General physical health advice for people with serious mental illness (Review)

Tosh G, Clifton AV, Xia J, White MM

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2014, Issue 3

http://www.thecochranelibrary.com

WILEY

TABLE OF CONTENTS

[Intervention Review]

General physical health advice for people with serious mental illness

Graeme Tosh[1], Andrew V Clifton[2], Jun Xia[3], Margueritte M White[4]

[1]Early Intervention in Psychosis and Community Therapies, Rotherham, Doncaster and South Humber NHS Foundation Trust (RDASH), Swallownest, UK. [2]School of Human and Health Sciences, University of Huddersfield, Huddersfield, UK. [3]Cochrane Schizophrenia Group, The University of Nottingham, Nottingham, UK. [4]Valley Center, Global Community Writer, California, USA

Contact address: Jun Xia, Cochrane Schizophrenia Group, The University of Nottingham, Institute of Mental Health, University of Nottingham Innovation Park, Triumph Road,, Nottingham, NG7 2TU, UK. Jun.Xia@nottingham.ac.uk.

Editorial group: Cochrane Schizophrenia Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 3, 2014.
Review content assessed as up-to-date: 26 October 2013.

Citation: Tosh G, Clifton AV, Xia J, White MM. General physical health advice for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2014, Issue 3. Art. No.: CD008567. DOI: 10.1002/14651858.CD008567.pub3.

ABSTRACT

Background

There is currently much focus on provision of general physical health advice to people with serious mental illness and there has been increasing pressure for services to take responsibility for providing this.

Objectives

To review the effects of general physical healthcare advice for people with serious mental illness.

Search methods

We searched the Cochrane Schizophrenia Group's Trials Register (last update search October 2012) which is based on regular searches of CINAHL, BIOSIS, AMED, EMBASE, PubMed, MEDLINE, PsycINFO and registries of Clinical Trials. There is no language, date, document type, or publication status limitations for inclusion of records in the register.

Selection criteria

All randomised clinical trials focusing on general physical health advice for people with serious mental illness..

Data collection and analysis

We extracted data independently. For binary outcomes, we calculated risk ratio (RR) and its 95% confidence interval (CI), on an intention-to-treat basis. For continuous data, we estimated the mean difference (MD) between groups and its 95% CI. We employed a fixed-effect model for analyses. We assessed risk of bias for included studies and created 'Summary of findings' tables using GRADE.

Main results

Seven studies are now included in this review. For the comparison of physical healthcare advice versus standard care we identified six studies (total n = 964) of limited quality. For measures of quality of life one trial found no difference (n = 54, 1 RCT, MD Lehman scale 0.20, CI -0.47 to 0.87, *very low quality of evidence*) but another two did for the Quality of Life Medical Outcomes Scale - mental component (n = 487, 2 RCTs, MD 3.70, CI 1.76 to 5.64). There was no difference between groups for the outcome of death (n = 487, 2 RCTs, RR 0.98, CI 0.27 to 3.56, *low quality of evidence*). For service use two studies presented favourable results for health advice,

uptake of ill-health prevention services was significantly greater in the advice group (n = 363, 1 RCT, MD 36.90, CI 33.07 to 40.73) and service use: one or more primary care visit was significantly higher in the advice group (n = 80, 1 RCT, RR 1.77, CI 1.09 to 2.85). Economic data were equivocal. Attrition was large (> 30%) but similar for both groups (n = 964, 6 RCTs, RR 1.11, CI 0.92 to 1.35). Comparisons of one type of physical healthcare advice with another were grossly underpowered and equivocal.

Authors' conclusions

General physical health could lead to people with serious mental illness accessing more health services which, in turn, could mean they see longer-term benefits such as reduced mortality or morbidity. On the other hand, it is possible clinicians are expending much effort, time and financial resources on giving ineffective advice. The main results in this review are based on *low or very low quality* data. There is some limited and poor quality evidence that the provision of general physical healthcare advice can improve health-related quality of life in the mental component but not the physical component, but this evidence is based on data from one study only. This is an important area for good research reporting outcome of interest to carers and people with serious illnesses as well as researchers and fundholders.

PLAIN LANGUAGE SUMMARY

General physical health care advice for people with serious mental illness

People with serious mental illness tend to have poorer physical health than the general population with a greater risk of contracting diseases and often die at an early age. In schizophrenia, for example, life expectancy is reduced by about 10 years. People with mental health problems have higher rates of heart problems (cardiovascular disease), infectious diseases (including HIV and AIDS), diabetes, breathing and respiratory disease, and cancer.

Advising people on ways to improve their physical health is not without problems since there is often a perception, that advice offered is ineffective and will be ignored but it has been shown that healthcare professional advice can have a positive impact on behaviour. Advice can often motivate people to seek further support and treatment. Health advice could improve the quality and duration of life of people with serious mental illness. There is currently much focus on general physical health advice for people with serious mental illness with increasing pressure for health services to take responsibility for providing better advice and information.

This review focuses specifically on studies of general physical health advice and excludes more targeted health interventions.

Based on an electronic search carried out in 2012, this review now includes seven studies that randomised a total of 1113 people with serious mental illness. Six studies compared general physical health advice with standard care, one compared advice on healthy living with artistic techniques such as sketching and pottery. Information was of limited *low or very low quality*, there were a small number of participants and findings were ambiguous.

There is some limited evidence that the provision of physical healthcare advice can improve health-related quality of life mentally but not physically. No studies returned results that suggest that physical healthcare advice has a powerful effect on physical healthcare behaviour or risk of ill health. More work is needed in this area. Only one adverse effect outcome was presented, death, but there were no differences between the treatment groups for this outcome.

Funders and policy makers should be aware that there may be some benefit for physical health advice for people with serious mental illness. There is an increased demand for preventative health services that involve the provision of advice and which may also reduce costs to health services.

This plain language summary has been written by a consumer, Ben Gray from RETHINK.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

PHYSICAL HEALTH ADVICE versus STANDARD CARE for people with serious mental illness

Patient or population: patients with people with serious mental illness
Settings:
Intervention: PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	PHYSICAL HEALTH ADVICE versus STANDARD CARE				
Physicl health awareness - not reported	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome, which we had pre-stated to be of importance
Physical health behaviour moderate or vigorous physical activity Follow-up: 6 months	The mean physical health behaviour in the control groups was **152 minutes**	The mean physical health behaviour in the intervention groups was **39 higher** (76.53 lower to 154.53 higher)		80 (1 study)	⊕⊕◯◯ **low**[1,2,3]	
Quality of life Lehman Quality of Life Scale. Scale from: 1 to 7 Follow-up: 18 months	The mean quality of life in the control groups was **4.45 points**[4]	The mean quality of life in the intervention groups was **0.2 higher** (0.47 lower to 0.87 higher)		54 (1 study)	⊕◯◯◯ **very low**[1,2,3,5]	

Adverse effects Death of participant Follow-up: median 6-12 months	**Low-risk population**[6]		**RR 0.98** (0.27 to 3.56)	487 (2 studies)	⊕⊕◯◯ **low**[2,3,7]	
	10 per 1000	**10 per 1000** (3 to 36)				
	Medium-risk population[6]					
	15 per 1000	**15 per 1000** (4 to 53)				
	High-risk population[6]					
	50 per 1000	**49 per 1000** (14 to 178)				
Economic - not reported	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome we had pre-stated to be of importance
Leaving the study early	**Study population**		**RR 1.11** (0.92 to 1.35)	964 (6 studies)	⊕◯◯◯ **very low**[1,2,3,8]	
	300 per 1000	**333 per 1000** (276 to 405)				
	Medium-risk population					
	292 per 1000	**324 per 1000** (269 to 394)				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Limitations of design: rated 'serious' (lack of allocation concealment)
[2] Limitations of design: rated 'serious' (lack of blinding)
[3] Imprecision: rated 'serious' (small sample size)
[4] Based on seven point Likert scale
[5] Indirectness: rated 'serious' (authors admit that measurement tool was difficult to interpret)
[6] Range based around data from control group
[7] Limitations of design: rated 'serious' (duration of study may have negative effect on motivation)
[8] Inconsistency: rated 'very serious' (some of the trials were cluster trials)

BACKGROUND

Description of the condition

The definition of serious mental illness with the widest consensus is that of the National Institute of Mental Health (NIMH) (Schinnar 1990) and is based on diagnosis, duration and disability (NIMH 1987). People with serious mental illness have conditions such as schizophrenia or bipolar disorder, over a protracted period of time, resulting in erosion of functioning in day to day life. A European survey put the total population-based annual prevalence of serious mental illness at approximately two per thousand (Ruggeri 2000). People with serious mental illness have a higher morbidity and mortality from chronic diseases than the general population, and this results in a significantly reduced life expectancy (Robson 2007). In schizophrenia, for example, life expectancy is reduced by around 10 years (Newman 1991). Sufferers from serious mental illness have increased rates of cardiovascular disease, infectious diseases (including HIV) (Cournos 2005), non-insulin dependent diabetes, respiratory disease and cancer (Dixon 1999; Robson 2007).

Description of the intervention

Physical health advice/promotion can take many forms, and these are highly divergent and dependent on environmental and socioeconomic factors. Physical health monitoring is the focus of a previous review (Tosh 2010a). Whereas monitoring is passive, advice is the active provision of preventative information. It has an educative component and is delivered in a gentle non-patronising manner (Stott 1990). In the context of this review we suggest that physical health advice should not be delivered solely in the form of a structured programme or training approach. Currently, much health promotion/advice exists (Smith 2007; Smith 2007a; Solty 2009). This is often targeted at a discrete problem, such as poor diet or smoking. In this review, however, we focus on studies of general physical health advice and exclude more targeted approaches. By general physical health we mean that which is not in any way focused on any one condition, system or behaviour/intervention.

How the intervention might work

Advising people on ways to improve their physical health is not without problems since there is often a perception, from family doctors in particular, that advice offered is ineffective and patients will reject it (Sutherland 2003). This is not necessarily the case. It has been demonstrated that physician or healthcare professional advice can have a positive impact on behaviour (Kreuter 2000; Russell 1979). Advice can often act as the catalyst for motivating people to seek further support and treatment (Sutherland 2003). Given the evidence of increased rates of potentially preventable health problems in people with serious mental illness (Cournos 2005; Dixon 1999; Robson 2007), and the suggestion from a 2005 systematic review (Bradshaw 2005) that methodologically robust, healthy living interventions give "promising outcomes" in people with schizophrenia, we believe that appropriate health advice could improve the quality and duration of life for sufferers of serious mental illness. Additional benefits may include a reduction in dependence on medical services. "There are potential savings to be made on prescribing acute care budgets through prevention or early detection of serious illness in these groups of service users" (DoH 2006).

Why it is important to do this review

There is evidence to suggest that the physical health needs of people with serious mental illness are often "unrecognised, unnoticed or poorly managed" (DoH 2006). Neglecting the physical healthcare needs of people with serious mental illness adds to the already high burden placed on individuals, careers, communities and society as a whole. It is estimated that the economic and financial cost of mental health problems in the UK stands at £77 billion, mainly as *a* result of lost productivity (HM Government 2009). In November 2004 the UK's Department of Health published 'Choosing health: making healthy choices easier' (DoH 2005). This set out key principles to support the public to make healthier and more informed choices about lifestyles. A report by the UK's King's Fund indicated that 86% of the general public agreed that the UK Government has a responsibility to provide information and advice to prevent illness (Kings Fund 2004). Despite government policy and the public desire for more physical healthcare advice, we could not identify any systematic reviews that refer to randomised controlled trials *though* a "systematic review of the published and grey literature" (Bradshaw 2005) concluded that "further research is needed to assist *in* the development of effective interventions to help this client group" (people with serious mental illness). This is one of a series of reviews (Table 1).

OBJECTIVES

To review the effects of general physical healthcare advice for people with serious mental illness.

METHODS

Criteria for considering studies for this review

Types of studies

We considered all relevant randomised controlled trials (RCTs) and economic evaluations conducted alongside included RCTs. We excluded quasi-randomised studies, such as those allocating by using alternate days of the week. If we had encountered trials described in some way as to suggest or imply that the study was randomised and where the demographic details of each group's participants were similar, we intended to include them and in a sensitivity analysis of the effects of the presence or absence of these data.

Types of participants

We required that the majority of participants should be within the age range 18 to 65 years and suffering from severe mental disorder, preferably as defined by NIMH 1987 or, in the absence of this, from diagnosed illnesses such as schizophrenia, schizophrenia-like disorders, bipolar disorder, or serious affective disorders. We did not consider substance abuse to be a severe mental disorder in its own right; however, we did feel that studies should remain eligible if they dealt with people with dual diagnoses, that is those with severe mental illness plus substance abuse. We did not include studies focusing on dementia, personality disorder and mental retardation, as they are not covered by our definition of severe mental disorder.

Types of interventions

1. General physical health advice

We have found it difficult to find a useful definition of 'advice'. In the context of this review we define 'advice' as preventative information (Greenlund 2002) or counsel (Oxford English Dictionary) that leaves the recipient to make the final decision; it should have at least a suggestion of: i. an educative component; ii. a preventative aim; and iii. an ethos of self-empowerment. Advice may be directional but not paternalistic in its delivery. It is not a programmed or training approach, focusing on the acquisition of knowledge, skills, and competencies as a result of formal teaching sessions.

We defined 'physical health' as 'soundness of body' as opposed to the World Health Organization's definition of 'health' which includes mental and social well being (WHO 1948).

'General' physical health advice involves the giving of advice that is not in any way focused on any one condition or system or behaviour/intervention.

2. Treatment as usual

Care in which physical health advice is not specifically emphasised above and beyond care that would be expected for people suffering from severe mental illness.

Types of outcome measures

For the purposes of this review we divided outcomes into four time periods, i. immediate (within one week) ii. short term (one week to six months) iii. medium term (six months to one year) and, iv. long term (over one year).

Primary outcomes

1. Physical health awareness

1.1 Failure to raise awareness of common physical health problems
1.2 Failure to raise awareness of behaviours which can contribute to ill-health

2. Physical health behaviour

2.1 No substantial change in behaviour

Secondary outcomes

1. Physical health behaviour

1.1 No change in behaviour
1.2 Deterioration in physical health behaviour

2. Physical health

2.1 Failure to act on known risk factors
2.2 Failure to address disease potentially associated with psychiatric diagnosis
2.3 Failure to raise awareness of common physical health problems
2.4 Unchecked adverse effects of treatment

3. Quality of life

3.1 Loss of independence
3.2 Loss of activities of daily living (ADL) skills
3.3 Chronic pain
3.4 Immobility
3.5 Loss of social status
3.6 Healthy days
3.7 No clinically important change in general quality of life

4. Adverse event

4.1 Number of participants with at least one adverse effect
4.2 Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count)
4.3 Average endpoint in specific adverse effects
4.4 Average change in specific adverse effects
4.5 Death - natural or suicide

5. Service use

5.1 Hospital admission
5.2 Emergency medical treatment
5.3 Use of emergency services

6. Financial dependency

6.1 Claiming unemployment benefit
6.2 Claiming financial assistance because of a physical disability

7. Social

7.1 Unemployment/loss of earnings
7.2 Social isolation as a result of preventable incapacity
7.3 Increased burden to caregivers

8. Economic

8.1 Increased costs of health care
8.2 Days off sick from work
8.3 Reduced contribution to society
8.4 Family claiming careers' allowance

9. Leaving the studies early (any reason, adverse events, inefficacy of treatment)

10. Global state

10.1 No clinically important change in global state (as defined by individual studies)
10.2 Relapse (as defined by the individual studies)

11. Mental state (with particular reference to the symptoms of schizophrenia)

11.1 No clinically important change in general mental state score
11.2 Average endpoint general mental score
11.3 Average change in general mental state score
11.4 No clinically important change in specific symptoms (positive/negative symptoms of schizophrenia)
11.5 Average endpoint specific symptom score
11.6 Average change in specific symptom score

12. 'Summary of findings' tables

We used the GRADE approach to interpret findings (Schünemann 2008) and used the GRADE profiler (GRADE PRO) to import data from RevMan 5 (Review Manager) to create 'Summary of findings' tables. These tables provide outcome-specific information concerning the overall quality of evidence from each included study in the comparison, the magnitude of effect of the interventions examined, and the sum of available data on all outcomes that we rated as important to patient-care and decision making. We intended to include the following outcomes in a 'Summary of findings' table.

- Physical health awareness - Failure to raise awareness of common physical health problems or behaviours which can contribute to ill-health
- Physical health behaviour - No substantial change in behaviour
- Quality of life - Loss of independence
- Adverse event - Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count
- Economic - Increased costs of health care
- Financial dependency - Claiming financial assistance because of a physical disability
- Global state - No clinically important change in global state (as defined by individual studies)

Search methods for identification of studies

Electronic searches

1. Original search (2009)

The Cochrane Schizophrenia Group's Trials Register was searched (November 2009) using the phrase:
[(*physical* or *cardio* or *metabolic* or *weight* or *HIV* or *AIDS* or *Tobacc* or *Smok* or *sex* or *medical* or *dental* or *alcohol* or *oral* or *vision* or *sight*or *hearing* or *nutrition* or *advice* or *monitor* in title of REFERENCES) AND (*education* OR *health promot* OR *preventi* OR *motivate* or *advice* or *monitor* in interventions of STUDY)]
This register is compiled by systematic searches of major databases, handsearches and conference proceedings (see Group Module).

2. Update search (2012)

The Trials Search Co-ordinator, Samantha Roberts, searched the Cochrane Schizophrenia Group's Trials Register (October 2012) using the phrase:
[(*physical* or *cardio* or *metabolic* or *weight* or *HIV* or *AIDS* or *Tobacc* or *Smok* or *sex* or *medical* or *dental* or *alcohol* or *oral* or *vision* or *sight*or *hearing* or *nutrition* or *advice* or *monitor* in title of REFERENCES) AND (*education* OR *health promot* OR *preventi* OR *motivate* or *advice* or *monitor* in interventions of STUDY)]
The Cochrane Schizophrenia Group's Registry of Trials is compiled by systematic searches of major resources (including AMED, BIOSIS, CINAHL, EMBASE, MEDLINE, PsycINFO, PubMed, and registries of Clinical Trials) and their monthly updates, handsearches, grey literature, and conference proceedings (see Group

Module). There is no language, date, document type, or publication status limitations of inclusion of records in the register.

Searching other resources

1. Reference searching

We inspected the references of all identified studies for other relevant studies.

2. Personal contact

We contacted the first author of each included trial for information regarding unpublished studies, we also contacted the first author of each ongoing study and requested information about current progress. If authors responded with relevant information we used this and noted their response in the Characteristics of included studies.

Data collection and analysis

Selection of studies

For the original review, review authors GT, AC and SM screened the results of the*original* electronic search; to ensure reliability another review author MB inspected a random sample of the electronic search, comprising 10% of the total. GT and AC inspected all abstracts of studies identified through screening and identified potentially relevant reports. Where disagreement occurred we resolved this by discussion, and where there was still doubt, we acquired the full article for further inspection. We then requested the full articles of relevant reports for reassessment and carefully inspected them for a final decision on inclusion (see Criteria for considering studies for this review). In turn, GT and AC inspected all full reports and independently decided whether they met the inclusion criteria.

The results from the most recent 2012 electronic search were screened by JX who inspected all abstracts and identified potentially relevant reports. MW inspected full articles for final inclusion. JX, GT and AC were consulted in cases where there was uncertainty and a final decision was made when an agreement was reached by all authors. We were not blinded to the names of the authors, institutions or journal of publication.

Data extraction and management

1. Extraction

For the original review, authors GT and AC independently extracted data from included studies. Again, we discussed any disagreement, documented our decisions and, if necessary, we contacted the authors of studies for clarification. Whenever possible we only extracted data presented in graphs and figures, and we only included data if two review authors independently had the same result. We made attempts to contact authors through an open-ended request in order to obtain any missing information or for clarification whenever necessary. Where possible, we extracted data relevant to each component centre of multi-centre studies separately. From the 2012 update search, one of the studies previously listed as ongoing had been finished and the study was included in the review. JX and MW independently extracted data.

2. Management

2.1 Forms

For the original review, GT and AC extracted data onto standard, simple forms.

For the 2012 update, JX and MW independently extracted data from the new included study.

2.2 Data from multi-centre trials

Where possible the authors verified independently calculated centre data against original trial reports.

3. Rating scales

A wide range of instruments are available to measure outcomes in mental and physical health studies. They vary in quality and are often not validated or are created for a particular study. It is accepted generally that measuring instruments should be both reliable and have reasonable validity (Rust 1989). For the original review, we included continuous data from rating scales only if the measuring instrument had been described in a peer-reviewed journal (Marshall 2000); and not those written or modified by one of the trialists for a particular trial.

4. Endpoint versus change data

We preferred to use scale endpoint data, which typically cannot have negative values and are easier to interpret from a clinical point of view. Change data are often not ordinal and are very problematic to interpret. We did not identify such data for this review update. For future updates of this review, If endpoint data are unavailable, we will use change data.

5. Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we applied the following standards to all data before inclusion: (a) standard deviations (SDs) and means are reported in the paper or obtainable from the authors; (b) when a scale starts from the finite number zero, the SD, when multiplied

by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution (Altman 1996); (c) if a scale starts from a positive value (such as the Positive and Negative Syndrome Scale (PANSS) (Kay 1986), which can have values from 30 to 210), the calculation described above was modified to take the scale starting point into account. In these cases skew is present if 2 SD > (S-S min), where S is the mean score and S min is the minimum score. Endpoint scores on scales often have a finite start and end point and these rules can be applied. When continuous data are presented on a scale which includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not. We entered skewed data from studies of less than 200 participants in other tables within the data analyses section rather than into an statistical analysis. Skewed data pose less of a problem when looking at means if the sample size is large, and in future updates of the review, we will enter skewed data from studies with large sample sizes into syntheses, if more data are identified.

6. Common measure

To facilitate comparison between trials, we intended to convert variables that can be reported in different metrics, such as days in hospital, (mean days per year, per week or per month) to a common metric (e.g. mean days per month). Although common measure was not an issue in this update review, the above procedures will be followed in future updates.

7. Conversion of continuous to binary

We had planned to convert outcome measures to dichotomous data wherever possible, however the need did not arise. The conversion could be done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It is generally assumed that a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS, Overall 1962) or the PANSS (Kay 1986; Kay 1987), could be considered as a clinically significant response (Leucht 2005; Leucht 2005a). In future updates if data based on these thresholds are not available, we will use the primary cut-off presented by the original authors.

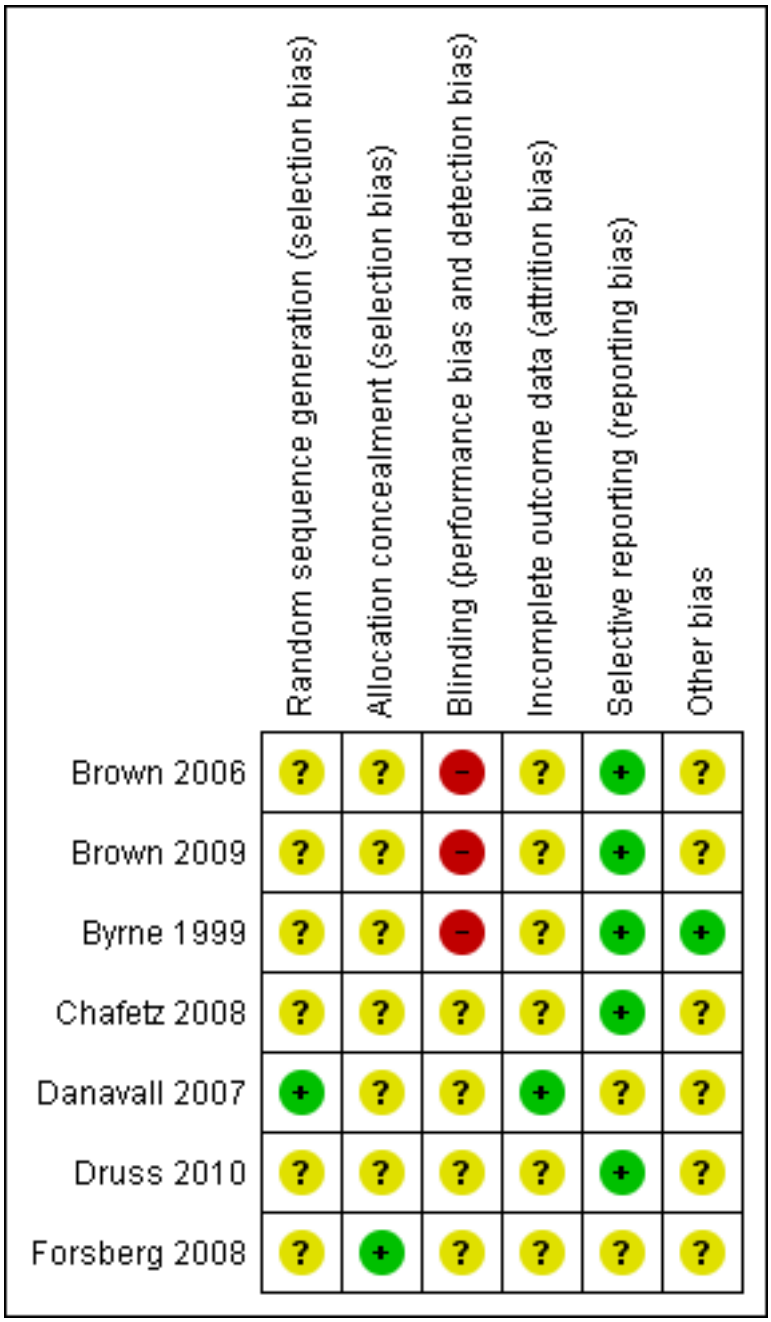
8. Direction of graphs

Where possible, we entered data in such a way that the area to the left of the line of no effect indicated a favourable outcome for general physical health advice.

Assessment of risk of bias in included studies

Again working independently, for the original review, GT and AC and for the update review JX and MW assessed risk of bias using the tool described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). This tool encourages consideration of how the sequence was generated, how allocation was concealed, the integrity of blinding at outcome, the completeness of outcome data, selective reporting and other biases. We excluded studies where allocation was clearly not concealed. We did not include trials with high risk of bias (defined as at least three out of five domains categorised as 'No') in the meta-analysis; we have summarised the results of our assessment of risk of bias in Figure 1. Where the raters disagreed, the final rating was made by consensus with the involvement of another member of the review group. Where inadequate details of randomisation and other characteristics of trials were provided, we contacted the authors of the studies in order to obtain further information. We reported non-concurrence in quality assessment.

Figure 1. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study



Measures of treatment effect

1. Binary data

For binary outcomes we calculated a standard estimation of the risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive (Boissel 1999) than odds ratios and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). The Number Needed to Treat/Harm (NNT/H) statistic with its confidence intervals is intuitively attractive to clinicians but is problematic both in its accurate calculation in meta-analyses and interpretation (Hutton 2009). For binary data presented in the 'Summary of findings' tables, where possible, we calculated illustrative comparative risks.

2. Continuous data

For continuous outcomes we estimated the mean difference (MD) between groups. We preferred not to calculate effect size measures (standardised mean difference SMD). However, for future updates if scales of very considerable similarity are used, we will presume there is a small difference in measurement, and will calculate effect sizes and transform the effect back to the units of one or more of the specific instruments.

Unit of analysis issues

1. Cluster trials

Studies increasingly employ 'cluster randomisation' (such as randomisation by clinician or practice) but analysis and pooling of clustered data poses problems. Firstly, authors often fail to account for intra class correlation in clustered studies, leading to a 'unit of analysis' error (Divine 1992) whereby P values are spuriously low, CIs unduly narrow and statistical significance overestimated. This causes type I errors (Bland 1997; Gulliford 1999).

For studies where clustering was not accounted for, we would have presented data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. If we find cluster-randomised trial data in subsequent versions of this review, we will seek to contact first authors of studies to obtain intra class correlation coefficient (ICC) of their clustered data and to adjust for this by using accepted methods (Gulliford 1999). If clustering has been incorporated into the analysis of primary studies, we will present these data as if from a non-cluster randomised study, but adjusted for the clustering effect.

We sought statistical advice during the protocol state of this review, and were advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the ICC (Design effect = 1+(m-1)*ICC) (Donner 2002). If the ICC is not reported, we will assume it to be 0.1 (Ukoumunne 1999).

If cluster studies have been appropriately analysed taking into account ICC and relevant data documented in the report, synthesis with other studies will be possible using the generic inverse variance technique.

2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. It occurs if an effect (e.g. pharmacological, physiological or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence, on entry to the second phase the participants can differ systematically from their initial state despite a wash-out phase. For the same reason cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). No cross-over trials were identified from either search for this review, but as both effects are very likely in serious mental illness, in future updates we will only use data from the first phase of cross-over studies.

3. Studies with multiple treatment groups

No studies with multiple treatment groups were identified for this review, but for future updates, it is planned that where a study involves more than two treatment arms, if relevant, we will present the additional treatment arms in comparisons. Where the additional treatment arms are not relevant, we will not reproduce these data.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility (Xia 2009). In the original review, for any particular outcome, if more than 50% of data were unaccounted for, we did not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study were lost, but the total loss was less than 50%, we have addressed this within the 'Summary of findings' tables by down-rating quality. Finally, we also downgraded quality within the 'Summary of findings' tables where loss was 25% to 50% in total.

2. Binary

In the original review, in the case where attrition for a binary outcome was between 0% and 50% and where these data were not clearly described, we presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat analysis). Those leaving the study early were assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death and adverse effects. For these outcomes, the rate of those who remained in the study - in that particular arm of the trial - were used for those who did not. We intended to undertake sensitivity analysis to test how prone the primary outcomes were to change when data only from people who complete the study to that point are compared to the intention-to treat analysis using the above assumptions, but only two studies in separate comparisons reported data for the primary outcome so this was not possible. We intend to follow this procedure in future updates if new studies with data for this outcome are identified.

3. Continuous

3.1 Attrition

In the case where attrition for a continuous outcome was between 0% and 50%, and data only from people who completed the study to that point were reported, we reproduced these.

3.2 Standard deviations

All data used in analyses were provided in the study reports. We had planned that if standard deviations (SDs) were not reported, we would first tried to obtain the missing values from the authors. If not available, where there were missing measures of variance for continuous data, but an exact standard error (SE) and confidence intervals (CIs) available for group means, and either 'P' or 't' values available for differences in mean, we could calculate them according to the rules described in the *Cochrane Handbook for Systemic reviews of Interventions* (Higgins 2011): When only the SE is reported, SDs are calculated by the formula SD = SE * square root (n). Chapters 7.7.3 and 16.1.3 of the *Cochrane Handbook for Systemic reviews of Interventions* (Higgins 2011) present detailed formulae for estimating SDs from P, t or F values, CIs, ranges or other statistics. If these formulae do not apply, we can calculate the SDs according to a validated imputation method which is based on the SDs of the other included studies (Furukawa 2006). Although some of these imputation strategies can introduce error, the alternative would be to exclude a given study's outcome and thus to lose information. We nevertheless examined the validity of the imputations in a sensitivity analysis excluding imputed values. We will follow these procedure in future updates.

3.3 Last observation carried forward

We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing data, LOCF introduces uncertainty about the reliability of the results (Leucht 2007). Therefore, in the original review, where LOCF data were used in the trial, if less than 50% of the data had been assumed, we presented and used these data and indicated that they were the product of LOCF assumptions. This will be followed in future updates.

Assessment of heterogeneity

1. Clinical heterogeneity

To judge clinical heterogeneity, we considered all included studies, initially without seeing comparison data. We simply inspected all studies for clearly outlying situations or people which we had not predicted would arise. Where such situations or participant groups arose, we fully discussed these. The same procedure will be followed for future updates.

2. Methodological heterogeneity

For future updates, we will consider all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We will simply inspect all studies for clearly outlying methods which we had not predicted would arise. When such methodological outliers arise in updates, we will fully discuss these. This was carried out for the original review.

3. Statistical

3.1 Visual inspection

We visually inspected graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I-squared statistic

In the original review, we investigated heterogeneity between studies by considering the I^2 method alongside the Chi^2 P value. The I^2 provides an estimate of the percentage of inconsistency thought to be due to chance (Higgins 2003). The importance of the observed value of I^2 depends on i. magnitude and direction of effects and ii. strength of evidence for heterogeneity (e.g.) value from Chi ^{2} test, or a confidence interval for I^2). An I^2 estimate greater than or equal to around 50% accompanied by a statistically significant Chi^2 statistic was interpreted as evidence of substantial levels of heterogeneity (Higgins 2011). If relevant studies are identified in

updated versions of this review where substantial levels of heterogeneity are found in the primary outcome, we will explore the reasons for heterogeneity (Subgroup analysis and investigation of heterogeneity). If the inconsistency is high and clear reasons are found, we will present data separately.

Assessment of reporting biases

Reporting biases arise when the dissemination of research findings is influenced by the nature and direction of results (Egger 1997). These are described in Section 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We are aware that funnel plots may be useful in investigating reporting biases but are of limited power to detect small-study effects. We did not plan to use funnel plots for outcomes where there were 10 or fewer studies, or where all studies were of similar sizes. In future updates of this review, where funnel plots are possible, we will seek statistical advice in their interpretation.

Data synthesis

Where possible, we used a fixed-effect model for analyses. We understand that there is no closed argument for preference for use of fixed-effect or random-effects models. The random-effects method incorporates an assumption that different studies are estimating different, yet related, intervention effects. According to our hypothesis of an existing variation across studies, to be explored further in the meta-regression analysis, despite being cautious that random-effects methods do put added weight onto the smaller of the studies, we will favour using the fixed-effect model in future updates. The reader is, however, able to choose to inspect the data using the random-effects model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We did not conduct any subgroup analyses.

2. Investigation of heterogeneity

2.1 Unanticipated heterogeneity

For future updates, should unanticipated clinical or methodological heterogeneity be obvious, we will simply state hypotheses regarding these. We have not undertaken and do not anticipate undertaking analyses relating to these.

2.2 Anticipated heterogeneity

We are concerned that focused physical healthcare advice may have different effects than a more general approach. We therefore anticipate some heterogeneity for the primary outcomes and will propose to summate all data but also present them separately.

Sensitivity analysis

1. Implication of randomisation

We aimed to include trials in a sensitivity analysis if they were described in some way as to imply randomisation. In future updates of this review, for the primary outcomes we will include these studies and if there is no substantive difference when we add the implied randomised studies to those with better description of randomisation, we will then use all data from these studies.

2. Assumptions for lost binary data

For future updates, where assumptions will need to be made regarding people lost to follow-up (see Dealing with missing data), we will compare the findings of the primary outcomes where we used our assumptions with completer data only. If there is a substantial difference, we will report results and discuss them, but will continue to employ our assumption.

RESULTS

Description of studies

For substantive description of studies please see Characteristics of included studies and Characteristics of excluded studies.

Results of the search

The initial search of the Cochrane Schizophrenia Group's register of trials in November 2009 was a combined search designed to identify studies which would be relevant to this review and to a series of sister reviews looking at more targeted advice relating to specific problems or behaviours (e.g. oral health, HIV, smoking), some of these are already underway and some are already published, *see* Table 1. This search PRISMA diagram is seen in Figure 2). An additional electronic search was performed in October 2012 in order to identify recent studies relevant to this review (Figure 3).

Figure 2. PRISMA search flow diagram - 2009 search

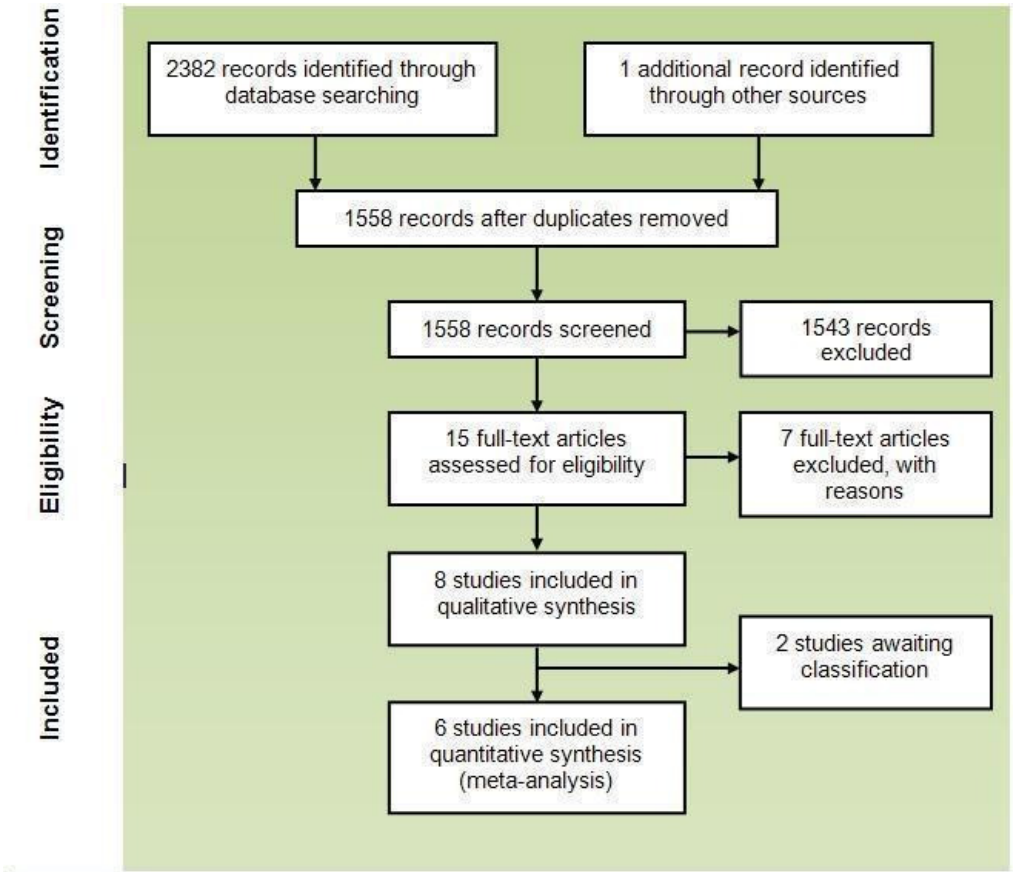
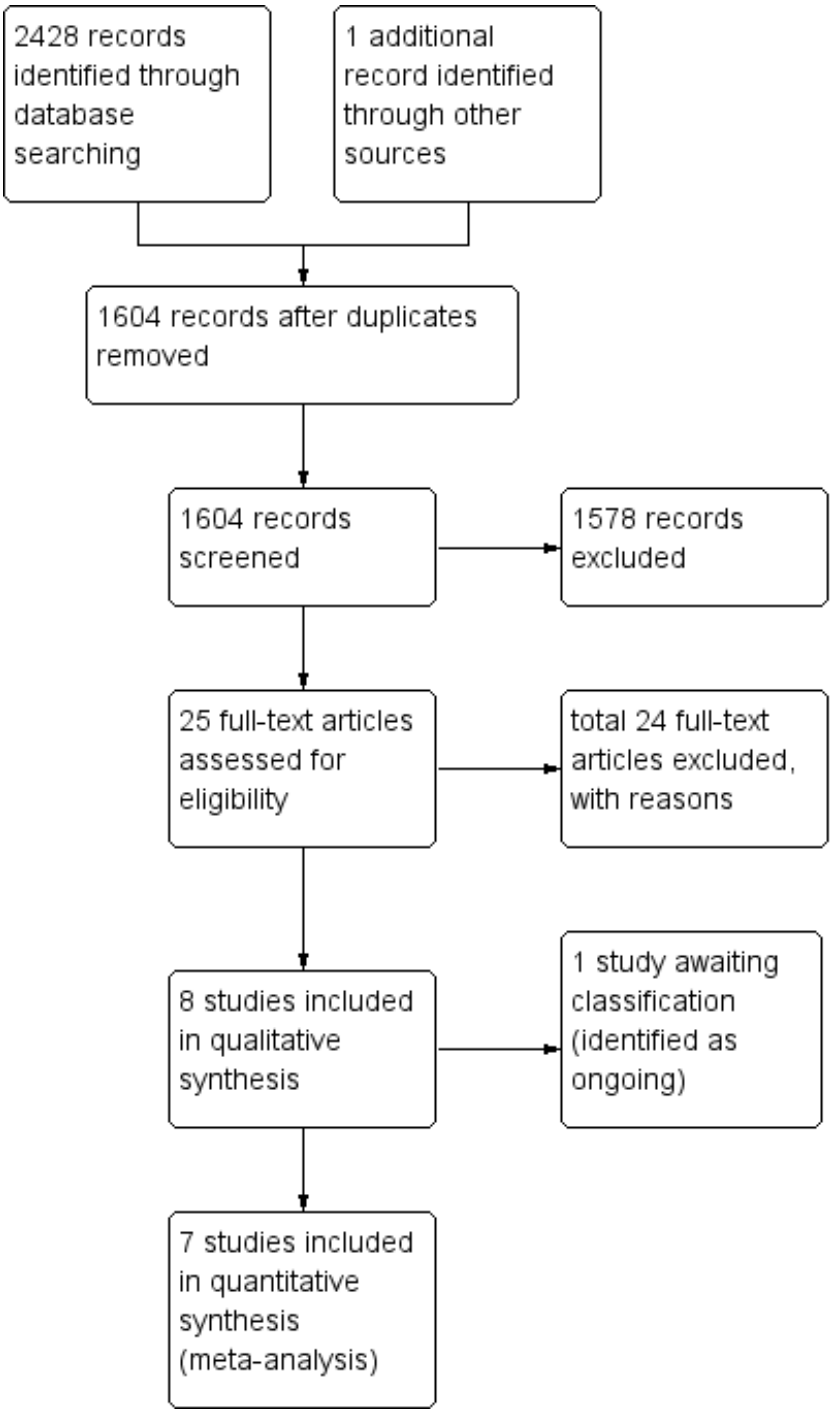


Figure 3. Study flow diagram - updated 2012



The original search identified 2382 references (from 1558 studies). After examining search results, we identified 15 reports which were suitable for further assessment. Of these, six fulfilled criteria for inclusion, we excluded seven and confirmed that two were awaiting classification. In our most recent search in 2012, 2428 (46 additional) studies were identified, 33 of these were suitable for further evaluation, one of which ended up fulfilling criteria for inclusion and was a study that was previously listed as awaiting classification.

Included studies

For details of included studies please see Characteristics of included studies. The seven included studies randomised 1113 people. No study was double blind although Brown 2006, Brown 2009 and Danavall 2007 did attempt to maintain rater (single) blindness. Byrne 1999 and Forsberg 2008 were cluster trials.

1. Length of studies

Two of the included studies fell in to the short-term category with a duration of six to 10 weeks. Danavall 2007 was categorised as medium term with a six-month follow-up, and the remaining four studies were in the long-term category and had a duration of 12-18 months.

2. Setting

Brown 2006, Brown 2009 and Danavall 2007 were conducted in community mental health teams, while Druss 2010 was set in primary care. Byrne 1999 and Forsberg 2008 took place in supported accomodation in the community and Chafetz 2008 was conducted in a crisis residential unit .

3. Participants

Participants in Brown 2006 and Brown 2009 were diagnosed using the International Classification of Diseases ((ICD), version 10) (WHO 2007). Byrne 1999 asked participants to self-report what type of mental health problems they had, while Chafetz 2008, Danavall 2007 and Druss 2010 included patients who were diagnosed with a 'severe mental illness', but they did not specify any diagnostic manual. The remaining study, Forsberg 2008, used the Diagnostic and Statistical Manual of Mental Disorders IV (DSM IV 1994).

4. Study size

The largest studies were Druss 2010 (n = 407) and Chafetz 2008 (n = 309); the smallest were Brown 2006 (n = 28) and Brown 2009 (n = 26). Danavall 2007 involved 80 participants. The other two studies were cluster trials. Byrne 1999 randomised 22 clusters, with a total of 214 people therein, and Forsberg 2008 10 clusters that comprised 97 people.

5. Interventions

5.1 General physical health advice

Brown 2006 and Brown 2009 looked at semi-structured health promotion that involved participants receiving six semi-structured health promotion sessions, which followed the Lilly "Meaningful Day" (Lilly 2002) manual. Byrne 1999 involved a one-year physical health educational programme consisting of an intensive 12-week programme with less intensive follow-up for nine months focusing on overall wellness. Chafetz 2008 promoted skills in self-assessment, self-monitoring, and self-management of physical health problems. Danavall 2007 delivered six sessions to help participants become more effective managers of their chronic illnesses involving chronic disease management, exercise and physical activity, pain and fatigue management, healthy eating on a limited budget, medication management and finding and working with a regular doctor. Druss 2010 examined the effect of care management. Care managers provided "communication and advocacy with medical providers", health education and support in overcoming barriers to primary health care. This was based on standardised approaches documented in the care management literature (Druss 2010). The program was designed to help overcome patient, provider, and system-level barriers to primary medical care experienced by persons with mental disorders. Forsberg 2008's intervention took the form of a study circle: study material comprised a book focusing on motivation, food content, stress and fitness and they also used a further comparator (aesthetic study circle) as described below. Although the trials we inspected used different methods of delivering general physical health advice, we thought these methods to be comparable on the basis that all fell under our broad definition of general physical healthcare advice.

5.2 Comparators

Comparators were largely 'standard care', which was variously described as 'treatment as usual' (Brown 2006; Brown 2009), 'control group' (Byrne 1999) and 'usual care' (Chafetz 2008; Danavall 2007; Druss 2010). Three studies, however, did not give any detailed description of their comparators (Brown 2006; Brown 2009; Byrne 1999). Both Brown studies failed to describe what 'treatment as usual' was and Byrne 1999 did not explain what treatment the 'control group' received. Chafetz 2008 described 'usual care' as basic primary care delivered by nurse practitioners and

was an established part of the crisis residential unit which was the setting for the study. Danavall 2007 reported that participants should receive all medical, mental health, and peer-based services that they were otherwise receiving prior to entry into the study. Druss 2010 described 'usual care' in which participants were given a list with contact information for local primary care medical clinics, which accepted uninsured and Medicaid patients, and these participants were allowed to obtain any type of medical care or medical service. Forsberg 2008 compared the effect of their experimental 'healthy living study circle' with a control in the form of an 'aesthetic study circle'. This was a study circle in which participants had the opportunity to learn and practice various kinds of artistic techniques such as sketching and pottery (Forsberg 2008). Additionally, because Byrne 1999 was the three-arm study, this trial compared a one-year health education programme not only with 'standard care' but also with an empowerment programme based on a model developed by Freire (Freire 1974; Freire 1983). This involved "group efforts identifying their problems, assessing the roots of their problems, and developing their goals" in a three-phase process. First "the listening phase", second the "participatory dialogue" and in the final stage "group members tested out their understanding of the problem in the real world" (Byrne 1999).

6. Outcomes

6.1 General remarks

We were unable to use data from some studies (Brown 2006; Brown 2009; Chafetz 2008) because raw scores were not presented. Instead, outcomes were presented as inexact P values without means and standard deviations. We were unable to use some data in Forsberg 2008 as they were not reported by group. Byrne 1999 failed to report changes between baseline and completion of the intervention, and Druss 2010 did not reveal the distribution of individuals between the intervention arm and the control.

6.2 Outcome scales

Details of scales that provided usable data are shown below. Reasons for exclusion of data from other instruments are given under 'Outcomes' in the Characteristics of included studies.

6.2.1 Physical health behaviour

6.2.1.1 SILVA™ Pedometer plus
The SILVA™ Pedometer plus was used to obtain measure of physical activity by counting the number of steps for 10 hours per day for one week. A higher score represents a higher rate of physical activity (high = good).

6.2.2.2 Physical health

6.2.2.1 Metabolic syndrome defined by the National Cholesterol Education Programme Adult Treatment Panel (NCEP 2001)
This is a criterion for identifying metabolic syndrome where at least three of the following five criteria are needed: i) glucose ≥ 6.1 mmol/L, ii) blood pressure ≥ 130/85 mmHg or treatment for this, iii) triglycerides ≥ 1.7 mmol/L, iv) high-density lipoprotein (HDL) men > 1.0 mmol/L or female > 1.3 mmol/L, and v) waist men >102 cm or female > 88 cm. A decrease in the number of people with metabolic syndrome was the desired outcome (low = good).
6.2.2.2 Incremental Shuttle Walk Test - ISWT (Singh 1992)
The ISWT requires participants to walk up and down a 10-m shuttle course in a set time. It provides a direct comparison of an individual's performance (high=good).
6.2.2.3 Borg RPE (Rate of perceived exertion) Scale (Borg 1982)
The Borg RPE is used to measure the perceived exertion before and after the Incremental Shuttle Walk Test was measured. The scale ranges between six and 20. Six means 'no exertion at all' and 20 means 'maximal exertion' (high=good).

6.2.3 Quality of life

6.2.3.1 Lehman Quality of Life Scale (Lehman 1988)
The 127-item questionnaire was administered in an interview format and assessed both subjective and objective indicators in eight domains: living situation daily activities and skills, family relations, social relations, finances, work and school, legal and safety issues and health. Satisfaction with life domains rated on a seven-point scale: one is 'terrible' and seven is 'delighted' (high = good).

6.2.3.2 Medical Outcomes Study 36-Item Short-Form Health Survey - MOS SF-36 Health Survey (Ware 1998)
The MOS SF-36 Health Survey is a measure of health status designed for use in clinical practice, research, health policy evaluations, and general population surveys. It includes eight scales that assess the following general health concepts: physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. Summary scores can be constructed ranging from zero (poor health) to 100 (perfect health) (high = good).

6.2.4 Service use

6.2.4.1 U.S. Preventative Services Task Force guidelines - USPSTF guidelines (AHRQ 2009)
This scale is used to assess the quality of primary care. The USPSTF conducts rigorous, impartial assessments of the scientific evidence for the effectiveness of a broad range of clinical preventive

services, including screening, counselling, and preventive medications. Its recommendations are considered the "gold standard" for clinical preventive services. A total of 23 indicators were included across four domains: 1) physical examination, 2) screening tests, 3) vaccination and 4) education. The primary study outcome was an aggregate preventive services score representing the proportion of services for which an individual was eligible that was obtained by the participant. The higher the value represents the percentage of recommended preventative services received (high = good).

6.2.5 Economic

6.2.4.1 Health Service Utilization Inventory (Browne 1990)
The Health Service Utilization Inventory is designed to assess direct and indirect costs of health resources. A dollar value of health resource consumption is determined (low = good).

6.3 Missing outcomes

We had outlined in the first protocol for this review that we wished to find outcomes relevant to physical health awareness and behaviour, general physical health, quality of life, adverse events, service use, financial dependency, social functioning, economic implications, leaving the study early, global state and mental state. Of these outcomes, we failed to find any data at all relating to physical health awareness, financial dependency, social functioning, global state or mental state.

Excluded studies

For details of the excluded studies please see Characteristics of excluded studies. The original search strategy yielded 2382 references (from 1558 studies). From these we requested 15 studies for closer inspection. We excluded seven of these studies because their focus was on global mental well being rather than general physical health. In our most recent search from 2012 that yielded 46 studies, 18 underwent closer inspection, one of which met criteria for inclusion. An additional 14 of the studies were excluded because their focus was not on general physical health, two were not randomised and one included an education component in both arms of the trial.

1. Awaiting assessment

There are no studies awaiting assessment.

2. Ongoing studies

One study remains ongoing for the 2012 update review. For further details please see Characteristics of ongoing studies. Given the relatively small projected sample size in this study (n = 170) and considering the potential dropout rate, we do not anticipate that data from this study would significantly alter or add to the results of this review, although we look forward to them for further insights, or to be proved wrong.

Risk of bias in included studies

For details please refer to the Risk of bias in included studies tables and Figure 1.

Allocation

All included studies were stated to be randomised. Three did not describe the randomisation procedure (Brown 2006; Byrne 1999; Chafetz 2008). One randomised using a hidden computer-generated random number programme (Brown 2009) and two using a "computerised algorithm" (Danavall 2007; Druss 2010). The final study was randomised at group level by drawing lots by a "person not in the project" (Forsberg 2008).

Blinding

Two studies failed to provide details about blinding (Byrne 1999; Forsberg 2008). One (Brown 2006) "attempted to maintain rater blindness" and, in a similar study (Brown 2009), the rater was blind to the interviewees status. In Danavall 2007 and Druss 2010 the "interviewers were blinded to subjects' randomisation status" and in the remaining study (Chafetz 2008), the "baseline severity of medical comorbidity was rated by Nurse Practitioners blind to study group". No study reported if they tested blinding.

Incomplete outcome data

The overall rate of leaving the study early was considerable (34%). In five of the studies the rate of leaving the study early was clearly above 30% (Brown 2006; Brown 2009; Byrne 1999; Chafetz 2008; Druss 2010). It is possible that reasons for this attrition were balanced across groups - but there is no evidence to support this and there is also the possibility that the reasons differed for leaving early. This makes the studies vulnerable to bias. Danavall 2007 lost all but one of their participants due to being unable to locate them at follow-up. Forsberg 2008 was a cluster trial and did not report the rate of leaving early by group.

Selective reporting

It would appear that all of the included studies reported on all of their intended outcomes. We did not, however, have access to any of the study protocols to confirm this.

Other potential sources of bias

Brown 2006 was supported by Eli Lilly (pharmaceutical industry) who supplied the Lilly "Meaningful Day" package; this package was then adapted for use in the subsequent study (Brown 2009). Danavall 2007 reported that one of the authors received royalties from the publisher of the book that was written for the intervention delivered the in the study. For Druss 2010 the lead author "received research funding from Pfizer", a pharmaceutical company which manufactures a wide range of medicines for conditions such as heart disorders, cancer, raised blood pressure, high cholesterol and sexual health. Chafetz 2008 was supported by the National Institute of Nursing Research and Forsberg 2008 received grants from five different public bodies in Sweden. The remaining study (Byrne 1999) was funded by the Ontario Ministry of Health. Additionally, all trials were small trials that are themselves particularly associated with risks of bias.

Effects of interventions

See: **Summary of findings for the main comparison** PHYSICAL HEALTH ADVICE versus STANDARD CARE for people with serious mental illness; **Summary of findings 2** HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION for people with serious mental illness; **Summary of findings 3** HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE for people with serious mental illness

Comparison 1. Physical health advice versus standard care

Six studies provided data for the comparison physical health advice versus standard care. We calculated risk ratios (RR) for dichotomous data and mean differences (MD) for continuous data, with their respective 95% confidence intervals (CIs) throughout.

1.1 Physical health behaviour

Danavall 2007 reported no significant difference between groups for moderate or vigorous physical activity, the data were skewed (n = 80, 1 RCT, MD 39.00, CI -76.53 to 154.53, Analysis 1.1).

1.2 Quality of life

This outcome (Analysis 1.2) was reported by Byrne 1999, Danavall 2007 and Druss 2010 using different scales. Byrne 1999 (using the Lehman scale) reported no significant difference in quality of life (n = 54, 1 RCT, MD 0.20, CI -0.47 to 0.87). Danavall 2007 and Druss 2010 reported separately on the mental and physical components of the Quality of Life Medical Outcomes Study reporting a significant difference for the mental component (n = 487, 2 RCTs, MD 3.70, CI 1.76 to 5.64) and in the physical component (n = 487, 2 RCTs, MD 2.46, CI 0.33 to 4.59).

1.3 Adverse effects: death

Danavall 2007 reported only on death and Druss 2010 reported seven deaths with "no significant difference" between treatment and control groups (n = 487, 2 RCTs, RR 0.98, CI 0.27 to 3.56, Analysis 1.3).

1.4 Service use

One study (Druss 2010) provided data for the comparison care management versus usual care. Results significantly favoured the active treatment group (n = 363, 1 RCT, MD 36.90, CI 33.07 to 40.73, Analysis 1.4). Danavall 2007 also reported that significantly more people who received physical health advice attended primary care appointments than those receiving standard care alone (n = 80, 1 RCT, RR 1.77, CI 1.09 to 2.85).

1.4 Economic

Byrne 1999 reported no significant difference between groups for general health service expenses. These data are, however, skewed and we report them in a table (Analysis 1.6).

1.5 Leaving the study early

Six studies reported on participants leaving early for a variety of reasons; none identified any significant difference between experimental and control groups (Analysis 1.7).

1.5.1 Any reason

Six of our seven included studies provided data for the outcome of leaving the study early for any reason (n = 964, 6 RCTs, RR 1.11, CI 0.92 to 1.35). Brown 2006 and Brown 2009 reported considerable loss to follow-up with 39% in the first study and 35% in the second. However, attrition occurred relatively evenly across intervention groups (n = 54, 2 RCTs, RR 1.49 CI 0.71 to 3.14). Byrne 1999 saw 31.6 % of participants leaving early but did not comment on the reasons for leaving (n = 114, 1 RCT, RR 1.38, CI 0.73 to 2.63). Chafetz 2008 reported 35.6% of participants leaving early (n = 309, 1 RCT, RR 1.44, CI 1.05 to 1.95) and defined these simply as "lost to follow up", citing that some had died, some had "moved on" and some were incarcerated. Further specifics were not available for these different reasons for leaving early. Danavall 2007 had the smallest percentage of participants leaving the study early of 18.8% with only one having died and the remaining being unable to locate for follow-up (n = 80, 1 RCT, RR 0.35, CI 0.12 to 1.00). Druss 2010 only commented on "loss to follow up" (30.5%, n = 407, 1 RCT, RR 0.83, CI 0.61 to 1.13).

1.5.2 Lost to follow-up

Brown 2009, Chafetz 2008, Danavall 2007 and Druss 2010 all reported on loss to follow-up (n = 822, 4 RCTs, RR 0.97, CI 0.79 to 1.20).

1.5.3 Withdrawn

Druss 2010 reported on those "withdrawn" (n = 407, 1 RCT, RR 6.90, CI 0.86 to 55.56).

1.5.4 Discontinued

Brown 2009 provided data for those who 'discontinued' meaning they left for 'various personal reasons' (n = 26, 1 RCT, RR 8.25, CI 0.50 to 135.21).

Comparison 2. Health education versus empowerment education

Byrne 1999 provided data for the comparison health education versus empowerment education.

2.1 Quality of life

There was no significant difference in quality of life as assessed on the Lehman Quality of Life scale (n = 51, 1 RCT, MD -0.30, CI -0.99 to 0.39, Analysis 2.1).

2.2 Economic

There was no significant difference between groups for general health education versus empowerment education; however, these data are skewed and we report them in a table (Analysis 2.2).

2.3 Leaving early

There was no significant difference in the number of participants leaving the study early (n = 78, 1 RCT, RR 0.56, CI 0.26 to 1.19, Analysis 2.3).

Comparison 3. Programme of healthy living in the form of a study circle versus aesthetic study circle

Forsberg 2008 provided data for the comparison programme of healthy living in the form of a study circle versus aesthetic study circle.

3.1 Physical health behaviour

There was an increase in physical activity (steps per day) in the intervention group, but no significant difference was reported. These data, however, are skewed and we report them in a table (Analysis 3.1). Additionally, the method of measurement, the Silva pedometer, had been discredited as an "unacceptably inaccurate" activity promotion tool, due to its lack of testing.

3.2 Physical health - metabolic syndrome

There was no significant difference in the presence of metabolic syndrome (n = 13, 1 RCT, RR 1.25, CI 0.35 to 4.49, Analysis 3.2).

3.3 Physical health - physical working capacity

3.3.1 Incremental Shuttle Working Test

In the control group there was a non-significant increase in physical working capacity measured by the Incremental Shuttle Working Test (n = 30, 1 RCT, MD -157.00, CI -321.11 to 7.11, Analysis 3.3).

3.3.2 Borg Exertion Test

In the control group there was a very slight decrease for the Borg Exertion Test (n = 25, 1 RCT, MD 2.10, CI 0.04 to 4.16).

3.4 Physical health: various continuous data

3.4.1 Metabolic criteria

Forsberg 2008 reported that at 12 months follow-up among residents, the only significant change was a decrease in the mean number of metabolic criteria in the intervention group. Residents had decreased their mean number of metabolic criteria at the follow-up and the number of with metabolic syndrome had decreased from 13 to 10; however, these data are skewed and are reported only as a table (Analysis 3.4).

3.4.2 Fatal cardiovascular disease

There was no significant difference in the initial risk of fatal cardiovascular disease between the intervention and the control groups; however, these data are skewed and are reported only as a table.

3.4.3 10-year risk Heart Score

There was no significant difference in the 10-year risk Heart Score between the intervention and the control groups; however, these data are skewed and are reported only as a table.

ADDITIONAL SUMMARY OF FINDINGS *[Explanation]*

HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION for people with serious mental illness

Patient or population: people with serious mental illness
Settings:
Intervention: HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION				
Physical health awareness - not reported	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome we had pre-stated to be of importance
Physical health behaviour - not measured	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome we had pre-stated to be of importance
Quality of Life Lehaman Quality of Life Scale. Scale from: 1 to 7. Follow-up: 12 months	The mean quality of life in the control groups was **4.45 points**	The mean Quality of Life in the intervention groups was **0.3 lower** (0.99 lower to 0.39 higher)		51 (1 study)	⊕⊕◯◯ **low**[1,2,3,4]	
Adverse Effects	**Study population**		**RR 0** (0 to 0)	0 (0)	See comment	
	See comment	See comment				
	Medium-risk population					

Economic - not reported	See comment	See comment	Not estimable	-	See comment
Leaving the study early Follow-up: mean 12 months	**Low-risk population**[5]		**RR 0.56** (0.26 to 1.19)	78 (1 study)	⊕⊕◯◯ **low**[1,2,3,4]
	200 per 1000	**112 per 1000** (52 to 238)			
	Medium-risk population[5]				
	300 per 1000	**168 per 1000** (78 to 357)			
	High-risk population[5]				
	500 per 1000	**280 per 1000** (130 to 595)			

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Limitations of design: rated 'serious' (lack of allocation concealment)
[2] Limitations of design: rated 'serious' (lack of blinding)
[3] Imprecison: rated 'serious' (small sample size)
[4] Imprecision: rated 'serious' (high attrition rate)
[5] Fewtrell et al. Arch Dis Child 2008; 93: 458-461 (doi: 10.11361adc.2007.127316)

HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE for people with serious mental illness

Patient or population: patients with people with serious mental illness
Settings:
Intervention: HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE				
Physical health: Identification of disease state (Metabolic syndrome)	**Study population**		**RR 1.25** (0.35 to 4.49)	13 (1 study[7])	⊕⊕◯◯ **low**[2,3,4,5,6]	
	400 per 1000[1]	**500 per 1000** (140 to 1000)[1]				
	Medium-risk population					
	400 per 1000[1]	**500 per 1000** (140 to 1000)[1]				
Physical health behaviour - not measured	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome we had prestated to be of importance
Quality of life - not measured	See comment	See comment	Not estimable	-	See comment	
Adverse Effects - not reported	See comment	See comment	Not estimable	-	See comment	
Economic - not reported	See comment	See comment	Not estimable	-	See comment	

Leaving the study early	**Study population**		**RR 0** (0 to 0)	0 (0)	See comment
	See comment	See comment			
	Medium-risk population				

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Cluster trial (n = 10), results subject to design effect calculation (D.E.=1.23)
[2] Limitations of design: rated 'serious' (lack of allocation concealment)
[3] Limitations of design: rated 'serious' (lack of blinding)
[4] Duration of study may have a negative effect on motivation
[5] Imprecison: rated 'serious' (small sample size)
[6] Imprecision: rated 'serious' (high attrition rate)
[7] National Institue of Health - National Cholestrol Education Programme - Adult Treatment Panel III 2001

DISCUSSION

Summary of main results

We included seven studies with a total number of 1113 participants. Only Comparison 1 included more than one study. Across the six studies which reported data for leaving early, the attrition rate was 32%. Some studies had significant potential for influence from industry (Brown 2006; Brown 2009; Druss 2010). Much data were often reported in such a way as to make comparative analyses impossible and we were unable to report data for many outcomes These factors must be a threat to the validity, or at the very least, the credibility of results (Xia 2009).

1. Comparison 1: Physical health advice versus standard care

Most studies we identified were included in this comparison (6 RCTs, n = 964). There was, however, an attrition of 32% (Summary of findings for the main comparison).

1.1 Physical health behaviour

Danavall 2007 reported an increase in the time spent doing moderate or vigorous exercise per week for participants receiving physical health advice but it was not statistically significant when compared to standard care. At the six-month follow-up, the intervention group reported spending an additional 40 minutes per week undertaking moderate or vigorous exercise which represents a 20% increase from baseline. It should be kept in mind that these findings are from a single small trial (n = 80), so although it appears that physical health advice has influenced the increase in moderate or vigorous exercise this should be investigated further before strong conclusions can be drawn.

1.2 Quality of life

Only three studies provided data for this important outcome and only two used the same rating scales, making interpretation difficult. Byrne 1999 reported no significance difference in quality of life, while Danavall 2007 and Druss 2010 reported separately on the mental and physical components of quality of life and both said that, at follow-up, the intervention group had a "significantly higher" score than controls on the mental component summary score and a "nearly significant" difference in the physical component summary score. These differences are in the range of three and two points and we are not clear about their meaning to carers or participants. The meaning is not explained in the original papers. It is possible that this rating does represent a good improvement, but the trialists have left us unclear if this is so.

1.3 Adverse effects: death

Only two studies reported on adverse effects with no statistically significant difference reported for this outcome (Danavall 2007; Druss 2010). Danavall 2007 reported only one participant had died in the standard care group. In Druss 2010 about 2% died in each group by one year. There is no indication of any effect physical health advice may have on this important outcome. Certainly, much larger studies are needed if this is to be investigated within the context of trials.

1.4 Service use: average percentage uptake of recommended health preventative services

Druss 2010 compared medical care management versus standard care and showed a statistically significant effect on service use. At 12-month follow-up, the average proportion of indicated preventive services more than doubled in the intervention group but remained constant in the usual care group. This suggests that there are benefits for physical healthcare advice (care management) in the primary care setting. Care managers did not provide any medical interventions; however, they did facilitate improved primary care through a combination of "advocacy, education, and helping patients overcome logistical barriers to care" (Druss 2010). Results are only available from one study and should be interpreted with caution, but do seem encouraging.

1.5 Service use: one or more primary care visit

Danavall 2007 reported that significantly more people who received physical health advice had attended one or more primary care appointments than those receiving standard care alone. There was not a dramatic increase from baseline for those receiving physical health advice (baseline = 24 people, six-month follow-up 26 people), in fact, there was a decrease for those receiving standard care (baseline = 23 people, six-month follow-up = 14 people). Results do seem to suggest that receiving physical health advice encouraged people to continue to visit primary care more than those who did not, but the reason for the drop in visits for those who received standard care is unclear.

1.6 Economic: health service utilisation

A total (US) dollar value of health resource consumption was determined. These data were skewed but trial authors did not report a significant statistical difference between groups (Byrne 1999).

1.7 Leaving the study early

Six of the seven studies reported on 'leaving the study early', an outcome which can be considered as a composite measure of acceptability of treatment. There was no difference in premature discontinuations due to leaving early for any reason - but over 30% of people left these trials. This has to leave us with an issue

of credibility (Xia 2009), as 30% losses are not what would be expected in clinical life and simply ignoring this attrition in analyses is not the best option. It is reassuring that there is not imbalance in numbers lost to follow-up - but it remains a worry that there may be imbalance in reasons for attrition.

2. Comparison 2: Health education versus health empowerment

Byrne 1999 is the only included study (n = 214, Summary of findings 2).

2.1 All outcomes

There were no differences apparent for measures of quality of life, economic outcomes or attrition. Byrne 1999 was a small study and there may be real differences to be seen by use of a larger trial. However, comparing different types of health advice would seem inadvisable until more data were supporting its use overall.

3. Comparison 3. Healthy living study circle versus aesthetic study circle

Only Forsberg 2008 (97 participants in 10 clusters) was included in this comparison. The attrition rate was not reported (Summary of findings 3).

3.1 All outcomes

Forsberg 2008 measured both behaviour and health indicators. It found no clear differences in physical activity, but that residents in the intervention group did have a decrease rate of metabolic syndrome compared with an increase in the control group. Once differences were calculated in these data using the Design Effect (see Unit of analysis issues), no clear difference was apparent. Physical working capacity measures and risk of physical disease data were difficult to interpret with confidence. Again, it seems advisable that more data be created on the first comparison (physical healthcare advice versus standard care) before different ways of delivering this advice are investigated.

Overall completeness and applicability of evidence

1. Completeness

1.1 Duration of follow-up

Four of the seven included studies presented long-term data (over one year of follow-up). This is a good length of time to assess any difference in the intervention effects. One study had a six-month follow-up and two studies presented short-term data, a duration of six to 10 weeks, which is probably too short a time to assess any difference in the intervention effects.

1.2 Coverage of outcomes

The was a range of outcomes reported including quality of life, health behaviour, service use and economic impact. However, even for these outcomes, there are very few and poorly reported data. Much more robust data are needed in this important area that relate directly to clinicians, policymakers and consumers of care. It would not be difficult to generate better data on other outcomes such as service use (use of primary care, Accident & Emergency (A&E)), general state, adverse event or costs.

2. Applicability

2.1 Origin

In this review, 50% of the included studies were completed in Europe and the other half in North America. The great majority of people with serious mental illnesses such as schizophrenia live in low- or middle-income countries where advice regarding malaria, tuberculosis, sexually transmitted diseases and accident avoidance may be more pertinent than advice regarding cholesterol monitoring. More relevant studies need to be undertaken.

2.2 Interventions

Experimental interventions were provided by nurses and key workers who had training or experience of providing care for people with serious mental illness. These are healthcare personnel who are widely accessible in many settings. However, it may also be possible to delegate the intervention role to volunteer workers within a health system.

Quality of the evidence

Overall quality was poor (Figure 1). All studies report that they were randomised; however, further details on how randomisation was achieved were provided by only four studies. Brown 2009 used a "hidden computer-generated random number programme", Danavall 2007 and Druss 2010 used "a computerised algorithm" and Forsberg 2008 randomised on a group level by "drawing lots". No further details are given on any randomisation techniques. Blindness was attempted in Brown 2006, Brown 2009 and Druss 2010, but there was no investigation as to whether this had been successful. In most of the studies it is unclear if randomisation and blinding were done appropriately. There were high rates of participants leaving the study prematurely and three studies were supported by the pharmaceutical industry. These factors limit the overall quality of the evidence (Cohen 2010).

Potential biases in the review process

The search criteria on the Cochrane Schizophrenia Group Trials Register (October 2012) should have been robust enough to detect relevant studies. It is possible that we have failed to identify small studies, but we think it unlikely that we would have missed large trials.

Studies published in languages other than English, and those with equivocal results, are often difficult to find (Egger 1997). Our search was biased by use of English phrases. However, given that the Cochrane Schizophrenia Group's register covers many languages but is indexed in English, we feel that this would not have missed many studies within the register. For example, the search uncovered 101 studies for which the title was only available in Chinese characters. These were checked for relevance by a Chinese-speaking colleague (Jun Xia) and we identified three as possibly relevant to this review. These had to be excluded after closer inspection. We did not perform a funnel plot analysis.

Agreements and disagreements with other studies or reviews

The only other similar systematic review that we are aware of is Bradshaw 2005. This reports on efficacy of healthy living interventions for people with schizophrenia. Our findings do agree with Bradshaw 2005, in that we too feel that data point to the need for rigorous studies.

AUTHORS' CONCLUSIONS

Implications for practice

1. For people with serious mental illness

There is some limited and poor quality evidence that the provision of general physical healthcare advice can improve health-related quality of life in the mental component but not the physical component. This evidence comes from one study, which only looked specifically at benefits in the primary care setting. Otherwise, no studies returned results that suggest that physical healthcare advice has a powerful effect on physical healthcare behaviour or risk of ill health. More work is needed in this area and people with serious mental illness could best contribute by becoming involved in research that is meaningful to their interests and needs.

2. For clinicians

Clinicians should know there is some randomised evidence that the provision of general physical healthcare advice to people with serious mental illness may improve health-related quality of life. There is little current evidence that providing physical healthcare advice is an effective way of improving the physical health of people with serious mental illness. It is possible clinicians are expending much effort, time and financial expenditure on giving ineffective advice. Clinicians should therefore attempt to initiate or get involved with any studies which could provide an evidence base for this practice.

3. Funders and policy makers

Funders and policy makers should be aware that there may be some benefit for physical health advice for people with serious mental illness. It is equally possible clinicians are expending much effort, time and financial expenditure on giving ineffective advice. There is an increased demand for preventative health services through provision of advice, so there may be a requirement for short-term speculative investment in services in order to make long-term savings. This is a ripe area for good real-world research.

Implications for research

1. General

Strict adherence to the CONSORT statement (Moher 2001) would have provided us with more useable data. We were unable to use data from some studies because raw scores were not presented. Instead, outcomes were presented as inexact P values without means and standard deviations. Randomisation techniques were not always made clear and blinding was untested - although, of course, difficult to achieve for this type of study. Nevertheless, pioneering researchers have shown that this type of work is possible. We hope that future trialists will sign up for ensuring that all data are publicly available (ALLTRIALS).

2. Specific

There is an obvious lack of research in this area and the small number of included studies fails to reflect the huge amount of healthcare advice given to people with serious mental illness. We realise that much thought and care goes into the design of randomised studies. We have, however, also given this issue some consideration and suggest the outline of a feasible design (see Table 2).

ACKNOWLEDGEMENTS

Thanks to Professor Clive Adams, Claire Irving and the editorial team at the Nottingham University Cochrane Schizophrenia Group for their unwavering support in the writing of this review. To Sheeren Mala for her contributions in helping write the review and screening results from the searches. The Cochrane Schizophrenia Group Editorial Base in Nottingham produces and maintains

standard text for use in the Methods sections of their reviews. We have used this text as the basis of what appears here and adapted it as required.

We would also like to thank and acknowledge the contribution of Mick Bachner a co-reviewer from previous versions of this review who helped screen the results of 2010 electronic search.

REFERENCES

References to studies included in this review

Brown 2006 *{published data only}*
Brown AS. An evaluation of the effectiveness of delivery of health promotion interventions to people with serious mental illness by their key workers. http://www.controlled-trials.com/ISRCTN95265680. United Kingdom, (accessed 04 March 2014).

Brown 2009 *{published data only}*
Brown S, Smith E. Can a brief health promotion intervention delivered by mental health key workers improve clients' physical health: a randomized controlled trial. *Journal of Mental Health* 2009;**18**(5):372–8 .

Byrne 1999 *{published data only}*
Byrne C, Brown B, Voorberg N, Schofield R, Browne G, Gafni A, et al.Health education or empowerment education with individuals with a serious persistent psychiatric disability. *Psychiatric Rehabilitation Journal* 1999;**22**(4): 368–80.

Chafetz 2008 *{published data only}*
Chafetz L, White M, Collins-Bride G, Cooper BA, Nickens J. Clinical trial of wellness training: health promotion for severely mentally ill adults. *Journal of Nervous and Mental Disease* 2008;**196**(6):475–83. [PUBMED: 18552625]

Danavall 2007 *{published data only}*
Danavall L, Druss B. Medical self-management for improving health behaviour among individuals in community mental health settings. National Institue of Mental Health (NIMH) 2007.

Druss 2010 *{published data only}*
Druss BG, Von Esenwein SA, Compton MT, Rask KJ, Zhao L, Parker RM. A randomized trial of medical care management for community mental health settings: the primary care access, referral, and evaluation (PCARE) study. *American Journal of Psychiatry* 2010;**167**:151–9. [PUBMED: 20008945]

Forsberg 2008 *{published data only}*
Forsberg KA, Bjorkman T, Sandman PO, Sandlund M. Physical health - a cluster randomized controlled lifestyle intervention among persons with a psychiatric disability and their staff. *Nordic Journal of Psychiatry* 2008;**62**(6): 486–95. [PUBMED: 18843564]

References to studies excluded from this review

Almomani 2009 *{published data only}*
Almomani F, Williams K, Catley D, Brown C. Effects of an oral health promotion program in people with mental illness. *Journal of Dental Research* 2009;**88**:648–52.

Baker 2009 *{published data only}*
Baker A, Geddes J. Healthy lifestyle intervention for cardiovascular disease risk reduction among smokers with psychotic disorders. Australian New Zealand Clinical Trials Registry 2009.
* Baker A, Kay-Lambkin FJ, Richmond R, Filia S, Castle D, Williams J, et al.Study protocol: a randomised controlled trial investigating the effect of a healthy lifestyle intervention for people with severe mental disorders. *BMC Public Health* 2011;**11**(1):10. [DOI: 10.1186/1471-2458-11-10]

Berti 2011 *{published data only}*
Berti L, Bonfioli E, Castellazzi M, Fiorini I, Mazzi M, Muraro F, et al.Physico-physical comorbidity, poor health behaviour and health promotion in south verona patients with functional psychoses. *Psychiatrische Praxis* 2011;**38**: OP02˙TP.

Brown 2011 *{published data only}*
Brown C, Goetz J, Hamera E. Weight loss intervention for people with serious mental illness: a randomized controlled trial of the RENEW program. *Psychiatric Services* 2011;**62**: 800–2.

Eberhard 2009 *{published data only}*
Eberhard S, Nordstrom G, Hoglund P, Ojehagen A. Secondary prevention of hazardous alcohol consumption in psychiatric out-patients: a randomised controlled study. *Social Psychiatry and Psychiatric Epidemiology* 2009;**44**(12): 1013–21.

Gao 2001 *{published data only}*
Gao XC, Wu CJ, Kong Y. An investigation about the rehabilitation of schizophrenics insight by health education. *Journal of Qilu Nursing* 2001;**7**(9):641–3.

Goetz 2011 *{published data only}*
Goetz J, Brown C, Hamera E. Preliminary 1-year results of the renew program for weight loss. *Schizophrenia Bulletin* 2011;**1**:304.

Huang 2005 *{published data only}*
Huang R-E, Chen K-J, Zheng L, Zheng A-Q. Study on the practice of health education in convalescent psychotic patients. *Journal of Nursing Administration* 2005;**5**(8): 18–20.

Jiang 2006 *{published data only}*

Jiang J, Shen X, Jiang C. The study of the application of the clinical pathway during health education for schizophrenics. *Journal of Nurses Training* 2006;**21**(10):887–9.

Jones 2001 *{published data only}*

Jones RB, Atkinson JM, Coia DA, Paterson L, Morton AR, McKenna K, et al.Randomised trial of personalised computer based information for patients with schizophrenia. *BMJ* 2001;**322**(7290):835–40. [MEDLINE: 11290639]

Kuosmanen 2009 *{published data only}*

* Kuosmanen L, Valimaki M, Joffe G, Pitkanen A, Hatonen H, Patel A, et al.The effectiveness of technology-based patient education on self-reported deprivation of liberty among people with severe mental illness: a randomized controlled trial. *Nordic Journal of Psychiatry* 2009;**63**:383–9.
Pitkanen A, Valimaki M, Kuosmanen L, Katajisto J, Koivunen M, Hatonen H, et al.Patient education methods to support quality of life and functional ability among patients with schizophrenia: A randomised clinical trial. *Quality of Life Research* 2012;**21**(2):247–56.

Leutwyler 2009 *{published data only}*

Leutwyler H, Wallhagen M, McKibbin C. The impact of symptomatology on response to a health promoting intervention among older adults with schizophrenia. Proceedings of the 162nd Annual Meeting of the American Psychiatric Association; 2009 May 16-21; San Francisco, CA 2009.

Li 2005 *{published data only}*

Li S, Zhu Y, Zhao X. Study of health education on improving and maintaining treatment compliance of schizophrenia. *Health Psychology Journal* 2005;**13**(1):33–5.

Lothringer 2009 *{published data only}*

Lothringer L, Borges C, Elkington K, Mann CG, Wainberg M. A Brazilian HIV prevention intervention for adults with severe mental illness: a randomized clinical trial feasibility study. Proceedings of the 162nd Annual Meeting of the American Psychiatric Association; 2009 May 16-21; San Francisco, CA 2009.

NCT00902694 *{published data only}*

Casagrande SS, Jerome GJ, Dalcin AT, Dickerson FB, Anderson CA, Appel LJ, et al.Randomized trial of achieving healthy lifestyles in psychiatric rehabilitation: The achieve trial. *BMC Psychiatry* 2010;**10**:108. [MEDLINE: 21144025]
NCT00902694. Examining an exercise and nutrition program for reducing weight in people with severe mental illnesses (the achieve study). http://ClinicalTrials.gov/show/NCT00902694 2009.

NCT00990925 *{published data only}*

NCT00990925. Lifestyle modification for weight loss in schizophrenia. http://www.clinicaltrials.gov 2009.

NCT01324973 *{published data only}*

NCT01324973. Web-based weight management for individuals with mental illness. http://ClinicalTrials.gov/show/NCT01324973 2011.

NCT01547026 *{published data only}*

NCT01547026. Self-regulation strategies to improve exercise behavior among schizophrenic patients. http://ClinicalTrials.gov/show/NCT01547026 2012.

Osborn 2010 *{published data only}*

Osborn DPJ, Nazareth I, Wright CA, King MB. Impact of a nurse-led intervention to improve screening for cardiovascular risk factors in people with severe mental illnesses. Phase-two cluster randomised feasibility trial of community mental health teams. *BMC Health Services Research* 2010;**10**:61.

Stockings 2011 *{published data only}*

Stockings EA, Bowman JA, Wiggers J, Baker AL, Terry M, Clancy R, et al.A randomised controlled trial linking mental health inpatients to community smoking cessation supports: A study protocol. *BMC Public Health* 2011;**11**(1):570. [MEDLINE: 21762532]

Subramaniam 2010 *{published data only}*

Subramaniam K, Luks T, Aldebot S, Hearst A, Thangavel A, Fisher M, et al.Neuroplasticity-based cognitive training improves reality monitoring in schizophrenia patients: Behavioral and fMRI assessments. *Schizophrenia Research* 2010;**117**(2-3):471. [MEDLINE: ISI:000276936801257]

Walker 2005 *{published data only}*

Walker L, Doody G, Arthur T, Abbott M. Engaging people with schizophrenia in health promotion in the UK: a challenge for healthcare professionals. *Schizophrenia Bulletin* 2005;**31**:554.

Zhou 2007 *{published data only}*

Zhou W-D, Li S-F, Liu X-L, Zheng G-Z, Zeng D-Z, Luo J-W. Effect of systematic health education on home rehabilitation of first episode schizophrenics. *Nursing Journal of Chinese People's Liberation Army* 2007;**24**(5):1–3.

林素兰 2010 *{published data only}*

林素兰，张实秋，林贵兰. health education intervention on the impact of schizophrenia patients with constipation [Google Translate]

[健康教育干预对精神分裂症病人便秘影响的研究].

全科护理 2010; Vol. 8, issue 7C:1891–3.

References to ongoing studies

NCT00137267 *{published data only}*

NCT00137267. A brief community linkage intervention for dually diagnosed individuals. http://clinicaltrials.gov/ct2/show/NCT00137267 2005.

Additional references

AHRQ 2009

AHRQ - Agency for Healthcare Research and Quality. 2009 guide to clinical preventive services. http://www.ahrq.gov/Clinic/pocketgd.htm (accessed 12th February 2010).

Altman 1996

Altman DG, Bland JM. Detecting skewness from summary information. *BMJ* 1996;**313**(7066):1200.

Bland 1997
Bland JM. Statistics notes. Trials randomised in clusters. *BMJ* 1997;**315**:600.

Boissel 1999
Boissel JP, Cucherat M, Li W, Chatellier G, Gueyffier F, Buyse M, et al.The problem of therapeutic efficacy indices. 3. Comparison of the indices and their use [Apercu sur la problematique des indices d'efficacite therapeutique, 3: comparaison des indices et utilisation. Groupe d'Etude des Indices D'efficacite.]. *Therapie* 1999;**54**(4):405–11. [PUBMED: 10667106]

Borg 1982
Borg GA. Psychophysical bases of perceived exertion. *Medicine & Science in Sports & Exercise* 1982;**14**(5):377–81.

Bradshaw 2005
Bradshaw T, Lovell K, Harris N. Healthy living interventions and schizophrenia: a systematic review. *Journal of Advanced Nursing* 2005;**49**(6):634–54. [PUBMED: 15737224]

Browne 1990
Browne GB, Arpin K, Corey P, Fitch M, Gafni A. Individual correlates of health service utilization and the cost of poor adjustment to chronic illness. *Medical Care* 1990;**28**:43–58.

Cohen 2010
Cohen D, Carter P. Conflicts of interest. WHO and the pandemic flu "conspiracies". *BMJ* 2010;**340**:c2912. [PUBMED: 20525679]

Cournos 2005
Cournos F, McKinnon K, Sullivan G. Schizophrenia and comorbid human immunodeficiency virus or hepatitis C virus. *Journal of Clinical Psychiatry* 2005;**66**(Suppl 6): 27–33. [PUBMED: 16107181]

Deeks 2000
Deeks J. Issues in the selection for meta-analyses of binary data. Proceedings of the 8th International Cochrane Colloquium; 2000 Oct 25-28; Cape town. Cape Town: The Cochrane Collaboration, 2000.

Divine 1992
Divine GW, Brown JT, Frazier LM. The unit of analysis error in studies about physicians' patient care behavior. *Journal of General Internal Medicine* 1992;**7**(6):623–9.

Dixon 1999
Dixon L, Postrado L, Delahanty J, Fischer PJ, Lehman A. The association of medical comorbidity in schizophrenia with poor physical and mental health. *Journal of Nervous and Mental Disease* 1999;**187**(8):496–502. [PUBMED: 10463067]

DoH 2005
Department of Health. Choosing health: making healthy choices easier. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH˙4097491 2005 (accessed 14 Dec 2009).

DoH 2006
Department of Health. Choosing Health: Supporting the physical needs of people with severe mental illness. www.dh.gov.uk/prod˙consum˙dh/groups/dh˙digitalassets/@dh/@en/documents/digitalasset/dh˙4138290.pdf (accessed 5 Nov 2009).

Donner 2002
Donner A, Klar N. Issues in the meta-analysis of cluster randomized trials. *Statistics in Medicine* 2002;**21**:2971–80.

DSM IV 1994
American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Health Disorders*. 4th Edition. Washington DC: American Psychiatric Association, 1994.

Egger 1997
Egger M, Davey-Smith G, Schneider M, Minder CSO. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**13**:629–34.

Elbourne 2002
Elbourne D, Altman DG, Higgins JPT, Curtina F, Worthingtond HV, Vaile A. Meta-analyses involving cross-over trials: methodological issues. *International Journal of Epidemiology* 2002;**31**(1):140–9.

Freire 1974
Freire P. *Pedagogy of the Oppressed*. New York: Seabury Press, 1974.

Freire 1983
Freire P. *Education for Critical Consciousness*. New York: Seabury Press (1973); Continuum Press, 1983.

Furukawa 2006
Furukawa TA, Barbui C, Cipriani A, Brambilla P, Watanabe N. Imputing missing standard deviations in meta-analyses can provide accurate results. *Journal of Clinical Epidemiology* 2006;**59**(7):7–10.

Greenlund 2002
Greenlund KJ, Giles WH, Keenan NL, Croft JB, Mensah GA. Physician advice, patient actions, and health-related quality of life in secondary prevention of stroke through diet and exercise. *Stroke* 2002;**33**(2):565–70. [PUBMED: 11823671]

Gulliford 1999
Gulliford MC. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the health survey for England 1994. *American Journal of Epidemiology* 1999;**149**: 876–83.

Higgins 2003
Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;**327**: 557–60.

Higgins 2011
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2 [updated September 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org..

HM Government 2009
HM Government. New horizons: a shared vision for mental health. http://www.dh.gov.uk/prod˙consum˙dh/

groups/dh˙digitalassets/@dh/@en/documents/digitalasset/dh˙109708.pdf (accessed 7 December 2009).

Hutton 2009
Hutton JL. Number needed to treat and number needed to harm are not the best way to report and assess the results of randomised clinical trials. *British Journal of Haematology* 2009;**146**(1):27–30.

Kay 1986
Kay SR, Opler LA, Fiszbein A. *Positive and Negative Syndrome Scale (PANSS) manual*. North Tonawanda, NY: Multi-Health Systems, 1986.

Kay 1987
Kay SR, Fiszbein A, Opler LA. The positive and negative syndrome scale (PANSS) for schizophrenia. *Schizophrenia Bulletin* 1987;**13**(2):261–76. [PUBMED: 3616518]

Khanna 2012
Khanna P, Clifton A, Banks D, Tosh G. Smoking cessation advice for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2012, Issue 3. [DOI: 10.1002/14651858.CD009704]

Khokhar 2011
Khokhar WA, Clifton A, Jones H, Tosh G. Oral health advice for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2011, Issue 11. [DOI: 10.1002/14651858.CD008802.pub2]

Kings Fund 2004
Kings Fund. Public attitudes to public health policy. www.kingsfund.org.uk/free (accessed December 2009).

Kreuter 2000
Kreuter MW, Chheda SG, Bull FC. How does physician advice influence patient behavior? Evidence for a priming effect. *Archives of Family Medicine* 2000;**9**(5):426–33. [PUBMED: 10810947]

Lehman 1988
Lehman AF. A quality of life interview for the chronically mentally ill. *Evaluation and Program Planning* 1988;**11** (1): 51–62.

Leucht 2005
Leucht S, Kane JM, Kissling W, Hamann J, Etschel E, Engel R. Clinical implications of brief psychiatric rating scale scores. *British Journal of Psychiatry* 2005;**187**:366–71. [PUBMED: 16199797]

Leucht 2005a
Leucht S, Kane JM, Kissling W, Hamann J, Etschel E, Engel RR. What does the PANSS mean?. *Schizophrenia Research* 2005;**79**(2-3):231–8. [PUBMED: 15982856]

Leucht 2007
Leucht S, Engel RR, Bauml J, Davis JM. Is the superior efficacy of new generation antipsychotics an artifact of LOCF?. *Schizophrenia Bulletin* 2007;**33**(1):183–91. [PUBMED: 16905632]

Lilly 2002
Lilly. A meaningful day [multimedia package]. Eli Lilly Pharmaceuticals 2002.

MacDonald 1988
Macdonald EM, Pica S, Mcdonald S, Hayes R, Baglioni AJ. Stress and coping in early psychosis. Role of symptoms, self-efficacy, and social support in coping with stress. *British Journal of Psychiatry* 1998;**172**(33):122–7.

Marshall 2000
Marshall M, Lockwood A, Bradley C, Adams C, Joy C, Fenton M. Unpublished rating scales: a major source of bias in randomised controlled trials of treatments for schizophrenia. *British Journal of Psychiatry* 2000;**176**: 249–52. [PUBMED: 10755072]

Moher 2001
Moher D, Schulz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. *Lancet* 2001;**357**:1191–4.

NCEP 2001
National Institute of Health. Third report of national cholesterol education programme expert panel on detection, evaluation and treatment of high blood cholesterol in adults. Adult Treatment Panel III 2001. [: NIH Publication 01–3670]

Newman 1991
Newman SC, Bland RC. Mortality in a cohort of patients with schizophrenia: a record linkage study. *Canadian Journal of Psychiatry* 1991;**36**(4):239–45. [PUBMED: 1868416]

NIMH 1987
National Institute of Mental Health. *Towards a Model for a Comprehensive Community-Based Mental Health System*. National Institute of Mental Health Washington, DC: NIMH, 1987.

Overall 1962
Overall JE, Gorham DR. The brief psychiatric rating scale. *Psychological Reports* 1962;**10**:799–812.

Robson 2007
Robson D, Gray R. Serious mental illness and physical health problems: a discussion paper. *International Journal of Nursing Studies* 2007;**44**(3):457–66. [PUBMED: 17007859]

Ruggeri 2000
Ruggeri M, Leese M, Thornicroft G, Bisoffi G, Tansella M. Definition and prevalence of severe and persistent mental illness. *British Journal of Psychiatry* 2000;**177**:149–55. [PUBMED: 11026955]

Russell 1979
Russell MA, Wilson C, Taylor C, Baker CD. Effect of general practitioners' advice against smoking. *British Medical Journal* 1979;**2**(6184):231–5. [PUBMED: 476401]

Rust 1989
Rust J, Golonbok S. *Modern Psychometrics*. London: Routledge, 1989.

Schinnar 1990
Schinnar AP, Rothbard AB, Kanter R, Jung YS. An empirical literature review of definitions of severe and persistent

mental illness. *American Journal of Psychiatry* 1990;**147**(12): 1602–8. [PUBMED: 2244636]

Schünemann 2008
Schünemann HJ, Oxman AD, Vist GE, Higgins JPT, Deeks JJ, Glasziou P, et al.Chapter 12: Interpreting results and drawing conclusions. In: Higgins JPT, Green S editor(s). *Cochrane Handbook for Systematic Reviews of Interventions*. The Cochrane Collaboration, 2008:359–83.

Singh 1992
Singh SJ, Morgan MD, Scott S, Walters D, Hardman AE. Development of a shuttle walking test of disability in patients with chronic airways obstruction. *Thorax* 1992;**47**: 1019–24.

Smith 2007
Smith S, Yeomans D, Bushe CJ, Eriksson C, Harrison T, Holmes R, et al.A well-being programme in severe mental illness. Baseline findings in a UK cohort. *International Journal of Clinical Practice* 2007;**61**(12): 1971–8. [PUBMED: 17997803]

Smith 2007a
Smith S, Yeomans D, Bushe CJ, Eriksson C, Harrison T, Holmes R, et al.A well-being programme in severe mental illness. Reducing risk for physical ill-health: a post-programme service evaluation at 2 years. *European Psychiatry* 2007;**22**(7):413–8. [PUBMED: 17765483]

Solty 2009
Solty H, Crockford D, White WD, Currie S. Cigarette smoking, nicotine dependence, and motivation for smoking cessation in psychiatric inpatients. *Canadian Journal of Psychiatry* 2009;**54**(1):36–45. [PUBMED: 19175978]

Stott 1990
Stott NC, Pill RM. 'Advise yes, dictate no'. Patients' views on health promotion in the consultation. *Family Practice* 1990;**7**(2):125–31. [PUBMED: 2369980]

Sutherland 2003
Sutherland G. Smoking: can we really make a difference?. *Heart* 2003;**89**(Suppl 2):ii25-7; discussion ii35-7.

Tosh 2010a
Tosh G, Clifton A, Mala S, Bachner M. Physical health care monitoring for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2010;**3**:CD008298. [DOI: 10.1002/14651858.CD008298.pub2; PUBMED: 20238365]

Ukoumunne 1999
Ukoumunne OC, Gulliford MC, Chinn S, Sterne JAC, Burney PGJ. Methods for evaluating area-wide and organisation-based intervention in health and health care: a systematic review. *Health Technology Assessment* 1999;**3**(5): 1–75.

Ware 1998
Ware JE, Gandek B. Overview of the SF-36 health survey and the international quality of life assessment (IQOLA) project. *Journal of Clinical Epidemiology* 1998;**51**(11): 903–12.

WHO 1948
World Health Organization. Definition of health. Preamble to the constitution of the world health organization as adopted by the international health conference, New York. Official Records of the World Health Organization. New York, 1948; Vol. 2:100.

WHO 2007
World Health Organization. International statistical classification of diseases and related health problems. http://apps.who.int/classifications/apps/icd/icd10online/ 2007; Vol. (accessed 20th June 2010).

Wright 2012
Wright N, Akhtar A, Tosh G, Clifton A. HIV prevention advice for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2012, Issue 2. [DOI: 10.1002/14651858.CD009639]

Xia 2009
Xia J, Adams CE, Bhagat N, Bhagat V, Bhoopathi P, El-Sayeh H, et al.Loss to outcomes stakeholder survey: the LOSS study. *Psychiatric Bulletin* 2009;**33**(7):254–7.

References to other published versions of this review

Tosh 2011
Tosh G, Clifton A, Bachner M. General physical health advice for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2011, Issue 2. [DOI: 10.1002/14651858.CD008567.pub2]

* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Brown 2006

Methods	Allocation: random. Blinding: attempted to maintain rater blindness. Duration: 6 weeks.
Participants	Diagnosis: severe and enduring mental Illness (ICD -10 diagnosis of psychosis, major affective illness, or severe personality disorder). N = 28. Age: range 18-65 years. Sex: 4 men, 24 women. History: excluded if screening doctor thought that anyone with health problems, such as uncontrolled hypertension, severe cardiac disease, or any other medical condition, which might have worsened by unaccustomed exercise
Interventions	1. Semi-structured health promotion sessions: based on the Lilly "Meaningful Day"* manual which draws on extensive experience of best practice in delivering health promotion interventions. The six sessions covered weight control, healthy eating, exercise, structured daily activity and substance misuse. N = 15 2. Treatment as usual. N = 13.
Outcomes	Leaving early. Unable to use - Diet: Dietary Instrument for Nutrition Education Questionnaire (mean change, no SD, impossible to calculate lost data).** Exercise: Godin Leisure-Time Exercise Questionnaire (mean change, no SD, impossible to calculate lost data).** Psychological health: Hospital Anxiety and Depression scale (mean change, no SD, impossible to calculate lost data).** Subjective well being: Likert rating scale (mean change, no SD, impossible to calculate lost data).**
Notes	* (Lilly 2002) ** Sought statistical advice.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomised" - no further details.
Allocation concealment (selection bias)	Unclear risk	No details.

Brown 2006 (*Continued*)

Blinding (performance bias and detection bias) All outcomes	High risk	Not blinded but "... attempted to maintain rater blindness but in many cases this was not possible"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	11 of 28 included patients were missing at outcome. "Subjects failed to attend or cancelled at short notice a total of 73 (out of 199) appointments" - described but not addressed
Selective reporting (reporting bias)	Low risk	Four rating scales were listed in the methods, all four reported
Other bias	Unclear risk	Supported by Eli Lilly (pharmaceutical industry) who supplied the Lilly "Meaningful Day" package

Brown 2009

Methods	Allocation: random. Blinding: rater was blind to interviewee status. Duration:10 weeks.
Participants	Diagnosis: severe and enduring mental Illness (ICD -10 diagnosis of schizophrenia, major affective disorder, neurotic or personality disorder). N = 26. Age: range 18-65 years. Sex: 8 men, 18 women. History: excluded if anyone had "significant health problems" - none were
Interventions	1. Semi-structured health promotion session: based on the Lilly "Meaningful Day"* manual which draws on extensive experience of best practice in delivering health promotion interventions. The six sessions covered weight control, healthy eating, exercise, structured daily activity and substance misuse. N = 15 2. Treatment as usual. N = 11.
Outcomes	Leaving early. Unable to use - Diet: Dietary Instrument for Nutrition Education Questionnaire (mean change, no SD, impossible to calculate lost data).** Exercise: Godin Leisure-Time Exercise Questionnaire (mean change, no SD, impossible to calculate lost data).** Psychological health: Hospital Anxiety and Depression scale (mean change, no SD, impossible to calculate lost data).** Substance use: direct enquiry (mean change, no SD, impossible to calculate lost data).**
Notes	* (Lilly 2002) ** Sought statistical advice.

Brown 2009 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Randomised, using a hidden computer-generated random number programme" - no further details
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	High risk	Not blinded but "pre and post intervention measurements were made by the same rater who was blind to the interviewees' status in the study"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Five subjects (33%) did not complete the programme, most deciding not to continue with the programme after just one session" - described but not addressed
Selective reporting (reporting bias)	Low risk	Four rating scales were listed in the methods, all four reported
Other bias	Unclear risk	Health promotion operating manual was adapted from the Lilly "Meaningful Day" package (Lilly 2002).

Byrne 1999

Methods	Allocation: random, clustered by home. Blinding: no. Duration: 18 months.
Participants	Diagnosis: chronic psychiatric illness.* N = 22 homes (214 people). Age: mean 49.9 years. Sex: 140 men, 74 women. History: excluded if less than 50% of residents in the home agreed to attend sessions and if the majority of the residents in a home did not speak English
Interventions	1. Health Education: intensive 12-week educational session focusing on enhancing overall wellness, reducing smoking, and increasing activity facilitated by public health nurses. N = 7 homes (77 individuals) 2. Health Empowerment: a three-phase process, first "the listening phase", second the "participatory dialogue" and finally in the final stage "group members tested out their understanding of the problem in the real world". N = 7 homes (69 individuals).** 3. Control group. N = 8 homes (68 individuals).

Byrne 1999 (*Continued*)

Outcomes	Leaving early. Quality of Life: Lehman Quality of Life Scale. Health service utilization: resource consumption quantified according to their dollar value (using Ontario Health Insurance Plan schedule of fees). "A total dollar value of health resource consumption was determined in all groups" using the Health Service Utilization Inventory similar to Browne 1990. Unable to use - Life satisfaction: Cantril Self-Anchoring Ladder (did not report changes between baseline and completion of intervention)
Notes	* participants asked to report what type of mental health problem they had - 31% schizophrenia, 14.1% affective disorders, 16.4% "other mental health problems", 25. 8% "did not know", 12.2% "said they had no problem of this type" ** for the purposes of this review we considered both health empowerment and health education as 'general healthcare advice' We calculated the design effects for the health education versus health empowerment education (D.E.=1.873) and health education versus control (D.E.=1.418); both were applied accordingly

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"The homes in each strata were then randomly assigned to one of the three study groups" - no further details
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"By time 3 only 53% of the original sample remained in the study, and those actually participating in the groups (completing more than 20% of the sessions) were 40% of the original sample"
Selective reporting (reporting bias)	Low risk	Three rating scales were listed in the methods, all three reported
Other bias	Low risk	State funded (Ontario Ministry of Health, Canada), no evidence of other bias

Chafetz 2008

Methods	Allocation: random. Blinding: no. Duration: 18 months.
Participants	Diagnosis: severe mental illness. N = 309. Age: mean 38.2 years. Sex: 210 men, 99 women. History: excluded if did not speak English, unable to provide informed consent, diagnosed with cognitive/adjustment disorder
Interventions	1. Wellness training + basic primary care: promote skills in self-assessment, self-monitoring, and self-management of physical health problems, including use of health services. ..... + basic primary care (see below). N = 154 2. Basic primary care: provide health assessments, immediate or short-term care, health education, and referrals. N = 155
Outcomes	Leaving early. Unable to use - Physical functioning: Medical Outcomes Health Survey Short Form 36 (no mean change, no SD, impossible to calculate lost data).* Health-related self-efficacy: assessed using a method adapted by MacDonald 1988 (no mean change, no SD, impossible to calculate lost data).* Psychosocial function: Global Assessment of Function (no mean change, no SD, impossible to calculate lost data).*
Notes	* Sought statistical advice.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomisation" - no further details.
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	"Baseline severity of medical comorbidity was rated by NPs [Nurse Practitioners] blind to study group....." - no further details
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"... we are confident that results for outcomes reported here are not biased by differences between study groups in number of interviews completed" - described and addressed

Selective reporting (reporting bias)	Low risk	Three rating scales were listed in the methods, all three reported
Other bias	Unclear risk	Supported by the National Institute of Nursing Research

Danavall 2007

Methods	Allocation: randomised. Blinding: no. Duration: six months.
Participants	Diagnosis: people who are receiving care at a community mental health centre and who suffer from chronic mental illness. N = 80. Sex: both. Age: 18 and older. History: active patient roster at the CMHC, have a severe mental illness (National Advisory Mental Health Council, 1993) have one or more chronic medical condition, and have the capacity to provide informed consent
Interventions	1. Peer-led medical illness self-management group sessions. N = 41 2. Standard care. N = 39.
Outcomes	Physical health behaviour - minutes of moderate/vigorous exercise. Health-related quality of life. Leaving the study early. Adverse events.
Notes	

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Using a computerised algorithm, patients were randomised to the intervention or usual care group by the project manager
Allocation concealment (selection bias)	Unclear risk	Allocation "by the project group manager" - no further details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	"Interviewers were blinded to subjects' randomization status" - no further details

Danavall 2007 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	15 participants were lost to follow-up. Stated that "all analyses were conducted as intent-to-treat"
Selective reporting (reporting bias)	Unclear risk	All outcomes stated in the method appear to have been reported
Other bias	Unclear risk	Dr. Lorig receives royalties from Bull Publisher for being an author of Living a Healthy Life with Chronic Conditions. This book was written for the self-management course and is used in this study

Druss 2010

Methods	Allocation: random. Blinding: interviewers blinded to participants' randomisation status. Duration: 12 months.
Participants	Diagnosis: severe mental illness. N = 407. Age: mean age 47 (intervention), mean age 46.3 (usual care). Sex: 210 men, 197 women. History: excluded if not on active patient roster at community mental health centres, could not provide informed consent and did not have a severe mental illness
Interventions	1. Care management intervention: a manualised protocol for care based on standardised approaches documented in the care management literature. "The program was designed to help overcome patient, provider, and system-level barriers to primary medical care experienced by persons with mental disorders". N = 205 2. Usual care: individuals were given a list with contact information for local primary care medical clinics that accept uninsured and Medicaid patients. N = 202
Outcomes	Leaving early. Death. Quality of preventative services: U.S. Preventative Services Task Force guidelines. Health-related quality of life: Medical Outcomes Study 36-Item Short-Form Health Survey Unable to use - Quality and outcomes of cardio-metabolic care: RAND Community Quality Index study*, Framingham Cardiovascular Risk Index score.**
Notes	*The RAND Community Quality Index study was completed for individuals who had one or more cardio-metabolic conditions (n = 202) the distribution of these individuals is unknown. **The Framingham Cardiovascular Risk Index score was only completed for individuals with complete blood test results available (n = 100) the distribution of these individuals is unknown

Druss 2010 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Using a computerized algorithm, patients were randomly assigned to a care management intervention group or a usual care group" - no further details
Allocation concealment (selection bias)	Unclear risk	Allocation "by the project group manager" - no further details
Blinding (performance bias and detection bias) All outcomes	Unclear risk	"Interviewers were blinded to subjects' randomisation status" - no further details
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"Of those randomly assigned, 73% completed 6-month follow-up interviews and 68% completed 12-month follow-up interviews". Lost to follow-up was "unable to locate", "deceased", and "withdrawn" - described but not addressed
Selective reporting (reporting bias)	Low risk	Four rating scales were listed in the methods, all four reported
Other bias	Unclear risk	Lead author "Dr Druss received research funding from Pfizer", who manufacture a wide range of medicines for conditions such as heart disorders, cancer, raised blood pressure, high cholesterol and sexual health

Forsberg 2008

Methods	Allocation: random, clustered by "supported housing facilities".* Blinding: no. Duration: 12 months.
Participants	Diagnosis: psychiatric diagnosis in accordance with DSM-IV. N = 49 residents, 48 staff members. Age: range 22-71 (residents), range 27-62 (staff). Sex: 28 men (residents), 21 women (residents), 16 men (staff) 25 women (staff). History: people with psychiatric disability and their staff working with housing support or in supported housing facilities
Interventions	1. A programme of healthy living in the form of a study circle: study material comprised of a book focusing on motivation, food content, stress and fitness. N = 24 (residents), 22 (staff)

	2. Aesthetic study circle: participants had an opportunity to learn and practice various kinds of artistic techniques. N = 17 (residents), 19 (staff)
Outcomes	Physical working capacity: i) Incremental Shuttle Walk Test ii) Borg RPE (Rate of perceived exertion) Scale. Rate of metabolic syndrome:NCEP ATP 2001. Physical activity: SILVA™ "Pedometer plus". Heart score: "estimates the present and 10-year risk of fatal Coronary Vascular Disease". ** Unable to use - Leaving early (not reported by group). Satisfaction of programme: "Satisfaction in participating in the study" questionnaire (not applicable to outcomes)
Notes	* Author kindly clarified that suggestion that people within housing facilities were randomised (page 489 of report) is incorrect **This is done "by using factors of age, sex, cholesterol level, systolic blood pressure and smoking habits" We calculated the design effect for the healthy living circle versus the aesthetic living circle as 1.23 and applied it accordingly

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	"Randomisation was conducted on group level by the drawing of lots" - no further details
Allocation concealment (selection bias)	Low risk	Allocation "by a person not involved in the project".
Blinding (performance bias and detection bias) All outcomes	Unclear risk	No details.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Clients leaving early: "no informed reasons were mentioned", or "informed reasons were studies, health reasons", or "dissatisfaction of their study circle", "health problem" and "job" - described but not addressed. Staff leaving early: "no informed reasons", "new job", dissatisfaction of study circle" and "sick list" - described but not addressed
Selective reporting (reporting bias)	Unclear risk	Five rating scales were listed in the methods, all five reported Leaving the study early - not reported by

Forsberg 2008 (*Continued*)

		group. Study reported as if not clustered - no intra-class correlation coefficient
Other bias	Unclear risk	Supported by grants from "The Vasterbotten County Council, The Swedish Institute for Health Sciences,The Swedish Council for Working Life and Social Research, Stiftelsen J C Kempes Minnes Stipendiefond and The Foundation of Medical Research in Skelleftea"

DSM IV: Diagnostic and Statistical Manual, 4th edition
ICD 10 - International Classification of Diseases
SD: standard deviation

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Almomani 2009	Allocation: randomised Participants: schizophrenia, bipolar, depression Intervention: education + mechanical toothbrush vs mechanical toothbrush alone. Not focused on general physical health
Baker 2009	Allocation: randomised. Participants: severe mental disorder - schizophrenia or bipolar disorder Intervention: multi-component intervention for smoking cessation and CVD risk reduction vs telephone-based minimal intervention focusing on smoking cessation. Not focused on general physical health
Berti 2011	Allocation: non-randomised for phase 1 of study, phase 2 to be randomised (has not begun) Participants: affective and non-affective functional psychotic disorders Intervention: none in phase 1, phase 2 reported to focus on weight loss vs standard care; not focused on general physical health
Brown 2011	Allocation: randomised. Participants: serious mental illness (not specified). Intervention: six months of special meal schedule and education. Not focused on general physical health
Eberhard 2009	Allocation: randomised. Participants: non-psychotic psychiatric patients.
Gao 2001	Allocation: unclear - people "divided" into groups. Participants: people with schizophrenia. Intervention: health education vs standard care, health education refers to mental health rather than general

(*Continued*)

	physical health
Goetz 2011	Allocation: randomised. Participants: 50% schizophrenia, 26% bipolar, 24% major depression Intervention: 12-week program of education/skills training aimed at improved nutrition vs control (unclear what control was), increased activity and weight loss. Does not focus on general physical health
Huang 2005	Allocation: unclear - people "divided" into groups. Participants: convalescent psychotic patients. Intervention: health education vs standard care, health education refers to mental health rather than general physical health
Jiang 2006	Allocation: randomised. Participants: people with schizophrenia. Intervention: health education + routine care vs routine care. Focused on mental health rather than general health
Jones 2001	Allocation: randomised. Participants: people with schizophrenia. Intervention: education by community mental health nurse vs computer-assisted Instruction vs standard care. Focused on mental health rather than general physical health
Kuosmanen 2009	Allocation: randomised. Participants: schizophrenia. Intervention: needs-based computerised patient education on deprivation of liberty vs oral sessions and written material education on deprivation of liberty vs standard treatment. Not focused on general physical health
Leutwyler 2009	Allocation: randomised. Participants: schizophrenia and schizoaffective disorder. Intervention: 24-week diabetes education program vs usual care plus information. Focus is on diabetes, not on general physical health
Li 2005	Allocation: unclear - people "divided" into groups. Participants: Outpatients with schizophrenia Intervention: health education vs standard care. Not focused on general physical health
Lothringer 2009	Allocation: randomised. Participants: severe mental illness, 50% schizophrenia. Intervention: HIV prevention vs control. Not focused on general physical health advice
NCT00902694	Allocation: randomised. Participants: overweight psychiatric patients. Intervention: group and individual weight counselling and group physical activity classes vs group health classes quarterly with topics not related to weight. Intervention not focused on general physical health
NCT00990925	Allocation: randomised. Participants: schizophrenia, schizoaffective disorder, obesity Intervention: lifestyle Modification for Weight Loss in Schizophrenia. Not focused on general physical health

(*Continued*)

NCT01324973	Allocation: randomised. Participants: serious mental illness, overweight. Intervention: a web-based weight management program that includes computerised delivery of evidence-based education regarding diet and physical activity vs care as usual. Not focused on general physical health
NCT01547026	Allocation: randomised. Participants: schizophrenia and schizo-affective disorder. Intervention: structured procedure to build up implementation intentions to participate in the sports therapy vs individual 10-minute psycho-education session on the helpfulness of sports to improve the health. Focused on weight gain and improving sports uptake, not focused on general physical health
Osborn 2010	Allocation: randomised. Participants: serious mental illness, no details provided. Those "too unwell" were excluded Intervention: nurse-led intervention + education vs education alone, outcome limited to numbers that received screening for cardiovascular risk factors and not the impact of the screening on physical health
Stockings 2011	Allocation: randomised. Participants: acute mental illness without severe distress at time of interview Intervention: smoking cessation program vs regular hospital smoking program. Not focusing on general health advice
Subramaniam 2010	Allocation: randomised. Participants: schizophrenia vs healthy controls. Intervention: computerised targeted cognitive training. Not focusing on general physical health advice
Walker 2005	Allocation: not randomised, feasibility study for conducting RCT
Zhou 2007	Allocation: randomised. Participants: people with first episode schizophrenia. Intervention: systematic healthcare education vs standard care, not focused on general physical health
林素兰 2010	Allocation: randomised. Participants: schizophrenia. Intervention: education in both study and control group.

CVD: cardiovascular disease
RCT: randomised controlled trial
vs: versus

Characteristics of ongoing studies *[ordered by study ID]*

NCT00137267

Trial name or title	A brief community linkage intervention for dually diagnosed individuals
Methods	Allocation: randomised. Blinding: open label. Duration: 8 weeks.
Participants	Diagnosis: people who have a substance abuse disorder and a diagnosis of schizophrenia, schizoaffective disorder, or bipolar I disorder. N = 170 (estimated enrolment). Sex: both. Age: 18 and older.
Interventions	1.Time-Limited Case (TLC) Management. 2.Treatment as usual.
Outcomes	Rate at outpatient day treatment centre within one week post-hospitalisation. Differences in TLC group completion at 2 months. Number of days treatment attended at 6 months and 12 months. Number days re-hospitalised at 6 months and 12 months. Global Level of Functioning at 2 months, 6 months and 12 months. Number of days alcohol use at 2 months, 6 months, 12 months. Number of days drug use at 2 months, 6 months, 12 months.
Starting date	06/08/2007 completed 6/2009
Contact information	Selvija Gjonbalaj-Marovic * - selvija.gjonbalaj-marovic@va.gov,
Notes	* We have emailed project lead for further details. New PI David Smelson PSYD, Edith Nourse Rogers Memorial Veterans Hospital, Bedford

DATA AND ANALYSES

Comparison 1. PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Physical health behaviour: Moderate or vigorous physical activity (min/week, skewed)	1	80	Mean Difference (IV, Fixed, 95% CI)	39.0 [-76.53, 154.53]
2 Quality of life: Average scores - various scales	3		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Global score (Lehman Quality of Life Scale, high = good)	1	54	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.47, 0.87]
2.2 Mental component score (Medical Outcomes Study 36-Item Short-Form Health Survey, high = good)	2	487	Mean Difference (IV, Fixed, 95% CI)	3.70 [1.76, 5.64]
2.3 Physical component score (Medical Outcomes Study 36-Item Short-Form Health Survey, high = good)	2	487	Mean Difference (IV, Fixed, 95% CI)	2.46 [0.33, 4.59]
3 Adverse effects/events: Death	2	487	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.27, 3.56]
4 Service use: Average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high = good)	1	363	Mean Difference (IV, Fixed, 95% CI)	36.90 [33.07, 40.73]
5 Service use: One or more primary care visit	1	80	Risk Ratio (M-H, Fixed, 95% CI)	1.77 [1.09, 2.85]
6 Economic: Total value of health resource consumption (dollars, low = good, skewed data)			Other data	No numeric data
7 Leaving the study early	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 any reason	6	964	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.92, 1.35]
7.2 lost to follow-up	4	822	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.79, 1.20]
7.3 withdrawn	1	407	Risk Ratio (M-H, Fixed, 95% CI)	6.90 [0.86, 55.56]
7.4 discontinued	1	26	Risk Ratio (M-H, Fixed, 95% CI)	8.25 [0.50, 135.21]

Comparison 2. HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Quality of life: Average global score (Lehman Quality of Life scale, high = good)	1	51	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.99, 0.39]
2 Economic: Total value of health resource consumption (dollars, low = good, skewed data)			Other data	No numeric data
3 Leaving the study early	1	78	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.26, 1.19]

Comparison 3. HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Physical health behaviour: Average steps per day (high = good, skewed)			Other data	No numeric data
2 Physical health: 1. Metabolic syndrome - present	1	13	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.35, 4.49]
3 Physical health: 2. Average score for working capacity - various tests	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 shuttle test - lengths of 10 metres walked (Incremental shuttle walk test, high = good)	1	30	Mean Difference (IV, Fixed, 95% CI)	-157.0 [-321.11, 7.11]
3.2 Borg test (RPE - rate of perceived exertion test, high = good)	1	25	Mean Difference (IV, Fixed, 95% CI)	2.10 [0.04, 4.16]
4 Physical health: 3. Various continuous data (skewed)			Other data	No numeric data
4.1 metabolic syndrome - average criteria score			Other data	No numeric data
4.2 average risk of fatal cardiovascular disease - at present (Heart Score, high = good, skewed data)			Other data	No numeric data
4.3 average risk of fatal cardiovascular disease - by 10 years (Heart Score, high = good, skewed data)			Other data	No numeric data

Analysis 1.1. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 1 Physical health behaviour: Moderate or vigorous physical activity (min/week, skewed).

Review: General physical health advice for people with serious mental illness

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

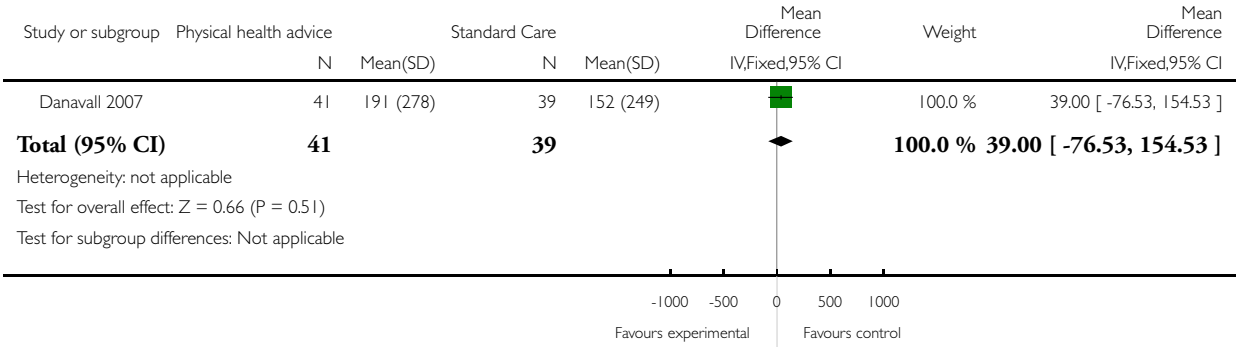
Outcome: 1 Physical health behaviour: Moderate or vigorous physical activity (min/week, skewed)

Study or subgroup	Physical health advice		Standard Care		Mean Difference	Weight	Mean Difference
	N	Mean(SD)	N	Mean(SD)	IV,Fixed,95% CI		IV,Fixed,95% CI
Danavall 2007	41	191 (278)	39	152 (249)		100.0 %	39.00 [-76.53, 154.53]
Total (95% CI)	**41**		**39**			**100.0 %**	**39.00 [-76.53, 154.53]**

Heterogeneity: not applicable

Test for overall effect: Z = 0.66 (P = 0.51)

Test for subgroup differences: Not applicable



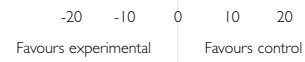
Analysis 1.2. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 2 Quality of life: Average scores - various scales.

Review: General physical health advice for people with serious mental illness

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 2 Quality of life: Average scores - various scales

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Mean Difference IV,Fixed,95% CI
1 Global score (Lehman Quality of Life Scale, high = good)						
Byrne 1999	26	4.6 (1.3)	28	4.4 (1.2)		0.20 [-0.47, 0.87]
Subtotal (95% CI)	**26**		**28**			**0.20 [-0.47, 0.87]**
Heterogeneity: not applicable						
Test for overall effect: Z = 0.59 (P = 0.56)						
2 Mental component score (Medical Outcomes Study 36-Item Short-Form Health Survey, high = good)						
Danavall 2007	41	36.8 (10)	39	11.8 (0)		0.0 [0.0, 0.0]
Druss 2010	205	39.3 (9.9)	202	35.6 (10.1)		3.70 [1.76, 5.64]
Subtotal (95% CI)	**246**		**241**			**3.70 [1.76, 5.64]**
Heterogeneity: Chi^2 = 0.0, df = 0 (P = 1.00); I^2 =0.0%						
Test for overall effect: Z = 3.73 (P = 0.00019)						
3 Physical component score (Medical Outcomes Study 36-Item Short-Form Health Survey, high = good)						
Danavall 2007	41	42.9 (14.2)	39	40 (13.7)		2.90 [-3.21, 9.01]
Druss 2010	205	37.1 (11.5)	202	34.7 (11.9)		2.40 [0.13, 4.67]
Subtotal (95% CI)	**246**		**241**			**2.46 [0.33, 4.59]**
Heterogeneity: Chi^2 = 0.02, df = 1 (P = 0.88); I^2 =0.0%						
Test for overall effect: Z = 2.26 (P = 0.024)						
Test for subgroup differences: Chi^2 = 13.92, df = 2 (P = 0.00), I^2 =86%						

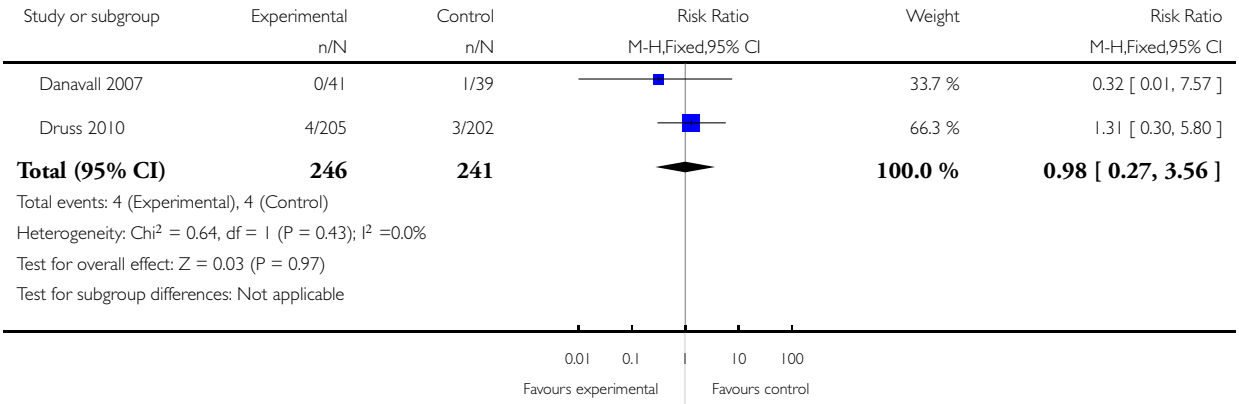


Analysis 1.3. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 3 Adverse effects/events: Death.

Review: General physical health advice for people with serious mental illness

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 3 Adverse effects/events: Death

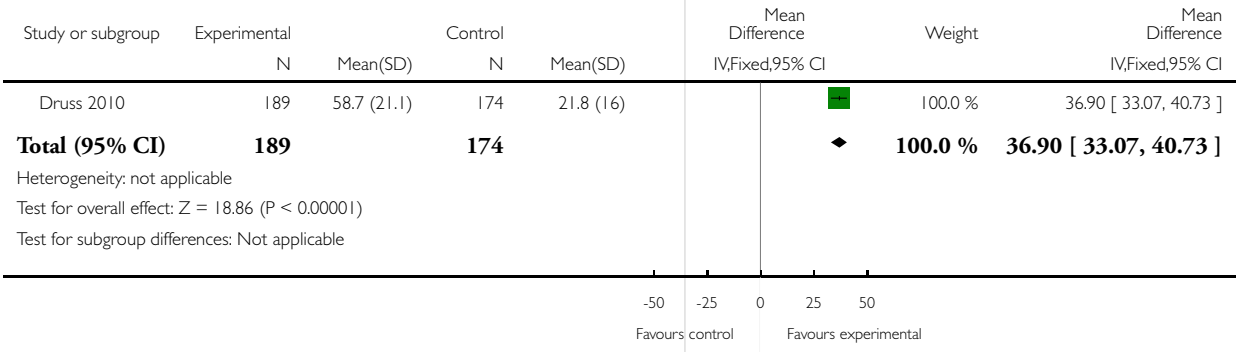


Analysis 1.4. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 4 Service use: Average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high = good).

Review: General physical health advice for people with serious mental illness

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 4 Service use: Average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high = good)

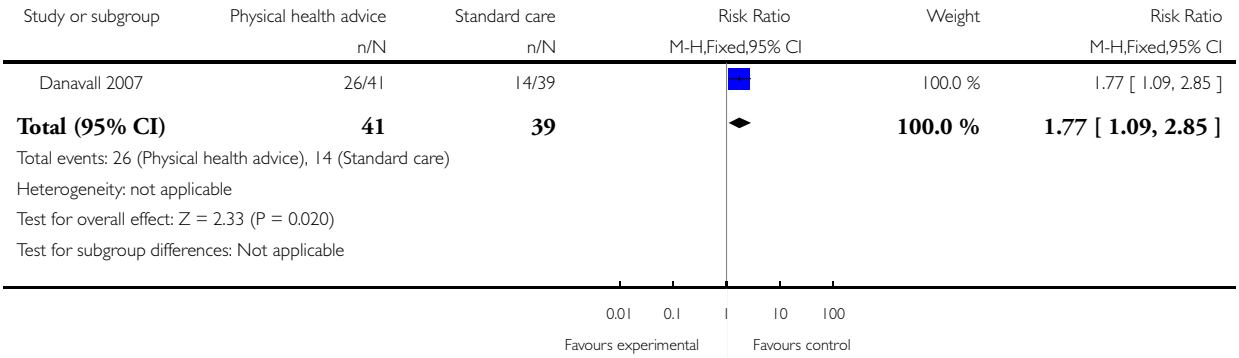


Analysis 1.5. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 5 Service use: One or more primary care visit.

Review: General physical health advice for people with serious mental illness

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 5 Service use: One or more primary care visit



Analysis 1.6. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 6 Economic: Total value of health resource consumption (dollars, low = good, skewed data).

Economic: Total value of health resource consumption (dollars, low = good, skewed data)

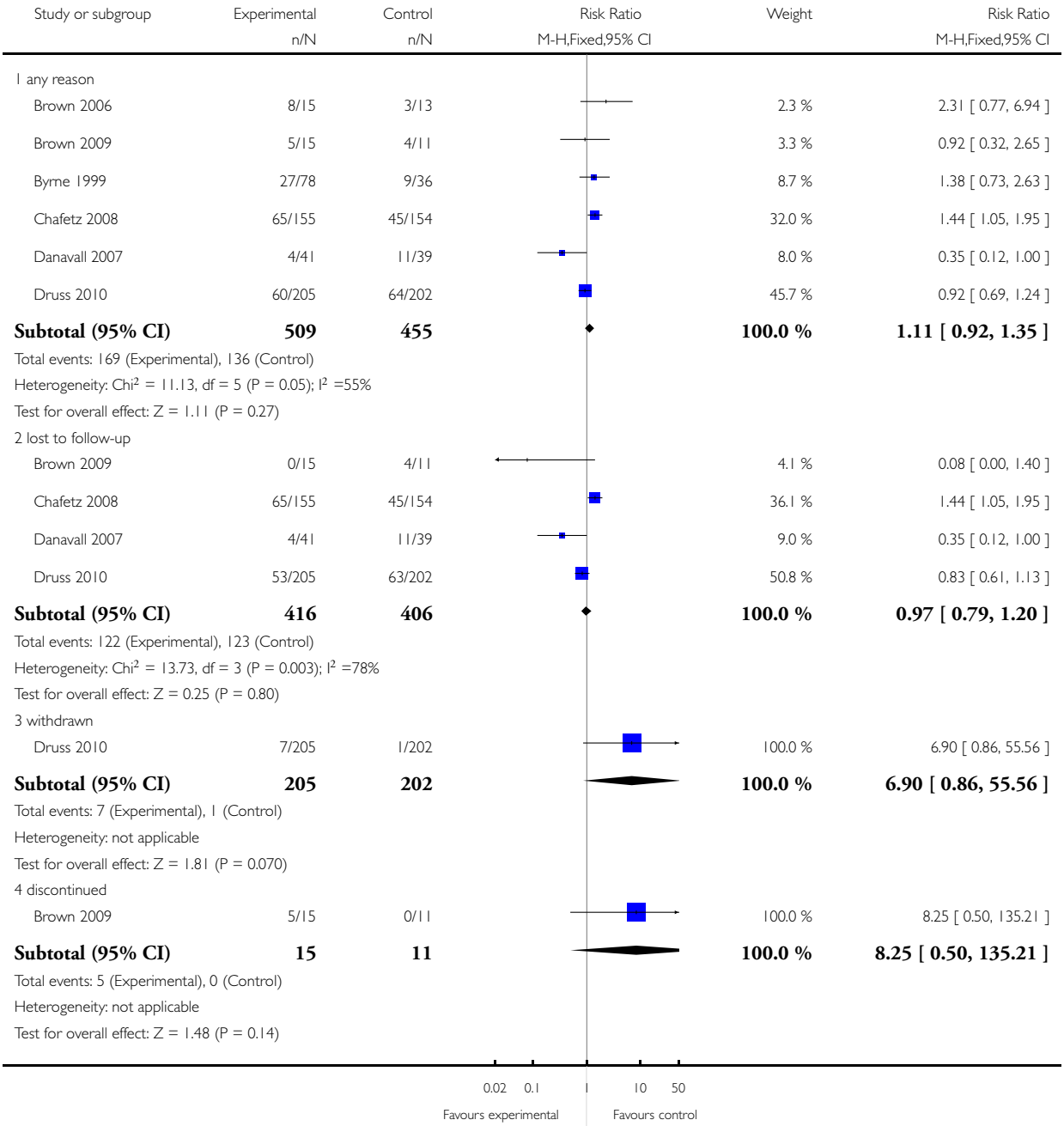
Study	Interventions	Average consumption (US $)	SD	N
Byrne 1999	Health empowerment	1476.51	2191.98	36
Byrne 1999	Control	956.63	2506.18	39

Analysis 1.7. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 7 Leaving the study early.

Review: General physical health advice for people with serious mental illness

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 7 Leaving the study early

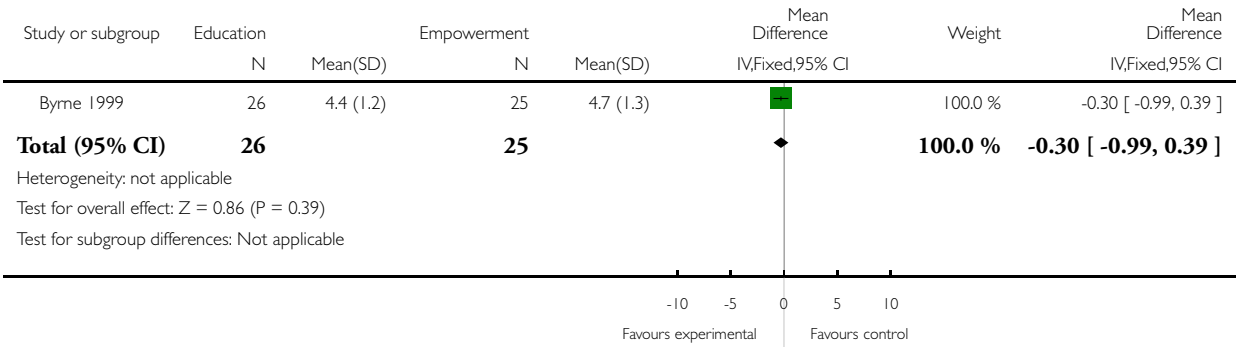


Analysis 2.1. Comparison 2 HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION, Outcome 1 Quality of life: Average global score (Lehman Quality of Life scale, high = good).

Review: General physical health advice for people with serious mental illness

Comparison: 2 HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION

Outcome: 1 Quality of life: Average global score (Lehman Quality of Life scale, high = good)



Analysis 2.2. Comparison 2 HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION, Outcome 2 Economic: Total value of health resource consumption (dollars, low = good, skewed data).

Economic: Total value of health resource consumption (dollars, low = good, skewed data)

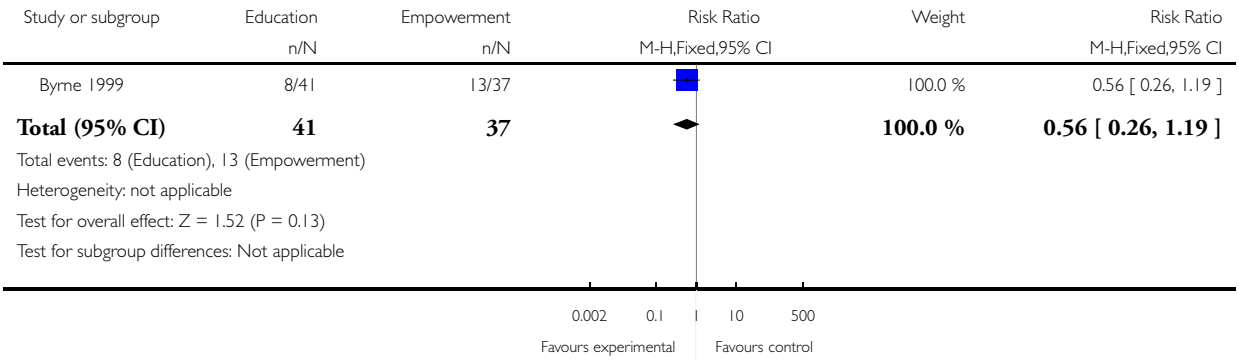
Study	Intervention	Mean (US $)	SD	N
Byrne 1999	Health education	1432.03	2588.67	39
Byrne 1999	Health empowerment	1476.51	2191.98	36

Analysis 2.3. Comparison 2 HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION, Outcome 3 Leaving the study early.

Review: General physical health advice for people with serious mental illness

Comparison: 2 HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION

Outcome: 3 Leaving the study early



Analysis 3.1. Comparison 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE, Outcome 1 Physical health behaviour: Average steps per day (high = good, skewed).

Physical health behaviour: Average steps per day (high = good, skewed)

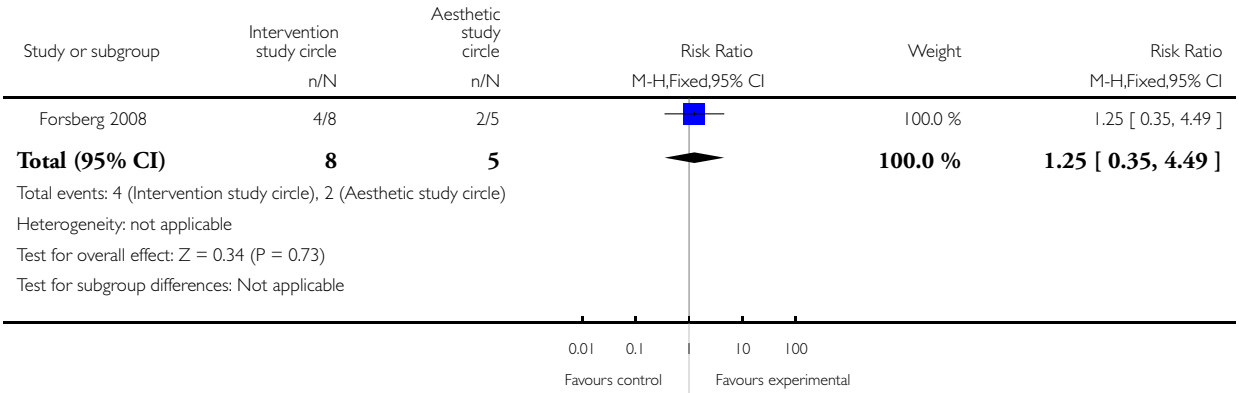
Study	Intervention	Mean	SD	n	Notes
Forsberg 2008	Healthy living study circle	5586	3313	9	Clustered data - but analysed as non-clustered in report.
Forsberg 2008	Aesthetic study circle	6487	2743	8	Clustered data - but analysed as non-clustered in report.

Analysis 3.2. Comparison 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE, Outcome 2 Physical health: 1. Metabolic syndrome - present.

Review: General physical health advice for people with serious mental illness

Comparison: 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE

Outcome: 2 Physical health: 1. Metabolic syndrome - present

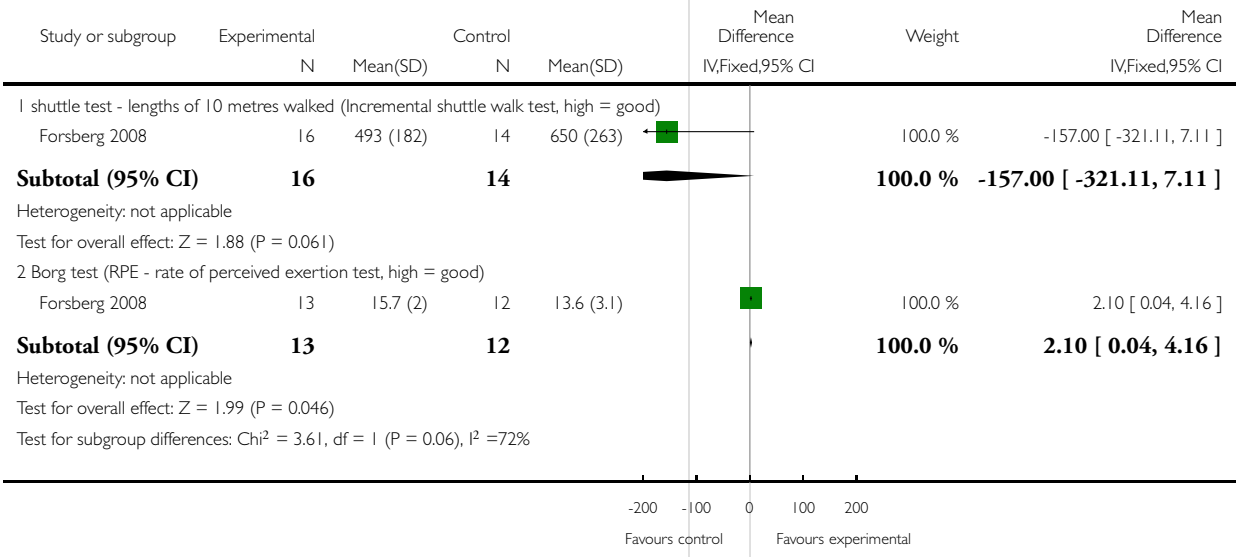


Analysis 3.3. Comparison 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE, Outcome 3 Physical health: 2. Average score for working capacity - various tests.

Review: General physical health advice for people with serious mental illness

Comparison: 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE

Outcome: 3 Physical health: 2. Average score for working capacity - various tests



Analysis 3.4. Comparison 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE, Outcome 4 Physical health: 3. Various continuous data (skewed).

Physical health: 3. Various continuous data (skewed)

Study	Intervention	Mean	SD	n	Notes
metabolic syndrome - average criteria score					
Forsberg 2008	Healthy living study circle	2.24	1.44	21	Clustered data - but analysed as non-clustered in report.
average risk of fatal cardiovascular disease - at present (Heart Score, high = good, skewed data)					
Forsberg 2008	Healthy living study circle	0.86	1.07	21	Clustered data - but analysed as non-clustered in report.
average risk of fatal cardiovascular disease - by 10 years (Heart Score, high = good, skewed data)					
Forsberg 2008	Healthy living study circle	4.67	3.9	21	Clustered data - but analysed as non-clustered in report.

ADDITIONAL TABLES

Table 1. Series of related reviews

Title	Reference
General physical healthcare monitoring	Tosh 2010a
General physical healthcare advice	This review
Advice regarding smoking cessation	Khanna 2012
Advice regarding oral health care	Khokhar 2011
Advice regarding HIV/AIDs prevention	Wright 2012
Advice regarding substance use	Underway

Table 2. Suggested design for future study

Methods	Allocation: randomised, clearly described. Blinding: single - tested. Duration: 10 years.
Participants	Diagnosis: schizophrenia or any serious mental illness. N = 900. Age: 18-65. Sex: both. History: any.
Interventions	1. Physical health assessment: volunteer worker encouraging an acceptable form of physical healthcare advice including information, advice regarding access to services to reduce barriers to interventions and provide sustained encouragement for engagement/behavioural change 2. Care as usual: no change to current practice.
Outcomes	Adverse health events: death, major illness - recorded by type (open list). Quality of life - social relations, family relations, financial situation (EuroQol). Physical health - healthy days. Service use - physical healthcare admission, days in hospital due to physical illness, visit to healthcare practitioner. Mental state - no clinically important change in general mental state (CGI). Leaving the study early - why. Economic outcomes.
Notes	For 20% difference between groups for a binary outcome to be highlighted with reasonable degree of confidence, 150 people are needed per group

CG-I: Clinical Global Impression

APPENDICES

Appendix 1. Previous methods text

Data extraction and managment

5. Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we aimed to apply the following standards to all data before inclusion: (a) standard deviations and means are reported in the paper or obtainable from the authors; (b) when a scale starts from the finite number zero, the standard deviation, when multiplied by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution (Altman 1996); (c) if a scale starts from a positive value (such as PANSS which can have values from 30 to 210) the calculation described above will be modified to take the scale starting point into account. In these cases skew is present if 2SD>(S-S min), where S is the mean

score and S min is the minimum score. Endpoint scores on scales often have a finite start and end point and these rules can be applied. When continuous data are presented on a scale which includes a possibility of negative values (such as change data), it is difficult to tell whether data are skewed or not. We entered skewed data from studies of less than 200 participants in additional tables rather than into an analysis. Skewed data pose less of a problem when looking at means if the sample size is large, and we entered skewed data from large sample sizes into syntheses.

Measures of treatment effect

1. Binary data

For binary outcomes we calculated a standard estimation of the random-effects RR and its 95% CI. It has been shown that RR is more intuitive (Boissel 1999) than odds ratios (OR) and that ORs tend to be interpreted as RR by clinicians (Deeks 2000). Within the 'Summary of findings' table we assumed for calculation of the low risk groups that the lowest control risk applied to all data. We did the same for the assumption of the highest risk groups. We used the 'Summary of findings' table to calculate absolute risk reduction for primary outcomes.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility (Xia 2009). For any particular outcome, should more than 50% of data be unaccounted for, we did not reproduce these data or use them within analyses. If, however, more than 50% of those in one arm of a study were lost, but the total loss was less than 50%, we marked such data with '*' to indicate that such a result may well be prone to bias.

2. Binary

In the case where attrition for a binary outcome was between 0% and 50% and where these data were not clearly described, we presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat analysis). Those lost to follow-up were all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death. We undertook a sensitivity analysis testing how prone the primary outcomes were to change when 'completed' data only were compared to the intention-to-treat analysis using the above assumption.

3. Continuous

3.1 Attrition

In the case where attrition for a continuous outcome is between 0% and 50% and completer-only data were reported, we have reproduced these.

3.2 Standard deviations

Where there are missing measures of variance for continuous data but exact standard error and CI are available for group means, either P value or T value are available for differences in mean, we calculated standard deviation value according to method described in Section 7.7.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). If standard deviations were not reported and could not be calculated from available data, we asked authors to supply the data. In the absence of data from authors, we used the mean standard deviation from other studies.

3.3 Last observation carried forward

We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing data, LOCF introduces uncertainty about the reliability of the results. Therefore, where LOCF data have been used in the trial, if less than 50% of the data had been assumed, we reproduced these data, and indicated that they are the product of LOCF assumptions.

WHAT'S NEW

Last assessed as up-to-date: 26 October 2013.

Date	Event	Description
4 March 2014	New citation required but conclusions have not changed	New data added to review but no overall change to conclusions
9 September 2013	New search has been performed	Results of 2012 update search added to review. A previous ongoing study is now complete and added to the included studies

HISTORY

Protocol first published: Issue 7, 2010

Review first published: Issue 2, 2011

Date	Event	Description
17 October 2012	Amended	Update search of Cochrane Schizophrenia Group's Trial Register (see Search methods for identification of studies), 43 studies added to awaiting classification.
17 October 2012	Amended	Contact details updated.
5 October 2011	Amended	Contact details updated.

CONTRIBUTIONS OF AUTHORS

Graeme Tosh - project initiation, protocol writing, primary reviewer, results and discussion writing.

Andrew Clifton - co-reviewer protocol writing, primary reviewer, results and discussion writing.

Jun Xia - co-reviewer, screened results of review 2012 update search.

Margueritte White - co-reviewer, screened results of 2012 update search.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Nottinghamshire CLAHRC (Collaboration for Leadership in Applied Health Research and Care), UK.
- National Institute of Health Research, UK.
- Nottinghamshire Healthcare NHS Trust, UK.
- NHS Nottingham City, UK.
- NHS Nottinghamshire County, UK.
- Nottingham University Hospitals NHS Trust, UK.
- NHS Derby City, UK.
- Derbyshire County PCT, UK.
- Derbyshire Mental Health NHS Trust, UK.
- Lincolnshire Partnership NHS Foundation Trust, UK.
- Bassetlaw PCT, UK.
- NHS East Midlands, UK.
- University of Nottingham, UK.
- Nottingham City Council, UK.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Minor corrections to outcomes.

Correction of wording to ensure that we are referring to general physical health.

For the 2013 update, we amended some sections of Methods to reflect the latest changes to the Cochrane Schizophrenia Group Template for methods. To see previous published versions of the amended section see Appendix 1.

INDEX TERMS

Medical Subject Headings (MeSH)

*Health Status; *Quality of Life; Awareness; Health Behavior; Health Promotion [*methods]; Mental Disorders [*complications; mortality]; Randomized Controlled Trials as Topic; Standard of Care

MeSH check words

Humans