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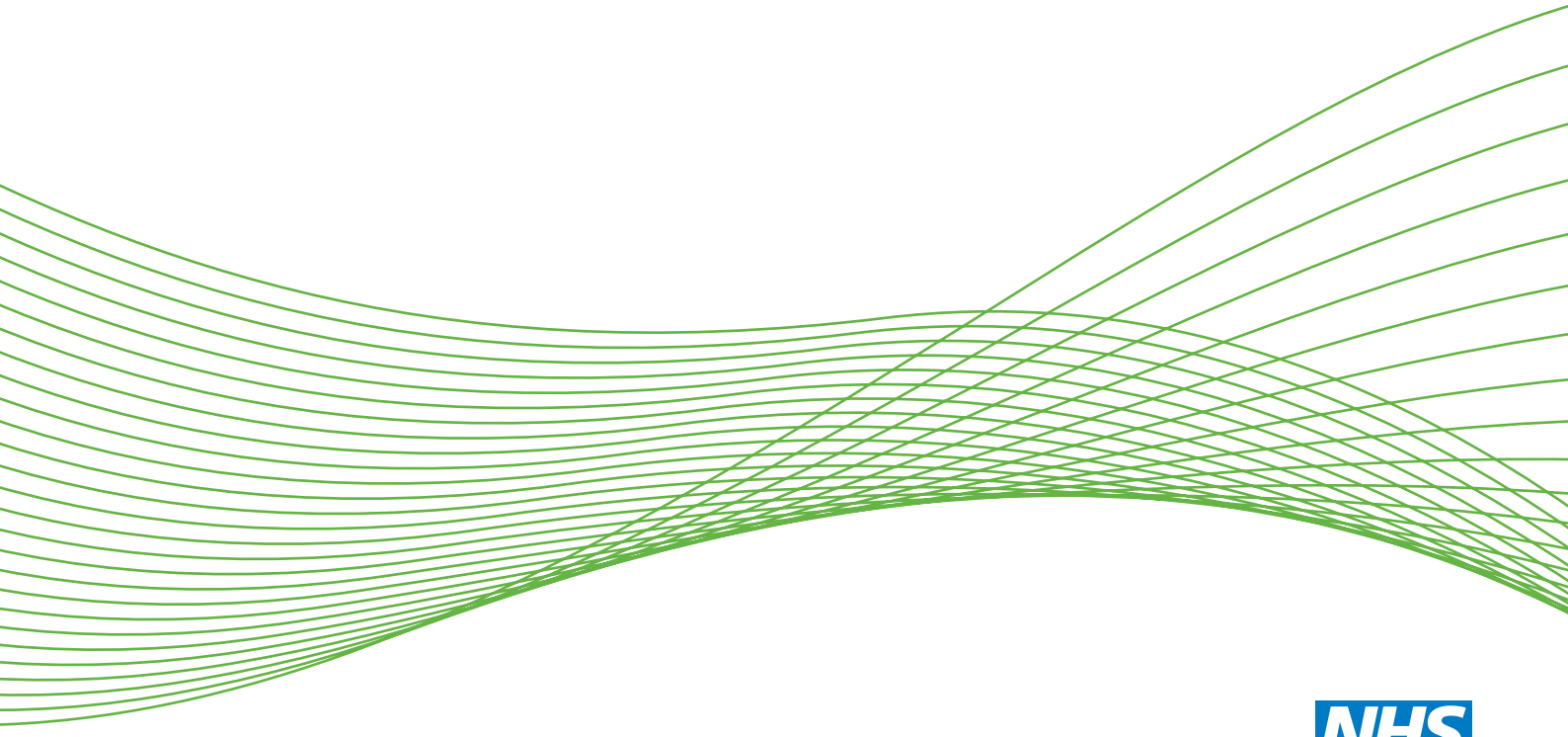

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The effectiveness of sexual health interventions for people with severe mental illness: a systematic review

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Abstract

The effectiveness of sexual health interventions for people with severe mental illness: a systematic review

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Background: Severe mental illnesses (SMIs), such as schizophrenia and bipolar disorder, persist over time and can cause extensive disability leading to impairments in social and occupational functioning. People with SMI have higher morbidity and mortality due to physical illness than the general population and may be more likely to engage in high-risk sexual behaviour (e.g. unprotected intercourse, having multiple partners, involvement in the sex trade and illicit drug use), putting them at risk of poorer sexual health outcomes including sexually transmitted infections. Sexual health promotion interventions, developed and implemented for people with SMI, may improve participants' knowledge, attitudes, beliefs or behavioural practices and could lead to a reduction in risky sexual behaviour.

Objectives: To evaluate the effectiveness of sexual health interventions for people with SMI compared with usual care and their applicability to the UK NHS setting.

Data sources: Thirteen electronic databases were searched from inception to December 2012. All controlled trials (randomised or non-randomised) that met the following criteria were included: any sexual health promotion intervention or combination of interventions intended to change the knowledge, attitudes, beliefs, behaviours or practices of individuals with SMI (defined as adults aged $\geq$ 18 years who have received a diagnosis of schizophrenia or bipolar disorder) living in the community.

Review methods: A systematic review of the clinical evidence was undertaken following recommended guidelines. Data were tabulated and discussed in a narrative review.

Results: Thirteen randomised controlled studies met the inclusion criteria. The methodological quality of the included studies varied considerably, with only a minority of studies ($n = 2$) being considered as having very few methodological limitations. Despite wide variations in the study populations, interventions, comparators and outcomes, four studies showed significant improvements in all measured sexual risk behaviour outcomes (e.g. human immunodeficiency virus knowledge and behaviour change) in the intervention groups compared with the control groups. In contrast, four studies found significant improvements in the intervention groups for some outcomes only and three studies found significant improvements in certain subgroups only, based on either gender or ethnicity. Finally, two studies reported no significant differences in any sexual risk behaviour outcomes between the intervention and control groups. Moreover, positive findings were not consistently sustained at follow-up in many studies.

Limitations: Little detail was provided in the studies regarding the content of interventions, how they were delivered and by whom, making replication or generalisability difficult.

Conclusions: Owing to the large between-study variability (especially in the populations, interventions, comparators and reported outcomes) and mixed results, there is insufficient evidence to fully support or reject the identified sexual health interventions for people with SMI. In addition, there are considerable uncertainties around the generalisability of these findings to the UK setting. Further research recommendations include well-designed, UK-based trials of sexual health interventions for people with SMI as well as training and support for staff implementing sexual health interventions.

Study registration: PROSPERO number CRD42013003674.

Funding: The National Institute for Health Research Health Technology Assessment Programme.

Contents

List of tables

List of figures

Glossary

Severe mental illness Severe and long-lasting mental illness associated with functional impairment that typically involves psychosis (losing touch with reality or experiencing delusions). Someone with a severe mental illness may nevertheless also have long periods when they are well and are able to manage their illness. Examples of severe mental illnesses include schizophrenia and bipolar disorder.

Bipolar disorder A severe mental illness with a long course usually characterised by episodes of depression and also periods of elation and increased activity (mania or hypomania). However, for many people the predominant experience is of low mood. In its more severe forms, bipolar disorder is associated with significant impairment of personal and social functioning.

Schizophrenia A major psychiatric disorder, or cluster of disorders, characterised by psychotic symptoms that alter a person's perceptions and thoughts and affect their behaviour. Each person with the disorder will have a unique combination of symptoms and experiences.

Proxy outcome Outcomes used to demonstrate change where a direct measure is not feasible. A proxy outcome would be used when the outcome of interest cannot feasibly be calculated or when a large sample size may be required to detect change, e.g. changes in sexual health knowledge, attitudes and intentions or self-efficacy.

List of abbreviations

AIDS	acquired immunodeficiency syndrome
EPHPP	Effective Public Health Practice Project
HIV	human immunodeficiency virus
NIHR	National Institute for Health Research
NIMH	National Institute of Mental Health
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RCT	randomised controlled trial
ScHARR	School of Health and Related Research
SexG	Sex, Games and Videotapes
SMI	severe mental illness
STI	sexually transmitted infection
VEE	vaginal episode equivalent

Scientific summary

Background

Severe mental illnesses (SMIs), such as schizophrenia and bipolar disorder, persist over time and can cause extensive disability leading to impairments in social and occupational functioning. While some individuals have long periods when they are well and are able to manage their illness, people with SMI have higher morbidity and mortality due to physical illness than the general population. Many of these individuals will also have co-existing drug and alcohol problems and difficulties in establishing stable and sexual relationships. These issues mean that they may be more likely to engage in high-risk sexual behaviour such as unprotected intercourse, having multiple partners, involvement in the sex trade and illicit drug use than the general population. As a consequence, they are at risk of poorer sexual health outcomes including sexually transmitted infections such as human immunodeficiency virus (HIV) and unintended pregnancies. Sexual health promotion interventions (such as educational and behavioural interventions, motivational exercises, counselling and service delivery), developed and implemented for people with SMI, may improve participants' knowledge, attitudes, beliefs or behavioural practices (including assertiveness skills) and could lead to a reduction in risky sexual behaviour.

Objectives

The aim of this review was to evaluate the effectiveness of sexual health interventions for people with SMI and their applicability to the UK NHS setting, and to identify key areas for primary research.

Methods

Thirteen electronic databases and research registers were searched from inception to December 2012. Searches were supplemented by hand-searching relevant articles (including citation searching), systematic keyword searches of the internet and mental health organisation websites, and contacting experts in the field. The systematic review included all controlled trials (randomised or non-randomised) that met the following criteria: any sexual health promotion intervention or combination of interventions (e.g. educational, behavioural, psychological, counselling, etc., delivered at the individual, group or community level) intended to change the knowledge, attitudes, beliefs, behaviours or practices of individuals with SMI (defined as adults aged $\geq$ 18 years who have received a diagnosis of schizophrenia or bipolar disorder) living in the community. Adults with dementia, personality disorder or intellectual disability were excluded as they were not included in our definition of SMI. The methodological quality of each included study was assessed using the Effective Public Health Practice Project tool for quantitative studies. Data were tabulated and discussed in a narrative review. A meta-analysis was not possible because of the heterogeneity of study designs, interventions and types of outcome data available.

Results

The literature searches identified 2590 citations. Of these, 13 randomised controlled studies (representing 14 references) met the inclusion criteria. The methodological quality of the included studies varied considerably with only a minority of studies ($n = 2$) being considered as having very few methodological limitations. The content of the health promotion interventions for improving sexual health varied between studies but generally included strategies to increase knowledge, assess and reduce sexual health risk, change behaviour and develop condom skills. The duration of the interventions ranged from four to

15 sessions. Standard usual care included educational sessions on HIV, money management, or HIV and substance misuse, waiting list or no treatment, or health promotion covering a variety of topics. Most studies included participants with a range of psychiatric diagnoses, which included schizophrenia, schizoaffective disorder, bipolar affective disorder and major depressive disorders. Despite wide variations in the study populations, interventions (e.g. programme content and duration), comparators and outcomes, four studies showed significant improvements in all measured sexual risk behaviour outcomes (e.g. HIV knowledge and behaviour change) in the intervention groups compared with the control groups. In contrast, four studies found significant improvements in the intervention groups for some outcomes only and three studies found significant improvements in certain subgroups only, based on either gender or ethnicity. Finally, two studies reported no significant differences in any sexual risk behaviour outcomes between the intervention and control groups. Moreover, positive findings were not consistently sustained at follow-up in many studies.

Discussion and conclusions

Owing to the large between-study variability (especially in the populations, interventions, comparators and reported outcomes) and mixed results, there is insufficient evidence to fully support or reject the identified sexual health interventions for people with SMI. In addition, there are considerable uncertainties around the generalisability of these findings to the UK setting as all the evidence is based on studies from the USA. The ethnic groups represented in the included studies, for example, are not directly comparable to those in the UK. On account of study heterogeneity, issues with generalisability and the methodological quality of the included studies, the findings need to be interpreted with caution. Further research recommendations include well-designed, UK-based trials of sexual health interventions for people with SMI and an assessment of the location and costs of proposed services, as well as training and support for staff implementing sexual health interventions. In addition, patient acceptability of proposed interventions also needs to be given careful consideration.

Study registration

This study is registered as PROSPERO:CRD42013003674.

Funding

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Chapter 1 Background

Description of the health problem

Severe mental illness (SMI) describes a wide range of major psychiatric disorders (including schizophrenia and bipolar disorder)[1] which persist over time and cause extensive disability leading to impairments in social and occupational functioning.[2] There are occasional inconsistencies in the use of the term and some studies may include severe anxiety and depressive symptoms and borderline personality. Schizophrenia is estimated to affect approximately 180,471[3] to 220,000[4] people in the UK and bipolar disorder approximately 136,440[3] to 297,000.[5] The incidence of schizophrenia is higher in men than in women[6] whereas bipolar disorder is equally distributed.[5] Incidence rates among black and ethnic minority groups are higher than in a comparable white population.[5,6] About 45% of people who receive a diagnosis of schizophrenia experience recovery after one or more episodes, but about 20% show continuous symptoms and increasing disability and the remaining 35% show a mixed pattern with varying periods of remission and relapse.[7] For most patients, bipolar disorder is chronic and recurrent. Recovery may or may not be complete between episodes. Considerable variability exists in the pattern of remissions and relapses; however, remissions tend to get shorter as time goes on and depressions become more frequent and longer lasting.[5]

People with SMI have higher morbidity and mortality due to physical illness than the general population.[8,9] De Hert *et al.*[10] reported prevalence rates of several physical illnesses in people with SMI. They found nutritional and metabolic, cardiovascular, viral, respiratory tract and musculoskeletal diseases as well as sexual dysfunction, pregnancy complications, stomatognathic diseases and possibly obesity-related cancers to be more prevalent among people with SMI. Levels of obesity are extremely high among people with SMI – nearly twice those of the overall population.[11] This can have a perceived effect on sexual attractiveness and consequent functioning. Daumit *et al*.[11] conducted a randomised controlled trial (RCT) to address this serious problem. The study of overweight or obese adults with SMI used a behavioural weight loss intervention programme and resulted in significantly reduced weight over a period of 18 months in the group of patients receiving the intervention.

Reasons for physical health problems in people with SMI were explored by Robson and Gray,[9] who found that limitations in health services, the effects of having a SMI, health behaviours and the effects of psychotropic medication may contribute to disparities in health. A systematic review by Tosh *et al*.[12] found no evidence from RCTs that physical health-care monitoring for people with SMI is useful in preventing deterioration in physical health and maintaining quality of life, although the authors add that this does not mean that physical health monitoring does not affect the physical health of people with SMI.

People with SMI are often on medications, which may have an impact on sexual function. The European Schizophrenia Outpatient Health Outcome (SOHO) study,[13] a large prospective, observational study of the health outcomes associated with antipsychotic treatment in approximately 11,000 outpatients with schizophrenia in 10 European countries, found that sexually related adverse events were frequent at baseline before commencing medication and included erectile dysfunction in 40% of men and loss of libido in 50% of both male and female patients. The study also found that some second-generation atypical antipsychotics such as olanzapine (ZypAdhera®, Eli Lilly and Company), clozapine (Zaponex®, TEVA UK) and quetiapine (Seroquel®, AstraZeneca) were significantly less likely to result in drug-induced sexual dysfunction after six months of treatment than other atypical antipsychotics [risperidone (Risperdal Consta®, Janssen-Cilag Ltd) and amisulpride (Solian®, Sanofi-aventis)]. Montejo *et al*.[14] report in a study of 243 patients with a psychotic disorder that 46% of patients exhibited drug-related sexual dysfunction, which included 50% of the males and 37% of females in the study. A review by Baggaley[15] that looked at the relative impact of antipsychotics on sexual dysfunction found that risperidone was associated with

the greatest level of sexual dysfunction and aripiprazole (Abilify®, Bristol-Myers Squibb) with the least. Sexual dysfunction included reduced libido, erectile dysfunction, ejaculatory difficulties and impaired orgasm in men and menstrual irregularity/amenorrhoea, reduced libido, impaired orgasm and decreased vaginal lubrication in women. Various strategies have been suggested for the management of sexual dysfunction due to antipsychotic drug therapy, including dose reduction, drug holidays, adjunctive medication and switching to another drug. These options were reviewed by Schmidt *et al*.,[16] who found little evidence to support these strategies, although sildenafil (Viagra®, Pfizer; Revatio®, Pfizer), a drug typically prescribed to men to treat erectile dysfunction, was considered to be a useful treatment option in men with schizophrenia. Although antipsychotic medication is an important cause of sexual dysfunction in SMI, Aizenberg *et al*.[17] found that even patients with a diagnosis of schizophrenia who were not receiving medication exhibited decreased sexual desire. Few studies have examined diagnostic differences and sexual activity and results have been inconclusive.[18]

People with SMI are more likely to engage in high-risk sexual behaviour (e.g. unprotected intercourse, having multiple partners, involvement in the sex trade and illicit drug use), putting them at risk of poorer sexual health outcomes, including sexually transmitted infections (STIs), e.g. with human immunodeficiency virus (HIV).[2,19,20] HIV infection rates among people with SMI have been estimated to be approximately 6.9%, much higher than rates for the general US population for the same time period, estimated to be 0.4%.[18] The HIV infection range among those with SMI is reported to be 3–23%, with the highest rates found among those with SMI and substance abuse disorders.[21] Homeless people with SMI were also reported to have higher rates. Among people with SMI, the age and ethnic distributions of those infected with HIV appear to be similar to those in the general population, although women with SMI are as likely as males to be infected with HIV, in contrast to the general US population, in which the ratio of men to women is 5 : 1.[18] A number of risk behaviours are thought to contribute to the higher rates of HIV among people with SMI, and these include comorbid alcohol and drug use disorders; more frequent same-sex intercourse than the non-psychiatric population; multiple sex partners; lack of condom use; trading sex for drugs or money; and transient living circumstances, among others.[18] A review of the risk behaviour associated with people with SMI explored this more fully.[2] The authors found 52 studies which showed that the majority of adults with SMI were sexually active and engaged in risk behaviours associated with HIV transmission. Correlates of HIV risk were organised into the domains of psychiatric illness, substance use, childhood abuse, cognitive behavioural factors, social relationships and demographics. Most studies identified in this review found that people with a schizophrenia spectrum disorder were significantly less likely to be sexually active compared with those with other major psychiatric disorders. Although many correlates of HIV risk factors were identified in this review, the authors suggest caution in view of the cross-sectional design of many studies and the heavy reliance on univariate analyses. Most studies also recruited participants from centres where they were receiving treatment; thus, the results may not be generalisable to people with SMI who do not seek or receive mental health care. Meade *et al*.[22] reviewed the evidence regarding the relationship between substance abuse and HIV sexual risk behaviour among people with SMI. The authors concluded that little is known about how substance misuse contributes to sexual health risk. Gray *et al*.[19] reported that, although people with schizophrenia are more likely than the general population to engage in high-risk behaviours (e.g. men having sex with men, illicit drug use and having multiple sexual partners), many health policy reports do not address the risk of HIV in people with schizophrenia and recommend that research, policy and clinical practice need to be developed to address this issue.

Many individuals with SMI will also have co-existing drug and alcohol problems[23] and difficulties in establishing stable and sexual relationships.[9] O'Cleirigh and Safren[24] suggest that those with SMI and substance use disorders present complexities that may be better suited to adapted or modified models of cognitive behavioural therapy to support HIV prevention. The authors suggest that these models need to incorporate design elements of efficacy (such as random assignment) and design elements that support external validity (such as usual treatment comparison). Individuals with SMI report high rates of childhood sexual abuse, which is associated with sexual risk behaviour in individuals with SMI as well as in the general population.[25]

Sexual health promotion interventions (such as educational and behavioural interventions, motivational exercises, counselling and service delivery), developed and implemented for people with SMI, may improve participants' knowledge, attitudes, beliefs or behavioural practices (including assertiveness skills) and could lead to a reduction in risky sexual behaviour.[20] McCann[26] states that although there have been many initiatives in the UK to make health and social care more responsive and inclusive, the sexual needs of individuals with psychosis appear to remain marginalised and neglected. In this study of 30 people with schizophrenia living in community, 90% of clients felt some need in relation to sexual expression and only 10% of staff recognised sexual expression as a need in their clients.

Two narrative reviews of interventions to improve the sexual health of people with SMI were identified. Johnson-Masotti *et al*.,[27] in their review of the clinical effectiveness and cost-effectiveness studies of HIV prevention interventions, report that the studies identified in their review have shown only limited success in helping people with SMI reduce their HIV risk. The cost-effectiveness literature they identified also showed mixed results. Higgins *et al*.[20] undertook a review on sexual health education. The authors identified six studies that were descriptive or anecdotal, three using post-evaluation or pre–post-evaluation designs and five studies with a randomised intervention design. The review found that people who attended sexual health education programmes which were facilitated in a sensitive and supportive manner developed attitudes more favourable to condom use, improved intention to avoid unsafe sexual practices, reduced the number of casual partners and were less likely to engage in unprotected vaginal intercourse. Education tended to produce a self-reported reduction in sexual risk behaviour as opposed to complete cessation. Small-group interventions combining information giving, motivational exercises and skills acquisition were found to be effective in reducing sexual risk behaviour and raising awareness of personal risk behaviour. The authors highlight the limitations of the included studies such as small sample size, lack of quality tools tested for reliability and validity and short follow-up periods. Most outcomes were self-reported and participants were self-selected. Studies did not describe method of random allocation or provide information on refusal or attrition rates and were mostly conducted in the USA.

Other studies identified in the literature explored different aspects of sexual health interventions. Melo *et al*.[28] conducted a cross-sectional national multicentre study throughout Brazil to measure HIV/acquired immunodeficiency syndrome (AIDS) knowledge among patients with mental illness. The study included 2475 patients from 26 mental health institutions. The authors found that psychiatric patients in Brazil lag behind the general population with regard to HIV/AIDS knowledge scores. Sikkema *et al*.[21] report a pilot study involving a community level HIV prevention programme for people with SMI living in supportive housing. This study of 28 residents involved a cognitive behavioural skills training HIV risk reduction programme and a 4-month follow-up period. The results were considered promising and demonstrated significant improvements in psychosocial risk factors with indications of sexual behaviour change at follow-up. DiFranceisco *et al*.[29] looked at differences between completers and early dropouts from two HIV intervention trials, including one with severely mentally ill participants. Non-attendees in the SMI group were younger than completers, more likely to associate condom use with positive outcomes and somewhat more confident of their ability to negotiate safe sex with their partners. Johnson-Masotti *et al*.[30] assessed the cost-effectiveness of a RCT by Kelly *et al*.,[31] which had three interventions: single session, one-on-one, multisession small group and multisession small-group advocates. For men, all three were found to be cost-effective, with advocacy training the most cost-effective. Cost-effectiveness was measured using cost–utility analysis in terms of the quality-adjusted life-years saved by the intervention as a result of preventing participants from becoming infected with AIDS. For women, only the single-session intervention was cost-effective.

Blank and Hennessy[32] explored the feasibility of a reasoned action approach for this population through the use of two interventions: Preventing AIDS Through Health (PATH), delivered by case managers to persons with mental illnesses who were HIV negative, and PATH PLUS, delivered by nurses to persons with mental illness who were HIV positive. The authors concluded that this approach may be useful for changing behaviour and intentions in people with SMI. As part of the same study, Tennille *et al*.[33] conducted focus groups and interviews with case managers and administrators to determine changes in

the service and the case managers as a result of their skills training and experience. Case managers felt transformed by their training experience and that this improved their understanding of the issues around sexual health faced by their clients. In a related study by Tennille *et al*.,[34] the researchers held focus groups with people with mental illnesses to focus on HIV risks and condom use. Participants discussed the sexual side effects of medication and how this may be associated with HIV risk behaviours, such as not using a condom. A final qualitative study by Solomon *et al*.[35] used rapid assessment procedures to look at HIV prevention services, and found that case managers had little formalised training on HIV prevention and felt that doctors or nurses would be better placed to deliver HIV prevention interventions.

The studies described above highlight the challenges and risk of poor sexual health outcomes (including establishing relationships) encountered by people with SMI, which may be exaggerated by co-existing drug and alcohol problems. The purpose of this review is to evaluate the effectiveness of sexual health interventions that may be suitable for people with SMI in the UK.

Current service provision

Health promotion interventions, whether brief interventions or longer-term programmes, are used to improve various aspects of health and health behaviours. Interventions can be delivered at different levels (individual, group and community) through an action or group of actions intended to change the knowledge, attitudes, beliefs or behavioural practices of individuals and populations to reduce their sexual health risk.[36] Individual-level interventions focus on one individual at a time in an attempt to help change behaviour and may include partner notification, individual risk counselling by professionals and detached education and outreach (for those not accessing mainstream services). Group-level interventions are delivered to small groups of individuals. Group-level interventions use peer and non-peer models involving a range of skills, information and support. Community-level interventions are delivered by or within a defined 'community'. They seek to improve the risk conditions and influence behaviour by changing social norms, policies or characteristics of the environment.[36,37]

Mental health nurses and other professionals working with people with SMI would be well placed to include sexual health as part of their contribution to health promotion.[20] A study by Apantaku-Olajide *et al*.[38] used a survey questionnaire to determine mental health patients' attitude to psychotropic medication for sexual dysfunction and found that participants were willing to discuss their sexual problems with health-care professionals. However, staff may require specific training in order to deliver such interventions. In a qualitative study of 27 mental health nurses in Ireland, Higgins *et al*.[39] found that the main concerns reported by the nurses around sexuality were related to feelings of personal and professional vulnerability, due to a lack of competence, comfort and confidence in this area. Penna and Sheehy[40] administered questionnaires to occupational therapists involved in the care of people with SMI in the UK to determine their attitudes towards sex education for people with schizophrenia. The majority of occupational therapists thought sex education was within the domain of their profession but were not providing sex education currently. The study found that the length of time in practice and knowledge of employers' policies may influence this. In NHS Shetland all mental health staff working with people with psychiatric illnesses receive sexual health training,[36] although it is not clear exactly what this training includes and whether or not this varies with different types of staff.

Overall aims and objectives of assessment

The review will aim to evaluate the following objectives:

1. evaluate the effectiveness of sexual health interventions for people with SMI compared with usual care and their applicability to the UK NHS setting
2. identify key areas for primary research.

Chapter 2 Assessment of clinical effectiveness

A systematic review of the literature was undertaken to evaluate the effectiveness of sexual health interventions for people with SMI compared with usual care. A review of the evidence was undertaken in accordance with the general principles recommended in the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (www.prisma-statement.org).

Methods for reviewing effectiveness

Identification of studies

Electronic databases

Studies were identified by searching the following electronic databases and research registers:

- MEDLINE(R) In-Process & Other Non-Indexed Citations and MEDLINE(R) (Ovid) 1948 to December 2012
- EMBASE (Ovid) 1980 to December 2012
- Cumulative Index to Nursing and Allied Health Literature (CINAHL; EBSCO) 1982 to December 2012
- Cochrane Database of Systematic Reviews (Wiley Online Library) 1996 to December 2012
- Cochrane Central Register of Controlled Trials (CENTRAL; Wiley Online Library) 1898 to December 2012
- Health Technology Assessment Database (HTA; Wiley Online Library) 1995 to December 2012
- Database of Abstracts of Reviews of Effects (DARE; Wiley Online Library) 1995 to December 2012
- Psychological Information Database (PsycINFO; Ovid) 1806 to December 2012
- Conference Proceedings Index-Science (Web of Science) 1990 to December 2012
- Conference Proceedings Citation Index-Social Science & Humanities (Web of Science) 1990 to December 2012
- UK Clinical Research Network (CRN) Portfolio Database [National Institute for Health Research (NIHR)] (www.crncc.nihr.ac.uk)
- ClinicalTrials.gov (US NIH) (www.clinicaltrials.gov)
- The *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com/mrct/).

Sensitive keyword strategies using free text and, where available, thesaurus terms using Boolean operators and database-specific syntax were developed to search the electronic databases. Synonyms relating to the condition (e.g. severe mental illness) were combined with terms for sexual health interventions (e.g. sexual behaviour, sexually transmitted diseases and sexual health). A pre-defined validated methodological filter aimed at restricting search results to controlled trials was used in the searches of MEDLINE, EMBASE, CINAHL and PsycINFO. Date and language restrictions were not used on any database. An example of the MEDLINE search strategy is provided in *Appendix 2*.

Other resources

To identify additional published, unpublished and ongoing studies, the reference lists of all relevant studies (including identified reviews) were checked for relevant studies and a citation search of relevant articles (using the Web of Knowledge's Science Citation Index and Social Science Citation Index) was undertaken to identify articles that cite the relevant articles. In addition, systematic keyword searches of the internet and organisational websites, especially in the context of the UK (e.g. Royal College of Psychiatrists, British Psychological Society, Department of Health, Welsh Assembly Government, International AIDS Society, the Campbell Collaboration and National Collaborating Centre for Mental Health) were undertaken and key experts in the field were contacted.

All identified citations from the electronic searches and other resources were imported into and managed using the Reference Manager bibliographic software, version 12.0 (Thomson Reuters, Philadelphia, PA, USA).

Inclusion and exclusion criteria

The inclusion of potentially relevant articles was undertaken using a two-step process. First, all titles were examined for inclusion by one reviewer. Any citations that clearly did not meet the inclusion criteria (i.e. non-human, unrelated to sexual health interventions for people with SMI) were excluded. Second, all abstracts and full-text articles were examined independently by two reviewers. Any disagreements in the selection process were resolved through discussion. The relevance of each article for the systematic review was assessed according to the following criteria.

Study design

All controlled trials (randomised or non-randomised) that evaluated sexual health interventions with usual care for adults with SMI were included. Before-and-after studies without a concurrent control group were excluded because the absence of a control group to record concurrent changes over time means that changes due to the intervention or due to temporal trends, concurrent changes or a Hawthorne effect would be conflated. Such studies therefore represent very weak evidence of effectiveness.[41,42]

Reviews of primary studies were not included in the analysis, but were retained for discussion and identification of additional studies. Moreover, the following publication types were excluded from the review: animal models; preclinical and biological studies; editorials; opinions; non-English-language papers; and reports published as meeting abstracts only, where insufficient methodological details are reported to allow critical appraisal of study quality. Studies from developing countries were also excluded as it is difficult to generalise (e.g. transferability and acceptability) the characteristics of the effective interventions to developed countries.

Population

The population comprised adults (defined as $\geq$ 18 years of age) with SMI living in the community and their carers or staff. SMI was defined as people who have received a diagnosis of schizophrenia or bipolar disorder.[1] Adults with dementia, personality disorder, chronic depression or intellectual disability were excluded as they are not included in the definition of SMI.

Interventions

Any health promotion intervention or combination of interventions (e.g. educational, behavioural, psychological, counselling, etc. delivered at individual, group and community levels) intended to change the knowledge, attitudes, beliefs, behaviours or practices of individuals and populations to improve their sexual health were included. Interventions that focused on sexual dysfunction and sexual violence or prescribed drugs were excluded.

Relevant comparators

The relevant comparator was considered as standard usual care in the community. This may involve ad hoc advice on health risks by health-care professionals working with people with SMI, but is not integrated into routine practice. Studies including active control groups were also included.

Outcomes

The outcomes of the review included the following:

- biological: STIs (including HIV), unintended pregnancy
- behavioural: numbers of partners, use of contraception/condoms, uptake of screening or treatment services
- proxy: knowledge, attitudes and beliefs, barriers and facilitators, intentions, skills.

Data abstraction strategy

Data abstraction was performed by one reviewer into a standardised data extraction form and independently checked for accuracy by a second. Discrepancies were resolved through discussion. Where multiple publications of the same study were identified, data were extracted and reported as a single study. Where necessary, authors of the included studies were contacted to provide further details or clarification.

The following information was extracted for all studies when reported: study characteristics (e.g. author, year of publication, country, duration of follow-up, funding); participant details (e.g. age, sex, diagnosis, level of education, marital status, comorbidities); intervention and comparator details (e.g. description, frequency of measurement, parameters measured); and outcomes (including definitions).

Quality assessment strategy

The methodological quality of each included study was assessed by one reviewer and independently checked by another. Disagreements were resolved through discussion. The study quality characteristics were assessed according to (adapted) criteria based on those proposed by the Effective Public Health Practice Project (EPHPP) (www.ephpp.ca/Tools.html).[43] This is a generic tool used to evaluate a variety of intervention study designs such as controlled trials and observational studies. This tool has been judged suitable for use in systematic reviews of effectiveness[44] and has been reported to have content and construct validity.[43,45] Consideration of study quality included the following six criteria: (1) selection bias – the extent to which study participants were representative of the target population; (2) study design; (3) control of confounders; (4) blinding – whether outcome assessors, intervention providers and participants were aware of the research question; (5) data collection methods; and (6) withdrawals and dropouts. The six domain-based criteria were each rated as strong, moderate or weak depending on the characteristics of each criterion reported in the included study. An overall assessment of study quality was based on the following ratings: studies with at least four criteria rated as 'strong' and with no criteria rated as 'weak', were given an overall rating of 'strong'. Those studies receiving less than four 'strong' ratings and only one 'weak' rating were given an overall rating of 'moderate'. A rating of 'weak' was given if two or more criteria were rated as 'weak'. Additional study quality criteria included an assessment of intervention integrity, statistical analysis and generalisability to the UK. Further details of the assessment tool (and dictionary) are provided in *Appendix 3*.

Methods of data synthesis

Data were tabulated and discussed in a narrative review. A meta-analysis was not possible owing to the heterogeneity of study designs, interventions and types of outcome data available.

Results

Quantity and quality of research available

Number of studies identified and included

The literature searches identified 2590 citations. Of these, 13 studies (representing 14 references)[31,46–58] met the inclusion criteria. These studies were all defined by the authors as RCTs. A flow chart describing the process of identifying relevant literature can be found in *Figure 1*.

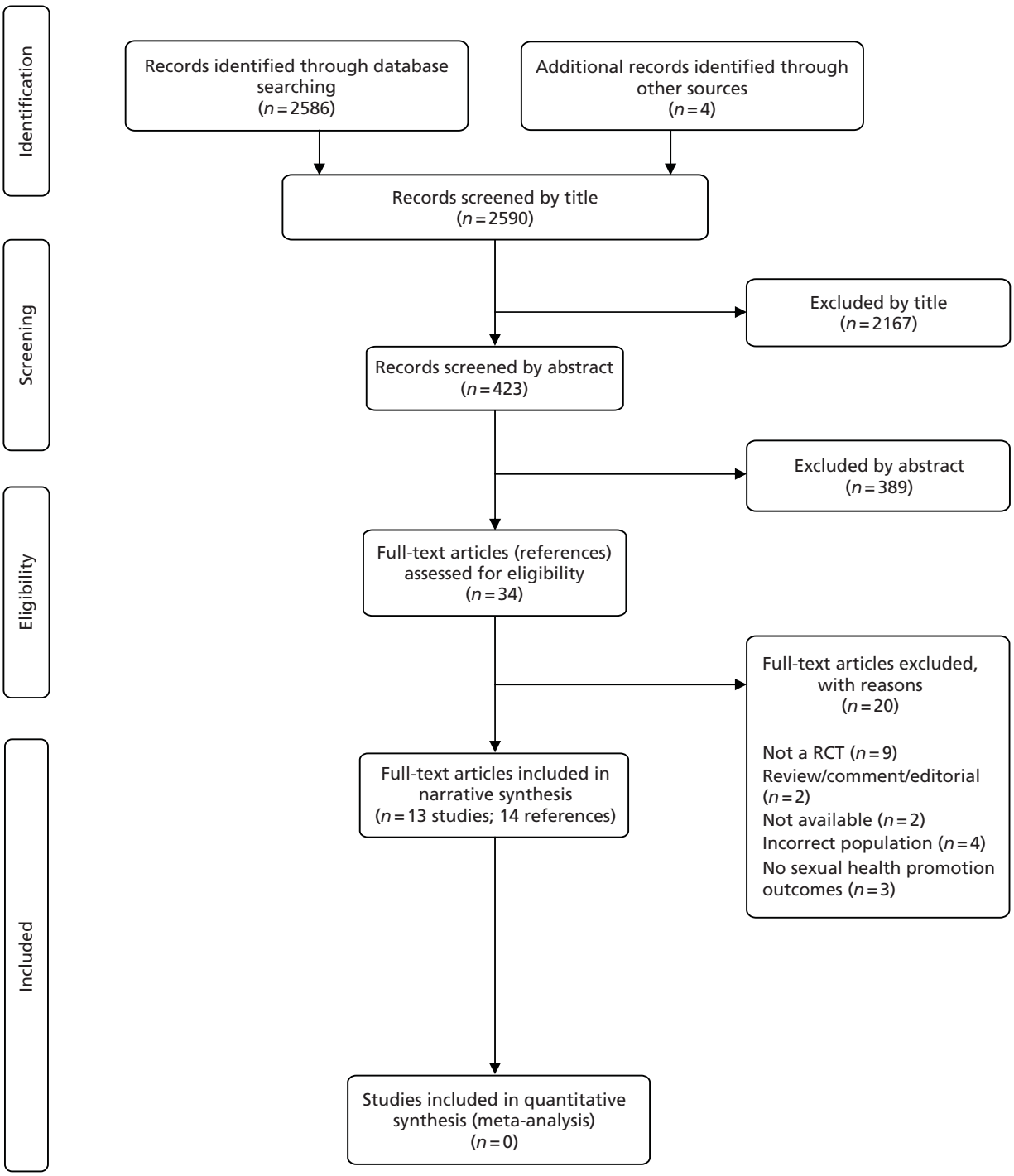

FIGURE 1 Study flow chart (adapted PRISMA diagram).

Number and type of studies excluded

A total of 20 full-text articles were excluded as they did not meet all the pre-specified inclusion criteria. The majority of the articles were excluded primarily on the basis of inappropriate study design (not controlled clinical trials),[21,28,32–35,40,59,60] incorrect population (adolescents,[61] inpatients only[62] or patients without SMI),[63,64] outcomes not identified in the protocol,[65–67] not available[68,69] or unsuitable publication type (reviews, commentaries or editorials).[70,71] Of the two studies that were not available, one study appeared to be a conference abstract[69] of an included study (Susser *et al*.[56]). The other study,[68] which was identified on a trials register, was a planned open-label RCT that was designed to evaluate the effectiveness of motivational interviewing plus skill-building exercises compared with behavioural skill-building exercises alone in reducing HIV risk behaviour in people with SMI. Although the authors of the study were contacted, no further details were forthcoming, including information on study completion (and if the results were unpublished) or recruitment failure. A full list of excluded studies with reasons for exclusion is presented in *Appendix 4*.

Description of included studies (design and study characteristics)

The study characteristics of the included studies are shown in *Table 1* and presented as described in the studies. All studies were published between 1996 and 2012, included populations with mental illness and were conducted in the USA. It should be noted that not all studies used the term 'severe mental illness', with other descriptions used including 'chronically mentally ill outpatients' (Katz *et al*.[52] and Kalichman *et al*.[51]). The population groups are briefly described in *Table 1*. Sample sizes ranged from 20 (Weinhardt *et al*.[58]) to 408 (Carey *et al*.[49]) patients. Study populations were recruited from different settings and included homeless shelters (Berkman *et al.*,[46,47] Linn *et al*.[53] and Susser *et al*.[56]), outpatient psychiatric clinics [Berkman *et al.*,[48] Carey *et al.*,[49] Kalichman *et al.*,[51] Kelly *et al.*,[31] National Institute of Mental Health (NIMH),[57] Otto-Salaj *et al*.[55] and Weinhardt *et al*.[58]], residential facilities in a community setting (Collins *et al*.[50]), a drop-in socialisation centre (Katz *et al*.[52]), and a treatment programme for substance misusers (Malow *et al*.[54]). Length of follow-up ranged from 2 weeks (Katz *et al*.[52]) to 18 months (Susser *et al*.[56]).

The content of the health promotion interventions for improving sexual health varied and included strategies to increase knowledge, assess and reduce sexual health risk, change behaviour and develop condom skills. These are more fully described in *Table 1*. Sex, Games and Videotapes (SexG) was used in two studies (Linn *et al.*[53] and Susser *et al*.[56]), while variations of SexG were used in two additional studies including SexG-Brief (Berkman *et al*.[46,47]) and enhanced SexG (Berkman *et al*.[48]). Other studies included HIV risk reduction programmes (Carey *et al.*,[49] Katz *et al.*[52] and Kelly *et al*.[31]), HIV prevention interventions (Collins *et al.*,[50] Kalichman *et al.*[51] and Otto-Salaj *et al.*[55]), enhanced cognitive behavioural skill building (Malow *et al*.[54]), a sexual assertiveness intervention (Weinhardt *et al*.[58]) and Project LIGHT (Living in Good Health Together), covering HIV prevention and reduction (NIMH[57]). The duration of the intervention sessions ranged from four (Kalichman *et al.*[51] and Katz *et al*.[52]) to 15 sessions (Susser *et al*.[56]).

The standard care in the control groups included educational sessions on HIV (Berkman *et al.*,[46,47] Kelly *et al.*,[31] Linn *et al*.[53] and NIMH[57]), money management (Berkman *et al.*,[48] Collins *et al.*[50] and Susser *et al.*[56]) or HIV and substance misuse (Carey *et al.*[49]), waiting list or no treatment (Kalichman *et al.*,[51] Katz *et al.*[52] and Weinhardt *et al*.[58]), or health promotion covering a variety of topics (Malow *et al*.[54] and Otto-Salaj *et al*.[55]).

Sources of funding were not reported in four studies (Berkman *et al.*,[46,47] Katz *et al*.[52] and Weinhardt *et al*.[58]). The majority of studies were funded at least in part by the NIMH in the USA.

TABLE 1 Summary of RCT study characteristics

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
Berkman *et al.*, 2006,[46,47] New York, USA	92	Men attending a homeless shelter with SMI	Social skills intervention (SexG-Brief: six sessions). Interventions included the following:[46] 1. a humorous videotape to increase knowledge, increase sense of personal risk and introduce condom use 2. promote individual risk assessment through storytelling; increase intent and motivation for condom use through role playing 3. condom use skills; negotiating use 4. behavioural change options including how to respond to a partner's request for condoms; condom skills 5. education on risk from unprotected anal sex to reduce practice 6. problem-solving skills; condom skills; graduation ($n = 50$, of whom 33 sexually active)	Standard (2-hour) HIV educational session ($n = 42$, of whom 23 sexually active)	*Intervention*: Two 60-minute sessions per day, every other day (total six sessions) *Control*: One 120-minute session Follow-up: 6 months	Details not reported but authors state study underpowered	Not reported

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
Berkman *et al.*, 2007,[48] New York, USA	149	Men with SMI attending an outpatient psychiatric clinic	Social skills intervention (enhanced SexG: 10 sessions). Interventions included the following: 1. increase knowledge, and sense of personal risk 2. promote individual risk assessment through storytelling; increase intent and motivation for condom use through role playing 3. condom use skills; negotiating use 4. identify and problem solve barriers to condom use 5. behavioural change options including how to respond to a partner's request for condoms; condom skills 6. education on risk from unprotected anal sex to reduce practice 7. modify behaviour and practice 8. develop ethics and goals for protecting themselves and a partner 9. evaluate personal goals, problem-solving skills 10. increase commitment to practising safer sex, increase problem-solving and condom skills; graduation ($n = 73$)	Money-management group with matched treatment for dosage and format of the intervention group ($n = 76$)	*Intervention*: Ten 60-minute sessions. First eight sessions twice a week for 4 weeks, followed by 4-week break and then final two sessions. Booster sessions at 3, 6 and 9 months Follow-up: 12 months	Details not reported but authors state study underpowered	NIMH, USA

continued

TABLE 1 Summary of RCT study characteristics (*continued*)

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
Carey *et al.*, 2004,[49] New York, USA	408	Men and women receiving outpatient psychiatric care for a mental illness	*HIV group*: Standard care plus attending a 10-session HIV risk reduction programme. Sessions included enhancing knowledge about HIV transmission, and prevention, motivation for behaviour change and strengthening behavioural skills and self-management training ($n = 142$) *SUR intervention group*: Standard care plus attending a 10-session reduction (substance abuse) programme. Sessions included enhancing knowledge, motivation and skills to reduce caffeine consumption, smoking, and alcohol use ($n = 140$)	Standard care which included HIV and substance use education, if needed ($n = 126$)	*HIV and SUR groups*: Twice weekly for 5 weeks (total 10 sessions) Follow-up: 6 months	Not reported	NIMH, USA
Collins *et al.*, 2011,[50] New York, USA	79	Women with SMI residing in an urban community setting	HIV prevention intervention with social cognitive theory, with focus on self-efficacy and skills training Sessions included increasing knowledge and awareness of HIV and STI risk, and sense of personal risk; HIV prevention methods and contraceptive options; asserting oneself and	Money-management group (10-session workshop on managing finances and making money last through the month) ($n = 40$)	Twice weekly for 5 weeks (total 10 sessions) Follow-up: 6 months	Details not reported but authors state study underpowered	NIMH and Robert Wood Johnson Harold Amos Medical Faculty Development Program, USA

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
			negotiating sexual encounters safely; condom use skills; negotiating use of condoms, identifying and problem-solving barriers to condom use and making commitment to self-protection (*n* = 39)				
Kalichman *et al.*, 1995,[51] WI, USA	52	Men and women receiving outpatient psychiatric community support for a chronic mental illness	HIV prevention intervention based on behavioural skills training (risk education and skills instruction). Intervention included education on risk reduction, sexual assertiveness, negotiation skills (risk-related behavioural self-management), condom use and problem-solving skills (*n* = 23)	Waiting list group (who later received the intervention) (*n* = 29)	Four weekly 90-minute sessions Follow-up: 2 months	Details not reported but authors suggest study underpowered	NIMH, USA
Katz *et al.*, 1996,[52] CA, USA	27	Men and women from a drop-in socialisation centre for psychiatric outpatients with a chronic mental illness	AIDS education and risk reduction training programme. Intervention included education about HIV and AIDS, refusal skills training and problem-solving skills (*n* = 15)	No treatment (*n* = 12)	Four 2-hour (8 hours) group training over 4 consecutive days Follow-up: 2 weeks	Details not reported but authors suggest study underpowered	Not reported
Kelly *et al.*, 1997,[31] WI, USA	104	Men and women with SMI receiving outpatient psychiatric care	Intervention 1: Cognitive–behavioural intervention that focused on behaviour changes to reduce the risk of contracting HIV	A single 60-minute AIDS education session (*n* = 28)	Cognitive–behavioural therapy included seven 90-minute group sessions	Details not reported but authors suggest study underpowered	NIMH, USA

continued

TABLE 1 Summary of RCT study characteristics (*continued*)

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
			Interventions included education on risk reduction, sexual assertiveness, negotiation skills (risk-related behavioural self-management), condom use and problem-solving skills (*n* = 34) Intervention 2: Cognitive–behavioural therapy combined with advocacy training (to act as a risk reduction advocate to their friends and acquaintances) (*n* = 42)		Follow-up: 3 months		
Linn *et al.*, 2003,[53] Nashville, USA	257	Men with chronic disabling mental illnesses attending a homeless shelter	SexG: *Sessions 1 and 2 – Say the word*: create environment where men feel comfortable talking about sex *Session 3 – A quick fix*: sex with female commercial and casual partners *Session 4 – All you need is love*: sex with special partners *Session 5 – Peanut butter*: anal sex with men and women	A 6-session intervention including HIV and sexually transmitted diseases information and basic instruction on condom use (*n* = 127)	Six sessions, 3 days per week over a 6-week period Follow-up: 6 months	Not reported	Research Center in Minority Institutions Program (RCMI), Minority Biomedical Research Support (MBRS) and Center for Medicare and Medicaid Services (CMS) grants to Tennessee State University

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
			Session 6 – Graduation: receive ID cards as HIV prevention specialists (*n* = 130)				
Malow *et al.*, 2012,[54] FL, USA	290	Severely mentally ill men and women with a diagnosis of substance misuse attending outpatient psychiatric treatment centres	E-CB: *Sessions 1 and 2*: HIV education, personalised HIV risk *Sessions 3 and 4*: condom use, safe sex *Sessions 5 and 6*: high-risk situations, communication skills (*n* = 164)	HPC: *Session 1*: HIV information *Session 2*: information on heart attacks *Session 3*: good food habits *Session 4*: exercise *Session 5*: smoking *Session 6*: stress (*n* = 126)	Six 90-minute sessions over 6 weeks Follow-up period: 6 months	Not reported	Not reported
NIMH, 2006,[57] New York City and Los Angeles, USA	99	Men with mental health problems (who had unprotected sexual intercourse and at high HIV risk) attending outpatient mental health clinics	Project LIGHT: Small group intervention in seven sessions covering knowledge of HIV, personal triggers for risk behaviour, use of problem solving skills, condom use, assertiveness, negotiation strategies and relapse prevention (*n* = 52)	One-session video intervention (*n* = 47)	Seven 90-minute sessions, twice a week Follow-up period: 12 months	Not reported	NIMH, USA

continued

TABLE 1 Summary of RCT study characteristics (*continued*)

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
Otto-Salaj *et al.*, 2001,[55] WI, USA	189	Men and women with SMI attending community mental health outpatient clinics	HIV prevention intervention: *Sessions 1 and 2*: HIV risk reduction *Session 3*: condom use *Session 4*: problem solving strategies *Session 5*: discussion and role play *Session 6*: negotiation and assertiveness skills *Session 7*: review of individual's plan for behaviour change Two booster sessions 1 and 2 months later (*n* = not reported)	Health promotion comparison intervention: Seven sessions and booster sessions with same use of educational discussion and skills-building exercises but focused on personal relationships, stress, nutritional health, cancer, heart disease and general sexual health (*n* = not reported)	Seven sessions held twice weekly plus two booster sessions, 1 and 2 months later Follow-up period: 12 months	Not reported	NIMH, USA
Susser *et al.*, 1998,[56] New York, USA	97 (59 sexually active)	Homeless sexually active men with SMI	SexG: Interactive intervention with storytelling, competitive games and acting scenes with true-to-life scenarios (*n* = 52, of whom 33 sexually active)	Two sessions with information on HIV, sexually transmitted diseases and condom use (*n* = 45, of whom 26 sexually active)	15 sessions, 2 days per week over an 8-week period Follow-up: 18 months	Not reported	NIMH and Centers for Disease Control and Prevention, USA

Study, year, country	Sample size (at baseline)	Population	Intervention	Control	Duration of intervention and follow-up	Power calculation	Funding
Weinhardt *et al.*, 1998,[58] New York, USA	20	Women with SMI receiving outpatient psychiatric care	Sexual assertiveness intervention: *Sessions 1 to 3*: HIV-related information and risk-behaviour reduction *Sessions 4 to 7*: skill acquisition and fluency building *Sessions 8 to 10*: generalisation of skills to actual interactions ($n = 9$)	Assessments completed during the same periods as intervention participants but no treatment ($n = 11$)	Ten treatment sessions over 2 weeks Follow-up period: 4 months	Not reported	Not reported

E-CB, enhanced cognitive–behavioural skill building; HPC, health promotion comparison; LIGHT, Living in Good Health Together; NIMH, National Institute of Mental Health; SexG, Sex, Games and Videotapes; SUR, substance use reduction.

Patient characteristics of included studies

The patient characteristics of the included studies are shown in *Table 2*. With regard to the gender of study participants, five studies included males only (Berkman *et al.*,[46,47] Berkman *et al.*,[48] Linn *et al.*,[53] NIMH[57] and Susser *et al*.[56]) and two included females only (Collins *et al*.[50] and Weinhardt *et al*.[58]). The remaining studies included both men and women and ranged from 45% (Malow *et al*.[54]) to 52% male (Kalichman *et al*.[51]) One study did not report the percentage of male and female participants although the authors stated that the ratio of male to female participants was 2 : 1 (Katz *et al*.[52]).

Most studies, apart from two (Katz *et al*.[52] and NIMH[57]) reported the percentage of participants with psychiatric diagnoses which included schizophrenia, schizoaffective disorder, bipolar affective disorder and major depressive disorder. Although the Katz *et al*.[52] study did not include percentages, the authors stated that the majority of patients were diagnosed with schizophrenia or bipolar disorder. It is worth noting that some studies included other diagnoses, such as mood, anxiety and personality disorders[31] and other undefined illnesses.[53,55,56] The percentage of participants with schizophrenia or schizoaffective disorder varied widely between the studies and ranged from 15.7% (Malow *et al*.[54]) to 85% (Kalichman *et al*.[51]).

The studies varied in how they reported the age of the study participants. Eight of the 13 studies reported the mean age of the participants which varied from 33.7 (Kelly *et al*.[31]) to 42.3 years (Collins *et al*.[50]). The age range in the included studies was only reported in two studies, with the widest range (22–59 years) reported by Katz *et al*.[52] Three studies (Linn *et al.*,[53] NIMH[57] and Susser *et al*.[56]) reported only the percentage of participants above or below a certain age.

There was also variation in the ethnicity of participants between the studies, with seven studies reporting the majority of participants to be African Americans (Berkman *et al.*,[46,47] Berkman *et al.*,[48] Linn *et al.*,[53] Malow *et al.*,[54] NIMH,[57] Otto-Salaj *et al*.[55] and Susser *et al*.[56]). One study did not report information on the ethnicity of the participants.[52] Only four studies reported information regarding the marital status of participants (Berkman *et al.*,[48] Carey *et al.*,[49] Kalichman *et al*.[51] and Malow *et al*.[54]). Most of the studies provided at least some information on the educational level of participants, apart from two studies (Berkman *et al*.[46,47] and Katz *et al*.[52]) which provided no information. Nine of the 13 studies reported some information regarding comorbidities, which was usually substance misuse, and four studies (Carey *et al.*,[49] Kelly *et al.*,[31] Otto-Salaj *et al*.[55] and Weinhardt *et al*.[58]) provided no information.

TABLE 2 Summary of patient characteristics

Study and year	% male	Diagnosis	Mean age (years) ± SD (range)	Ethnicity	Mean education (years) ± SD (range)	Marital status	Comorbidities
Berkman *et al.*, 2006[46,47]	100	Major depressive disorder (10%) Schizophrenia or schizoaffective disorder (72%) Bipolar affective disorder (3%)	38.0 ± 9.2 (25–45)	65% African American 21% Latino 14% other	Not reported	Not reported	18% alcohol dependent only 16% drug dependent only 25% alcohol and drug dependent
Berkman *et al.*, 2007[48]	100	Major depressive disorder (5.4%) Schizophrenia (49.0%) Schizoaffective disorder (22.8%) Bipolar affective disorder (9.4%)	*Enhanced SexG*: 37.2 ± 8.8 (range not reported) *Control*: 40.0 ± 9.1 (range not reported)	53.7% African American 27.5% Latino 11.4% White 7.4% other	Not reported *Additional data*: Less than high school (44.3%) High school graduate (36.9%) Some college or college graduate (18.1%)	8.7% married	Lifetime dependency on alcohol (34.2%), marijuana (24.8%) and cocaine (34.9%)
Carey *et al.*, 2004[49]	46%	Major depressive disorder (49%) Schizophrenia (18%) Schizoaffective disorder (15%) Bipolar affective disorder (19%)	36.5 ± 9.5 (range not reported)	67% European American 21% African American 12% other	Not reported *Additional data*: Less than high school (33%) High school graduate (34%) Some college or college graduate (33%)	28% married	Not reported

continued

TABLE 2 Summary of patient characteristics (*continued*)

Study and year	% male	Diagnosis	Mean age (years) ± SD (range)	Ethnicity	Mean education (years) ± SD (range)	Marital status	Comorbidities
Collins *et al.*, 2011[50]	0	Schizophrenia (50%) Schizoaffective disorder/psychosis not otherwise specified (14%) Mood disorder with psychosis (13%) Mood disorder without psychosis (23%)	42.3 ± 8.3 (range not reported)	61% Black 20% Latino 11% White 8% other	Not reported *Additional data*: Less than 12th Grade (43%) 12th Grade or General Educational Development (32%) Greater than 12th Grade (25%)	9% married	Lifetime substance abuse, use or dependency (77%) Current substance use (past month) (9%)
Kalichman *et al.*, 1995[51]	52	Schizophrenia (62%) Schizoaffective disorder (23%) Major affective disorder including bipolar disorder (13%)	39.2 ± 8.0 (range not reported)	19% African American 73% White 8% other	12.3 ± 2.5 *Additional data*: < 12 (67%)	37% married	Alcohol and drug treatment programmes (31%)
Katz *et al.*, 1996[52]	Not reported (male : female ratio 2 : 1)	Not reported (majority of patients diagnosed with schizophrenia and bipolar disorder)	Not reported (22–59)	Not reported	Not reported	Not reported	Assorted personality disorders, chemical dependencies or both
Kelly *et al.*, 1997[31]	47	Schizophrenia (19%) Mood disorder (58%) Anxiety disorder (11%) Substance use or personality disorder (11%)	33.7 ± 6.4 (range not reported)	39% African American 52% White 9% other	Not reported *Additional data*: High school education (61%)	Not reported	Not reported

Study and year	% male	Diagnosis	Mean age (years) ± SD (range)	Ethnicity	Mean education (years) ± SD (range)	Marital status	Comorbidities
Linn *et al.*, 2003[53]	100	Schizophrenia/schizoaffective disorder: 58% in SexG and 64% in control Major depression/bipolar: 37% in SexG and 14% in control Other: 5% in SexG and 22% in control	Not reported < 35 years: 38% in SexG and 47% in control ≥ 35 years: 62% in SexG and 53% in control	African American: 54% in SexG and 64% in control Caucasian: 42% in SexG and 28% in control Hispanic: 4% in SexG and 8% in control	Not reported *Additional data*: Less than high school: 53% in SexG and 61% in control	Not reported	Cocaine and/or alcohol dependence: 25% in SexG and 27% in control
Malow *et al.*, 2012[54]	45	Major depressive disorder (21.2%) Schizophrenia (15.7%) Bipolar affective disorder (9.6%) Schizoaffective disorder (8.4%)	39.59 ± 10.42 (range not reported)	24% non-Hispanic White 55% African American 20% Hispanic 1% other	11.47 ± 2.64 (range not reported)	5% married	All patients were substance abusers
NIMH, 2006[57]	100	Not reported but authors stated that people with SMI were eligible	Not reported (78% > 31 years)	72.4% African American 14.3% Caucasian 6.1% Hispanic African American 2.0% Hispanic 5.1% other	Not reported *Additional data*: 66.3% completed high school	Not reported but 60% never been married	56.1% drug use in previous 3 months

continued

TABLE 2 Summary of patient characteristics (*continued*)

Study and year	% male	Diagnosis	Mean age (years) ± SD (range)	Ethnicity	Mean education (years) ± SD (range)	Marital status	Comorbidities
Otto-Salaj *et al.*, 2001[55]	46	Schizophrenia (35%) Affective disorder (34%) Schizoaffective disorder (18%) Other disorders (13%)	38.4 ± 10.1 (range not reported)	35% White 51% African American 6% Hispanic/Latino 8% other	11.9 ± 2.0 (range not reported)	Not reported	Not reported
Susser *et al.*, 1998[56] (data on sexually active only)	100	Schizophrenia or schizoaffective disorder: 58% in intervention and 65% in control Major depression or bipolar: 36% in intervention and 16% in control Other: 6% in intervention and 19% in control	Not reported (39% < 35 years in intervention and 46% < 35 years in control)	African American: 52% in intervention and 65% in control Latino: 42% in intervention and 27% in control Other: 6% in intervention and 8% in control	Not reported *Additional data*: Educational level less than high school: 52% in intervention and 62% in control	Not reported	33% in intervention group and 27% in control group with no substance abuse
Weinhardt *et al.*, 1998[58]	0	Schizophrenia spectrum disorders (50%) Bipolar disorder (30%) Major depressive disorder (20%)	36 ± SD (not reported) (range not reported)	65% Caucasian	Not reported *Additional data*: Average 11th Grade education	Not reported	Not reported

SD, standard deviation.

Quality characteristics

The overall methodological quality of the 13 included studies is summarised in *Table 3* and *Appendix 5*. Generally, only two studies (Linn *et al*.[53] and Susser *et al*.[56]) were considered as having very few methodological limitations. All studies, except one (NIMH[57]), selected participants who were 'somewhat likely' to be representative of the target population; however, most studies (54%) did not report the number of individuals who were eligible to participate (Berkman *et al.*,[47] Berkman *et al.*,[48] Kalichman *et al.*,[51] Malow *et al.*,[54] Otto-Salaj *et al*.[55] and NIMH[57]) or reported very low numbers of eligible individuals who agreed to participate in the study (Carey *et al*.[49]).

Although all the studies were described as RCTs, only three studies reported the method of randomisation (Berkman *et al.*,[48] Collins *et al*.[50] and Susser *et al*.[56]). In seven studies confounders were well controlled (Carey *et al.*,[49] Kalichman *et al.*,[51] Linn *et al.*,[53] Malow *et al.*,[54] Otto-Salaj *et al.*,[55] Susser *et al*.[56] and Weinhardt *et al*.[58]); however, in the remaining studies (Berkman *et al.*,[47] Berkman *et al.*,[48] Collins *et al.*,[50] Katz *et al.*,[52] Kelly *et al.*,[31] and NIMH[57]) no details were provided on baseline compatibility or whether a variable was associated with the intervention or exposure and causally related to the outcome of interest. None of the studies was graded as 'strong' for blinding. Only five studies (Berkman *et al.*,[48] Carey *et al.*,[49] Linn *et al.*,[53] Malow *et al*.[54] and Susser *et al*.[56]) blinded the outcome assessors and protected against detection bias.

TABLE 3 Summary of methodological quality. Review of authors' judgements about each methodological quality item for each included study

Author, year	Selection bias	Study design	Confounders	Blinding	Data collection	Withdrawals and dropouts	Overall rating
Berkman *et al.*, 2006[46,47]	Moderate	Strong	Weak	Moderate	Strong	Strong	Moderate
Berkman *et al.*, 2007[48]	Moderate	Strong	Weak	Moderate	Strong	Strong	Moderate
Carey *et al.*, 2004[49]	Weak	Strong	Strong	Moderate	Strong	Strong	Moderate
Collins *et al.*, 2011[50]	Moderate	Strong	Weak	Moderate	Strong	Strong	Moderate
Kalichman *et al.*, 1995[51]	Moderate	Strong	Strong	Moderate	Strong	Weak	Moderate
Katz *et al.*, 1996[52]	Moderate	Strong	Weak	Moderate	Strong	Weak	Weak
Kelly *et al.*, 1997[31]	Moderate	Strong	Weak	Moderate	Weak	Weak	Weak
Linn *et al.*, 2003[53]	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Malow *et al.*, 2012[54]	Moderate	Strong	Strong	Moderate	Strong	Moderate	Moderate
NIMH, 2006[57]	Weak	Strong	Weak	Moderate	Weak	Strong	Weak
Otto-Salaj *et al.*, 2001[55]	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate
Susser *et al.*, 1998[56]	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Weinhardt *et al.*, 1998[58]	Moderate	Strong	Strong	Moderate	Strong	Weak	Moderate

All studies failed to provide details on whether or not study participants were aware of the research question (reporting bias). Reliable and valid outcome measures were used in most (77%) of the studies (Berkman *et al.*,[47] Berkman *et al.*,[48] Carey *et al.*,[49] Collins *et al.*,[50] Kalichman *et al.*,[51] Katz *et al.*,[52] Linn *et al.*,[53] Malow *et al.*,[54] Susser *et al.*[56] and Weinhardt *et al*.[58]). While three studies (Kalichman *et al.*,[51] Kelly *et al*.[31] and Weinhardt *et al*.[58]) failed to provide details of withdrawals and dropouts, the follow-up rate was 80% or greater in eight studies (Berkman *et al.*,[47] Berkman *et al.*,[48] Carey *et al.*,[49] Collins *et al.*,[50] Linn *et al.*,[53] Otto-Salaj *et al*.,[55] Susser *et al.*[56] and NIMH[57]). Intervention integrity (assurance that the intervention was delivered according to plan) is an important part of programme delivery. Only five studies (Collins *et al.*,[50] Kalichman *et al.*,[51] Linn *et al.*,[53] Otto-Salaj *et al*.[55] and Susser *et al*.[56]) reported that > 80% of participants received the allocated intervention and eight studies measured the consistency of the intervention (Carey *et al.*,[49] Collins *et al.*,[50] Kalichman *et al.*,[51] Kelly *et al.*,[31] Linn *et al.*,[53] Otto-Salaj *et al.*,[55] Susser *et al*.[56] and NIMH[57]), which was considered satisfactory. Contamination or co-intervention was unlikely in three studies (Berkman *et al.*,[47] Kalichman *et al*.[51] and Linn *et al*.[53]), likely in one study (Collins *et al*.[50]) and not reported in nine studies (Berkman *et al.*,[48] Carey *et al.*,[49] Katz *et al.*,[52] Kelly *et al.*,[31] Malow *et al.*,[54] Otto-Salaj *et al.*,[55] Susser *et al.*,[56] NIMH[57] and Weinhardt *et al*.[58]).

No studies reported a sample size calculation. Many of the studies had small sample sizes so it is likely they had inadequate statistical power to detect between-group differences, even if these were present. The statistical analysis in most studies was appropriate and used intention-to-treat analysis. All the included studies were conducted in the USA, thus making generalisability of the findings to the UK setting uncertain.

Study outcomes

Sexual risk behaviours were stated to be the main outcome of the studies apart from Otto-Salaj *et al.*,[55] which listed HIV risk behaviours as the primary outcome (*Table 4*). How sexual risk behaviours were measured varied between the studies. Five studies (Berkman *et al.*,[46,47] Berkman *et al.*,[48] Collins *et al.*,[50] Linn *et al*.[53] and Susser *et al*.[56]) included vaginal episode equivalent (VEE) scores in the reported outcomes. The VEE score is weighted on the basis of statistical estimates of the relative risk of various sexual behaviours (unprotected vaginal, anal and oral sex). A greater weight is assigned to unprotected anal sex (2 points) than unprotected vaginal sex (1 point), and also allows for some contribution from unprotected oral sex (0.1 points). A VEE score is calculated by summing VEE points for various sexual behaviours over a designated period of time.[72] A wide range of other outcomes included the total number of sexual partners, number of casual partners, unprotected anal, vaginal or oral sex, self-report of sexually transmitted diseases, condom use, knowledge, attitudes, intentions, assertiveness and motivation.

Three studies (Berkman *et al.*,[48] Katz *et al*.[52] and NIMH[57]) reported no information regarding number of participants completing at least part of the intervention. It was unclear in Linn *et al*.[53] how many participants completed all sessions although the authors stated that all participants were available for follow-up at 6 months. Kelly *et al*.[31] reported the mean number of sessions only and Susser *et al*.[56] reported that all participants completed the initial 6-month study period. The remaining studies reported the percentage of participants who completed either all sessions or at least some of the sessions, as shown in *Table 4*.

Effects of interventions

This section provides a narrative summary of the results by the following sexual health-related outcomes: biological, behavioural and proxy. Further details are provided in *Tables 4* and *5*.

TABLE 4 Outcomes and key findings

Study	Primary outcome	Included outcomes	Completion of programme	Findings
Berkman *et al.*, 2006[46,47]	Sexual risk behaviours with casual partners (measured by VEE score)[a]	Unprotected anal, vaginal, oral sex with casual partners (women or men)	For the intervention, 28 men (56%) attended all six sessions, 16 (32%) attended four sessions, and six (12%) attended two sessions	*Mean VEE score – sexually active group*: The mean VEE score of the 56 sexually active men at 6-month follow-up was less in the SexG-Brief (1.64 ± 4.06) than in the control group (3.50 ± 5.90), which was not a significant difference *Mean VEE score – non-sexually active group*: The mean VEE score of the 36 men who were not sexually active at baseline was similar, although the variance was even higher (SexG-Brief, 0.26 ± 0.58 vs. control group, 0.63 ± 2.35)
Berkman *et al.*, 2007[48]	Sexual risk behaviours with casual partners (measured by VEE score)[a]	Unprotected anal, vaginal, oral sex with casual partners (women or men)	Not reported	*Mean VEE score*: During the first and second follow-up intervals, there were no significant differences in sexual risk behaviours with casual partners as measured by VEE Additional analyses demonstrated a trend towards sexual risk reduction at 6 months post intervention ($p = 0.06$) but not at 12 months
Carey *et al.*, 2004[49]	Sexual risk behaviours	Frequency of unprotected vaginal sex, total number of sex partners, total number of casual partners, number of safer sex communications before intercourse and self-report of STIs Other secondary measures included HIV knowledge, personal condom attitudes and intentions and behavioural skills relative to the SUR and control groups	*HIV group*: 103 (73%) patients attended at least one session, and 95 (67%) completed five or more sessions (overall average 5.7 sessions) *SUR group*: 106 (76%) patients attended at least one session, and 94 (67%) completed five or more sessions (overall average 6.0 sessions)	*HIV vs. control*: Compared with the control group, the HIV risk reduction intervention (over time) reported less unprotected sex ($p = 0.004$), fewer casual sex partners ($p = 0.001$), fewer partners ($p = 0.037$), more safer sex communications ($p = 0.053$), improved HIV knowledge ($p = 0.001$), more positive condom attitudes ($p = 0.003$), stronger condom use intentions ($p = 0.001$), and improved behavioural skills as indicated by the role playing ratings ($p = 0.002$) *HIV vs. SUR*: Compared with the SUR group, the HIV risk reduction intervention (over time) reported less unprotected sex ($p = 0.001$), fewer casual

continued

TABLE 4 Outcomes and key findings (*continued*)

Study	Primary outcome	Included outcomes	Completion of programme	Findings
				sex partners ($p = 0.015$), fewer new STIs ($p < 0.013$), more safer sex communications ($p = 0.001$), improved HIV knowledge ($p = 0.001$), more positive condom attitudes ($p = 0.045$), stronger condom use intentions ($p = 0.001$), and improved behavioural skills ($p = 0.005$) *SUR vs. control*: Compared with the control group, the SUR intervention (over time) reported fewer casual sex partners ($p = 0.001$), more positive condom attitudes ($p = 0.003$), stronger condom use intentions ($p = 0.002$), and improved behavioural skills ($p = 0.001$) No differences were observed in the number of incident STIs, the overall frequency of unprotected sex over time ($p = 0.864$), the number of communications about safer sex ($p = 0.081$) and HIV knowledge ($p = 0.291$) *Additional analyses*: Exploratory analyses suggested that female patients and patients diagnosed with a major depressive disorder were more likely to benefit from the HIV risk reduction intervention. Women were more responsive than men to the intervention with regard to the total frequency of unprotected sex and men improved their HIV knowledge more than women
Collins *et al.*, 2011[50]	Sexual risk behaviours (measured by VEE score)[a]	Unprotected anal, vaginal, oral sex with sexual partners (casual, steady, exchange)	*HIV group*: Two patients did not attend any sessions, and 34 (89.5%) completed five or more sessions *Control group*: Five patients did not attend any sessions, and 29 (72.5%) completed five or more sessions	Women in the HIV prevention intervention showed a threefold reduction in mean VEE score at the 3-month follow-up compared with the control group [9.94 vs. 31.89, but the difference was not significant ($p = 0.37$)]. At 6 months no differences were observed in the mean VEE scores between the intervention and control groups (12.23 vs. 11.58; $p = 0.91$) These women were significantly more likely to know about female condoms ($p = 0.1$) and to have inserted one ($p = 0.0001$) and used it with a sexual partner ($p = 0.04$) at the 3-month follow-up, and to have inserted one ($p = 0.02$) at 6 months, compared with controls

Study	Primary outcome	Included outcomes	Completion of programme	Findings
Kalichman *et al.*, 1995[51]	Sexual risk behaviours	Knowledge, condom use, behaviour change interventions	Eight patients did not complete the programme and 44 (85%) patients completed two of the four intervention sessions	Compared with the control group, the intervention group demonstrated significant gains in knowledge ($p < 0.001$) and intention to change risk behaviour ($p < 0.05$). At 1-month follow-up, the intervention group reported reduced rates of unprotected sex ($p < 0.01$) and increased frequency of condom use ($p < 0.05$)
Katz *et al.*, 1996[52]	Sexual risk behaviours	Knowledge, behaviour change interventions	Not reported	Compared with the control group, the intervention group demonstrated improvements in their knowledge about AIDS after training ($p = 0.005$). This was maintained at the 2-week follow-up ($p =$ not reported). Similarly, compared with the control group, participants in the intervention group were more confident to deal with high-risk situations after training ($p = 0.005$). This was maintained at the 2-week follow-up ($p =$ not reported). Although no significant differences were observed at follow-up, behavioural measures of coping in high-risk situations were significantly different to the control group ($p = 0.0002$) after training
Kelly *et al.*, 1997[31]	Sexual risk behaviours	AIDS risk behaviour (knowledge and safer-sex practices) and condom use: barriers to behaviour change and perceived risk reduction, self-efficacy for use	Not reported; however, all patients attended at least one session of the intervention to which they were assigned. Mean 5.6 sessions in the cognitive behavioural intervention and 5.9 sessions in the cognitive behavioural intervention plus advocacy	Although all participants exhibited change at follow-up in some risk-related psychological characteristics and sexual risk behaviours, participants who received the cognitive–behavioural intervention that included the advocacy training reported greater reductions in rates of unprotected sex ($p < 0.01$) and had fewer sexual partners at follow-up ($p < 0.02$) compared with cognitive–behavioural training alone. In addition, a non-significant reduction was observed in the number of casual and new sexual partners ($p < 0.1$) and unprotected sexual activity ($p < 0.09$) Improvements in AIDS risk behaviour knowledge for all groups, with the greatest improvement in both intervention groups ($p < 0.001$ for within-group change from baseline for both intervention groups)
Linn *et al.*, 2003[53]	Sex risk activity (sexual risk index)	VEE sexual risk index; total number of sexual episodes and percentage protected by condom use	All participants available at 6-month follow-up	*Mean VEE score*: significantly lower in SexG group compared with control ($p = 0.01$) *Number of sex encounters*: no difference between groups *Percentage protected by condom use*: the proportion of all encounters that were protected by condom use was greater (*p*-value not reported) in SexG (0.74) than in the control group (0.51) and was specific to sex with women (*p*-value not reported)

continued

TABLE 4 Outcomes and key findings (*continued*)

Study	Primary outcome	Included outcomes	Completion of programme	Findings
Malow *et al.*, 2012[54]	Sex risk behaviours	HIV knowledge, perceived susceptibility, AIDS-related anxiety, personal condom attitudes, peer and partner sexual attitudes, condom use skills, sexual self-efficacy, total number of unprotected vaginal sex acts, proportion of unprotected vaginal sex acts, total number of sex partners	All participants attended at least four sessions; 72% of E-CB and 63% of HPC attended all six sessions	*HIV knowledge and perceived susceptibility*: no significant difference for I × G × T or I × T analyses for either (all *p*-values > 0.10) *AIDS-related anxiety*: significant time effect reflecting reduction in levels of HIV anxiety across intervention and gender ($p < 0.001$) *Condom attitudes*: women demonstrated more favourable attitudes across interventions and times ($p = 0.013$) *Sexual attitudes*: males in E-CB demonstrated an improvement in intentions and males had greater improvements than females in E-CB group ($p = 0.013$) *Condom use skills*: males in E-CB group demonstrated greater condom use skills than females in E-CB and both males and females in HPC (all *p*-values < 0.05) *Sexual self-efficacy*: women had modestly higher levels than men ($p = 0.02$) *Total number of unprotected vaginal sex acts*: no I × G × T or I × T or gender effects (all *p*-values > 0.10) *Proportion of unprotected vaginal sex acts*: males in E-CB demonstrated reduction in proportion of unprotected vaginal sex acts at follow-up ($p = 0.01$) *Total number of sex partners*: reduction from baseline but not significant
NIMH, 2006[57]	Sexual risk behaviours	Number of partners, number of risky sexual acts, proportion with condom use, consistent condom use	88% completed 3-month follow-up; 85.5% completed 6-month and 82% completed 12-month follow-up	*Number of partners*: no significant difference between groups *Number of risky sex acts*: decreased significantly more in intervention group than in control group ($p = 0.001$) *Condom use*: significantly greater condom use among African Americans only in the intervention group compared with the control ($p = 0.0004$) *Consistent condom use*: significantly greater among African Americans only in the intervention group compared with the control ($p = 0.016$)

Study	Primary outcome	Included outcomes	Completion of programme	Findings
Otto-Salaj *et al.*, 2001[55]	HIV risk behaviours	HIV risk knowledge, attitudes towards condom use, risk reduction behavioural intentions, frequency of protected and unprotected intercourse, intercourse occasions protected by condoms, number of partners	84.1% attended all of the sessions; 80.4% completed 12-month follow-up	*HIV risk knowledge*: men only in intervention group showed significant increase in HIV knowledge at 3, 6, 9 and 12 months compared with control group ($p < 0.05$ for all time points) *Attitudes towards condom use*: in intervention group, women only showed significant improvement in attitudes towards condom use at 6 and 9 months ($p < 0.05$ for both) but not at 12 months ($p < 0.1$) compared with control *HIV risk reduction behaviour intentions*: no significant differences between groups *Frequency of protected intercourse*: mean frequency of condom-protected intercourse for women only in intervention group increased significantly compared with control group at 3 months ($p < 0.05$), 6 months ($p < 0.01$) and 9 months ($p < 0.05$) but not at 12 months *Frequency of unprotected intercourse*: no significant difference between groups *Intercourse protected by condoms*: significant percentage of condom-protected intercourse occasions for women only in intervention group at 3 months ($p < 0.05$) and 6 months ($p < 0.005$) but decline at 12 months *Number of sexual partners*: no significant differences between groups
Susser *et al.*, 1998[56]	Sexual risk behaviours (measured by VEE score)[a]	Unprotected anal, vaginal, oral sex with casual and occasional partners (women or men)	All participants completed the initial 6 months and 95% were available for 18-month follow-up	*Mean VEE score at 6 months*: significantly lower in intervention group ($p = 0.01$) *Condom use*: episodes protected by condom use higher in the intervention group ($p = 0.04$) *High-risk behaviours (multiple partners, unprotected anal or vaginal sex)*: significantly lower in the intervention group ($p = 0.01$)

continued

TABLE 4 Outcomes and key findings (*continued*)

Study	Primary outcome	Included outcomes	Completion of programme	Findings
Weinhardt *et al.*, 1998[58]	Sexual risk behaviour	Sexual assertiveness, knowledge, motivation, HIV risk behaviour	All intervention participants completed at least 6 of 10 sessions (mean 8.2)	*Sexual assertiveness*: intervention group improved more than control at each assessment period ($p < 0.001$ at 2 months and $p < 0.005$ at 4 months) *Knowledge*: intervention group exhibited greater knowledge at each assessment period ($p < 0.01$ at 2 months and $p < 0.05$ at 4 months) *Motivation*: no difference between groups on perceived risk or behavioural intentions *HIV risk behaviour*: intervention group showed significant increase in protected sex at 2 months ($p < 0.01$) but not at 4 months. No significant differences for frequency of unprotected intercourse

E-CB, enhanced cognitive–behavioural skill building; G, gender; HPC, health promotion comparison; I, intervention; SUR, substance use reduction; T, time; VEE, vaginal episode equivalent.

a The VEE score is a sexual behaviour risk index. It is calculated using the following formula: (number of unprotected vaginal episodes) + (2 × number of unprotected anal episodes) + (0.1 × number of unprotected oral episodes). The VEE can be refined when data are extensive. For further details see Susser *et al.*[72]

TABLE 5 Types of outcomes reported in the studies

Outcome type	Specific outcome	Studies
Biological	STI (including HIV)	Carey *et al.*, 2004[49]
	Unintended pregnancy	None
Behavioural	Number of partners or episodes of unprotected intercourse	Berkman *et al.*, 2006[46,47]
		Berkman *et al.*, 2007[48]
		Carey *et al.*, 2004[49]
		Collins *et al.*, 2011[50]
		Kelly *et al.*, 1997[31]
		Linn *et al.*, 2003[53]
		Malow *et al.*, 2012[54]
		NIMH, 2006[57]
		Otto-Salaj *et al.*, 2001[55]
		Susser *et al.*, 1998[56]
	Use of contraception	None
	Use of condoms	Kalichman *et al.*, 1995[51]
		Linn *et al.*, 2003[53]
		Malow *et al.*, 2012[54]
		NIMH, 2006[57]
		Otto-Salaj *et al.*, 2001[55]
		Susser *et al.*, 1998[56]
	Uptake of screening or treatment services	None
Proxy	Knowledge, attitudes and beliefs	Carey *et al.*, 2004[49]
		Kalichman *et al.*, 1995[51]
		Katz *et al.*, 1996[52]
		Kelly *et al.*, 1997[31]
		Malow *et al.*, 2012[54]
		Otto-Salaj *et al.*, 2001[55]
		Weinhardt *et al.*, 1998[58]
	Barriers and facilitators	None
	Intentions	Carey *et al.*, 2004[49]
		Kalichman *et al.*, 1995[51]
		Otto-Salaj *et al.*, 2001[55]
		Weinhardt *et al.*, 1998[58]
	Skills	Carey *et al.*, 2004[49]
		Weinhardt *et al.*, 1998[58]

Biological outcomes

The biological outcomes included in the protocol were STIs (including HIV) and unintended pregnancy. Only one study (Carey *et al.*[49]) reported information on STIs, with the intervention group reporting significantly fewer new STIs than the control group. No studies reported information on unintended pregnancies.

Behavioural outcomes

Four behavioural outcomes were included in this review: number of partners, use of contraception, use of condoms and uptake of screening or treatment services. No studies were identified reporting information on the use of contraception or uptake of screening or treatment services. Seven studies reported information on the number of partners (Carey *et al.*,[49] Kelly *et al.*,[31] Linn *et al.*,[53] Malow *et al.*,[54] NIMH,[57] Otto-Salaj *et al*.[55] and Susser *et al*.[56]), with two of these studies[49,31] reporting patients having significantly fewer partners in the intervention groups than the control groups. The other studies showed no difference between the intervention and control groups with regard to the number of partners.

Indirectly related to number of partners is the number of episodes of unprotected intercourse, which was reported in six studies. Kelly *et al*.[31] found significant changes in risk-related behaviours such as unprotected sex and number of sexual partners in the intervention group, which included advocacy training. Three studies found no significant improvements or differences in the reported VEE scores (which included the number of unprotected episodes of intercourse) between the intervention and control groups (Berkman *et al.*,[46,47] Berkman *et al*.[48] and Collins *et al*.[50]). In contrast, Linn *et al*.[53] and Susser *et al*.[56] found significant improvements in VEE scores in the intervention groups compared with the control groups.

With regard to use of condoms, six studies reported some information on condom use. Kalichman *et al*.[51] and Susser *et al*.[56] both reported a significant increase in the frequency of condom use in the intervention groups, and Linn *et al*.[53] also reported a greater proportion of encounters protected by condom use. Malow *et al*.[54] reported significant improvements in condom use skills in males only in the intervention group, whereas Otto-Salaj *et al*.[55] found a significant percentage of intercourse occasions protected by condoms for females only in the intervention group. The NIMH[57] study found significantly greater condom use for African Americans only in the intervention group.

Proxy outcomes

The proxy outcomes included in the review were knowledge, attitudes and beliefs; intentions; skills; and barriers and facilitators. No studies reported outcomes that were related to barriers and facilitators to sexual health interventions.

Carey *et al*.[49] reported more positive condom attitudes and stronger condom use intentions, improved HIV knowledge and improved behavioural skills in the intervention group. Kalichman *et al*.[51] reported that the intervention group demonstrated significant gains in knowledge and intention to change risk behaviour. Kelly *et al*.[31] reported improvements in AIDS risk behaviour knowledge for all groups with the greatest improvement in both intervention groups. Malow *et al.*,[54] however, found no improvement in HIV knowledge but did find an improvement in intentions regarding sexual attitudes for males only in the intervention group. Katz *et al*.[52] also found that the intervention group demonstrated significant improvement in knowledge about AIDS. Otto-Salaj *et al*.[55] reported improvements in HIV knowledge for men only, improvements in attitudes for condom use for women only and no significant change in HIV risk reduction behaviour intentions. Weinhardt *et al*.[58] found improvements in sexual assertiveness, knowledge and HIV risk reduction behaviour although no difference was found with regard to behavioural intentions.

Chapter 3 Discussion

Main findings

This is the first comprehensive systematic review of sexual health interventions for people with SMI. Despite wide variations in the study populations, interventions (e.g. programme content and duration), comparators and outcomes, four studies[49,51,52,56] showed significant improvements in all measured sexual risk behaviour outcomes (e.g. HIV knowledge and behaviour change) compared with the control groups. In contrast, four studies[31,50,53,58] found significant improvements in the intervention groups for some outcomes only and three studies found significant improvements in subgroups only, based on either gender[54,55] or ethnicity.[57] Finally, two studies[46–48] reported no significant differences in any sexual risk behaviour outcomes between the intervention and control groups. Moreover, positive findings were not consistently sustained at follow-up in many studies. These mixed results are similar to those reported in other previous reviews of the literature.[20,27] In addition, in a systematic review of sexual health improvement interventions, conducted by Fullerton and Burtney[73] for NHS Scotland, the authors concluded that there was insufficient evidence to fully support or reject the identified sexual health interventions for people with SMI. The findings from this systematic review reinforce this view.

Strengths and limitations of the assessment

Although an extensive literature search was conducted, it is possible that some relevant studies may have been missed. However, such omissions are likely to have been minimal, as the search included all identifiable publications in the grey literature (including contact with clinical experts in the field). Another limitation is that the initial screening was undertaken by only one reviewer and relevant studies may have potentially been missed.

Many of the studies included in the systematic review included participants with major depression, which was not included in the definition of SMI used for this review, which only included bipolar disorder and schizophrenia. Many studies also included participants with schizoaffective disorder, which again was not part of our initial definition of SMI. It was not possible to differentiate results for patients with different diagnoses reported in the studies. Patients with major depression may respond differently to interventions than those with bipolar disorder or schizophrenia, or indeed there may be differences between these two diagnoses. Another issue related to diagnosis is the lack of uniformity in determining how the diagnoses were made.

Little detail was provided in the studies regarding the content of interventions, how they were delivered and by whom, making replication or generalisability difficult. The control groups used in the studies often included components of the intervention such as education or were not appropriate controls; for example, the control group may have received one session where the intervention group received six or more. This makes it difficult to assess the true effectiveness of the intervention. It was not always clear in the studies what the primary outcomes were and whether or not data from all recorded outcomes were reported. This could potentially result in outcome reporting bias.[74] In addition, the follow-up periods reported in the studies varied and were often quite short, ranging from 2 weeks to 18 months, and positive results were often diminished at follow-up assessments. The main threats to validity in this group of patients relate to study outcomes and participants. Most outcomes were measured by self-reporting and participants self-selecting, thus raising the possibility of bias and recall problems.[20]

Although none of the studies reported that it had been designed to have adequate power to assess differences in subgroups, some reported differences in results between male and female participants.

This issue needs to be explored further as there may be differences between male and female responses to sexual health interventions. There was also a lack of data and analysis reported in the studies regarding the relationship between education levels and outcomes, as well as that between the age of the participants and outcomes, both of which are important variables in the context of sexual health.

In general, the studies identified were mostly considered to be of moderate quality although there were issues in the methods of randomisation, which were often not fully described. Other limitations were: limited blinded assessment of outcomes; little information provided regarding loss of participants to follow-up; no power calculations reported; and small sample sizes in most studies. Only some studies used validated instruments to collect data on outcomes and most relied on self-report of these outcomes. Little information was provided in any of the studies regarding acceptability to participants or those delivering the interventions. There was also little information provided regarding the feasibility of the interventions and how much they would cost to implement. None of the studies provided any information on unintended pregnancies, use of contraception, uptake of screening or treatment services, or facilitators and barriers to providing interventions.

Assessment of factors relevant to the NHS and other parties

There are considerable uncertainties around the generalisability of these findings to the UK setting as the evidence is based on studies from the USA. In addition, the ethnic groups represented in the included studies are not directly comparable to those in the UK. Nevertheless, several factors discussed above are relevant to implementing sexual health interventions for people with SMI in the NHS. These include consideration of who will deliver the interventions and where they will be delivered. There needs to be an assessment of whether or not sexual health interventions could be integrated into the current care provision provided for people with SMI on the NHS. White *et al*.[75] described an ongoing study to assess ways that physical comorbidity in SMI could be addressed by mental health nurses working in NHS community mental health teams. Lessons may be learned from this research that could be incorporated into sexual health intervention programmes.

The choices made regarding location of sexual health services for people with SMI will have resource implications. Likewise, whether or not interventions are delivered to groups of participants or individually will have resource implications and the potential to impact on the effectiveness of the intervention. The follow up of patients also needs to be taken into account as many of the included studies in the review showed a diminished impact at follow-up. Higgins *et al*.[20] suggested the need for an ongoing process rather than a single intervention.

Chapter 4 Conclusions

Implications for service provision

Despite the methodological limitations and variations in the populations, sexual health interventions, use of control groups and outcomes measured in the included studies, the overall findings were mixed, with only 4 of the 13 studies showing significant benefits in sexual risk behaviour interventions (e.g. HIV knowledge and behaviour change) compared with control groups in people with SMI living in the community. In view of study heterogeneity, issues with generalisability and the methodological quality of the included studies, the findings need to be interpreted with caution. Recommendations for further research are listed below.

Suggested research priorities

Primary research

Further research in this area should incorporate the following.

- UK-based trials of sexual health interventions for people with SMI should be conducted. These need to be well designed (use clear methods of randomisation and blinded outcome assessment) and appropriately powered.
- Care needs to be given to the selection of patients and their diagnoses need to be clearly recorded. Sample sizes need to be large enough to ensure that analyses for each relevant subgroup of patients are possible or studies need to be conducted with recruitment of patients with a single diagnosis. Methods of recruitment need to be standardised, transparent and clearly reported. Comorbidities and other treatments need to be reported.
- Interventions should be clearly described and could potentially include behavioural skills, relationship development, condom use and other issues. Controls also need to be clearly described and should include usual care. If active control groups are included, then the components of these groups need to be clearly described.
- Reliable and valid tools for measuring outcomes are needed. Alternatives to measures of self-report need to be considered.
- Follow-up periods need to be long enough to determine how long change can be maintained. The optimal duration of studies requires further research. The provision of 'booster' sessions and long-term interventions needs to be considered.

Other issues

- Staff training should include support for communicating sexual health messages and attitudes towards such work. Research is needed to find the most cost-effective way of providing this.
- The location of services needs to be given consideration and whether or not sexual health interventions can be incorporated into existing services.
- The costs of providing sexual health interventions need to be addressed and should include the incorporation of any savings from reduced incidence of STIs.
- The acceptability of sexual health interventions to people with SMI needs to be researched.

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The final report and any errors remain the responsibility of the University of Sheffield. Eva Kaltenthaler and Matt Stevenson are guarantors.

Contributions of authors

Eva Kaltenthaler and **Abdullah Pandor** carried out the systematic review and quality assessment of the studies and wrote the report. **Ruth Wong** carried out the searches.

About ScHARR

The School of Health and Related Research (ScHARR) is one of the nine departments that comprise the Faculty of Medicine, Dentistry and Health at the University of Sheffield. ScHARR specialises in health services and public health research, and the application of health economics and decision science to the development of health services and the improvement of public health.

The ScHARR Technology Assessment Group (ScHARR-TAG) synthesises research on the clinical effectiveness and cost-effectiveness of health-care interventions for the NIHR Health Technology Assessment Programme on behalf of a range of policy-makers, including the National Institute for Health and Care Excellence (NICE). ScHARR-TAG is part of a wider collaboration of a number of units from other regions including Southampton Health Technology Assessment Centre (SHTAC), University of Southampton; Aberdeen Health Technology Assessment Group (Aberdeen HTA Group), University of Aberdeen; Liverpool Reviews & Implementation Group (LRiG), University of Liverpool; Peninsular Technology Assessment Group (PenTAG), University of Exeter; the NHS Centre for Reviews and Dissemination, University of York; Warwick Evidence, University of Warwick; the BMJ Group and Kleijnen Systematic Reviews.

References

1. Department of Health. *No Health Without Mental Health: A Cross-Government Mental Health Outcomes Strategy for People of all Ages.* London: Department of Health; 2010.
2. Meade C, Sikkema K. HIV risk behavior among adults with severe mental illness: a systematic review. *Clin Psychol Rev* 2005;**25**:433–57. http://dx.doi.org/10.1016/j.cpr.2005.02.001
3. Kirkbride JB, Errazuriz A, Croudace TJ, Morgan C, Jackson D, McCrone P, *et al. Systematic Review of the Incidence and Prevalence of Schizophrenia and Other Psychoses in England, 1950–2009*. Cambridge: University of Cambridge; 2011.
4. Schizophrenia Commission. *The Abandoned Illness: A Report from the Schizophrenia Commission*. London: Rethink Mental Illness; 2012.
5. National Collaborating Centre for Mental Health. *The Management of Bipolar Disorder in Adults, Children and Adolescents, in Primary and Secondary Care*. London: National Institute for Health and Care Excellence; 2006.
6. McGrath J, Saha S, Welham J, El Saadi O, MacCauley C, Chant D. A systematic review of the incidence of schizophrenia: the distribution of rates and the influence of sex, urbanicity, migrant status and methodology. *BMC Med* 2004;**2**:13.
7. Barbato A. *Schizophrenia and Public Health*. Geneva: World Health Organization; 1998.
8. Dixon L, Postrado L, Delahanty J, Fischer P, Lehman A. The association of medical comorbidity in schizophrenia with poor physical and mental health. *J Nerv Ment Dis* 1999;**187**:496–502. http://dx.doi.org/10.1097/00005053-199908000-00006
9. Robson D, Gray R. Serious mental illness and physical health problems: a discussion paper. *Int J Nurs Stud* 2007;**44**:457–66. http://dx.doi.org/10.1016/j.ijnurstu.2006.07.013
10. De Hert M, Correll CU, Bobes J, Cetkovich-Bakmas M, Cohen DAN, Asai I, *et al.* Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry* 2011;**10**:52–77.
11. Daumit G, Dickerson F, Wang N-Y, Dalcin A, Jerome G, Anderson C, *et al.* A behavioral weight-loss intervention in persons with serious mental illness. *New Engl J Med* 2013;**368**:1594–602. http://dx.doi.org/10.1056/NEJMoa1214530
12. Tosh G, Clifton A, Mala S, Bachner M. Physical health care monitoring for people with serious mental illness. *Cochrane Database Syst Rev* 2010;**3**:CD008298.
13. Haro JM, Salvador-Carulla L. The SOHO (Schizophrenia Outpatient Health Outcome) study: implications for the treatment of schizophrenia. *CNS Drugs* 2006;**20**:293–301. http://dx.doi.org/10.2165/00023210-200620040-00003
14. Montejo AL, Majadas S, Rico-Villademoros F, Llorca G, de la Gandara J, Franco M, *et al.* Frequency of sexual dysfunction in patients with a psychotic disorder receiving antipsychotics. *J Sex Med* 2010;**7**:3404–13. http://dx.doi.org/10.1111/j.1743-6109.2010.01709.x
15. Baggaley M. Sexual dysfunction in schizophrenia: focus on recent evidence. *Hum Psychopharmacol* 2008;**23**:201–9. http://dx.doi.org/10.1002/hup.924
16. Schmidt HM, Hagen M, Kriston L, Soares-Weiser K, Maayan N, Berner MM, *et al.* Management of sexual dysfunction due to antipsychotic drug therapy. *Cochrane Database Syst Rev* 2012;**11**: CD003546. http://dx.doi.org/10.1002/14651858.CD003546.pub3

17. Aizenberg D, Zemishlany Z, Dorfman-Etrog P, Weizman A. Sexual dysfunction in male schizophrenic patients. *J Clin Psychiatry* 1995;**56**:137–41. http://dx.doi.org/10.4088/JCP.v62n07a07

18. McKinnon K, Cournos F, Herman R. HIV among people with chronic mental illness. *Psychiatr Q* 2002;**73**:17–31.

19. Gray R, Brewin E, Noak J, Wyke-Joseph J, Sonik B. A review of the literature on HIV infection and schizophrenia: implications for research, policy and clinical practice. *J Psychiatr Ment Health Nurs* 2002;**9**:405–9. http://dx.doi.org/10.1046/j.1365-2850.2002.00511.x

20. Higgins A, Barker P, Begley CM. Sexual health education for people with mental health problems: what can we learn from the literature? *J Psychiatr Ment Health Nurs* 2006;**13**:687–97. http://dx.doi.org/10.1111/j.1365-2850.2006.01016.x

21. Sikkema KJ, Meade CS, Doughty-Berry JD, Zimmerman SO, Kloos B, Snow DL. Community-level HIV prevention for persons with severe mental illness living in supportive housing programs: a pilot intervention study. *J Prev Interv Community* 2007;**33**:121–35. http://dx.doi.org/10.1300/J005v33n01_10

22. Meade CS, Weiss R. Substance abuse as a risk factor for HIV sexual risk behavior among persons with severe mental illness: review of evidence and exploration of mechanisms. *Clin Psychol Sci Pract* 2007;**14**:23–33. http://dx.doi.org/10.1111/j.1468-2850.2007.00059.x

23. Marshall J, Farell M. Substance use and psychiatric comorbidity. *Psychiatry* 2007;**6**:23–6. http://dx.doi.org/10.1053/j.mppsy.2006.10.004

24. O'Cleirigh C, Safren S. Breaking the mold or business as usual? Meeting the challenges of HIV prevention in people with serious mental illness and substance use disorders. *Clin Psychol Sci Pract* 2007;**14**:34–8. http://dx.doi.org/10.1111/j.1468-2850.2007.00060.x

25. Senn T, Carey M. HIV, STD, and sexual risk reduction for individuals with a severe mental illness: review of the intervention literature. *Curr Psychiatry Rev* 2008;**4**:87–100. http://dx.doi.org/10.2174/157340008784529313

26. McCann E. The sexual and relationship needs of people who experience psychosis: quantitative findings of a UK study. *J Psychiatr Ment Health Nurs* 2010;**17**:295–303. http://dx.doi.org/10.1111/j.1365-2850.2009.01522.x

27. Johnson-Masotti AP, Weinhardt LS, Pinkerton SD, Otto-Salaj LL. Efficacy and cost-effectiveness of the first generation of HIV prevention interventions for people with severe and persistent mental illness. *J Ment Health Policy Econ* 2003;**6**:23–35.

28. Melo AP, Cesar CC, Acurcio FA, Campos LN, Ceccato MG, Wainberg ML, *et al.* Individual and treatment setting predictors of HIV/AIDS knowledge among psychiatric patients and their implications in a national multisite study in Brazil. *Community Ment Health J* 2010;**46**:505–16. http://dx.doi.org/10.1007/s10597-010-9303-7

29. DiFranceisco W, Kelly JA, Sikkema KJ, Somlai AM, Murphy DA, Stevenson LY. Differences between completers and early dropouts from 2 HIV intervention trials: a health belief approach to understanding prevention program attrition. *Am J Public Health* 1998;**88**:1068–73. http://dx.doi.org/10.2105/AJPH.88.7.1068

30. Johnson-Masotti AP, Pinkerton SD, Kelly JA, Stevenson LY. Cost-effectiveness of an HIV risk reduction intervention for adults with severe mental illness. *AIDS Care* 2000;**12**:321–32.

31. Kelly JA, McAuliffe TL, Sikkema KJ, Murphy DA, Somlai AM, Mulry G, *et al.* Reduction in risk behavior among adults with severe mental illness who learned to advocate for HIV prevention. *Psychiatr Serv* 1997;**48**:1283–8.

32. Blank M, Hennessy M. A reasoned action approach to HIV prevention for persons with serious mental illness. *Ann Am Acad Polit Soc Sci* 2012;**640**:173–88. http://dx.doi.org/10.1177/0002716211424711

33. Tennille J, Solomon P, Blank M. Case managers discovering what recovery means through an HIV prevention intervention. *Community Ment Health J* 2010;**46**:486–93. http://dx.doi.org/10.1007/s10597-010-9326-0

34. Tennille J, Solomon P, Fishbein M, Blank M. Elicitation of cognitions related to HIV risk behaviors in persons with mental illnesses: implications for prevention. *Psychiatr Rehabil J* 2009;**33**:32–7. http://dx.doi.org/10.2975/33.1.2009.32.37

35. Solomon P, Tennille J, Lipsitt D, Plumb E, Metzger D, Blank M. Rapid assessment of existing HIV prevention programming in a community mental health center. *J Prev Interv Community* 2007;**33**:137–50. http://dx.doi.org/10.1300/J005v33n01_11

36. Burtney E, Fullerton D. *Sexual Health Improvement Interventions in Scotland*. Mapping exercise. Edinburgh: NHS Health Scotland; 2011.

37. Ellis S, Grey A. *Prevention of Sexually Transmitted Infections (STIs): A Review of Reviews into the Effectiveness of Non-clinical Interventions*. Evidence briefing. London: Health Development Agency; 2004.

38. Apantaku-Olajide T, Gibbons P, Higgins A. Drug-induced sexual dysfuntion and mental health patients' attitude to psychotropic medications. *Sex Relation Ther* 2011;**26**:145–55. http://dx.doi.org/10.1080/14681994.2011.567259

39. Higgins A, Barker P, Begley CM. 'Veiling sexualities': a grounded theory of mental health nurses' responses to issues of sexuality. *J Adv Nurs* 2008;**62**:307–17. http://dx.doi.org/10.1111/j.1365-2648.2007.04586.x

40. Penna S, Sheehy K. Sex education and schizophrenia: should occupational therapists offer sex education to people with schizophrenia? *Scand J Occup Ther* 2000;**7**:126–31.

41. Armstrong R, Waters E, Jackson N, Oliver S, Popay J, Shepherd J, *et al. Guidelines for Systematic Reviews of Health Promotion and Public Health Interventions*. Version 2. Melbourne: Melbourne University; 2007.

42. Cook TD, Campbell DT. *Quasi Experimentation. Design & Analysis Issues for Field Settings.* Boston, MA: Houghton Mifflin Company; 1979.

43. Thomas B, Ciliska D, Dobbins M, Micucci S. A process for systematically reviewing the literature: providing the research evidence for public health nursing interventions. *Worldviews Evid Based Nurs* 2004;**1**:176–84. http://dx.doi.org/10.1111/j.1524-475X.2004.04006.x

44. Deeks J, Dinnes J, D'Amico R, Soeden A, Sakarovitch C, Song F, *et al.* Evaluating non-randomised intervention studies. *Health Technol Assess* 2003;**7**(27).

45. Jackson N, Waters E. Criteria for the systematic review of health promotion and public health interventions. *Health Promot Int* 2005;**20**:367–74. http://dx.doi.org/10.1093/heapro/dai022

46. Berkman A. Reducing sexual risk behaviors of men with severe mental illness. *Psychiatr Serv* 2006;**57**:417. http://dx.doi.org/10.1176/appi.ps.57.3.417

47. Berkman A, Cerwonka E, Sohler N, Susser E. A randomized trial of a brief HIV risk reduction intervention for men with severe mental illness. *Psychiatr Serv* 2006;**57**:407–9. http://dx.doi.org/10.1176/appi.ps.57.3.407

48. Berkman A, Pilowsky DJ, Zybert PA, Herman DB, Conover S, Lemelle S, *et al.* HIV prevention with severely mentally ill men: a randomised controlled trial. *AIDS Care* 2007;**19**:579–88. http://dx.doi.org/10.1080/09540120701213989

49. Carey M, Carey K, Maisto S, Gordon C, Schroder K, Vanable P. Reducing HIV-risk behavior among adults receiving outpatient psychiatric treatment: results from a randomized controlled trial. *J Consult Clin Psychol* 2004;**72**:252–68. http://dx.doi.org/10.1037/0022-006X.72.2.252

50. Collins PY, von Unger H, Putnins S, Crawford N, Dutt R, Hoffer M, *et al.* Adding the female condom to HIV prevention interventions for women with severe mental illness: a pilot test. *Community Ment Health J* 2011;**47**:143–55. http://dx.doi.org/10.1007/s10597-010-9302-8

51. Kalichman SC, Sikkema KJ, Kelly JA, Bulto M. Use of a brief behavioral skills intervention to prevent HIV infection among chronic mentally ill adults. *Psychiatr Serv* 1995;**46**:275–80.

52. Katz RC, Westerman C, Beauchamp K, Clay C. Effects of AIDS counseling and risk reduction training on the chronic mentally ill. *AIDS Educ Prev* 1996;**8**:457–63.

53. Linn JG, Neff JA, Theriot R, Harris JL, Interrante J, Graham ME. Reaching impaired populations with HIV prevention programs: a clinical trial for homeless mentally ill African-American men. *Cell Mol Biol* 2003;**49**:1167–75.

54. Malow RM, McMahon RC, Devieux J, Rosenberg R, Frankel A, Bryant V, *et al.* Cognitive behavioral HIV risk reduction in those receiving psychiatric treatment: a clinical trial. *AIDS Behav* 2012;**16**:1192–202. http://dx.doi.org/10.1007/s10461-011-0104-y

55. Otto-Salaj LL, Kelly JA, Stevenson LY, Hoffmann R, Kalichman SC. Outcomes of a randomized small-group HIV prevention intervention trial for people with serious mental illness. *Community Ment Health J* 2001;**37**:123–44.

56. Susser E, Valencia E, Berkman A, Sohler N, Conover S, Torres J, *et al.* Human immunodeficiency virus sexual risk reduction in homeless men with mental illness. *Arch Gen Psychiatry* 1998;**55**:266–72. http://dx.doi.org/10.1001/archpsyc.55.3.266

57. The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. HIV prevention with persons with mental health problems. *Psychol Health Med* 2006;**11**:142–54.

58. Weinhardt LS, Carey MP, Carey KB, Verdecias RN. Increasing assertiveness skills to reduce HIV risk among women living with a severe and persistent mental illness. *J Consult Clin Psychol* 1998;**66**:680–4. http://dx.doi.org/10.1037//0022-006X.66.4.680

59. Goldberg RW, Tapscott SL, Calmes CA, Wolfe RS. HIV and hepatitis C knowledge among individuals with serious mental illness. *Psychiatr Rehabil J* 2009;**33**:47–9. http://dx.doi.org/10.2975/33.1.2009.47.49

60. Weinhardt LS, Carey MP, Carey KB. HIV risk reduction for the seriously mentally ill: pilot investigation and call for research. *J Behav Ther Exp Psychiatry* 1997;**28**:87–95. http://dx.doi.org/10.1016/S0005-7916(97)00002-5

61. Brown LK. *HIV Prevention for Youth with Severe Mental Illness*. ClinicalTrials.gov identifier: NCT00496691; 2009.

62. Collins PY, Geller PA, Miller S, Toro P, Susser ES. Ourselves, our bodies, our realities: an HIV prevention intervention for women with severe mental illness. *J Urban Health* 2001;**78**:162–75. http://dx.doi.org/10.1093/jurban/78.1.162

63. Mansergh G, Koblin BA, McKirnan DJ, Hudson SM, Flores SA, Wiegand RE, *et al.* An intervention to reduce HIV risk behavior of substance-using men who have sex with men: a two-group randomized trial with a nonrandomized third group. *PLoS Med* 2010;**7**:e1000329. http://dx.doi.org/10.1371/journal.pmed.1000329

64. Markowitz JC, Spielman LA, Sullivan M, Fishman B. An exploratory study of ethnicity and psychotherapy outcome among HIV-positive patients with depressive symptoms. *J Psychother Pract Res* 2000;**9**:226–31.

65. Colom F, Vieta E, Martinez-Aran A, Reinares M, Goikolea JM, Benabarre A, *et al.* A randomized trial on the efficacy of group psychoeducation in the prophylaxis of recurrences in bipolar patients whose disease is in remission. *Arch Gen Psychiatry* 2003;**60**:402–7. http://dx.doi.org/10.1001/archpsyc.60.4.402

66. Craig TK, Garety P, Power P, Rahaman N, Colbert S, Fornells-Ambrojo M, *et al.* The Lambeth Early Onset (LEO) Team: randomised controlled trial of the effectiveness of specialised care for early psychosis. *BMJ* 2004;**329**:1067. http://dx.doi.org/10.1136/bmj.38246.594873.7C

67. Hafner RJ, Badenoch A, Fisher J, Swift H. Spouse-aided versus individual therapy in persisting psychiatric disorders: a systematic comparison. *Fam Process* 1983;**22**:385–99.

68. Brady SM. *Improving HIV Prevention Skills in People with Serious Mental Illnesses*. ClinicalTrials.gov identifier: NCT00356291; 2008.

69. Collins P, Susser E, Valencia E, Miller S, Saez H, Geller P. HIV prevention for mentally ill men and women. Xth World Congress of Psychiatry, Madrid, 23–28 August 1996.

70. Holder S. Skills training reduced sexual risk behaviours in homeless men with mental illness [commentary on Susser E, Valencia E, Berkman A, *et al.* Human immunodeficiency virus sexual risk reduction in homeless men with mental illness. *Arch Gen Psychiatry* 1998 May;**55**:266–72]. *Evid Based Nurs* 1999;**2**:15. http://dx.doi.org/10.1136/ebn.2.1.15

71. Peters AT, Nierenberg AA. Stepping back to step forward: lessons from the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD). *J Clin Psychiatry* 2011;**72**:1429–31. http://dx.doi.org/10.4088/JCP.11ac07357

72. Susser E, Desvarieux M, Wittkowski KM. Reporting sexual risk behavior for HIV: a practical risk index and a method for improving risk indices. *Am J Public Health* 1998;**88**:671–4. http://dx.doi.org/10.2105/AJPH.88.4.671

73. Fullerton D, Burtney E. *An Overview of the Effectiveness of Sexual Health Improvement Interventions*. Final report. Edinburgh: NHS Health Scotland; 2010.

74. Kirkham J, Dwan K, Altman D, Gamble C, Dodd S, Smyth R, *et al.* The impact of outcome reporting bias in randomised controlled trials on a cohort of systematic reviews. *BMJ* 2010;**340**:c365. http://dx.doi.org/10.1136/bmj.c365

75. White J, Gray R, Swift L, Barton G, Jones M. The serious mental illness health improvement profile (HIP): study protocol for a cluster randomised controlled trial. *Trials* 2011;**12**:167. http://dx.doi.org/10.1186/1745-6215-12-167

Appendix 1 Study protocol

HTA REFERENCE NO. 12/74 SEXUAL HEALTH OF PEOPLE WITH SEVERE MENTAL ILLNESS

29 January 2013.

1. Title of the project:

What is the effectiveness of sexual health interventions for people with severe mental illness?

2. Name of TAR team and project 'lead'

School of Health and Related Research (ScHARR), The University of Sheffield.

Project lead:

Dr Eva Kaltenthaler, Reader in Health Technology Assessment, Health Economics and Decision Science, ScHARR, University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA

3. Plain English Summary

Severe mental illness describes a wide range of major psychiatric disorders (including schizophrenia and bipolar disorder)[1] which persist over time and cause extensive disability leading to impairments in social and occupational functioning.[2] People with severe mental illness have higher morbidity and mortality due to chronic disease than the general population,[3] and are more likely to engage in high-risk sexual behaviour (e.g. unprotected intercourse, multiple partners, sex trade and injection drug use), putting them at risk of worse sexual health outcomes including sexually transmitted infections, including HIV.[2,4] Many of these individuals will also have coexisting drug and alcohol problems[5] and have difficulties in establishing stable and sexual relationships.[6] Sexual health promotion interventions (such as educational and behavioural interventions, motivational exercises, counselling and service delivery), developed and implemented for people with severe mental illness, may improve participants' knowledge, attitudes, beliefs or behavioural practices (including assertiveness skills) and could lead to a reduction in risky sexual behaviour.[4] The aim of this review is to evaluate the effectiveness of sexual health interventions for people with severe mental illness, its applicability to the UK NHS setting, and identify key areas for primary research.

4. Decision problem

Purpose of the decision to be made

The assessment will address the question 'What is the effectiveness of sexual health interventions for people with severe mental illness?'

Clear definition of the intervention

Health promotion interventions, whether brief interventions or longer term programmes are used to improve various aspects of health and health behaviours. Interventions can be delivered at different levels

(individual, group and community) through an action or group of actions intended to change the knowledge, attitudes, beliefs, or behavioural practices of individuals and populations to reduce their sexual health risk.[7] Individual level interventions focus on one individual at a time in an attempt to help change behaviour and may include partner notification, individual risk counselling by professionals and detached education and outreach (for those not accessing mainstream services). Group level interventions are delivered to small groups of individuals. Group level interventions use peer and non-peer models involving a range of skills, information and support. Community level interventions are delivered by or within a defined 'community'. They seek to improve the risk conditions and influence behaviour by changing social norms, policies or characteristics of the environment.[7,8]

Place of the intervention in the treatment pathway(s)

Mental health nurses and other professionals working with people with SMI would be well placed to include sexual health as part of their contribution to health promotion.[4] However, staff may require specific training in order to deliver such interventions.

Relevant comparators

The relevant comparator is considered as usual care in the community. Professionals working with people with severe mental illness may currently provide ad hoc advice on health risks, but this is not integrated into routine practice.

Population and relevant sub-groups

The population will include any adults (defined as ≥ 18 years of age) of either gender living in the community with severe mental illness and their carers/staff. As recommended in the vignette (produced by NETSCC HTA), severe mental illness is defined as people who have received a diagnosis of schizophrenia or bipolar disorder.[1] The identification of subgroups will be governed by the available evidence. However, on *a priori* grounds, information will be sought from people with dual diagnoses, that is, those with severe mental illness plus substance abuse.

Key factors to be addressed

The review will aim to evaluate the following objectives:

1. Evaluate the effectiveness of sexual health interventions for people with severe mental illness compared with usual care and its applicability to the UK NHS setting.
2. Identify key areas for primary research

5. Report methods for synthesis of evidence of clinical effectiveness

A review of the evidence for clinical effectiveness will be undertaken systematically following the general principles recommended in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (http://www.prisma-statement.org/). The review will assess the effectiveness of sexual health interventions for people with severe mental illness compared with usual care.

Inclusion/Exclusion criteria:

Population

The population will comprise adults (defined as ≥ 18 years of age) with severe mental illness living in the community and their carers/staff. Severe mental illness is defined as people who have received a diagnosis of schizophrenia or bipolar disorder. Adults with dementia, personality disorder, or mental retardation will be excluded as they are not included in our definition of severe mental illness

Interventions

Any health promotion intervention or combination of interventions (e.g. educational, behavioural, psychological, counselling etc. delivered at the individual, group and community level) intended to change the knowledge, attitudes, beliefs, behaviours or practices of individuals and populations to improve their sexual health will be considered. Interventions that focus on sexual dysfunction and sexual violence or prescribed drugs will be excluded.

Comparators

Usual care (defined as standard community care)

Outcomes

The outcomes of the review will include the following:

- Biological: sexually transmitted infections (including HIV), unintended pregnancy
- Behavioural: numbers of partners, use of contraception/condoms, uptake of screening or treatment services
- Proxy: knowledge, attitudes and beliefs, barriers and facilitators, intentions, skills

Search strategy

A comprehensive search will be undertaken to systematically identify clinical effectiveness literature on sexual health interventions for people with severe mental illness.The search strategy will comprise the following main elements:

- Searching of electronic databases
- Contact with experts in the field
- Scrutiny of bibliographies of all retrieved papers

A list of the electronic databases and grey literature sources that will be searched is provided in Table 1. The search strategy will be adapted across the databases and language and date restrictions will not be applied. However, due to the large number of potentially relevant citations, searches in the major databases will be restricted by study type (i.e. controlled trials). An example of the MEDLINE search strategy is provided in Section 9.

TABLE 1 Data sources – electronic databases and grey literature

Electronic database sources
• MEDLINE(R) In-Process & Other Non-Indexed Citations and MEDLINE(R) (Ovid) 1948 to present • EMBASE (Ovid) 1980 to present • Psychological Information Database PsycINFO (Ovid) 1806 to present • The Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), Cochrane Register of Controlled Trials (CENTRAL), Health Technology Assessment (HTA) and Database of Abstracts of Review of Effects (DARE) Databases 1898 to present
Grey literature and internet sources

• ISI Web of Knowledge Conference Proceedings Index
• UK Clinical Research Network (CRN) Portfolio Database (http://www.crncc.nihr.ac.uk/)
• ClinicalTrials.gov (http://www.clinicaltrials.gov/)
• metaRegister of Controlled Trials (mRCT) (http://www.controlled-trials.com/mrct/)
• Websites - societies and mental health organisations will include the following:
  ○ Royal College of Psychiatrists (http://www.rcpsych.ac.uk/)
  ○ British Psychological Society (http://www.bps.org.uk/)
  ○ International Aids Society (http://www.iasociety.org/)
  ○ National Collaborating Centre for Mental Health (www.nccmh.org.uk)

Inclusion criteria

All controlled trials (randomised or non-randomised) that evaluate sexual health interventions with usual care for adults with severe mental illness will be included. In the absence of trial evidence, other study designs such as observational cohort studies with a contemporaneous control group will be considered and identified via iterative searching methods.[9] Before and after studies without a concurrent control group will be excluded because the absence of a control group to record concurrent changes over time means that changes due to the intervention or due to temporal trends, concurrent changes or a Hawthorne effect would be conflated. Such studies therefore represent very weak evidence of effectiveness.[10,11]

The inclusion of potentially relevant articles will be undertaken using a two-step process. First all titles will be examined for inclusion by one reviewer (any citations that clearly do not meet the inclusion criteria i.e. non-human, unrelated to sexual health interventions for people with severe mental illness will be excluded). Second, all abstracts and full text articles will be examined independently by two reviewers. Any disagreements in the selection process will be resolved through discussion.

Exclusion criteria

Reviews of primary studies will not be included in the analysis, but will be retained for discussion and identification of additional studies. Moreover, the following publication types will be excluded from the review: animal models; preclinical and biological studies; narrative reviews, editorials, opinions; non-English language papers and reports published as meeting abstracts only, where insufficient methodological details are reported to allow critical appraisal of study quality. Studies from developing countries will also be excluded as it will be difficult to generalise (e.g. transferability and acceptability) the characteristics of the effective interventions to developed countries. Details of all full text excluded papers (including non-English language citations) will be provided in the review.

Data extraction strategy

Data will be extracted by one reviewer using a standardised data extraction form and independently checked for accuracy by a second. Uncertainties will be resolved by discussion. Where multiple publications of the same study are identified, data will be extracted and reported as a single study.

Quality assessment strategy

The methodological quality of each included study will be assessed according to (adapted) criteria based on those proposed by Effective Public Health Practice Project (http://www.ephpp.ca/Tools.html). This is a generic tool used to evaluate a variety of intervention study designs such as RCTs and observational studies. This tool has been judged suitable to be used in systematic reviews of effectiveness[12] and has been reported to have content and construct validity.[13,14] Consideration of study quality will include the following factors: (1) selection bias; (2) study design; (3) confounders; (4) blinding; (5) data collection method; (6) withdrawals/dropouts; (7) intervention integrity; (8) statistical analysis; and (9) generalisability.

Methods of analysis/synthesis

Data will be tabulated and discussed in a narrative review. If appropriate (i.e. populations, interventions and outcomes are comparable), meta-analysis will be employed to estimate a summary measure of effect on relevant outcomes based on intention to treat analyses. Meta-analysis will be undertaken using fixed or random effects models, using STATA Statistical Software or the Cochrane Collaboration Review Manager Software, for example. Heterogeneity will be explored through consideration of the study populations, methods and interventions, by visualisation of results and, in statistical terms, by the χ^2 test for homogeneity and the I^2 statistic. However, it is anticipated that heterogeneity of study designs and interventions, and the type of data available, may mean that it is not appropriate to perform meta-analysis. The likely form of analysis will be a narrative synthesis.

6. Expertise in this TAR team

TAR Centre

The ScHARR Technology Assessment Group (ScHARR-TAG) undertakes reviews of the effectiveness and cost-effectiveness of healthcare interventions for the NHS R&D Health Technology Assessment Programme on behalf of a range of policy makers in a short timescale, including the National Institute for Health and Clinical Excellence. A list of our publications can be found at: http://www.sheffield.ac.uk/scharr/sections/heds/collaborations/scharr-tag/reports.

Much of this work, together with our reviews for the international Cochrane Collaboration, underpins excellence in healthcare worldwide.

7. Competing interests of authors

The following authors do not have any competing interest: Eva Kaltenthaler, Abdullah Pandor, Ruth Wong, Professor Wylie and Dr Smith.

Professor Gray has received speaker fees and honoraria from companies (Wyeth, BMS, Otsuka, Janssen-Cilag, Eli Lilly and AstraZeneca) that manufacture products that can potentially impact on sexual functioning. He is also funded by the National Institute of Health Research to undertake a trial to promote physical (including sexual) health in patients with mental illness.

8. Timetable/milestones

Milestone	
Draft protocol	14 December 2012
Final protocol	14 January 2013
Progress report	1 March 2013
Assessment report	29 March 2013

9. Appendices

9.1 Draft search strategy (Ovid MEDLINE)

1. ((chronic$ or sever$ or persist$) and mental$ and (ill$ or disorder$)).mp.
2. exp Schizophrenia/
3. (schizo$ or hebephreni$ or oligophreni$ or psychotic$ or psychosis or psychoses).tw.
4. Paranoid Disorders/
5. exp Psychotic Disorders/
6. (paranoia or paranoid disorders or psychotic disorders or psychosis).tw.
7. exp Bipolar Disorder/
8. ((bipolar or bi polar) adj5 (disorder$ or depress$)).tw.
9. (hypomania$ or mania$ or manic$).tw.
10. (((cyclothymi$ or rapid or ultradian) adj5 cycl$) or RCBD).tw.
11. or/1-10
12. exp Sexual Behavior/
13. (sex* and (health or safe or safer or unsafe or risk or high-risk or unprotected or abstinence or behaviour* or behavior* or activit* or partner*)).mp.

14. exp Sexually Transmitted Diseases/
15. ((STI or STIs or STD or STDs) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
16. ((sexually transmitted disease* or sexually transmitted infection*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
17. or/12-16
18. Randomized controlled trials as Topic/
19. Randomized controlled trial/
20. Random allocation/
21. randomized controlled trial.pt.
22. Double blind method/
23. Single blind method/
24. Clinical trial/
25. exp Clinical Trials as Topic/
26. controlled clinical trial.pt.
27. or/18-26
28. (clinic$ adj25 trial$).ti,ab.
29. ((singl$ or doubl$ or treb$ or tripl$) adj (blind$ or mask$)).tw.
30. Placebos/
31. Placebo$.tw.
32. (allocated adj2 random).tw.
33. or/28-32
34. 27 or 33
35. Case report.tw.
36. Letter/
37. Historical article/
38. 35 or 36 or 37
39. exp Animals/
40. Humans/
41. 39 not (39 and 40)
42. 38 or 41
43. 34 not 42
44. 11 and 17 and 43

9.2 Team members' contributions

Eva Kaltenthaler, Reader in Health Technology Assessment. EK has extensive experience in systematic reviews of health technologies. EK will undertake the systematic review. She will coordinate the review process, protocol development, abstract assessment for eligibility, quality assessment of trials, data extraction, data entry, data analysis and review development of background information and clinical effectiveness.

Abdullah Pandor, Senior Research Fellow. AP has extensive experience in systematic reviews of health technologies. AP will assist EK with the project and undertake the systematic reviewing. He will be involved in assessing abstracts for eligibility, quality assessment of trials, data extraction, data entry, data analysis and review development of background information and clinical effectiveness.

Ruth Wong, Information Specialist. RW has extensive experience of undertaking literature searches for the ScHARR Technology Assessment Group systematic reviews and other external projects. RW will develop the search strategy and undertake the electronic literature searches.

Andrea Shippam, Project Administrator. AS will assist in the retrieval of papers and in preparing and formatting the report.

Professor Richard Gray, *Professor of Mental Health and Honorary Consultant, University of the West of England, Bristol, UK*. RG will assist with protocol development (advisor), help interpret data, provide a methodological, policy and clinical perspective on data and review development of background information and clinical effectiveness.

Professor Kevan Wylie, *Consultant in Sexual Medicine, NHS, Sheffield, UK.* KW will assist with protocol development (advisor), help interpret data, provide a methodological, policy and clinical perspective on data and review development of background information and clinical effectiveness.

Dr Shubulade Smith, Consultant Psychiatrist and Clinical Senior Lecturer, *South London & Maudsley NHS Foundation Trust, UK.* SS will assist with protocol development (advisor), help interpret data, provide a methodological, policy and clinical perspective on data and review development of background information and clinical effectiveness.

10. References

1. HM Government. No health without mental health: a cross-government mental health outcomes strategy for people of all ages. *Department of Health* 2010.
2. Meade C, Sikkema K. HIV risk behavior among adults with severe mental illness: a systematic review. *Clinical Psychology Review* 2005;**25**(4):433–457.
3. Dixon L, Postrado L, Delahanty J, Fischer P, Lehman A. The association of medical comorbidity in schizophrenia with poor physical and mental health. *J Nerv Ment Dis* 1999;**187**(8):496–502.
4. Higgins A, Barker P, Begley C. Sexual health education for people with mental health problems: what can we learn from the literature? *Journal of Psychiatric and Mental Health Nursing* 2006;**13**:687–697.
5. Marshall J, Farell M. Substance use and psychiatric comorbidity. *Psychiatry* 2007;**6**(1):23–26.
6. Robson D, Gray R. Serious mental illness and physical health problems: a discussion paper. *International Journal of Nursing Studies* 2007;**44**:457–466.
7. Burtney E, Fullerton D. Sexual Health Improvement Interventions in Scotland. Mapping Exercise. *NHS Health Scotland* 2011.
8. Ellis S, Grey A. Prevention of sexually transmitted infections (STIs): a review of reviews into the effectiveness of non-clinical interventions. Evidence briefing. *Health Development Agency* 2004; 1st ed.
9. Kaltenthaler E, Tappenden P, Paisley S, Squires H. NICE DSU Technical Support Document 13: Identifying and reviewing evidence to inform the conceptualisation and population of cost-effectiveness models. *NICE DSU* 2011.
10. Armstrong R, Waters E, Jackson N, Oliver S, Popay J, Shepherd J, *et al.* Guidelines for Systematic reviews of health promotion and public health interventions. Version 2. 2007. Melbourne University, Australia.
11. Cook TD, Campbell DT. *Quasi Experimentation. Design & Analysis Issues for Field Settings*. Houghton Mifflin Company, Boston, MA, USA; 1979.
12. Deeks J, Dinnes J, D'Amico R, Soeden A, Sakarovitch C, Song F, *et al.* Evaluating non-randomised intervention studies. *Health Technology Assessment* 2003;**7**(27):3–173.

13. Jackson N, Waters E. Criteria for the systematic review of health promotion and public health interventions. *Health Promotion International* 2005;**20**(4):367–374.

14. Thomas B, Ciliska D, Dobbins M, Micucci S. A process for systematically reviewing the literature: providing the research evidence for public health nursing interventions. *Worldviews on Evidence-Based Nursing* 2004;**1**(3):176–184.

Appendix 2 Literature search strategy: a MEDLINE example

Database searched:	Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R)
Platform or provider used:	Ovid SP
Date of coverage:	1948 to December 2012
Search undertaken:	6 December 2012

1. ((chronic$ or sever$ or persist$) and mental$ and (ill$ or disorder$)).mp.
2. exp Schizophrenia/
3. (schizo$ or hebephreni$ or oligophreni$ or psychotic$ or psychosis or psychoses).tw.
4. Paranoid Disorders/
5. exp Psychotic Disorders/
6. (paranoia or paranoid disorders or psychotic disorders or psychosis).tw.
7. exp Bipolar Disorder/
8. ((bipolar or bi polar) adj5 (disorder$ or depress$)).tw.
9. (hypomania$ or mania$ or manic$).tw.
10. (((cyclothymi$ or rapid or ultradian) adj5 cycl$) or RCBD).tw.
11. or/1-10
12. exp Sexual Behavior/
13. (sex* and (health or safe or safer or unsafe or risk or high-risk or unprotected or abstinence or behaviour* or behavior* or activit* or partner*)).mp.
14. exp Sexually Transmitted Diseases/
15. ((STI or STIs or STD or STDs) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
16. ((sexually transmitted disease* or sexually transmitted infection*) and (incidence or prevalen* or prevent* or control* or risk* or reduc*)).mp.
17. or/12-16
18. Randomized controlled trials as Topic/
19. Randomized controlled trial/
20. Random allocation/
21. randomized controlled trial.pt.
22. Double blind method/
23. Single blind method/
24. Clinical trial/
25. exp Clinical Trials as Topic/
26. controlled clinical trial.pt.
27. or/18-26
28. (clinic$ adj25 trial$).ti,ab.
29. ((singl$ or doubl$ or treb$ or tripl$) adj (blind$ or mask$)).tw.
30. Placebos/
31. Placebo$.tw.
32. (allocated adj2 random).tw.
33. or/28-32
34. 27 or 33
35. Case report.tw.
36. Letter/

37. Historical article/
38. 35 or 36 or 37
39. exp Animals/
40. Humans/
41. 39 not (39 and 40)
42. 38 or 41
43. 34 not 42
44. 11 and 17 and 43

Appendix 3 Quality assessment tool[43]

Reproduced with the permission of Thomas B, Ciliska D, Dobbins M, Micucci S. A process for systematically reviewing the literature: providing the research evidence for public health nursing interventions. *Worldviews Evid Based Nurs* 2004;**1**:176–84.

QUALITY ASSESSMENT TOOL
FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1. Very likely
2. Somewhat likely
3. Not likely
4. Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1. 80 - 100% agreement
2. 60 – 79% agreement
3. less than 60% agreement
4. Not applicable
5. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1. Randomized controlled trial
2. Controlled clinical trial
3. Cohort analytic (two group pre + post)
4. Case-control
5. Cohort (one group pre + post (before and after))
6. Interrupted time series
7. Other specify _____
8. Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1. Yes
2. No
3. Can't tell

The following are examples of confounders:

1. Race
2. Sex
3. Marital status/family
4. Age
5. SES (income or class)
6. Education
7. Health status
8. Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1. 80 – 100% (most)
2. 60 – 79% (some)
3. Less than 60% (few or none)
4. Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1. Yes
2. No
3. Can't tell

(Q2) Were the study participants aware of the research question?

1. Yes
2. No
3. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1. Yes
2. No
3. Can't tell

(Q2) Were data collection tools shown to be reliable?

1. Yes
2. No
3. Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1. Yes
2. No
3. Can't tell
4. Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1. 80 -100%
2. 60 - 79%
3. less than 60%
4. Can't tell
5. Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1. 80 -100%
2. 60 - 79%
3. less than 60%
4. Can't tell

(Q2) Was the consistency of the intervention measured?

1. Yes
2. No
3. Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

1. Yes
2. No
3. Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1. Yes
2. No
3. Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1. Yes
2. No
3. Can't tell

I) GENERALISABILITY (additional item)

(Q1) Are the results generalisable to the UK?

1. Yes
2. No
3. Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1	Oversight
2	Differences in interpretation of criteria
3	Differences in interpretation of study

Final decision of both reviewers (circle one): **1 STRONG**
2 MODERATE
3 WEAK

Quality Assessment Tool for Quantitative Studies

Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)

An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.
See below for more details.

Was the study described as randomized?
Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments.
If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT)

An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post)

An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study

A retrospective study design where the investigators gather 'cases' of people who already have the outcome of interest and 'controls' who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after)

The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series

A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs.

Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported.

The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

I) GENERALISABILITY (additional item)

How generalisable are the results to the UK setting

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN

Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS

Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1).

Moderate: will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2).

Weak: will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3) **or** control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and t**he study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or b**linding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of:

Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1).

Moderate: will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A).

Weak: will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix 4 Table of excluded studies with rationale

Author, year	Reason for exclusion
Brady, 2008[68]	Not available (from Trials register – author contacted but no reply)
Brown, 2009[61]	Adolescents
Blank *et al.*, 2012[32]	Not RCT (pooled analysis)
Collins *et al.*, 1996[69]	Not available
Collins *et al.*, 2001[62]	Inpatients only
Colom *et al.*, 2003[65]	No sexual health promotion outcomes
Craig *et al.*, 2004[66]	No sexual health promotion outcomes
Goldberg *et al.*, 2009[59]	Not RCT
Hafner *et al.*, 1983[67]	No sexual health promotion outcomes
Holder, 1999[70]	Comment/discussion
Mansergh *et al.*, 2010[63]	Not SMI
Markowitz *et al.*, 2000[64]	Not SMI
Melo *et al.*, 2010[28]	Not RCT
Penna and Sheehy, 2000[40]	Not RCT
Peters and Nierenberg, 2011[71]	Review
Sikkema *et al.*, 2007[21]	Not RCT
Solomon *et al.*, 2007[35]	Not RCT
Tennille *et al.*, 2009[34]	Not RCT
Tennille *et al.*, 2010[33]	Not RCT
Weinhardt *et al.*, 1997[60]	Not RCT

Appendix 5 Methodological quality summary

The following presents a review of the authors' judgements about each methodological quality item for each included study. The questions asked about each study, and the answers available for each question, are detailed in *Appendix 3*.

Author, year	1. Selection bias	2. Study design	3. Confounders	4. Blinding	5. Data collection	6. Withdrawals and dropouts	7. Intervention integrity	8. Analyses	9. Generalisability to UK setting	Overall rating (items 1–6 only)
Berkman *et al.*, 2006[46,47]	Moderate (Q1: 2; Q2: 5)	Strong (CCT, method of randomisation NR)[a]	Weak (Q1: 1; Q2: 4)	Moderate (Q1: 3; Q2: 3)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 2; Q2: 1)	Weak (Q1: 3; Q2: 3; Q3: 5)	Strong (Q4: 1; ITT)	Weak (USA only)	Moderate
Berkman *et al.*, 2007[48]	Moderate (Q1: 2; Q2: 5)	Strong (RCT, block random, allocation concealed)	Weak (Q1: 1; Q2: 4)	Moderate (Q1: 2; Q2: 3)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 2; Q2: 1)	Weak (Q1: 4; Q2: 3; Q3: 6)	Strong (Q4: 1; ITT)	Weak (USA only)	Moderate
Carey *et al.*, 2004[49]	Weak (Q1: 2; Q2: 3)	Strong (CCT, method of randomisation NR)[a]	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 2; Q2: 3)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 2; Q2: 1; Q3: 6)	Strong (Q4: 1; ITT)	Weak (USA only)	Moderate
Collins *et al.*, 2011[50]	Moderate (Q1: 2; Q2: 2)	Strong (RCT, block random)	Weak (Q1: 1; Q2: 4)	Moderate (Q1: 3; Q2: 3)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 2; Q2: 1)	Weak (Q1: 1; Q2: 1; Q3: 4)	Strong (Q4: 1; ITT)	Weak (USA only)	Moderate
Kalichman *et al.*, 1995[51]	Moderate (Q1: 2; Q2: 5)	Strong (CCT, method of randomisation NR)[a]	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 3; Q2: 3)	Strong (Q1: 1; Q2: 1)	Weak (Q1: 3; Q2: 4)	Strong (Q1: 1; Q2: 1; Q3: 5)	Weak (Q4: 2)	Weak (USA only)	Moderate
Katz *et al.*, 1996[52]	Moderate (Q1: 2; Q2: 2)	Strong (CCT, method of randomisation NR)[a]	Weak (Q1: 3; Q2: 4)	Moderate (Q1: 3; Q2: 3)	Strong (Q1: 1; Q2: 1)	Weak (Q1: 3; Q2: 3)	Weak (Q1: 4; Q2: 3; Q3: 6)	Weak (Q4: 2)	Weak (USA only)	Weak
Kelly *et al.*, 1997[31]	Moderate (Q1: 2; Q2: 2)	Strong (CCT, method of randomisation NR)[a]	Weak (Q1: 1; Q2: 4)	Moderate (Q1: 3; Q2: 3)	Weak (Q1: 3; Q2: 3)	Weak (Q1: 3; Q2: 4)	Weak (Q1: 4; Q2: 1; Q3: 6)	Moderate (Q4: 3)	Weak (USA only)	Weak

Author, year	1. Selection bias	2. Study design	3. Confounders	4. Blinding	5. Data collection	6. Withdrawals and dropouts	7. Intervention integrity	8. Analyses	9. Generalisability to UK setting	Overall rating (items 1–6 only)
Linn 2003[53]	Moderate (Q1: 2; Q2: 1)	Strong (CCT, method of randomisation NR)[a]	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 2; Q2: 3)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 1; Q2: 1; Q3: 5)	Strong (Q4: 1; ITT)	Weak (USA only)	Strong
Malow *et al.*, 2012[54]	Moderate (Q1: 2; Q2: 5)	Strong (CCT, method of randomisation NR)[a]	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 2; Q2: 3)	Strong (Q1: 1; Q2: 1)	Moderate (Q1: 2; Q2: 2)	Moderate (Q1: 2; Q2: 3; Q3: 6)	Weak (Q4: 2)	Weak (USA only)	Moderate
NIMH 2006[57]	Weak (Q1: 3; Q2: 5)	Strong (CCT; method of randomisation NR)[a]	Weak (Q1: 3; Q2: 4)	Moderate (Q1: 3; Q2: 3)	Weak (Q1: 3; Q2: 3)	Strong (Q1: 2; Q2: 1)	Weak (Q1: 4; Q2: 1; Q3: 6)	Moderate (Q4: 3)	Weak (USA only)	Weak
Otto-Salaj 2001[55]	Moderate (Q1: 2; Q2: 5)	Strong (CCT, method of randomisation NR)[a]	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 3; Q2: 3)	Weak (Q1: 3; Q2: 3)	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 1; Q2: 1; Q3: 6)	Weak (Q4: 2)	Weak (USA only)	Moderate
Susser 1998[56]	Moderate (Q1: 2; Q2: 1)	Strong (RCT, randomly ordered sealed envelopes)	Strong (Q1: 2, Q2: 1)	Moderate (Q1: 2; Q2: 3)	Strong (Q1: 1; Q2: 1)	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 1; Q2: 1; Q3: 6)	Strong (Q4: 1; ITT)	Weak (USA only)	Strong
Weinhardt 1998[58]	Moderate (Q1: 2; Q2: 1)	Strong (CCT; method of randomisation NR)[a]	Strong (Q1: 2; Q2: 1)	Moderate (Q1: 3; Q2: 3)	Strong (Q1: 1; Q2: 1)	Weak (Q1: 2; Q2: 4)	Weak (Q1: 4; Q2: 3; Q3: 6)	Moderate (Q4: 3)	Weak (USA only)	Moderate

CCT, controlled clinical trial; ITT, intention to treat; NR, not reported.
a If method of randomisation was not reported, the EPHPP quality assessment tool defined this study as a CCT.

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