mean that the individual is not impaired.

Each tai chi form will be initiated from the hand, followed by the upper body, then the waist, and finally the hips, legs and feet (Lipka, 2014). Each session will start with joint relaxation in a flowing manner to calm the mind and relax the muscles before practising modified tai chi forms (National Qigong Association, 2014).

In addition, participants will be given access to a DVD designed by myself (having had two years of experience practising tai chi) and the tai chi instructor. A home-practice information booklet will also be given to participants designed by myself. With these materials and what was taught in class, participants will be encouraged to practise at home, recording adherence in a diary. It is not certain how well participants will adhere to home practice and this study will explore this (Au-Yeung et al., 2009; Kessenich, 1998; Li et al., 2008).

Potential participants will be briefed in the information sheet and verbally that they may, if they wish, bring along a significant other. This may improve adherence and attendance. The significant other may also support the potential participant with home practice. Significant others may participate in the tai chi class but no data will be collected from them as part of the study, therefore consent will not be requested.

In order to encourage adherence to the tai chi until the end of the study, tea and coffee will be provided at the end of each tai chi session for a chance to allow the participants to socialise and encourage them to return. Peer support will help participants feel part of a group and encourage them to complete the programme and home practice.

Participants in the tai chi intervention will be given the falls calendar and home practice diary monthly and in turn they will hand them in to myself the previous month's diary and calendar. The observational cohort will be sent a diary and calendar monthly via S.A.E..

On completion of the 12 weeks, participants from the tai chi intervention group and the observational cohort will be given the questionnaires and the Berg Balance test will be administered, and blood pressure taken. Interviews will also be conducted at 12 weeks. Participants will be followed up six months after starting the study. Participants from the tai chi intervention group and the observational cohort will be sent the falls calendar and home practice diary monthly by S.A.E. They will be asked to return it in a S.A.E sent with that month's diaries/calendars. Non-returners will receive one telephone call per month to prompt them to return the diaries/calendars.

At six months, participants in the tai chi intervention group and the observational cohort will be given the questionnaires given previously. The Berg Balance test will be administered, and blood pressure taken.

On completion of the study, a £10 voucher will be given to all participants in both groups. This will act as a 'thank you' for their participation in the study rather than as a coercion. Participants will be advised that they will be eligible for this on completion of the final questionnaire.

In order to achieve sufficient data to inform sample size calculations for any subsequent full-scale trial, a minimum of 20 complete data sets is required to provide data to inform a future trial. In order to balance both groups, 20 complete data sets are required per group, giving a total of 40 participants. However, to allow for a 50% dropout rate, 30 participants per group need to be recruited. Experience suggests it will be more like a one-third drop-out rate. Therefore, the aim will be to recruit 27 per group, 54 participants in total.

Data from questionnaires, the Berg Balance Scale and blood pressure will be collected at baseline. Falls calendars and home practice diaries will be filled in by participants and collected monthly at the tai chi class or by post. At 12 weeks data will be collected through the questionnaires, blood pressure and Berg Balance Score. At this stage participants may also take part in interviews to give their perceptions of the study. All participants will be followed up with the same questionnaires, Berg Balance Scale and blood pressure. In addition, a six-month follow-up questionnaire will also be given. Participants will carry out the Berg Balance, interviews, blood pressure and questionnaires at the hospital. Quantitative data will be analysed using SPSS. A statistician (Dr John Stephenson from the University of Huddersfield) will be consulted to produce manageable quantitative questionnaires. Interviews will be transcribed (not word for word) and thematically analysed until saturation has been reached. Each interview will be an hour long and will take approximately six hours to transcribe.

Approval has been gained from SREP for the study to continue and is being sought from the R&D department at the hospital. MyTherapy and Locala have approved of the contact with the participants and will be kept updated on the progression of the study. As the researcher and registered nurse at the NHS hospital acute stroke unit involved in the recruitment process, potential participants will be identified by myself at my place of work.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research

☐ Undertaking the research

☐ Analysis of results

☐ Dissemination of findings

☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
I have contacted the Stroke Association based in Wakefield and have attended one of their monthly informal meetings where I informed service users who have had a stroke about my study. I gave service users the opportunity to voice their opinions and preferences regarding the trial. These comments were taken into consideration with the trial design.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Inclusion Criteria
• are diagnosed with stroke in the early rehabilitation phase.
• first stroke.
• receiving standard stroke rehabilitation post-discharge from hospital.
• aged 50+ years.
• Berg Balance scale between 30-45. If an individual has a score below 30, the individual would not be able to stand and would, therefore, be unable to practice tai chi. If a person has a score above 45, they would have no impairment.
• be able to access the intervention venue.
• be able to mobilise at least 6m with or without aids.
• able to give informed consent.
• willing to adhere to procedures of the study.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Exclusion Criteria
• diagnosis of cognitive impairment- as a registered nurse, I have sufficient clinical judgement to determine the mental capacity of both post-stroke patients and those with dementia. I have also received training in the Mental Capacity Act. Should stroke patients lose their capacity, this would have been documented in their medical notes by the time they are ready for rehabilitation.
. If participants have reading and writing difficulties due to stroke, they will be excluded because they will not be able to read and answer questionnaires (in English).
• diagnosis of severe visual impairment.
• diagnosis of uncontrollable hypertension, angina or diabetes.
• diagnosis of dementia.
• already practising tai chi, yoga, dance or any other balance-training exercise. Although stroke survivors practising tai chi already will be unlikely, one of the aims of the study is whether or not tai chi would be acceptable amongst stroke survivors without prior experience and if it can be taught in this population.
• involved in falls prevention programmes.
• unmanageable incontinence.
• catheter insitu.
• already participating in a study.
• diagnosis of uncontrolled epilepsy.
• unable to understand English. The questionnaires/outcomes instruments exist in (and are validated in) English, and this PhD project has no funds for translation and cross-cultural adaptation/validation.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Information sheet given	1	0	1 minute	myself
Consent obtained	1	0	5 minutes	myself
Personal details obtained	1	0	5 minutes	myself
Telephoned at home to arrange baseline assessments	1	0	5 minutes	myself
Baseline assessments obtained through questionnaires	1	0	45minutes	myself
Baseline assessments obtained for blood pressure	1	0	5 minutes	myself
Monthly falls calendars filled in/handed in	3	0	5 minutes	myself
Monthly home practice diaries filled in/handed in	3	0	5 minutes	myself
Interviews conducted	1	0	1 hour	myself
12-week data - questionnaires	1	0	30 minutes	myself
12-week data - Berg Balance Scale	1	0	30 minutes	myself
12-week data - blood pressure	1	0	5 minutes	myself
6-month follow-up - questionnaires	1	0	30 minutes	myself
6-month follow-up - Berg Balance Scale	1	0	30 minutes	myself
6-month follow-up - blood pressure	1	0	5 minutes	myself
Baseline Berg Balance Score - only if unobtainable from routine rehabilitation assessment	1	0	30 minutes	myself

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Tai chi intervention	24	0	24 hours	myself tai chi instructor

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

○ Yes ◉ No

A21. How long do you expect each participant to be in the study in total?

After gaining consent, participants will be required to take part in eligibility screening and baseline assessments which will take one hour. The study itself will take 12 weeks. Assessments will be made at this point. Participants will be expected to take part in a six-month follow-up. Therefore, the total time will be approximately six months. The study as a whole has been estimated to take approximately ten months following a pilot recruitment process undertaken by myself. An additional six months has been added to this for unexpected events.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

There are no known ill-effects on health from tai chi exercising (Taylor-Pilae & Coull, 2012) but there are consequences of taking part:
- Participants may experience a change of lifestyle by practising tai chi. This may be beneficial to the participant, however, which is why the study is taking place.
- Participants will be required to change their routine by travelling to hospital twice a week for 12 weeks. A shuttle bus service is available free of charge between Pinderfields and Dewsbury hospitals and participants will be informed about this service.
- Participants may feel nervous and pressurised. Participants will be amongst similar people and will be encouraged to practise tai chi at their own pace.
- Participants may forget to breath and hold their breath whilst exercising. The tai chi instructor and myself will encourage regular breathing throughout the study.
- Falls, and loss of balance may occur during tai chi. Chairs will be provided for each participant and participants will be encouraged to use these. The intervention will start seated. Patients can sit down at any time if they feel tired. As a registered nurse on the stroke unit I will be monitoring participants in case of imbalance. Safety will be maximised by use of the exclusion and inclusion criteria. As a nurse on the stroke unit, I will assess participants' capacity to do the tai chi exercises. If participants are capable of getting to and participating in the classes (as well as activities of daily living), they are capable of home tai chi (which is not more risky than activities of daily living). Participants will be under the care of community rehabilitation teams who will assess the safety of their homes to do physical activity.
- Lack of confidence and motivation in participants may occur. Participants' significant others will be invited to come along and be involved in the tai chi with the participant.
- Participants may be unwilling to participate. Participants will be reminded that participating in the study is voluntary and may withdraw at any time without reason. Opportunities for questions will be given in every session.
- Participants may feel awkward during the interview. Interviews are semi-structured and information will be kept confidential. Conversation will not divert outside the interview topic guide. If it does, I will redirect the conversation to the topic guide. Should the participant disclose any information which could suggest harm to themselves or others, then this disclosure will be relayed to the appropriate authorities.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

Tai chi has been shown to increase confidence, balance and reduce falls (Au-Yeung, Hui-Chan, & Tang, 2009), (Taylor-Piliae, Boros, & Coull, 2014), (Hart et al, 2004), (Li et al, 2008). It has also been shown to improve mood and quality of life (Taylor-Piliae et al, 2014). However, these studies have focussed on stroke survivors who are more than three months post stroke. The population in this study will be recently discharged from hospital. Tai chi given to those in the early phases of rehabilitation may prevent first falls as well as improve balance, confidence, blood pressure, sleep and mood (Department of Health, 2010). Given that high blood pressure is a major risk factor in stroke, tai chi may help in preventing further strokes by reducing blood pressure (Lo et al, 2012). Participating in the study will also give the participants an opportunity to meet others with similar problems to their own and socialise over refreshments at the end of each session. The participants may also be content in knowing that they will be contributing to research.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? *May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.*

Participants will be given details of tai chi classes held by the instructor.

A26. What are the potential risks for the researchers themselves? *(if any)*

There are no known potential risks for the researcher.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Whilst on the stroke unit, eligible potential participants will be informed about the study and asked if they wish to participate in the tai chi group. If they express an interest, an information sheet will be given and participants will be given one to two days to discuss this with significant others. This duration will be given as patients at the rehabilitation stage could be discharged at any time and the recruitment opportunity would be lost. Should patients agree, consent will be obtained for the study, and personal details of themselves and significant others (a contact in case of emergency) as well as medical records (past medical history, type of stroke and blood pressure) obtained before they are discharged. Berg Balance scores will be obtained from community rehabilitation services as part of the eligibility criteria following their discharge. Should the patients not be eligible due to the Berg Balance score, they will be informed via telephone with an explanation why and thanked for their interest. Following eligibility screening, a visit to the hospital will be arranged at a convenient time for the patient in order to carry out baseline assessments.

If participants at this stage do not wish to participate in the tai chi group, they will be offered the chance to contribute through being included in the observational cohort. According to Arain et al (2010), although randomisation can be used in feasibility studies, randomisation is not necessary when the intervention is not to evaluate the effectiveness of an intervention. For the present study, the effectiveness of tai chi is not being investigated, so randomisation is not a necessary process (and would add disproportionally to time and costs). The baseline Berg Balance Score will be obtained from community rehabilitation services. This will be kept confidential by using the hospital's notification programme on SystemOne computer system in order to transfer scores.

If the community rehabilitation services fail to produce this score, the hospital physiotherapist will perform the Berg Balance score and this will be added to SystemOne. This is required not only for baseline assessment, but also it is required as part of the eligibility criteria. Community physiotherapists should routinely administer the Berg Balance Score on all patients at their initial assessment. Therefore the community rehabilitation team will not be administering anything other than their normal routine practice.

Those potential participants who are discharged to rehabilitation units (based in Dewsbury or Wakefield) will be given an information sheet whilst on the acute stroke unit and consent will be sought for the study before they leave the acute stroke unit. The Berg Balance score will obtained as above. These participants will be contacted by telephone once discharged home, and will be informed if they are not eligible with an explanation.

Once participants in both groups have completed their 12 weeks, they may be invited to take part in an interview regarding their perceptions of the study.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(•) Yes ( ) No

Please give details below:
Identifying potential participants whilst in the acute stroke ward at hospital will require knowledge of whether the potential participants will be discharged to a rehabilitation unit for inpatient rehabilitation. These rehabilitation units are based in Dewsbury and Pinderfield (Wakefield) hospitals. It will also be noted whether or not patients will be eligible for community rehabilitation. This information will be deduced from patients' medical records. As a nurse working on the stroke unit, I will be able to identify myself potential participants. The stroke classification will also be obtained from patients' medical records with potential participants' consent. The initial Berg Balance score will also be obtained from MyTherapy and Locala, who have given their consent. This will be obtained confidentially from SystemOne. It will also be noted in medical records whether or not a patient lacks mental capacity to consent. Patients will also have given their consent for me to access these details.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

○ Yes ◉ No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

As a nurse on the stroke unit, I will identify those patients deemed fit for rehabilitation by the medical team. I will not approach the patients before this as they would not be medically fit. Then, I would further identify those patients who will be discharged either to further inpatient rehabilitation units or home with community rehabilitation. These patients will then be approached by myself who will inform them of the study, giving them an information sheet about the study. I will ask them if they would be willing to think about participating, stating that they will be given until the next day to discuss this with significant others. I will state that in order to contact them on discharge I would need their personal details as well as those of their significant other. I will also inform them that at this stage I would require their stroke classification as the medical notes would be filed away after discharge. After giving them time to think and to discuss this with their family, I would ask them if they would be willing to give me their consent to the study. If participants do not wish to give me their contact details before discharge, they will no longer be eligible for the study. Those going for further rehabilitation at hospitals will be identified whilst on the acute stroke unit and consent obtained before they leave the stroke unit.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

I have produced a written information sheet about the study. I will approach participants, once fit for rehabilitation, regarding obtaining their personal details and consent after being given time to think about their decision. Consent will be obtained before patients are discharged. A meeting will be arranged to perform baseline assessments at Pinderfields hospital. Participants may arrange this meeting after discharge via telephone.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants on the stroke unit are quickly discharged either to further inpatient rehabilitation units or to home, once they are fit for rehabilitation. Therefore, personal details and consent will be obtained the following day, or up to the point of discharge. This short duration is due to the fact that patients on the acute stroke unit are discharged very quickly once they are no longer in the acute phase of stroke. Therefore, recruitment opportunity may be lost.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

( ) Yes

(●) No

( ) Not Known

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Those people who can not understand or speak English will not be eligible as it is important that participants are able to doo this for safety as the intervention requires verbal instruction and understanding in English. Should a relative be present to interpret, then this would be allowed.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

If any information becomes available during the course of the research relevant to participants' continued participation, participants will be informed of this and given links to the original source of information either at the tai chi class or via mail.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

( ) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

(●) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

( ) The participant would continue to be included in the study.

( ) Not applicable – informed consent will not be sought from any participants in this research.

( ) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

Any data collected during the study will be included in analysis.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files (includes paper or film)
  - [ ] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [x] Laptop computers

Further details:
Participants' contact details will be stored on an encrypted computer and on paper records secured in a locked cupboard in a locked room on the research site. Only the researcher needs to have access to this. Information about participants' health conditions, past medical history and medications will also be collected and these will also be stored on a password-secure computer and on paper records. If direct quotes from participants will be used, participants' identities will be anonymised. A recording device will be used to record interviews at the end of the study. This will also be encrypted and kept confidential, carried in a locked bag. I will be the only person with access to personal data.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

The University of Huddersfield upholds the regulations of the Data Protection Act 1998, as well as the university's Data Protection policy. Data about participants will be processed fairly so as not to cause damage or distress. Minimum personal information necessary for research purposes only will be passed on to the University, the Stroke Association, MidYorkshire Hospitals Trust and publication journals. Results of the research will not be made available in a form which identifies data subjects.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The researcher (myself) will have access to participants' personal data. Consent has been sought through SREP at the University and will be sought through the R&D department at the NHS trust should approval from IRAS be gained.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

◯ Less than 3 months
◯ 3 – 6 months
◯ 6 – 12 months
◯ 12 months – 3 years
◉ Over 3 years

If longer than 12 months, please justify:
Ten years - the University has just issued a new research conduct code outlining good practice re. integrity and transparency, suggesting that anonymised data is to be kept for ten years, but not necessarily personal data.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes ◯ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
After completion of all questionnaires at six months, all participants will be given a £10 voucher, funded by the sponsor. This amount has been determined based on the academic supervisor's experience of previous trials. The voucher will not be an incentive but will be given to participants to say 'thank you' on completion of all questionnaires.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ◯ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ◯ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

○ Yes ◉ No

Please give details, or justify if not registering the research.
This is a feasibility trial, not a randomised controlled trial.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [x] Internal report
- [x] Conference presentation
- [ ] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

Data will be displayed in my PhD thesis which will be available in the University Repository.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
Participants will be informed how the data will be used and will be informed about the study outcomes via a letter. Feedback on the progress of the study will be given to all those involved at regular intervals, including funding bodies, MYTherapy and steering group members. Results will be disseminated via presentations, conferences, bulletins, team briefings and management reports. Final results will be released to the general public via an appropriate journal to be peer reviewed and published.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi−centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [ ] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
Regular progress monitoring has been conducted by two academic supervisors throughout the course of the research planning. The research has also been reviewed by the University of Huddersfield School Research Ethics Panel. The R&D department based at Pinderfields General Hospital has also reviewed the research prior to submission to via IRAS.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- [ ] Review by independent statistician commissioned by funder or sponsor
- [ ] Other review by independent statistician
- [ ] Review by company statistician
- [x] Review by a statistician within the Chief Investigator's institution
- [ ] Review by a statistician within the research team or multi−centre group
- [x] Review by educational supervisor
- [ ] Other review by individual with relevant statistical expertise
- [ ] No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	John	Stephenson

Department	Biomedical Statistics Human and Health Sciences
Institution	University of Huddersfield
Work Address	Queensgate Huddersfield West Yorkshire
Post Code	HD1 3DH
Telephone	01484 471513
Fax	
Mobile	
E-mail	j.stephenson@hud.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

1. The Berg Balance Scale (baseline, 12 weeks, six months) – an administered test

The Berg Balance Scale (BBS), developed by Berg, Wood-Dauphine, Williams & Maki (1992), is a validated detailed grading scale and has the best potential for detecting balance impairment. The BBS was found to be useful for predicting falls in stroke patients with a BBS score below 45 (Maeda, Kato & Shimada, 2009). The Berg Balance Score ranges from 0-57 where the higher the score the less the impairment of balance. A score above 45/57 indicates an individual is too independent to take part in the study in order for the intervention to show improvements over time. A score below 30/57 indicates an individual is too severely impaired to take part in the study. Therefore potential participants will have a baseline Berg Balance score between 30-45 (below 30 shows severe impairment, above 45 shows no impairment). This range fits a large enough proportion of the target population to make the intervention worthwhile. The study population includes a good proportion of people within this range in order for there to be enough potential participants to approach. It is easy to administer (taking about 20 minutes to complete), needing no specialist equipment. In addition, the interrater and intrarater reliability is strong (Bogle & Newton, 1996; Zwick, Rochelle, Choksi & Domowicz, 2000). Furthermore, the BBS has the ability to identify community-dwelling people having recurrent or multiple falls compared to those who fell once (Noohu, Dey & Hussain, 2014).

The Berg Balance Scale as well as questionnaires are necessary despite the fact that this study is not looking for outcomes and results because it is crucial to obtain standards deviations of the outcome measures in order to estimate a sample size for a full-scale trial.

The Berg Balance Scale:
- includes 14 items to measure balance with a five-point Likert scale.
- takes 15-20 minutes to administer.
- requires participants to maintain their balance whilst attempting tasks, e.g. reaching forward, retrieving an item of the floor, sitting to standing, standing to sitting, standing to sitting unsupported, standing with eyes closed.
- has strong intra- and inter-rater reliability.
- has tasks are similar to certain tai chi movements and will thus measure what it is supposed to measure.

2. Falls Calendar (weekly for six months) – self-completed

The falls calendar:
- contains the number of falls recorded by participants on days they fall, giving the reason why.
- takes two minutes to complete.
- will be collected monthly at each tai chi class. After 12 weeks, the falls calendar will continue monthly up to six months using S.A.Es.
- will be collected monthly by post for the control arm. These will be sent by post using S.A.E.s which will include the calendar for the next month.

A58. What are the secondary outcome measures?*(if any)*

Various secondary outcomes will also be explored in order to obtain data to assess the feasibility and refine procedures for a future randomised controlled trial.
Secondary outcome measures are:

1. The Falls Efficacy Scale (baseline, 12 weeks, six months) – a validated self-completed questionnaire
- a score scale of one to ten with ten items about confidence in daily activities.
- takes three to five minutes to complete.

2. SF-12 QUESTIONNAIRE (baseline, 12 weeks, six months) – a validated self-completed
- a quality of life questionnaire.
- takes five minutes to complete.
- participants will be required to answer questions regarding their health status on paper.

3. Geriatric Depression Scale (baseline, 12 weeks, six months) – a validated self-completed questionnaire that will not be offered to participants as a geriatric scale
- participants will be required to answer questions using yes/no responses relating to how they feel regarding their mood.
- takes three to five minutes to complete.

4. Blood Pressure (baseline, 12 weeks [before the final tai chi session], six months =three readings)
– this will be taken according to The Royal Marsden Hospital Manual of Clinical Nursing Procedures. The 12-week reading for those in the tai chi intervention group will be taken before the last tai chi session begins.

5. Home Practice Diary (daily for 12 weeks) – a self-completed
The University assessors suggested the use of the Scottish Physical Activity Questionnaire [SPAQ] instead of a home practice diary. After reading some background literature about it, I feel this questionnaire does not give enough information in order to establish the required frequency and duration of tai chi to inform a full-scale study. The SPAQ was originally developed to measure changes in the leisure physical activity of various groups. Moreover, this questionnaire focuses on physical activity in general rather than on one specific type. These activities may include walking to and from places, gardening, etc. Timescales covered is at least 30 minutes, whereas I require data for at least fifteen minutes.
Home practice diaries are, therefore preferred because:

- participants will record whether or not they practised tai chi for at least 15 minutes or not each day. A space for comments is provided.
- they take a moment to complete each day.
- they will be collected monthly at the tai chi class, then sent to participants by post monthly with a S.A.E with a request to post the previous month's diary. This will maintain monthly communication up to the six month questionnaires, enabling participants to continue to feel part of the study.

6. Follow-Up Questionnaire (six months) – a self-completed
- participants will be given a follow-up questionnaire after six months at the same time as the Falls Efficacy Scale, SF-12 questionnaire and Geriatric Depression Scale.

For the falls diary, home practice diary and follow-up questionnaire, the researcher recognises her effect on the processes and outcomes of the research. There are no suitably validated tools, these are part of the feasibility study to see if they are acceptable.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	54
Total international sample size (including UK):	
Total in European Economic Area:	

Further details:
In order to achieve sufficient data to inform sample size calculations for any subsequent full-scale trial, a minimum of 20 complete data sets per group is considered appropriate. For this feasibility study, the intention is to have the same number of exercise participants and observational cohort members. To allow for loss of follow-up, the aim will be to involve 27 patients per group, 54 in total. The tai chi classes have an optimum size of 12 people. Thus, accepting the rolling programme and drop outs, the number per class could drop below the optimum. To off-set this possibility, eligible patients will be initially recruited to the exercise (tai chi) group only, When a full class is obtained, additional eligible patients will be invited to join the observational cohort. In order to keep the class at an optimum level, eligible patients will continue to be invited into the exercise group as necessary. Recruitment into the exercise group will stop once 27 participants have been obtained. Invitations to join the observational cohort will continue until 27 participants have been obtained.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The proposed sample size is somewhat larger than previous studies, with the intention of ensuring sufficient data to inform a future trial. Taylor-Piliae and Coull (2011) conducted a pilot study involving 28 participants in total with 16 in a tai chi group and 15 in a control group. In the pilot study conducted by Hart et al. (2009), 18 participants were recruited in total, with nine in the intervention group and nine in the control group. Since the present feasibility study may inform a future RCT, the possibility of limited adherence to a novel rehabilitation programme (or parts of it) should be taken into account, as should the potential for loss-to-follow-up. An initial total of 27 per group is estimated to be adequate to achieve the desired 20 full data sets per group.

There were, on average, 101 potential participants altogether on the targeted stroke unit between March-August, 2015. This number has been obtained from a scoping exercise over a six month period at the stroke unit to be used for recruitment. These figures include those patients sent to further rehabilitation hospitals and those sent directly home with community rehabilitation services. It is believed that potential participants are likely to find the notion of the tai chi classes attractive. Thus, it is also believed that the patient population for this study will be sufficient to recruit the necessary numbers over a ten-month period.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

- data will be variously analysed by quantitative and qualitative methods (as appropriate) in order to provide relevant information to inform a future trial.
- assessment tools will be scored and data entered into SPSS.
- statistical advice will be sought from a statistician based at the university (Dr John Stephenson).
- falls diaries will be collected monthly, with telephone calls given to follow-up non-responders.
- changes over time will be monitored.
- in order to inform sample calculations for any further full-scale trial, population-specific variance parameters in the chosen outcome measures will be obtained.
- interviews will be transcribed (taking approximately six hours per interview)and analysed thematically, though interviews do not need to be transcribed word for word. Ten interviews will be conducted from both groups but will stop once saturation has been reached. Interviews will take place once participants have completed the 12-week period and will be transcribed afterwards. Therefore, the interview and analysis will be on-going throughout the study, enabling enough time for completion.
- electronic data will be stored on the University's k-drive for six years.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Kiara	Lewis
Post	Head of the Division of Health and Wellbeing		
Qualifications	PhD		
Employer	University of Huddersfield		
Work Address	Queensgate		
	Huddersfield		
	West Yorkshire		
Post Code	HD1 3DH		
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	Title	Forename/Initials	Surname
	Professor	Kim	Burton
Post	Occupational Health and Ergonomics Consultant		
Qualifications	PhD		
Employer	University of Huddersfield		
Work Address	Queensgate		
	Huddersfield		
	West Yorkshire		
Post Code	HD1 3DH		
Telephone	01484 472460		
Fax			
Mobile			
Work Email	a.k.burton2@hud.ac.uk		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ◯ NHS or HSC care organisation
- ◉ Academic
- ◯ Pharmaceutical industry
- ◯ Medical device industry
- ◯ Local Authority
- ◯ Other social care provider (including voluntary sector or private organisation)
- ◯ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of Huddersfield
Given name	Chair of School Research Ethics Panel
Family name	Dr Rachel Armitage
Address	Queensgate
Town/city	Huddersfield
Post code	HD1 3DH
Country	UNITED KINGDOM
Telephone	01484 473854
Fax	
E-mail	r.a.armitage@hud.ac.uk

Is the sponsor based outside the UK?

◯ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- ☐ Funding secured from one or more funders
- ☐ External funding application to one or more funders in progress
- ☑ No application for external funding will be made

What type of research project is this?

- (selected) Standalone project
- Project that is part of a programme grant
- Project that is part of a Centre grant
- Project that is part of a fellowship/ personal award/ research training award
- Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

(selected) Yes / No

If Yes, please give details of each rejected application:

Name of Research Ethics Committee or ethics authority:	Stanmore
Decision and date taken:	not favourable opinion 06/11/2015
Research ethics committee reference number:	171300/872342/1/160

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Judith	Holliday
Organisation	Mid Yorkshire Hospitals NHS Trust		
Address	Pinderfields General Hospital		
	Aberford Road		
	Wakefield		
Post Code	WF1 4DG		
Work Email	judith.holliday@midyorks.nhs.uk		
Telephone	01924 543772		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/06/2016
Planned end date: 01/10/2017
Total duration:

Years: 1 Months: 4 Days: 1

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland

- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	1
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	1

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

The reporting of adverse effects and minimal harm will be reported as per GCP guidelines should this happen.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

Should the intervention be deemed unsafe or is having a negative effect, or should any new information be made public stating that the intervention is unsafe the trial will be stopped.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The tai chi instructor has his own indemnity insurance. The University of Huddersfield have their own indemnity insurance for research projects.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The tai chi instructor has his own indemnity insurance. I am covered by the University's public liability insurance.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

This is for the whole study.

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

○ Yes ◉ No

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	MidYorkshire Hospitals Trust	Title	Ms
Department name	Pindersfields General Hospital	First name/ Initials	Elizabeth A
Street address	Aberford Road	Surname	Harkin
Town/city	Wakefield		
Post Code	WF1 4DG		
Institution name	N/A	Title	N/A
Department name	N/A	First name/ Initials	N/A
Street address	N/A	Surname	N/A
Town/city	N/A		
Post Code	N/A		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

- (x) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

[x] I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Ms Elizabeth Anne Harkin on 13/03/2016 13:16.

Job Title/Post:	Registered nurse
Organisation:	University of Huddersfield
Email:	u0553488@hud.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Professor Rachel Armitage on 14/03/2016 11:05.

Job Title/Post:	Professor of Criminology
Organisation:	University of Huddersfield
Email:	r.a.armitage@hud.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Kim Burton on 13/03/2016 18:53.

Job Title/Post:	Prof of Occupational Healthcare
Organisation:	University of Huddersfield
Email:	kim@spineresearch.org.uk

Academic supervisor 2

This section was signed electronically by Ms Kiara Lewis on 14/03/2016 15:44.

Job Title/Post:	Head of Division
Organisation:	University of Huddersfield
Email:	kiara.lewis@hud.ac.uk

Health Research Authority
Yorkshire & The Humber - Leeds West Research Ethics Committee
Room 001, Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0207 104 8087

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

15 July 2016

Ms Elizabeth Harkin
Registered Nurse
Mid-Yorkshire Hospitals NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
WF1 4DG

Dear Ms Harkin

Study title:	**Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors - a feasibility study.**
REC reference:	**16/YH/0130**
IRAS project ID:	**171300**

Thank you for your letter of 04 July 2016, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC. A list of the Sub-Committee members is attached.

Yorkshire & The Humber - Leeds West Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Michael Clarke	Senior Dento Legal Advisor	Yes	
Dr Vera Neumann	Consultant in Rehabilitation Medicine	Yes	Chair of the Ad-Hoc Sub-Committee
Mr Vishal Sharma	Research Fellow/PhD Student	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kirstie Penman	REC Assistant

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Assistant, Miss Kirstie Penman at nrescommittee.yorkandhumber-leedswest@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a **favourable** ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Within the Participant Information Sheet, regarding the section detailing the randomisation process, please amend this to read:
'You will be assigned to usual treatment or to Tai Chi + usual treatment at random (like tossing a coin). Half of the participants will get usual treatment and half will also get Tai Chi. Neither you nor the researcher will know which treatment group you have been assigned to until a sealed envelope giving this information is opened at the beginning of the study."
2. Within the Participant Information Sheet, under the heading 'What would taking part involve?' amend the sentence to read 'We expect about 50 people who are leaving hospital and about to start community rehabilitation to take part in the research.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ('participant identification centre'), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see 'Conditions of the favourable opinion' above).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]	1.0	04 October 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor indemnity]	1.0	14 September 2015
GP/consultant information sheets or letters [GP information sheet]	2.0	03 March 2016
Interview schedules or topic guides for participants [Interview topic guide]	2.0	16 May 2016
Interview schedules or topic guides for participants [Interview topic guide]	3.0	03 July 2016
Letter from sponsor [Letter from sponsor]	1.0	06 October 2015
Letter from statistician [Letter from statistician]	1.0	25 February 2016
Non-validated questionnaire [6monthquestionobs]	2.0	03 March 2016
Non-validated questionnaire [6 month question tai chi]	3.0	03 May 2016
Other [Falls Calendar]	2.0	23 February 2016
Other [Home Practice Diary]	1.0	23 February 2016
Other [Home Practice Booklet]	1.0	05 October 2015
Other [GCP Certificate]	1.0	15 May 2015
Other [Physiotherapy Numbers]	1.0	29 April 2015
Other [Indemnity Insurance for Tai Chi Instructor]	1.0	22 March 2015
Other [Permissions]	1.0	20 October 2015
Other [Berg Balance Instructions]	1.0	03 March 2016
Other [Tai Chi Instructor Guide]	1.0	04 October 2015
Other [Response to SREP]	1.0	03 March 2016
Other [Response to Stanmore REC]	1.0	03 March 2016
Other [Response to Progress Monitoring]	1.0	03 March 2016
Other [Stanmore Unfavourable Opinion Letter]	1.0	14 December 2015
Other [Supervisor 2 CV]	2.0	13 March 2016
Other [Support Contact Details]	3.0	08 May 2016
Other [Research Timeline]	3.0	03 May 2016
Other [Eligibility Screening]	2.0	16 May 2016
Other [Indemnity Insurance for Tai Chi Instructor]		10 May 2016
Other [LeedWest Opinion Letter Response]	1.0	16 May 2016
Other [Proof of indemnity for significant others]	1.0	18 April 2016
Other	Statistician Advice	10 May 2016
Other [Shuttle Bus Timetable]	1.0	08 May 2016
Other [RDS Advice 1]	1.0	22 April 2016
Other [RDS Advice 2]	1.0	26 April 2016
Other [Response from Stroke Association Service Users Panel 1]	1.0	28 April 2016
Other [Response from Stroke Association Service Users Panel 2]	1.0	10 May 2016

Other [Response from Stroke Association Service Users Panel 3]	1.0	28 April 2016
Other [Response from Stroke Association Service Users Panel 4]	1.0	30 April 2016
Other [Consent form for interviews]	2.0	16 May 2016
Other [Stroke PPi Response]	1.0	14 June 2016
Other [Tai chi insurance letter]	1.0	15 June 2016
Other [Eligibility Screening]	4.0	03 July 2016
Other [Response to Leeds West REC 31/5/16]	1.0	03 July 2016
Participant consent form [Consent Form]	2.0	03 March 2016
Participant consent form [Consent Form]	2.0	16 May 2016
Participant information sheet (PIS) [Participant Info1]	2.0	03 March 2016
Participant information sheet (PIS) [Participant Info2]	2.0	03 March 2016
Participant information sheet (PIS) [Participant Info1]	3.0	16 May 2016
Participant information sheet (PIS) [Participant Info1]	5.0	03 July 2016
REC Application Form [REC_Form_16032016]		16 March 2016
Referee's report or other scientific critique report [Referee report]	1.0	09 July 2015
Research protocol or project proposal [Protocol]	4.0	12 May 2016
Research protocol or project proposal [Protocol]	6.0	03 July 2016
Summary CV for Chief Investigator (CI) [Summary CV]	1.0	24 September 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol summary]	1.0	07 October 2015
Validated questionnaire [Berg Balance Scale]	2.0	03 March 2016
Validated questionnaire [Geriatric Depression Scale]	2.0	03 March 2016
Validated questionnaire [Falls Efficacy Scale]	2.0	03 March 2016
Validated questionnaire [SF-12 Questionnaire]	2.0	03 March 2016

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *'After ethical review – guidance for researchers'* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/YH/0130	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely
pp

Dr Vera Neumann
Vice-Chair

Email: nrescommittee.yorkandhumber-leedswest@nhs.net

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments* 'After ethical review – guidance for Researchers' *[SL-AR2]*
Copy to:	*Professor Rachel Armitage, University of Huddersfield* *Ms Judith Holliday, Mid Yorkshire Hospitals NHS Trust*

NHS
National Institute for Health Research
Clinical Research Network

Certificate of Attendance

Elizabeth Harkin

attended

Introduction to Good Clinical Practice (GCP):
A practical guide to ethical and scientific
quality standards in clinical research

on 15/05/2015

Sessions include:
1. The Value of Clinical Research and the role of the NIHR CRN
2. GCP: the standards and why we have them
3. Study set up: responsibilities, approvals and essential documents
4. The process of informed consent
5. Case report form, source data and data entry completion
6. Safety reporting in clinical trials

Emma Lowe
NIHR CRN Learning and Development Lead

The Mid Yorkshire Hospitals NHS
NHS Trust

Ms Elizabeth Harkin
Staff Nurse
Stroke Medicine A2
PGH

Research Office
Rowan House
Pinderfields Hospital
Aberford Road
Wakefield
WF1 4DG
Tel: 01924543772
Email: my.research@midyorks.nhs.uk

JH/VD/R&D

12 December 2016

Dear Ms Harkin

Confirmation of Capacity and Capability at Mid Yorkshire Hospitals NHS Trust
Full title of study: Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors – a feasibility study.
HRA 171300 REC 16/YH/0130 R&D 16/1057

This letter confirms that **Mid Yorkshire Hospitals NHS Trust** has the capacity and capability to deliver the above referenced study.

We agree to start this study on **12 December 2016**, dependant on the Occupational Health Authorisation for the Tai Chi instructor, Richard Morley.

To meet the national target of recruiting the first patient into this study within 30 days of this permission letter, the first patient should be recruited by **11 January 2017**. Please let us know if you believe you will be unable to meet this target and provide any reasons for this.

There are some conditions to this approval:

- The study may only begin after appropriate Research Ethics Committee approval has been received. I can confirm receipt of the REC approval dated 15 July 2016.

- To comply with the Research Governance Framework (DOH, 2001), the Local Investigator/Researcher should ensure that the study is conducted in accordance with the ~~approved protocol~~. Informed consent must be obtained in accordance with the protocol and a copy given to the participant, a copy kept in the medical record, where appropriate, and a copy kept by the investigator in their research file. The Trust may audit these requirements.

- Research activity must be monitored by the Trust. A copy of letters or reports received following monitoring visits or inspections relating to the conduct of this study, at this site, must be sent to this office.

- Research involving radiation exposures must comply with local Trust policies and procedures, including authorisation by a named local Practitioner.

- Annual progress reports will be required, and a copy of the final report. We will contact you annually to ensure we have up to date contact details and to confirm the status of the project.

- Any researchers not employed by this organisation who will be conducting research on Trust premises may require a research passport, an honorary contract, or a letter of access. If you require help with this, in the first instance, contact myself. **We are currently awaiting confirmation form Occupational Health in order to provide access to the trust to the Tai Chi Instructor Richard Morley. Before Richard can begin working with patients he must be in receipt of a letter of access from this research office.**

- For research within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004, investigators must provide evidence of appropriate ICH-GCP training. The Trust may audit this requirement.

- You have specified that this study will run for 12 months and will be completed by **31 December 2017**. If you require an extension to the recruitment or follow up period this must be submitted to R&D for approval.

If you agree with the terms stated, please will you sign a copy of this letter and return it to this office.

May I take this opportunity to wish you every success with your research.

Yours sincerely

Judith Holliday
RESEARCH MANAGER

cc: Julie Ball, r.a.armitage@hud.ac.uk,

Document	***Version***	***Date***
GP/consultant information sheets or letters [GP information sheet]	2.0	03 March 2016
Interview schedules or topic guides for participants [Interview topic guide]	3.0	03 July 2016
Non-validated questionnaire [6monthquestionobs]	2.0	03 March 2016
Non-validated questionnaire [6 month question tai chi]	3.0	03 May 2016
Other [Falls Calendar]	2.0	23 February 2016
Other [Home Practice Diary]	1.0	23 February 2016
Other [Home Practice Booklet]	1.0	05 October 2015

Striving for excellence

Other [Physiotherapy Numbers]	1.0	29 April 2015
Other [Berg Balance Instructions]	1.0	03 March 2016
Other [Tai Chi Instructor Guide]	1.0	04 October 2015
Other [Response to SREP]	1.0	03 March 2016
Other [Research Timeline]	3.0	03 May 2016
Other [Eligibility Screening]	2.0	16 May 2016
Other [Indemnity Insurance for Tai Chi Instructor]		10 May 2016
Participant consent form [Consent Form]	2.0	16 May 2016
Participant information sheet (PIS) [Participant Info2]	2.0	03 March 2016
Participant information sheet (PIS) [Participant Info1]	5.0	03 July 2016
Research protocol or project proposal [Protocol]	6.0	03 July 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Protocol summary]	1.0	07 October 2015
Validated questionnaire [Berg Balance Scale]	2.0	03 March 2016
Validated questionnaire [Geriatric Depression Scale]	2.0	03 March 2016
Validated questionnaire [Falls Efficacy Scale]	2.0	03 March 2016
Validated questionnaire [SF-12 Questionnaire]	2.0	03 March 2016

striving for **excellence**

Enhanced Certificate

Page 1 of 2

Disclosure & Barring Service

DBS Fee Charged

Certificate Number 001553406462

Date of Issue: 21 NOVEMBER 2016

Applicant Personal Details

Surname:	MORLEY
Forename(s):	RICHARD MICHAEL
Other Names:	NONE DECLARED
Date of Birth:	25 MAY 1969
Place of Birth:	WAKEFIELD
Gender:	MALE

Employment Details

Position applied for:
CHILD AND ADULT WORKFORCE RESEARCHER

Name of Employer:
UNIVERSITY OF HUDDERSFIELD

Countersignatory Details

Registered Person/Body:
UNIVERSITY OF HUDDERSFIELD

Countersignatory:
LAYLA SMITH

Police Records of Convictions, Cautions, Reprimands and Warnings

NONE RECORDED

Information from the list held under Section 142 of the Education Act 2002

NONE RECORDED

DBS Children's Barred List information

NONE RECORDED

DBS Adults' Barred List information

NONE RECORDED

Other relevant information disclosed at the Chief Police Officer(s) discretion

NONE RECORDED

Enhanced Certificate

This document is an Enhanced Criminal Record Certificate within the meaning of sections 113B and 116 of the Police Act 1997.

THIS CERTIFICATE IS NOT EVIDENCE OF IDENTITY

Continued on page 2

Disclosure and Barring Service, PO Box 165, Liverpool, L69 3JD Helpline: 03000 200 190

Schedule

Personal Trainer and Coaches Insurance

protectivity insurance

Protectivity Insurance, Belmont House, High Street, Lane End, High Wycombe, Bucks, HP14 3ER. Tel: 01494 887909

Date of issue:
10/05/2016

Richard Morley

61 Alverthorpe Road
Wakefield
West Yorkshire
WF2 9NU
United Kingdom

This is your insurance schedule from Protectivity, thank you for purchasing your insurance from us. This document is a summary of the details you have given us and should be read in conjunction with the wording. Please check carefully and contact us immediately if there are any discrepancies. We recommend that you keep this document safe for future reference.

Policy Details				
Policy Number:	444900013512			
Binding Authority Number:	SC3342016377			
Wording:	LSL-A 0315 - WORDING - SCD / LSL-A 0315 - KEY FACTS - CSD			
Insured:	richard morley			
Business:	Tai Chi			
Period of Insurance:	From:	10/05/2016	To:	09/05/2017
	Both dates inclusive local standard time at the **Insured's** address stated above. This policy will not automatically renew: notice is hereby given that the cover will terminate and not be renewed at the expiry date unless a new agreement is reached between the **insurer** and the **insured**.			
Covered Jurisdictions:	United Kingdom			

Liability Section		
Public Liability Sub-Section	Included	
Limit of Indemnity	£2,000,000.00	any one **Occurrence**
	Subject to the following sub-limits which shall be part of and not in addition to the above limit:	
	£250,000	any one **Occurrence** and in the aggregate in respect of Cyber
Excess:	£0.00	Applicable to **Injury** and **Damage**
Defence Costs:	Included	
Occurrence Limit:	Combined	
Product Liability Sub-Section:	Included	
Limit of Indemnity:	£2,000,000.00	any one **Occurrence** and in the aggregate
Excess:	£0.00	Applicable to **Injury** and **Damage**
Defence Costs:	Included	
Occurrence Limit:	Combined	
Professional Indemnity Sub-Section:	Included	
Limit of Indemnity:	£2,000,000.00	any one **Occurrence**
	Subject to the following sub-limits which shall be part of and not in addition to the above limit:	
	£100,000	any one **Occurrence** and in the aggregate in respect of

		Breach of Confidentiality
	£100,000	any one **Occurrence** and in the aggregate in respect of Breach of Copyright
	£250,000	any one **Occurrence** and in the aggregate in respect of Libel and Slander
Excess:	£0.00	Applicable to **Injury** and **Damage**
Defence Costs:	Included	
Occurrence Limit:	Combined	
Retroactive Date:	10/05/2016	

Personal Accident Section		
Personal Accident Benefits:	Not Included	
	This policy will not pay more than the Capital Sum stated below for **Permanent Partial Disablement** arising out of any one **Accident** regardless of the number of conditions diagnosed in the **Insured Person**	
Death:	Nil	
Permanent Total Disablement:	Nil	Any occupation
	Subject to the following percentage of Capital Sum payable which shall be part of and not in addition to the above limit:	
	Nil	**Loss of Limb** (one limb)
	Nil	**Loss of Limb** (two or more)
	Nil	**Loss of Sight** (one eye)
	Nil	**Loss of Sight** (both eyes)
	Nil	**Loss of Limb & Loss of Sight**
	Nil	**Loss of Hearing** (one ear)
	Nil	**Loss of Hearing** (both ears)
	Nil	**Loss of Speech**
Temporary Total Disablement:	Nil	Maximum. Subject to net weekly earnings not being exceeded
	Nil	Maximum Duration
	Nil	Deferment Period
Extension - Dental Expenses:	Nil	Subject to appropriate mouth protection being worn when participating in contact sports
	Nil	Excess

Material Damage Section						
Sports & Business Equipment:	Not Included					
Sum Insured:	Nil	Item Limit:	Nil	Excess:	Nil	

Premium		
Initial Purchase	£55.00	Including 9.50% Insurance Premium Tax
Premium Breakdown		
Public & Products Liability	£55.00	Including 9.50% Insurance Premium Tax
Professional Indemnity	£0.00	Including 9.50% Insurance Premium Tax
Personal Accident	£0.00	Including 9.50% Insurance Premium Tax
Material Damage	£0.00	Including 9.50% Insurance Premium Tax

Notification of Claims and Circumstances	
To:	Claims Department Catlin Insurance Company (UK) Ltd. 20 Gracechurch Street

	London EC3V 0BG Email: David.Pusiak@catlin.com Matt.Malone@catlin.com

Endorsements	
Extensions Cover under all individual policy Sub-Sections is subject to the following additional conditions:	[none]
Additional Exclusions Cover under all individual policy Sections is subject to the following additional exclusions. This policy does not apply to or include cover for or arising out of or relating to:	**Participant vs Participant - Contact Sports** any liability of the Insured or any person insured in respect of Injury and/or Damage suffered by one Participant and caused by another Participant whilst engaged in Contact Sports. For the purpose of this exclusion:, i. 'Participant' means any person engaged in an activity under the direction of the Insured or any person insured; ii. 'Contact Sports' means any sport or activity in which physical contact between players or participants is an accepted part of play.
Additional Conditions Subject to all other terms and conditions of this policy, cover is extended as follows:	**Coaching, Instruction, Supervision and Treatment - Qualifications** All persons actively involved in the coaching, instruction, supervision or treatment of others must have all qualifications required to do so. Any treatment administered must be complementary to a sport or activity, non-invasive and in the ordinary course of the Business as stated in the Schedule.

Authorisation	
Signed by:	Paul Jardine Director Catlin Insurance Company (UK) Ltd.
Date:	10/05/2016

15/06/2016

Richard M Morley
61 Alverthorpe Road, Wakefield,
W' York's, WF2 9NU
01924 376027

To whom it may concern, I guarantee that I will be renewing my Professional instructor insurance in May 2017. I intend to renew my policy 2 weeks before it is due; to ensure that there is no discontinuity of insurance. I am a busy, International level Instructor and it is imperative that I have Insurance throughout the year. Furthermore, I will continue to teach to a very high professional standard.

Yours Sincerely Richard Morley

Richard Morley

ZURICH
MUNICIPAL

To Whom It May Concern

Our ref: CM/ht1 14 September, 2015

Zurich Municipal Customer: University of Huddersfield Higher Education Corporation and its subsidiary companies

This is to confirm that the above mentioned Customer has in force with this Company until the policy expiry on 31 July 2016, Professional Negligence Insurance.

Policy Number: NHE-03CA03-0013

Services covered: Training, research and consultancy services provided by the insured to outside clients in accordance with details lodged with the insurer and excluding services more specifically insured under this policy or elsewhere.

Limit of Indemnity: £ 5,000,000 any one claim and *in the aggregate for all claims* first made against the Insured and notified to Zurich Municipal during the period of insurance

Excess :£500 any one claim in respect of training services
£5,000 any one claim in respect of research and consultancy services

Retroactive Date: 1st August 2002

Exclusions
Standard insurance market exclusions apply, notably exclusion of Pollution other than sudden and accidental; punitive or exemplary damages; express warranties or guarantees; claims the cause of which occurred prior to the Retroactive Date.

This is a brief summary and the full policy should always be referred to for exact details of cover.

Yours faithfully

Cathy Matthews
Underwriting Services
Zurich Municipal

Zurich Municipal
Zurich House
2 Gladiator Way
Farnborough
Hampshire
GU14 6GB

Telephone 0870 2418050
Direct Phone 01252 387130
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catherine.matthews@zurich.com

The Mid Yorkshire Hospitals **NHS**
NHS Trust

Mr Richard Morley
61 Alverthorpe Road
Wakefield
WF2 9NU

Research Office
Rowan House
Pinderfields Hospital
Aberford Road
Wakefield
WF1 4DG
Tel: 01924543772
Email: my.research@midyorks.nhs.uk

JH/VD/R&D

14 December 2016

Dear Mr Morley

Letter of access for research relating to Tai Chi Instruction for the research study, Exploring tai chi as an early intervention to improve balance and reduce falls among stroke survivors – a feasibility study. R&D ref 16/1057

This letter should be presented to each participating organisation before you commence your research at that site. The participating organisation is: **Mid Yorkshire Hospitals NHS Trust.**

In accepting this letter, each participating organisation confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on **15 December 2016** and ends on **31 December 2017** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research **Mid Yorkshire Hospitals NHS Trust**. Please note that you cannot start the research until the Principal Investigator, **Elizabeth Harkin,** for the research project has received a letter from us giving confirmation from the individual organisation of their agreement to conduct the research.

The information supplied about your role in research at the organisation(s) has been reviewed and you do not require an honorary research contract with the organisation(s). We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation(s).

You are considered to be a legal visitor to the organisations premises. You are not entitled to any form of payment or access to other benefits provided by **Mid Yorkshire Hospitals NHS Trust** or to employees and this letter does not give rise to any other relationship between you and this organisation, in particular that of an employee.

While undertaking research through the **Mid Yorkshire Hospitals NHS Trust** you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of the organisation or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with the organisations policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with the organisation in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on the organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify each organisation prior to commencing your research role at that organisation.

You are required to ensure that all information regarding patients or staff remains secure and strictly confidential at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the organisations premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation does not accept responsibility for damage to or loss of personal property.

This organisation may revoke this letter and any organisation may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

striving for excellence

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Occupational Health form and DBS application, you must inform your employer through their normal procedures. You must also inform your nominated manager in each participating organisation and the R&D office in this organisation.

Yours sincerely

Judith Holliday
RESEARCH MANAGER

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THE LEADERSHIP & MANAGEMENT AWARDS 2013 WINNER Outstanding Registry Team

3 August 2017
Ref: RES-EC/0553488

Elizabeth Harkin
Sent by email to: Elizabeth.Harkin@hud.ac.uk

Dear Elizabeth,

In light of the circumstances outlined in your claim, and the subsequent delays which were outside of your control, the University has approved an exceptionally long deferral period of 4 months in recognition of this. The deadline for the completion of your research active period is therefore **Wednesday 31 January 2018**.

If you intend to apply to enter into the submission pending period, please ensure you liaise with your school PGR research office who will advise you of the deadline for submitting an application.

Should you require further details or clarification regarding this claim for extenuating circumstances then please contact your School Research Office in the first instance.

Yours sincerely

Rachel Shuttleworth
Registry Executive Officer (Research)
T 01484 472286
r.shuttleworth@hud.ac.uk
www.hud.ac.uk
Registry | University of Huddersfield | Queensgate | Huddersfield | HD1 3DH

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INVESTORS IN PEOPLE

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Table presenting the raw quantitative data

RED indicates an outlier

AMBER indicates close to being an outlier

GREEN indicates no concern

Raw Data (1 = baseline; 2 = 12-week follow-up)															
Experimental Group (ID number)	**Age**	**Sex**	**Impairment**	**Co-morbidity**	**Falls**	**BBS1**	**BBS2**	**GDS1**	**GDS2**	**FES1**	**FES2**	**SF-12(p)1**	**SF-12(p2)**	**SF-12(m)1**	**SF-12(m)2**
3	51	Female	Right arm/leg		0	26	51	30	23	29	20	32	51	40	37
5	63	Male	Left arm/leg		0	48	51	18	18	34	25	45	40	27	26
6	85	Male	Visual disturbance	Spinal	1	52	38	3	3	31	31	19	19	64	64
10	80	Female	Left arm/leg		0	44	50	22	15	86	14	25	34	45	43
12	73	Male	Right arm/leg		0	49	51	22	5	12	10	51	53	47	50
14	81	Female	Right arm/leg		0	26	49	24	22	80	17	40	25	45	33
22	67	Female	Left arm/leg		0	-	53	19	9	15	10	35	47	41	52
29	82	Male	None		0	54	54	3	4	10	14	51	51	51	55
31	53	Female	Right arm/leg		0	54	56	4	2	10	10	50	46	51	47
37	72	Male	Left arm		0	55	55	9	8	39	26	35	36	46	50
38	83	Female	Left arm/leg		0	49	49	13	13	91	15	37	40	46	52
42	84	Female	Dizziness		0	27	46	18	14	81	22	43	40	40	42
47	71	Male	Left arm/leg		0	44	50	4	0	27	16	37	40	50	60
48	70	Male	Left arm/leg		0	38	44	2	4	42	80	38	50	28	65
Control Group (ID number)	**Age**	**Sex**	**Impairment**			**BBS1**	**BBS2**	**GDS1**	**GDS2**	**FES1**	**FES2**	**SF-12(p)1**	**SF-12(p)2**	**SF-12(m)1**	**SF-12(m)2**
2	73	Female	Right arm/leg			34	45	4	12	32	10	42	40	55	43
7	62	Male	Left arm/leg			52	55	6	5	48	10	35	59	51	52
8	78	Male	Left leg			32	42	10	4	79	88	48	38	36	33
11	73	Female	Left arm/leg			-	-	13	-	34	-	38	-	42	-
15	60	Male	None			-	-	-	-	-	-	51	-	47	-
19	78	Female	Left arm/leg			-	-	5	-	85	-	41	-	59	-

30	66	Male	None			53	53	1	1	10	10	51	53	41	56
33	70	Female	Right leg			-	39	5	11	46	35	20	23	56	41
35	60	Male	None			54	-	9	-	89	-	34	-	55	-
40	86	Male	Right arm/leg			54	54	2	16	10	12	58	54	47	35
41	63	Male	Right arm/leg			53	53	0	2	10	10	49	49	57	57
49	74	Female	None			49	44	9	11	12	14	35	37	55	52
56	74	Male	Left arm/leg			48	-	2	10	84	100	38	18	65	71

Key							
	Age	**Impairment**	**Falls**	**BBS**	**GDS**	**FES**	**SF-12**
Green	-	-	-	Low risk of falls	-	-	
Amber	-	-	-	Medium risk of falls	-	-	
Red	Young	No impairment	Number of falls	High risk of falls	Severe depression	Has a fear of falling	

Appendix 35 Cut-off scores for the outcome measures used in the TCAS study

Berg Balance Scale

A cut-off score of <45 indicates greater risk of falling (Berg, 1992).

41-56 = *independent*
21-40 = *walking with assistance*
0-20 = *wheelchairbound*

Geriatric Depression Scale

30 items, answer yes or no. Zero or one point for each answer.

Normal	= 0-9
Mild depressives	= 10-19
Severe depressives	= 20-30

Falls Efficacy Scale

10 items, rate each item from 1 (very confident) to 10 (not very confident). Total scores can range from 10 (best possible) to 100 (worse possible). Lower scores indicate more confidence, and higher scores lack confidence with a greater fear of falling.
Cutoff score is a total score >70 indicates somebody has a fear of falling.

SF 12

A score <40 is below the average range. Low scores across the profile are indicative of impairment in both physical and mental health components.

12 questions ranging from 0-100. Zero is the lowest and 100 is the highest.

<45 =*impaired*

<40 = *significantly impaired* 40-44 = *average* (Ware, 2010).

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To Whom It May Concern

I can confirm that I am employed by the University of Huddersfield to support health research within the School and will be able to provide additional statistical support to Elizabeth Harkin with regards to her study. I have over 50 publications in peer-reviewed journals and have published in this clinical area (1). My publications also include reports of RCTs and pilot/feasibility studies (2, 3).

A full list of publications may be found at http://www.hud.ac.uk/ourstaff/profile/index.php?staffid=763

1. Ross, D., McCluskey, S., Fletcher-Cook, P. and Stephenson, J. (2014) 'The reliability of the Leeds Movement Performance Index (LMPI): a new tool for neurological physiotherapy' *Physiotherapy Theory and Practice*, 30 (8), pp. 581-587. ISSN 0959-3985

2. Ousey, K., Milne, J., Cook, L., Stephenson, J. and Gillibrand, W. (2014) 'A pilot study exploring quality of life experienced by patients undergoing negative pressure wound therapy as part of their wound care treatment compared to patients receiving standard wound care' *International Wound Journal*, 11 (4), pp. 357-365. ISSN 17424801
3. McCann, T., Songprakun, W. and Stephenson, J. (2015) 'A randomized controlled trial of guided self-help for improving the experience of caring for carers of clients with depression' *Journal of Advanced Nursing*, 71 (7), pp. 1600-1610. ISSN 0309-2402

John Stephenson

Dr. John Stephenson

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INVESTORS IN PEOPLE

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Notes re sample sizes (*from Kim via IPS study with Warwick, June 2016*):

Our experience is that for feasibility studies of this nature that around 30 participants will be sufficient for us gain sufficient understanding of delivering the intervention to inform any proposal for a main study. No formal quantitative assessment of outcomes is needed and hence none is proposed for this study. However, data on around 30 people will give us sufficient data to inform the parameters for a main trial application. A key parameter requiring estimation is the population-specific standard deviation. Browne has shown that a sample size of 30 is sufficient for estimating this in feasibility studies.[1] This is now a *de facto* rule of thumb.[5] Further, in our qualitative work streams this sample size (and separate sample sizes of 15) will likely be conducive to surpassing data saturation levels (*i.e.* the point at which few or no novel themes are emerging).[3]

1 R. H. Browne, 'On the Use of a Pilot Sample for Sample Size Determination', *Stat Med,* 14 (1995), 1933-40.

3 P Fusch, and LR Ness, 'Are We There Yet? Data Saturation in Qualitative Research', *The Qualitative Report,* 20 (2015), 1408-16.

5 G. A. Lancaster, S. Dodd, and P. R. Williamson, 'Design and Analysis of Pilot Studies: Recommendations for Good Practice', *J Eval Clin Pract,* 10 (2004), 307-12.

From: John Stephenson
Sent: 10 May 2016 14:50
To: Elizabeth Harkin U0553488
Cc: Kim Burton
Subject: Sample size and randomisation

Hi Liz

Here is a summary of our discussion – any or all of which you can use in your ethics application if it would help.

Regards
John

TO WHOM IT MAY CONCERN

I have discussed the issue of sample size and randomisation with Elizabeth Harkin regarding randomisation and sample size for her study.

Liz explained that her study is a feasibility study, not a full-scale randomised controlled trial. Hence it is not appropriate to suggest a sample size that will give sufficient power to reject the null hypothesis that population and control means are equal. Furthermore, a feasibility study would probably lack the necessary information of data variability to estimate sample size.

Recent work by Lancaster et al., Sim and Lewis, and by Julious suggest that for 2-arm feasibility studies, total sample sizes of 24-50 for feasibility studies (i.e. 12-25 per arm) should be adequate under most circumstances. Liz informs me that her intervention is scheduled to take place over a 12-week period, will require participant attendance on 2 occasions per week, will be entirely supervised, and is not especially onerous to participants. Although it is difficult to predict attrition loss, under such circumstances I would expect attrition loss to be in the region of 20% (in fact, a sample size of 50 with an anticipated attrition loss of 20% allows us to be 95% confident that the true rate will be in the interval given by (9%, 31%)). Recruitment of 50 participants might therefore result in a sample for analysis of 40 in total (20 per arm) – about the mid-range of the estimates proposed in the sources below.

Liz informs me that she anticipates recruiting a range of participants who are reasonably homogenous in terms of age, sex and co-morbidities; this proposed sample size appears adequate to assess data variability for a subsequent follow-up full-scale study in the context of such a sample.

On the issue of randomisation, I suggest either simple randomisation using opaque sealed envelopes, or block randomisation using blocks of 2 or 4, again using opaque sealed envelopes.

Lancaster GA, Dodd S, Williamson PR. *Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Practice* 2004;10:307-312
Julious SA. *Sample size of 12 per group rule of thumb for a pilot study. Pharm Stat* 2005;4:287-291
Sim J, Lewis M. *The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. J Clin Epidemiol* 2012;65:301-308

Appendix 37 ***Qualitative interviews (excerpts)***

Legend for colour-coded themes

Theme 1: Expected outcomes = Lilac	
Theme 2: Perceived benefits = yellow	
Theme 3: Barriers to Tai Chi = green	
Theme 4: Facilitators to Tai Chi = red	
Theme 5: Acceptability of the Tai Chi programme = turquoise	

Excerpt from Interview 1

I: Interviewer

R: Respondent

I: Why did you want to participate in the study?

R: To get better. To get back to me

I: And what made you…

R: It was err…to do with my brother really because he had Guillain-Barré Syndrome which is basically a virus that attacks the whole nervous system and he couldn't err..feed himself or anything like that when he was poorly. And somebody recommended Tai Chi and he went to Tai Chi and he still goes to Tai Chi and he's a normal person now, so that's what attracted me to it **(1b)**

I: In the lessons, did you prefer it where there's a lot of people or just you on your own, or..?

R: Err…it doesn't really matter either way to me whether there's loadsa people or a small amount of people

I: And…when your husband is here, do you rather your husband be in the class with you?

R: It helped me to begin with with because I copied 'cos I couldn't comprehend what was being said to me and I had to literally copy everything that was done so I used to watch him 'cos Richard would be with somebody else, so. .**(4b)**

I: And if he hadn't have brought you, would you have been able to come to Tai Chi?

R: Err..I would have come on the bus, yes

I: Would you have found a way?

R: Oh yes, yeah. It was that important to get back to normal

I: Yeah, and what disability did you have?

R: I still got it. Well, my left side, my left upper arm and collar bone and basically chest

I: And have you found that Tai Chi has helped with that?

R: Oh yes. Yeah,yeah

I: In what way?

R: I can move it. I can lift it, whereas I couldn't lift my arm from above my head before. And now I can. I can literally…hands up (laughs)

I: Do you think it's affected your balance?

R: I'm more confident with my balance. When I first come here I was giddy all the time. I felt light-headed and..but as the previous participant said, it's probably the tablets (laughs)

I: (laughs) Have you changed your tablets since then?

R: No. no it's been the same medication ever since

I: How did you feel before you did the Tai Chi? About the tai chi classes. Was it what you expected?

R: It was better than I expected, one hundred per cent better than I expected

I: In what way?

R: My movements. Erm…before Tai Chi, the movements were eratic. I couldn't hold things without having to force myself to let go, but now I'm more aware of my left hand and my left arm. It'll actually do what I want it to do, whereas before tai chi, my left hand decided to do what it wanted to do **(2a)**

I: Erm…did you have a fear of falling before you did tai chi or…

R: No, I haven't had that experience of falling over but I've had the experience of being little and open spaces were unnerving is the word. I can use err…basically like car parks and supermarkets…the open space, it just used to unnerve me and I got giddy then but never to the point of falling over **(1a)**. But I always steady myself

I: What..you know, the actual exercises in Tai Chi…how did you find those?

R: Erm..at first, I couldn't comprehend other than following David, and David would walk with me and I'd just mimick his movement

I: That's due to the stroke?

R: Yeah

I: What did you think to the instructor?

R: Oh, fantastic. Ah, really good. Erm..encouragement. The encouragement that he gives you, and he's there if you've messed up. And show you the right way to do it, yeah. Absolutely wonderful, yeah. Can't fault him in anyway shape or form. I wasn't being detrimental to him when I said I couldn't comprehend what he said. That was me not comprehending what he was telling me to do because if anybody had told me to do anything, I'd just stare blankly at them and try and work out what they wanted me to do **(5a)**

Excerpt from Interview 2

I = Interviewer
R = Respondent

the booklet to do other stuff, dint you, like walking, so would you have preferred to have seen stuff from the actual class more, you know, the stepping and stuff in the booklet?
R: Yeah, possibly that, yeah, 'cos I did a lot of..we..we live on a farm on the flat areas round the house. That's when I did my…you know…if I was going out to hang washing out and things like that. Erm…and…yeah but err..but yeah..things…more things in the booklet about..for the walking, yeah
I: Erm..what about confidence levels?
R: Yeah, it wa' great for confidence 'cos at first you…you just feel really…you like you're not sure, you know what…what's going to happen in the future and it gave me that confidence..erm..to be able to go out an'…if my mum came for me shopping and my cousin, you know and…'cos when you're walking at first you feel..you think, oh everybody's looking at me and..but you just…it gives you the confidence to…to be able to do all these things, so **(2b)**
I: Erm..and do you feel it improved balance at all, or was balance a problem for you?
R: Erm..no, I think balance was improved **(2a)**. Erm..yeah, it was just everything about it was great really an' as I say, the support in the class in general was fantastic and yeah..and I still did other bits at home like physio but this was the main thing to get me back on track, so.. **(5a)**
I: Was it all easy to follow, like the instructor, the DVD and the booklet? Was it

easy to understand?

R: Yeah, yeah, everything was easy to follow and, of course, if you're coming every week, you've got those things in your mind and so you can, you know, do those at home if you've got space to err..do the exercises. But yeah, it was great **(5a)**

I: And what did you think of the instructor?

R: The instructor was lovely, yeah., he was very, kept you very calm and erm..yeah and…any problems you had you felt that you could, you know and I think on one occasion I did have a problem where emotionally and he just sat you down an' let you do things at your own pace and err..and he was fantastic, he was really nice **(5a)**, yeah

I: And did you find it repetitive or was it at the right pace..was it too slow, the pace that he was going…did you feel like, oh when am I going to move onto the next bit, or was the pace ok?

R:Yeah

I: Some people have thought it's a bit repetitive and they couldn't wait to move on but they were saying it wa' taking ages for you to move on to the next bit

R: Yeah

I: How did you find it?

R: Personally, I thought it was ok because I struggled with the coordination at first and going over that…and I think that's why emotionally I got very upset one day but you just keep going over it and over it and eventually, it clicks and it all falls into place and yeah and that gives you confidence to know you're doing the right thing, so…**(5a)**

I: Knowing you're doing it right before moving on?

R: Yeah..yeah, definitely for me, yeah

I: Erm..what's..did the therapists see you at home?

R: Errr..no I think initially the..erm..I had somebody come out, I think two, three days when I came out after having the stroke. Erm..

I: And they didn't see you after?

R: And I haven't seen them afterwards, no..so erm..

Theme 1: Expected Outcomes			
	1a Physical	**1b Emotional/psychological**	**1c ADLs**
	Participants expected to be able to get out of the house and revert back to their previous level of physical ability: Because it wa' just getting me out of the house and getting me limbs working again, 'cos I had an hour you doing things and different things whereas I dint wi' them. They want err…there that long enough, really. You know, it wa' just a matter of erm…quarter of an hour or so, that wa' all. So really, it dint do a lot of good. (PR, p.1, lines 43-46) It was err…to do with my brother really because he had Guillain-Barré Syndrome which	Some participants were depressed prior to the intervention. The study was a motivating factor to become active again in the hope of regaining the motivation to perform some ADLs: I wanted to get moving again. I felt that it wa' 'end o' line for me. I mean, err (sighs)…the way I felt…I felt so depressed to be quite truthful. [] I just felt I wa', you know, 'end o' line sort o' thing. I can't explain it how you felt, but I just dint feel well. [] And I just want to get walking and getting out to 'shops which I haven't been to 'shops yet. (BG, p.3, lines 98-106)	Outdoor ADLs were particularly frightening for some participants with regards to fear of falling: [] I've had the experience of being little and open spaces were unnerving is the word. I can use err…basically like car parks and supermarkets…the open space, it just used to unnerve me and I got giddy then but never to the point of falling over. (JM, p.1-2, lines41-44)

	is basically a virus that attacks the whole nervous system and he couldn't err…feed himself or anything like that when he was poorly. And somebody recommended Tai Chi and he went to Tai Chi and he still goes to Tai Chi and he's a normal person now, so that's what attracted me to it. (JM, p.1, lines 4-8) Some participants didn't know what to expect but thought that if Tai Chi made a difference it would be positive. I don't know, you saw me in 'hospital and I just thought it might be something, have a go, you know, you just don't know what to do when you've err…when you first have a stroke an' all that. You're		

	pretty shocked, you don't know what to do, do you? So, I thought, well, I'll have a go at anything, really. Try an' help, you know. (NM, p.1, lines 2-5) Err…I didn't know what to expect to be quite honest, I ant a clue, you know, ermm, when they say physio, you think right I'll work on this arm and go pumping iron or something, you know what I mean, it's not really, no. But yeah, it wa' alright, I've enjoyed it. (NM, p.1, lines 38-41)		

Theme 2: Perceived Benefits			
	2a Physical	**2b Emotional/psychological**	**2c QoL**
	Those with more severe weakness found less benefit than those with mild weakness: My movements. Erm…before Tai Chi, the movements were erratic. I couldn't hold things without having to force myself to let go, but now I'm more awarof my left hand and my left arm. I'll actually do what I want it to do, whereas before Tai Chi, my left hand decided to do what it wanted to do. (JM, p.1, lines 36-39) "Ermm..as I say, I think it's more for a well-being thing rather than erm…trying to overcome injury sort of thing, you know..err..I just..I don't	Despite some many participants feeling tired following Tai Chi, this tiredness was soon replaced by increased energy levels: At the beginning, I'd go home and I'd sit down and I'd fall asleep and I'd be asleep for couple of hours, but now it gives me energy, it wants me to go out and about, not to sit on the settee and fall asleep. I've got more energy now. (JM, p.2, lines 72-74) Tai Chi was perceived to increase mental wellbeing: [] I was really depressed, but when I started coming and doing Tai Chi, and then there	Participants were mindful of what was taught in class whilst performing household tasks: I walk more carefully than I did before, definitely. [] More conscious of when I'm walking, yeah, definitely, yeah. Otherwise, it's silly not to. You know, just be careful all 'time, really. An' try not to do things that you can't do, you know. But err…I'm careful, yeah. And nothing's happened so far, so hopefully, that's it. (PR, p.7, lines 287-292) Participants found social benefits in attending Tai Chi classes:

	know..” (NM, p2, lines 79-80) Participants acknowledged that they would not reach their previous physical ability but were grateful that they achieved some degree of independence: I just want to thank Liz and Richard for helping me so much and I appreciate it very much. An’ I thank them from the bottom of my heart. It’s really done me good. An’ I’m so grateful that they’ve helped me to get back to normal nearly. I’m not there yet, I know I’m not, but they’ve helped me immensely. An’ I’m so grateful. (BG, p.7, lines 178-181)	were other people there ‘same as me, it bucked me up and made me feel better that I want on my own [laughs]. [] But err…at first, I felt that wa’ it. But now, I feel me old self again. (PR, p.3, lines 99-105)	Yeah, an’, you know, you can…you can say, ‘I did so and so yesterday,’ and I want right good…it happened an’ you get their opinion, don’t you? I mean, it’s nice to have somebody’s opinion that’s in ‘same boat as you. (BC, p.6, lines 154-157) One participant found increased independence affected her emotional state, which suggests a holistic approach should be considered: (crying)…And then I thought I wished I hadn’t started driving ‘car…yeah, so when I started driving initially, that was…you can’t wait to drive but then…it was easier coming in the transport and somebody picking you up an’ taking you back.

	Some participants regarded Tai Chi as their main rehabilitation rather than community therapy: I felt the Tai Chi for me was the main…the main thing to get me better and to erm…for my walking and everything. I relied more on the Tai Chi than the books, although I did the books up and down them steps at home and erm…but yeah, for me, the Tai Chi was the main thing. (AM, p.4, lines 102-105)		Although the days were a bit longer, but you really appreciate the ambulance staff coming along and transporting you, so… (AM, p.5, lines 132-136) Ermm…no, I've wanted to come back really, but it was just that, yeah, you're life does get back to normal, then, of course, once you're driving and people erm…so you've appointments and you've got to…so it…it does the driving part did affect it really, so…it was a lot easier with the transport. (AM, p.6, lines 152-155)

Theme 3: Barriers to Tai Chi			
	3a Physical	**3b Emotional/psychological**	**3c Environmental**
	Co-morbidities were a hindrance for some participants, which may also be a reason some stroke survivors do not wish to take part in the study: "Well, I think if it hadn't been for my hip, I'd have been well away. But I haven't…but as soon as I try and put weight on this hip [points to hip], I know I'm going to wobble." (BB, p.2, lines 26-29)	Fear of falling and lack of confidence may contribute to stroke survivors taking part in Tai Chi: "Well, I wasn't very confident 'cos I wasn't balancing properly. And I was frightened of falling." (BG, p.1, lines 24-25)	Some participants experienced a delay in attending their first class due to community therapy service appointments: "Oh well, I couln't get in 'shower to start with, I had to wait for somebody coming and bringing me the err…buffets…and then somebody had to come an' fix the err…handle on 'outside the shower so I could get in the shower. And then sit on the buffet…and then there wa' somebody in wi' me all the time at the beginning." (PR, p.2, lines 87-90) Some participants relied upon the willingness of their

			significant other to bring them to the venue: He's daft. He's err…he'd have been better off dropping me off and then coming back for me. [] Or going to 'café and then coming when I…I could go an' look for him or sumat like that. [] 'Cos it want up to him. You know, he didn't…he didn't want to do it. (EJ, p.2, lines 27-33) The shuttlebus system and public transport were not used by any participants because of an inability to get to it: 'Cos like this…if I go from 'bus here, I can get a bus from 'bottom o' road to Wakefield and then I've got together one from there to Stanley Royd and

			walk over, you know, it's…I got 'bus.. I don't do buses. An' I got 'bus at end of this road 'other day and I went seven… [] …seven bus stops I went to. Two pounds sixty. Two pounds sixty! For seven bus stops, so I says to 'woman that wa' driving, which part o' 'bus 'ave I bought? (laughs)….Jesus… (PB, p.9, lines 379-386)

Theme 4: Facilitators to Tai Chi			
	4a Group Exercise	**4b Social Support**	**4c Environmental/Practical**
	Participants enjoyed the friendships made in classes and liked to share experiences and support each other: "It's like I say, the group, there's a bit of comradeship, you…you…you all get on…you can talk and 'experience that you've had, they'll tell you about what they've done and what you've done, yeah." (RG, p.5, lines 139-141) By observing others, progress could be assessed: Erm…well, I don't mind either way, it's nice to be with other people and err…I think you can assess your own progress when you see other people, yeah. []	Those who lived alone found that classes offered social support in terms of other participants and research staff: Err…just to communicate and talk to people because when you live on your own, it's funny, you've nobody there, only when they come visiting, whereas if you…it's a day out in a sense. I know it's to make me feel better, but it makes me feel better 'cos I'm going to see people. And talk to people. An' I've met some nice people. (PR, p.3, lines 119-122) Significant others were a source of support during classes in times of uncertainty:	The YAS service helped seven participants reach the tai chi venue. Without this transportation, the numbers in the class would have been halved: 'I wouldn't have been able to attend the classes if it wasn't for the transport.' (p1, JO).

	…but I don't make it obvious. I sort of look through the corner of my eye. (JO, p.2, lines 45-49)	It helped me to begin with because I copied 'cos I couldn't comprehend what was being said to me and I had to literally copy everything that was done so I used to watch him 'cos Richard would be with somebody else, so… (JM, p.1, lines 13-15)	

Theme 5: Acceptability of the Tai Chi programme				
	5a Tai Chi Classes	**5b Home Practice**	**5c Home Practice Materials**	**5d Questionnaires**
	knowledgeable staff made participants confident in performing the exercise, knowing that somebody was watching out for them. The appreciated individual encouragement and guidance. Liz and Richard know what they're doing an' they're there to advise you an'…and tell you what to do. An' I think that's better to have somebody with you who knows 'cos they don't just stand, that they walk with you and they do the exercises with you. An'	Home practice was adapted by participants to meet their individual needs, and incorporated movements taught in class into their ADLs: I incorporate it into everyday life like watching TV, holding cups. I do the walk all the time. I go out in the garden, I go out and make a cup o' tea. It's the walk that's…I want to do that more than I want to do the arm movements. And holding the ball. I've…I still have difficulty remembering which way it's supposed	The home practice materials were only used initially because participants found that they had memorised the exercises quickly. They chose which exercises would benefit them the most and deviated away from the home practice materials: Make the DVD with more precise movement because you think your DVD has stopped. And it's not, it's the slight movements and you can't really…they're not really defined on the CD I've got. [] Err…when	Overall, questionnaires were easy to understand and complete, with one participant getting confused over the scoring system on the FES, and one participant finding one GDS question ambiguous and difficult to answer: 'They were fine. Everything wa' laid out what you'd to do and how to fill it in, so yeah, so from that point of view it wa' perfect.' (p4, AM).

	they can see how you're doing, whether you're making it any better or not, but…in my case, they've done well for me. An' I can't thank 'em enough for the help and advice they've given me. (BG, p.8, lines 184-189) The encouragement that he gives you, and he's there if you've messed up. And show you the right way to do it, yeah. Absolutely wonderful, yeah. Can't fault him in any way, shape or form. I wasn't being detrimental to him when I said I couldn't comprehend what he said. That was me not comprehending what he	to go around, but I practice and persevere, so. (JM, p.3, lines 118-121) Most participants said they would continue taking part in home practice exercises after the study ended: Oh, I shall continue now, definitely, yeah…definitely. That is a must is that, yeah. I think you've got to keep yourself moving, you know. You sit down too long, I think. [] Exercises we do when we're sat down, I do that as well, you know, all 'time. (PR, p.5, lines 211-220)	Richard's got his back to you, it doesn't look like he's moving. [] There's no real definition, whereas here, I can physically see him moving, but on the DVD, whether it's…it looks like it's paused and you're fast-forwarding then you've lost it, so you have to go back and it's…it's the small movement that he makes, they're not defined on the CD. Pronounced, yeah. But it may be the DVD I've got. It may have been paused for a few minutes, you know what I mean, so… (JM, p.3-4, lines 131-135) Err…at the beginning it was down to the DVD and	

	was telling me to do because if anybody had told me to do anything, I'd just stare blankly at them and try and work out what they wanted me to do. (JM, p.2, lines 51-56) Some participants preferred more flexible days to attend Tai Chi, whereas others preferred set days and establish a routine: Err…the best part of it was erm…just initially for me was knowing every Thur…Tuesday and Thursday that you were going somewhere and that got you up an' made you get sorted, whereas		booklet, and I was following those in a mirror. And now, there's a couple that I miss out sometimes, the sitting up err…the sitting-standing, where it does your hips. Sometimes, I forget that and that comes in at the last, but it's basically from memory. (JM, p.3, lines 113-116)	

	when you just come out of hospital, you lose your confidence and err…so being able to come on a Tuesday an' a Thursday was great. (AM, p.4, lines 117-120)			

SPINE RESEARCH

30 Queen Street, HD1 2SP
Tel: 0484 535200

Analysis of invoice costs

Date: 09.12.15

Invoice # SR01/15

Cost centre	Item	Code #	Amount due
SRU002	Payment for Tai Chi classes involved in PhD project		£1,706.85
(Malcolm Tillotson Fund)	(Phd candidate: Elizabeth Harkin)		
Totals	This empties SRU002		£1,706.85

West Riding Masonic Charities Limited
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Email: iw.mason@zen.co.uk

Date: 19th December 2016

Our Ref: Minor 16/17-21

Dear Ms Harkin,

PGM's Fund Grant
Proposed by Friendly Lodge No. 1513

I am delighted to inform you that the Freemasons of Yorkshire West Riding through West Riding Masonic Charities Ltd. have awarded you a grant of £1000 from the PGM's Fund and a cheque for this amount is enclosed.

This award is granted solely for the purpose of financing the project contained in the application submitted by the proposing lodge, namely, towards purchase of laptop and projector.

Please be aware that if the Project for which this money is intended does not go ahead, for whatever reason, then the money must be returned.

Your assistance in gaining maximum publicity for this grant would be appreciated and representatives from the Lodge will be pleased to liaise with you on this matter.

Finally, please accept our sincere appreciation for the excellent work that you do. The Freemasons of Yorkshire West Riding are pleased to be associated with you and hope that your success goes from strength to strength.

With very best wishes.

Yours sincerely,

Ian Wright

Ian Wright
Administrator of PGM's Fund

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