Physical health care monitoring for people with serious mental illness (Review)

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This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2013, Issue 2

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[Intervention Review]

Physical health care monitoring for people with serious mental illness

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Editorial group: Cochrane Schizophrenia Group.
Publication status and date: Edited (no change to conclusions), published in Issue 2, 2013.
Review content assessed as up-to-date: 18 January 2010.

Citation: Tosh G, Clifton A, Mala S, Bachner M. Physical health care monitoring for people with serious mental illness. *Cochrane Database of Systematic Reviews* 2010, Issue 3. Art. No.: CD008298. DOI: 10.1002/14651858.CD008298.pub2.

ABSTRACT

Background

Current guidance suggests that we should monitor the physical health of people with serious mental illness and there has been a significant financial investment over recent years to provide this.

Objectives

To assess the effectiveness of physical health monitoring as a means of reducing morbidity, mortality and reduction in quality of life in people with serious mental illness.

Search methods

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

We updated this search October 2012 and added 61 new trials to the awaiting assessment section.

Selection criteria

All randomised or quasi-randomised clinical trials focusing on physical health monitoring versus standard care or comparing i) self monitoring vs monitoring by health care professional; ii) simple vs complex monitoring; iii) specific vs non-specific checks iv) once only vs regular checks or v) comparison of different guidance.

Data collection and analysis

The authors (GT, AC, SM) independently screened search results and identified three studies as possibly fulfilling the review's criteria. On examination, however, all three were subsequently excluded.

Main results

We did not identify any randomised trials which assessed the effectiveness of physical health monitoring in people with serious mental illness.

Authors' conclusions

There is no evidence from randomised trials to support current guidance and practice. Guidance and practice are based on expert consensus, clinical experience and good intentions rather than high quality evidence.

Note: the 61 citations in the awaiting classification section of the review may alter the conclusions of the review once assessed.

PLAIN LANGUAGE SUMMARY

Physical health care monitoring for people with serious mental illness

In recent years there has been an increasing focus on the physical health of people who suffer from mental illness, it has been recognised that these individuals are at greater risk of physical health problems for a variety of reasons. There are now a number of different guidelines telling us how we should monitor physical health in this population. We searched for randomised trials that looked at the effectiveness of physical health monitoring in preventing deterioration of physical health and maintaining quality of life. Despite the amount of guidance available we found no relevant studies. Consequently there is no evidence from randomised controlled trials that physical health monitoring in people with severe mental illness is useful in preventing deterioration in physical health and maintaining quality of life. This, however, does not mean that physical health monitoring does not affect the physical health of people with severe mental illness.

BACKGROUND

Description of the condition

The definition of severe 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). As a consequence of their illness people with serious mental illness have a significantly reduced life expectancy for a variety of reasons including: poor self care, adverse health behaviours (smoking, sedentary lifestyle) and negative effects from psychotropic medication (weight gain, metabolic syndrome) (Robson 2007). In schizophrenia, for example, life expectancy is reduced by around ten years (Newman 1991). A recent publication has shown that people with schizophrenia have a threefold increase in mortality compared with the general population of England and Wales, and that approximately 81% of that increase is from natural causes, especially cardiovascular disease (Brown 2010). There is historical evidence that sufferers from serious mental illness also have increased rates of infectious diseases (including HIV) (Cournos 2005), non-insulin dependent diabetes, respiratory disease and cancer (Dixon 1999, Robson 2007). Despite this, evidence says that there exists a lack of physical health monitoring in people with serious mental illness in both the primary care (Burns 1998) and in the secondary care setting (Paton 2004).

Description of the intervention

Physical health monitoring can take many forms, and these forms are highly divergent and dependent on environmental and socioeconomic factors. In some instances monitoring is indicated for a specific group of people because of demographic risk factors; one such population are those suffering from serious mental illness (Robson 2007). People with illnesses such as schizophrenia are at greater risk for a number of conditions. This is compounded by the fact that they are less likely to seek medical advice and more likely to be exposed to medications with potentially negative health consequences (Weinmann 2009). People with serious mental illnesses should stand to benefit greatly from a programme of well organised and regular physical health monitoring.

Monitoring differs from promotion in that its principle aim is to obtain information which can then be acted on to treat or prevent a physical health problem. Promotion, on the other hand, is the provision of information and encouragement to people in the hope that they will act to avoid deterioration of current health or development of future health problems. The effects of physical health promotion/advice for people with serious mental illness is evaluated in another future review in this series: Physical health

advice for people with serious mental illness.

Past reviewers have suggested that *"essential routine health monitoring* [for people with serious mental illness] *should include weight, body mass index (BMI) and waist circumference, blood pressure, lipid profiles, screening for insulin resistance and diabetes, dental checks and eye health checks"* (Robson 2007). Physical health care monitoring could, therefore, range from the simplest forms of self-monitoring, through to more systematised self-screening, to well-regulated and guideline-directed monitoring of health by health care professionals.

How the intervention might work

Information obtained from physical health monitoring is often the catalyst for more intensive medical input which can be either curative, palliative or preventative. The routine employment of simple and relatively inexpensive physical health monitoring has the potential to identify current, and pre-empt future, health problems. Subsequent action 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 and 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

In August 2006 the UK's Department of Heath published a commissioning framework (DoH 2006) which, based on examples of current practice (including pilot programmes and expert advice), was intended to provide best practice guidance on the physical health needs of people with severe mental illness. In conjunction with this publication there has been significant investment in 88 English Primary Care Trusts known as 'Spearhead' Trusts to implement the services it suggested. In addition, a raft of guidance around physical heath monitoring in psychiatry has arisen over recent years from organisations such as the Royal College of Psychiatrists (RCPsych 2009; RCPsych 2009a), the National Institute for Clinical Excellence (NICE 2006), Maudsley Prescribing Guidelines (Taylor 2009) and the Serious Mental Illness Physical Health Improvement Profile (White 2009). At no point does the current commissioning framework or guidance documents refer to evidence from randomised control trials or previous reviews. This pathway of identifying a problem, consultation, creation of guidelines and investment to implement the guidance would appear to make good sense. We feel that, at this point, it would be good to assess available evidence of the effects of physical health monitoring.

OBJECTIVES

1. Primary objective

To investigate the effects of the implementation of specific physical healthcare monitoring compared with standard care in a population suffering from severe mental illness.

2. Secondary objective

To compare types and techniques of monitoring.

METHODS

Criteria for considering studies for this review

Types of studies

We considered all relevant randomised controlled trials, and economic evaluations conducted alongside included randomised controlled trials. 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 a sensitivity analysis was undertaken to the presence or absence of these data.

Types of participants

We required that a majority of participants should be within the age range 18 to 65 years and suffering from severe mental disorder preferably as defined by National Institute of Mental Health (NIMH 1987) but in the absence of that, from diagnosed illness 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. Physical health care monitoring

1.1 General physical health care monitoring in addition to standard care: monitoring can be any means of observation, supervision, keeping under review or measuring or testing at intervals. We defined 'physical health' as 'soundness of body' as opposed to the world health organisation's definition of 'health' which includes mental and social well being (WHO 1948).

1.2 Focused physical health care monitoring: adherent to specific guidance e.g. as a result of an identified illness (blood sugar in diabetes) or as a result of pharmacological treatment (weight gain with atypical antipsychotic), in addition to standard care.
2. Standard care
Care in which physical health monitoring is not specifically emphasised above and beyond care that would be expected for people not suffering from severe mental illness.
3. Variations in delivery
We feel that there may be important studies comparing different types of monitoring delivered in several ways. We are interested in these studies and will endeavour to include them in a relevant comparison.
3.1 Differences in who undertakes the monitoring - self monitoring vs monitoring by health care professional.
3.2 Differences in complexity of monitoring - simple routine check/test vs complex check/test.
3.3 Differences in focus of checks - specific health check vs non-specific health check.
3.4 Differences in pattern of checking - once only checks vs regular checks.
3.5 Differences in guidance followed - one set of guidelines vs another.

Types of outcome measures

For the purposes of this review outcomes 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 - immediate
1.1 Failure to identify a disease state and provide appropriate treatment
1.2 Failure to effectively manage a known disease state
1.3 Failure to act on known risk factors
1.4 Unchecked adverse effects of treatment
2. Quality of life
2.1 Loss of independence
2.2 Loss of Activities of Daily Living (ADL) skills
2.3 Chronic pain
2.4 Immobility
2.5 Loss of earnings
2.6 Loss of social status
2.7 Healthy days

Secondary outcomes

1. Physical health - periods other than immediate
1.1 Failure to identify a disease state and provide appropriate treatment
1.2 Failure to improve management of a known disease state
1.3 Failure to act on known risk factors
1.4 Unchecked side-effects of treatment
2. Adverse event
2.1 Number of participants with at least one adverse effect.
2.2 Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count)
2.3 Average endpoint in specific adverse effects
2.4 Average change in specific adverse effects
2.5 Death - natural or suicide
3. Service use
3.1 Hospital admission
3.2 Emergency medical treatment
3.3 Use of emergency services
4. Financial dependency
4.1 Claiming unemployment benefit
4.2 Claiming financial assistance because of a physical disability
5. Social
5.1 Unemployment
5.2 Social Isolation as a result of preventable incapacity
5.3 Increased burden to caregivers
6. Quality of life/satisfaction with treatment
6.1 No clinically important change in general quality of life
6.2 Average endpoint general quality of life score
6.3 Average change in general quality of life score
6.4 No clinically important change in general functioning
6.5 Average endpoint general functioning score
6.6 Average change in general functioning score
7. Economic
7.1 Increased costs of health care
7.2 Days off sick from work
7.3 Reduced contribution to society
7.4 Family claiming carers' allowance
8. Leaving the studies early (any reason, adverse events, inefficacy of treatment)
9. Global state
9.1 No clinically important change in global state (as defined by individual studies)
9.2 Relapse (as defined by the individual studies)

10. Mental state (with particular reference to the positive and negative symptoms of schizophrenia)
10.1 No clinically important change in general mental state score
10.2 Average endpoint general mental score
10.3 Average change in general mental state score
10.4 No clinically important change in specific symptoms (positive symptoms of schizophrenia, negative symptoms of schizophrenia)
10.5 Average endpoint specific symptom score
10.6 Average change in specific symptom score

Search methods for identification of studies

Electronic searches

1. Cochrane Schizophrenia Group Trials Register (October 2009)
The register was searched using the phrase:[(*physical* or *cardio* or *metabolic* or *weight* or *HIV* or *AIDS* or *Tobacc* or *Smok* or *sex* or *medical* or *dental* or *alcohol* or *oral* or *vision* or *sight*or *hearing* or *nutrition* or *advice* or *monitor* in title of REFERENCES) AND (*education* OR *health promot* OR *preventi* OR *motivate* or *advice* or *monitor* in interventions of STUDY)]
The Cochrane Schizophrenia Group's Trials Register is compiled by systematic searches of major databases, handsearches of relevant journals and conference proceedings (see Group Module). Incoming trials are assigned to relevant existing or new review titles.
2. The Trials Search Co-ordinator, Samantha Roberts, searched the Cochrane Schizophrenia Group Trials Register register (October 2012) using the phrase:
[(*physical* or *cardio* or *metabolic* or *weight* or *HIV* or *AIDS* or *Tobacc* or *Smok* or *sex* or *medical* or *dental* or *alcohol* or *oral* or *vision* or *sight*or *hearing* or *nutrition* or *advice* or *monitor* in title of REFERENCES) AND (*education* OR *health promot* OR *preventi* OR *motivate* or *advice* or *monitor* in interventions of STUDY)]
The Cochrane Schizophrenia Group's Trials Register is compiled by systematic searches of major databases, handsearches of relevant journals and conference proceedings (see Group Module). Incoming trials are assigned to relevant existing or new review titles.

Searching other resources

1.Unsystematic Search
We undertook unsystematic searches of a sample of the component databases (BNI, CINHAL, EMBASE, MEDLINE and PsychINFO) to determine if any material may have been overlooked. We searched using specific phrases ('physical health', 'monitoring' and 'mental illness') as the searches that create the Cochrane Schizophrenia Group's register of trials are methodology specific. We did not identify any relevant trials.
2. Reference Searching
We inspected the references of all identified studies for other relevant studies.
3. Personal Contact
We contacted the first author of each included for information regarding unpublished trials.

Data collection and analysis

Selection of studies

Authors GT, AC and SM screened the results of the electronic search. MB inspected a random sample of these results, comprising 10% of the total. The principal reviewer GT and co-reviewer 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. Where difficulties or disputes arose, we asked author MB for help and if it was impossible to decide, these studies were added to those awaiting assessment and the authors of the papers contacted for clarification.

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. With remaining problems MB helped clarify issues and we documented our final decisions. We extracted data presented only in graphs and figures whenever possible, we only included it 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. Scale-derived data
We included continuous data from rating scales only if:
a. the psychometric properties of the measuring instrument had been described in a peer-reviewed journal (Marshall 2000); and
b. the measuring instrument was not written or modified by one of the trialists for that particular trial; and
c. the measuring instrument is either i. a self-report or ii. completed by an independent rater or relative (not the therapist).
4. Endpoint versus change data
We preferred to use scale endpoint data, which typically cannot have negative values and is 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 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, efforts were made 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 physical health monitoring.
9. Summary of findings table
We anticipate including the following outcomes in a summary of finding table.
1. Physical health - immediate
1.1 Failure to identify a disease state and provide appropriate treatment
1.2 Failure to effectively manage a known disease state
2. Quality of life
2.1 Loss of Activities of Daily Living (ADL) skills
3. Adverse event
3.1 Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count)
3.2 Death - natural or suicide
4. Economic
4.1 Increased costs of health care
5. Social
5.1 Social Isolation as a result of preventable incapacity

Assessment of risk of bias in included studies

Again working independently, GT,AC and MB assessed risk of bias using the tool described in the Cochrane Collaboration Handbook (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 would have excluded studies where allocation was clearly not concealed.
We did not include trials with high risk of bias (defined as at least 3 out of 5 domains were categorised as 'No') in the meta-analysis. If the raters disagreed, the final rating was made by consensus with the involvement of another member of the review group. Where inadequate details of randomisation and other characteristics of trials are provided, we contacted the authors of the studies in order to obtain further information. Non-concurrence in quality assessment was reported.

Measures of treatment effect

1. Binary data
For binary outcomes we calculated a standard estimation of the random-effect risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive (Boissel 1999) than odds ratios and that odds ratios tend to be interpreted as RR by clinicians (Deeks 2000). 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 fixed-effect mean difference 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, confidence intervals 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 it was assumed to be 0.1 (Ukoumunne 1999).

If cluster studies has been appropriately analysed taking into account intra class correlation co-efficient 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 carryover 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 severe 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 than 50% of data be unaccounted, 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 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. A sensitivity analysis was undertaken 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 confidence interval 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 (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, the mean standard deviation from other studies was used.

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 has 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 these will be fully discussed.

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 these will be fully discussed.

3. Statistical

3.1 Visual inspection
We visually inspected graphs to investigate the possibility of statistical heterogeneity.
3.2 Employing the I-squared statistic
Heterogeneity between studies was investigated by considering the I-squared 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. 'p' value from Chi^2 test, or a confidence interval for I^2).
I^2 estimate greater than or equal to 50% accompanied by a statistically significant Chi^2 statistic, was interpreted as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2008) and reasons for heterogeneity were explored. 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 (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 ten 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-effect model for analyses. We understand that there is no closed argument for preference for use of fixed or random-effect models. The random-effect method incorporates an assumption that different studies are estimating different, yet related, intervention effects. According to our hypothesis of an existing variation across studies, to be explored further in the meta-regression analysis despite being cautious that that random-effects methods does put added weight onto the smaller of the studies - we favoured using random-effect model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses
We anticipate no sub-group analyses.
2. Investigation of heterogeneity
2.1 Unanticipated heterogeneity
Should unanticipated clinical or methodological heterogeneity be obvious we will simply state hypotheses regarding these for future reviews or versions of this review. We do not anticipate undertaking analyses relating to these.
2.2 Anticipated heterogeneity
We are concerned that focused physical health care monitoring 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 are 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 excluded studies; Characteristics of studies awaiting classification.

Results of the search

The initial search of the Cochrane Schizophrenia Group's register of trials in 2009 was a combined search designed to identify studies which would be relevant to this review, and to another sister review on physical health advice for people with serious mental illness (Tosh 2010). The search identified 2382 references (from 1558 studies). After examining the reports, only three were suitable for further examination and all were excluded. Despite the fact that the Cochrane Schizophrenia Group's register of trials is compiled from large comprehensive and systematic searches for trials, we undertook unsystematic searches of a sample of the component databases (BNI, CINHAL, EMBASE, MEDLINE and PsychINFO) to determine if any material may have been overlooked. We searched using specific phrases ('physical health', 'monitoring' and 'mental illness') as the searches that create the Cochrane Schizophrenia Group's register of trials are methodology specific. We did not identify any further relevant trials.

Included studies

No studies met the criteria for this review.

Excluded studies

One trial was excluded, on the basis that it is an ongoing trial in the recruitment stage which is focusing on the monitoring of mental health parameters and not physical health (Jürgens 2008). Another was excluded as it monitored the effects of a pharmacological intervention on a physical health parameter (Lan 2007). The third exclusion was on the basis that the trial compared the effects of different ways of monitoring a specific anxiety symptom, and did not look at a physical health (Rostow 1980). For details please see Characteristics of excluded studies.

1. Awaiting assessment

Sixty one studies are awaiting assessment.

2. Ongoing studies

We are not aware of any ongoing studies.

Risk of bias in included studies

There were no studies that fulfilled the criteria for inclusion. We did not exclude any studies on the grounds of poor methodology.

Allocation

No studies met the criteria for this review.

Blinding

No studies met the criteria for this review.

Incomplete outcome data

No studies met the criteria for this review.

Selective reporting

No studies met the criteria for this review.

Other potential sources of bias

There were no studies that fulfilled the criteria for inclusion. We did not exclude any studies on the grounds of poor methodology.

Effects of interventions

Currently we know of no randomised studies describing the effects of monitoring physical health care of people with serious mental illnesses.

DISCUSSION

Summary of main results

1. No trial-based evidence

Current medical practice in the UK is led by guidance from bodies such as the National Institute of Clinical Excellence (NICE 2006) and The Maudsley Prescribing Guidelines (Taylor 2009) who predominantly base their guidance on little more than anecdotal evidence, consensus of opinion (Marder 2004) and good intentions. The association between schizophrenia and poor physical health is well established (Robson 2007) and, taken at face value, current guidance seems to make sense. Unfortunately history is littered with treatments and policies which 'seemed like a good idea at the time' but which, with the benefit of hindsight, were, at best, ineffective and, at worst, resulted in harm. Extreme examples of well-intentioned treatments could be trepanation for epilepsy (Adams 1856), ice-pick lobotomies for unruly children (El-Hai 2008), or radium water for high blood pressure (JAMA 1925). More contemporary and more subtle is the wide use of oil of evening primrose oil for many ailments when evidence for efficacy is poor (Bayles 2009). This could mean that hopes are raised inappropriately, and, perhaps other more effective treatments avoided. When it comes to mental health policy, the early legislation for the Care Programme Approach in the UK was well intentioned but ultimately imported a largely wasteful and ineffective package of care from the US (Marshall 1996, Marshall 1998) at a time when even those in the US had found it necessary to substantially evolve the approach into a more effective package (Assertive Outreach). In more recent times the evidence to support the view that specialist mental health services such as Dual Diagnosis Teams, Early Intervention or Assertive Outreach Teams are more beneficial than appropriately supported Community Mental Health Teams is not as strong as would have been originally thought (Ley 2000).

Care, and the time of people with serious mental illness is too costly to waste on ideas that are not of proven benefit. Vulnerable people with serious mental illness should surely expect that all aspects of their care has been subject to some degree of evaluation.

Overall completeness and applicability of evidence

No studies met the criteria for this review.

Quality of the evidence

The three studies we obtained for closer inspection were not excluded because of issues of quality. We were just unable to find any studies that were vaguely relevant, regardless of whether they were high or poor quality.

Potential biases in the review process

The search criteria both on the Cochrane Schizophrenia Group Trials Register (October 2009) and on our unsystematic search (see: Searching other resources) should have been robust enough to detect relevant studies. It is possible, however, 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 none were identified as possibly relevant to this review.

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. They too identified no trials of monitoring. We agree with Bradshaw 2005 that rigorous studies are needed.

AUTHORS' CONCLUSIONS

Implications for practice

1. For people with schizophrenia

Due to the lack of evidence for the current guidance based physical health monitoring it is important that people with schizophrenia expect clinicians to explain their intentions clearly. It would seem reasonable that people with schizophrenia are given the choice of whether they want to be monitored in this way or, whether they would want to add to the body of evidence, one way or another, by being part of a well designed trial from which outcomes relevant to their care would be derived.

2. For clinicians

Clinicians should be aware that current guidance on monitoring the physical health for people with serious mental illness is not supported by any evidence from randomised controlled trials. It would seem reasonable that this is explained to people with serious mental illness. It is possible clinicians are expending much effort, time and financial expenditure on monitoring the physical health of people with serious mental illnesses which is unnecessary, intrusive and costly. Clinicians should, therefore, take a much more critical view of current guidance and attempt to initiate or get involved with any studies which could provide an evidence-base for this practice.

3. For policy makers or managers

Current policies and guidelines are born out of good intentions and "the evidence for such interventions remains uncertain" (NICE 2006). This puts policy makers in a difficult position galvanising consensus rather than evidence. There remains an enduring concern that "L'enfer est plein de bonnes volontés ou désirs" [Hell is full of good intentions or wishes] (St. Bernard of Clairvaux 1150 quoted in Ammer 2003). Policy makers or managers should be better at recommending active research interest in this area.

4. Note: the 61 citations in the awaiting classification section of the review may alter the conclusions of the review once assessed.

Implications for research

1. General

We could not identify any randomised trials that assessed the effectiveness of physical health monitoring in people with serious mental illness which contradicted the view that current guidance and practice is based on good intentions and expert opinion. Basing care on solely evidence from trials is not realistic (Tanenbaum 2005 and Cooper 2003), however, many treatments or approaches that are not well-evaluated are given to people, when it is actually entirely possible to evaluate these approaches. Health care professionals may be doing far more good than they realise - or far more harm. As part of a duty of care, we argue, that 'what could be known, should be known'.

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 what we think to be a feasible design see Additional tables (Table 1).

ACKNOWLEDGEMENTS

Thanks to Professor Clive Adams, Lindsey Air and Samantha Roberts and the editorial team at the Nottingham University Cochrane Schizophrenia Group for their unwavering support in the writing of this review.

The Cochrane Schizophrenia Group Editorial Base in Nottingham produces and maintains standard text for use in the Methods sections of their reviews. We have used this text as the basis of what appears here and adapted it as required. Thanks also to Jun Xia who examined the Chinese language titles returned by our search.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
Jürgens 2008	Allocation: randomised. Participants: people diagnosed with schizophrenia. Intervention: genotype monitoring versus intense clinical monitoring, not focusing on physical health
Lan 2007	Allocation: randomised. Participants: people diagnosed with schizophrenia, schizoaffective disorder, or schizophreniform disorder. Intervention: monitoring of the effect of aripiprazole and aripiprazole plus haloperidol on prolactin levels, not focusing on physical health
Lan 2008	Allocation: randomised. Participants: people diagnosed with schizophrenia, schizoaffective disorder, or schizophreniform disorder. Intervention: monitoring of the effect of aripiprazole and aripiprazole plus risperidone on prolactin levels, not focusing on physical health
Rostow 1980	Allocation: randomised. Participants: people with "compulsive or persistent pacing", not necessarily having a diagnosis of serious mental illness

Characteristics of studies awaiting assessment *[ordered by study ID]*

AstraZeneca 2006

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Baptista 2010

Methods	
Participants	
Interventions	
Outcomes	

Baptista 2010 (*Continued*)

Notes	To be assessed.

Becker 2005

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Bobo 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Bushe 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Byerly 2010

Methods	
Participants	
Interventions	
Outcomes	

Byerly 2010 (*Continued*)

Notes	To be assessed.

Carmeli 2012

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

ChiCTR-TRC-12002273

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Cordes 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Fernandez 2010

Methods	
Participants	
Interventions	
Outcomes	

Fernandez 2010 (*Continued*)

Notes	To be assessed.

Henderson 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

IRCT201107187049N1

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

ISRCTN63382258

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Kent 2011

Methods	
Participants	
Interventions	
Outcomes	

Kent 2011 (*Continued*)

Notes	To be assessed.

Kluge 2012

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Krakowski 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Kreyenbuhl 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

L'Italien 2006

Methods	
Participants	
Interventions	
Outcomes	

Notes	To be assessed.

Lencz 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Lieberman 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Loza 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Miceli 2010

Methods	
Participants	
Interventions	
Outcomes	

Notes	To be assessed.

NCT00418171

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

NCT00484302

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

NCT01075295

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

NCT01368406

Methods	
Participants	
Interventions	
Outcomes	

NCT01368406 (*Continued*)

Notes	To be assessed.

NCT01567124

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

NCT01606436

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Newcomer 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Nicol 2011

Methods	
Participants	
Interventions	
Outcomes	

Nicol 2011 (*Continued*)

Notes	To be assessed.

Nielsen 2012

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Ozguven 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Peuskens 2007 b

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Saddichha 2011

Methods	
Participants	
Interventions	
Outcomes	

Saddichha 2011 (*Continued*)

Notes	To be assessed.

Scheewe 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Stroup 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Tanasiewicz 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

Tessier 2010

Methods	
Participants	
Interventions	
Outcomes	

Tessier 2010 (*Continued*)

Notes	To be assessed.

Tiwari 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

何淑芬 **2011**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

侯雪玲 **2009**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

冯亚芬 **2011**

Methods	
Participants	
Interventions	
Outcomes	

冯亚芬 **2011** (*Continued*)

Notes	To be assessed.

刘根 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

刘清连 **2009**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

张敏 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

张炀 **2009**

Methods	
Participants	
Interventions	

张炀 **2009** (*Continued*)

Outcomes	
Notes	To be assessed.

彭燕 **2009**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

徐清芝 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

方崇芳 **2011**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

李玉凤 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

李红 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

李萍 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

林素兰 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

温广妹 **2009**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

王宪琴 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

王继红 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

穆世铭 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

苏勉 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

苏爱东 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

蔡连秀 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

阚骁云 **2010**

Methods	
Participants	
Interventions	
Outcomes	
Notes	To be assessed.

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Suggested design of study

Methods	Allocation: randomised, clearly described. Blinding: single - particular to specific outcomes (see below). Duration: 6 months.
Participants	Diagnosis: schizophrenia, or any serious mental illness. N=450.* Age: any. Sex: both. History: any.
Interventions	1. General physical health care checklist (e.g. Physical Health Improvement Profile see White 2009): administered by Care Co-ordinator. N=150. 2. Specific aspect of physical health care checklist (e.g. BSDH 2000): administered by Care Co-ordinator. N=150. 3. Standard care: administered by Care Co-ordinator. N=150.
Outcomes	Death. Morbidity: serious/minor, categorised by type, rates of events - general or specific. Healthy days. Service use: visit to heath care practitioner. Acceptability of checklist. Compliance: with physical health care advice, including treatments. Adverse effects: any.
Notes	* For 20% difference between groups for a binary outcome to be highlighted with reasonable degree of confidence 150 people are needed per group

WHAT'S NEW

Last assessed as up-to-date: 18 January 2010.

Date	Event	Description
17 October 2012	Amended	Update search of Cochrane Schizophrenia Group's Trial Register (see Search methods for identification of studies), 61 studies added to awaiting classification.

HISTORY

Protocol first published: Issue 1, 2010

Review first published: Issue 3, 2010

Date	Event	Description
17 March 2010	Amended	Amendment of outcomes to be included in summary of findings table
17 March 2010	Amended	Previously combined studies split into separated studies and included in Excluded Studies section

CONTRIBUTIONS OF AUTHORS

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

Andrew Clifton - co-reviewer and liaison on discussion and results writing.

Shereen Mala - co-reviewer, liaison on protocol.

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

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- University of Nottingham, UK.

External sources

- National Institute for Health Research (CLAHRC), UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Subsequent to the publication of the protocol we identified that our search strategy may have excluded some relevant studies so we added the words 'advice' and 'monitor' in the title of references section and added *advice* and *monitor* to the interventions of study field.

The original search 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* in title of REFERENCES) AND (*education* OR *health promot* OR *preventi* OR *motivate* in interventions of STUDY)] yielded 2326 references whilst the new search 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)] yielded 2383 references.

INDEX TERMS

Medical Subject Headings (MeSH)

*Health Status; *Quality of Life; Disease Progression; Mental Disorders [*complications]

MeSH check words

Humans