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[Intervention Review]

Smoking cessation advice for people with serious mental illness

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ABSTRACT

Background

People with a serious mental illness are more likely to smoke more and to be more dependent smokers than the general population. This may be due to a wide range of factors that could include a common aetiology to both smoking and the illness, self medication, smoking to alleviate adverse effects of medications, boredom in the existing environment, or a combination of these factors. It is important to undertake this review to facilitate improvements in both the health and safety of people with serious mental illness who smoke, and to reduce the overall burden of costs (both financial and health) to the smoker and, eventually, to the taxpayer.

Objectives

To review the effects of smoking cessation advice for people with serious mental illness.

Search methods

We searched the Cochrane Schizophrenia Group Specialized Trials Register up to 2 April 2015, which is based on regular searches of CENTRAL, BIOSIS, PubMed, MEDLINE, EMBASE, CINAHL, PsycINFO, and trial registries. We also undertook unsystematic searches of a sample of the component databases (BNI, CINAHL, EMBASE, MEDLINE, and PsycINFO), up to 2 April 2015, and searched references of all identified studies

Selection criteria

We planned to include all randomised controlled trials (RCTs) that focussed on smoking cessation advice versus standard care or comparing smoking cessation advice with other more focussed methods of delivering care or information.

Data collection and analysis

The review authors (PK, AC, and DB) independently screened search results but did not identify any trials that fulfilled the inclusion criteria of this review.

Main results

We did not identify any RCTs that evaluated advice regarding smoking cessation for people with serious mental illness. The excluded studies illustrate that randomisation of packages of care relevant to smokers with serious mental illness is possible.

Authors' conclusions

People with serious mental illness are more likely to smoke than the general population. Yet we could not find any high quality evidence to guide the smoking cessation advice healthcare professionals pass onto service users. This is an area where trials are possible and needed.

PLAIN LANGUAGE SUMMARY**Specialised advice on stopping smoking for people with serious mental illness****Review question**

Does specialised advice about the benefits of stopping smoking work for people with a serious mental illness such as schizophrenia?

Background

People with serious mental health problems are more likely to smoke and to smoke more heavily than the general population. Around 60% to 70% of people with schizophrenia smoke, whereas around 20% of the general population smoke. People with mental illness may smoke more due to a range of factors. There may be a direct causal link between mental illness and smoking or it may be that smoking helps people deal with the stress of mental illness, or helps with the side effects of medication, such as tiredness, drowsiness, and boredom, or both. However, smoking is very bad for people's physical health in general and can lead to serious diseases such as cancer. The provision of specific advice from health professionals may help people with serious mental illness to stop smoking.

Study characteristics

The review authors searched for randomised controlled trials up to 2 April 2015 that investigated the effects of providing advice about the effects of smoking and the effects of stopping smoking to people with serious mental illness compared to no advice about stopping smoking. No trials that met the inclusion criteria of this review were found..

Key results

Currently there is no high quality evidence from randomised trials to guide healthcare professionals about how effective giving advice is to help people stop smoking. It is therefore unclear if advice has any effect on helping people with serious mental illness stop smoking.

Quality of the evidence

Good quality Evidence relevant to smokers with serious mental illness is much needed, important. It is possible if a large, high quality trial is undertaken and gathers relevant, high quality evidence on advice to help people stop smoking.

Ben Gray, Senior Peer Researcher, McPin Foundation (<http://mcpin.org/>).

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Smoking cessation advice versus standard care for people with serious mental illness

Smoking cessation advice versus standard care for people with serious mental illness

Patient or population: people with people with serious mental illness

Settings: anywhere

Intervention: smoking cessation advice

Comparison: standard care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	STANDARD CARE	SMOKING CESSATION ADVICE			
Raised awareness of common problems associated with smoking	No trials met the inclusion criteria and therefore no data for this series of important outcomes.				
Reduction in smoking					
Healthy days					
Clinically important adverse effect					
Economic outcome					

BACKGROUND**Description of the condition**

The National Institute of Mental Health's (NIMH) definition of severe mental illness has the widest consensus (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, which result in erosion of functioning in day-to-day life over a protracted period of time. A European survey estimated the total population-based annual prevalence of serious mental illness at approximately two per 1000 (Ruggeri 2000). People with serious mental illness have higher morbidity and mortality rates from chronic diseases than the general population, and this results in a significantly reduced life expectancy (Robson 2007). For example, people with schizophrenia have a shorter life

expectancy by around 10 years (Newman 1991). People with serious mental illness have increased rates of cardiovascular disease, infectious diseases (including human immunodeficiency virus (HIV)) (Cournos 2005), non-insulin dependent diabetes, respiratory disease, and cancer (Dixon 1999; Robson 2007). Evidence suggests that people with a serious mental illness are heavier, more dependent smokers than the general population. One study, for example, observed a very high smoking rate of 74% in people with schizophrenia (Meltzer 1996). It is likely that people with serious mental illness smoke more due to a wide range of factors which could include a common aetiology to both smoking and the illness, self medication, smoking to alleviate adverse effects of medications, boredom in the existing environment, and a combination of these factors. Smoking tobacco increases morbidity (Figure 1) and mortality (Figure 2).

Figure 1. AMA Family Medical Guide 2004: The risks of smoking.

Figure 2. [AMA Family Medical Guide 2004](#); Mortality risks from smoking.

Description of the intervention

Smoking cessation advice can take many forms. These are highly divergent and depend on environmental and socioeconomic factors. Advice is the active provision of preventive information. It has an educative component and is delivered in a gentle non-patronising manner ([Stott 1990](#)). Currently, much health promotion and advice exists. Smoking cessation advice can be defined as any verbal or intervention advice about the effects of smoking and smoking cessation from a healthcare professional.

How the intervention might work

Advice may motivate people to seek further support and treatment ([Sutherland 2003](#)). Advice from a healthcare professional can have a positive impact on behaviour ([Kreuter 2000](#); [Russell](#)

[1979](#)). Accordingly, the key to changing behaviour is that the recommended advice given by healthcare practitioners is consistent with the other sources of information encountered by people relating to their particular problem, for example on stopping smoking ([Kreuter 2000](#)). A variety of advice is available for smokers from healthcare professionals. Routine advice and support to stop smoking should be part of overall healthcare treatment for the general population and for people with serious mental illness. It is critical that health professionals who come into contact with smokers with serious mental illness routinely ask about smoking and advise their patients to stop. Following advice, many smokers with serious mental illness will need further support ([Health Development Agency 2004](#)). They should be referred to specialist smoking cessation advisors and key workers, psychiatrists or prescribers, and general physicians should be made aware. This is

to ensure that attempts at stopping smoking can be monitored and adjustments are made to psychotropic medications, as appropriate ([Health Development Agency 2004](#)).

Why it is important to do this review

Globally, tobacco continues to kill nearly six million people each year, including more than 600,000 non-smokers who die from exposure to tobacco smoke. Up to half of the world's one billion smokers will eventually die of a tobacco-related disease ([WHO 2011](#)). Smoking remains the leading cause of preventable morbidity and premature death in the UK. It is estimated that smoking caused an average of 86,500 deaths a year between 1998 and 2002 ([NICE 2006](#)). Smoking costs the NHS between GBP 1.4 and GBP 1.7 billion a year ([DoH 2004](#)) and tobacco consumption is recognised as the UK's single greatest cause of preventable illness and early death with around 107,000 people dying in 2006 from smoking-related diseases, including cancer ([Peto 2006](#)). Patients with mental health problems may be less likely to report or seek treatment for their physical symptoms, which often means that doctors may not conduct an appropriate physical assessment ([Phelan 2001](#)). Despite a high primary care consultation rate, people with serious mental illness are much less likely than the general population to be offered health promotion interventions, such as smoking cessation advice ([NHS 2011](#)). People with serious mental illness can spend a large proportion of their low income on smoking, thus depriving themselves of a better quality of life by not being able to spend their income on other things ([McDonald 2000](#)). [McCreadie 2000](#) estimated that there were at least 200,000 people with schizophrenia in the UK alone and, based on 60% of these people smoking an average of 26 cigarettes per day, this group

contributes GBP 139 million each year to the government treasury. This is considerably offset by outgoings on healthcare support. Interestingly, a small-scale study by Strathclyde Fire Brigade found that 12% of fires involving care in the community patients over a two-year period were due to careless dispersal of smoke materials ([Docherty 1999](#)). It is important that we undertake this review to facilitate improvements in both the health and safety of people with serious mental illness who smoke and to reduce the overall burden of costs to the smoker and to the taxpayer. This review is one of a series of related Cochrane reviews ([Table 1](#)).

OBJECTIVES

To review the effects of smoking cessation 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 any included RCTs. We excluded quasi-randomised studies, such as studies that allocated participants by using alternate days of the week. If we had encountered trials that suggested or implied the trial was randomised and where the demographic details of each group's participants were similar, we would have included them and conducted a sensitivity analysis to evaluate the effect of the presence or absence of these data. We have summarised the literature screening process in [Figure 3](#).

Figure 3. Study flow diagram for trial selection.

Types of participants

A requirement was that a majority of participants were within the age range 18 to 65 years and suffering from serious mental illness, 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. If the trials included participants with a range of serious mental illness we would have included them if the majority had schizophrenia, we would not have included trials that only randomised people with bipolar or serious affective disorders. We did not consider substance abuse to be serious mental illness in its own right, however those dealing with a dual diagnosis population i.e. those with serious mental illness plus substance abuse were eligible. We would not have included studies focusing on dementia, personality disorder and mental retardation, as these are not covered by our definition of serious mental illness. Despite the fact that personality disorder is now included in the NIMH 1987 definition we intended to exclude it from this review for the following reasons; the diagnosis of personality disorder has low interrater reliability (Zimmerman 1994); the duration of treatment can be assessed much more precisely than duration of illness (Schinnar 1990); there is insufficient information given on how to operationalise the disability criterion in both the original NIMH 1987 definition and in the further work of Schinnar 1990.

Types of interventions

1. Smoking cessation 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 (OED) that leaves the recipient to make the final decision. Advice may be directional but not paternalistic in its delivery. We do not consider that programmes of learning and educational or training groups fall into the definition of 'advice'. Advice should have at least a suggestion of: i. an educative component; ii. a preventative aim; and iii. an ethos of self-empowerment. We did not consider effects of training programmes as these are the focus of another Cochrane review (Tsoi 2013).

2. Standard care

Care in which smoking cessation advice is not specifically emphasised above and beyond the care that would be expected for people suffering from serious mental illness.

Types of outcome measures

For the purposes of this review we aimed to divide 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. Smoking cessation awareness

1.1 Raised awareness of common problems associated with smoking

2. Smoking behaviour

2.1 Substantial reduction in smoking behaviour

3. Quality of life

3.1 Healthy days

Secondary outcomes

1. Adverse events

- 1.1 Number of participants with at least one adverse effect
- 1.2 Clinically important specific adverse effects (withdrawal, irritability, weight gain, reduced appetite, insomnia, anxiety, craving, depression, decreased concentration)
- 1.3 Average endpoint in specific adverse effects
- 1.4 Average change in specific adverse effects
- 1.5 Death: natural or suicide

2. Service use

- 2.1 Hospital admission
- 2.2 Emergency medical treatment
- 2.3 Use of emergency services

3. Financial dependency

- 3.1 Claiming unemployment benefit
- 3.2 Claiming financial assistance because of a physical disability

4. Social

- 4.1 Unemployment
- 4.2 Social isolation as a result of preventable incapacity
- 4.3 Increased burden to caregivers

5. Economic

- 5.1 Increased costs of health care
- 5.2 Days off sick from work
- 5.3 Contribution to society
- 5.4 Family claiming carers' allowance

6. Leaving the trial early

- 6.1 Any reason
- 6.2 Adverse events
- 6.3 Inefficacy of treatment

7. Quality of life

- 7.1 Loss of independence
- 7.2 Loss of skills in activities of daily living (ADL)
- 7.3 Loss of earnings
- 7.4 Loss of social status

8. Global state

- 8.1 Clinically important change in global state (as defined by individual trials)
- 8.2 Relapse (as defined by the individual trials)

9. Mental state

- 9.1 Clinically important change in general mental state score
- 9.2 Average endpoint general mental state score
- 9.3 Average change in general mental state score
- 9.4 Clinically important change in specific symptoms (positive symptoms of schizophrenia, negative symptoms of schizophrenia)
- 9.5 Average endpoint specific symptom score
- 9.6 Average change in specific symptom score

'Summary of findings' table

When trials are available, we will use the GRADE approach to interpret findings ([Schünemann 2008](#)) and we will use [GRADEPRO](#) to import data from [Review Manager](#) to create 'Summary of findings' tables. These tables provide outcome specific information concerning the overall quality of evidence from each included study in the comparison, the magnitude of effect of the interventions examined, and the sum of the available data on all outcomes we rated as important to patient care and decision making. We aim to select the following main outcomes for inclusion in the 'Summary of findings' table:

1. Smoking cessation awareness: raised awareness of common problems associated with smoking
2. Smoking behaviour: reduction in smoking behaviour
3. Quality of life
4. Healthy days
5. Adverse event: clinically important adverse effect
6. Economic: increase in costs of care

Search methods for identification of studies

Electronic searches

Cochrane Schizophrenia Group Trials Register

The Trials Search Co-ordinator of the Cochrane Schizophrenia Group searched the Cochrane Schizophrenia Group Trials Register up to 2 April 2015 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 promote* OR *prevention* 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 the [Cochrane Schizophrenia Group module](#)).

Searching other resources

1. Unsystematic search (up to 2 April 2015)

We undertook unsystematic searches of a sample of the component databases (BNI, CINHALL, EMBASE, MEDLINE, and PsycINFO) to determine if we may have inadvertently overlooked any relevant material. We searched the databases using specific phrases ('smoking cessation', 'advice', and 'mental illness') as the searches that create the Cochrane Schizophrenia Group Trials Register are methodology specific. We did not identify any relevant trials for inclusion.

2. Reference searching

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

3. Personal contact

We planned to contact the first author of each included trial for information regarding unpublished trials; however, no trials met the inclusion criteria of this review. We will perform this as and

when we identify relevant trials for inclusion in future updates of this review.

Data collection and analysis

We did not find any relevant trials that fulfilled the criteria for inclusion of this review. We have detailed the literature screening methods we used and methods we had planned to use for data collection and analysis below.

Selection of studies

Two review authors, GT and AC, screened the electronic search results. Another review author, PK, inspected all study abstracts identified through screening. To ensure reliability, GT and DB inspected a random sample of these abstracts, comprising 10% of the total number of abstracts retrieved. We resolved any disagreements through discussion between all review authors. Where there was still doubt, we acquired the full-text article for further inspection. We carefully read full-text articles of relevant reports for a final decision on inclusion (see [Criteria for considering studies for this review](#)). Two review authors, GT and AC, read all full-text reports and independently decided whether they met the inclusion criteria. We were not blinded to the names of the study authors, institutions, or journal of publication. Where difficulties or disputes arose, we asked review author GT for help; if it was impossible to decide, we added these studies to those awaiting assessment and contacted the study authors for clarification.

Data extraction and management

1. Extraction

If we had found relevant trials that met the inclusion criteria, two review authors, PK and AC, would have independently extracted data from the included RCTs. We would have discussed any disagreements, documented our decisions and, if necessary, contacted the trial authors for clarification. Whenever possible, we would have extracted data presented only in graphs and figures and included the data when two review authors independently had the same result. We would have attempted to contact trial authors through an open-ended request in order to obtain any missing information or for clarification, whenever necessary. Where possible, we would have extracted data relevant to each component centre of multi-centre studies separately.

2. Management

2.1 Forms

Two review authors, GT and AC, would have extracted data onto standardised simple forms.

2.2 Data from multi-centre trials

If we had found multi-centre trials that satisfied the inclusion criteria, where possible we would have independently verified calculated centre data against original trial reports.

2.3 Scale-derived data

We planned to include continuous data from rating scales only if: i. a peer-reviewed journal had described the psychometric properties of the measuring instrument ([Marshall 2000](#)); and ii. one of the trial authors for that particular trial had not written or modified the measuring instrument. Ideally the measuring instrument should either have been: i. a self-report, or ii. completed by an independent

rater or relative (not the therapist). We realise that this is not often reported clearly; and in future updates of this review we will note whether or not this is the case in the [Description of studies](#) section.

2.4 Endpoint versus change data

There are advantages to both endpoint and change data. Change data can remove a component of between-person variability from the analysis. On the other hand, calculation of change needs two assessments (baseline and endpoint), which can be difficult in unstable and difficult to measure conditions, such as schizophrenia. We decided to primarily use endpoint data, and only use change data if the former were not available. For future updates of this review we will combine endpoint and change data in the analyses and use mean difference (MD) values rather than standardised mean difference (SMD) values throughout ([Higgins 2011](#), Chapter 9.4.5.2).

2.5 Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we aimed to apply the following standards to data before inclusion:

- standard deviations (SDs) and means are reported in the paper or obtainable from the study authors;
- when a scale starts from the finite number zero, the SD, when multiplied by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution) ([Altman 1996](#));
- if a scale starts from a positive value (such as the Positive and Negative Syndrome Scale (PANSS)), which can have values from 30 to 210), we would have modified the calculation described above to take the scale starting point into account. In these cases skew is present if $2 \text{ SD} > (\text{SS min})$, where S is the mean score and S min is the minimum score. Endpoint scores on scales often have a finite start and endpoint 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 planned to enter skewed data from trials including less than 200 participants in additional tables rather than in an analysis. Skewed data pose less of a problem when looking at mean values if the sample size is large, and we intended to enter skewed data from large sample sizes into the syntheses.

2.6 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 (for example, mean days per month).

2.7 Conversion of continuous to binary

Where possible, we would have tried to convert outcome measures to dichotomous data. This can be done by identifying cut-off points on rating scales and dividing participants into 'clinically improved' or 'not clinically improved' accordingly. It is generally assumed that if there is a 50% reduction in a scale-derived score, such as the Brief Psychiatric Rating Scale (BPRS) ([Overall 1962](#)) or the PANSS ([Kay 1986](#)), this could be considered as a clinically significant response ([Leucht 2005a](#); [Leucht 2005b](#)). If data based on these

thresholds were unavailable, we would have used the primary cut-off presented by the trial authors.

2.8 Direction of graphs

Where possible, we planned to enter data in such a way that the area to the left of the line of no effect indicates a favourable outcome for smoking cessation advice.

Assessment of risk of bias in included studies

Again, if trials had been found, review authors PK and AC would have worked independently to assess risk of bias by using the criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* to assess trial quality ([Higgins 2011](#)). This set of criteria is based on evidence of associations between overestimate of effect and high risk of bias of the article such as sequence generation, allocation concealment, blinding, incomplete outcome data and selective reporting.

If the raters disagreed, the final rating was to be made by consensus, with the involvement of GT. Where inadequate details of randomisation and other characteristics of trials were provided, we would have contacted authors of the studies in order to obtain further information. Non-concurrence in quality assessment was to be reported, but if disputes arose as to which category a trial was to be allocated, again, we would have resolved these by discussion.

The level of risk of bias would have been noted in both the text of the review and in the 'Summary of findings' table.

Measures of treatment effect

1. Binary data

For binary outcomes we planned to calculate a standard estimation of the fixed-effect risk ratio (RR) and its 95% confidence interval (CI). It has been shown that RR is more intuitive ([Boissel 1999](#)) than odds ratios (ORs) and that clinicians tend to interpret ORs as RRs ([Deeks 2000](#)). Within the 'Summary of findings' table we determined to calculate that the lowest control risk applies to all data. We would have assumed the same for the highest risk groups. We planned to use the 'Summary of findings' table to calculate absolute risk reduction for primary outcomes.

2. Continuous data

For continuous outcomes we planned to estimate a random-effects MD between groups. We did not aim to calculate effect size measures (SMD). However, in the case of where scales were of such similarity to allow, presuming there was a small difference in measurement, we would have calculated it and, whenever possible, 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, study authors often fail to account for intra-class correlation in clustered studies, leading to a 'unit of analysis' error ([Divine 1992](#)) whereby P values are spuriously low, CIs unduly narrow, and statistical significance are overestimated. This causes type I errors ([Bland 1997](#); [Gulliford 1999](#)).

If included trials did not account for clustering, we would have 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 contact first authors of included RCTs to obtain intra-class correlation coefficients (ICCs) for their clustered data and to adjust for this using accepted methods (Gulliford 1999). Where clustering had been incorporated into the analysis of primary studies, we would have presented these data as if from a non-cluster randomised study but adjusted for the clustering effect.

We have sought statistical advice and were advised that the binary data as presented in a report should be divided by a 'design effect'. This is calculated using the mean number of participants per cluster (m) and the ICC [Design effect = $1 + (m - 1) \times \text{ICC}$] (Donner 2002). If the included trial does not report the ICC value, we will assume it to be 0.1 (Ukoumunne 1999).

If cluster-RCTs have been appropriately analysed, taking into account ICCs, and the relevant data had been documented in the report, we would have been able to perform data synthesis with other included trials 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 (for example, 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 inappropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in people with severe mental illness, we would only have used the data from the first phase of cross-over trials.

3. Studies with multiple treatment groups

Where a study involved more than two treatment arms, if relevant, we would have presented the additional treatment arms in comparisons. If data were binary we would simply have added and combined these within the two-by-two table. If data were continuous we would have combined data following the formula in Section 7.7.3.8 (Combining groups) of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If the additional treatment arms were irrelevant, we would not have reproduced these data.

Dealing with missing data

1. Overall loss of credibility

At some degree of loss of follow-up, data must lose credibility (Xia 2009). In future updates of this review, for any particular outcome, should more than 50% of data be unaccounted for we will not reproduce these data or use them within analyses. If, however, more than 50% of participants in one trial arm are lost but the total loss is less than 50%, we will address this within the 'Summary of findings' table(s) by downgrading the quality of the evidence for this outcome. Finally, we will also downgrade quality within the 'Summary of findings' table(s) should the loss be 25% to 50% in total.

2. Binary

In the case where attrition for a binary outcome is between 0% and 50%, and where these data are not clearly described, we would have presented data on a 'once-randomised-always-analyse' basis (an intention-to-treat (ITT) analysis). Those leaving the study early are all assumed to have the same rates of negative outcome as those who completed, with the exception of the outcome of death and adverse effects. For these outcomes we would have used the rate of those who stayed in that particular arm of the trial for those who did not. We would have undertaken a sensitivity analysis to test how prone the primary outcomes were to change when 'completer' data only were compared to the ITT analysis using the above assumptions.

3. Continuous

3.1 Attrition

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

3.2 Standard deviations

Where there were missing measures of variance for continuous data but exact standard error and CIs were available for group means, and either P value or T value were available for differences in mean, we intended to calculate a SD value according to the method described in Section 7.7.3 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). If included trials did not report SD values and we could not calculate them from available data, we would have asked the trial authors to supply the data. In the absence of data from trial authors, we would have used the mean SD values from other studies.

3.3 Last observation carried forward

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

Assessment of heterogeneity

1. Clinical heterogeneity

To judge clinical heterogeneity, we would have considered all included trials, initially without seeing comparison data. We intended to inspect all included trials for clearly outlying situations or participants we had not predicted would arise. If such situations or participant groups arose we would have discussed these fully.

2. Methodological heterogeneity

We would have considered all included trials initially, without seeing comparison data, to judge methodological heterogeneity. We would have inspected all included trials for clearly outlying methods which we had not predicted would arise. If such methodological outliers arose, we would have discussed these fully in the review text.

3. Statistical heterogeneity

3.1 Visual inspection

We intended to visually inspect graphs to investigate the possibility of statistical heterogeneity.

3.2 Employing the I^2 statistic

We planned to investigate heterogeneity between included RCTs by considering the I^2 statistic method alongside the χ^2 P value. The I^2 statistic 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 (for example, P value from χ^2 test or a CI for I^2 statistic). We would have interpreted an I^2 estimate of greater than or equal to around 50% accompanied by a statistically significant χ^2 statistic as evidence of substantial levels of heterogeneity (Section 9.5.2 of the *Cochrane Handbook for Systematic Reviews of Interventions*) (Higgins 2011). If we had found substantial levels of heterogeneity in the primary outcome, we would have explored the reasons for heterogeneity (see [Subgroup analysis and investigation of heterogeneity](#)).

Assessment of reporting biases

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

Data synthesis

We understand that there is no closed argument for preference in the use of fixed-effect or random-effects models. Where possible we would have employed a fixed-effect model for analyses. We understand that there is no closed argument for preference for use of fixed-effect or random-effects models. The random-effects method incorporates an assumption that different studies are estimating different, yet related, intervention effects. This seems true. However, random-effects methods put added weight onto the smaller of the studies - those studies that are likely to carry most bias. The fixed-effect model is assumption-free and we favoured using this model.

Subgroup analysis and investigation of heterogeneity

1. Subgroup analyses

We anticipated no subgroup analyses.

2. Investigation of heterogeneity

2.1 Unanticipated heterogeneity

Should unanticipated clinical or methodological heterogeneity have become obvious, we would have simply stated hypotheses regarding these for future reviews or updates of this review. As no trials met the inclusion criteria of this review we have not undertaken analyses relating to these.

2.2 Anticipated heterogeneity

We had anticipated some heterogeneity for the primary outcomes, and would have summarised all data but also presented 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 would have included these trials and if there was no substantive difference when we added the implied randomised trials to those with better descriptions of randomisation, then we would have employed the data from these trials.

2. Assumptions for lost binary data

Where we would have had to make assumptions regarding people lost to follow-up (see [Dealing with missing data](#)), we would have compared the findings of the primary outcomes when we used our assumption compared with completer data only. If there was a substantial difference, we would have reported the results and discussed them but continued to employ our assumption.

3. Risk of bias

We would have analysed the effects of excluding trials that we judged were at high risk of bias across one or more of the domains of randomisation (implied as randomised with no further details available), allocation concealment, blinding, and outcome reporting for the meta-analysis of the primary outcome. If exclusion of trials at high risk of bias did not substantially alter the direction of effect or the precision of the effect estimates, then we would have included data from these trials in the analysis.

4. Imputed values

We would also have undertaken a sensitivity analysis to assess the effects of including data from trials where we used imputed values for ICC in calculating the design effect in cluster-RCTs.

If we had noted substantial differences in the direction or precision of effect estimates in any of the sensitivity analyses we have listed above, we would not have pooled data from the excluded trials with the other trials contributing to the outcome but would have presented them separately.

5. Fixed- and random-effects

We planned to synthesise all data using a random-effects model. However, we would also have used a fixed-effect model to synthesise data for the primary outcome to evaluate whether the greater weights assigned to larger trials with greater event rates altered the significance of the results compared to the more evenly distributed weights in the random-effects model.

RESULTS

Description of studies

See [Characteristics of excluded studies](#).

Results of the search

The initial search of the Cochrane Schizophrenia Group Specialized Trials Register in 2009 was a combined search designed to identify

trials which would be relevant to this review and to another sister review on physical health advice for people with serious mental illness (Tosh 2014a). The initial search identified 2382 references (from 1558 studies). After we examined the reports, we identified four articles that were suitable for further examination; we excluded three and one trial is ongoing (Figure 3). An update search (up to 2 April 2015) we identified a further 15 references. After we examined the reports, we found that none met the inclusion criteria.

Despite the fact that the Cochrane Schizophrenia Group Trials Register is compiled from large comprehensive and systematic searches for trials, we also undertook unsystematic searches of a sample of the component databases (BNI, CINHAL, EMBASE, MEDLINE, and PsycINFO), up to 2 April 2015, to determine if we may have inadvertently overlooked any material. We performed searches using specific phrases ('smoking cessation', 'advice', and 'mental illness') as the searches that create the Cochrane Schizophrenia Group Trials Register are methodology specific. We did not identify any further relevant trials for inclusion from this additional search.

Included studies

No studies met the inclusion criteria of this review. There is one ongoing study [NCT00500695](#) (see [Characteristics of ongoing studies](#)).

Excluded studies

[Brown 2009](#) compared the effects of a brief five-minute smoking cessation advice session versus a structured motivational interviewing (MI) treatment consisting of two 45-minute individual sessions, and additional self-help materials and follow-up telephone sessions to both participants and their family. The study participants were adolescent smokers (aged between 13 to 17 years) and therefore did not meet the inclusion criteria of (i.e. adults with serious mental illness). We excluded another study, [Baker 2006](#), as it focussed on eight individual one-hour sessions of motivational interviewing and cognitive behaviour therapy plus nicotine replacement therapy, and not smoking cessation advice. Finally we had to exclude [Ziedonis 1997](#) because it was an evaluation of a smoking cessation programme and not a trial focussing on smoking cessation advice (see '[Characteristics of excluded studies](#)' table).

Awaiting assessment

To our knowledge, there are no studies awaiting assessment.

Ongoing studies

One study, [NCT00500695](#), was reported as "completed" in November 2014, but we could not find any report with outcome data for this study (see [Characteristics of ongoing studies](#)).

Please see [Agreements and disagreements with other studies or reviews](#).

Risk of bias in included studies

No studies fulfilled the inclusion criteria of this review. We did not exclude any studies on the grounds of poor methodology.

Effects of interventions

See: [Summary of findings for the main comparison Smoking cessation advice versus standard care for people with serious mental illness](#)

Currently we do not know of any fully reported RCTs that describe the effects of smoking cessation advice on people with serious mental illnesses.

DISCUSSION

No trials met our inclusion criteria and we could not include any trials.

Summary of main results

No trials met the inclusion criteria. We did not find any trial-based evidence on our outcomes of raised awareness of common problems associated with smoking, reduction in smoking, healthy days, clinically important adverse effect, and any economic data ('Summary of findings' table 1). We did not identify any trials to enable a comparison on the effects of the highly prevalent approach of healthcare professionals giving advice.

Overall completeness and applicability of evidence

No trials met the inclusion criteria. The evidence base for this research question is incomplete.

Quality of the evidence

We did not exclude the four studies we had obtained for closer inspection because of issues of quality. We were unable to find any relevant studies, regardless of whether they were of high or poor quality.

Potential biases in the review process

The search criteria on the Cochrane Schizophrenia Group Trials Register should have been robust enough to detect relevant trials. However, it is possible that we failed to identify small studies but we think it unlikely that we would have missed any 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. Given that the Cochrane Schizophrenia Group's Register covers many languages but is indexed in English, we feel that we 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. A Mandarin-speaking colleague, Jun Xia, checked these studies for relevance but none were relevant to this review.

Agreements and disagreements with other studies or reviews

Currently we do not know of any RCTs that describe the effects of smoking cessation health advice for people with serious mental illnesses. We have identified one similar Cochrane review which sits in the Cochrane Tobacco Addiction Group ([Tsoi 2013](#)). This review reports on the inclusion of 34 trials (16 trials of cessation; nine trials of reduction; one trial of relapse prevention; and eight trials that reported smoking outcomes for interventions aimed at other purposes) but none of these reported trials for smoking cessation advice could be included in our review. The only other

similar systematic review that we are aware of is [Banham 2010](#). This review reports on the inclusion of eight randomised trials of pharmacological or psychological interventions (or both) aimed at smoking cessation for people with serious mental illnesses, but again, does not include any trials on smoking cessation advice.

AUTHORS' CONCLUSIONS

Implications for practice

1. For people with long-term mental health conditions who smoke

It is unclear if smoking cessation advice for people with serious mental illness has any effect. People with long-term mental illness who smoke are currently recipients of untested approaches, perhaps undertaken more for purposes of health professional audit than because of strong evidence of effectiveness. It is therefore important that any smoking cessation advice given to people with long-term mental illness, either by mental health clinicians or practitioners, is offered in a considered and measured way since the effect of the said advice is unclear.

2. For clinicians

The physical health of people with long-term mental health issues remains a significant concern for all health professionals. Strong evidence shows that cigarette smoking is highly prevalent among people with enduring mental health issues. Smoking is also well-understood as being a common self-administered first aid device for those suffering acute episodes of distress. People experiencing early onset psychosis may also be vulnerable to other potentially addictive behaviours, including alcohol and illicit substance abuse ([NICE 2011](#)). The impact of smoking on these groups of people will continue to require public health interventions at primary, secondary, and tertiary stages of care and healthcare practitioners will continue to be enjoined to implement service user education activities and tools, for which no trial-based evidence specifically aimed at people with serious mental illness exists. Giving advice about smoking cessation to people with serious mental illness could be effective or it could be undertaking an approach that may be well-meaning, please those who wish to be seen to be doing something - but actually be wasting time and opportunities. Clinicians should not be satisfied with this far from ideal situation, and take research action to elaborate the evidence base.

3. For policy makers

In the English NHS public health funding is facing unprecedented pressures in relation to the current cost-cutting demands of the Nicholson Challenge ([Ford 2013](#)). This is no exception to health

funding across the world. Policy makers should be concerned with any raft of interventions lacking an evidence base. This review signals that, for people with serious mental illness, the existing plethora of health promotion interventions remains unexamined for their utility, effects, and cost effectiveness. It remains worrying likely that national governments and health service organisations will continue to invest in a variety of health promotion strategies and interventions without specifically having evidence of their effects for people with serious mental illness.

Implications for research

1. General

We did not find any trials that met the inclusion criteria of this review either because there are none or perhaps we failed to identify them ([Potential biases in the review process](#)). In any event, full registration of every RCT using specific trial identifiers, such as an International RCT Number (ISRCTN), would ensure that we identify all relevant trial data.

2. Specific

2.1 Reviews

This review should be the focus of regular update. One new trial will completely change the overview. The excluded studies do suggest that a review on specific, motivational interviewing for this group of people is indicated. We suggest comparisons relevant to such a review in [Table 2](#).

2.2 Trials

We realise that much thought and care goes into RCT design. We have also given this issue some consideration and suggest an outline for a trial design ([Table 3](#)).

ACKNOWLEDGEMENTS

We thank Professor Clive Adams, and the Cochrane Schizophrenia Group editorial team, based at Nottingham University, for their support in the writing of this review. The Cochrane Schizophrenia Group editorial base produces and maintains standard text for use in the Methods sections of their Cochrane reviews. We have used this text as the basis of what appears in the [Methods](#) section of this review and have adapted it as required. We also thank Jun Xia, who examined the Chinese language titles we identified in our literature searches.

We are grateful to Professor Tarek A. Okasha for peer reviewing this review version and Deirdre Walshe for copy editing.

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CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Baker 2006	Allocation: randomised. Participants: smokers with non-acute psychotic disorders.

Study	Reason for exclusion
	Intervention: 8 individual 1-hour sessions of motivational interviewing and cognitive behaviour therapy plus nicotine replacement therapy, and not smoking cessation advice.
Brown 2009	Allocation: randomly assigned by cohort (of 16 participants). Participants: adolescent smokers (aged between 13 to 17 years) admitted to inpatient psychiatric hospital, not adults. Intervention: motivational interviewing (MI) treatment consisting of two 45-minute individual sessions and additional self help materials and follow-up telephone sessions to both patients and family versus brief advice (BA) consisting of a 5- to 10-minute advice session to quit smoking.
Ziedonis 1997	Allocation: none. Participants: 24 smokers with schizophrenia. Intervention: an evaluation of a smoking cessation programme (nicotine replacement, motivational enhancement therapy, and relapse prevention behavioral therapy were important components of treatment), this was a treatment programme and not focussing on smoking cessation advice.

Characteristics of ongoing studies [ordered by study ID]

[NCT00500695](#)

Trial name or title	Enhancing Motivation To Quit Smoking In Smokers With Serious Mental Illness.
Methods	RCT, parallel assignment.
Participants	Smokers over 18 years of age with diagnosis of schizophrenia or schizoaffective disorder.
Interventions	Motivational interviewing versus psychoeducational intervention.
Outcomes	Primary outcome: attendance at first smoking cessation session. Secondary outcome: cigarettes per day.
Starting date	May 2006.
Contact information	Refer to this study by its ClinicalTrials.gov identifier: NCT00500695.
Notes	Last updated 03 November 2014.

ADDITIONAL TABLES

Table 1. Series of related reviews

Title	Reference
Physical health care monitoring	Tosh 2014a
General physical health advice	Tosh 2014b
Advice regarding smoking cessation	This review

Table 1. Series of related reviews *(Continued)*

Advice regarding oral health care	Khokhar 2011
Advice regarding HIV/AIDs prevention	Wright 2014
Advice regarding substance use	Protocol in preparation

Table 2. Comparisons which were the focus of the excluded studies

Comparison	Excluded study
Individually administered smoking cessation intervention versus standard care	Baker 2006
Motivational interview versus brief advice	Brown 2009
Evaluation of a smoking cessation programme versus none	Ziedonis 1997

Table 3. Suggested trial design

Method	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.
Intervention	1. Smoking cessation advice. 15 mins anti-smoking advice, delivered by "peer support worker" based around the " Take steps NOW to stop smoking " website. 2. Standard care: administered by care co-ordinator.
Outcomes	Raised awareness of common problems associated with smoking (any time period). Substantial reduction in smoking behaviour. Healthy days. Mental state: no clinically important change in general mental state. Economic outcomes. Leaving the study early: reason. Adverse events: clinically important adverse events.
Notes	*For 20% difference between groups for a binary outcome to be highlighted with reasonable degree of confidence, 150 people are needed per group.

CONTRIBUTIONS OF AUTHORS

Priya Khanna wrote the protocol, and the [Results](#) and [Discussion](#) sections of the review.
Andrew Clifton wrote the protocol, and the [Results](#) and [Discussion](#) sections of the review.
David Banks wrote the protocol, and the [Results](#) and [Discussion](#) sections of the review.
Graeme Tosh initiated this project, wrote the protocol, and [Results](#) and [Discussion](#) sections of the review.

DECLARATIONS OF INTEREST

Priya Khanna has no known conflicts of interest.
Andrew Clifton has no known conflicts of interest.
David Banks has no known conflicts of interest.
Graeme Tosh has no known conflicts of interest.

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Internal sources

- Huddersfield University, UK.
- Queen Margaret University, UK.

External sources

- None provided, Other.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

There are no differences between the protocol and this review update.

INDEX TERMS

Medical Subject Headings (MeSH)

*Counseling; *Mental Disorders; *Smoking Cessation

MeSH check words

Humans