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## HIV prevention advice for people with serious mental illness (Review)

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[Intervention Review]

# HIV prevention advice for people with serious mental illness

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## ABSTRACT

### Background

People with serious mental illness have rates of Human Immuno-deficiency Virus (HIV) infection higher than expected in the general population for the same demographic area. Despite this elevated prevalence, UK national strategies around sexual health and HIV prevention do not state that people with serious mental illness are a high risk group. However, a significant proportion in this group are sexually active and engage in HIV-risk behaviours including having multiple sexual partners, infrequent use of condoms and trading sex for money or drugs. Therefore we propose the provision of HIV prevention advice could enhance the physical and social well being of this population.

### Objectives

To assess the effects of HIV prevention advice in reducing morbidity, mortality and preserving the quality of life in people with serious mental illness.

### Search methods

We searched the Cochrane Schizophrenia Group's Trials Register (24 January 2012; 4 July 2016).

### Selection criteria

We planned to include all randomised controlled trials focusing on HIV prevention advice versus standard care or comparing HIV prevention advice with other more focused methods of delivering care or information for people with serious mental illness.

### Data collection and analysis

Review authors (NW, AC, AA, GT) independently screened search results and did not identify any studies that fulfilled the review's criteria.

### Main results

We did not identify any randomised studies that evaluated advice regarding HIV for people with serious mental illness. The excluded studies illustrate that randomisation of packages of care relevant to both people with serious mental illness and HIV risk are possible.

### **Authors' conclusions**

Policy makers, clinicians, researchers and service users need to collaborate to produce guidance on how best to provide advice for people with serious mental illness in preventing the spread of HIV infection. It is entirely feasible that this could be within the context of a well-designed simple large randomised study.

## **PLAIN LANGUAGE SUMMARY**

### **HIV prevention advice for people with serious mental illness**

The human immunodeficiency virus (HIV) is a condition in humans in which our immune systems steadily begins to fail and allows life-threatening infections and cancers. People with mental illness have higher than usual rates of HIV than in the general population. Despite this, UK national strategies around sexual health and HIV prevention do not state that people with serious mental illness are a high risk group. A significant number of people with mental health problems are sexually active and engage in HIV-risk behaviours such as having multiple sexual partners, not using condoms and trading sex for money or drugs. In addition, during relapse, mental illness may lead people to engage in practices they would not usually be engaged in.

The provision of HIV prevention advice could enhance the physical and social well being of people with mental health problems. HIV health advice can take many forms. Advice is the active provision of information. It has an education component and is delivered in a gentle and non-patronising manner. Advice from a healthcare professional can have a positive impact on behaviour and may motivate people to seek further support and treatment.

The review's aim was to assess the potential beneficial or harmful effects of HIV prevention advice in people with serious mental illness (SMI). A search for randomised trials comparing HIV prevention advice with standard care for people with SMI was run in January 2012 and July 2016. However, no studies or trials were found. Policy makers, health professionals, researchers and people with mental health problems need to collaborate to produce evidence-based guidance on how best to provide advice for people with serious mental illness in preventing the spread of HIV. Better guidance and information about HIV in people with mental illness could be found by conducting well-designed, simple and large studies on this important topic.

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

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

HIV ADVICE versus NO HIV ADVICE for people with serious mental illness						
Patient or population: people with serious mental illness						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	HIV ADVICE versus NO HIV ADVICE				
HIV infection	See comment	See comment	Not estimable	0 (0)	See comment	We found no relevant studies.
Quality of life: Improved						
Adverse events						
Service use: Hospitalisation						
Costs of care						
Safe practice: 1. Sexual practice/knowledge						
Safe practice: 2. Needle practice/knowledge						

## BACKGROUND

### Description of the condition

The definition of severe mental illness with the widest consensus is that of the US 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, which last over a protracted period of time resulting in the 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). Evidence suggests that those with serious mental illness have rates of Human Immuno-deficiency Virus (HIV) infection which are higher than expected in the general population in the same demographic area (Hughes 2009). The current prevalence rate of HIV infection for the general population in North America is 0.3%, which is marginally lower than Europe (prevalence 0.4% - UNAIDS 2010). In contrast, studies from the USA report prevalence rates of between 9% and 19%, while in Europe 5% prevalence rates have been reported for people with serious mental illness (Cournos 1991; Grassi 1999; Susser 1993). Despite this higher than expected prevalence, UK national strategies around sexual health and HIV prevention do not state that people with serious mental illness are a high risk group. However, a significant proportion in this group are sexually active and engage in HIV-risk behaviours including having multiple sexual partners, infrequent use of condoms and trading sex for money or drugs (Rosenberg 2001). Additionally, during relapse, symptoms of serious mental illness may lead people to engage in practices they would not engage in if functioning at their optimum level (Carey 2004).

### Description of the intervention

HIV health advice can take many forms, depending on environmental and socio-economic factors. Advice is the active provision of preventative information; it has an educative component and is delivered in a gentle non-patronising manner (Stott 1990). Therefore, in this context it could be defined as any advice about HIV health delivered by a healthcare professional.

### How the intervention might work

Advice from a healthcare professional can have a positive impact on behaviour (Kreuter 2000; Russell 1979) and may motivate people to seek further support and treatment (Sutherland 2003). Given the evidence of increased rates of potentially preventable health problems in people with serious mental illness (Cournos 2005;

Dixon 1999; Robson 2007), and the suggestion that methodologically robust, healthy living interventions give “promising outcomes” in people with schizophrenia (Bradshaw 2005), we believe that appropriate HIV health advice could improve the quality of life and increase life expectancy for sufferers of serious mental illness. HIV advice from a healthcare professional may encourage those with serious mental illness to; be sexually abstinent, delay the initiation of sexual activity, decrease the numbers of sexual partners, engage in the consistent and correct use of condoms (if they are sexually active) and in harm reduction and needle exchange programmes (if they are injecting drug users).

### Why it is important to do this review

People with serious mental illness are some of the most vulnerable and socially excluded members of society; the same could be said for those with HIV. Therefore, the combination of both debilitating conditions could have a profound social, psychological and economic impact on individuals, their families and friends (Hughes 2009). It has been identified that fewer than one in five people at risk of HIV currently have access to infection prevention (The Global HIV Prevention Working Group 2006). Given the effects of serious mental illness and the difficulties this population have in accessing general healthcare advice (Tosh 2010), it is important that appropriate targeted advice is given to this group. The completion of this review is required because there is no cure or vaccination for HIV; the only way to prevent infection is by the adoption of safer sexual and injection behaviours. We are not aware of any systematic review that compares HIV advice-giving interventions with standard care for people with serious mental illness. This is one of a series of reviews (Table 1).

## OBJECTIVES

To assess the effects of HIV prevention advice in reducing morbidity, mortality and preserving the quality of life in people with serious mental illness.

## METHODS

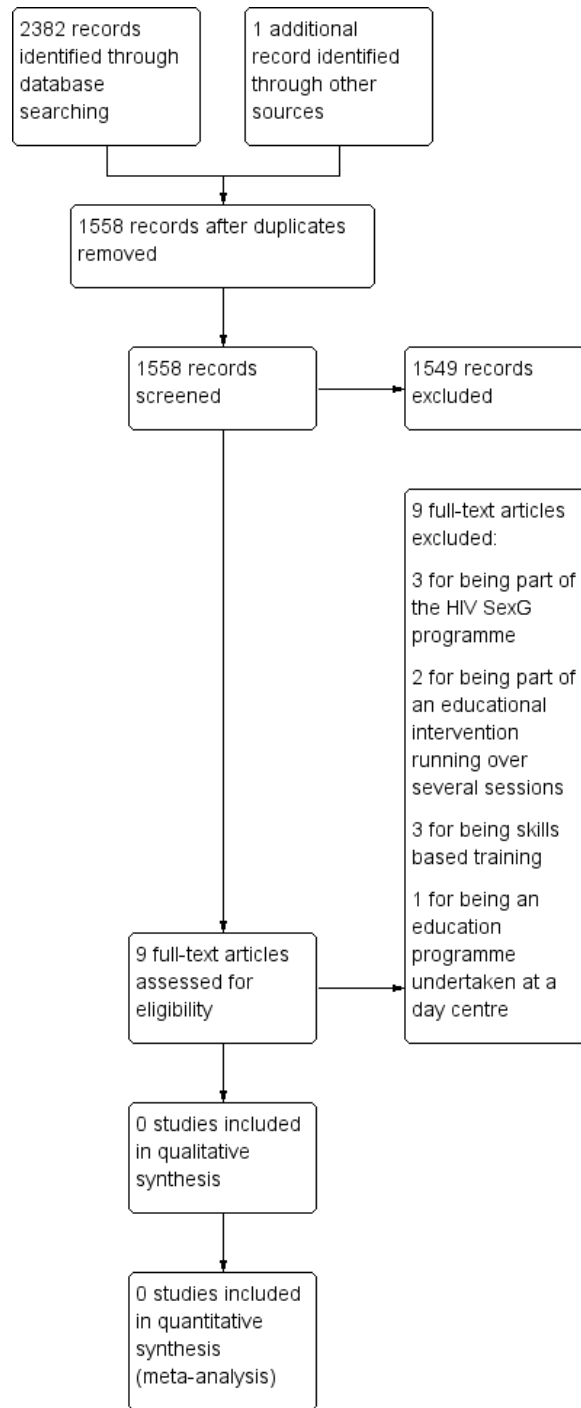
### Criteria for considering studies for this review

#### Types of studies

We considered all relevant randomised controlled trials (RCTs), and economic evaluations conducted alongside any potential RCTs. Quasi-randomised studies, such as those allocating by using alternate days of the week were not eligible for inclusion. If we

had encountered trials which suggested or implied the study 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. The study process is summarised in [Figure 1](#).

**Figure 1. Study flow diagram.**





## 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 a serious mental illness in its own right, however, those trials dealing with a dual diagnosis population i.e. those with serious mental illness plus substance abuse were eligible. We did not include studies focusing on dementia, personality disorder and mental retardation, as they were not covered by our definition of serious mental illness. Despite the fact that personality disorder is now included in the NIMH definition, we excluded 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 (NIMH 1987) definition and in the further work of Schinnar 1990.

## Types of interventions

### 1. HIV prevention advice

It has been difficult to find a useful definition of 'advice'. In the context of this review we have defined '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. It is not a programmed or training approach, focusing on the acquisition of knowledge, skills and competencies as a result of formal teaching sessions. The effects of programmes and/or training approaches for HIV prevention in people with serious mental illness were not considered in this review.

### 2. Standard care

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

## Types of outcome measures

For the purposes of this review we planned 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 (more than one year).

## Primary outcomes

### 1. HIV infection (any time period)

### 2. Risk-taking behaviour (short term)

- 2.1 Unprotected sex.
- 2.2 Sexual promiscuity.
- 2.3 Sharing needles for drug use.

## Secondary outcomes

### 1. Adverse events

- 1.1 Number of participants with at least one adverse effect.
- 1.2 Clinically important specific adverse events (cardiac events, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count).
- 1.3 Average endpoint specific adverse events score.
- 1.4 Average change in specific adverse events score.
- 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. Quality of life

- 5.1 Loss of independence.
- 5.2 Loss of activities of daily living (ADL) skills.
- 5.3 Loss of earnings.
- 5.4 Loss of social status.
- 5.5 Healthy days.

## 6. Economic

- 6.1 Increased costs of health care.
- 6.2 Days off sick from work.
- 6.3 Reduced contribution to society.
- 6.4 Family claiming care allowance.

## 7. Leaving the study early (any reason, adverse events, inefficacy of treatment)

## 8. Global state

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

## 9. Mental state (with particular reference to the positive and negative symptoms of schizophrenia)

- 9.1 Clinically important change in general mental state score.
- 9.2 Average endpoint general mental 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.

## 10. Risk-taking behaviour

- 10.1 Unprotected sex (not short term).
- 10.2 Sexual promiscuity (not short term).
- 10.3 Sharing needles for drug use (not short term).
- 10.4 Sexually Transmitted Infection incidences.
- 10.5 Knowledge of HIV transmission routes.

## 11. Health behaviours

- 11.1 Behavioural intentions.
- 11.2 Behavioural intentions regarding safe needle practices.

## 12. 'Summary of findings' table

We anticipated including the following outcomes in a 'Summary of findings' table:

### 12.1 HIV infection (measured by CD4+ count and viral load)

- Not using a condom.
- Number of casual sexual partners.
- Prevalence of needle sharing.

### 12.2 Quality of life

- Loss of independence.
- Loss of activities of daily living (ADL) skills.
- Loss of social status.
- Healthy days.

### 12.3 Adverse events

- Clinically important specific adverse effects (cardiac effects, death, movement disorders, prolactin increase and associated effects, weight gain, effects on white blood cell count).

### 12.4 Service use

- Hospital admission.

### 12.5 Leaving the study early

- Increased costs of health care.

### 12.6 Sexual health practices

- Sexually Transmitted Infection incidences - knowledge of HIV transmission.

### 12.7 Safer needle practices

- Attitude towards safer needle practice.
- Behavioural intentions and safer needle intention.

## Search methods for identification of studies

### Electronic searches

#### Cochrane Schizophrenia Group's Study-Based Register of Trials

On July 4, 2016, the information specialist searched the register using the following search strategy:

(\*AIDS Education\* OR \*HIV Prevention\*) in Intervention Field OR \*Human Immunodeficiency Virus (HIV)\* in Health Care Condition Field of STUDY

In such study-based register, searching the major concept retrieves all the relevant keywords and studies because all the studies have already been organised based on their interventions and linked to the relevant topics.

The Cochrane Schizophrenia Group's Register of Trials is compiled by systematic searches of major resources (including AMED, BIOSIS, CINAHL, EMBASE, MEDLINE, PsycINFO, PubMed, and registries of clinical trials) and their monthly updates, hand-searches, grey literature, and conference proceedings (see [Group's Module](#)). There is no language, date, document type, or publication status limitations for inclusion of records into the register.

For previous searches, please see [Appendix 1](#).

## Searching other resources

### 1. Reference searching

Had we found studies for inclusion in the review, the references of all included studies would have been inspected to identify any further relevant citations.

### 2. Personal contact

If we had found studies for inclusion in the review, the first author of each study would have been contacted for information regarding unpublished trials.

## Data collection and analysis

### Selection of studies

Two review authors (NW, AC) screened the results of the electronic search. NW inspected all the abstracts of studies identified through screening. To ensure reliability, GT and AA inspected a random sample of these abstracts, comprising 10% of the total. Where disagreement occurred, this was resolved by discussion, and where there was still doubt, we acquired the full article for further inspection. The full articles of relevant reports for reassessment were carefully read for a final decision on inclusion (see [Criteria for considering studies for this review](#)). In turn NW and AC read all full reports and independently decided on whether they met the 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 GT for help; if it was impossible to decide, we added these studies to those awaiting assessment and contacted the authors of the papers for clarification.

## Data extraction and management

### 1. Extraction

If we had found relevant trials to include, we planned that two review authors (NW and AC) would independently extract data from the included studies. We would have discussed any disagreement, documented our decisions and, if necessary, contacted the authors of studies for clarification. Whenever possible, we would have extracted data presented only in graphs and figures and included the data if two review authors independently had the same result. We would have attempted to contact 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

If we had found relevant data to include, NW and AC would have extracted it onto standard, simple forms.

#### 2.2 Data from multi-centre trials

If we had found multi-centre trials to include, where possible, the review authors would have independently verified calculated centre data against original trial reports.

### 3. Scale-derived data

We would have 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](#)); b. the measuring instrument was not written or modified by one of the trialists for that particular trial; and c. the measuring instrument was either i. a self-report or ii. completed by an independent rater or relative (not the therapist). Often this is not reported clearly, but if we had encountered it this would have been noted in the [Description of studies](#).

### 4. Endpoint versus change data

We aimed 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 intended to use change data.

## 5. Skewed data

Continuous data on clinical and social outcomes are often not normally distributed. To avoid the pitfall of applying parametric tests to non-parametric data, we aimed to apply the following standards to all data before inclusion: (a) standard deviations (SDs) and means are reported in the paper or obtainable from the authors; (b) when a scale starts from the finite number zero, the SD, when multiplied by two, is less than the mean (as otherwise the mean is unlikely to be an appropriate measure of the centre of the distribution), (Altman 1996); (c) if a scale starts from a positive value (such as PANSS (Positive and Negative Syndrome Scale), 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  $2 \text{ SD} > (S - S_{\text{min}})$ , where  $S$  is the mean score and  $S_{\text{min}}$  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 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 intended to enter skewed data from large sample sizes into the syntheses.

## 6. Common measure

To facilitate comparison between trials, we intended to convert variables that may have been reported in different metrics, such as days in hospital, (mean days per year, per week or per month) to a common metric (e.g. mean days per month).

## 7. Conversion of continuous to binary

Where possible, we planned 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'. We would have assumed that if there has been a 50% reduction in a scale-derived score such as the Brief Psychiatric Rating Scale (Overall 1962) or the Positive and Negative Syndrome Scale (Kay 1986; Kay 1987), this would have been considered as a clinically significant response (Leucht 2005; Leucht 2005a). If data based on these thresholds were not available, we planned to use the primary cut-off presented by the original authors.

## 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 HIV advice.

## Assessment of risk of bias in included studies

Again working independently, review authors NW and AC planned to assess the risk of bias using the tool described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). This tool encourages consideration of how the sequence was generated, how allocation was concealed, the integrity of blinding at outcome, the completeness of outcome data, selective reporting and other biases. We planned to exclude studies where allocation was clearly not concealed. The risk of bias in each domain, and overall, would have been assessed and categorised into: a. low risk of bias: plausible bias unlikely to seriously alter the results (categorised as 'Yes' in 'Risk of bias' table); b. high risk of bias: plausible bias that seriously weakens confidence in the results (categorised as 'No' in 'Risk of bias' table); or c. unclear risk of bias: plausible bias that raises some doubt about the results (categorised as 'Unclear' in 'Risk of bias' table). We would not have included trials with high risk of bias (defined as at least three out of five domains categorised as 'No') in the meta-analysis. If the raters disagreed, the final rating would have been made by consensus with the involvement of another member of the review group. If we had considered that details of randomisation and other characteristics of trials were inadequate, we would have contacted the authors of the studies in order to obtain further information. We planned to report non-concurrence in quality assessment.

## 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 and that odds ratios tend to be interpreted as RR by clinicians (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 mean difference (MD) between groups. We aimed 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 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 pose 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 was not accounted for in primary studies, we intended to present the 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 (ICC) of their clustered data and to adjust for this by using accepted methods (Gulliford 1999). If clustering had been incorporated into the analysis of primary studies, we intended to present these data as if from a non-cluster randomised study, but would have 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 ICC [Design effect =  $1+(m-1)*ICC$ ] (Donner 2002). If the ICC had not been reported, we would have assumed it to be 0.1 (Ukoumunne 1999).

Where cluster studies had been appropriately analysed, taking into account the OCC and relevant data documented in the report, synthesis with other studies may be possible using the generic inverse variance technique.

### 2. Cross-over trials

A major concern of cross-over trials is the carry-over effect. It occurs if an effect (e.g. pharmacological, physiological or psychological) of the treatment in the first phase is carried over to the second phase. As a consequence, on entry to the second phase the participants can differ systematically from their initial state despite a wash-out phase. For the same reason, cross-over trials are not appropriate if the condition of interest is unstable (Elbourne 2002). As both effects are very likely in severe mental illness, we intended to use only data from 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 would have presented the additional treatment arms in comparisons. If the additional treatment arms were not relevant, we did not intend to 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 with less than 50% of data unaccounted, we did not intend to reproduce or use it within the analyses. If, however, more than 50% of those in one arm of a study are lost, but the total loss is less than 50%, we planned to mark such data with '\*' to indicate that such a result may be prone to bias.

### 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 aimed to present data on a 'once-randomised-always-analyse' basis (an intention-to-treat analysis). We would have assumed those lost to follow-up had the same rates of negative outcome as those who completed, with the exception of the outcome of death. We planned to undertake a sensitivity analysis to test how prone the primary outcomes were to change when 'completer' 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 was between 0% and 50% and completer-only data were reported, these would have been reproduced.

#### 3.2 Standard deviations

Where there were missing measures of variance for continuous data but exact standard error and confidence intervals were available for group means, and either P value or T value were available for differences in mean, we intended to calculate a standard deviation value according to the method described in Section 7.7.3 of the *Cochrane Handbook* (Higgins 2011). If standard deviations were not reported and could not be calculated from available data, we would have asked authors to supply the data. In the absence of data from authors, we would have used the mean standard deviation from other studies.

#### 3.3 Last observation carried forward

We anticipated that in some studies the method of last observation carried forward (LOCF) would be employed within the study report. As with all methods of imputation to deal with missing

data, LOCF introduces uncertainty about the reliability of the results. Therefore, where LOCF data had been used in the trial, if less than 50% of the data had been assumed, we would have reproduced 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 studies, initially without seeing comparison data. We intended to inspect all studies for clearly outlying situations or people which we had not predicted would arise. If such situations or participant groups arose we would have discussed these fully.

### 2. Methodological heterogeneity

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

### 3. Statistical

#### 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 aimed to investigate heterogeneity between studies by considering the  $I^2$  method alongside the  $\text{Chi}^2$  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; a. magnitude and direction of effects and b. strength of evidence for heterogeneity (e.g. P value from  $\text{Chi}^2$  test, or a confidence interval for  $I^2$ ). We would have interpreted an  $I^2$  estimate greater than or equal to 50% accompanied by a statistically significant  $\text{Chi}^2$  statistic as evidence of substantial levels of heterogeneity (Section 9.5.2 - Higgins 2011) and explored reasons for heterogeneity. If the inconsistency was high and we had found clear reasons, we would have presented the 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 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 studies, or where all studies were of similar sizes. In other cases, where funnel plots were possible, we would have sought statistical advice in their interpretation.

## Data synthesis

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. Random-effects methods, however, 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

There are no included studies, therefore we have carried out no subgroup analysis.

### 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 versions of this review. There are no included studies, therefore we have not undertaken analyses relating to these.

#### 2.2 Anticipated heterogeneity

We had anticipated some heterogeneity for the primary outcomes, and so 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 intended to include these studies and if there was no substantive difference when we added the implied randomised studies to those with a better description of randomisation, we would then have employed all data from these studies.

### 2. Assumptions for lost binary data

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

## RESULTS

### Description of studies

See: [Characteristics of excluded studies](#).

### 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 physical health monitoring and physical healthcare advice for people with serious mental illness. One review based on this search has already been published ([Tosh 2010](#)) and work has begun on a series of sister reviews looking at physical health advice for people with serious mental illness. One review has been published which looks at general physical health advice ([Tosh 2011](#)) and this is the second of several looking at more targeted advice relating to specific problems or behaviours, e.g. weight gain, smoking and oral health ([Khokhar 2011](#)). The initial search identified 2382 references (from 1558 studies). After examining all the reports, nine were suitable for further examination, all of which we had to exclude ([Figure 1](#)).

### Included studies

No studies met the criteria for this review.

### Excluded studies

Three studies were excluded on the basis that they were part of a HIV Sex G programme ([Berkman 2006](#); [Berkman 2007](#); [Susser 1998](#)). Sex G (Sex, Games and Videotapes) is an intervention designed to reduce sexual risk and was developed as a programme for homeless mentally ill men in a New York City, NY shelter that is built around activities central to shelter life: competitive games, storytelling, and watching videos. For many of these men sex is conducted in public spaces, revolves around drug use, and must be conducted quickly. One component of the programme is a competition to see which man can put a condom on a banana fastest (without tearing the condom); this teaches important skills for using a condom quickly. The program allows for sex issues to be brought up in a nonjudgmental way ([Susser 1994](#)). Another two were excluded on the basis that they were HIV education programmes running over several sessions, this constituted a structured programme of education rather than HIV advice ([Collins 2001](#); [Otto-Salaj 2001](#)). Three more studies were excluded as they were skills based training programmes, and, again, not advice ([Katz 1996](#); [Kelly 1997](#); [Weinhardt 1998](#)). The final paper was excluded because it was an education programme undertaken at a day treatment centre ([Kern 1996a](#), see [Characteristics of excluded studies](#)).

### Awaiting assessment

No studies await assessment.

### 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.

### Effects of interventions

See: [Summary of findings for the main comparison HIV ADVICE versus NO HIV ADVICE for people with serious mental illness](#)

Currently we know of no randomised studies describing HIV advice for people with serious mental illness.

## DISCUSSION

### Summary of main results

No studies met the inclusion criteria ([Summary of findings for the main comparison](#)).

### No trial-based guidance

Current medical practice, certainly in the UK, is led by guidance from a number of professional and third-sector organisations, who appear to base their advice on little more than anecdotal evidence produced by working groups and stakeholder consultation. The background literature summarised in support of this review demonstrates that people with serious mental illness are at an increased risk in comparison to the general population of contracting HIV. Although the guidance at face value appears to make sense, there are concerns around the implementation of something which has little evidence to support it. It could be argued that people with serious mental illness should expect that all aspects of their care has been subjected to some degree of evaluation.

### Overall completeness and applicability of evidence

No studies met the inclusion criteria for this review.

### Quality of the evidence

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

### Potential biases in the review process

The search criteria both in 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 the 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 relevant to this review.

### Agreements and disagreements with other studies or reviews

We are not aware of any other similar reviews or studies.

## AUTHORS' CONCLUSIONS

### Implications for practice

#### 1. For people with serious mental illness

We are unable to reach any conclusion as the excluded studies focused on HIV educational interventions, which cannot be classified as HIV preventative advice for reducing risk-taking behaviour in individuals with serious mental illness. However, the fact that we have not found any high quality evidence does not mean there is no effect, merely that there are no eligible studies addressing this issue. People with serious mental illness should recognise that the advice given regarding HIV is well-intentioned but untested.

#### 2. For clinicians

Clinicians and policy makers need to think about how HIV preventative advice is given to people with serious mental illness. In the absence of randomised evidence it is not clear the best format this advice should be and we would encourage clinicians to work with researchers and service users to co-produce a well-designed randomised controlled trial of a suitable intervention.

#### 3. For policy makers

Policy makers are given little choice by the paucity of research but to act on good will and hope that if they recommend provision of advice regarding HIV, that it does no harm.

### Implications for research

#### 1. General

We could not identify any randomised trials that assessed the effects of HIV advice in people with serious mental illness, which contradicts the view that current guidance and practice is based on good intentions and expert opinion. Basing care only on evidence from trials is not realistic ([Cooper 2003](#); [Tanenbaum 2005](#)), however, many treatments or approaches that are not appropriately evidenced are given to people, when it is possible to evaluate these approaches. Healthcare professionals may be doing far more good than they realise - or conversely far more harm. As part of a duty of care, we argue, that 'what could be known, should be known'.



## 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, active, education packages regarding HIV 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 the design of randomised studies. We have, however, also given this issue some consideration and suggest a feasible design ([Table 3](#)).

## ACKNOWLEDGEMENTS

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

We are also grateful to Dr Edward J Bryan for providing peer review comments.

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.

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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
Berkman 2006	Allocation: randomised. Participants: schizophrenia, schizoaffective disorder, bipolar, major depressive disorder. Intervention: 'SexG' brief education intervention versus 2-hour standard HIV educational session, not focusing on HIV advice
Berkman 2007	Allocation: randomised. Participants: schizophrenia, schizoaffective disorder, bipolar with psychosis, major depression with psychosis. Interventions: enhanced SexG education intervention versus money management intervention, not focusing on HIV advice
Collins 2001	Allocation: randomised. Participants: schizophrenia, schizoaffective disorder or bipolar disorder. Intervention: education course versus educational presentation, not focusing on HIV advice
Katz 1996	Allocation: randomised. Participants: schizophrenia or bipolar disorder. Intervention: training sessions consisting of education and training, not focusing on HIV advice
Kelly 1997	Allocation: randomised. Participants: mood disorder, schizophrenia or anxiety disorder. Intervention: risk reduction education session versus skills group versus skills group plus advocacy, not focusing on HIV advice
Kern 1996a	Allocation: randomised. Participants: seriously or chronically mentally ill who met diagnostic criteria within DSM-III-R (American Psychiatric Association, 1987). Intervention: AIDS education programme cross over trial, not focusing on HIV advice
Otto-Salaj 2001	Allocation: randomised. Participants: seriously or chronically mentally ill who met diagnostic criteria within DSM-III-R (American Psychiatric Association, 1987). Intervention: 7-session small-group cognitive-behavioral HIV risk reduction intervention or a time-matched comparison intervention, but not focused on HIV advice
Susser 1998	Allocation: randomised. Participants: severe mental illness. Intervention: SexG education intervention versus control intervention based on educational manual, not focusing on HIV advice
Weinhardt 1998	Allocation: randomised. Participants: schizophrenia spectrum disorder, bipolar disorder and major depressive disorder. Interventions: education and training based on risk reduction and assertiveness training, not focusing on HIV advice



## DATA AND ANALYSES

This review has no analyses.

## ADDITIONAL TABLES

Table 1. Series of related reviews

Title	Reference
Physical health care monitoring	<a href="#">Tosh 2010</a>
General physical health advice	<a href="#">Tosh 2011</a>
Advice regarding smoking cessation	<a href="#">Khanna 2012</a>
Advice regarding oral health care	<a href="#">Khokhar 2011</a>
Advice regarding HIV/AIDs prevention	This review
Advice regarding substance use	Protocol in preparation

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

Comparison	Excluded study	
<b>Educational courses</b>		
versus	training course	<a href="#">Katz 1996</a> ; <a href="#">Kern 1996a</a> ; <a href="#">Weinhardt 1998</a>
	financial incentive	<a href="#">Berkman 2007</a>
	educational presentation/manual	<a href="#">Collins 2001</a> ; <a href="#">Susser 1998</a>
	different education course	<a href="#">Otto-Salaj 2001</a>
	skills group	<a href="#">Kelly 1997</a>
	skills group + advocacy	<a href="#">Kelly 1997</a>
<b>Duration of educational course</b>		
- Brief HIV education course vs standard HIV course	<a href="#">Berkman 2006</a>	
<b>HIV Advocacy</b>		
- Skills group + advocacy vs skills group alone	<a href="#">Kelly 1997</a>	

**Table 3. Suggested trial design**

<b>Method</b>	Allocation: randomised, clearly described. Blinding: single - particular to specific outcomes (see below). Duration: 6 months.
<b>Participants</b>	Diagnosis: schizophrenia, or any serious mental illness. N = 300.* Age: any. Sex: both. History: any.
<b>Intervention</b>	1. Health promotion HIV Advice Checklist (Adapted version of the <a href="#">NAPWA 2012</a> checklist guide for people living with HIV) administered by Care Co-ordinator. 2. Standard care: administered by Care Co-ordinator.
<b>Outcomes</b>	HIV infection (any time period). Risk-taking behaviour (short term). Improve physical health (unprotected sex, sexual promiscuity, sharing needles for drug use) Mental state - no clinically important change in general mental state Economic outcomes. Leaving the study early - reason. Adverse vents - clinically important adverse events.
<b>Notes</b>	* For 20% difference between groups for a binary outcome to be highlighted with reasonable degree of confidence 150 people are needed per group

## APPENDICES

### Appendix I. Previous searches

#### Search in 2012

##### Electronic searches

#### 1. Cochrane Schizophrenia Group's Trials Register

The Trials Search Co-ordinator (TSC) searched the Cochrane Schizophrenia Group's Registry of Trials (24 January, 2012) using the following search strategies:

(\*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 REFERENCE AND (\*education\* or \*health promot\* or \*preventi\* or \*motivate\* or \*advice\* or \*monitor\*) in Interventions of STUDY

The Cochrane Schizophrenia Group's Registry of Trials is compiled by systematic searches of major resources (including AMED, BIOSIS, CINAHL, EMBASE, MEDLINE, PsycINFO, PubMed, and registries of clinical trials) and their monthly updates, hand-

searches, grey literature, and conference proceedings (see [Group's Module](#)). There is no language, date, document type, or publication status limitations for inclusion of records into the register.

## Searching other resources

### 1. Reference searching

Had we found studies for inclusion in the review, the references of all included studies would have been inspected to identify any further relevant citations.

### 2. Personal contact

If we had found studies for inclusion in the review, the first author of each study would have been contacted for information regarding unpublished trials.

## WHAT'S NEW

Last assessed as up-to-date: 4 July 2016.

Date	Event	Description
8 July 2016	New citation required but conclusions have not changed	No new studies found, conclusions not changed.
4 July 2016	New search has been performed	Search updated, no new study identified.

## CONTRIBUTIONS OF AUTHORS

Nicola Wright - protocol writing, primary review author, results and discussion writing.

Andrew Clifton - protocol writing, primary review author, results and discussion writing.

Athfah Akhtar - protocol writing, primary review author, results and discussion writing.

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

## DECLARATIONS OF INTEREST

None known.



## **SOURCES OF SUPPORT**

### **Internal sources**

- East Midlands Workforce Deanery, Nottingham, UK.
- NIHR CLAHRC-NDL, University of Nottingham, UK.
- Huddersfield University, UK.
- University of Nottingham, UK.

### **External sources**

- No sources of support supplied

## **DIFFERENCES BETWEEN PROTOCOL AND REVIEW**

None known.

## **NOTES**

None.

## **INDEX TERMS**

### **Medical Subject Headings (MeSH)**

\*Sexual Behavior; HIV Infections [\*prevention & control]; Mental Disorders [\*complications]

### **MeSH check words**

Humans