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

Tosh G, Clifton A, Bachner M

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[Intervention Review]

General physical health advice for people with serious mental illness

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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 assess the effects of general physical health advice as a means of reducing morbidity, mortality and improving or maintaining quality of life in people with serious mental illness.

Search strategy

We searched the Cochrane Schizophrenia Group Trials Register (November 2009) which is based on regular searches of CINAHL, EMBASE, MEDLINE and PsycINFO.

Selection criteria

All randomised clinical trials focusing on general physical health advice.

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 mean difference (MD) between groups and its 95% CI. We employed a random-effects model for analyses.

Main results

For the comparison of physical healthcare advice versus standard care we identified five studies (total n = 884) of limited quality. For measures of quality of life one trial found no difference (n = 54, 1 RCT, MD Lehman scale 0.00 CI -0.67 to 0.67) but another did (n = 407, 1 RCT, MD Quality of Life Medical Outcomes Scale - mental component 3.7 CI 1.7 to 5.6). There was no difference between groups for the outcome of death (n = 407, 1 RCT, RR 1.3 CI 0.3 to 6.0), for the outcome of uptake of ill-health prevention services, one study found percentages significantly greater in the advice group (n = 363, 1 RCT, MD 36.9 CI 33.1 to 40.7). Economic data were equivocal. Attrition was large (> 30%) but similar for both groups (n = 884, 5 RCTs, RR 1.18 CI 0.97 to 1.43). Comparisons of one type of physical healthcare advice with another were grossly underpowered and equivocal.

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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 expenditure on giving ineffective advice. 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 have worse physical health than the general population. This review looks at whether giving advice about general physical health has any effect on the physical health and quality of life of people with serious mental illness.

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SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

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

Patient or population:
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				
Physical health awareness - not reported	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome we had prestated to be of importance.
Physical health behaviour - not reported	See comment	See comment	Not estimable	-	See comment	No studies reported on this outcome we had prestated to be of importance.
Quality of Life Lehman Quality of Life Scale. Scale from: 1 to 7. Follow-up: median 18 months	The mean quality of life in the control groups was **4.45 Points**[1]	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**[2,3,4,5]	
Adverse Effects Death of participant Follow-up: median 12 months	**Low risk population**[6]		**RR 1.31** (0.3 to 5.8)	407 (1 study)	⊕⊕○○ **low**[3,5,7]	

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	10 per 1000	**13 per 1000** (3 to 58)			
	Medium risk population[6]				
	15 per 1000	**20 per 1000** (5 to 87)			
	High risk population[6]				
	50 per 1000	**65 per 1000** (15 to 290)			
Economic - not reported	See comment	See comment	Not estimable	-	See comment
Leaving the study early	**Study population**		**RR 1.18** (0.97 to 1.43)	884 (5 studies)	⊕○○○ **very low**[2,3,8,9]
	300 per 1000	**354 per 1000** (291 to 429)			
	Medium risk population				
	292 per 1000	**345 per 1000** (283 to 418)			
Service Use: Average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high=good)		The mean Service Use: Average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high=good) in the intervention groups was **36.9 higher** (33.07 to 40.73 higher)		363 (1 study)	⊕⊕⊕○ **moderate**[2,3]

*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] Based on seven point Likert scale
[2] Limitations of design: rated 'serious' (lack of allocation concealment)
[3] Limitations of design: rated 'serious' (lack of blinding)
[4] Indirectness: rated 'serious' (authors admit that measurement tool was difficult to interpret)
[5] Imprecision: rated 'serious' (small sample size)
[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)
[9] Imprecision: rated 'serious' (small sample size)

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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 2010). 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, carers, 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 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 which refer to randomised controlled trials but a "systematic review of the published and grey literature" (Bradshaw 2005) concluded that "further research is needed to assist 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).

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Table 1. Series of related reviews

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

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. When we 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 included them and undertook 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.

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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

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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 carers' 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

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Search methods for identification of studies

Electronic searches

The Cochrane Schizophrenia Group Trials Register 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).

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.

Data collection and analysis

Selection of studies

Authors GT, AC and SM screened the results of the electronic search; to ensure reliability another 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 inclusion criteria. We were not blinded to the names of the authors, institutions or journal of publication.

Data extraction and management

1. Extraction

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 reviewers 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.

2. Management

2.1 Forms

GT and AC extracted data onto standard, simple forms.

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). 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. If endpoint data were unavailable, we used 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 aim to apply the following standards to all data before inclusion: (a) standard deviations and

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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.

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).

7. Conversion of continuous to binary

Where possible, we made efforts to convert outcome measures to dichotomous data. This could be done by identifying cut-off points on rating scales and dividing participants accordingly into 'clinically improved' or 'not clinically improved'. It was generally assumed that if there had been a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (BPRS, Overall 1962) or the Positive and Negative Syndrome Scale (Kay 1986; Kay 1987), this could be considered as a clinically significant response (Leucht 2005; Leucht 2005a). If data based on these thresholds were not available, we used 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 indicates a favourable outcome for general physical health advice.

9. Summary of findings table

We anticipate including the following outcomes in a Summary of Findings table.

9.1 Physical health awareness

- Failure to raise awareness of common physical health problems

- Failure to raise awareness of behaviours which can contribute to ill-health

9.2 Physical health behaviour

- No substantial change in behaviour

9.3 Quality of life

- Loss of independence

9.4 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

9.5 Economic

- Increased costs of health care

9.6 Financial dependency

- Claiming financial assistance because of a physical disability

9.7 Global state

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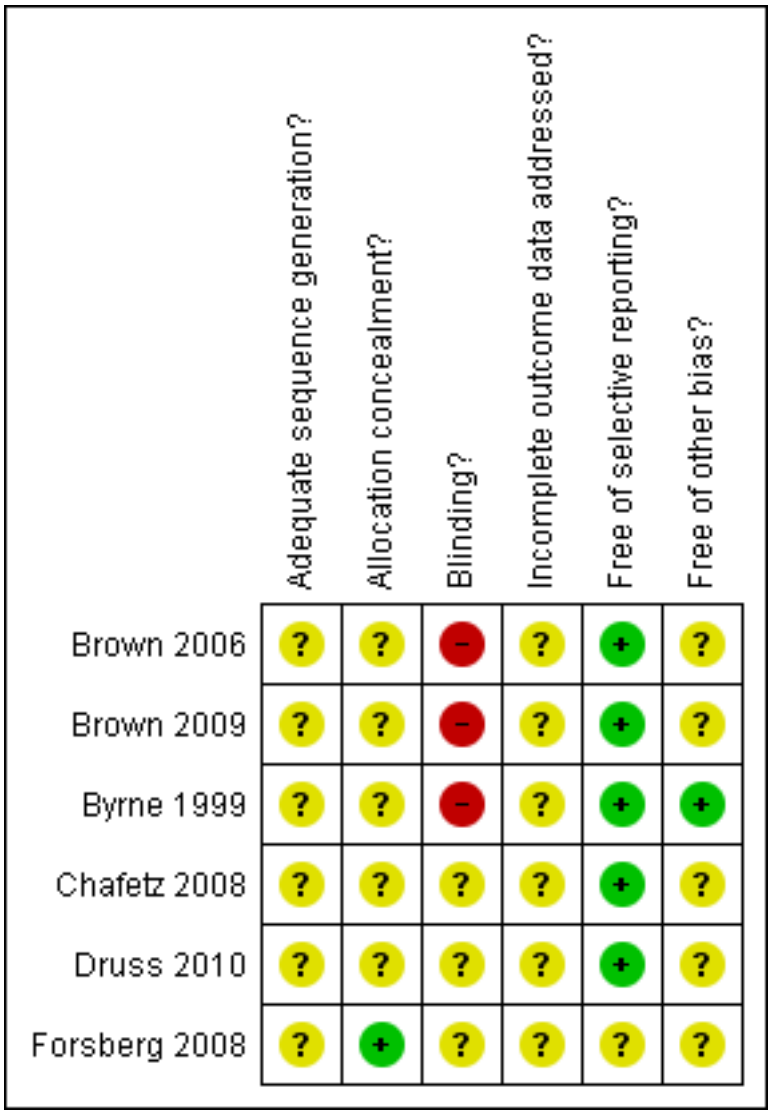
- No clinically important change in global state (as defined by individual studies)

Assessment of risk of bias in included studies

Again working independently, GT and AC assessed risk of bias using the tool described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). 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. If the raters disagreed, we made the final rating by consensus with the involvement of another member of the review group. Where inadequate details of randomisation and other characteristics of trials are 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



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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.

2. Continuous data

2.1 Summary statistic

For continuous outcomes we estimated a random-effects mean difference (MD) between groups. We preferred not to calculate effect size measures (standardised mean difference (SMD)). However, in the case of where scales were of such similarity to allow presuming there was a small difference in measurement, we calculated it and, whenever possible, we transformed 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, CI unduly narrow and statistical significance overestimated. This causes type I errors (Bland 1997; Gulliford 1999).

Where clustering is not accounted for in primary studies, we presented data in a table, with a (*) symbol to indicate the presence of a probable unit of analysis error. In subsequent versions of this review we will seek to contact first authors of studies to obtain intra class correlation co-efficient of their clustered data and to adjust for this by using accepted methods (Gulliford 1999). Where clustering had been incorporated into the analysis of primary studies, we present these data as if from a non-cluster randomised study, but adjusted for the clustering effect.

We have sought statistical advice and have been 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 intra class correlation co-efficient (ICC) (Design effect = 1+(m-1)*ICC) (Donner 2002). If the ICC was not reported, we assumed 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 would have been 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). As both effects are very likely in serious mental illness, we only used data of the first phase of cross-over studies.

3. Studies with multiple treatment groups

Where a study involved more than two treatment arms, if relevant, we presented the additional treatment arms in comparisons. Where the additional treatment arms were not relevant, we did 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). 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 is between 0% and 50% and where these data were not clearly described, we presented data on a 'once-randomised-always-analyse' basis (an intention-

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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.

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. Should such situations or participant groups arise, we fully discuss these.

2. Methodological heterogeneity

We considered all included studies initially, without seeing comparison data, to judge methodological heterogeneity. We simply inspected all studies for clearly outlying methods which we had not predicted would arise. Should such methodological outliers arise, we fully discuss these.

3. Statistical

3.1 Visual inspection

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

3.2 Employing the I-squared statistic

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).
We interpreted I^2 estimates greater than or equal to 50% accompanied by a statistically significant Chi^2 statistic, as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2008) and explored reasons for heterogeneity. If the inconsistency was high and the clear reasons were found, we presented 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 2008). 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 use funnel plots for outcomes where there were 10 or fewer studies, or where all studies were of similar sizes. In other cases, where funnel plots were possible, we sought statistical advice in their interpretation.

Data synthesis

Where possible we employed a random-effects 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

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be explored further in the meta-regression analysis despite being cautious that that random-effects methods does put added weight onto the smaller of the studies - we favoured using the random-effects model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We have not carried out any sub-group analyses.

2. Investigation of heterogeneity

2.1 Unanticipated heterogeneity

Should unanticipated clinical or methodological heterogeneity be obvious, we would simply state hypotheses regarding these for future reviews or versions of this review. 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 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. For the primary outcomes we included these studies and if there was no substantive difference when we added the implied randomised studies to those with better description of randomisation, we then employed all data from these studies.

2. Assumptions for lost binary data

Where assumptions had to be made regarding people lost to follow-up (see Dealing with missing data), we compared the findings of the primary outcomes where we used our assumption and compared with completer data only. If there was a substantial difference, we reported results and discussed them, but continue to employ our assumption.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of ongoing 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 (Tosh 2010).

The 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 are ongoing. The numbers of reports and studies inspected for this review is illustrated in Figure 2.

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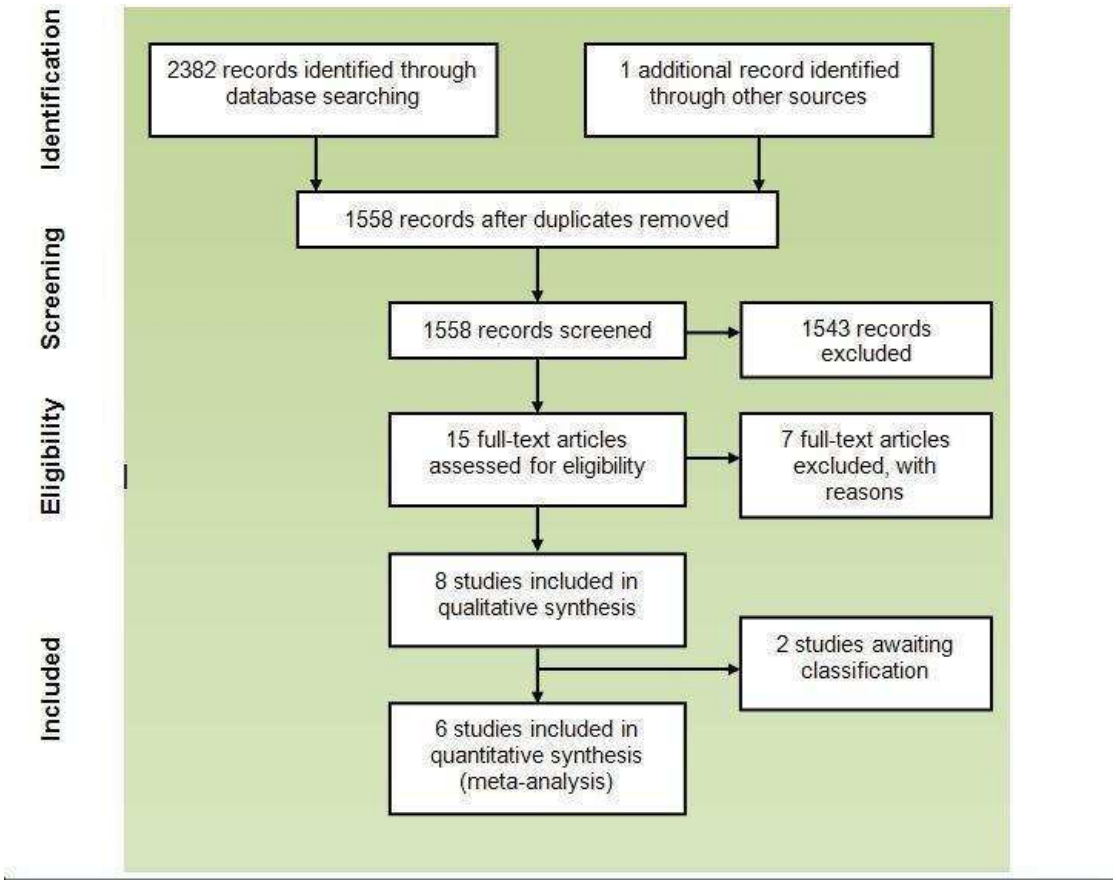
Figure 2. PRISMA search flow diagram



Included studies

For details of included studies please see Characteristics of included studies. The six included studies randomised 1033 people. No study was double blind although Brown 2006 and Brown 2009 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 the short-term category with a duration of 6-10 weeks. The remaining four were in the long-term category and had a duration of 12-18 months. There were no immediate or medium-term studies.

2. Setting

Brown 2006 and Brown 2009 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 (version 10) (WHO 2007). Byrne 1999 asked participants to self report what type of mental health problems they had, while Chafetz 2008 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

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2009 (n = 26). 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 which 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, while 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; 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. Druss 2010 described 'usual care' in which participants were given a list with contact information for local primary care medical clinics, that 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 finally 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 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 $\geq$ 6.1 mmol/l, ii) blood pressure $\geq$130/85 mmHg or treatment for this, iii) triglycerides $\geq$1.7 mmol/l, iv) high-density lipoprotein (HDL) men >1.0 mmol/l or female >1.3 mmol/l, and v) waist men >102cm or female >88cm. A decrease in the number of people with metabolic syndrome was the desired outcome (low = good).

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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: 1 is 'terrible' and 7 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 0 (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 subject. 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 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.

1. Awaiting assessment

At present we do not have any studies awaiting assessment.

2. Ongoing studies

Two studies are ongoing. For further details please see Characteristics of ongoing studies. Both of these ongoing studies, Danavall 2007 and NCT00137267, have similar characteristics in relation to size, interventions and outcomes to the included studies. Given the relatively small projected sample size in each study (n = 111 and n = 170 respectively) and considering the potential-drop out rates we do not anticipate that data from these studies 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.

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 one using a

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"computerised algorithm" (Druss 2010). We have no further details regarding these last two studies. The final trial 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 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. 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). 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

Five studies provided data for the comparison physical health advice versus standard care.

1.1 Quality of life

This outcome (Analysis 1.1) was reported by Byrne 1999 and Druss 2010 using different scales, which means we cam only compare them individually. Byrne 1999 (using the Lehman scale) reported no significant difference in quality of life (n = 54, 1 RCT, MD 0.00 CI -0.67 to 0.67). Druss 2010 reported separately on the mental and physical components of the Quality of Life Medical Outcomes Study and said that at 12-month follow-up the intervention group had a "significantly higher" score than controls on the mental component summary score (n = 407, 1 RCT, MD 3.7 CI 1.7 to 5.6) and a "nearly significant" difference in the physical component summary score (n = 407, 1 RCT, MD 2.4 CI 0.1 to 4.7).

1.2 Adverse effects: death

Druss 2010 reported seven deaths with "no significant difference" between treatment and control groups (n = 407, 1 RCT, RR 1.3 CI 0.3 to 6.0, Analysis 1.2).

1.3 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 36.9 CI 33.1 to 40.7, Analysis 1.3).

1.4 Economic

Byrne 1999 reported no significant difference between groups for general health service expenses. These are, however, skewed and we report them in a table (Analysis 1.4).

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1.5 Leaving early

Five studies reported on participants leaving early for a variety of reasons; none identified any significant difference between experimental and control groups (Analysis 1.5).

1.5.1 Any reason

Five of our six included studies provided data for the outcome of leaving the study early for any reason (n = 884, 5 RCTs, RR 1.18 CI 0.97 to 1.43). 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 1.8 CI 0.6 to 5.6). Chafetz 2008 reported 35.6% of participants leaving early (n = 309, 1 RCT, RR 1.8 CI 1.1 to 2.8) 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. Druss 2010 only commented on "loss to follow up" (30.5%, n = 407, 1 RCT, RR 0.89 CI 0.6 to 1.4). Byrne 1999 saw 31.6 % of participants leaving early but did not comment on the reasons for leaving (n = 214, 1 RCT, RR 1.38 CI 0.73 to 2.63).

1.5.2 Lost to follow up

Brown 2009, Chafetz 2008 and Druss 2010 all reported on loss to follow-up (n = 744, 3 RCTs, RR 1.04 CI 0.84 to 1.28).

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 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 = 29, 1 RCT, MD 2.10 CI 0.19 to 4.01).

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

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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.

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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 prestated 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 prestated 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	

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	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)

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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	

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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 six studies with a total number of 1044 participants. Only comparison number 1 included more than one study. Across the five studies which presented data for leaving early, the attrition rate was 33%. Some studies had significant potential for influence from industry (Brown 2006; Brown 2009; Druss 2010). Much data were reported in such a way as to make comparative analysis impossible. We were unable to report on 15 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 (5 RCTs, n = 884). There was, however, an attrition of 33% (Summary of findings for the main comparison).

1.1 Quality of life

Only two studies provided data for this important outcome and they both used different rating scales, making interpretation difficult. Byrne 1999 reported no significance difference in quality of life, while Druss 2010 reported separately on the mental and physical components of quality of life and said that, at 12-month 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.

1.2 Adverse effects: death

Only one study reported on adverse effects with no significant difference reported for this outcome (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.

1.3 Service use

A single study comparing medical care management versus standard care 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 (Druss 2010). 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 from a single study and should be interpreted with caution, but do seem encouraging.

1.4 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).

1.5 Leaving early

Five of the six studies reported on 'leaving the study early' 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

This trial 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

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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 six 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. The remaining two studies presented short-term data, a duration of 6-10 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, 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 three studies. Brown 2009 used a "hidden computer-generated random number programme", 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 (November 2009) 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.

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AUTHORS' CONCLUSIONS

Implications for practice

1. For people with serious mental illness

There is some limited and poor quality evidence that the provision of 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 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. 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.

2. Specific

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).

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.

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Table 2. Suggested design for future study (*Continued*)

	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.

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* *Indicates the major publication for the study*

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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
Adequate sequence generation?	Unclear risk	"Randomised" - no further details.
Allocation concealment?	Unclear risk	No details.
Blinding? All outcomes	High risk	Not blinded but "... attempted to maintain rater blindness but in many cases this was not possible".

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Brown 2006 (*Continued*)

Incomplete outcome data addressed? 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.
Free of selective reporting?	Low risk	Four rating scales were listed in the methods, all four reported.
Free of 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.

Risk of bias

Bias	Authors' judgement	Support for judgement

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Brown 2009 (*Continued*)

Adequate sequence generation?	Unclear risk	"Randomised, using a hidden computer-generated random number programme" - no further details.
Allocation concealment?	Unclear risk	No details.
Blinding? 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 addressed? 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.
Free of selective reporting?	Low risk	Four rating scales were listed in the methods, all four reported.
Free of 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).
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

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Byrne 1999 (*Continued*)

	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
Adequate sequence generation?	Unclear risk	"The homes in each strata were then randomly assigned to one of the three study groups" - no further details.
Allocation concealment?	Unclear risk	No details.
Blinding? All outcomes	High risk	No blinding.
Incomplete outcome data addressed? 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".
Free of selective reporting?	Low risk	Three rating scales were listed in the methods, all three reported.
Free of 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.

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	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**
Adequate sequence generation?	Unclear risk	"Randomisation" - no further details.
Allocation concealment?	Unclear risk	No details.
Blinding? 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 addressed? 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.
Free of selective reporting?	Low risk	Three rating scales were listed in the methods, all three reported.
Free of other bias?	Unclear risk	Supported by the National Institute of Nursing Research

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Druss 2010

Methods	Allocation: random. Blinding: interviewers blinded to subjects' 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.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	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?	Unclear risk	Allocation "by the project group manager" - no further details.
Blinding? All outcomes	Unclear risk	"Interviewers were blinded to subjects' randomisation status" - no further details.

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Druss 2010 (*Continued*)

Incomplete outcome data addressed? 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.
Free of selective reporting?	Low risk	Four rating scales were listed in the methods, all four reported.
Free of 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

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Forsberg 2008 (*Continued*)

	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**
Adequate sequence generation?	Unclear risk	"Randomisation was conducted on group level by the drawing of lots" - no further details.
Allocation concealment?	Low risk	Allocation "by a person not involved in the project".
Blinding? All outcomes	Unclear risk	No details.
Incomplete outcome data addressed? 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.
Free of selective reporting?	Unclear risk	Five rating scales were listed in the methods, all five reported. Leaving the study early - not reported by group. Study reported as if not clustered - no intraclass correlation coefficient.
Free of 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".

SD: standard deviation

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

Study	Reason for exclusion
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 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. Focusing 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. Focusing on mental health rather than general physical health.
Li 2005	Allocation: unclear - people "divided" into groups. Participants: Outpatients with schizophrenia Intervention: health education vs standard care, does not focus on general physical health.
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

RCT: randomised controlled trial
vs: versus

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

Danavall 2007

Trial name or title	Medical self-management for improving health behavior among individuals in community mental health settings.
Methods	Allocation: randomised. Blinding: open label. Duration: 6 weeks.

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Danavall 2007 (*Continued*)

Participants	Diagnosis: people who are receiving care at a community mental health centre and who suffer from chronic mental illness. N = 111 (estimated enrolment). Sex: both. Age: 18 and older.
Interventions	1. Peer-led medical illness self-management group sessions. 2. Standard care.
Outcomes	Behavioral self-efficacy: measured at months 6 and 12. Patient activation. Health behaviours, including exercise, physical activity, and smoking. Health service use. Health-related quality of life: measured at months 6 and 12. Body mass index (BMI).
Starting date	26/08/2008
Contact information	Linda Danavall * - ldanava@sph.emory.edu
Notes	* We have emailed project lead for further details.

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.

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NCT00137267 (*Continued*)

Starting date	06/08/2007
Contact information	Selvija Gjonbalaj-Marovic * - selvija.gjonbalaj-marovic@va.gov
Notes	* We have emailed project lead for further details.

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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 Quality of life: average scores - various scales	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 global score (Lehman Quality of Life Scale, high = good)	1	54	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.47, 0.87]
1.2 mental component score (Medical Outcomes Study 36-Item Short-Form Health Survey, high = good)	1	407	Mean Difference (IV, Fixed, 95% CI)	3.70 [1.76, 5.64]
1.3 physical component score (Medical Outcomes Study 36-Item Short-Form Health Survey, high = good)	1	407	Mean Difference (IV, Fixed, 95% CI)	2.40 [0.13, 4.67]
2 Adverse effects: death	1	407	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.30, 5.80]
3 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]
4 Economic: total value of health resource consumption (dollars, low = good, skewed data)			Other data	No numeric data
5 Leaving the study early	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 any reason	5	884	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.97, 1.43]
5.2 lost to follow-up	3	742	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.84, 1.28]
5.3 withdrawn	1	407	Risk Ratio (M-H, Fixed, 95% CI)	6.90 [0.86, 55.56]
5.4 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]

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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
1.1 average steps per day			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 ten 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

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Analysis 1.1. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 1 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: 1 Quality of life: average scores - various scales

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	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)		100.0 %	0.20 [-0.47, 0.87]
Subtotal (95% CI)	**26**		**28**			**100.0 %**	**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)							
Druss 2010	205	39.3 (9.9)	202	35.6 (10.1)		100.0 %	3.70 [1.76, 5.64]
Subtotal (95% CI)	**205**		**202**			**100.0 %**	**3.70 [1.76, 5.64]**
Heterogeneity: not applicable							
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)							
Druss 2010	205	37.1 (11.5)	202	34.7 (11.9)		100.0 %	2.40 [0.13, 4.67]
Subtotal (95% CI)	**205**		**202**			**100.0 %**	**2.40 [0.13, 4.67]**
Heterogeneity: not applicable							
Test for overall effect: Z = 2.07 (P = 0.039)							
Test for subgroup differences: Chi^2 = 13.45, df = 2 (P = 0.00), I^2 =85%							

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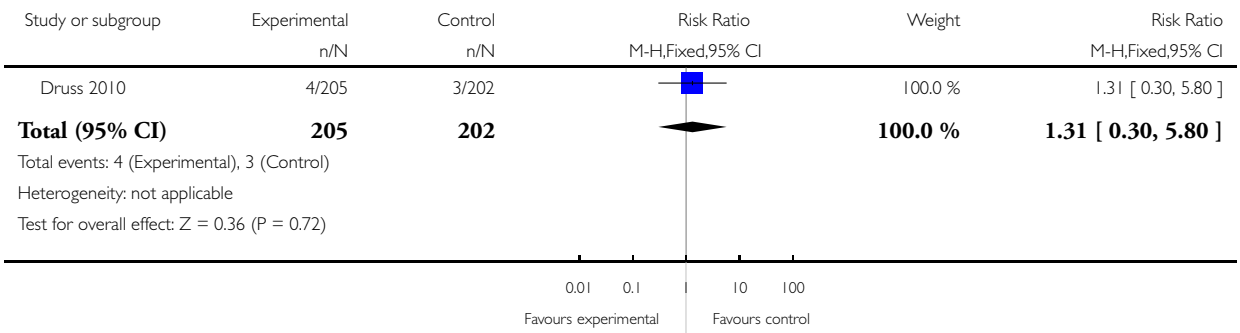
Analysis 1.2. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 2 Adverse effects: death.

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

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 2 Adverse effects: death

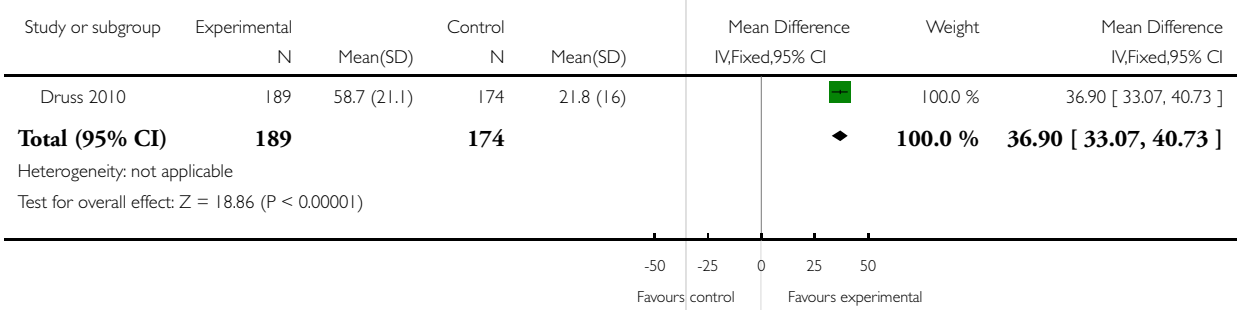


Analysis 1.3. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 3 Service use: average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high = good).

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

Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE

Outcome: 3 Service use: average percentage uptake of recommended health preventative services (US Preventative Services Task Force guidelines, high = good)



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Analysis 1.4. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 4 Economic: total value of health resource consumption (dollars, low = good, skewed data).

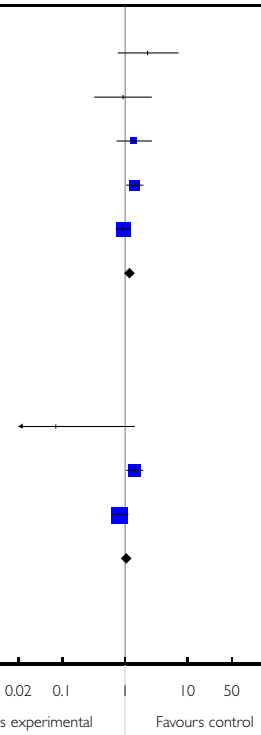
Economic: total value of health resource consumption (dollars, low = good, skewed data)

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 1.5. Comparison 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE, Outcome 5 Leaving the study early.

Review: General physical health advice for people with serious mental illness
Comparison: 1 PHYSICAL HEALTH ADVICE versus STANDARD CARE
Outcome: 5 Leaving the study early

Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
1 any reason					
Brown 2006	8/15	3/13		2.5 %	2.31 [0.77, 6.94]
Brown 2009	5/15	4/11		3.6 %	0.92 [0.32, 2.65]
Byrne 1999	27/78	9/36		9.5 %	1.38 [0.73, 2.63]
Chafetz 2008	65/155	45/154		34.8 %	1.44 [1.05, 1.95]
Druss 2010	60/205	64/202		49.7 %	0.92 [0.69, 1.24]
Subtotal (95% CI)	**468**	**416**		**100.0 %**	**1.18 [0.97, 1.43]**
Total events: 165 (Experimental), 125 (Control)					
Heterogeneity: Chi^2 = 6.11, df = 4 (P = 0.19); I^2 =35%					
Test for overall effect: Z = 1.67 (P = 0.095)					
2 lost to follow-up					
Brown 2009	0/15	4/11		4.5 %	0.08 [0.00, 1.40]
Chafetz 2008	65/155	45/154		39.7 %	1.44 [1.05, 1.95]
Druss 2010	53/205	63/202		55.8 %	0.83 [0.61, 1.13]
Subtotal (95% CI)	**375**	**367**		**100.0 %**	**1.04 [0.84, 1.28]**
Total events: 118 (Experimental), 112 (Control)					
Heterogeneity: Chi^2 = 9.36, df = 2 (P = 0.01); I^2 =79%					



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Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Test for overall effect: Z = 0.32 (P = 0.75)					
3 withdrawn					
Druss 2010	7/205	1/202		100.0 %	6.90 [0.86, 55.56]
Subtotal (95% CI)	**205**	**202**		**100.0 %**	**6.90 [0.86, 55.56]**
Total events: 7 (Experimental), 1 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.81 (P = 0.070)					
4 discontinued					
Brown 2009	5/15	0/11		100.0 %	8.25 [0.50, 135.21]
Subtotal (95% CI)	**15**	**11**		**100.0 %**	**8.25 [0.50, 135.21]**
Total events: 5 (Experimental), 0 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.48 (P = 0.14)					

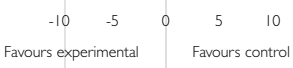
Analysis 2.1. Comparison 2 HEALTH EDUCATION versus HEALTH EMPOWERMENT EDUCATION, Outcome 1 Quality of life: average global score (Lehman Quality of Life scale, high = good).

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)

Study or subgroup	Education N	Mean(SD)	Empowerment N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Byrne 1999	26	4.4 (1.2)	25	4.7 (1.3)		100.0 %	-0.30 [-0.99, 0.39]
Total (95% CI)	**26**		**25**			**100.0 %**	**-0.30 [-0.99, 0.39]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.86 (P = 0.39)							



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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).

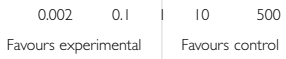
Economic: total value of health resource consumption (dollars, low = good, skewed data)

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

Study or subgroup	Education n/N	Empowerment n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Byrne 1999	8/41	13/37		100.0 %	0.56 [0.26, 1.19]
Total (95% CI)	**41**	**37**		**100.0 %**	**0.56 [0.26, 1.19]**
Total events: 8 (Education), 13 (Empowerment)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.52 (P = 0.13)					



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
average steps per day					
Forsberg 2008	Healthy living study circle	5586	3313	9	Clustered data - but analysed as non-clustered in report.

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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

Study or subgroup	Intervention study circle n/N	Aesthetic study circle n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Forsberg 2008	4/8	2/5		100.0 %	1.25 [0.35, 4.49]
Total (95% CI)	**8**	**5**		**100.0 %**	**1.25 [0.35, 4.49]**
Total events: 4 (Intervention study circle), 2 (Aesthetic study circle)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.34 (P = 0.73)					

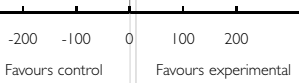
Analysis 3.3. Comparison 3 HEALTHY LIVING STUDY CIRCLE versus AESTHETIC STUDY CIRCLE, Outcome 3 Physical health: 2. Average score for working capacity - various tests.

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

Study or subgroup	Experimental N	Mean(SD)	Control N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
1 shuttle test - lengths of ten metres walked (Incremental shuttle walk test, high = good)							
Forsberg 2008	16	493 (182)	14	650 (263)		100.0 %	-157.00 [-321.11, 7.11]
Subtotal (95% CI)	**16**		**14**			**100.0 %**	**-157.00 [-321.11, 7.11]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.88 (P = 0.061)							
2 Borg test (RPE - rate of perceived exertion test, high = good)							
Forsberg 2008	13	15.7 (2)	12	13.6 (3.1)		100.0 %	2.10 [0.04, 4.16]
Subtotal (95% CI)	**13**		**12**			**100.0 %**	**2.10 [0.04, 4.16]**
Heterogeneity: not applicable							
Test for overall effect: Z = 1.99 (P = 0.046)							
Test for subgroup differences: Chi^2 = 3.61, df = 1 (P = 0.06), I^2 =72%							



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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.

HISTORY

Protocol first published: Issue 7, 2010

Review first published: Issue 2, 2011

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.

Shereen Mala - co-reviewer, screened results of electronic search.

Mick Bachner - co-reviewer, screened results of electronic search.

DECLARATIONS OF INTEREST

None known.

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Internal sources

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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.

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

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