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Effectiveness of primary preventive programmes using motivational interviewing to support cardiovascular risk factor modification in individuals at increased risk; a systematic review and meta-analysis of randomised controlled trials

Justin Lee Mifsud

A thesis submitted to the University of Huddersfield in fulfilment of the requirements for the degree of MSc by Research (Human and Health)

Submission date April 2019

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Abstract

Background: Programmes using motivational interviewing, are promising in encouraging lifestyle change, but have not been well established and explored. The objectives of this systematic review and meta-analysis was to determine the effectiveness of motivational interviewing in supporting modifiable risk factor change, in individuals at increased cardiovascular risk.
Methods: Systematic review and meta-analysis with results reported using Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement. Health related data bases were searched for randomised controlled trials, from February 2013 to August 2018. Criteria for inclusion included; preventive programmes, using motivational interviewing principles, aiming to modify cardiovascular risk factors in adults of both genders, representing all ethnicities and employment status, and having at least one or more modifiable cardiovascular risk factor/s. Two reviewers independently conducted a quality appraisal of included studies using an adapted Cochrane framework.
Results: Seven studies met inclusion criteria. No statistical difference between groups for smoking status and physical activity were reported. A random effects analysis from 3 studies, determined a synthesized estimate for standardised mean difference in weight of -2.60kg (95% CI –4.793 to -0.404 kg; p=0.005), with high statistical heterogeneity. Pooled results from 2 studies, determined a mean difference in LDL-c of 0.43mg/dl, but was insignificant. A range of possible effective intervention characteristics were identified: application of affirmation, compassion and evocation, combined with education, consisting of 1 in person and 12 telephone-based sessions of 15 to 30 minutes each for 12 consecutive weeks, delivered by a nurse expert in MI through an outpatient-clinic.
Discussion: While motivational interviewing may support individuals to modify risk, its effectiveness remains uncertain. Methodological quality to date is limited, having studies contaminated with performance, detection and reporting bias. Application of motivational interviewing was found to be insufficiently reported across all studies. Its strengths and limitations need to be explored further, through robust studies.

Keywords: cardiovascular disease, motivational interviewing, prevention, modifiable risk, clinical trial

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List of abbreviations.

MI- motivational interviewing.
CVD- cardiovascular disease.
CHD- coronary heart disease.
OARS- open-ended questions, affirmation, reflection, summarization.
LDL-c- low density lipo-protein cholesterol.
BMI- body mass index.
PICOs- population, intervention, comparison, outcome, study design.
PRISMA- preferred reporting items for systematic reviews and meta-analyses.
GRADE- grading of recommendations, assessment, development and evaluation.
RCT- randomised controlled trial.
MITI4- motivational interviewing treatment integrity.
MISC- motivational interviewing skill code.

Chapter 1 – Introduction

1.1 Introduction.

To better address the needs of individuals with a high-risk profile, the European guidelines on cardiovascular disease (CVD) prevention in clinical practice have focused on prevention through behaviour change by highlighting and promoting lifestyle therapies (Piepoli et al., 2016). Central to these preventive guidelines is the delivery of a person-centred approach; the active engagement of the individual in the treatment decisions and management of wellness. Motivational Interviewing (MI) has been graded by the European Society of Cardiology as class 1 level A of evidence, in promoting behaviour change (Piepoli et al., 2016). A recent systematic review has identified that while some evidence indicates changes in behaviour following the application of MI, it is unclear whether this style of counselling can ultimately support modifiable risk factor change. In addition, it is uncertain in which ways this can work with regards to primary prevention, as this area of research has remained suboptimal (Lee, Choi, Yum, & Doris, 2016). However, it is evident that lifestyle behaviour change is challenging and complex. The predominant reason for the desire to identify and comprehend mechanisms and the conditions under which they are effective, lies in the wish to encourage at increased CVD risk individuals to modify their risk-taking behaviour and adhere to lifestyle therapies (Mifsud, 2017; Piepoli et al., 2016). In this chapter the rationale for the proposed review will be highlighted in context of current research and its limitations.

1.2 Background.

1.2.1 Primary prevention.

Primary prevention involves the screening and assessment of populations for CVD risk, and in turn, the implementation of preventive strategies (including lifestyle and pharmacological interventions) to reduce the risk of developing diseases and their complications (Piepoli et al., 2016). The European guidelines emphasize the need for CVD risk assessments in asymptomatic individuals without CVD, who have a positive family history of early onset CVD (Piepoli et al., 2016). A systematic review of 16 studies highlighted the importance of identifying individuals at the highest risk, as these individuals have the most to gain in terms of reduction in the percentage of CVD risk (Willis, Davies, Yates, & Khunti, 2012). For example, systematic screening of first degree relatives with premature CVD has potential benefits for primary prevention efforts in preventing developing CVD (De Sutter et al., 2003; Horan et al., 2007). The European Society of Cardiology suggests that populations at increased CVD risk should have improved access to diagnosis and treatment options, and a priority should be given to attaining lower risk targets (Piepoli et al., 2016). According to the European Society of

Cardiology, those Individuals with major traditional risk factors such as hyperlipidaemia, high blood pressure, diabetes mellitus, smoking, and those with familial hyperlipidaemia or family history of premature CVD, are considered as individuals at increased CVD risk (Piepoli et al., 2016). The European Society of Cardiology has also developed a risk calculator which was based on population studies from 12 different countries, with a total of 205,000 individuals. This calculator showed a predictive value of about 79% (C-index 0.73-0.85) for cardiovascular death in ages ranging from 35 to 64 years in both men and women (Berard et al., 2014). The more risk factors an individual has, the higher is the total CVD risk. This calculator categorizes the individual as being at low risk (<1% chance of having fatal CVD in 10 years' time) moderate risk (1-5%), high risk (5-10%) or very high risk (≥10%). This will all depend on the individuals' age, gender, country of origin and presence of traditional risk factors, namely increased systolic blood pressure, increased cholesterol levels and smoking status (Piepoli et al., 2016).

1.2.2 Cardiovascular disease attributable deaths and its modifiable risk factors.

CVD remains a dominant cause of disability and death globally, with an estimated 17.7 million individuals dying of CVDs in 2015. Of these, it is estimated that 7.4 million were due to coronary heart disease (CHD) (WHO, 2018). Furthermore, in the European region, about 3.9 million deaths per year are attributed to CVD and of these, 1.8 million were due to CHD. The fifth edition of the European Cardiovascular Disease Statistics (Wilkins et al., 2017) has reported that the strongest behavioural risk factor contributing to the risk of CVD mortality across the European region is diet, with an increase in fat consumption over the past 3 decades being reported. Moreover, levels there is a high prevalence of obesity in both adults and children and also prevalence of diabetes has rapidly increased by 28 % in the past decade , and in some countries more than others (Wilkins et al., 2017). Countries such as Belgium, Malta and Portugal, diabetes prevalence has reached 6 %, 9 % and 9.5 % of the total population respectively, whilst Greece has the lowest prevalence (2.8 %), which have remained constant throughout the past years.

1.2.3 Preventing the development of cardiovascular disease through healthy lifestyle.

There is no doubt that engaging in a variety of unhealthy lifestyle activities, or failure to make healthy lifestyle choices, is associated with the incidence of CVD (Yusuf et al., 2004). In part because of the known seriousness of the cardiovascular health risks, preventive cardiology has highlighted the importance of lifestyle interventions, namely smoking cessation, physical activity as per JES 5 guidelines (Perk et al., 2012) and a cardio-protective diet, such as the Mediterranean diet. Adherence to these lifestyle interventions proved to be impactful on the reduction of CVD risk (Piepoli et al., 2016). Smoking cessation in patients with established CHD showed a reduction in risk of future coronary

events of about 36% and a significant reduction in premature mortality (Critchley & Capewell, 2003; Health & Services, 2004). After one year of abstaining from smoking, the excess risk of CHD is postulated to decrease by about 50%. Smoking cessation, apart from being the most cost effective, was shown to be superior to any other cardio-protective drug in reducing the risk of mortality (Freemantle, Cleland, Young, Mason, & Harrison, 1999; Pignone, Phillips, & Mulrow, 2000; Trialists'Collaboration, 2002). A Mediterranean diet score of only 2 points over the median score, was associated with a 10% reduction in the incidence of CVD and an 8% reduction in all-cause mortality (Sofi, Abbate, Gensini, & Casini, 2010). Moreover, the PREDEMID study, a multi-centre randomised controlled study, has also shown a significant cardio-protective effect by getting patients to adhere to a Mediterranean diet (Estruch et al., 2013). Physical activity of approximately fifteen minutes each day was also found to be impactful on the reduction of mortality, even if it is of a low frequency (Wen et al., 2011). The impact is even greater in patients with established CHD (Anderson et al., 2016; C. K. Chow et al., 2010). In addition, physical activity can significantly lower the risk of weight gain and helps in preventing developing hypertension (Committee, 2018). Obesity, overweight and body fat distribution, are associated with a cascade of other risk factors, such as insulin resistance, hypertension and hyperlipidaemia (Rippe, 2018). Weight reduction of about 7 %, was reported to be effective in improving blood pressure and glucose and lipid metabolism (Group, 2010; Johnston, Moreno, & Foreyt, 2014). Although there is enough evidence showing a cardio protective effect associated with adherence to healthy lifestyle interventions, lifestyle change leading to coronary risk factor modification can be challenging and generally the results are dismal (Kotseva et al., 2019; Mifsud, 2017). This is why researchers try to find effective methods to motivate individuals to adhere to these lifestyle changes (Perk et al., 2012). MI has been described as promising with regards to encouraging clients to adhere to lifestyle change in an attempt to improve their coronary risk factor profiles (Thompson et al., 2011). This approach proposes that as collaborative communication takes place between the clinician and the client, the client's motivation is strengthened, resulting in an increase in commitment towards behaviour change (Levounis, Arnaout, & Marienfeld, 2017; Miller & Rollnick, 2012; Thompson et al., 2011).

1.2.4 Motivational interviewing.

MI is reported to be effective in primary clinical settings, and one MI session of fifteen to twenty minutes seems to be effective in changing behavioural outcomes, including an improvement in modifiable CVD risk factors (Thompson et al., 2011; Van Nes & Sawatzky, 2010; VanBuskirk & Wetherell, 2014). It is also of note that MI has been found to outperform traditional advice-giving (Rubak, Sandbæk, Lauritzen, & Christensen, 2005). In MI, the healthcare professional provides open-ended questions, affirmations, reflective

listening, acceptance, understanding and support to the individual (Franklin & Vanhecke, 2008; Stewart & Fox, 2011). In general practice, there could be times when patients are given little authority to make their own decisions (Zikmund-Fisher et al., 2010), an element which was highlighted in a Cochrane review of controlled trials, where it was suggested that future research should involve participants in the decision-making process, particularly with regards to promoting informed choices with individualized risk communication during screening tests (Edwards et al., 2013). Another systematic review, which made use of the National Heart, Lung and Blood Institute (NHLBI) hierarchy of evidence to screen the identified literature and exclude any published literature below level C, has identified thirteen studies (1 systematic review, 3 literature reviews, 4 meta-analyses and 5 primary studies). These studies have looked at the impact of MI on lifestyle risk factor modification (Thompson et al., 2011). The results of this demonstrated that use of MI is beneficial in supporting lifestyle behavioural modification. This may also come in a dose response relationship. The greater the dose of MI, the greater the extent of the impact. Furthermore, evidence shows that MI may be more useful with specific groups of individuals. While, MI is challenging in clinics with a busy patients caseload it is more effective when used in opportunistic encounters (Thompson et al., 2011). MI has also proven to be effective in small doses and, thus, this was suggested for the busy clinician. However, it is of utmost importance that the clinicians have received training in MI. For this reason, it was recommended that clinicians should be trained appropriately (Thompson et al., 2011). Another suggestion was directed towards furthering research so as to determine whether MI can be used with specific groups of at risk individuals, maximising the impact that it could have (Thompson et al., 2011). A more recent systematic literature review with meta-analyses which included research from 1980 to February of 2013, looked at the impact of MI on primary and secondary prevention of CVD risk factors (Lee et al., 2016). This showed that MI could be more effective than usual care in changing smoking habits, whilst indicating that MI positively impacted systolic and diastolic blood pressure, the result was however, not statistically significant. The review also showed that MI might have favourable effects on improving psychological measures. However, results for other outcomes were inconclusive. The researchers have suggested that there is the need for further research thus helping in identifying the ideal frequency and format of MI. It was further recommended that research should be carried out to provide more concrete data on the effectiveness of MI in increasing clients' motivation and lifestyle modification (Lee et al., 2016).

1.2.5 Theory of motivational interviewing.

The theory of MI is about avoiding the specialist trap; the communication style is mostly concerned with listening and understanding the person's views, without the clinicians superimposing their own views. There are four important elements which are interrelated and underpin the spirit of MI. These are: partnership, acceptance, compassion, and evocation.

Partnership entails that the collaboration between the clinician and client is active, with the clients being experts of their own lives, and the clinician doing less than half of the talking. The second element is acceptance. Acceptance is comprised of four major elements in MI; absolute worth, accurate empathy, autonomy and affirmation. Absolute worth refers to seeing the potential in every client and accepting what the client brings. The second key aspect is accurate empathy; the ability to understand the individual's experiences, without ever losing the 'as if' quality. The third element is the support of the client's autonomy, while the forth key involves affirmation; the clinician's identification and acknowledgment of the client's strengths and efforts. Compassion, the third element of the spirit of MI, requires the clinician to actively promote the welfare of their client and to give priority to the needs of their client. Lastly, the forth element of evocation, implies an evocation of the client's existent strengths (change motivations) (Miller & Rollnick, 2012).

Moreover, MI has four central processes. These are engaging, focusing, evoking and planning, Engaging is the process by which the clinician and the client establish a working relationship, leading to a focus (focusing) on the particular plan which the client wants to discuss, which in turn clarifies the direction the client wants to move (the goal). Once there is a goal, the third process is to elicit the client's own motivations for change (evoking). The forth process is planning which encompasses the structuring of a specific plan of action and developing commitment towards change (Miller & Rollnick, 2012).

Having these interrelated elements and processes, MI has been criticized for not having a coherent theoretical base. Primarily, MI is a clinical method (Miller & Rollnick, 2009), however there seem to be several theoretical influences which may contribute to its development. Researchers have made reference to the self-determination theory, a theory which may clarify the understanding of the methods of MI, its application and how can it lead to change. Till date, there seem to be lack of evidence-based knowledge in how MI methods can actually impact motivation towards a successful change. According to Markland (2005), the self-determination theory can provide a framework to understand how behaviour change occurs in MI. This theory focuses on autonomy. This is when, clients perceive themselves as the source of their own action to change. This is in line with the principles of MI, where the clinician respects autonomy to facilitate independent choices (Markland, 2005). Vansteenkiste (2012) pointed out that it is important for MI to become

a theory rather than remain a clinical model. Yet, it seems that little has been done in moving MI from a clinical method to having a more theoretical base. MI needs to clarify its theoretical uniqueness or similarities with other theories, and to clearly highlight the active mechanism which leads to change in outcome measures (Vansteenkiste, 2012). Otherwise, for researchers to clearly understand how MI works and why it can be effective, will remain uncertain.

1.2.6 Application of Motivational interviewing.

The practice of MI involves some important communication skills which go by the mnemonic acronym OARS (Levounis et al., 2017). This includes the use of open questions, affirmation, reflective listening, summarizing, informing and advising. By asking open questions, the clinician invites the client to reflect and elaborate. Affirmation allows the clinician to identify the client's strengths and reflect it back to the client to nourish their confidence in their ability to change. Reflective listening involves a demonstration of deep understanding from the clinician's end. This is when the clinician paraphrases the client's expressed thoughts in a way that allows the client to obtain a greater understanding of their situation. At the end of the session, summarizing is carried out by the clinician in an attempt to provide an overall summary of what has been said. This skill also highlights the notion that the clinician was carefully listening to the client and there is true understanding. Another important skill comes in informing and advising. This communication will take place, after permission has been obtained from the client, or if the client asks for information or advice (Levounis et al., 2017; Miller & Rollnick, 2012).
Application of MI, is dependent on the clinician's abilities of using MI skills (Ashton, 2011). For example, if the clinician is unable to recognize change talk, or unable to empathise with the client, this can diminish the effectiveness of MI. Another issue which could diminish the effectiveness of MI, is the application of the skill to a group of individuals together. In fact this was critiqued, as it would be difficult to reach a client centred approach, (Levounis et al., 2017; Lundahl & Burke, 2009). Therefore it was suggested that group based MI should be used only in a resource limited setting (Levounis et al., 2017).

1.3 Limitations of current research.

There are several limitations with regards to current research which provide a rationale for the proposed review. To our knowledge, no other systematic reviews have specifically focused on the effectiveness of MI as an intervention to promote the modification of modifiable risk factor amongst individuals at increased CVD risk, but without established disease. Lee et al (2016) conducted a systematic review about the effect of MI on lifestyle modification, physiological and psychological outcomes, and included both individuals with

and without established CVD. Their search was conducted in February 2013, so is now rather dated, therefore further supports the rationale for our review (Lee et al., 2016). Lee et al. (2016) included a total number of nine randomised controlled studies. Of which, seven studies were conducted in Western countries and two studies were conducted in Asian countries. Five of the studies recruited individuals at increased risk of developing CVD, two studies recruited individuals with established CVD and one study recruited both those at increased risk and those with established CVD, including both genders aged from 16 to 89. The MI interventions consisted of in person (in person sessions- time 30-60 minutes, frequency 2-5 times), or a combination of both face to face and telephone sessions (telephone sessions- time 10-30 minutes, frequency 1-4 times), delivered by people with different professional backgrounds, namely nurses, occupational physicians, physical activity specialist, registered dietician, exercise professional, life coach and a clinical psychologist. Results for smoking cessation and smoking reduction, showed a significant improvement after MI, but only one study reported a statistically significant difference between groups. Only two studies from five reported a significant difference between groups for physical activity levels, and no studies showed a statistical improvement for fruit and vegetable intake and reduction in the consumption of dietary fat after the MI intervention. An impact limitation noticed in the review by Lee et al. (2016), is that researchers had to rely on a relatively limited data to assess for blood pressure and BMI changes in individuals at increased CVD risk. This is because, to test for such variables in individuals at increased risk, data was only available in one of the studies.

Amongst individuals with established disease, three studies from four did not have a significant difference between groups for blood pressure after the MI intervention. Moreover, no significant change was found between groups for BMI. LDL-c and triglycerides did decrease after receiving the MI intervention, however there was no statistical difference between groups. Likewise, HDL-c did not differ when compared with control group (Lee et al., 2016).

Several limitations were identified in the review by Lee et al. (2016) which were not acknowledged by the authors. First, no specific details were reported about the characteristics of those who delivered the intervention, such as the MI training they received, or if they had experience in using MI. However, Lee et al. (2016), did mention that appropriate training should be provided and that MI clinicians should be appropriately experienced to be able to deliver MI sessions. The review would have been strengthened if the researchers had elaborated on the characteristics of those health professionals delivering MI such as the type of training they received, the number of hours of training, and years of experience delivering MI sessions.

The omission of this information is important as this could create bias with regards to the quality of the implemented interventions. In addition, Lee et al. (2016) did not elaborate

on other important intervention characteristics such as the format and dosage of the interventions using MI, and the MI session content.
Second, to rate the quality of a body of evidence, the Cochrane tool was not used, and this may have limited to inform risk of bias domains more in depth (J Higgins, 2011; JPT Higgins, Lasserson, Chandler, Tovey, & Churchill, 2016; Movsisyan, Dennis, Rehfuess, Grant, & Montgomery, 2018). Thus, based on the limitations of current research evidence, it is important to conduct an updated and expanded systematic review to assess the effectiveness of MI in supporting modifiable risk factor change in individuals at increased risk of CVD.

A systematic review is defined as an efficient and effective method to identify, critically appraise, and assess several relevant studies, pertaining to a single pre-specified review question (Akhter, Pauyo, & Khan, 2019). In the hierarchy of evidence, a systematic review is described as the cornerstone in evidence-based medicine. This approach was chosen as an appropriate methodology to summarise, elucidate, and present the evidence of the effectiveness of MI in supporting modifiable risk factor change. Additionally, the proposed review will assess the quality of recent international RCT publications and summarise the characteristics of the intervention in terms of the setting for the participants receiving the MI session, the identification of the session deliverer, the length, type and number of sessions, any requirements with regards to clinician training, and the MI session content. Furthermore, this approach will facilitate the identification of gaps about current knowledge and allow for evidence-based recommendations to be made for the implementation of key elements to support in developing a primary prevention programme to reduce CVD risk in at risk individuals.

1.4 Conclusion.

A systematic review to identify existing research focusing on MI to address modifiable cardiovascular risk factors in at increased CVD risk individuals is necessary. This will determine the intervention effectiveness and provide an account of the suggested mechanisms by which the intervention might encourage recipients at risk of developing CVD to change modifiable cardiovascular risk factors. This review will consist of a search from February of 2013 to August 2018, and include studies which specifically looked at the effect of MI on lifestyle and physiological outcomes in at increased risk individuals without existent CVD. In the next chapter an overview of the methods used will be provided in detail.

Chapter 2 – Methodology.

2.1 Introduction.

In this chapter the review question, aim and objectives being addressed will be provided, making reference to the study participants, intervention, comparisons, outcomes and chosen study design (PICOs). The design to guide the reporting of this review will be provided. The eligibility criteria using specific inclusion and exclusion parameters relating with the PICO elements, will be specified. This is followed by a detailed search strategy, describing the applied search limiters, and detailing the study characteristics used for eligibility. All information sources are described, together with the process taken to select studies, the methods used for data extraction and the method for collecting and confirming data. Finally, methods used to assess risk of bias and methods for data synthesis, are provided.

2.2 Aim.

This systematic review will evaluate the effectiveness of MI in supporting adults at increased risk of cardiovascular disease to make healthy lifestyle changes to reduce cardiovascular risk.

2.3 Review questions.

2.3.1 Is MI effective in supporting adults at increased risk of cardiovascular disease to make healthy lifestyle changes to reduce cardiovascular risk?

2.3.2 What are the characteristics of effective programme interventions using MI?

2.4 Objectives.

The objective of this review is to;

2.4.1 Determine if using MI in primary prevention is effective in modifying lifestyle behaviours (change in smoking status, dietary eating patterns and physical activity levels) compared to non-MI preventative interventions.

2.4.2 Determine if using MI in primary prevention is effective in modifying blood pressure compared to non-MI preventative interventions.

2.4.3 Determine if using MI in primary prevention is effective in modifying serum cholesterol compared to non-MI preventative interventions.

2.4.4 Determine if using MI in primary prevention is effective in modifying anthropometric measurements (BMI, weight and waist circumference) compared to non-MI preventative interventions.

2.4.5 Identify the characteristics of the study interventions using MI in terms of: the number, duration, type and setting of sessions, characteristics of the deliverer (professional discipline, training and experience), and the reported motivation interviewing content of the session.

Table 2.1 Shows the PICOs components which has led to the development of the review question.

Formulating the review question using the PICOs; population, intervention, comparative intervention, outcome components and study design	
P	Adults of 18 years or over, of both genders, all ethnicities and employment status, with at least one or more cardiovascular disease modifiable risk factor/s
I	MI as part of a preventive intervention programme
C	Other preventative interventions not consisting of MI
O	Changes in modifiable risk factors i.e. smoking, dietary patterns, physical activity, blood pressure and serum cholesterol, BMI, weight and waist circumference
S	Randomised controlled trials

2.5 Design.

Systematic review and meta-analysis reported using the PRISMA guidelines.

To reach good quality standards in reporting, that is a comprehensive analysis of the full range of literature on this particular topic, the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis)(Liberati et al., 2009) guidelines were utilized to guide the reporting of this systematic review. The PRISMA consist of 27-item checklist (Appendix 1. pg. 80), and a four-phase flow diagram (figure 3.1 pg. 31). This checklist was used to guide the reporting of this review in the most transparent manner.

In summary, the PRISMA checklist, highlights that the study title should identify itself as a systematic review, meta-analysis or both, and the title should reflect the PICOs approach used. Moreover, there should be a good rationale for undertaking such a review, including the potential contribution towards further research. The guidelines also highlight the importance of clear and specific inclusion and exclusion criteria. The summary of the results should be presented in a coherent way and with a clear conclusion, offering insight of the importance of the findings and providing future implications, and also recognizing any potential limitations (Liberati et al., 2009). As previously mentioned, the PRISMA guidelines strongly recommend the inclusion of a four-phase flow diagram. This diagram displays the number of records tracked by all of the searches, the number of records rejected after first screening, the number of records read in full text and the number of selected studies after applying the eligibility criteria. This is presented in the next chapter of this dissertation.

2.6 Inclusion criteria.

2.6.1 Types of participants.

The cohort consisted of adult participants of eighteen years and over, of both genders, representing all ethnicities and employment status, having at least one or more modifiable risk factor/s.

2.6.2 Types of intervention(s).

The intervention consisted of MI as part of a preventative intervention programme with the aim to support changes in cardiovascular modifiable risk factors amongst participants with one or more modifiable risk/s.

2.6.3 Types of comparisons.

The comparisons consisted of any other approach used that aimed to support participants to change modifiable cardiovascular risk factors, but did not include MI as part of the intervention. In this review the comparison may not have a heterogenic baseline of treatment across different study settings).

2.6.4 Types of studies.

Any international studies, but limited to randomised controlled trials as these are initially considered to have a high body of evidence (Akhter et al., 2019; Balshem et al., 2011). Studies using this design will be considered for inclusion to assess if the intervention brings about significant changes in modifiable risk factors, and to assist in identifying the characteristics behind its effectiveness. Other studies not using a randomized controlled methodology, such as case studies and qualitative studies, were not incorporated for this review.

2.6.5 Types of outcomes.

Primary outcomes.

The primary outcome in this review was to determine if MI supports change in modifiable cardiovascular risk factors (smoking status, dietary patterns, physical activity levels, serum cholesterol levels, blood pressure levels, weight, waist circumference, body mass index).

Measures of process.

The secondary outcome was to identify the requirements for the intervention to be optimally effective. To measure any improvements, this review extracted data which addressed the intervention elements which were likely to be associated with effectiveness. This was defined in terms of: the number, duration, type and setting of sessions, characteristics of the deliverer (professional discipline, training and experience), and the reported motivation interviewing content of the session.

2.7 Search strategy.

A systematic search strategy was formulated and piloted to comprehensively identify published primary literature of RCTs testing MI as an intervention for the modification of cardiovascular risk factors in primary prevention of CVD in adults.

Electronic searches of relevant databases were conducted to retrieve peer reviewed articles, published in English, from February 1st2013 to August 2018, as this search will adapt on an existing published review. A total number of eleven databases and three electronic journals were searched;

EBSCO (CINAHL Complete, PsycINFO, Academic Search Complete, Cochrane Central Register of Controlled Trials), (2013- August, 2018).

MEDLINE ProQuest, (2013- August, 2018).

DynaMed Plus, (2013- August, 2018).

Ovid, (2013- August, 2018).

PubMed, (2013- August, 2018).

Wiley, (2013- August, 2018).

SCOPUS (2013- August, 2018).

Web of Science (2013- August, 2018).

Electronic journals searched:
EBSCO- E-Journals (2013- August, 2018).

BMJ journals, (2013- August, 2018).

PLOS, (2013- August, 2018).

A draft of the search strategy was tested using EBSCO database and MEDLINE ProQuest using 5 concepts (Motivational interviewing, Adult, Prevention, Risk modification, and Clinical trial). When using the drafted search strategy via the MEDLINE ProQuest, this did not let us complete the search at the 4th concept (Risk modification). For this particular reason, we have decided to add another concept (Cardiovascular disease) to increase the sensitivity of the search. This gave us a more comprehensive search enabling the identification of relevant studies. The revised search strategy was discussed with the supervisory team and no further amendments made to the index search. A full electronic search strategy for the EBSCO databases, including the limiters used, is presented in the appendices section (appendix 2. pg. 82). This is presented in a transparent manner for others to be able to replicate it. The pre-defined combination of the identified indexing terms which have used both free-text and subject headings, were used consistently

throughout the search (table 2.2). Some of the identified indexing terms were adapted from the existing systematic review (Lee et al., 2016), however this was further modified to link to the PICOs presented earlier. In particular, the terms "secondary prevention'' and ''quality of life'' were not used, as it was not of interest for the purpose of this review. Whilst developing the indexing terms, alternative spellings, abbreviations, synonyms, were all taken in consideration. Then the relevant subject heading terms were identified. The search used a high sensitivity search strategy, which has resulted in a low precision, hence the large number of results. Search concepts were kept limited to six concepts and a wide combination of search terms were combined using the Boolean operator OR in each concept. Then each concept was combined using the Boolean operator AND. This has ensured that all search terms appear in the record to make the search more focused. Truncations and wildcard symbols were used to broaden the search results. The Boolean operator NOT, was not used. This search strategy was repeated throughout all the aforementioned databases, where the search strategy was copied and pasted when appropriate, to avoid introducing errors in the search. However, the search strategy was not always possible to be repeated in all databases. For smaller database (DynaMed) and electronic journals (PLOS, BMJ journals), a broad strategy was used, by using a main keyword "motivational interviewing" only, this was done to ensure completeness of the search.

At this initial stage, duplicates were removed and recorded, titles or abstracts of retrieved articles were screened for their relevance to motivational interviewing and change in modifiable risk factors. If the article was deemed as being potentially eligible, the full text was obtained for further evaluation. The identified articles were then read in full text to identify the final studies meeting the eligibility criteria placed for this review.

The reference lists of studies were manually searched to identify possible eligible studies which might have been missed in prior searches. The search for unpublished studies included Web of Science, conference proceedings and the ClinicalTrials.gov trial registry.

Table 2.2 Development of search terms according to PICOs model and research question

Concepts and Boolean operator AND	Keywords, Boolean operator OR, truncations and wildcards
Concept 1- Cardiovascular disease	"coronary disease*" OR "cerebrovascular disorder*" OR "cardiovascular disease*" OR "cardiovascular disorder*" OR "cerebrovascular disease*" OR "heart disease*" OR "myocardial infarction" OR "heart disease*" OR "coronary*disease" OR "ischemic*disease" OR "athero*" OR "myocardial"
AND	
Concept 2- Motivational interviewing	"motivation" OR "motivational interviewing" OR "counseling" OR "counsel*" OR "nondirective therapy"
AND	
Concept 3- Adult	"adult*"
AND	
Concept 4- Prevention	"prevention" OR "primary prevention"
AND	
Concept 5- Risk modification	"modification of risk" OR "risk modification" OR "compliance" OR "patient compliance" OR "guideline adherence" OR "adherence" OR "lifestyle" OR "behavio#r*" OR "blood pressure" OR "cholesterol" OR "LDL" OR "HDL" OR "dietary" OR "lipids" OR "weight" OR "waist circumference" OR "obesity" OR "body mass index" OR "smoking" OR "smoking cessation" AND ("tobacco" OR " cigarette*") OR "tobacco" OR "tobacco use cessation" OR "physical activity" OR "exercise" OR "exercise tolerance" OR "exercise" OR "exercise capacity" OR "food habits" OR "diet*" AND ("pattern*" OR "habit*" OR "Mediterranean" OR "change*") OR "health* behavio#r" OR "behavio#r"
AND	
Concept 6- Clinical trial	"clinical trial" OR "comparative study" OR "experimental study" OR "controlled trial" OR "random assignment" OR "random allocation" OR "randomized" OR "randomised" OR "experimental group" OR "control group"

2.8 Eligibility criteria.

For inclusion, studies deemed eligible were those which:

- Focused on MI that could be implemented in primary prevention programmes for the management of modifiable risk factors.
- Were published between February, 2013–August, 2018.
- Measured modifiable risk factor changes as an outcome.
- Reported using a randomised controlled design.

Papers were excluded if they:

- Included research with samples consisting exclusively of individuals who have already developed cardiovascular disease.

Table 2.3 summarises the details of the inclusion and exclusion criteria.

Elements	Inclusion	Exclusion
Population	Adult, aged 18 years and over having at least 1 or more CVD modifiable risk factor/s	Studies consisting of Individuals with established CVD
Intervention	MI to enhance modifiable risk factor modification	Studies using any other form of counselling
Comparative intervention	Usual general practice/other interventions not including MI	Studies which their comparative intervention includes MI
Outcomes	Measurements of modifiable risk factors such as smoking cessation, engagement in physical activities, changes in dietary habits such as increase in fruit and vegetable consumption, changes in serum cholesterol and blood pressure status, changes in anthropometric measurements (BMI, weight, waist circumference)	All other form of outcomes and not including measurements of modifiable risk factors such as smoking cessation, engagement in physical activities, changes in dietary habits such as increase in fruit and vegetable consumption, changes in serum cholesterol and blood pressure status, changes in anthropometric measurements (BMI, weight, waist circumference)
Studies	Randomised controlled studies published between 2013-2018	All other methodological studies

2.9 Study selection.

Once the search strategy was finalized and assessed, the author retrieved all the relevant studies from the different databases and electronic journals used. All the relevant studies were saved on a computer reference software for further analysis (endnote). All the titles and abstracts which were identified by the search, were screened independently by two researchers and were assessed for eligibility against the criteria (table 2.3). Any disagreements were solved through discussion. Duplicates were identified and excluded. Final decisions on the study inclusion was made by the author of this review (Mifsud, J) and two other reviewers, which have examined the full text reports independently for compliance of studies with the eligibility criteria. The selection process was recorded in sufficient detail to complete the PRISMA flow chart (figure. 3.1) and concise reasons for exclusion of studies were recorded as presented in the next chapter.

2.10 Data collection.

A standardized form (appendix 3. pg.83) was developed and piloted for data extraction of the eligible studies (J Higgins, 2011). Key information extracted included:

1. The characteristics of included studies;
    - Study design
    - Randomization specifics (cluster/cross-over)
    - Duration of follow-up
2. Participant characteristics;
    - Total number
    - Setting (e.g. hospital, community)
    - Diagnostic criteria (e.g. hyperlipidaemia, obesity)
    - Age
    - Sex
    - Country
    - Ethnicity

3. Assessments of risk of bias domains;
    - Selection bias
    - Performance bias
    - Detection bias
    - Attrition bias
    - Reporting bias

4. Nature of intervention;
    - Total number of intervention groups
    - Intervention specifics (sufficiency for replication, if feasible)
    - Session content- 1. Number and length of sessions, type, 2. Characteristics of the clinician who delivered the intervention, 3. Coverage of MI elements
    - Comparator group

5. Type of outcomes measured;
    - Time points of collection and reporting
    - Definition of outcome, unit of measurements used (e.g. physical activity measured in METS)

6. Relevant findings/results;
    - Number of participants allocated to each intervention group
    - Sample size of each outcome,
    - Details about missing participants
    - Summary data for each intervention group (effect on modifiable risk factors)

7. Miscellaneous;
    - Funding source
    - Key conclusions of authors
    - Comments from the study authors

2.11 Assessment of risk of bias.

Study results may include systematic errors and biases, which may misrepresent the true effect of an intervention. When study results are not biased although having the possibility of methodological errors, it would be more appropriate to refer to this as "risk of bias". Therefore, the Cochrane collaboration have developed a tool to assess for risk of bias, to determine whether the studies answer their research question clearly, and, in a manner which is considered as free from any form of bias. This is described as the study's "internal validity" (J Higgins, 2011).

The Cochrane reviews have the highest quality systematic reviews internationally and are considered as the gold standard. For this reason, we have decided to make use of the Cochrane Risk of Bias tool and the Cochrane handbook for systematic reviews of interventions (J Higgins, 2011).

Cochrane tools have been widely used amongst Cochrane reviews and, overall, those who have used such tools, have reported positive experiences and praised their application (Savović et al., 2014). Moreover, these tools are supported by the UK Medical Research

Council (J. P. Higgins & Altman, 2008). Using the Cochrane Risk of Bias tool and the Cochrane handbook, has facilitated judgement of how confident can the assessors be in relying on the studies' conclusions, and will enable in determining if important criteria were fulfilled.

The quality of the studies was appraised on the following defined domains.

1. Selection bias,

   Selection bias refers to the possibility of having different baseline participants' characteristics which could act as confounding factors. Two common examples of these are having a different age group or different ethnicities between the groups being compared. Unless the process of randomization (random sequence generation) is carried out appropriately, such factors would introduce selection bias. If the process of randomization is carried out appropriately, this may minimize the risk of confounding. Moreover, random allocation sequence needs to be concealed, by avoiding foreknowledge of intervention allocation (J. P. Higgins & Altman, 2008).

2. Performance bias,

   Performance bias refers to the possibility of having differences in how the interventions were delivered between the groups. One other possibility of introducing the risk of performance bias is having participants being exposed to other factors rather than just the intervention components alone. One way of minimizing the risk of performance bias is by not having the participants or personnel know which intervention was delivered. An appropriate double blinding method may minimize the risk of introducing performance bias (J. P. Higgins & Altman, 2008)..

3. Detection bias,

   Detection bias refers to the possibility of having differences between groups, in the way how outcome measures were collected or verified. If outcome assessors are blinded, this may minimize the risk of knowing which intervention was received, thus minimizing the risk of detection bias (J. P. Higgins & Altman, 2008).

4. Attrition bias

   Attrition bias refers to the possibility of having differences between groups due to unequal dropouts. Having unequal dropouts could result in introducing the risk of attrition bias because of unbalanced confounding factors between the groups, such as age, gender or ethnicity. One way to minimize the risk of attrition bias is for researchers to enrol an adequate sample size to compensate for expected withdrawals and apply statistical methods, such as intension to treat analysis. It is also suggested to try to obtain reasons for withdrawal whenever possible (J. P. Higgins & Altman, 2008).

5. Reporting bias

   Reporting bias refers to the possibility of having differences between the groups in the reported and unreported findings. One way for researchers to minimize the risk of reporting bias is to register the study protocol prospectively. This will help to avoid publishing reports of analyses with statistically significant differences only, and will facilitate publication of non-statistically significant study results as well (J. P. Higgins & Altman, 2008).

An exemplar of the Cochrane Risk of Bias tool is shown in table 2.4 (J. P. Higgins & Altman, 2008). This tool enabled the authors to judge the quality of research evidence as being at 'High risk', 'unclear risk', or 'Low risk' of bias. Judgements were made transparent and are presented in the next chapter.

Table 2.4

Cochrane Collaboration's tool for assessing risk of bias (adapted from Higgins and Altman, 2008)

Bias domain	Source of bias	Support for judgement	Review authors' judgement (assess as low, unclear or high risk of bias)
Selection bias	Random sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence
	Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrolment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations before assignment
Performance bias	Blinding of participants and personnel	Describe all measures used, if any, to blind trial participants and researchers from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study
Detection bias	Blinding of outcome assessment*	Describe all measures used, if any, to blind outcome assessment from knowledge	Detection bias due to knowledge of the allocated

Bias domain	Source of bias	Support for judgement	Review authors' judgement (assess as low, unclear or high risk of bias)
		of which intervention a participant received. Provide any information relating to whether the intended blinding was effective	interventions by outcome assessment
Attrition bias	Incomplete outcome data*	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomised participants), reasons for attrition or exclusions where reported, and any re-inclusions in analyses for the review	Attrition bias due to amount, nature, or handling of incomplete outcome data
Reporting bias	Selective reporting	State how selective outcome reporting was examined and what was found	Reporting bias due to selective outcome reporting
Other bias		State any important concerns about bias not covered in the other domains in the tool	Bias due to problems not covered elsewhere
*Assessment should be made for each main outcome or class of outcomes			

2.12 Data synthesis.

The primary analysis is a comparison of interventions which made use of MI as part of their preventive intervention, versus interventions not using MI, for changes in modifiable risk factors in at increased CVD risk individuals. Data from the studies was extracted and organised under the following topics; effect of MI on smoking status, dietary change, physical activities, blood pressure, serum cholesterol, and anthropometric measurements (Weight, waist circumference, BMI).

The data which describes the intervention was also extracted. The availability of the data was assessed against a checklist (Appendix 4 pg. 99). The data which describes the intervention was considered for the synthesis and the interpretation, together with the data results for modifiable risk factor change. To identify whether the intervention is effective, we looked at statistically significant within group improvements after the delivery of the intervention sessions, and also at statistical group differences between the intervention groups and control groups. An increase in the mean smoking quit attempts,

an increase in the mean physical activity level and cardio-protective diet adherence, a decrease in the mean blood pressure level, in serum cholesterol, waist circumference and body mass index were considered as lifestyle improvements, if statistically significant. This was done for each individual study. Any trends identified across the results were explored and any possible associations between the intervention characteristics and the reported findings was discussed in the next chapters. Whenever quantitative synthesis was not possible, data was summarised narratively. To be able to summarise narratively, we produced a table to compare and contrast the outcomes of each study intervention programme. This enabled us to identify and understand the likely effective programme intervention characteristics. Furthermore, in conjunction with the systematic review, when it was possible to conduct a meta-analysis was, statistical tests were performed. Meta-analysis is when, quantitative synthesis of data from several studies are statistically analysed together (Akhter et al., 2019; Gurevitch, Koricheva, Nakagawa, & Stewart, 2018). This allowed to extrapolate the results, and increase the statistical power, hence increasing the accuracy of the true effect (Akhter et al., 2019; Gurevitch et al., 2018).
To report the meta-analyses results, we generated data output and forest plots, using Stata software. Forest plots showed homogeneity, however when statistical tests were applied to quantitatively measure the variability between results, the I^2 statistic (appendix 5, pg. 100) indicated high statistical heterogeneity (above 80%). Random effects meta-analyses was considered as more appropriate as this is more conservative than using fixed effects, and also what the data appeared to suggest. As the outcomes seemed to be consistent across studies, we used unstandardized measures to construct meta-analyses.

2.13 Conclusion

In this chapter, a review question was formulated which is reflective of the identified PICOs elements, the search strategy and the eligibility criteria have been reported. The stages of the search method, screening, reviewing, data extraction, and reporting process of the identified studies to answer the review question, are reported in detail. Tools to assess the quality of evidence were identified. The methodology to synthesize the data have been provided, where this is dependent on the heterogeneity and dissimilarities in identified studies. Whenever this was possible, meta-analyses was performed. The next chapter will present the findings of this review, together with a concise descriptive summary of the study characteristics, which are presented in a table format.

Chapter 3 – Results.

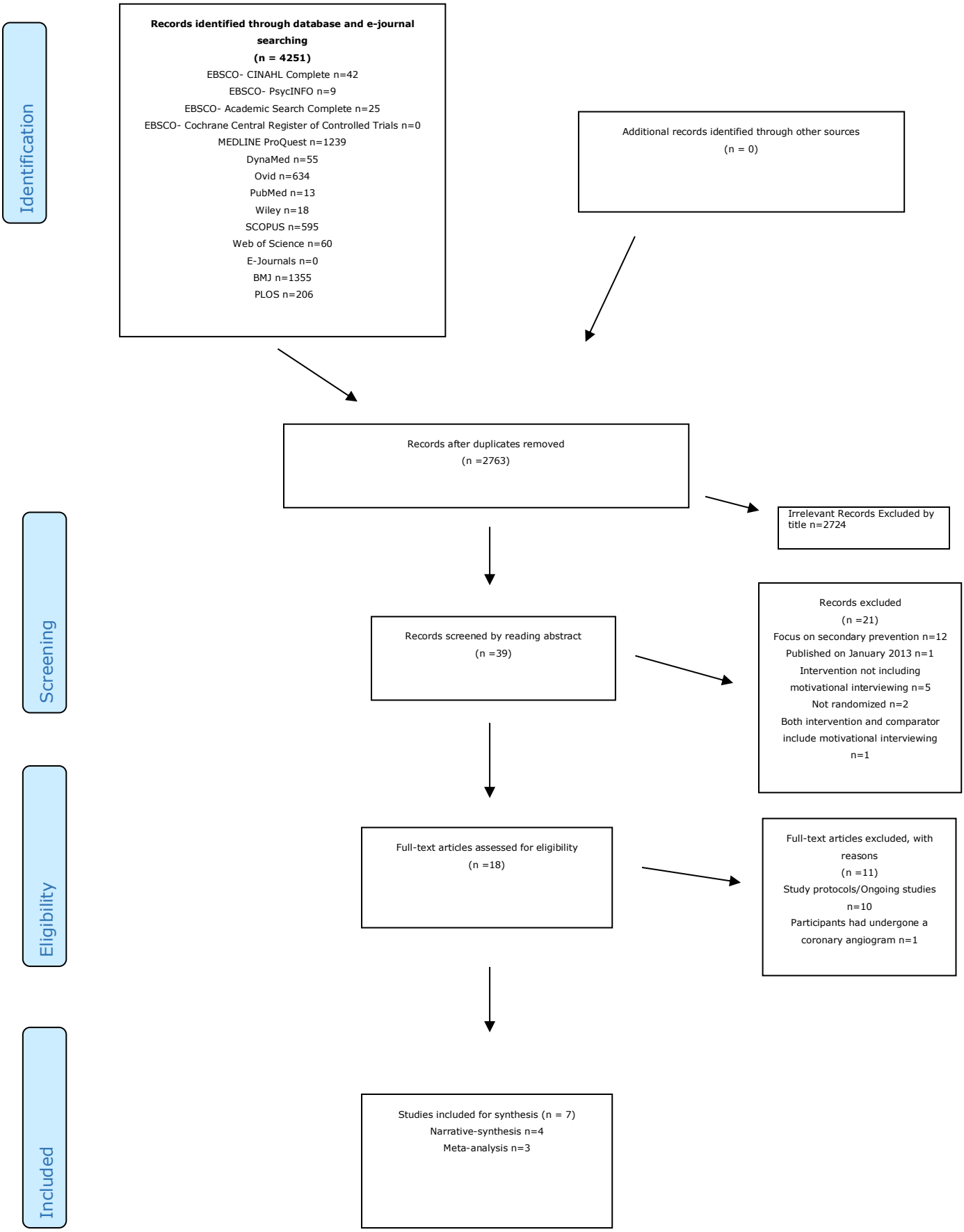
3.1 Introduction.

This chapter includes an accurate and comprehensive flow diagram of the studies (figure 3.1) retrieved through the database searching, showing the number of studies screened and assessed for eligibility, the number of studies included in this review, and the number of studies excluded, including the reasons for this. Assessment of risk of bias of each study is provided in detail. This is followed by, a detailed description of the study characteristics, including the study sample size and PICOs. Study outcomes are summarized for each study. Effect estimates and confidence intervals, using forest plots for LDL-c and weight, are provided. For other outcomes, data is summarised narratively.

3.2 Study selection.

The systematic search identified a total of 4251 records through the database searching. Following the removal of duplicates, 2763 records remained. 2724 records were found to not be directly relevant to the primary aim of this review. From 39 records, 21 records were excluded due to the parameters of the specific inclusion and exclusion criteria. 18 full text records were assessed and, from these, ten were found to be ongoing studies (protocol version) and one study consisted of participants who had undergone a coronary angiogram due to having angina symptoms on exertion. In total, 7 studies met the eligibility criteria for this systematic review and were, thus, included. The article selection process, detailing the number of records present at each stage and reasons for omissions, is illustrated in the PRISMA flow chart in figure 3.1.

Figure 3.1 PRISMA flow chart.



3.3 Quality appraisal and risk of bias.

3.3.1 Selection bias.

Random sequence generation

Four studies randomised participants to the intervention group using a computer-generated sequence (Aadahl et al., 2014; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016).

The study by Lin et al. (2016), as reported, is methodologically sound and strengths include the specific random sequence generation used. This involved the use of computer-generated random serial numbers. Similarly, Kouwenhoven-Pasmooij et al. (2018), Aadahl et al. (2014), and Lakerveld et al. (2013), carried out randomization using a computer random number generator. This kept the risk of selection bias minimal. On the other hand, Bóveda-Fontán et al. (2015), did not report whether a computer method was used to generate the allocation sequence. As such, comparable groups might not have been produced. The study failed to use methods such as central allocation or sequentially numbered opaque sealed envelope techniques to lower the risk of selection bias. While Kong, Jok, Ayub, and Bau (2017) represents their study as being a randomised controlled trial, the allocation method of this study seems to involve the non-random categorization of participants to the study groups. Therefore, this study seems to be susceptible to selection bias. In the study by Boutin-Foster et al. (2016), there is insufficient information about how the randomisation was scheduled.

Allocation concealment

Three studies have concealed their allocation method (Aadahl et al., 2014; Lakerveld et al., 2013; Lin et al., 2016). In the study by Lin et al. (2016), the researchers made use of opaque sealed envelopes to conceal allocation.

In the study by Kouwenhoven-Pasmooij et al. (2018) randomization process was done by a researcher who was not involved in the study, and, thus, allocation was concealed, and the risk of selection bias was minimalised. Similarly, Aadahl et al. (2014), had the random sequence generation managed by a blinded research data officer. The study by Lakerveld et al. (2013), had an independent administrative assistant who was blinded to the study participants, performing the randomization. This kept the risk of selection bias minimal. On the other hand, as Bóveda-Fontán et al. (2015), used an open random schedule, this entailed patients being recruited by their general practitioners and, as such, concealment was not ensured. The study failed to use methods such as central allocation or sequentially numbered opaque sealed envelope techniques to lower the risk of selection bias.

In the study by Kong et al. (2017), no details were provided with regards to procedures taken to avoid allocation concealment. In the study by Boutin-Foster et al. (2016), there is insufficient information whether the allocation schedule was concealed to prevent the risk of selection bias, which can affect which participants are given which intervention.

3.3.2 Performance bias.

Blinding of participants was only performed in one study (Kong et al., 2017) and blinding of personnel was performed in two of the studies (Aadahl et al., 2014; Lakerveld et al., 2013). Participants were blinded by having different investigators for both groups and by running the interventions concurrently using a different treatment room. This was done to avoid contact between participants during the study, thus decreasing the risk of performance bias (Kong et al., 2017). In the study by Aadahl et al. (2014), the investigators who processed the data of the device were blinded to whether the device belonged to a participant from the experimental group or control group. Any research personnel who were directly involved in conducting the data processing were also blinded to the randomization. However, in this study participants were not blinded due to the study having an open trial design (Aadahl et al., 2014). Lakerveld et al. (2013), blinded all research personnel to group assignment. However, there is a lack of procedural detail if participants were blinded to study groups (Lakerveld et al., 2013). Neither the participants nor the research personnel were blinded to the study intervention in the remaining three studies, (Boutin-Foster et al., 2016; Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016), and in the study by Bóveda-Fontán et al. (2015), as no blinding methods were mentioned, there is uncertainty regarding performance bias (Bóveda-Fontán et al., 2015).

3.3.3 Detection bias.

Blinding of outcome assessment was performed in two of the studies (Aadahl et al., 2014; Lin et al., 2016). In the study by Aadahl et al. (2014), the investigators who processed the data of the device were blinded to whether the device belonged to a participant from the experimental group or control group (Aadahl et al., 2014). Similarly, in the study by Lin et al. (2016), measurement collection was carried out by an independent researcher who was blinded to the study participants (Lin et al., 2016). On the other hand, the remaining five studies, two of which, whilst having their primary outcome assessments measured objectively and using validated measurements, blinding of outcome assessments was not performed (Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015). Blinding was also not performed in one of the studies which based the primary outcome on self-reporting (Kouwenhoven-Pasmooij et al., 2018). The other two studies seem to lack information about blinding procedures used during outcome assessments (Kong et al., 2017; Lakerveld et al., 2013).

3.3.4 Attrition bias.

Five studies have taken action to reduce the risk of attrition bias (Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016). Three of which have their missing outcome data balanced in

numbers across groups and similar reasons for missing data across groups were reported, hence reducing the risk of attrition bias (Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Lakerveld et al., 2013). Of the remaining two, one study has used intention to treat statistical analysis to handle incomplete outcome data (Lin et al., 2016), thus lowering the risk of attrition bias (Lin et al., 2016), and the other study, has applied statistical control, to determine if dropping-out was linked with participants' baseline characteristics or with the characteristics of intervention (Kouwenhoven-Pasmooij et al., 2018).On the other hand, one of the studies had an imbalance in the number of missing outcome data across the groups and reasons for this missing data are inconsistent, possibly increasing the risk of attrition bias (Aadahl et al., 2014). The study by Kong et al. (2017), the management of attrition bias is unclear.

3.3.5 Reporting bias.

Selective reporting was kept minimal in only two of the seven studies (Bóveda-Fontán et al., 2015; Lin et al., 2016). One of these two studies provide a published protocol and all the study's pre-specified outcomes are reported in the pre-specified way, decreasing the risk of reporting bias (Bóveda-Fontán et al., 2015). In the other study, while a study protocol was not made available, the study included all the expected outcomes, and the outcomes were investigated using validated measurements (Lin et al., 2016). Of the remaining five, three studies have failed to provide sufficient detail about the reporting of study outcomes. As such, a judgement regarding the risk of reporting bias could not be carried out (Aadahl et al., 2014; Boutin-Foster et al., 2016; Kong et al., 2017). One study, had a protocol which was approved by the medical Ethics Committee. However, it seems that this was not published and, therefore, an assessment of the reporting bias was not possible (Lakerveld et al., 2013). In another study, although a study protocol was made available, it was noted that not all pre-specified outcomes that are of interest in the review were reported in a pre-specified way. In this way, this can be indicative of selective reporting, as it allows for reporting bias (Kouwenhoven-Pasmooij et al., 2018).

3.3.6 Summary of perceived bias.

Overall four of the studies used a computer method to generate the allocation sequence (Aadahl et al., 2014; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016). Only three of the studies prevented the risk of selection bias by using a method to conceal allocation (Aadahl et al., 2014; Lakerveld et al., 2013; Lin et al., 2016).The lack of blinding of participants and investigators to group allocation was noted in four of the studies (Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016). Two studies blinded the assessment of the outcomes to prevent the risk of detection bias (Aadahl et al., 2014; Lin et al., 2016).

Attrition bias was minimalised throughout most studies (Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016). Although all the authors claimed to use randomization to assign participants into groups, the process may not have been optimal, introducing the risk of selection bias. The studies also have several further weaknesses that may hinder their credibility, including the sample size of some of the studies which may have been too small to detect a statistically significant change. Table 3.1 illustrates a summary of risk of bias across domains.

Table 3.1 Risk of bias summary (across domains).

Authors	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting
	Selection		Performance	Detection	Attrition	Reporting
Aadahl 2014	+	+	+	+	-	?
Boutin-Foster 2016	?	-	-	-	+	?
Boveda-Fonatan 2015	?	-	-	-	+	+
Kong 2017	-	?	+	?	?	?
Kowenhaven-Poamooin 2018	+	-	-	-	+	-
Lakervald 2013	+	+	+	?	+	?
Lin 2016	+	+	-	+	+	+
+ =action performed to reduce risk, - =action not performed, ? =insufficient information given.						

3.4 Study characteristics.

Seven studies, met the inclusion criteria and are shown in table 3.2. The randomised controlled trials were conducted in six countries. Four in Europe; Spain (Bóveda-Fontán et al., 2015), Netherlands (Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013) and Denmark (Aadahl et al., 2014). Two in Asia; Taiwan (Lin et al., 2016) and Malaysia (Kong et al., 2017) and one in the United States of America (Boutin-Foster et al., 2016).

Studies were designed in different ways and MI was used as part of a broader educational intervention, with several components across three out of seven studies. For example MI was combined with an individualized healthy lifestyle educative session (Lin et al., 2016), an educational workbook about hypertension (Boutin-Foster et al., 2016), and dietary education and a weight management dietary menu (Kong et al., 2017). Other studies combined MI with online health risk assessment and tailored feedback (Kouwenhoven-Pasmooij et al., 2018), behaviour theoretical frameworks (Aadahl et al., 2014; Lakerveld

et al., 2013), and clinical dyslipidaemia protocol recommendations (Bóveda-Fontán et al., 2015).

A broad description of MI has been given previously in the background section. Moreover, the intervention characteristics of each study are given in detail under section 3.4.

Table 3.2 Study characteristics of included studies.

Study	Participants	Intervention	Comparison	Outcome	Study Design
Bóveda-Fontán, (2015) Effectiveness of motivational interviewing in patients with dyslipidaemia: a randomised cluster trial	Inclusion: Individuals aged 40 to 75 years with dyslipidaemia of both genders. Exclusion: Individuals having underlying causes which are linked to secondary dyslipidaemia and need statin therapy; individuals with established CVD or diabetes or severe COPD, cancer, hepatic disease, chronic kidney failure, substance or alcohol abuse; individuals who are unfit to comply with the study procedures or to be subject to follow-up review; pregnancy or having anti diabetic pharmacological agents	Had a MI-based approach delivered by MI trained General practitioners.	Had a consultation delivered by general practitioners who did not receive any training in MI.	Improvement of the serum cholesterol.	A multicentre, open, controlled, randomised, cluster, two-parallel arm trial.
lKouwenhoven-Pasmooij, (2018) Effectiveness of the blended-care lifestyle intervention 'PerfectFit': a cluster randomised trial in employees at risk for cardiovascular diseases	Inclusion: Individuals aged 40 years and over, of both genders and having at least one of the following risks; a first degree relative with CHD, not meeting the Dutch physical activity guidelines ; use of tobacco; self-reported diabetes mellitus or random glucose of ≥ 11.1 mmol/l; obesity (BMI ≥ 30 kg/m2 and / or waist circumference ≥ 102 cm for men or BMI ≥ 30 kg/m2 and/or ≥ 88 cm for women); hypertension (diastolic	Online Health Risk Assessment, with a motivational letter. Seven individual coaching sessions (3 face-to-face and 4 by telephone) with a MI trained occupational health physician, and a personalized approach to promote health using MI.	Online Health Risk Assessment, consisting of personalized feedback based on the participant's risk , engaging health promotion activities, electronic newsletter, providing information on the intervention (PerfectFit), and general information on a healthy	Secondary outcomes; weight, BMI, work performance, self-reported daily intake of vegetables and fruits.	Cluster randomization of 17 from 3 large organisations.

Table 3.2 Study characteristics of included studies.

Study	Participants	Intervention	Comparison	Outcome	Study Design
	value > 90 mmHg or a systolic value > 140 mmHg) or the use of antihypertensive drugs; and dyslipidaemia (total cholesterol ≥ 5 mmol/l or LDL cholesterol ≥ 2.5 mmol/l or triglycerides: ≥ 1.7, mmol/l or HDL cholesterol: ≤ 1.0 mmol/l). Exclusion: Not specified.		lifestyle, sent via email		
Aadahl, (2014) Motivational Counselling to Reduce Sitting Time A Community-Based Randomised Controlled Trial in Adults (2014)	Inclusion: Individuals aged between 18 and 69 years, who self-reported 3.5 hours of daily leisure-time sedentary behaviours Exclusion: Not specified.	4 individual theory-based (Behavioural choice Theory) in person sessions conducted by a research nurse. Program consisted of individual behaviour goal-setting, self-efficacy, and MI techniques. Sessions took place at approximately 6-week intervals during 6-months. Preliminary session took place on the day of randomisation. Each session lasted between	Had usual lifestyle.	Primary outcome involved total volume of daily sitting.	"Open-ended" randomization using computer-generated random numbers.

Table 3.2 Study characteristics of included studies.

Study	Participants	Intervention	Comparison	Outcome	Study Design
		30 and 45 minutes.			
Lakerveld, (2013) Motivational interviewing and problem solving treatment to reduce type 2 diabetes and cardiovascular disease risk in real life: a randomised controlled trial	Inclusion: Adults with ≥10% estimated risk of T2DM and/or CVD mortality. Exclusion: Not specified.	Theory-based (Theory of planned behaviour and Theory of self-regulation) lifestyle intervention using MI and problem-solving sessions provided by nurses.	Existing health brochures.	Estimated risk of T2DM development and estimated CVD risk mortality. Secondary outcome: Self-reported smoking, physical activity, fruit and vegetable intake.	Randomizatio n using a computerized random number generator.
Boutin-Foster, (2016) Results from the Trial Using Motivational Interviewing, Positive Affect, and Self-Affirmation in African Americans with Hypertension (TRIUM PH)	Inclusion: African American adults with uncontrolled hypertension. Exclusion: Not specified.	Participants were engaged to think about things that made them happy and that reminded them of their inner values on a daily basis. These strategies were reinforced every two months through MI.	Received a workbook of strategies on blood pressure control.	Blood pressure control rate.	Randomised in a 1:1 ratio to either an active intervention group or an education-based control group.
Kong, (2017) Worksite	Inclusion:	Received a 12-week lifestyle program that	Traditional counselling and	Weight and waist	Single-centre, randomised

Table 3.2 Study characteristics of included studies.

Study	Participants	Intervention	Comparison	Outcome	Study Design
weight management program A three-months intervention study in a primary health care setting	Individuals aged between 18 and 59 years with a BMI of at least 18.5 kg/m2 or above. Exclusion: Known CVD or severe liver or kidney disease.	modify dietary intake. Community Registered Dietitian (RDs) promoted to increase high intensity interval training with MI to support changes.	weekly aerobic exercise from a medical officer and a Physiotherapist.	circumference reduction.	controlled trial.
Lin, (2016) Effects of telephone-based motivational interviewing in lifestyle modification program on reducing metabolic risks in middle-aged and older women with metabolic syndrome: A randomised controlled trial.	Inclusion: Women aged over 40 diagnosed with metabolic syndrome. Ability to speak and understand Mandarin, walk without assistance, and agreed to be randomised to one of the three groups. Exclusion: History of end-stage renal disease with dialysis, cancer, a confirmed psychiatric disease. Inability to participate due to comorbid neuromusculoskeletal disease.	In person 12-week lifestyle modification program using MI.	Single brief lifestyle modification counselling session with a brochure on lifestyle modification	Weekly physical activity amount, MetS, and MetS risks.	Randomised controlled trial with a three-parallel intervention-group Design.

3.5 Participant characteristics and recruitment settings.

The inclusion criteria used across studies varied, with some having very specific requirements and others having broad eligibility criteria. One study included only black Americans with hypertension (Boutin-Foster et al., 2016), while another included only women diagnosed with metabolic syndrome (Lin et al., 2016). Other studies included participants who had at least one cardiovascular disease risk factor (Kouwenhoven-Pasmooij et al., 2018), or participants who scored high for risk when using risk calculators for calculating cardiovascular risk, or diabetes risk (Lakerveld et al., 2013). Other studies included participants who had a history of dyslipidaemia (Bóveda-Fontán et al., 2015), or participants who had a sedentary lifestyle (Aadahl et al., 2014). Across all the studies, the ages included, ranged from 18 to 75 years. Four of the studies recruited participants from community clinics (Aadahl et al., 2014; Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kong et al., 2017), while others recruited participants from an outpatient clinic (Lin et al., 2016), occupational health centres (Kouwenhoven-Pasmooij et al., 2018) or general practices (Lakerveld et al., 2013).

3.6 Intervention characteristics.

Table 3.2 (pg. 36) shows an overview of the characteristics and content of the interventions.

3.6.1 Characteristics.

The interventions used in the seven studies were somehow dissimilar in several ways. Three studies included MI as part of an educational intervention (Boutin-Foster et al., 2016; Kong et al., 2017; Lin et al., 2016). Two studies based their MI on theoretical frameworks (Aadahl et al., 2014; Lakerveld et al., 2013), one study consisted of MI and clinical guidelines (Bóveda-Fontán et al., 2015), and another study consisted of a web-based health risk screening with tailored feedback.

3.6.1.1 Sample size, the number, length, type and setting of sessions.

Sample size ranged from 88 (Kong et al., 2017) to 622 participants (Lakerveld et al., 2013). The number of MI sessions offered, ranged from 1 to 12 sessions, the length of the sessions ranged from 15 to 45 minutes, four studies consisted of face to face combined with telephone based MI (Boutin-Foster et al., 2016; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016) and three studies consisted of face to face MI only (Aadahl et al., 2014; Bóveda-Fontán et al., 2015; Kong et al., 2017). Four from seven studies, sessions took place in community clinics (Aadahl et al., 2014; Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kong et al., 2017), other studies used an outpatient

clinic (Lin et al., 2016), an occupational health centre (Kouwenhoven-Pasmooij et al., 2018), and a diabetes research centre (Lakerveld et al., 2013).

3.6.1.2 Characteristics of the deliverer (professional discipline, training and experience).

An expert nurse in MI (Lin et al., 2016), other nurses (Aadahl et al., 2014; Lakerveld et al., 2013), general practitioners (Bóveda-Fontán et al., 2015), occupational health physicians (Kouwenhoven-Pasmooij et al., 2018), licensed dieticians (Kong et al., 2017), or research assistants (Boutin-Foster et al., 2016) delivered the sessions in all the studies. The training they had received ranged from 0 to 36 hours of MI training, and only one study had an expert in MI to deliver the session (Lin et al., 2016).

In the study by Lakerveld et al. (2013), practice nurses had 18 hours of MI training delivered by an experienced psychologist. A treatment manual was used during this training course. Practice nurses also had coaching sessions half way through the course. These consisted of an hour of in person mentoring with feedback. Furthermore, some of the sessions were audio recorded at random and were used for training purposes during coaching (Lakerveld et al., 2013). General practitioners had a 16-hour course delivered by a person with expertise focusing on eight basic MI elements (Bóveda-Fontán et al., 2015). Apart from the 16 hours of training, general practitioners had two simulated patient scenarios. Feedback was provided by a MI expert. This training was further reinforced by educative SMS messages, and task assignment with feedback. Moreover, the general practitioners were required to attend group sessions to analyse their real patients' consultations, using problem-based interviewing strategies (Bóveda-Fontán et al., 2015). Occupational health physicians had three full days of basic MI training. This was followed by three four-hour coaching sessions (Kouwenhoven-Pasmooij et al., 2018). Three of the studies failed to give a description of what sort of training those who delivered the intervention had received (Aadahl et al., 2014; Boutin-Foster et al., 2016; Kong et al., 2017).

3.6.2 Motivational Interviewing Content.

None of the studies reported all of the twelve expected components of MI shown in Table 3.3). The reported MI components in studies ranged from 0/12 (Bóveda-Fontán et al., 2015) to 6/12 (Kouwenhoven-Pasmooij et al., 2018) (table 3.3 pg. 43). Evocation appeared to be the most commonly used strategy evident in five studies (Boutin-Foster et al., 2016; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016). Developing a change plan appeared to be the second most commonly used strategy (Aadahl et al., 2014; Boutin-Foster et al., 2016; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018). This was followed by compassion (Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016), and affirmation (Boutin-Foster et al., 2016; Lin et

al., 2016). Profound acceptance, use of open-ended questions, reflection (Kouwenhoven-Pasmooij et al., 2018), rolling with resistance (Boutin-Foster et al., 2016), and eliciting and strengthening change talk (Kong et al., 2017) appeared to be evident in at least one of the studies respectively. Summarization, recognizing and reinforcing change talk, and consolidating a client's commitment did not appear to be evident in any of the studies.

Table 3.3 Motivational interviewing elements summary.

MI elements reported in the study	1. Evocation	2. Developing a change plan	3. compassion	4. affirmation	5. profound acceptance	6. Open-ended questions	7. reflection	8. Rolling with resistance	9. Eliciting and strengthening change talk	10. Summarization	11. Recognizing and reinforcing change talk	12. Consolidating a client's commitment
Aadahl 2014	-	+	-	-	-	-	-	-	-	-	-	-
Boutin-Foster 2016	+	+	-	+	-	-	-	+	-	-	-	-
Boveda-Fonatan 2015	-	-	-	-	-	-	-	-	-	-	-	-
Kong 2017	+	+	-	-	-	-	-	-	+	-	-	-
Kowenhaven-Poamooin 2018	+	+	+	-	+	+	+	-	-	-	-	-
Lakervald 2013	+	-	-	-	-	-	-	-	-	-	-	-
Lin 2016	+	-	+	+	-	-	-	-	-	-	-	-
+ reported, - not reported, ? partially reported												

3.6.3 Intervention Content.

3.6.3.1 Motivational interviewing and educational resources.

The intervention strategies used in the research studies varied widely in their nature, with three studies using lifestyle education material as part of the intervention combined with MI (Boutin-Foster et al., 2016; Kong et al., 2017; Lin et al., 2016). Of these three, one study provided participants with an educational brochure about physical activities (Lin et al., 2016). The MI component of the intervention used in this study consisted of one face-to-face lifestyle modification counselling session of approximately fifteen to twenty minutes, and twelve telephone-delivered MI sessions of fifteen to thirty minutes each, for twelve weeks. The telephone MI calls focused on physical activity promotion (Lin et al., 2016). Boutin-Foster et al. (2016), provided participants with a hypertension education workbook, which focused on the aetiology of blood pressure treatment options and recommendations about lifestyle modification that may improve blood pressure target values. The intervention also consisted of an induction protocol which focused on positive effects and self-affirmation. The positive affect strategy engaged to focus on positive thinking to help with stressful situations. MI sessions involved one face-to-face session followed by six telephone calls to reinforce the motivation, confidence, and to discuss any barriers and the pros and cons of medication adherence (Boutin-Foster et al., 2016).

While Kong et al. (2017) did not use telephone-based MI in their study, a portion of their intervention process also consisted of educative resources, where participants were educated about the basic principles of a low-calorie diet. In addition, in this study, participants also took part in 45 to 60-minute Zumba classes three times a week for twelve weeks. MI was delivered face-to-face and participants had three sessions which focused on eliciting self-directed change speech, agenda setting and the exploration of the pros and cons when negotiating a plan of change.

3.6.3.2 Motivational interviewing and theoretical frameworks.

Two other studies used a behavioural theoretical framework (Aadahl et al., 2014; Lakerveld et al., 2013). Aadahl et al. (2014), made reference to the behavioural choice theory which incorporated goal setting and improving self-efficacy. The MI sessions consisted of four face-to-face sessions with each session lasting between 30 to 45 minutes. The sessions focused on television reduction time, substituting sitting with standing, breaking up prolonged sitting and targeting no more than 30 minutes of sitting per episode. Participants were also provided with booklets, postcards and stickers that had key massages to promote the aforementioned points. On the other hand, Lakerveld et al. (2013), made reference to the theory of planned behaviour with the aim to make the attitude and intention to modify risk stronger. The intervention consisted of 6 in person MI sessions of 30 minutes each, followed by 4 telephone-delivered sessions. The MI

component focused on highlighting the discrepancy between the participants' personal goals and their current situation. The intervention also used problem solving strategies to find solutions to overcome these discrepancies, strengthen the participants' perceived control and provide solutions to overcome barriers that could hinder behavioural changes (Lakerveld et al., 2013).

3.6.3.3 Motivational interviewing and clinical guidelines.

Only one study in this review has used MI combined with clinical guidelines. In the study of Bóveda-Fontán et al. (2015), an approach involving dyslipidaemia protocol and face-to-face MI was undertaken.

3.6.3.4 Motivational interviewing and web-based health screening with tailored feedback.

In the study by Kouwenhoven-Pasmooij et al. (2018), the intervention consisted of a web-based health risk assessment which included tailored feedback according to the participant's risk profile. Furthermore, the intervention provided electronic information about healthy lifestyle choices which was sent to the participants every two to three months. The MI component consisted of seven individual sessions. Of these, three were delivered face-to-face and four were delivered via telephone. The MI strategy started with problem feedback by discussing the individual's CVD risk profile and motivating participants to change behaviour, which was integrated with important lifestyle goals and values. Moreover, the strategy used a client-centred approach, asking open-ended questions, making use of reflection, and addressing ambivalence (Kouwenhoven-Pasmooij et al., 2018).

3.7 Outcomes.

3.7.1 Lifestyle behaviour measurements.

3.7.1.1 Smoking.

Out of the seven studies, smoking was only taken into consideration as a secondary outcome by two studies (Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018). Kouwenhoven-Pasmooij et al. (2018) measured this outcome by asking the participants whether they still smoke. Bóveda-Fontán et al. (2015), did not report details on how this outcome was measured.

3.7.1.2 Dietary patterns.

Dietary patterns were measured by three of the seven studies, where one study used the Mediterranean diet score to measure dietary outcome change (Bóveda-Fontán et al., 2015) the second study used the 8-item Food Frequency Questionnaire (Lakerveld et al.,

2013) and the third study used a 24-hour dietary recall, and a computerised software to calculate the nutritional intake (Kong et al., 2017).

3.7.1.3 Physical activity levels.

Of the seven selected studies, five measured physical activity levels as an outcome. To measure physical activity levels, the study of Lin et al. (2016) used the metabolic equivalents calculation, that of Kouwenhoven-Pasmooij et al. (2018) used percentage adherence to local physical activity guidelines, which of Lakerveld et al. (2013) used the Short Questionnaire to assess Health-enhancing physical activity, one study used the international physical activity questionnaire (Bóveda-Fontán et al., 2015) and, lastly, the study of Aadahl et al. (2014) used the physical activity scale.

3.7.2 Serum cholesterol measurements.

From the seven selected studies, serum cholesterol profile was investigated by four of the studies. In the studies by Bóveda-Fontán et al. (2015) and in that of Lin et al. (2016), researchers measured serum cholesterol as a primary outcome, while the other two studies looked at serum cholesterol profile as a secondary outcome (Aadahl et al., 2014; Kong et al., 2017). Only the study by Aadahl et al. (2014) and the study by Kong et al. (2017) stated how serum cholesterol outcome was calculated, using enzymatic procedure to measure the total cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides. In addition, Aadahl et al. (2014) stated the use of the Friedewald's formula to calculate the low-density lipoprotein cholesterol. Lastly, Lin et al. (2016) stated that blood samples were investigated after 12 hours of fasting, and Kong et al. (2017) noted that blood samples were investigated after fasting.

3.7.3 Blood pressure measurements.

Blood pressure was measured as a primary outcome by the study of Boutin-Foster et al. (2016). This was recorded using an electronic blood pressure monitor to measure the proportion of those participants meeting blood pressure targets. However, in the study by Kong et al. (2017), blood pressure was measured as a secondary outcome to measure the mean differences between the groups of participants. In this study, two to three recordings were taken by auscultation, and an average was taken as the final measurement (Kong et al., 2017).

3.7.4 Anthropometric measurements.

Anthropometric measurements were used by five of the studies. However, the only studies which looked at anthropometric measurement as a primary outcome were those by Bóveda-Fontán et al. (2015); Kong et al. (2017) and Lin et al. (2016). In the study by

Kong et al. (2017), measurements for BMI (kg/m2) and waist circumference (cm) were taken to the nearest 0.1 kg and 0.1cm and both measurements were recorded twice. Lin et al. (2016), investigated only waist circumference, with measurements being taken while the participant is standing. A measuring tape was placed at the midpoint between the iliac crest and the lowest rib, and at the level of the umbilicus. This measurement was taken at the end of expiration. The other two studies looked at anthropometric measurements as a secondary outcome. In the study by Kouwenhoven-Pasmooij et al. (2018), weight and height were measured using calibrated scales with the measurement being expressed as BMI (kg/m^2). In the study by Aadahl et al. (2014), researchers took into consideration the measure of body fat percentage and both waist circumference and BMI. The waist circumference was measured using a non-elastic tape. The tape was placed midway between the lower rib margin and the iliac crest to the nearest 0.5 cm. Percentage of body fat was calculated using bioelectrical impedance.

3.8 Synthesis of results.

With regards to the findings, out of the seven studies, three studies found that MI had no significant difference between groups, on outcome measurements, namely reduction in sitting time, increase in stepping time, reduction in weight, body fat, serum cholesterol (Aadahl et al., 2014), blood pressure (Boutin-Foster et al., 2016), increase in vegetable and fruit intake, physical activity levels and smoking cessation (Lakerveld et al., 2013). The remaining four studies showed otherwise. Lin et al. (2016) showed a significant reduction in metabolic risks in the MI group (4.0-3.6, p= 0.002) when compared with the usual group (4.4-4.6, p= 0.003) and also a significant decrease in the mean number of metabolic risks in the motivational group at 12 weeks when compared with both the brief intervention group (beta= -0.3, p= 0.002) and the usual care group (beta= -0.5, p= 0.001). In the study by Kong et al. (2017), there are positive group differences in favour of the motivational group namely in waist circumference, body weight, blood pressure, serum cholesterol, total calorie intake, dietary fibre intake, carbohydrate intake and fat intake. Additionally, Bóveda-Fontán et al. (2015) found a significant within group difference in weight, in favour of the MI group. Lastly, in the study by Kouwenhoven-Pasmooij et al. (2018), a significant within group difference in BMI was noticed at 12 months.

Due to the heterogeneity in the studies, resulting from significant methodological differences, the studies will each be described in a narrative format. The only variables for which it was possible to conduct a meta-analysis were weight and cholesterol changes (Appendix 5. pg. 100). A supplementary table of all the included studies with details including author, year of publication, country of origin, measuring outcome used,

intervention specifics, relevant results and risk of bias assessment can be found in Appendix 3. (pg. 83).

3.8.1 Motivational interviewing and modifiable risk factor change; effectiveness of programmes.

3.8.1.1 Lifestyle behaviour measurements.

Smoking outcome measurements (%).

The two studies which have measured smoking outcome, results between group differences were insignificant. The authors reported a reduction of 33% amongst the intervention group and a 37% reduction amongst the control group, with no statistical differences between the intervention group and the control groups. Following MI, there was a significant difference in the reduction of the number of cigarettes smoked per day (95% CI: -3.32 to -7.94: mean difference= -5.66: p= <0.001), but there was no significant difference between the groups (p= 0.749) (Bóveda-Fontán et al., 2015). In line with Bóveda-Fontán et al. (2015), Lakerveld et al. (2013), found no significant differences between the groups at the twelve-month follow up for smoking cessation. There is a trend towards smoking cessation in both groups as indicated at the six-month follow-up mark and the twelve-month follow-up mark. However, this change was not statistically significant.

Dietary outcome measurements (Mediterranean diet score, g/day).

From three studies which measured dietary outcomes, two studies showed no statistical significance effect. The Mediterranean diet score increased from 8.30 (SD= 2.43) at baseline to 9.41 (SD= 2.47) (MD= 1.11: 95% CI: 1.42 to 7.29: p= < 0.001), at the twelve-month follow-up mark. However, there was no statistically significant difference between the intervention and control group (Bóveda-Fontán et al., 2015). In the study by Lakerveld et al. (2013), the only group difference was for daily fruit consumption of 0.2 pieces of fruit (95% CI, beta -0.3 to 0.0, p= <0.05) in favour of the control group, but this was only evident at the six-month follow up mark. On the other hand, between group significant differences was noted by Kong et al. (2017), in the total calorie intake (-553.02, SD= 339.18, CI= -448.64 to -657.41, p= 0.01), dietary fibre intake (5.11, SD= 0.93, CI= 3.26 to 6.95, p= 0.01), carbohydrate intake (33.23, SD= 10.72, CI= -54.54 to 11.91, p= 0.03), fat intake (-23.29, SD= 4.42, -32.07 to -14.51, p= 0.01) and protein intake (-12.45, SD= 3.41, CI= -19.23 to -5.68, p= 3.65). Caution is advocated with these results due to the relatively small sample size (n=88) (Kong et al., 2017).

Physical activity outcome measurements (METS/wk, %).

From five studies, which measured physical activity levels, none of the studies showed a between group statistical difference in physical activity outcomes post intervention at three

months (Lin et al., 2016) , at six-month follow-up mark (Aadahl et al., 2014), and at twelve-month follow-up mark (Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013). The international physical activity questionnaire (IPAQ), which is a validated research tool, was used to calculate the metabolic equivalent minutes per week, in two of the studies (Bóveda-Fontán et al., 2015; Lin et al., 2016). In the study by Lin et al. (2016), at the twelve-week time-point, results showed that the MI group exhibited no statistically significant difference with regards to physical activity levels when compared to the other groups, although there was a trend for the MI group to illustrate higher physical activity levels from baseline to the twelve-week time point (Lin et al., 2016). When a generalised estimating equation was used, it showed that participants in the MI group had a greater increase in the physical activity levels than the non-MI intervention group at the twelve-week time point (beta= 337, p= 0.02), but no differences were noted when compared to those participants who received the brief intervention. In the study by Bóveda-Fontán et al. (2015), and Kouwenhoven-Pasmooij et al. (2018), an improvement in both groups was exhibited, where lack of physical activity was reduced by 96.6% (Bóveda-Fontán et al., 2015), and 50% (Kouwenhoven-Pasmooij et al., 2018) at the twelve-month time point.

3.8.1.2 Serum cholesterol outcome measurements (mg/dl, mmol/l, %).

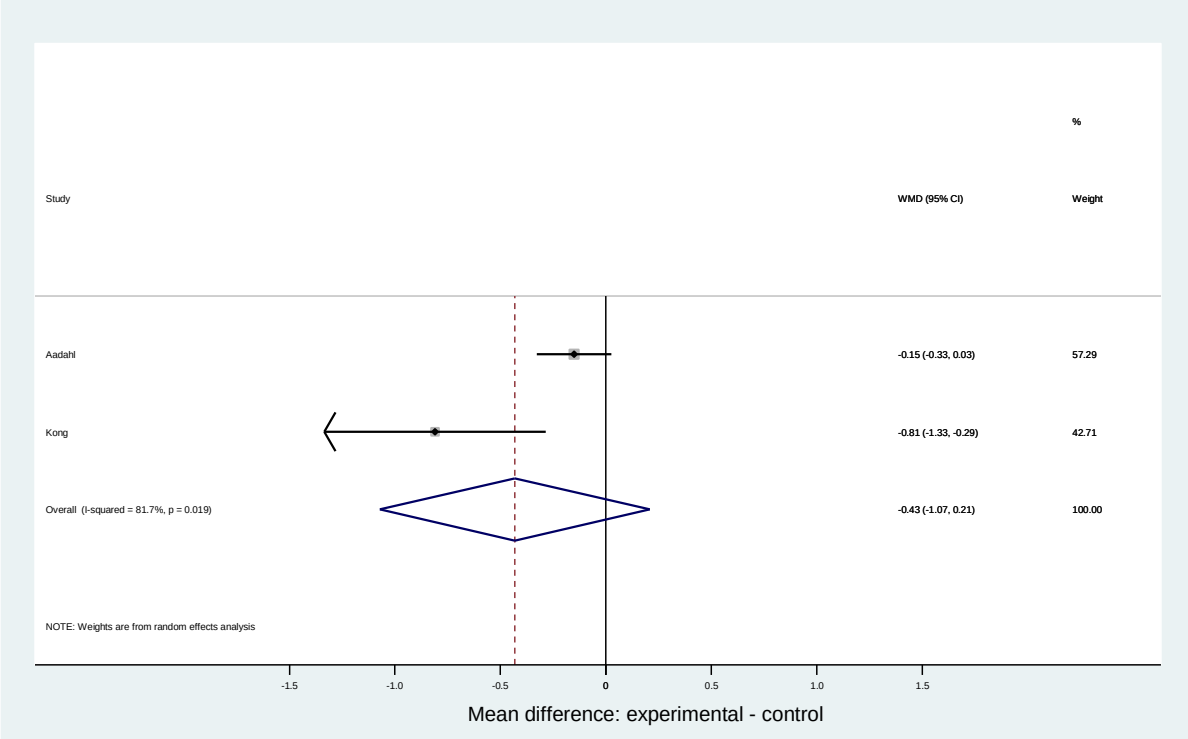
From three studies which have measured serum cholesterol outcomes, two exhibited statistically significant group differences following MI intervention. Significant reductions in total cholesterol levels (-1.3 mmol/l, SD= 0.3, CI= -0.9 to -0.7, p= 0.01), low density lipoprotein cholesterol (-0.8 mmol/l, SD= 0.3, CI= -1.3 to 0.3, p= 0.01) and triglyceride cholesterol (-2.2 mmol/l, SD= 0.2, CI= -2.7 to -1.7, p= 0.01) favoured the motivational intervention group (Kong et al., 2017). Significant reductions were also evident in the study by Aadahl et al. (2014), for total cholesterol (intervention= -22.7%, control= -1%, p= <0.05) and low density lipoprotein cholesterol (intervention -30.5%, control -11%, p= <0.05). On the other hand, in the study by Bóveda-Fontán et al. (2015), participants in the MI group exhibited no significantly greater reduction in total cholesterol, low density lipoprotein cholesterol or triglycerides cholesterol, than the control group at 12 months. In this study, it is interesting to note that when the researchers assessed the degree of lipid control by combining those participants who achieved the target total cholesterol and the target LDL-c (Tot-c <200mg/dl, LDL-c <130mg/dl) parameters, it was noticed that a higher number of patients achieved the target figures in the experimental group versus comparator group (13.1 % vs 5.0%: adjusted OR= 5.77, 95% CI: 1.67 to 19.91) (Bóveda-Fontán et al., 2015). Moreover, an overall improvement was observed, with both groups achieving better results in total cholesterol levels (Total sample mean difference= -19.60: 95% CI: -15.33 to -23.87 mg/dl: p= < 0.00.1), in low density lipoprotein cholesterol (Total

sample MD= -13.78: 95% CI: -9.77 to -17.79 mg/dl: p= < 0.001) and triglycerides (Total sample MD= -19.14: 95% CI: -11.29 to -26.99 mg/dl: p= < 0.001), but no differences were observed in the high density lipoprotein cholesterol levels (Total sample MD= 0.28: 95% CI: -2.26 to 1.69 mg/dl: p= 0.309) (Bóveda-Fontán et al., 2015). The overall improvement in lipid profile, could be indicative of the increase in physical activity levels amongst the study participants (Bóveda-Fontán et al., 2015).

Meta-analysis for LDL-c (mmol/l).

In view of variations in methodological and clinical heterogeneity, a random effects meta-analysis was used for LDL-c data outcome. Meta-analysis determined that a synthesized estimate for the unstandardized mean difference in total LDL-c reduction (no intervention vs intervention) was -0.43 mmol/l (95%CI -1.07 to 0.21). For overall effect, a Z-test determined no evidence that the value was non zero (Z= 1.32, p=0.186). Individual estimates for the unstandardized mean difference range from -0.81 (Kong et al., 2017) to -0.15 (Aadahl et al., 2014). Cochran's Q-test determined evidence for statistical heterogeneity at the 0.1 significance level (Heterogeneity x^2 = 5.46; p= 0.019). The I^{2-} statistic was 81.7%, thus indicating high statistical heterogeneity. The T^2 statistic was calculated to be 0.1779. The data is summarised in a forest plot (figure 3.2), where it shows that the overall results favour the intervention in reducing LDL-c, however it is not statistically significant, in fact it crosses the line of no effect.

Figure 3.2 Forest-plot for total LDL-c reduction outcome.



3.8.1.3 Blood pressure outcome measurements (mmHg, %).

Two studies have measured blood pressure outcomes. Significant group differences favouring the motivational intervention group, in systolic blood pressure (-5.14, SD= 2.02, CI= -9.15 to 1.14, p= 0.01) was evident in the study by Kong et al. (2017). On the contrary, Boutin-Foster et al. (2016), found no statistically significant difference in the proportion of participants who had achieved blood pressure control between the intervention and control group. Furthermore, the intervention did not statistically prove to be effective in maintaining blood pressure in target range (OR= 1.33, CI: 0.57 to 3.10, p= 0.50), that is <140/90 mmHg, at the twelve month follow-up mark, suggesting that the intervention did not play a role in lowering blood pressure (Boutin-Foster et al., 2016). However, this study shows that blood pressure control was achieved by the majority of the participants in both groups at twelve months (83.7% intervention group, 82.2% control).

3.8.1.4 Anthropometric outcome measurements (cm, kg, %, kg/m^2).

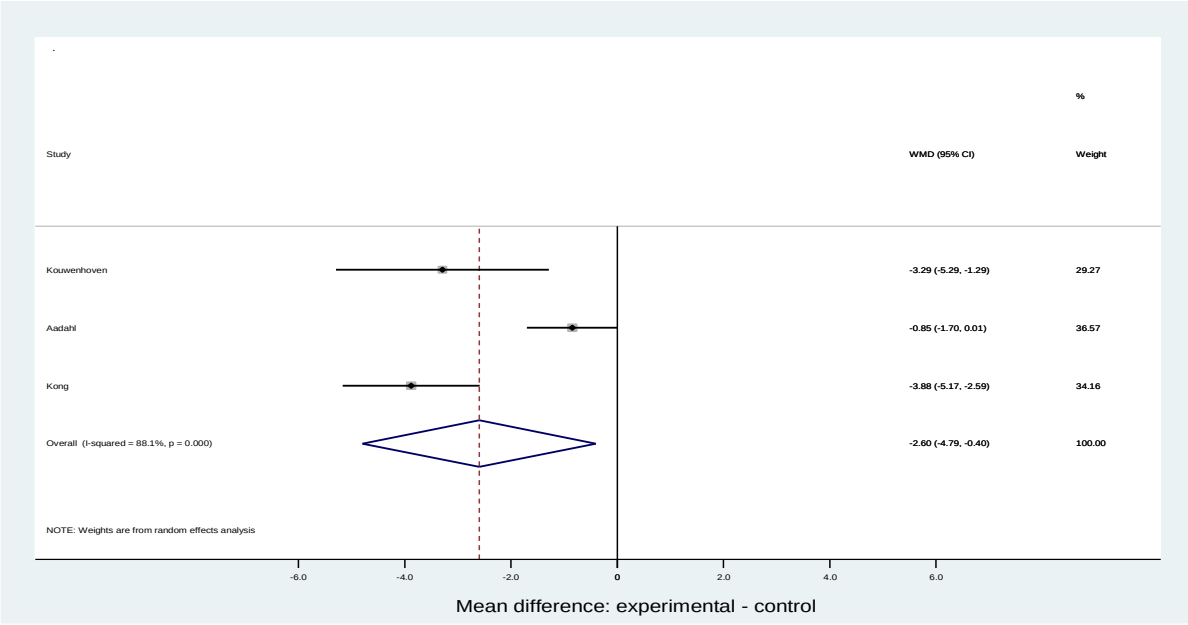
From the seven selected studies, five have measured anthropometric outcomes, of which three studies exhibited statistical between group differences. Waist circumference was lowered amongst the MI group, from 84.2% to 63.2% (p= 0.03) (Lin et al., 2016). This resulted in a decrease in the proportion of those with metabolic syndrome by 18.4% (p= 0.01) at three-month time point (Lin et al., 2016). Waist circumference was also improved in the study by Aadahl et al. (2014) in favour of the experimental group, at six-month time point, (-1.42 cm, 95% CI= -2.54 to -0.29, p= 0.01). This is in line with the study by Kong et al. (2017), where the MI group (n=43), waist circumference and body weight decreased by 8.4% and 6.8% respectively, while percentage reductions for the control group (n=45) were only of 1.1% and 0.8% respectively (p= <0.05) (Kong et al., 2017). In the same study, significant group differences in favour of the MI group, were noticed in waist circumference (-6.92, SD= 0.87, 95% CI= -8.65 to 5.18, p= 0.01) and body weight (-3.35, SD= 0.65, CI= -5.17 to 2.59, p= 0.01). On the contrary, Bóveda-Fontán et al. (2015) found no significant difference between groups (p= 0.449) in waist circumference. However, waist circumference was significantly reduced when analyses were carried out for total sample (N=196) (MD= -0.100 to - 1.607 cm: p= < 0.001). Moreover a significant reduction was also noticed in waist circumference of obese and overweight patients from baseline to post intervention (MD= -79 cm: 95% CI: -0.287 to -1.746 cm: p= < 0.001), but there was no statistical difference between intervention group and control group (p= 0.703) (Bóveda-Fontán et al., 2015). In the intervention group (n=98), proportion of obese patients decreased by 8.4% versus 6.7% in the control group (n=98), indicating a 1.7% difference between groups (McNemar test= 13.899, p= 0.001). There was a decrease of 1.77kg (MD) (CI -0.91 to -2.64 kg p= <0.001) in overweight or obese

subgroup from baseline to 12-month time point. Although this was not statistically significant (p= 0.452), when researchers analysed the total sample (N=198), it was noted that difference between groups becomes significant (MD= -0.61 kg/m^2: 95% CI: -0.34 to -0.88 kg/m^2 p= <0.001) (Bóveda-Fontán et al., 2015). Improved BMI was also evident in the study by Kouwenhoven-Pasmooij et al. (2018), where at twelve-month follow-up mark, after conducting a within-test analysis, there was a statistical difference favouring the extensive intervention group (n=271), a significant reduction of 0.69 kg/m^2 in body mass index, while no reduction was observed in control group (n=213).

Meta-analysis for weight (kg)

In view of variations in methodological and clinical heterogeneity, a random effects meta-analysis was conducted on weight outcome data. The meta-analysis illustrated that a synthesized estimate for unstandardized mean difference in total weight reduction (no intervention vs intervention) was -2.60 kg (95%CI -4.79 to -0.40). A Z-test for overall effect determined evidence that the value was non zero (Z= 2.32, p=0.020). Individual estimates for the unstandardized mean difference ranged from -0.85 (Aadahl et al., 2014) to -3.88 (Kong et al., 2017). Cochran's Q-test determined evidence for statistical heterogeneity at 0.1 significance level (Heterogeneity x^2 = 16.75; p= 0.001). The I^2 statistic was 88.1%, indicating high statistical heterogeneity, thus it indicates generalizability. The T^2 statistic was calculated to be 3.2378. The data is summarised in a forest plot (figure 3.3), where it shows that overall results favour the intervention in reducing weight.

Figure 3.3 Forest-plot for total weight reduction outcome.



3.8.2 Summary of findings

Summary of findings for each outcome using the Grading of Recommendation, Assessment, Development and Evaluation rating (Balshem et al., 2011; Guyatt, Oxman, Kunz, Brozek, et al., 2011; Guyatt, Oxman, Kunz, Woodcock, et al., 2011; Guyatt, Oxman, Montori, et al., 2011; Guyatt, Oxman, Vist, et al., 2011), are shown in table 3.4. The quality level was graded depending on the number of concerns across all domains.

Table 3.4 Programme consisting of MI compared to non-MI programme for individuals at increased risk of CVD.

Outcome	MI group vs non-MI group	95% CI	No of participants	Quality	Comments	Grading the quality across domains
Smoking cessation	Insignificant differences	-	N= 191 (2RCTs) (Bóveda-Fontán et al., 2015; Lakerveld et al., 2013)	⊕⊕⊕◯ Moderate	Trend towards smoking cessation in both groups	Risk of Bias- serious Inconsistency- not serious Indirectness- not serious Imprecision- not serious Publication bias- unlikely
Improved diet	Inconsistent effects	-	N= 992 (3RCTs) (Bóveda-Fontán et al., 2015; Kong et al., 2017; Lakerveld et al., 2013)	⊕⊕◯◯ Low	Significant dietary group differences was only evident in 1 study	Risk of Bias- serious Inconsistency- serious Indirectness- not serious Imprecision- not serious Publication bias- unlikely
Increased physical activity	Insignificant differences	-	N= 1621 (5RCTs) (Aadahl et al., 2014; Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018; Lakerveld et al., 2013; Lin et al., 2016)	⊕⊕⊕◯ Moderate	2 studies have showed significant improvement in both groups	Risk of Bias- serious Inconsistency- not serious Indirectness- not serious Imprecision- not serious Publication bias- unlikely
Improved LDL-c	Pooled weighted mean difference of -0.432	CI= -1.072 to 0.208	N= 309 (2RCTs) (Aadahl et al., 2014; Kong et al., 2017)	⊕◯◯◯ Very low	Pooled results favour the intervention but not statistically significant. CI cross the line of no effect	Risk of Bias- serious Inconsistency- not serious Indirectness- not serious Imprecision- serious Publication bias- likely
Improved blood pressure	Inconsistent effects	-	N=381 (2RCTs) (Boutin-Foster et al., 2016; Kong et al., 2017)	⊕◯◯◯ Very low	Significant group differences was evident in 1 of the studies	Risk of Bias- very serious Inconsistency- serious Indirectness- not serious Imprecision- not serious Publication bias- likely
Decreased weight	Pooled weighted mean difference of -2.598	CI= -4.793 to -0.404	N=800 (3RCTs) (Aadahl et al., 2014; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018)	⊕◯◯◯ Very low	Pooled results favour the intervention in reducing weight	Risk of Bias- very serious Inconsistency- not serious Indirectness- not serious Imprecision- not serious Publication bias- likely

CI: Confidence interval
Quality level and current definitions (Balshem et al., 2011);

High quality ⊕⊕⊕⊕- We are very confident that the true effect lies close to that of the estimate of the effect
Moderate ⊕⊕⊕◯- We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low ⊕⊕◯◯- Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low ⊕◯◯◯- We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

3.8.3 The characteristics of programmes.

The reviewed primary research shows conflicting evidence regarding effectiveness of interventions which made use of MI for addressing modifiable lifestyle risk factors. Although four of the studies were illustrated to be effective (Bóveda-Fontán et al., 2015; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016), the remaining three studies found that MI intervention had no significant influence on objectively measured sitting time, stepping time, self-reported stepping time, weight, body fat, serum cholesterol and blood pressure (Aadahl et al., 2014; Boutin-Foster et al., 2016; Lakerveld et al., 2013).

3.8.3.1 Programmes which were effective.

Lin et al. (2016), designed a programme, which consisted of a single face-to-face individualized lifestyle counselling session and an educative brochure, followed by twelve-weeks of telephone-based MI sessions which took place on weekly basis, lasting up to fifteen to thirty minutes for each telephone call. During these telephone calls participants were reminded to engage in adequate amounts of physical activity levels. Sessions were delivered by a nurse with expertise in MI. Each session focused on empowering participants' strength for motivation and commitment towards increasing their levels of physical activity. The group which received the MI intervention was compared with two other non-MI groups. The brief group received one face-to-face lifestyle counselling session together with an educational brochure, whilst the usual care group received only one session of individualized lifestyle counselling. 115 participants with metabolic syndrome were successfully recruited (Lin et al., 2016). In contrast to the other studies, this research used a more restrictive inclusion criteria, including only middle-aged women with a cluster (three or more risk factors) of conditions which are known to increase risk of cardiovascular disease. Participants were randomised in three groups: experimental group (n=38), brief group (n=38), and the group which received usual care (n=39). This programme intervention showed statistically significant improvements in anthropometric, physical activity and metabolic risk outcome measures.

Kong et al. (2017) designed a programme intervention, which investigated if an intervention consisting of MI combined with a dietary plan and Zumba classes improves anthropometric measurements, serum cholesterol and blood pressure outcomes. Researchers were also interested in blood pressure improvements and serum cholesterol improvement. Only individuals with a body mass index of >18.5 kg/m^2 were included in the study. 88 participants were randomised to either the intervention group or control group, of which 72% were females (n= 43 intervention group, n= 45 control group), with a mean age of thirty-four years (SD= $_{+/-}$9). In the experimental group, certified registered dieticians took an educative approach to teach participants about basic principles of a low-

calorie diet and encouraged participants to follow their weight reduction programme dietary menu. The menu was aimed at reducing sugar intake and increasing fruit and fibre intake. Participants were also supervised by a Zumba instructor where they had circuit high intensity dancing sessions for 45 to 65 minutes, three times a week for twelve weeks. Unlike the control group, intervention group received MI from a registered dietician to support behaviour modifications in reducing weight and waist circumference. The sessions received were three face-to-face MI sessions. Sessions consisted of a patient-centred approach to explore ambivalence and induce self-directed change speech, building motivation towards change, setting up an agenda and exploring advantages and disadvantages when negotiating a plan of change. Each of these sessions took around 20 to 30 minutes. On the other hand, the control group received printed material about diet and lifestyle recommendations and had traditional counselling by a medical officer. Moreover, participants in the control group had aerobic exercises for 30 to 45 minutes three times per week for a duration of twelve weeks, which were supervised by an exercise physiologist. Exercise consisted of treadmill walking or stationary cycling. Activity logs were reviewed by an investigator which was required to monitor adherence and if participants were found to have low adherence, they were contacted by an investigator to discuss any barriers related to this low adherence. This programme was carried out in a primary healthcare setting in Malaysia, were complete follow up data was attainable for 88 participants at three-month follow-up mark (63%). This programme intervention showed statistically significant improvements in anthropometric, cholesterol, physiological and lifestyle outcome measures.

Kouwenhoven-Pasmooij et al. (2018), designed a programme which used health promotion activities based on MI elements. The programme intervention consisted of seven individual sessions of MI: three face-to-face and four telephone-based sessions. Individuals also had an additional motivational paragraph in the newsletter, after having a web-based health risk assessment, which was tailored according to the individual's risk profile, where feedback was provided accordingly. No details were given regarding how these sessions were scheduled such as whether or not they were delivered at weekly intervals. On average, the intervention group attended four MI sessions of 140 minutes in total (mean). The intervention session was delivered by occupational health physicians who have received three full days of training in basic MI techniques, together with three follow-up mentoring sessions of four hours. The content of sessions appears to be dynamic, starting with feedback about the health problem by discussing the person's cardiovascular disease risk profile and motivation towards healthy behavioural changes, which was integrated with lifestyle targets and their values. Furthermore, sessions consisted of the inclusion of a client-centred counselling style using MI techniques, namely use of open-ended questions, reflecting, supporting, and raising ambivalence. 491

participants were randomised to either the experimental group (n=274) or control group (n=217) care. Participants of 40 years and over who had an elevated risk for cardiovascular disease, were eligible to participate in the study. Physical activity levels, dietary measurements, anthropometric measurements, and smoking status were measured after twelve months. These were presented in percentage adherence based on the Dutch guidelines for physical activity targets, healthy diet, healthy body weight (kg/m2), and smoking cessation targets. This programme intervention showed statistically significant improvements in anthropometric and physical activity outcome measures.

Bóveda-Fontán et al. (2015), designed a programme intervention, which consisted of face-to-face MI consultations combined with lifestyle clinical protocol recommendations. On the other hand, the control group received advice on the importance of shifting unhealthy lifestyle patterns towards cardio protective interventions, using clinical protocol recommendations. Sessions were delivered by trained general practitioners who had received a sixteen-hour training course from an expert focusing on eight MI tasks. Training also involved two simulated scenarios similar to the pre-recorded visits they had with two of their patients, where debriefing was carried out by the same MI expert. The time allocated for each session was not reported. However, visits occurred after two months, four months, eight months and twelve months. This study was carried out in twenty-five community health centres, which evaluated the effectiveness of MI mainly on serum lipid parameters. 227 participants were recruited for the study. These were required to meet the inclusion criteria which consisted of an age range from 40 to 75 years old, and a history of dyslipidaemia (hypercholesterolemia: total cholesterol >250 mg/dl and triglycerides <200mg/dl or hypertriglyceridemia: total cholesterol < total cholesterol <200mg/dl and triglycerides >200 mg/dl or mixed hyperlipidaemia: total cholesterol >200 mg/dl and triglycerides > 200 mg/dl). This programme intervention showed statistically significant improvements in lifestyle, anthropometric, and physiological outcome measures.

3.8.3.2 Programmes which were not effective.

Aadahl et al. (2014), designed a programme, based on the behavioural choice theory, which consisted of individual behaviour goal settings, self-efficacy enhancement, and using MI techniques, to reduce daily sitting time. Only individuals who were engaging in minimal or no physical activity were included in the study. The study consisted of 166 participants, of which 53% were females (n= 98 intervention group, n= 98 control group). The intervention consisted of 4 individualized sessions which lasted between 30 to 45 minutes each. The sessions were delivered at the community clinics by one of the two research nurses at six-week intervals throughout six-months. On the other hand, the control group received only one 45-minute session, consisting of individual counselling aimed at reducing daily sitting time. No details were reported with regards to training and experience of the

research nurses. Complete follow up data for this study was attainable for 149 participants (90%). No significant differences were found between groups following the six-month follow-up for objectively measured sitting time (-0.32 hours/day, 95% CI= -0.87 to 0.24, p= 0.26), stepping time (p= 0.11), self-reported sitting time, weight, body fat and serum cholesterol. The only improvement from baseline to the six-month time point was in waist circumference outcome measurement, in favour of the experimental group (-1.42 cm, 95% CI= -2.54 to -0.29, p= 0.01) (Aadahl et al., 2014).

Lakerveld et al. (2013), have designed a programme based on the theory of planned behaviour and on the theory of self-regulation. The programme intervention which was carried out at a diabetes research centre, consisted of six face-to-face motivational counselling sessions of thirty minutes each, followed by three monthly telephone-based MI sessions. Sessions were delivered by practice nurses who had received eighteen hours of training by experienced psychologists. Practice nurses used MI to empower the attitude and intention to change. Focus was given to developing discrepancy between personal goals of the participant and the actual lifestyle related situation. Problem solving measures were used to support participants in overcoming this discrepancy, thus conquering barriers that may hinder lifestyle change. On the other hand, the control group received existing Dutch Heart Foundation brochures which consisted of guidelines to promote physical activity and a healthy diet. Those who were smokers were given an additional brochure to promote smoking cessation. 622 participants were recruited, of which 58.4% were females (n=249 intervention group, n=253 control group) who had a high-risk profile for cardiovascular disease or type two diabetes mellitus. Complete follow up data was attainable for 382 participants (81%, n=184 intervention group, n=198 control group) after a twelve-month follow-up. Overall, participants in the intervention group received a median of two face-to-face MI sessions and a median of two telephone-based sessions. The intervention was not more effective than health leaflets in reducing risk.

Boutin-Foster et al. (2016), designed a programme which focused on combining positive effect and self-affirmation methods with MI. Research assistants delivered MI-based counselling, which consisted of an evaluation of the confidence and motivation for adhering to drug medications, the elucidation of barriers to adherence, advantages and disadvantages of participants' concerns, and finding options to address such barriers and concerns in improving adherence to drug medications. Participants were recruited from health centres and community ambulatory practices. Black American participants who were found to be on at least one antihypertensive pharmacological agent but still had a blood pressure not to target value at time of recruitment, were included in the study. 238 participants were randomised to either the intervention group or to the control group (n=116 intervention group, n= 122 control group) of which 70% were females. Both groups were provided with an educational workbook about elevated blood pressure,

treatment options, lifestyle modification to improve blood pressure targets and they were also asked to develop a behavioural change contract for improving medication adherence. On the other hand, participants in the intervention group received a positive effect strategy to support positive thinking, along with small gifts every two months to help induce a positive effect. Furthermore, these participants were instructed to visualise positive self-values whenever they encountered barriers to medication adherence. In the intervention group, participants also received one session of MI from research assistants who were trained to deliver the intervention components. This was followed by six telephone-based calls to reinforce their motivation and confidence, address barriers and concerns, and reassess their values and goals towards change. There was no difference in blood pressure control rates between intervention and control group.

3.8.4 The level of evidence.

When the available evidence was assessed, for most of the outcomes, the body of evidence was rated as low quality. The level of evidence did not provide precise evidence whether interventions using MI can modify CVD risk. Several issues were identified, namely that some of the results are based on poor methodology (Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kong et al., 2017), that there is significant insufficient reporting of the MI process (Aadahl et al., 2014; Boutin-Foster et al., 2016; Bóveda-Fontán et al., 2015; Kong et al., 2017; Lakerveld et al., 2013; Lin et al., 2016) and in some cases, the studies made use of small sample sizes (Kong et al., 2017; Lin et al., 2016). Although authors claim to use an intervention using MI principles, few details could be identified from their reports about the MI components being used. Without access to further information, replication of the study is severely limited. The MI components used were not well defined, and their consistency throughout the study is questionable. This is further exacerbated by the fact that clinicians in some of the studies (Aadahl et al., 2014; Boutin-Foster et al., 2016; Kong et al., 2017) may not have been specifically trained in MI methods. This considerably weakens the reliability of the study as bias is introduced due to the indefinite MI compliancy. Further to this, the multitude of intervention components used in conjunction with the MI, such as educational material, create difficulty when trying to identify the active ingredients in interventions which produced significant changes. For this reason, we have produced a table (table 3.5) to try to compare, contrast and understand which components could have brought the significant group differences or significant post intervention outcome improvement. In table 3.5, a judgement depending on the individual risk of bias domains was made for each individual study. Programme characteristics which seem to have worked, and others which seemed not to have worked are illustrated in tables 3.5 and 3.6 (pg. 64-65) The selected and identified components

are categorised according to the study methodological qualities based on the Cochrane tool.

Table 3.5 Components of studies which showed significant positive outcomes from baseline to post intervention or significant estimated between group effects.

Authors	Risk of bias	Session characteristics		MI elements used	Deliverer's characteristics	Setting	Participant's characteristics	Mean differences from baseline	Estimated between group effect
Lin et al. (2016)	Low risk	MI combined with education	Type- 1 face to face, combined with 12 telephone-based MI Time- 15-30 minutes each	Affirmation Compassion Evocation	Professional discipline- Nurse with expertise in MI.	Outpatient clinic	Women aged over 40 and over, with metabolic syndrome. Ability to speak and understand Mandarin, no difficulty in walking, and agreed to randomization	Intervention group (n=38): Central obesity- baseline: 32 (84.2), 12 weeks: 24(63.2); 95% CI- 0.00 to 0.08; **p<0.03** MetS n (%)- baseline: 38(100), 12 weeks: 31(81.6), 95%CI- 0.00-0.08; **p <0.01** Numbers of MetS risks, mean (SD)- baseline: 4.0 (0.8), 12 weeks: 3.6(1.1), 95% CI- 0.1-0.5; **p<0.002**	Numbers of MetS risks- 0.4 beta; **p<0.02**
Kong et al. (2017)	High risk	MI combined	Type-3 face to face MI	Developing a change plan	Professional discipline-	Community health centre	Individuals aged between 18 and 59	Intervention group (n=43):	

Authors	Risk of bias	Session characteristics		MI elements used	Deliverer's characteristics	Setting	Participant's characteristics	Mean differences from baseline	Estimated between group effect
		with education and Zumba classes (3x/week,45-65 minutes)	Time- 20-30 minutes each	Eliciting and strengthening change talk Evocation	Licenced dieticians Training- not reported.		years with a BMI of at least 18.5 kg/m2 or above.	Weight (kg): -4.73, sd: +/- 3.80; **p <0.01** Waist circumference (cm): -7.60, sd: +/- 5.48; **p <0.01** Total cholesterol (mmol/l): 1.34 +/- 1.45; **p <0.01** LDL-cholesterol: 1.28 +/- 1.34; **p <0.01** HDL-cholesterol: 0.25 +/- 0.62; **p <0.01** Systolic blood (mmHg) pressure: -4.19, sd: +/-	Weight: -3.88 +/- 0.65, 95% CI- -5.17-2.59; **p <0.01** Waist circumference: -6.92 +/- 0.87, 95% CI- -8.65-5.18; **p <0.01** Total cholesterol: -2.7 +/- 0.30, 95% CI- -1.86-0.69; **p <0.01** LDL-cholesterol: -0.81 +/- 0.27, 95% CI- -1.34-0.28; **p <0.01** HDL-cholesterol: 0.26 +/- 0.13, 95% CI- 0.00-0.52; **p <0.05** Systolic blood pressure: -5.14 +/- 2.02, 95%CI- -9.15-

Authors	Risk of bias	Session characteristics		MI elements used	Deliverer's characteristics	Setting	Participant's characteristics	Mean differences from baseline	Estimated between group effect
								11.4; **p <0.02**	1.14; **p <0.01**
Kouwenhoven-Pasmooij et al. (2018)	High risk	MI combined with online health screening with tailored feedback	Type-3 face to face, combined with 4 telephone-based MI Note- (average attendance- four MI sessions of 140 minutes in total (mean))	Compassion Developing a change plan Evocation Profound acceptance Open-ended questions Reflection	Professional discipline- Occupational health physicians Training- 3 full days of training in MI, with three follow-up coaching sessions of 4 hours.	Occupational health centre	Individuals aged 40 years and over, of both genders and having at least one of the following risks; first degree relative with CHD, not adherent to physical activity guidelines ;smokers; self-reported diabetes mellitus or random glucose of ≥ 11.1 mmol/l; obesity (BMI ≥ 30 kg/m2 and / or waist circumference ≥ 102 cm for men or BMI ≥ 30 kg/m2 and/or ≥ 88 cm for women);hypertension (diastolic value > 90	Intervention group (n=271): Weight (kgs): − 3.12 (− 4.26; -1.99); **p <0.05** BMI (kgs/m^2): − 0.69 (− 1.00; -0.39); **p <0.05** Lack of physical activity (%): −50.3; **p <0.05** Smoking (%): 0	Weight: (− 2.16; 95%CI -5.49-1.17; p >0.05 BMI: − 0.81; 95% CI -1.87-0.26; p >0.05 Lack of physical activity (%): -5.6 (-14.2;5.0); p >0.05 Smoking (%): 8.6 (−0.1;15.7); p>0.05

Authors	Risk of bias	Session characteristics		MI elements used	Deliverer's characteristics	Setting	Participant's characteristics	Mean differences from baseline	Estimated between group effect
							mmHg or a systolic value > 140 mmHg) or the use of antihypertensive drugs; and dyslipidaemia (total cholesterol ≥ 5 mmol/l or LDL cholesterol ≥ 2.5 mmol/l or triglycerides: ≥ 1.7, mmol/l or HDL cholesterol: ≤ 1.0 mmol/l).		
Bóveda-Fontán et al. (2015)	High risk	MI combined with lifestyle clinical guidelines	Type-4 face to face MI Time-Not reported	Not reported	Professional discipline-General practitioners Training-16 hr training course from an expert focusing on 8 MI tasks	Community health centre	Individuals aged 40 to 75 years with dyslipidaemia of both genders.	Total sample (N=196): Total cholesterol: MD = −19.60; 95 % CI: −15.33 to −23.87 mg/dl; Friedman test = 91.756; **p < 0.001** LDL-c: MD = −13.78; 95 % CI: −9.77 to −17.79 mg/dl;	Total cholesterol: F = 0.021; p = 0.996 LDL-c: F = 0.067; p = 0.977

Authors	Risk of bias	Session characteristics		MI elements used	Deliverer's characteristics	Setting	Participant's characteristics	Mean differences from baseline	Estimated between group effect
								Friedman test = 58.856; **p < 0.001** Triglycerides: MD = −19.14; 95 % CI: −11.29 to −26.99 mg/dl; Friedman test = 23.390; **p < 0.001** Weight: MD = −1.77 kg; 95 % 95 % CI: −0.91 to −2.64 kg; Friedman = 47.599; **p < 0.001** Waist circumference : MD = −0.100 to −1.607 cm; Friedman = 47.086; **p < 0.001** International Physical Activity Questionnaire (IPAQ	Triglycerides: F = 0.216; p = 0.886 Weight: F = 1.258; p = 0.285 Waist circumference : F = 0.927; p = 0.449 International Physical Activity Questionnaire (IPAQ

Authors	Risk of bias	Session characteristics		MI elements used	Deliverer's characteristics	Setting	Participant's characteristics	Mean differences from baseline	Estimated between group effect
								Questionnaire) : Chi-squared = 23.3; **p < 0.01** Mediterranean diet score: MD = 1.11; 95 % CI: 1.42-7.29; Friedman test = 44.366; **p < 0.001** Reduction in Smoking: 33%	Questionnaire) : Chi-squared =23.3; p > 0.05 Mediterranean diet score: 95 % CI of MD: −0.626 to 0.582; p >0.05

Table 3.6 Programme characteristics which seemed to have worked.

High quality individual study showing positive impact/s (low risk of bias)	**Insufficient quality individual studies showing positive impact/s (high risk of bias)**
MI combined with education, using a brochure to promote physical activity (Lin et al., 2016)	MI combined with education and Zumba classes (3x/week,45-65 minutes) or MI combined with online health screening with tailored feedback or MI combined with lifestyle clinical guidelines (Kong et al., 2017)
Type-1 face to face, combined with 12 telephone-based MI using short intervals (once weekly call) for 3 months Time- 15-30 minutes each (Lin et al., 2016).	Type-3 face to face MI (Kong et al., 2017) Time-20-30 minutes each (Kong et al., 2017). Type-4 MI sessions of 140 minutes in total (Kouwenhoven-Pasmooij et al., 2018)Type-4 face to face MI sessions (Bóveda-Fontán et al., 2015).
MI consisting of affirmation, compassion, evocation and engagement (Lin et al., 2016).	MI consisting of developing a change plan, eliciting and strengthening change talk and evocation (Kong et al., 2017). MI consisting of compassion, developing a change plan, evocation, profound acceptance, open-ended questions, reflection (Kouwenhoven-Pasmooij et al., 2018).
Professional discipline-Nurse with expertise in MI (Lin et al., 2016).	Professional discipline-Licenced dieticians (Kong et al., 2017) or occupational health physicians (Kouwenhoven-Pasmooij et al., 2018) or General practitioners (Bóveda-Fontán et al., 2015).
Setting-Outpatient clinic (Lin et al., 2016).	Setting-Community health centre (Bóveda-Fontán et al., 2015) or Occupational health centre (Kouwenhoven-Pasmooij et al., 2018).

Table 3.7 Programme characteristics which seemed not to have worked.

Moderate to High quality individual studies showing no impact/s (low risk of bias)	**Insufficient quality individual study showing no impact/s (high risk of bias)**
MI programme based on behavioural choice theory (Aadahl et al., 2014). MI programme based on theory of planned behaviour and theory of self-regulation (Lakerveld et al., 2013).	MI combined with positive effect strategy and self-affirmation methods. Using an educational workbook (Boutin-Foster et al., 2016).
Type- 2 face to face and 2 telephone-based sessions only. 4 face to face sessions Time- 30 to 45 minutes each delivered at prolonged intervals (6-week) throughout 6-months (Aadahl et al., 2014). Type- 6 face-to-face, followed by 3 telephone-based MI sessions at prolonged intervals (monthly) Time- 30 minutes each (Lakerveld et al., 2013).	Type- in person and 6 telephone-based calls Intervals- n/a Time- n/a (Boutin-Foster et al., 2016).
MI consisting of individual behaviour goal settings, self-efficacy enhancement (Aadahl et al., 2014).	MI consisting of motivation and confidence reinforcement, addressing barriers and concerns, reassessment of values and goals towards change (Boutin-Foster et al., 2016).
Professional discipline- Any deliverers without MI training or experience (Aadahl et al., 2014).	Professional discipline- research assistants (Boutin-Foster et al., 2016)
Setting- Community clinic (Aadahl et al., 2014).	Setting- Community clinic (Boutin-Foster et al., 2016).

From the MI elements, compassion was used in two of the studies, of which programmes showed significant difference effect between groups (Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016). Furthermore, evocation which was performed in three of the reviewed studies have also showed significant differences effect between groups (Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016). However, this element did not have a significant difference effect between groups in other programmes (Boutin-Foster et al., 2016; Lakerveld et al., 2013). Being trained in MI techniques or being an expert, also seemed to be one of the components towards a significant group difference effect. In fact, the two studies who have failed to give a description whether those who have delivered the intervention were trained professions, their programmes were ineffective (Aadahl et al., 2014; Boutin-Foster et al., 2016). This gives the impression that training in MI was not received. Also, programmes which have used MI in conjunction with theoretical frameworks such as the behavioural choice theory or theory of planned behaviour and theory of self-regulation, were ineffective (Aadahl et al., 2014; Lakerveld et al., 2013). Programmes which have used MI combined with education (Lin et al., 2016), or combined

with education and Zumba classes (Kong et al., 2017), or combined with online health screening with tailored feedback (Kouwenhoven-Pasmooij et al., 2018), or combined with lifestyle clinical guidelines (Bóveda-Fontán et al., 2015), all had a significant group difference effect.

Of all the studies, the only study which is largely methodologically sound and incorporated use of validated measurements is the study by Lin et al. (2016). However, the study is not without its own limitations. The fact that the study has a small sample size which consisted only of women (n= 115) and the fact that the duration of follow up was short term (3 months) are significantly restrictive. However, this is the only study which claims that MI was delivered by a nurse who is an expert in MI. This study has shown that there is potential for use of MI in reducing metabolic risks amongst middle-aged and older women at risk of developing CVD (Lin et al., 2016).

3.9. Conclusion.

In conclusion, this systematic review and meta-analysis shows that MI is not an effective intervention to support smoking cessation and an increase in physical activity levels in adults at increased risk. Only one study out of two, showed statistically significant differences between groups for dietary outcomes in favour of the MI intervention. Two studies exhibited statistically group differences for improved serum cholesterol. When results were pooled from three studies, meta-analyses for LDL-c did not show a statistically significant group difference, although the trend of LDL-c reduction favoured the MI intervention. From two studies, one study exhibited statistically significant group differences in reducing blood pressure. From five studies, three studies exhibited statistical differences between groups in improving anthropometric outcomes, and meta-analyses from three studies demonstrated statistically significant weight reduction favouring the MI intervention group. Although these findings may not be reliable due to the low quality body of evidence, our review highlights the notion that the primary characteristics of an effective programme might be the application of MI elements such as compassion, affirmation and evocation. Moreover, having the intervention delivered by a nurse expert in MI, or having MI combined with educative resources. Other evidence, however with quality limitations are; using MI elements with health screening resources and tailored feedback, or having MI applied in conjunction with a set of clinical guidelines. It is also notable that Lin et al. (2016), delivered a programme through a sound study methodology, which consisted of one in person session followed by weekly telephone-based MI calls for up to 12 weeks, which lasted between 15 to 30 minutes each. The telephone sessions focused on physical activity engagement, modifying undesirable attributes, strengthening participants' commitment and motivation to increase physical

activity levels by using a brochure timetable, and answering questions and clarifying concerns with regards to the participants' goals.

Chapter 4 – Discussion.

4.1 Introduction

The aim of this review was to evaluate the effectiveness of MI in supporting adults at increased cardiovascular disease risk to make healthy lifestyle changes to reduce cardiovascular risk.

The reviewed literature suggests that there is research which supports the recommendation of lifestyle interventions using MI to address modifiable risk factors. From the seven included studies, four have reported positive significant effects. However, these results should be interpreted with caution. This is because there are large variations in the studies' methodological quality, lowering the grade of evidence. Similar systematic reviews focusing on reducing cardiovascular disease risk by using MI have also reported large variations in intervention designs, and that most of the results remained inconclusive (Lee et al., 2016; Lindson-Hawley, Thompson, & Begh, 2015).

While the studies seem to have different elements, this does not necessarily mean they are incompatible. In our review, significant heterogeneity in the research methods in terms of sample group, ethnicity, control, intervention, statistical analysis used, and presentation of outcome measurements, means that a coherent quantitative synthesis of the results, was generally unattainable. There are other clear sources of heterogeneity, with four out of seven studies being rated as at high risk of bias. Therefore, this review is mainly narrative in nature. Identified key issues are discussed further under the sub-headings; overall completeness and acceptability of evidence, quality of evidence, potential biases in the review process, new research knowledge added, identified gaps and recommendations for future research.

4.2 Overall completeness and applicability of evidence.

The included studies addressed if an intervention using MI is effective in modifying lifestyle behaviours, physiological parameters, lipid profile and anthropometric measurements. The data extracted from the studies has supported identification of intervention characteristics such as the number, duration, type and setting of sessions, characteristics of the deliverer and the reported MI content of the session. All relevant participants, interventions and outcomes of the seven studies were evaluated. It was identified that the context and programme design of the studies varied widely from one study to another, possibly contributing to the variations in outcome.

In the included studies, it was noted that lifestyle behaviours, physiological parameters, cholesterol profile and anthropometric measurements are not pragmatically separate but

just a wider spectrum of the socio-biometrics. The combination of the programme content with MI is not a direct independent variable to physiological or metabolic changes. However, it is a cascade of independent variables that consequently may lead to behavioural change and in return changes in physiological parameters, cholesterol profile and anthropometric changes (dependant variables). Therefore, direct links may be seen as incomprehensible. None of our studies had significant group differences for smoking cessation, although results from the included studies did show a trend towards smoking cessation in both groups. This is in accordance with findings reported by Lee et al. (2016) which show an improvement for smoking cessation after MI intervention, however one of their studies showed a significant difference between groups. In our review, two studies have indicated that programmes using MI as part of their intervention can support diet modification (Bóveda-Fontán et al., 2015; Kong et al., 2017), however significant differences between groups, was only evident in one of the studies. In the review by Lee et al. (2016), none of the studies showed statistical improvements for fruit and vegetable intake and reduction in the consumption of dietary fat after MI intervention. In our review, no statistically significant differences between groups were found for physical activity levels, after receiving the intervention. Contrary to the findings of Lee et al. (2016), two of their studies did report statistically significant differences between groups for such variable.

Furthermore, Lee et al. (2016), noticed that, three studies from four did not find a significant difference between groups for blood pressure after the MI intervention. In our review, from two studies which have looked at blood pressure as an outcome, one study did find a significant difference between groups (Kong et al., 2017).

Overall, in our review, within group differences in the studies have indicated that programmes using MI as part of their intervention can lower systolic blood pressure (Kong et al., 2017), and lower serum cholesterol (Bóveda-Fontán et al., 2015; Kong et al., 2017), lower metabolic risk (Lin et al., 2016), and decrease anthropometric measurements (Bóveda-Fontán et al., 2015; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016). These interventions showed significant and clinically effective results within MI intervention groups in modifying behaviour (Bóveda-Fontán et al., 2015; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018) and an equal effect on those with physiological, metabolic and anthropometric conditions (Bóveda-Fontán et al., 2015; Kong et al., 2017; Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016). Between group differences after receiving the MI intervention, was evident in decreasing metabolic risk (Lin et al., 2016), improving anthropometric outcomes, serum cholesterol and blood pressure outcomes (Kong et al., 2017).

Our meta-analysis showed no evidence for LDL-c reduction, although the trend towards reduction, favours the intervention. This is consistent with results by Lee et al. (2016),

where LDL-c did decrease, however there was no significant differences between groups after receiving the MI intervention. Lee et al. (2016), found no statistical differences for anthropometric measurements between the groups, after receiving MI. On the contrary, our meta-analysis, shows evidence but with limited quality (⊕◯◯◯) for weight reduction after receiving MI intervention with significant differences between groups.

From our review, although the theory and application of MI consists of four key interrelated elements, it seems that some elements might be more impactful than others (Kouwenhoven-Pasmooij et al., 2018; Lin et al., 2016). Compassion, which is noted in two of the studies, is the component that allows the prioritization of the wellbeing and needs of the clients. It is believed that having a compassionate attitude towards the client can help motivate life changes and increase the adoption of behaviour that favours a healthy lifestyle (Miller & Rollnick, 2012). However, this systematic literature review did not sufficiently address the characteristics of the effective MI elements. This is because there is an absence of data which identifies the specific MI elements which might have been applied. Furthermore, studies had different sample populations originating from different societies and, therefore, replication of the results may not be permissible. This is primarily due to the fact that populations could have different varying external exposures/factors and different internal exposures, including MI deliverers with different capabilities. As such, the generalisability of the results is questionable.

4.3 Quality of the evidence.

RCTs are known to represent the strongest evidence and are considered the 'gold standard' of clinical trials. For this reason, this review chose to assess those studies which have reported using an RCT design. The evidence-based medicine ideology has highlighted that using an RCT design may reduce the risk of bias and, a systematic review and meta-analysis of high-quality RCTs are considered the pinnacle of evidence-based research, and are considered as level 1 in the hierarchy of evidence (Akhter et al., 2019). However, if the trials are not carefully and rigorously planned and coordinated, there is the risk of contamination with bias (Sami & Sedgwick, 2011). For this reason, and as bias has potential to affect decisions and conclusions, an integral part of this review was to evaluate the included studies for risk of bias. This assessment depended on information provided in the included studies. All the seven studies were assessed and evaluated qualitatively for risk of bias. From seven studies, only one study was found to be at low risk for bias (Lin et al., 2016). The outcome of our bias-risk assessment showed that the rest of the studies are possibly contaminated with risk of bias which could impact the quality of evidence ((EPOC), 2017; Sami & Sedgwick, 2011). The GRADE rating was used for each outcome measure, taking into consideration other factors, namely inconsistency,

imprecision, indirectness and publication bias. The body of evidence was rated down in quality depending on the risk of bias and these factors (Balshem et al., 2011).

Another issue is the fact that detailed description of MI content is absent. Therefore, it was difficult to identify and compare the outcome results of the studies and the combined intervention components, together with the MI elements. Thus, the application of the elements of MI is questionable. If principles of MI are not being applied correctly, what we might be looking at, is not the results of all the elements, processes and communication skills of MI motives. Instead, this would be the results of partial implementation of MI. It is, therefore, critical that on publication there should be detailed reporting, allowing for replication and implementation. Absence of complete comprehension of MI implementation, can impact the quality of evidence. Therefore, comprehension needs to be assured. Other researchers have highlighted that the description in complex behaviour interventions is often vague and generalised, without the necessary details to replicate or implement effective interventions (Hoffmann et al., 2014).

While the included studies have addressed the review objectives, there are limitations in clearly answering the PICOs research question due to quality issues. All these issues can result in inaccurate data, leading to an indirect yet significant impact on quality decisions. Sample sizes of the included studies ranged from 88 to 622 participants (Kong et al., 2017; Lakerveld et al., 2013) and the response rate ranged from 86.4% to 90% (Aadahl et al., 2014; Bóveda-Fontán et al., 2015). While, we are aware that small studies can have a higher possibility of selection bias, the study by Lin et al. (2016), although having a small sample (n= 115), is the only study which used a robust methodology. The overall assessment showed that the included studies are contaminated with risk of bias and, therefore, the results should be interpreted with caution. For most of the outcomes, the body of evidence was rated as low quality, thus, the evidence of this systematic review does not give the confidence to conclude that MI is effective on modifiable CVD risk factors amongst individuals at increased risk (Low quality body of evidence).

4.4 Other limitations of the existing reviewed research.

4.4.1 Interventions.

Other factors noted in the reviewed studies which may have contributed to conflicting results are the provision of only a few sessions or poor attendance, as noticed in the study by Lakerveld et al. (2013). Possibly inappropriate intensity of the MI content due to insufficient levels of MI adherence, as was noticed in all seven studies. The presence of these two factors places the quantity and quality of the delivered MI content under scrutiny. Although there is the process of randomization, another factor which we consider as a limitation is the fact that none of the studies considered the participants' awareness of their magnitude of the need for change. The reason behind this is because participants

who may underestimate the magnitude of the need for change, may react differently than others who have high expectations of change benefits. If the magnitude for the need for change in some individuals is higher than others or vice versa, the outcome result might not be representative of the true effect of the intervention. In fact, it would be representative of the group differences in magnitude of the need for change, driven by other factors such as psychological trauma or symbolic events. The only study which seems to have counter balanced for such possible differences between the groups is the study by Lin et al. (2016), where it was reported that all study participants were individuals who are interested in learning and participating in self-care activities. We understand that this is an important step as it can be argued that external exposures such as life events, symbolic events, knowledge and abilities to use that knowledge could all be factors which can be more powerful than the treatment with discourse for changing lifestyle and behaviour. This could be a key indicator as to why some participants exhibit successful behaviour changes while others do not. This is evidenced by the fact that even brief MI is effective in hazardous and harmful drinkers. However, one must note that the quality of evidence for this is moderate (Kaner et al., 2018) and that it could be argued that even life events, such as having had a full blown myocardial infarction (ST-segment elevation myocardial infarction), might not be enough to trigger behaviour change, such as smoking cessation, exercise or an increase in healthy eating (Kotseva et al., 2019; Mifsud, 2017). Furthermore, unlike drug trials, clinician-to-patient interventions may vary greatly from one clinician to another, based on their training, experience, counselling style, assessment and participant observation. Thus, the clinician factor can have a potential effect on the intervention results. Therefore, conflicting results from MI interventions could be partially due to the differences in how the intervention content is being delivered by the clinician and in how competent the clinician is in using MI (Hall, Staiger, Simpson, Best, & Lubman, 2016).

4.4.2 Measurement.

Since some of the data collected in the studies is based on varying self-report measures, such as in the assessment of physical activity levels (Aadahl et al., 2014; Bóveda-Fontán et al., 2015; Lakerveld et al., 2013), diet (Bóveda-Fontán et al., 2015; Lakerveld et al., 2013) and smoking cessation attempts (Bóveda-Fontán et al., 2015; Kouwenhoven-Pasmooij et al., 2018), there is the possibility of social desirability bias, and therefore positive outcome measurements may have been overestimated. On the other hand, Lin et al. (2016) used the metabolic equivalents calculation to measure physical activity levels, and thus, was not based on participants' recall and honesty. Other measurements, such as blood pressure (Boutin-Foster et al., 2016; Kong et al., 2017), serum cholesterol (Aadahl et al., 2014; Bóveda-Fontán et al., 2015; Kong et al., 2017; Lin et al., 2016) and

anthropometric measurements (Aadahl et al., 2014; Bóveda-Fontán et al., 2015; Kong et al., 2017; Lin et al., 2016) were also recorded objectively.

4.4.3 Sampling.

Another limitation noted in these studies, is that six of the studies did not include a third arm (non-intervention group). Only Lin et al. (2016) included a non-intervention group.

4.5 New research knowledge added through this review.

Likely intervention components towards effectiveness.

Unlike Lee et al. (2016), our review has focused on primary prevention studies only.

Our review has not only focused on the effectiveness of MI, but have elaborated on the characteristics of the intervention, such as the number, duration, type and setting of sessions, characteristics of the deliverer (professional discipline, training and experience), and also has identified the reported motivation interviewing content of each reviewed study. Our review adds to the current MI and lifestyle behavioral change literature, the likely intervention components which could work better than other components, acknowledging that, if MI is combined with an educative tool, this might work better. In addition, an intervention which consists of 1 face to face, followed by 12 telephone-based MI sessions, using short intervals (once weekly call) for 3 months, of about 15-30 minutes each, seems to be the ideal format and dosage of the intervention. Having the intervention delivered by a nurse with expertise in MI, adjusting the focus on affirmation, compassion, evocation, and engagement, seem to be other important characteristics of intervention effectiveness. As our review has identified these components, this add value into how new study interventions should be developed and delivered.

Insufficient reporting of interventions.

Our review, also highlights to the recommendations that speculate on the importance for researchers to report sufficient information about what they actually did in terms of the intervention components applied, such as the use of MI. We need to make sure that MI is used appropriately. Having such details could have strengthened our report immensely.

In addition to Lee et al. (2016), we suggest that if an intervention is not MI compliant, the researchers should state this clearly in the study abstract, stating that the intervention uses a counselling style adapted from MI. This might ensure researchers to use MI compliancy assessment tools to test for MI compliancy levels, and only if found to be compliant, then this would be acknowledged as MI intervention.

Conclusion.

Identifying and understanding the active ingredients of interventions is paramount to delivering a MI intervention. Although having studies with insufficient reporting of MI elements this systematic review attempted to provide valuable knowledge, which may

have useful implications for researchers and clinicians. Gaps and recommendations for research is further discussed in the dedicated section below (4.7).

4.6 Potential biases in the review process.

The search of our review intended to provide an exhaustive review of the current literature. This should have identified all the relevant studies, which ensured to answer the review PICOs question to its extent. Although this systematic review inherently attempts to minimize bias by using transparent and rigorous methods making it replicable, several limitations at study and outcome level could not be avoided. This is due to the fact that the summary of this review is based on the reliability of the methods used to evaluate for effectiveness in the included studies. Thus, where the quality of the research is possibly contaminated with risk of bias due to inherent problems in the design and its methodology, the results presented in this systematic review need to be interpreted with caution. Heterogeneity between studies made it generally inappropriate to pool results and arrive at an overall conclusion. Data such as the application of MI elements was found to be insufficient across the seven studies and, therefore, it is difficult to detect potential meaningful interactions. Combining results of studies which differ in methodology and quality may lead to false estimates of results, which can manipulate the true intervention effect. As such, the majority of the results had to be interpreted narratively ((EPOC), 2017).

4.7 Identified gaps and recommendations for research.

Gaps in the literature.

Although there is a plethora of research evaluating the effectiveness of interventions using MI in addressing modifiable risk, from our assessment for risk of bias, we are confident in reporting that the methodological quality to date is limited. This systematic review has identified five important gaps in the literature.

Firstly, there is a wide variation in the context and programme designs between the reviewed studies. Future research on MI should aim to evaluate interventions using standardised measuring tools, with comparable data outcomes. Thus, enabling for pooling of standard results to quantitively synthesize in case of a systematic review, to support a conclusive reliable assessment of the intervention effectiveness.

Furthermore, it is unclear whether application of MI is being performed correctly as the MI content reported in the reviewed studies is insufficient. There is a need to use effective objective observation tools to allow the assessment of MI reliability and quality. To ensure the integrity of the MI method, the MITI 4 or MISC coding system can be used. These are reliable and valid tools to assess the integrity of MI, identify MI dimensions and participant's readiness to change. These tools can be utilized by an experienced

independent MI coach to monitor these important points (Hall et al., 2016). If the resources are limited, it is suggested that simpler strategies are used. For example, counting the reflection and questions, assessing the ratio of reflection to question, counting the change talk and sustain talk and assessing the ratio of change talk to sustain talk, and counting the OARS responses once change talk has been achieved (Miller & Rollnick, 2012).

Recommendations for future research.

We highly recommend transparency in the reporting of the intervention which has been implemented, as taking this approach would allow other researchers to replicate the source in their respective population of interest.

Yet, it is uncertain how viable the use of MI in real life practice is. Firstly, more explanatory trials (efficacy trials) are required to determine whether an intervention using MI produces the expected result under ideal circumstances. While randomised controlled trials are the most robust, caution should be taken to avoid contamination with bias. Preferably using a mixed method design, as what empowers the participants to change, such as the clinician being compassionate, still needs to be explored. Thus, we highlight the need for future studies to undergo qualitative exploration. While MI might be a good counselling method which includes risk communication, on its own, it might not be sufficient to bring about behaviour change. Additionally, the practicality of this intervention on the day to day circumstances and the cost for its application still needs to be investigated (pragmatic and efficiency trials). We suggest that MI communication skills (OARS) should be combined with another resource, such as a CVD risk calculator. A CVD risk calculator, might act as a triple effect resource; an evaluative, educative, communicative tool which might further support to modify cardiovascular risk.

MI may be an ideal approach for supporting a specific group of individuals who, while may not be substantial in numbers, are at a high risk of CVD and may likely react to MI by modifying lifestyle risk factors. Using this approach might be ideal amongst siblings of CVD patients as they are more likely to have a higher incidence of central obesity, smoking, hypertension and hypercholesterolemia than populations who do not have a biological sibling with CVD (Allen et al., 1996; Hurrell et al., 2007; Soman, Kar, Satheesh, & Ramalingam, 2016; Yanek et al., 1998). Therefore, it can be argued that as siblings would generally have multiple risk factors, it would be more viable to implement MI amongst such a population, rather than implementing this approach amongst other populations which are likely to be less at risk and perhaps in healthy parameters. If the intervention is successful in reducing risk, it is estimated that risk reduction in middle aged siblings of patients with premature CVD can prevent about one sibling coronary event for every fourteen patients admitted with premature coronary event in five years (42%) (C. Chow et al., 2007). Systematic risk screening of high-risk individuals, such as siblings of patients

with premature CVD could have potential benefits for primary prevention efforts in preventing developing CVD (Perk et al., 2012; Piepoli et al., 2016). Using a MI style combined with another resource which may ease communication, might be more effective to support risk modification, than using MI on its own.

4.8 Conclusion.

In conclusion, while we possess a motivational style of counselling for individuals who are captive to their risk factors, the effectiveness of this intervention method remains uncertain as its strengths and limitations need to be explored further. While MI may support individuals to modify their risk, the results of this review should be interpreted with caution due to several factors, namely the small number of studies included, variations in study quality, heterogeneity, intervention fidelity, and the possibility of having randomised controlled studies contaminated with performance, detection and reporting bias. As such, programmes using MI may be effective and some intervention components might be more powerful in effecting cardiovascular risk factor change than others. Elements such as compassion, affirmation and evocation, if adhered to, could be an important gear in the larger mechanism that needs to be established for successful risk factor change. Furthermore, MI elements seems to blend well with education. As a final note, a combination of one face-to-face session, with weekly telephone-based sessions for twelve consecutive weeks, of fifteen to thirty minutes each, delivered by a trained nurse expert at the outpatient clinic, seems to be the most effective method of delivery.

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Supporting information;

Appendix 1. PRISMA checklist

Section/topic	Item No	PRISMA Checklist item	Reported on page No
Title			
Title	1	Identify the report as a systematic review, meta-analysis, or both	1.
Abstract			
Structured summary	2	Provide a structured summary including, as applicable, background, objectives, data sources, study eligibility criteria, participants, interventions, study appraisal and synthesis methods, results, limitations, conclusions and implications of key findings, systematic review registration number	3
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known	14-16
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOs)	17-18
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (such as web address), and, if available, provide registration information including registration number	n/a
Eligibility criteria	6	Specify study characteristics (such as PICOs, length of follow-up) and report characteristics (such as years considered, language, publication status) used as criteria for eligibility, giving rationale	19-20
Information sources	7	Describe all information sources (such as databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched	20-21
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated	82
Study selection	9	State the process for selecting studies (that is, screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis)	24
Data collection process	10	Describe method of data extraction from reports (such as piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators	25-26
Data items	11	List and define all variables for which data were sought (such as PICOs, funding sources) and any assumptions and simplifications made	25-26
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis	26-28
Summary measures	13	State the principal summary measures (such as risk ratio, difference in means).	28
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (such as I2) for each meta-analysis	28-29
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (such as publication bias, selective reporting within studies)	32-37
Additional analyses	16	Describe methods of additional analyses (such as sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified	n/a
Results			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram	30-31
Study characteristics	18	For each study, present characteristics for which data were extracted (such as study size, PICOs, follow-up period) and provide the citations	36-40

Section/topic	Item No	PRISMA Checklist item	Reported on page No
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome-level assessment (see item 12).	32-35
Results of individual studies	20	For all outcomes considered (benefits or harms), present for each study (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot	46-63
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency	50-52
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15)	35
Additional analysis	23	Give results of additional analyses, if done (such as sensitivity or subgroup analyses, meta-regression [see item 16])	n/a
Discussion			
Summary of evidence	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (such as health care providers, users, and policy makers)	67-70
Limitations	25	Discuss limitations at study and outcome level (such as risk of bias), and at review level (such as incomplete retrieval of identified research, reporting bias)	70-71
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research	72-75
Funding			
Funding	27	Describe sources of funding for the systematic review and other support (such as supply of data) and role of funders for the systematic review	7

Appendix 2. EBSCO database search

EBSCO was searched on August 20th for the period 2013 to August week 3 2018		Searches	Results
Concept 1- Coronary heart disease	"coronary disease*" OR "cerebrovascular disorder*" OR "cardiovascular disease*" OR "cardiovascular disorder*" OR "cerebrovascular disease*" OR "heart disease*" OR "myocardial infarction" OR "heart disease*" OR "coronary*disease" OR "ischemic*disease" OR "athero*" OR "myocardial"	All fields	2,139,429
AND			
Concept 2- Motivational interviewing	"motivation" OR "motivational interviewing" OR "counseling" OR "counsel*" OR "nondirective therapy"	Abstract	12,593
AND			
Concept 3- Adult	"adult*"	All fields	4,190
AND			
Concept 4- Prevention	"prevention" OR "primary prevention"	All fields	1,734
AND			
Concept 5- Risk modification	"modification of risk" OR "risk modification" OR "compliance" OR "patient compliance" OR "guideline adherence" OR "adherence" OR "lifestyle" OR "behavio#r*" OR "blood pressure" OR "cholesterol" OR "LDL" OR "HDL" OR "dietary" OR "lipids" OR "weight" OR "waist circumference" OR "obesity" OR "body mass index" OR "smoking" OR "smoking cessation" AND ("tobacco" OR " cigarette*") OR "tobacco" OR "tobacco use cessation" OR "physical activity" OR "exercise" OR "exercise tolerance" OR "exercise" OR "exercise capacity" OR "food habits" OR "diet*" AND ("pattern*" OR "habit*" OR "Mediterranean" OR "change*") OR "health* behavio#r" OR "behavio#r"	All fields	1,607
AND			
Concept 6- Clinical trial	"clinical trial" OR "comparative study" OR "experimental study" OR "controlled trial" OR "random assignment" OR "random allocation" OR "randomized" OR "randomised" OR "experimental group" OR "control group"	All fields	719
After date limiter applied (2013-2018)			719
After selecting peer reviewed journals only			76: • CINAHL Complete, 42 • PsycINFO, 9 • Academic Search Complete, 25
After excluding children and adolescents			33
After removing duplicates	EBSCO Duplicates are removed without showing records by comparing the following citation metadata: Title Author Date published ISSN or Journal name or ISBN		33
After reading titles and abstracts to remove irrelevant reports			11 retrieved relevant studies
After reading studies in full text and eligible criteria applied			2 selected papers. 9 excluded, reasons were; 4 ongoing studies, 3 participants with established disease, 1 participants with diabetes, 1 lifestyle counselling not MI
Selected studies that fulfilled eligibility criteria			2

Appendix 3. Data collection sheets.

Characteristics of included studies		
Bóveda-Fontán et al. (2015)		
Methods	Multicentre, open, controlled, randomized, cluster, two-parallel arm trial	
Participants	Patients from 25 community health centres Unit of randomization: Inclusion criteria: 40-75 years of age , history of hypercholesterolemia Exclusion criteria: Secondary causes of dyslipidaemia needing statin agents; Established CVD or chronic diabetes, severe COPD, cancer, hepatic failure, chronic kidney failure, substance and alcohol abuse; individuals who unable to comply with the study procedures or follow-up review due to work; pregnant or nursing mothers; and individuals on anti-diabetic agents. 227 participants randomized: n= 227	
Duration of follow-up	12-month follow-up	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
• Selection bias		
Random sequence generation	Unclear risk	There are no details about the method used to generate the allocation sequence. Quote "We carried out a multicentre, open, controlled, randomized, Cluster, two-parallel arm trial". As this detail is insufficient and we cannot say whether the randomization method used, have produced comparable groups. Therefore, the overall comments for this domain, since no information was provided to permit judgement of 'low risk' or 'high risk', we judge this domain as 'unclear risk' of bias
Allocation concealment	High risk	This study has used an open random schedule, where patients were recruited by their general practitioner. Therefore, general practitioners could possibly foresee assigning of participants and thus introducing selection bias. Therefore, the overall comments for this domain, since the investigators of this trial did not use a method to conceal allocation such as central allocation or sequentially numbered opaque sealed envelope technique, the judgement of this domain is 'high risk' of bias
• Performance bias		
Blinding of participants and personnel	High risk	No blinding method was mentioned; therefore, the outcome is likely to be influenced by lack of blinding. We do understand the fact that personnel delivering the intervention cannot be blinded, however there is no detail that ensures that the patients were blinded to the intervention being received. Therefore, the overall comments for this domain, since no blinding method was described with patients, we judge this domain as being at 'high risk' of bias
• Detection bias		
Blinding of outcome assessment	Low risk	The study did not address this outcome. However, since all outcome assessments have been measured objectively, this may have not influenced the outcome measurements. Therefore, the overall comments for this domain, since objective measurements were used, we do believe that this should not introduce bias, therefore the judgment is 'low risk' of bias
Attrition bias		
Incomplete outcome data	Low risk	The study has reported the missing outcome data, which is balanced in numbers across both groups, with similar reasons for missing data across groups.

		Therefore, the overall comments for this domain is that the attrition bias is of 'low risk'.	
Reporting bias			
Selective reporting	Low risk	A study protocol is available and all the study's pre-specified outcomes have been reported in the pre-specified way. Therefore, we judge this domain as being at 'low risk' of reporting bias.	
3. Participant characteristics;			
Total number	227		
Setting (e.g. hospital, community)	Community clinics		
Diagnostic criteria (e.g. hyperlipidaemia, obesity)	uncontrolled dyslipidaemia		
Age	40 to 75 years		
Sex	Men and women		
Country	Spain		
Ethnicity	White Caucasians		
4. Nature of intervention;			
Total number of intervention groups	2 groups		
Intervention specifics (sufficiency for replication, if feasible)	MI-based approach with clinical dyslipidaemia protocol recommendations.		
Session content-			
number of sessions	5 sessions		
type	In person consultations with the patients' usual GPs		
characteristics of the clinician who delivered the intervention	General practitioners had training consisting of 16-hour training. Training was delivered by a person with expertise in MI. This focused on the eight basic MI tasks. After completion of the training program. Physicians attended an individual feedback session with an expert in MI. Initial training was reinforced and maintained during work shop through the following actions: a) GP received "educational micro pills" regularly via Internet and SMS messages; b) each GP was assigned a task. Feedback was then received later; c) GPs attended group sessions to evaluate their own performance with real patients using Problem Based Interviewing techniques.		
5. Type of outcomes measured;			
Time points of collection and reporting	At baseline and at 12 months		
Definition of outcome, unit of measurements used	Lipid parameters		
6. Relevant findings/results;	Intervention		Control
Number of participants allocated to each intervention group	107 patients		120 patients
Sample size of each outcome,	98 patients		98 patients
Details about missing participants	5 patients lost at 2 months (3 refused to continue, 2 did not go back). Another 2 patients lost at 4 months (did not go back). Another 2 lost at 8 months (1 personal problem and the other a serious illness)		6 patients lost at 2 months (4 patients did not go back, 1 refused to continue, 1 changed job position). Another 3 lost at 4 months (1 did not go back, 1 changed residence, 1 changed job). 9 patients lost at 8 months (3 did not go back, 6 changed job position)
Lost to follow rate	13.6 %		
Summary data for each intervention group	**Total sample**		**Estimated between group effect**
Lipid profile			
Total cholesterol (mg/dl)	MD- = −19.60; 95 % 95 % CI: −15.33 to −23.87 mg/dl; Friedman test = 91.756; p < 0.001		F = 0.021; p = 0.996

LDL Cholesterol (mg/dl)	MD = −13.78; 95 % CI: −9.77 to −17.79 mg/dl; Friedman test = 58.856; p < 0.001	F = 0.067; p = 0.977
Triglycerides (mg/dl)	−19.14; 95 % CI: −11.29 to −26.99 mg/dl; Friedman test = 23.390; p < 0.001	F = 0.216; p = 0.886
Diet status –using MEDITERRANEAN DIET Questionnaire Score (Mean difference)	MD = 1.11; 95 % CI: 1.42-7.29; Friedman test = 44.366; p < 0.001	95 % CI of MD: −0.626 to 0.582; p >0.05
Physical activity status-using IPAQ: No. (%)	Chi-squared = 23.3; p < 0.01	Chi-squared = 23.3; p < 0.01
Smoking status (%)	-33.0	n/a
Anthropometric measurement status		
Weight	−1.77 kg; 95 % 95 % CI: −0.91 to −2.64 kg; Friedman = 47.599; p < 0.001	F = 1.258; p = 0.285
Waist circumference	MD = −0.100 to −1.607 cm; Friedman = 47.086; p < 0.001	F = 0.927; p = 0.449
7.Miscellaneous;		
Funding source	LAPT and JBF conceived the study	
Key conclusions of authors	Both MI and Standard Care significantly reduced total cholesterol, LDL-cholesterol and triglyceride levels, as well improved Mediterranean diet score and weight management after a one-year follow-up program. MI performed better than usual care in achieving objectives namely lipid control and physical exercise. It is necessary that quality studies continue research about the use of MI. Health professionals can learn MI skills to integrate into practice and help achieve changes in patients. There is the possibility to combine it with other educational interventions.	
Comments from the study authors	Nil	

1. The characteristics of included studies;		
Kouwenhoven-Pasmooij et al. (2018)		
Methods		Randomized, Cluster randomisation using R version 3.0.1.
Participants		Participants from occupational health centres Inclusion criteria: Exclusion criteria: Participants randomized: n=491
Duration of follow-up		12 months
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
• Selection bias		
Random sequence generation	Low risk	A computer random number generator was used, therefore the judgement is of 'low risk' of bias towards the sequence generation process
Allocation concealment	Low risk	Randomization was performed by a researcher who was not involved in the trial, therefore allocation was concealed which makes this domain at 'low risk' of bias.
• Performance bias		
Blinding of participants and personnel	High risk	Occupational health physicians, lifestyle coaches and participants were not blinded, however the authors judge that due to the design, it was not possible for blinding. Therefore, we judge bias at 'high risk'
• Detection bias		
Blinding of outcome assessment	High risk	Blinding did not take place and the authors judged that this was due to the nature of the study design. However, we think that this can lead to biased of estimates of the intervention effect. A step which could have been taken to avoid this element of bias, is the use of an independent assessor. Therefore, we judge this domain as having 'high risk' of bias.
Attrition bias		
Incomplete outcome data	Low risk	We judge that the authors of this study have applied statistical control to imbalanced factors effectively. Non-

		response analyses were conducted to determine if drop-out was associated with any baseline characteristics or with the sort of intervention used. For Imputation of missing baseline characteristics, the authors have used the mice package in R. Since the percentage of missing values was low the authors have used single imputation. Missing values of adjustment variables were imputed using chained equations using the mice package in R. Therefore, we judge this domain as being at 'low risk' of bias	
Reporting bias			
Selective reporting	High risk	A study protocol is available, but not all pre-specified outcomes that are of interest in the review have been reported in the pre-specified way. For this reason, we judge this domain as having a 'high risk' of bias	
3. Participant characteristics;			
Total number		491	
Setting (e.g. hospital, community)		occupational health centres	
Diagnostic criteria (e.g. hyperlipidaemia, obesity)		Clients with elevated risk for CVD	
Age		40 years and over	
Sex		Both males and females	
Country		Netherlands	
Ethnicity		White Caucasian	
4. Nature of intervention;			
Total number of intervention groups		2 groups	
Intervention specifics (sufficiency for replication, if feasible)		The intervention group and control group, received an online risk assessment, including personalized feedback based on the participant's risk, with suggestions for particular health promotion activities. An electronic newsletter was sent, providing information on the intervention and information on a healthy lifestyle. This was sent via email every 2 to 3 months. The intervention group received an extension with seven in person coaching sessions (3 in person and 4 by telephone) with an Occupational health physician, together with more personalized health promotion activities based on motivational elements, and an additional motivational reference letter.	
Session content-			
Planned number of sessions		seven individual coaching sessions	
Delivered		4 MI sessions	
time		140 minutes in total (mean)	
type		3 face-to-face and 4 by telephone	
characteristics of the clinician who delivered the intervention		Occupational health physicians who received 3 full days of basic training in MI and also 3 follow-up coaching sessions of 4 hours. The occupational health physicians have applied a client-centred counselling approach using open questions, supporting, reflecting, and raising ambivalence. The starting point of the counselling was problem feedback by discussing the person's CVD risks and motivation to change health behaviour.	
5. Type of outcomes measured;			
Time points of collection and reporting		At 6 months and at 12 months	
Definition of outcome, unit of measurements used			
6. Relevant findings/results;		Intervention	Control
Number of participants allocated to each intervention group		274	217
Sample size of each outcome,		271	213
Details about missing participants		49 participants lost to follow up at 6 months. Another 75 lost to follow up at 12 months. 20 participants discontinued during web-based	87 participants lost to follow up at 6 months. Another 92 lost to follow up at 12 months. 39 discontinued during web-based health risk assessment. Details reported about missing participants are personal, work, programme, unknown.

	health risk assessment. 155 participants did not receive the full MI sessions. Details reported about missing participants are personal, work, programme, unknown		
Lost to follow rate	34%		
Summary data for each intervention group at 12 months follow up	Intervention	Control	
Lack of physical activity (%)	−50.3	−53.6	p = >0.05
Estimated effect for lack of physical activity (difference) between intervention groups (95% CI)	−5.6 (− 14.2;5.0)		
Smoking status	0 % reduction	−3.2% reduction	p = >0.05
Estimated effect for Smoking (%) (difference) between intervention groups (95% CI)	8.6 (−0.1;15.7)		
Anthropometric measurement status			
Body weight	− 3.12c (− 4.26; -1.99)	0.17 (−1.44;1.77)	
Estimated effect for Body weight (kg), (difference) between intervention groups (95% CI)	− 2.16 (− 5.49;1.17)		
BMI (kg/mb), (mean, 95%CI)	− 0.69c (− 1.00; -0.39)	0.24 (− 0.20;0.67)	p = <0.05
Estimated effect for BMI (kg/mb), (mean, 95%CI) (difference) between intervention groups (95% CI)	−0.81 (− 1.87; 0.26)		
Mean differences from baseline (intervention group)	Weight (kgs)- − 3.12 (− 4.26; -1.99); p <0.05 BMI (kgs/m2)- − 0.69 (− 1.00; -0.39); p <0.05 Lack of physical activity (%) -−50.3; p <0.05 Smoking (%)-		
Estimated between group effect	Weight- (− 2.16; 95%CI -5.49-1.17; p >0.05 BMI- − 0.81; 95% CI -1.87-0.26; p >0.05 Lack of physical activity (%)- -5.6 (- 14.2;5.0); p >0.05 Smoking (%)-8.6 (−0.1;15.7); p>0.05		
7. Miscellaneous;			
Funding source	Financial support was provided by ZonMW (grant number: 208030007). Additional funding was received from Erasmus Medical Centre (grant number: 2013–13110).		
Key conclusions of authors	Via a website with individualised health assessment and information, body weight improved significantly. MI coaching sessions through a website with tailored care is promising in improving anthropometric measurements of at increased CVD risk individuals.		
Comments from the study authors	Several issues may have reduced the beneficial effects of the extensive intervention; methodological issues, insufficient delivery of the intervention, or ineffectiveness for certain outcomes. The methodological limitation is linked to the cluster design with large cluster-size differences (ranging 1–124). This could have caused under-powering of the study. An associated issue is that a cluster RCT is sensitive to allocation bias. This is noted in		

		the imbalance in gender, age, and education at baseline between the extensive and limited intervention groups. In regards to the delivery of MI, both quantity and quality as provided by OPs need to be considered. 75% of the individuals did not adhere with the full attendance of the 7 planned MI sessions. What is interesting is that BMI decreased statistically significantly, which could suggest that the optimum MI-dose is lower than 7 or, alternatively, that this is determined by personal needs rather than one-size-fits-all. The quality of MI in this study is fairly low. MITI thresholds determined insufficient level of MI compliancy. Since the quality of MI is an important factor in effectiveness of MI, a more detailed exploration of MI-fidelity is needed
1. The characteristics of included studies;		
Lin et al. (2016)		
Methods		3 group randomized controlled trial
Participants		Recruited from an outpatient clinic
Duration of follow-up		3 months
2. Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Selection bias		
Random sequence generation	Low risk	Investigators have made use of computer-generated random serial numbers. 'low risk' of bias
Allocation concealment	Low risk	Opaque sealed envelopes. 'low-risk of bias'
Performance bias		
Blinding of participants and personnel	High risk	No blinding took place; therefore, the outcome can be influenced by lack of blinding. For this reason, we judge this domain as being open to a 'high risk' of bias
Detection bias		
Blinding of outcome assessment	Low risk	Outcome measures were collected by a separate research nurse, blinded to the group assignment. Therefore, we judge this as being at 'low risk' of bias
Attrition bias		
Incomplete outcome data	Low risk	Handling of incomplete outcome data have been imputed using appropriate methods. Here the investigators used intension to treat analysis. Therefore, this fits to the criteria of being at 'low risk' of bias
Reporting bias		
Selective reporting	Low risk	The study protocol is not available, but it is clear that the published reports include all expected outcomes. Therefore, we judge this domain as being at 'low risk' of bias
3. Participant characteristics;		
Total number		115
Setting (e.g. hospital, community)		Outpatient clinic
Diagnostic criteria (e.g. hyperlipidaemia, obesity)		Metabolic syndrome
Age		40 and over
Sex		Women
Country		Taiwan
Ethnicity		White Asian
4. Nature of intervention;		
Total number of intervention groups		three parallel intervention-group design
Intervention specifics (sufficiency for replication, if feasible)		Women in the experimental and brief groups each received a single, individual, brief (15–20 min) face-to-face lifestyle modification counselling session and an educational brochure. An extension to this, was a 12-week individualized lifestyle modification program that focused on physical activity promotion by telephone-delivered MI for the intervention group
Session content-		
number of sessions		12 telephone-based MI
time		15 – 30 minutes each

type	The lifestyle modification program began with an individualized education session. Then telephone-based MI for twelve weeks.		
characteristics of the clinician who delivered the intervention	The intervention was delivered by a nurse, who is an expert in MI. The nurse delivered individualized MI for 12 weeks that focused on physical activity promotion. The women were reminded each week with 15–30 min telephone calls to engage in an adequate level of physical activity, and were rewarded for achieving their target physical activity level. At each session, the goal was to encourage women to strengthen their motivation and commitment, to increase their physical activity amount using the brochure timetable, and to address any questions or concerns by telephone.		
5. Type of outcomes measured;	Physical activity		
Time points of collection and reporting	At 12 weeks		
Definition of outcome, unit of measurements used	(MET-min/week)		
6. Relevant findings/results;	Experimental	Brief	Usual care
Number of participants allocated to each intervention group	38	38	39
Sample size of each outcome,	38	38	39
Details about missing participants	1 Withdrew from study (Went abroad) 3Lost to follow-up (Did not return to the outpatient clinic s)	6 Lost to follow-up (Did not return to the outpatient clinic s/ moved to another county)	5 Were lost to follow-up (Incomplete telephone number to contact/did not return to the outpatient clinics)
Lost to follow rate	13%		
Summary data for each intervention group	Experimental G vs. Usual G	Experimental G vs. Brief G	
Metabolic syndrome (p-value) [confidence interval]	-0.17 (.003) [-0.29to -0.06]	-0.17 (.02) [-0.27 to -0.03]	
Lipid profile			
Elevated triglyceride: >150 mg/dl. (p-value) [confidence interval]	-0.03 (.27) [-0.08 to0.02]	-0.03 (.31) [-0.08 to 0.02]	
Physical activity amount, MET-min/week			
Vigorous-intensity PA (p-value) [confidence interval]	41.1(.26) [-30.8 to 113]	21.1(.41) [-28.5 to70.6]	
Total physical activity (p-value) [confidence interval]	846(.01) [173to1519]	456(.09) [-157 to1070]	
Moderate-intensity PA (p-value) [confidence interval]	337(.02) [43.2to630]	206(.08) [-26.2 to 438]	
Walking (p-value) [confidence interval]	468(.11) [-105 to1042]	271(.36) [-310 to 852]	
Anthropometric measurement status			
Central Obesity (p-value) [confidence interval]	-0.23 (.001) [-0.37to -0.09]	-0.16 (.03) [-0.28 to -0.02]	
Elevated blood pressure (p-value) [confidence interval]	-0.07 (.09) [-0.15 to 0.01]	0.06 (.10) [-0.01 to 0.14]	
Mean differences from baseline (intervention group)	Central obesity- baseline: 32 (84.2), 12 weeks: 24(63.2); 95% CI- 0.00 to 0.08; p<0.03 MetS n (%)- baseline: 38(100), 12 weeks: 31(81.6), 95%CI- 0.00- 0.08; p <0.01 Numbers of MetS risks, mean (SD)-baseline: 4.0 (0.8), 12 weeks: 3.6(1.1), 95% CI- 0.1-0.5; p<0.002		
Estimated between group effect	Numbers of MetS risks- 0.4 beta; p<0.02		
7. Miscellaneous;			
Funding source	This study was funded by the Tri-Service General Hospital (TSGH-C102-138), Taipei, Taiwan		
Key conclusions of authors	A nurse-delivered individualized lifestyle modification Program, which focused on physical activity promotion using telephone MI sessions, to		

		support middle-aged and older females with metabolic syndrome achieve physical activity targets, reduce metabolic risks, and metabolic syndrome diagnoses. Based on the outcome results, this is an ideal intervention to be used by clinicians to share decision-making with clients based on evidence-based nursing practice.
Comments from the study authors		Further studies are needed to evaluate long term follow-up effects of the 12-week personalized lifestyle modification program focused on physical activity promotion using MI among middle aged and older adults of both gender having a diagnosis of metabolic syndrome or have metabolic risk/s. Since healthy diet patterns and increased physical activity have different effects on body composition, with both contributing to fat loss, further study might be needed to incorporate diet-pattern modification into future health promotion programs or to comprehensively assess the diet for changes. Moreover, exploratory studies are needed to assess whether the program actually did empower participants. Mixed designs using focus groups or qualitative examination of what participants perceived as most helpful are considered.
1. The characteristics of included studies;		
Aadahl et al. (2014)		
Method		Randomized, open-end randomized, controlled trial
Participants		Inclusion criteria: Individuals aged between 18 and 69 years, who self-reported 3.5 hours of daily leisure-time sedentary behaviours Exclusion criteria; n/a Participants randomized: n=166
Duration of follow-up		6 months
2. Risk of bias	**Authors' judgement**	**Support for judgement**
• Selection bias		
Random sequence generation	Low risk	open-ended randomization using Computer-generated random numbers operated by a blinded data manager.
Allocation concealment		
• Performance bias		
Blinding of participants and personnel	Low risk	In view this was an open trial where participants and some of the researchers were aware of the randomization, the authors of this study claim that the data of the gadget used were not shown to the participants. Also, the investigators who processed the data of the ActivPAL, were "blinded". An important step which was taken is that research staff who were directly involved in conducting the objective measurements and data processing, were blinded to the randomization. Therefore, by this information we judge that this domain is at 'low risk' of bias.
• Detection bias		
Blinding of outcome assessment	Low risk	The investigators who processed the data of the ActivPAL, were "blinded". An important step which was taken is that research staff who were directly involved in conducting the objective measurements and data processing, were blinded to the randomization. Therefore, we judge this as being at 'low risk' of bias
Attrition bias		
Incomplete outcome data	High risk	There is imbalance in numbers of missing outcome data across the intervention groups (control n=5, intervention n=12) and not having similar reasons for missing data across the groups, hence we judge this as being at "high risk" of bias
Reporting bias		
Selective reporting	Unclear risk	There is insufficient information to permit judgement of 'low risk' or 'high risk'. Therefore,

		the criteria for the judgement is of 'unclear risk' of bias	
3. Participant characteristics;			
Total number		166	
Setting (e.g. hospital, community)		community-based trial	
Diagnostic criteria (e.g. hyperlipidaemia, obesity)		sedentary adults	
Age		18-69	
Sex		Mixed	
Country		Denmark	
Ethnicity		White Caucasian	
4. Nature of intervention;			
Total number of intervention groups		2 group	
Intervention specifics (sufficiency for replication, if feasible)		Intervention using behavioural choice theory, incorporating individual behaviour goal-setting, self-efficacy, and MI techniques. At each of the following sessions (Sessions 2–4), behaviour goals were reviewed and evaluated. With the support of a research nurse, goals were modified and new goals were set. The intervention program focused on four key messages or themes: (1) reduce daily TV viewing; (2) substitute sitting with standing when possible—at work and at home (no time restrictions); (3) break up prolonged sitting by standing up frequently; and (4) 30 minutes maximum of sitting per episode. Written information with key messages, strategies and suggestions for reduction of sitting time, were distributed to participants at each session.	
Session content-			
number of sessions		4 sessions	
Time		30 and 45 minutes each.	
type		individualized face-to-face motivational counselling intervention	
characteristics of the clinician who delivered the intervention		Research nurse. No other details given in regard to the experience or training the research nurse has.	
5. Type of outcomes measured;			
Time points of collection and reporting			
Definition of outcome, unit of measurements used		Objectively measured overall sitting time	
6. Relevant findings/results;		Intervention	Control
Number of participants allocated to each intervention group		93	73
Sample size of each outcome,		93 patients	73 patients
Details about missing participants		Drop out, n=12 Pregnancy, n=1 Lack of time, n=3 Illness in family, n=2 Unknown reason, n=6	Drop out, n=5 Cancer, n=1 Lack of time, n=1 Unknown reason, n=3
Lost to follow rate		10 %	
Difference in change between groups (95% CI)			
Lipid profile			p-value
Total cholesterol (mg/dl)		-0.18 (-0.39, 0.31)	0.09
LDL Cholesterol (mg/dl)		-0.15 (-0.33, 0.04)	0.11
Triglycerides (mg/dl)		-0.06 (-0.23, 0.10)	0.43
Anthropometric measurement status			
Body fat		-0.74 (-1.55, 0.07)	0.08
Weight		-0.83 (-1.73, 0.06)	0.07
Waist circumference		-1.42 (-2.54, -0.29)	0.01
Physical activity status			
Sitting time		-0.32 (-0.87, 0.24)	0.26
Standing time		0.44 (0.8, 0.80)	0.02
Stepping time		0.15 (-0.04, 0.33)	0.11
7. Miscellaneous;			
Funding source		Supported by health insurance foundation & Lundbeck foundation	
Key conclusions of authors			
Comments from the study authors		Nil	

Characteristics of included studies		
Lakerveld et al. (2013)		
Methods	parallel group randomized controlled trial	
Participants	Patients from 12 general practices. Unit of randomization: primary care. Inclusion criteria: participants with at least a 10.0% T2DM risk and/or CVD mortality risk and no known prevalent T2DM or CVD Exclusion criteria: Not specified 622 participants randomized: n= 314 intervention, n= 308 control. Mean (SD) age: 43.6 (5.1) years, females= 56.7%	
Duration of follow-up	12-month follow-up	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
• Selection bias		
Random sequence generation	Low risk	A randomization schedule was drawn up using a computerized random number generator. Note: Members from the same family were randomized to the same group as the first member, to avoid contamination.
Allocation concealment	Low risk	To ensure concealment of the treatment allocation, an independent individual, who had no information about the study participants, performed the randomization.
• Performance bias		
Blinding of participants and personnel	Unclear risk	The research assistants, the principal investigator and the general practitioners were blinded to group assignment. However, the study gives insufficient information how the blinding procedures did take place. Also, it seems that the participants were not blinded.
• Detection bias		
Blinding of outcome assessment	Unclear risk	There is insufficient information to permit judgement of 'low risk or high risk'
Attrition bias		
Incomplete outcome data	Low risk	Few participants were lost to follow-up (19%). Missing outcome data is balanced in numbers across intervention groups, with similar reasons for missing data across groups
Reporting bias		
Selective reporting	Unclear risk	The authors of the study state that the study protocol was approved by the Medical Ethics Committee of the VU University Medical Centre in Amsterdam, however it seems that this was not published
3. Participant characteristics;		
Total number	622	
Setting (e.g. hospital, community)	Diabetes Research Centre	
Diagnostic criteria (e.g. hyperlipidaemia, obesity)	High risk profiles for CVD/type 2 diabetes	
Age	43.5 years (SD 5.3)	
Sex	363 participants were female (58.4%)	
Country	Netherlands	
Ethnicity	White	
4. Nature of intervention;		
Total number of intervention groups	2 groups	

Intervention specifics (sufficiency for replication, if feasible)	Intervention: Trained practice nurses delivered six in person 30-minute counselling sessions, followed by 3-monthly telephone sessions, MI and problem-solving treatment were used. The aim of MI was to make the attitude and intention to change stronger, guided by the Theory of Planned Behaviour. Focusing on discrepancy between the personal goals of the participants and their actual situation was the key method used, as described in the theory of self-regulation. Problem Solving Treatment was used to support participants in finding solutions to overcome this discrepancy, to strengthen their perceived control, and to enable capability to overcome barriers that could stop them from lifestyle modification. Control: control group received existing leaflets containing health guidelines regarding physical activity and a healthy diet. Smokers received an additional leaflet about smoking cessation.		
Session content-			
number of sessions	Six followed by 4 telephone sessions		
type	Face to face of 30 minute each		
characteristics of the clinician who delivered the intervention	Practice nurses who received 18 hours of specific training from MI experienced psychologists prior to the intervention (12 hours of MI and 6 hours of Problem-Solving Treatment). During training practice nurses used a treatment manual developed by the project leader and the psychologists who provided the training. Practical coaching was provided halfway through the sessions, and consisted of one hour of individual coaching with feedback. A random selection of sessions per practice nurse, was voice recorded, and used during training.		
5. Type of outcomes measured;	Primary outcome measures were the estimated risk of developing T2DM (and the estimated risk of CVD mortality (SCORE). Secondary outcome measures: Self-reported physical activity using METS Fruit and vegetable intake using the 8-item food frequency questionnaire Smoking status using WHO assessment		
Time points of collection and reporting	6 months, 12 months		
Definition of outcome, unit of measurements used			
6. Relevant findings/results;	Intervention	Control	
Number of participants allocated to each intervention group	Patients n=249	Patients n=253	
Sample size of each outcome,	patients	patients	
Details about missing participants	38 unable to attend 8 withdrew consent 1 became pregnant 9 unable to attend 4 withdrew consent 1 unable to contact 4 had diagnosed T2DM at follow-up 1 N=65	29 unable to attend 5 withdrew consent 3 became pregnant 2 unable to contact 8 unable to attend 3 withdrew consent 3 unable to contact 1 became pregnant 1 died of CVD N=55	
Lost to follow rate	19%		
Summary data for each intervention group	Intervention	Control	
Lipid profile			p-value
Total cholesterol (mg/dl)	n/a		
LDL Cholesterol (mg/dl)	n/a		
Triglycerides (mg/dl)	n/a		
Meeting recommendations fruit intake (%)	58 (18.5)	68 (22.1)	
Meeting recommendations vegetable intake	62 (19.7)	56 (18.2)	
Self-reported physical activity (METs)			
Low or inactive			
Meeting recommendations (%)	162 (51.6)	160 (51.9)	
Smoking status (%)	46 (18.3)	43 (17)	n/a
Anthropometric measurement status			

Overweight/Obesity	n/a		
BMI	n/a		
Waist circumference	n/a		
7. Miscellaneous;			
Funding source	No information reported		
Key conclusions of authors	The provision of this primary prevention approach was not effective in a Dutch 'real life' primary care setting.		
Comments from the study authors	Attendance rate of sessions was low, down to 2 counselling sessions. This may have contributed to the absence of an intervention effect. Analysis of the participants who had attended at least 4 counselling sessions showed no improvement. This could mean that 6 or less sessions may not have been enough to induce change. However, as the participants in our effectiveness study were not keen enough to attend 6 sessions, it is unlikely that they would want to attend for more.		
Characteristics of included studies			
Boutin-Foster et al. (2016)			
Methods	Randomization in a 1:1 ratio to either an active intervention group or an education- based control group.		
Participants	Patients from health centres and community ambulatory practices. Unit of randomization: primary care. Inclusion criteria: participants having a diagnosis of hypertension, being on at least one antihypertensive medication and having an elevated blood pressure reading at the time of recruitment, African American or Black. Exclusion criteria: Not specified 238 participants randomized: n= 116 intervention, n= 122 control. Mean (SD) age: 56 (11) years, females= 70%		
Duration of follow-up	12-month follow-up		
Risk of bias			
Bias	**Authors' judgement**	**Support for judgement**	
• Selection bias			
Random sequence generation	Unclear risk	Equal randomisation 1:1 ratio was used to support a balanced allocation ratio and not to reduce the power of the study, however there is insufficient information how this was done such using a computer-generated randomisation schedule.	
Allocation concealment	High risk	Same study personnel administered the follow-up calls to maintain continuity and therefore were not blinded to randomization group and any protocol-specific issues.	
• Performance bias			
Blinding of participants and personnel	High risk	Given the interactive nature of the intervention, participants and assessors cannot be blinded to the study intervention.	
• Detection bias			
Blinding of outcome assessment	Unclear risk	The study did not address this outcome	
Attrition bias			
Incomplete outcome data	Low risk	Lost to follow-up (26%). Missing outcome data is balanced in numbers across intervention groups, with similar reasons for missing data across groups	
Reporting bias			
Selective reporting	Unclear risk	There is insufficient information to permit judgement, and no protocol was located for this study.	
3. Participant characteristics;			
Total number	238		
Setting (e.g. hospital, community)	health centres and community ambulatory practices		

Diagnostic criteria (e.g. hyperlipidaemia, obesity)	Hypertension		
Age	56 years (SD 11)		
Sex	167 participants were female (70%)		
Country	America		
Ethnicity	Black African Americans		
4. Nature of intervention;			
Total number of intervention groups	2 groups		
Intervention specifics (sufficiency for replication, if feasible)	Intervention: Research assistants delivered MI-based counselling. The MI intervention included of assessing the motivation and confidence for medication adherence; assessing for barriers which could hinder adherence; eliciting the advantages and disadvantages of any concerns; and a reassessment of their goals and values and linking their current health behaviour pattern to these inner values and life target goals. These strategies were reinforced every 2 months via telephone calls. Participants were provided with an educational workbook plus a positive effect and self-affirmation induction protocol. This helped to focus on positive thoughts that made them feel good throughout their day or when they encountered stressful situations. Moreover, participants had access to a hypertension workbook about the aetiology of blood pressure, treatment options, and lifestyle changes that one could take to modify blood pressure. A behaviour contract was also part of the intervention, where particpants were asked to sign this contract that specified steps that they would take in an effort to improve their ability to take their blood pressure medications as prescribed Control: control group received existing hypertension workbook. Were also asked to develop a behaviour contract that specified steps that they would take in an effort to improve their ability to take their blood pressure medications as prescribed. Received reinforcement every 2 months via telephone calls.		
Session content-			
number of sessions	One MI session followed by 6 telephone calls		
type	Telephone based		
characteristics of the clinician who delivered the intervention	Research assistants were trained to deliver the intervention components. However, no information was given about what sort of training did they receive and for how long.		
5. Type of outcomes measured;			
Time points of collection and reporting	12 months		
Definition of outcome, unit of measurements used	Blood pressure control, mmHg		
6. Relevant findings/results;	Intervention	Control	
Number of participants allocated to each intervention group	Patients n=116	Patients n=122	
Sample size of each outcome,	patients n=90	Patients n=87	
Details about missing participants	Attrition n=26 Withdrew n=5 Lost contact n=14 Moved n=1 Could not make time commitment n=3 No show to closeout n=2 Death n=1	Attrition n=35 Withdrew n=6 Lost contact n=19 Moved n=2 Could not make time commitment n=3 No show to closeout n=3 Death n=1 Travelled out of country n=1	
Lost to follow rate	26 %		
Summary data for each intervention group	Intervention	Control	
			p-value
Meeting blood pressure target range of <140/90	83.7%	82.2%	P=.50
7. Miscellaneous;			
Funding source	Centre of Excellence in Health Disparities		

	Research and Community Engagement (CEDREC) NIMHD P60 MD003421-02.	
Key conclusions of authors	The results illustrate the importance of addressing the psychosocial context of blood pressure medication adherence and blood pressure control. We also achieved success in 82% of the patients in this setting, which is above the national average of approximately 50% and which is much higher than rates for community health settings.	
Comments from the study authors	While these findings did not demonstrate a difference in control between the two arms, lessons learned can be used to refine behavioural interventions for blood pressure control.	
Characteristics of included studies		
Kong et al. (2017)		
Methods	a single-centre, randomized controlled trial	
Participants	Employees from Sarawak Government Polyclinic. Unit of randomization: primary care. Inclusion criteria: aged 18 to 59 years with BMI at least 18.5 kg/m2 or above, able to understand Bahasa Malaysia or English; not planning to transfer or leave employment in the next 12 months; not pregnant; Malaysian; and not taking any weight loss supplementation three months before beginning of the intervention. Exclusion criteria: known coronary artery disease or a procedure to treat such disease 143 participants randomized: n=70 intervention, n=70 control. Mean (SD) age: 34(9) years, females= 72%	
Duration of follow-up	3-month follow-up	
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
• Selection bias		
Random sequence generation	High risk	The study states '70 participants (employees), who met the initial screening criteria were recruited into the intervention group. On the other hand, 73 participants from outpatient clinic by physician were recruited as the control group'. Therefore, it seems that allocation was done in a method of non-random categorization of participants.
Allocation concealment	Unclear risk	Insufficient information to permit judgement of low risk or high risk
• Performance bias		
Blinding of participants and personnel	Low risk	The authors of the study state 'Blinding of subjects was performed to avoid unnecessary interpersonal and intrapersonal bias'. This was done by having different investigators for both groups. Also having the interventions running concurrently at a different treatment room during the 12-week study, so there was no contact between participants during the study.
• Detection bias		
Blinding of outcome assessment	Unclear risk	The study did not address this outcome
Attrition bias		
Incomplete outcome data	Unclear risk	This study did not address this outcome
Reporting bias		
Selective reporting	Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'
3. Participant characteristics;		
Total number	88	
Setting (e.g. hospital, community)	Community clinic	

Diagnostic criteria (e.g. hyperlipidaemia, obesity)	BMI of 18.5 kg/m2 or above	
Age	34 years (SD 9)	
Sex	63 participants were female (72%)	
Country	Malaysia	
Ethnicity	Asian	
4. Nature of intervention;		
Total number of intervention groups	2 groups	
Intervention specifics (sufficiency for replication, if feasible)	Intervention: Certified Registered Dieticians taught basic principles of low-calorie diet (reduction of 500 kcal from estimated total calorie intake) and encouraged individuals to follow their weight reduction Worksite weight management program dietary menu which focused in reducing calorie from total fat intake. Sugars and simple carbohydrates were discouraged, and participants were taught how to ensure taking sufficient 20-30 gram of dietary fibre by: two servings of instant oatmeal together with two servings of toasted flakes of corn breakfast cereals as breakfast or dinner; one-two servings of high fibre wheat cereal crackers as snacks; including one serving of fruit in main meal; and four-five servings of leafy vegetables in a day. Participants were supervised by trained ZUMBA instructor to perform a circuit-style of high intensity interval dance, approximately 45-60 minutes with three days per week throughout the 12-week study. A patient-centred, tailored MI counselling sessions were delivered by trained RDs by exploring ambivalence and eliciting self-directed change talk. Participant were given appointment for their face-to-face cognitive consultation once a month, approximately 20-30 minutes, to identify their motive to change. Typical strategies adopted by counsellors to build motivation in those ambivalent behaviour change included agenda setting and exploration of pros and cons in negotiating a change plan. Control: Received traditional counselling regarding diet in the form of pre-printed material by Medical Officer. These handouts were based on Ministry of Health diet and lifestyle recommendations. They were taught about the aerobic exercise and supervised by an exercise physiologist for attending at least three sessions/week, 30-45 minute each session during the 12-week study. Facility-based exercise consisted of treadmill walking and stationary cycling; while variety of home exercises were encouraged including walking and cycling. Activity logs were reviewed weekly by investigator to monitor adherence. Participants who were not meeting target were contacted by the investigator to discuss their barrier and approaches. Specifically, this group was not interfered by any dietary (personal goal setting) or MI for behaviour support by Registered dietitians.	
Session content-		
number of sessions	3	
type	Face to face	
time	20-30 minutes each	
characteristics of the clinician who delivered the intervention	Trained registered dieticians	
5. Type of outcomes measured;		
Time points of collection and reporting	3 months	
Definition of outcome, unit of measurements used	BMI (kg/m2), Blood Pressure (mmHg)	
6. Relevant findings/results;	Intervention	Control
Number of participants allocated to each intervention group	Patients n=70	Patients n=70
Sample size of each outcome,	Patients=43	Patients=45
Details about missing participants	non-compliance towards physical activity (16; respectively), medically unfit (four obtained study leave and two pregnant; two transferred to district clinic, Klinik Kesihatan Kapit and one diagnosed with acute kidney failure, respectively) and high stress level (five and seven, respectively)	15, unclear 7

Lost to follow rate	37%		
Changes from baseline Mean (+/- SD) for each intervention group	Intervention	Control	
Lipid profile			p-value
Total cholesterol (mg/dl)	1.34 +/- 1.45 (p-value <0.01) -22.7%	0.06+/-0.69 (p-value 0.56) -1%	
LDL Cholesterol (mg/dl)	1.28 +/- 1.34 (p-value <0.01) (-30.5%)	3.7 +/-1.6 (p-value <0.01) [–11 %)	
Triglycerides (mg/dl)	0.18+/- 0.80 (p-value <0.14) (-15%)	0.66 +/- 1.22 (p-value <0.01) (47.1%)	
Systolic Bp mmHg (+/-SD)	4.19 +/- 11.4 (p-value <0.02) (-3.8%)	0.96 +/- 7.07 (p-value <0.37) (-0.9%)	
Systolic Bp Mean difference	5.14 +/- 2.02		0.01
Anthropometric measurement status changes from baseline			
Overweight/Obesity			
Weight (SD)	4.73 +/- 3.80 (p-value <0.01) (-6.8%)	0.85 +/- 2.08 (p-value <0.01) (-1.1%)	
Waist circumference (SD)	7.60 +/- 5.48 (p-value <0.01) (-8.4%)	0.69 +/- 1.99 (p-value <0.03) (-0.8%)	
Waist circumference mean difference	6.92 +/- 0.87		0.01
7. Miscellaneous;			
Funding source	No funding		
Key conclusions of authors	The role of RDs in adopting MI as a strategy to facilitate client's personal motives for behaviour change is undoubtedly important in a primary healthcare setting.		
Comments from the study authors	The major strength of the present study is the involvement of a large number of free-living adults who participated in an already established community-based clinic program without interacting with a team of researchers (i.e. an "effectiveness" rather than "efficacy" study).		

Appendix 4. Session characteristics and Motivational interviewing elements checklist.

Session characteristics and Motivational interviewing elements					
Session characteristics	Item No	Characteristics	**Content reported in the study**		
			YES	NO	
Number of sessions	1				
Length of sessions	2				
Type of session	3				
Setting of session	4				
Characteristics of the clinician	5				
Motivational interviewing elements	Item No	Checklist item	**Element reported in the study**		
			YES	NO	PARTIALLY
The principles of MI					

Session characteristics and Motivational interviewing elements					
Session characteristics	Item No	Characteristics	**Content reported in the study**		
			YES	NO	
Number of sessions	1				
Length of sessions	2				
Type of session	3				
Setting of session	4				
Characteristics of the clinician	5				
Motivational interviewing elements	Item No	Checklist item	**Element reported in the study**		
			YES	NO	PARTIALLY
Profound acceptance	1	Description of acceptance; e.g. clients accepted the way they are without judgements, the clinician being empathetic, supporting autonomy and not telling clients what to do,			
Compassion	2	Description of compassion; e.g. actively promoting the other's welfare and giving priority to their needs.			
Evocation	3	Description of evocation; e.g. the clinician attempts to evoke and strengthen the motivations to change that already exist in the client			
OARS					
Open-ended questions	4	Description of open-ended questions; e.g. the clinician asks questions which require the client to answer in more than few words			
Affirmation	5	Description of affirmation; e.g. acknowledging the client's inherent strengths and efforts (affirmation)			
Reflection	6	Description of reflection; e.g. rephrasing the client's words and thoughts to establish clarity			
Summarization	7	Description of summarization; e.g. compiling together the main points, with a purpose to emphasize, refocus or change direction			
Recognizing and reinforcing change talk					
	8	Description; e.g. listen for, elicit, reinforce, and point out change talk of the related behaviour to clients.			
Eliciting and strengthening change talk					
	9	Description; e.g. use of evocative questions, asks for a description when the client has made a change statement, asking the client how they view the future, gives the client individualized feedback from an assessment and have the client interpret the meaning of the assessment, making use of readiness rulers and following it up with questioning client why did they rate themselves where they did.			
Rolling with resistance					
	10	Description; e.g. reflecting on what the client says, emphasizing autonomy			
Developing a change plan					
	11	Description; e.g. negotiating with the client, answering questions, provide advice and information			
Consolidating a client's commitment					
	12	Description; e.g. listening for client's commitment language and strengthening such commitment			

Appendix 5. Data table and statistical meta-analysis

Authors	Variable	Number in control group	Mean value of outcome measure in control group	CI	SD of outcome measure in control group	Number in treatment group	Mean value of outcome measure in treatment group	CI	SD of outcome measure in treatment group
Kouwenhoven	Weight kg	213	0.17	−1.44 to 1.77		271	− 3.12	−4.26 to -1.99	
Aadahl	Weight kg	68	0.007		2.2	81	−0.84		3.1
Kong	Weight kg	45	-0.85		+-2.08	43	-4.73		+-3.80
Aadahl	LDL-c mmol/l	68	-0.06		0.5	81	-0.21		0.6
Kong	LDL-c mmol/l	45	-0.47		+-1.16	43	-1.28		+-1.34

Statistical work for weight outcome

Study	WMD	[95% Conf.	Interval]	% Weight
Kouwenhoven	-3.290	-5.293	-1.287	29.27
Aadahl	-0.847	-1.701	0.007	36.57
Kong	-3.880	-5.168	-2.592	34.16
D+L pooled WMD	-2.598	-4.793	-0.404	100.00

Heterogeneity chi-squared = 16.75 (d.f. = 2) p = 0.000
I-squared (variation in WMD attributable to heterogeneity) = 88.1%
Estimate of between-study variance Tau-squared = 3.2378

Test of WMD=0: z= 2.32 p = 0.020

Statistical work for LDL-c outcome

Study	WMD	[95% Conf.	Interval]	% Weight
Aadahl	-0.150	-0.327	0.027	57.29
Kong	-0.810	-1.335	-0.285	42.71
D+L pooled WMD	-0.432	-1.072	0.208	100.00

Heterogeneity chi-squared = 5.46 (d.f. = 1) p = 0.019
I-squared (variation in WMD attributable to heterogeneity) = 81.7%
Estimate of between-study variance Tau-squared = 0.1779
Test of WMD=0: z= 1.32 p = 0.186