Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment (RESPECT): a feasibility study of an intervention aimed at improving the Sexual Health of People with Severe Mental Illness

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TITLE	Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment (RESPECT): a feasibility study of an intervention aimed at improving the Sexual Health of People with Severe Mental Illness
Short Title	The RESPECT Study
Protocol Version **Date** **ISRCTN**	Version 1.3 15.12.16 ISRCTN15747739
Methodology	Pragmatic, randomised controlled, open feasibility trial delivered in community mental health services within four NHS Trusts.
Funder	NIHR HTA Programme grant number 14/172/01
Sponsor	University of Huddersfield
Study Duration	14 months
Study Centres	Community mental health services in: Leeds and York Partnership NHS Foundation Trust; Camden and Islington NHS Foundation Trust; Sussex Partnership NHS Foundation Trust and South West Yorkshire Partnership NHS Foundation Trust
Objectives	To demonstrate the feasibility of recruiting people with SMI to a sexual health intervention and the feasibility of delivering the intervention in a community mental health services. To evaluate the level of treatment retention and explore through qualitative interviews the participants' views, acceptability and experiences of the intervention and the study process.

Number of Subjects/Patients	One hundred participants will be recruited to the trial on the basis of 30% sample attrition, expecting data to be successfully collected on 70.
Main Inclusion Criteria	People currently in treatment (Care Programme approach) in the community mental health services diagnosed with a severe mental illness and aged over 18.

Study Summary

People with serious mental illness (SMI) have significant needs in terms of physical health compared to general population. Initiatives have commenced to address this, however sexual health has been missed off the agenda. People with SMI aspire to have safe and satisfying sexual relationships, however the reality for people with SMI is often more bleak. They are more at risk of sexually acquired infections such as HIV and hepatitis C (and B) and more likely to face violence and exploitation in their relationships. An examination of published studies has looked at whether there are any ways of working that can show that they help promote sexual health. This found that all the studies were from USA, and were very different in how they had been delivered. This has made it difficult to know what might help people with their sexual health needs in the UK. Therefore, there is a need to develop a package of care (intervention) that is relevant to the needs of people with SMI in the UK, and establish whether this is practical, acceptable and useful for people with SMI. Practical issues in establishing such a study will also be examined.

People who agree to take part will be randomly allocated to care as usual, or to care as usual with the extra intervention by chance to the extra intervention. We will collect information on how many people we are able to sign up to the study, the numbers of people who drop out along the way, missed appointments for the intervention, as well as trying out the questionnaires chosen to assess sexual health knowledge, motivation, behaviour. We will interview a small group of people about their experience of being part of the study.

Protocol status:

Details of previous amendments:

Version:	Ethics approval date:	Notes:
1.1	30/09/16	
1.2	n/a	Minor amendment, V1.2 returned to HRA only 3.11.16
1.3	n/a/	Minor amendment, v1.3 returned to HRA only

List of Common abbreviations

AE	Adverse event
BBV	Blood borne virus (hepatitis B, C and HIV)
CLAHRC-YH	Collaborations for Leadership in Applied Health Research and Care
CPA	Care Programme Approach
CRF	Case Report Form
DH	Department of Health
DMEC	Data monitoring and Ethics Committee
DSM	Diagnostic and Statistical Manual of Mental Disorder
EQ-5D	European Quality of Life -5 Dimensions
GUM/GU	Genito-urinary medicine
HPA	Health Protection Agency
HPV	Human Papilloma Virus
HRA	Health Research Authority
IPV	Intimate Partner Violence
MHaSH	Mental Health (and) Sexual Health Intervention
MSM	Men who have sex with men
NHS	National Health Service
PHE	Public Health England
PIS	Participant Information Sheet
PMG	Project management group
PPI	Patient and Public Involvement

PWLE	People with lived experience
RCT	Randomised Controlled Trial
R&D	Research and Development
SAE	Serious Adverse Event
SMI	Serious mental illness
SOP	Standard Operating Procedure
TAU	Treatment as Usual
TSC	Trial Steering Committee

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1. Background and rationale

People with Serious Mental Illness (SMI; such as psychosis, bipolar affective disorders who require the services of secondary mental health care) experience significant inequalities in physical health and die on average 15-20 years earlier than the general population (BMA, 2014). In order to address this, physical health is higher on the health policy and practice agenda (DH, 2010).However, sexual health has been missed from this agenda. The WHO definition of sexual health (WHO, 2006) is broader than just being free from sexually acquired infections; rather it defines it as experiencing sexuality that is satisfying, positive, and respectful; free from exploitation and violence. Evidence suggests the sexual health of people with SMI is poor. There are several areas of concern:

- High levels of exploitation and violence in sexual relationships (intimate partner violence- IPV) (Howard et al., 2010a, Khalifeh et al., 2014)
- Stigma, leading to higher sexual risk behaviour (Elkington et al., 2010)
- People with SMI include key risk groups including men who have sex with men, and sex workers (and sex-trading) (Meade et al., 2009).
- An elevated risk of HIV, Hepatitis B and C, and other Sexually Transmitted Infections (STIs) (Campos et al., 2008b)
- Reduced use and access to contraceptives and higher levels of terminations of pregnancy (Coverdale et al., 1997, Matevosyan, 2009, Seeman and Ross, 2011)

Global prevalence rates of people with SMI have indicated a greater risk of HIV, hepatitis B and C infections compared with expected rates found in the general population (Hughes et al, 2015). There is limited research from Europe, however, prevalence rates in the USA ranged from 1.7to 5% compared with general population infection around 0.3 to0.4% (Campos et al., 2008a). The range of rates reflects the differences in the demographics of the samples; for example, higher rates of HIV among younger homeless samples. In addition, research has shown that people with SMI are sexually active, and some engage in “high risk” sexual behaviours including unprotected sex,

multiple partners, sex trading and sex work as well as risks associated with drug use itself (intoxication impairing decision-making or leading to being exploited whilst under the influence) (Elkington et al., 2010, Meade et al., 2009). In addition, People with SMI are more at risk of violence and abuse in relationships (Howard et al., 2010b, Khalifeh et al., 2014). People who experience intimate partner violence are more at risk of infection with STIs, and Blood Borne Viruses (BBVs). The link between SMI and high risk sexual behaviour is complex and likely to be influenced by unstable psychiatric symptoms (such as hyper-sexuality), comorbid drug and alcohol problems, and sexual abuse and exploitation (Meade et al., 2008). People with SMI aspire to have healthy and safe intimate relationships; this is an important component in recovery. There is however limited evidence for effective interventions to promote sexual health. Therefore there is a pressing need to develop and evaluate an intervention that can promote sexual health for people engaging in mental health services.

Current evidence around improving sexual health, have primarily been based in the USA, where a different set of cultural, organisational and socio-economic factors exist compared to the UK. Additionally, only a limited number of trials have been carried out in this area. Evidence in this area suggests that improving sexual health knowledge alone is insufficient to bring about behavioural change, and psychosocial interventions that address knowledge, skills, confidence, motivation and behaviour are recommended (Shield et al., 2005). However two recent reviews (Walsh et al., 2014) and (Kaltenthaler et al., 2014) found limited evidence of efficacy for such interventions; that the trials included had some risk of bias, and were all conducted in the USA.

There is a need for the development of an intervention as well as feasibility of undertaking a study that addresses sexual health needs in SMI. The mental health workforce is not addressing sexual health needs of people with SMI. Sexuality and sexual health issues are rarely discussed with service users in mental health settings (Hughes and Gray, 2009, McCann, 2010, Quinn et al., 2011, Lagios and Deane, 2011). In focus groups undertaken by Hughes and Nolan (paper in preparation), mental health clinicians were aware of a range of sexual health needs of the people on their caseloads,

but reported that they would avoid raising the topic of sexuality, sexual health and abuse. The reasons for this ranged from fear of offending the service user, to lacking knowledge about how to address sexual health and not being aware of the range of services to access. In addition, they reported a lack of knowledge about the local services, and pathways into care.

In order to address the sexual health of a population, three areas need to be considered: prevention of infection, early detection and treatment, and reducing onward transmission. Untreated sexually transmitted infections can lead to significant health problems (HPV can lead to cervical cancer; other STIs can result in infertility): and blood borne viruses such as Hepatitis B and C can result in premature death). Co-morbidity of HIV and a serious mental illness such as schizophrenia poses particular challenges for both users and services; in particular engagement with services and treatment adherence, as well as the psychiatric and neurological consequences compounding a pre-existing mental health problem (Angelino and Treisman, 2008). Early diagnosis and treatment has resulted in people living well with HIV and also has the potential to reduce onwards transmission (Treatment as Prevention). However, many people are receiving late diagnosis of HIV and starting treatment after the point of maximum benefit (HPA, 2012). In addition, service users themselves value positive sexual relationships (McCann, 2010) yet due to “self-stigma” they feel limited in their choices of sexual partners and therefore end up being exposed to harmful relationships (Elkington et al., 2010).

There is evidence from other fields of medicine that people with SMI don’t engage with general medical services and find that mainstream services don’t often understand their specific needs and challenges (DH, 2010, DH, 2014). Therefore, mental health services are often the only health service that some people with SMI are engaged with (BMA, 2014). Therefore, an intervention that can be delivered by mental health clinicians to address sexual health issues, and support referral to other services, may be an acceptable and feasible model for the intervention.

The evidence suggests that an intervention should focus on the specific needs of individuals and should include an assessment of need, access to appropriate information and services for contraception and testing for STIs (GU Clinics, primary care, family planning). In addition, an intervention should target vulnerability in terms of intimate partner violence, sexual risk behaviour including Men who have Sex with Men (MSM), sexual partners of People Who Inject Drugs (PWID), multiple partners and sex-trading. Quinn et al (2013) has demonstrated that mental health clinicians can be trained to work with sexual health issues. Therefore a sexual health intervention delivered 'within mental health services', has the potential to make a significant impact on the persons' sexual health and wider well-being and recovery, reduce costs to the NHS as a result of prevention of late diagnoses, as well as wider public health benefits to prevention of transmission (DH, 2013).

2. The research question

This study aims to demonstrate the feasibility of recruiting people with serious mental illness to a specifically developed sexual health intervention. Qualitative interviews will elicit the participants' views on the acceptability of the intervention and their experiences of both it and the study processes. Additionally, the study will identify key parameters required to inform a sample size calculation for a main trial.

Study intervention: A manualised sexual health intervention is being developed and content as well as format is being derived from a synthesis of current evidence and co-produced with public involvement members and other key stakeholders from mental health and sexual health services. The sexual health intervention will be delivered according to the developed purpose-designed therapy manual. Participants randomised to the sexual health intervention will be offered three, 60 minute sessions over a maximum period of 8 weeks. The intervention will be delivered face to face by a specifically trained mental health clinician. Where consent is obtained, sessions will audio-recorded and reviewed by the research team to ensure fidelity with the manual and principles of practice.

Control intervention: Treatment as usual (TAU). There is no specific service for people with SMI in terms of sexual health. Those participants randomised to receive TAU will continue to receive their usual care. Treatment as usual for sexual health (including contraception) would include the local primary care and/or specialist sexual health services. People using mental health services should have the same access to these services as the general population, and should be sign-posted or referred to these services if a sexual health need is identified within a mental health consultation.

3. Research Objectives and Design

3.1 Main objectives

The overall aim of the project is to establish the feasibility and acceptability of an evidence based intervention to promote sexual health, and to establish key parameters to inform a future main trial.

Objective 1: Assess the feasibility and acceptability of undertaking a trial by:

a) Quantitative assessment of numbers screened, number eligible and those agreeing to participate,

b) Qualitatively assessing feasibility and acceptability of randomisation process, as well as the intervention.

c) Quantitatively evaluate acceptability of the intervention by assessing retention in treatment (number of sessions attended)

d) Quantitatively evaluate acceptability of proposed method of data collection and data collection tools by assessing overall questionnaire response rates and for each data collection tool.

Objective 2: Identify key parameters to inform the sample size calculation for the main trial: the standard deviation of the primary outcome measure, quantify the average caseload per therapist and tentatively explore clustering within therapist using ICCs.

3.2 Secondary objectives

In addition to the main aims, there are a number of secondary aims that will also be met by this study:

- To develop an understanding of sexual health needs of people with SMI who use NHS mental health services;
- To establish the use and uptake of sexual health services by people with SMI;
- To establish the barriers to accessing information and service provision;
- To establish workforce capacity to undertake such an intervention in mental health services;
- To explore cost effectiveness in preparation for a future main trial;
- To develop recommendations for care pathways between mental health and sexual health service.

4. Study design

Pragmatic, randomised controlled, open feasibility trial delivered in community mental health services within four NHS Trusts.

5. Outcomes

The main objectives of this feasibility study are to evaluate the feasibility of recruiting people diagnosed with SMI to a sexual health intervention across four NHS Trusts, the

acceptability of the intervention to participants, and explore elements of the design and processes of the trial.

The primary data collection method of patient reported outcome measures will be by face-to-face meetings with a member of the research team. Where a face-to-face meeting is not possible the research fellows will collect the outcome measures over the telephone, and these will be restricted to follow up data only, not baseline measures.

6. Primary outcome

In conjunction with the qualitative aspect of the study, the feasibility of this pilot trial and the potential for undertaking a future large-scale main trial will be measured by: Recruitment rates: Quantitative assessment of the acceptability of the research will be assessed by numbers referred, number eligible and those agreeing to participate,

7. Secondary outcomes

Sexual and Risk behaviour measures

SERBAS- Sexual Risk Behavour Assessment Schedule- is a validated HIV risk behaviour measure which was developed in the USA, and has been validated for use with populations who have serious mental illness (McKinnon, et al 1993). It gathers information on sexual activity in the last 3 months and records frequency of high risk behaviours (for HIV infection) such as intercourse without a condom, sexual activity under influence of drugs and alcohol, and sex work/sex trading. It takes into account sexuality and gender within the schedule.

NATSAL 3. We have included specific items which cover broader aspects of sexual health (as the SERBAS focuses on HIV risk) from the NATSAL 3 which is a general population Sexual health and lifestyle survey. (**http://www.natsal.ac.uk/home.aspx**)

Knowledge about HIV (HIV-KQ) This is a measure to assess knowledge about HIV developed by Sacco and colleagues (1991) and adapted for use in people with serious mental illness including Carey et al (2004) as well in the recent study (PRISSMA) in Brazil (Wainberg, et al 2014).

Motivations to engage in safer sex: Risk Perceptions Questionnaire is 4 item scale to assess people's own perception of their risk of infection with a sexually transmitted infections (Carey et al, 1997)

Condom Self-efficacy Scale is an 18 item Likert scale to assess attitudes towards the use of condoms as well as questions on self-efficacy in the use and negotiation of use. The 10 item attitudes sub-scale has been used in previous study in the USA with this population (Carey et al 2004), and the additional self-efficacy questions were designed for the PRISSMA intervention trial in Brazil by Milton Wainberg (2014).

Behavioural Intentions for Safer Sex (Carey et al 2004) are assessed using a six-item measure. Patients were presented with a scenario describing a possible sexual encounter and asked to rate how likely it was that they would engage in six risky or protective behaviors (e.g., "I will tell the person I don't want to have sex without a condom"). Patients responded to each behavior using a 6-point scale (ranging from 0 definitely will not do to 5 definitely will do).

Mental illness stigma scale (MSS-Q) (Elkington, 2010; Wainberg et al, 2016) has been developed and validated to measure a person's perceived stigma as a result of their mental health problem and its impact on perceptions of attractiveness and opportunities for intimate relationships. A link between self-perceived sexual stigma and engaging in sexual risk taking has been reported.

EQ-5D5L (EuroQol) L A standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, the EQ-5D health questionnaire provides a simple descriptive profile and a single index value for health status (http://www.euroqol.org/home.html)

ASSIST: The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) was developed for the World Health Organization (WHO) by an international group of substance abuse researchers to detect and manage substance use and related problems in primary and general medical care settings. It has been used in the PRISSMA study in Brazil with people with serious mental illness
http://www.who.int/substance abuse/activities/assist/en/

Recovering Quality of Life (ReQol) (Brazier 2014) is a new 20 item patient Reported Outcome Measure (PROM) that has been developed to assess the quality of life for people with different mental health conditions. This measure is not reliant on diagnosis and is valid across a range of conditions for people who use mental health services. As we are recruiting people across a range of diagnoses the ReQOL has been chosen as a measure of the impact of mental health.

Cost assessment:

Feasibility of conducting a cost-effectiveness analysis alongside a full-scale RCT will be evaluated to inform the choice of appropriate outcome measures and relevant healthcare resource use in the target population. Commonly used generic instruments to measure health-related quality of life (such as EQ-5D-5L) will be used and assessed for completion rates at various time points and patterns of missing data. Sensitivity of generic instruments will be evaluated against sexual health-specific clinical outcomes. A bespoke resource use questionnaire will be designed and piloted in the target population and responses will be evaluated to identify the key cost drivers. This pilot study will inform the choice of appropriate effectiveness measure for the economic analysis. Also it will identify the relevant

resource use categories for the cost-effectiveness analysis, and evaluate the feasibility and challenges of measuring costs and outcomes in the target population.

Qualitative interviews

The acceptability of the sexual health intervention to people with SMI and the wider context of the impact of the intervention will be explored by undertaking semi-structured qualitative interviews. The qualitative study will aim to recruit a purposive sample of participants from both arms of the study.

8. Summary of treatments

Participants will be randomised to either the sexual health intervention or TAU.

Sexual Health Intervention: The sexual health intervention has been developed during an earlier phase of work, using Intervention Mapping which comprised an analysis of the content of available manuals from previous trials, evidence of risk and unmet needs, public involvement involving service users, and consultation with clinicians in mental health and sexual health services.

Timing: 3 x 60mins sessions (or 6 x 30mins) with the intervention to be completed over a maximum period of 8 weeks

Location: This is to be delivered within local clinical services at a location to be agreed between the participant and interventionist. This could be at a person's home or team base. If delivered at home, the interventionist will adhere to local Trust "lone working" policy as well as establish with case managers that home visits are low risk.

Interventionist: The intervention will be delivered by a clinician from within the same mental health trust as the participant, and they will have received the bespoke RESPECT training.

Fidelity: there will be a fidelity check-list that is completed at every session by the interventionist. In addition (with permission from the participant) audio-recordings will be made for all sessions and a sample of these will be reviewed. All interventionists will receive scheduled monthly supervision by phone and can access advice at any time during the delivery phase.

Engagement: reminders will be sent via the participant's preferred communication method (e.g. such as text or phone calls)

The intervention draft is being reviewed by a range of stakeholders in small groups, individually in all 4 study sites and by those who will be delivering the intervention in the trial (interventionist).

There are three main areas that will be focused on in the intervention: knowledge and perception of risk (session 1); ways to keep safe focusing on condom use as well as contraceptive choices and where to seek advice and help (session2) and negotiating safer sex in relationships including social skills and focus on "mutual respect" (session 3). The person will be encouraged to develop their own "action plan" based on needs and goals identified and (with permission) will be shared with care coordinators to incorporate into their overall care plan.

Outline of each session

Session 1: Knowledge of HIV, and STIs and keeping Safe

Objectives

- To increase knowledge of STIs and HIV
- To accurately identify low, moderate and high risk sexual behaviour
- To know where to seek help if concerned about sexual health

Content: what STIs are, their symptoms, how they are transmitted, how STIs they are tested and treated (and where) using a knowledge quiz, risk rating game and discussion

Session 2: Keeping Safe: focus on role of condoms and contraception choices

Objectives:

- Increase positive attitudes to condoms
- Be able to identify the pros and cons of condom use
- Increase intention to use condoms
- Safe use of condoms
- Know where to access supply of condoms
- Planning for future sexual encounters (i.e. contraception/condoms)
- Focus on contraceptive choices and where to access

Content: discussion about knowledge of condoms, pros and cons and myths about condoms, practical on how to put condoms on and take off safely, discussion on how to access condom supply, discussion about use of contraceptives and family planning

Session 3: RESPECT: Relationships and communication

Objectives:

- Being able to identify components of a mutually respectful sexual relationship
- Be able to accurately describe assertiveness and / gain assertiveness skills
- Be able to practice negotiating within sexual encounters (saying no to sex or type of sex, negotiating condom use)
- Summary of intervention, care plan, goodbye and thank you

Content: use of discussions about relationships and communication and impact on sexual risk and safety behaviour. Reviewing scenarios to respond to questions about how the person in each scenario could safely negotiate safer sex practices (in the third person)

Re-capping on whole intervention and devising a care plan* (*shared with case manager or other professional only with signed permission)

Treatment as Usual (TAU): There is no specific service for people with SMI in terms of sexual health. Those participants randomised to receive TAU will continue to receive their usual care. Treatment as usual for sexual health (including contraception) would include the local primary care and/or specialist sexual health services. People using mental health services should have the same access to these services as the general population, and should be sign-posted or referred to these services if a sexual health need is identified within a mental health consultation.

All participants will be given a leaflet listing the local sexual health, family planning and Domestic Abuse services relevant to the local area during baseline data collection. If a significant sexual health need is identified at any point during the study (either arm) then participants will be given information about local services and with consent, their case manager will be informed in order to assist and facilitate this referral.

9. Study Scheme Diagram A flow

diagram is detailed in Appendix 1

10. Frequency and duration of follow-up

Data will be collected face-to-face at baseline, at each treatment session and three and six months post randomisation.

11. Participant selection

11.1 Source

People currently in the care of the community mental health services at four recruiting sites in the UK (two sites based in the north and two sites based in the south) will be invited to take part. Potential participants will be either directly approached by the local mental health team or by self-referral to the research team. Potential participants who will be directly approached will be identified during a screening process of the caseloads at each recruiting site. A Clinical Study Officer from the NIHR Clinical Research Network will work collaboratively with the local community mental health team to carry out the screening.

12. Number of centres

This feasibility study will be conducted in four centres:

Leeds and York Partnership NHS Foundation Trust: provider of specialist mental health and learning disability services to the people of Leeds. We plan to recruit from community mental health team in the East Leeds locality including Assertive Outreach, Rehabilitation and Recovery and intensive community support teams.

South West Yorkshire Partnership NHS Foundation Trust: Provider of specialist NHS Foundation trust providing mental health and learning disability to the people of Barnsley, Kirklees and Calderdale areas. The RESPECT study will recruit from assertive outreach, early intervention and community mental health teams in the Barnsley locality.

Camden and Islington NHS Foundation Trust: Provider of NHS health services to adults of working age, adults with learning disability and older people in London boroughs of Camden and Islington. We plan to recruit from community mental health team including Assertive Outreach, Rehabilitation and Recovery and intensive community support teams

Sussex Partnership NHS Foundation Trust: provides NHS care for people living in South East England including mental health services for people across the life-span. The RESPECT study will be conducted in teams providing community mental health care in Brighton and Hove.

13. Eligibility Criteria

13.1 Inclusion criteria

- Patients will be considered eligible if all the following apply:
- People on the case load of selected community mental health services within each NHS site;
- Diagnosed with a severe mental illness (schizophrenia, other psychosis, bipolar affective disorder, schizoaffective disorder);
- In receipt of Care Programme approach;
- Are aged 18 and over;
- Willing to provide written informed consent;
- Able to provide written informed consent.

13.2 Exclusion criteria

Patients will be considered ineligible if one or more of the following apply:

- Acute exacerbation of their mental illness that precludes them from active participation (as indicated by hospitalisation and/or being under the crisis/home treatment team at the time of consenting);
- Severe physical illness that precludes them from active participation;
- Significant cognitive impairment (such as an organic brain disorder) as determined by case notes;
- Non-English speaker (adapting the intervention is currently beyond the scope of this study);

- Lacking capacity to consent (as guided by the Mental Capacity Act);
- Unable or unwilling to give written informed consent;
- Those on the Sex Offender Register.

14. Expected number of eligible participants

In previous studies of sexual health interventions for people with serious mental illness (Carey et al, 2004, Berkman 2007) approximately 50-60% of people screened were eligible; and of those eligible, around 40% consented to take part.

In our sites, if we assume we recruit from 2 community services with on average 300 patients on each team case load we could screen up to 600 per site. This means that there will be potentially 2400 people for screening over the whole study. Of these 1200 (50%) may fit with eligibility, and using a conservative estimate of 25% who then give informed consent, then we should be potentially able to recruit 300 (target is 100).

15. Participant recruitment

15.1 Method

Two routes to participant recruitment will be used for the trial in the four NHS Trusts, screening of caseloads and self-referral.

15.2 Caseload screening

Local researchers employed by the Clinical Research Network (CRN) based in each site's Research and development office will work with the Trust clinical staff to promote the study, and undertake case load screening for potentially eligible participants using the eligibility criteria outline above. Clinical staff in specific teams and services that have agreed to participate will be asked to distribute information to those identified as potentially eligible. This information pack will include an invitation letter, the Patient Information Sheet (PIS) and consent to contact form.

Completed consent to contact forms will be passed (either by fax, scanned or hard copy) onto the CRN research staff for eligibility screening at a local level. Eligibility screening will be carried out by CRN clinical study officers at each recruiting site.

15.3 Self-referral

Staff at clinical services in each recruiting site will be sent posters and leaflets about the study for them to display in the waiting areas of their team base. The information will contain an email, QR code and website address to the project website. This website has been designed to provide information about the study for staff and potential participant as well as other interested parties. The posters and leaflets will provide a brief description of the study and methods for contacting the local RESPECT research team directly. The RESPECT researchers will not approach or be present to give out leaflets themselves. By contacting the RESPECT research team directly we will assume the potential participant has implicitly agreed to contact by the research team and the consent to contact form will not be completed, however, a record of the contact and any contact information will be recorded by the research team. An information pack (to include an invitation letter, PIS and consent to contact form will be sent to anyone self-referring if they request. The local RESPECT research team will re-contact potentially eligible participants following the receipt of their pack to determine interest and determine eligibility. However, self-referring participants will be unable to participate the study without agreement from their case manager that there are no factors that could affect them participating. The potential participant will be informed that as a final aspect of eligibility we will have to check with their case manager but no information will be shared (other than their interest in taking part) and have self-referred to the research team. We are utilising this method of recruitment to ensure all potentially eligible participants have the opportunity to take part. The method of recruitment will be recorded to inform the most effective recruitment strategies for the main trial. We will establish a study email address specifically to manage enquiries regarding the study which will be administered by the RESPECT research team.

16. Eligibility assessment

All potentially eligible participants identified either by caseload screening or self-referral will be contacted by telephone to confirm their eligibility by staff employed by the Clinical Research Network at each site. For each potential participant an Eligibility and Screening Form will be completed. Once eligibility is confirmed the CRN researchers will inform the RESPECT researcher who will arrange a convenient time and venue to meet with the potential participant. The purpose of this meeting is to discuss the study in more detail, and to gain informed consent. As part of this process we will record of the number of people who received a pack, who gave consent to contact, method of recruitment and how many of those screened were eligible and consent will be recorded and used to populate the CONSORT flow chart.

Eligible patients who do not wish to take part (i.e. unwilling to give consent) and those found to be ineligible will go on to receive usual care from the service without prejudice.

Reasons for non-participation will be collected to inform future studies. Keyworkers wlll hand out feedback forms to those they discuss the study with, and who then decline to participate. We will send all people who returned a consent to contact form, a feedback form which asks questions about how they found the recruitment process.

17. Information regarding study

Eligible participants will be given an information pack inviting them to take part in the study either from the care coordinator at the NHS Trust or from the RESPECT team. If after reading the materials they are interested, they will be asked to return a completed consent to contact form. Once this form is received by the CRN researchers, then an eligibility screen will take place. If eligible and agree to meet the researcher, their contact details will be passed on to the RESPECT researcher. They will arrange to meet face to face with the potential participant. At this meeting, the RESPECT researcher will fully explain the study verbally, and give the patient the opportunity to ask questions. If the person is willing, then the researcher will invite the patient to participate. Written informed consent to be included in the trial will then be sought. Potential participants will be assured of confidentiality, what to expect after the study ceases and given contact details in case of complaint or need for further information. They will be informed that participation is not compulsory and that they can withdraw from the intervention and /or data collection at any time without affecting their care. They will also be informed that if randomly allocated to the sexual health intervention that they can withdraw from the intervention at any point but still have the option of staying in the study for the purposes of follow-up data collection. The PIS will meet the

requirements of the NHS ethics committees and will clearly present the potential positives and negatives associated with taking part in the trial.

18. Consent procedure

For those that agree to participate, the researcher will:

- Obtain written informed consent to participate in the trial;
- Conduct a baseline assessment;
- Telephone the York Trials Unit Freephone randomisation service or use the online system to randomise the patient (hereafter referred to as the participant);
- Inform the participant of their allocated group and the next steps in the trial;
- Provide a leaflet on local sexual health, family planning and domestic abuse services.

19. Definition for the End of Trial

End of study will be defined as the date at which the last participant has completed the study processes.

20. Trial Interventions

Participants will be randomised to receive treatment from a clinician trained in delivery of the manualised intervention:

1) **Sexual Health Intervention:** an initial appointment with one of the interventionists, followed by two further sessions in a maximum of 8 weeks.

   The sexual health intervention has been developed during an earlier phase of work, which comprised of an analysis of available manuals, information about risk and unmet needs, public involvement involving service users, and consultation with therapists and service managers. The intervention will include a number of facets in order to provide a comprehensive intervention. One of the main aims of the intervention is to help a person to identify their needs in relation to sexual health and relationships, as well as how to access and use the appropriate services. The intervention will be delivered by a clinician employed within the NHS sites who has undertaken the RESPECT training. The intervention will be delivered face to face. Participants will receive the intervention in addition to treatment as usual (including access to local primary care and /or specialist sexual health services).

2) **TAU:** There is no specific service for people with SMI in terms of sexual health. Those participants randomised to receive TAU will continue to receive their usual care. Treatment as usual for sexual health (including contraception) would include the local primary care and/or specialist sexual health services. People using mental health services should have the same access to these services as the general population, and should be sign-posted or referred to these services if a sexual health need is identified within a mental health consultation.

21. Concurrent treatments

Wherever there is a need for medical treatment of a physical condition, surgical or psychiatric condition, these will be available through the usual processes. Such concurrent treatments will not affect study participation unless they preclude delivery of the study intervention or follow-up.

22. Randomisation

22.1 Treatment Allocation

Patients who fulfil the eligibility criteria, who provide written consent to take part in the study and provide baseline data will be eligible for randomisation. Randomisation, will be on a 1:1 basis using stratified block randomisation with stratification by centre and variable block sizes. Patients will be randomised by remote computer to either the sexual health intervention or TAU. This will be conducted using the remote secure randomisation service at York Trials Unit. This will be available as a web-based system (24 hours) and a telephone system (09:00 to 17:00, Monday to Friday, excluding Bank Holidays).

The following information will be collected at randomisation:

- Centre;
- Patient details including full name, gender, date of birth, NHS number, full postal address, contact telephone number(s) and email address;
- Confirmation that patient meets all the eligibility criteria;
- Confirmation that written informed consent has been obtained;
- Confirmation that all baseline data has been collected;
- Confirmation if they can be contacted for future studies.

23. Blinding

23.1 Level of blinding

By the nature of the interventions used within this study, blinding of the participants, clinicians and the researchers is not possible. However, those involved in the analysis of the data will be blind to treatment allocation.

24. Measures to avoid/ minimising bias

Potential sources of bias will be minimised by having minimal exclusion criteria, randomisation, standard training of clinicians guided by a treatment manual, measures of treatment fidelity and adherence to the manual, validated outcome measures and an intention to treat analysis.

25. Data collection

All information collected during the course of the trial will be kept strictly confidential. Information will be held securely in paper format at York Trials Unit, University of Huddersfield University College London and within the R&D departments of each participating Trust and electronically at York Trials Unit. All trial data will be identified using a unique trial identification number. Analytical datasets will not contain any identifiable information. Data will be archived for a period of 5 years following the end of the study.

25.1 Baseline data

At baseline, information will be collected from the participant regarding sexual risk behaviour perceptions, knowledge, sexual stigma, condom use and attitudes, self-efficacy, drug and alcohol use, quality of life, sexual health service use and demographics.

25.2 Follow up data collection

Participants will be followed for a total of 24 weeks. Follow up data collection will be conducted at 3 months (12 weeks) and 6 months (24 weeks) post-randomisation for both groups. We will operate strict “windows” for data collection. At three-month follow-up data collection window will operate from the start of week 11 to the end of week 14. If data is not collected within that time period, this is not pursued and the next time point will be focused on. The 6 month follow-up data collection window will operate from the start of week 23 to end of week 26.

Members of the RESPECT research team will arrange face to face appointments with participants; during these appointments the researchers will collect follow up data covering the main and secondary outcome measures.

The researchers will record missed appointments, as well as how many times they contacted (by text, phone or via case managers) to arrange follow-ups.

26. Qualitative data

There will also be qualitative interviews to gather data on acceptability and feasibility from the perspective of the participants using a sub-sample of consenting participants (see section 13)

27. Data related to fidelity to the intervention

At the end of each session, a short form will be completed by the clinicians delivering the intervention. This will list the content of the session with the clinician ticking what was covered during the session and space to make any additional notes or observations. In addition the participant will be invited to complete a very brief evaluation form.

28. Table of data collection schedule

Event	Time period	Data collected
Pre	Day 0	Consent for study; Baseline CRF:
		Feedback form for refusers

		Randomisation: including confirmation of consent; contact details; confirmation of baseline questionnaire completion
1	1-2 weeks	Intervention participants – First appointment: time of session; the length of session; participant attendance; therapist involved; location; and any materials used. Audio recording of sessions
2-6	2-12 weeks	Intervention participants subsequent appointments: time of session; the length of event; participant attendance; therapist involved; location; any materials used. Audio recording of sessions.
3	12 weeks	Three month CRF: follow-up.
4	24 weeks	Six month CRF: follow-up. Exit questionnaire We will undertake semi-structured qualitative interviews with participants from intervention and TAU groups to gather data on acceptability and feasibility of both the study and the intervention.

We will conduct post-study de-brief sessions with the interventionists to gather information and feedback about delivery of the intervention in order to inform any future model of roll-out in a subsequent study.

29. Completeness of data

As data collection is being undertaken by face to face appointments with researchers at baseline and follow up assessments, it is anticipated that missing data will be minimal with the exception of those participants who do not attend/engage with appointments or follow up and researchers are not able to locate.

30. Data handling and storage

Information with regards to the study participants will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldicott Guardian, Research Governance Framework for Health and Social Care and the Health Research Authority.

Personal addresses, postcodes and other contact details of consenting participants will be stored on a secure password protected server located at the University of York, for the purposes of assisting in follow-ups during the study. All paper data collected from participants will be maintained in a safe secure environment at each of the research team sites. Paper records will be identified using identifiers rather than personally identifiable information.

Participants allocated to the sexual health intervention will be asked to give permission to have their intervention session(s) audio recorded. These data will be used by the research team to assess clinician fidelity to the intervention manual at the end of the treatment. All recordings will be identified by an identification number rather than personal information. Research findings addressing the process of the intervention may contain anonymised participant quotations. These recordings will be archived in a secure location for a minimum period of 10 years.

Data will be collected through questionnaires designed on paper. Scanned data from the paper forms are stored in a download database where they are checked against the hard copy of the questionnaire. Data is error checked and then validation checks are run against the validate database. Discrepancies identified during validation which require resolution are communicated to the relevant person who is in a position to be able to obtain the information required to rectify the discrepancy. Analytical datasets will not contain any identifiable information. Data will be archived for a minimum period of 10 years following the end of the study.

Qualitative interview participants' confidentiality will be ensured by assigning a unique identification code to electronic sound files and transcripts of individual interviews, known only to the qualitative researcher and appropriate members of the research team. Any personal information required will also be coded with this identification number and kept in a password protected electronic file or separate filing cabinet which will be locked at all times. Any quotes published will be anonymous further protecting participant confidentiality. All qualitative data will be stored and analysed at the University of Huddersfield.

31. Treatment fidelity

A simple tick list will be completed for every session indicating what content of the manual was covered in each session and space for any comments about how it was implemented, and any modifications made. This will be completed by the interventionist. Participants receiving the intervention will also be asked to complete a short evaluation sheet at the end of each session and these will cover usefulness, relevance and levels of comfort for each session. Where consent is given, intervention sessions will be audio recorded and used for fidelity checks. The research team will listen to a 10% random sample (no more than 15 sessions) to assess clinician fidelity and adherence to the intervention protocol. Should a participant not be willing to have their sessions audio recorded (which can be indicated on the consent form), this will not affect their treatment nor preclude them from participating. These audio recordings will be stored and archived securely at the University of Huddersfield for the northern sites, and at UCL for the southern sites.

32. Clinician interviews

The clinicians delivering the sexual health intervention at each site will be invited to participate in a focus group/debriefing session at the end of the intervention delivery. The purpose of this single session is to explore a number of themes, including the training and implementation process, their views around sustainability and capacity, and around use of the intervention in routine clinical practice in mental health services. This single session will seek to identify any problems that clinical staff encountered in delivery of the intervention and the trial process, with a view resolving these in a full trial.

33. Statistical considerations

33.1 Sample size

This will be an external feasibility trial, the main purpose of which is to assess feasibility of the new intervention and the methods of recruitment, randomisation and follow up for a full trial in a population with SMI. The sample size calculations are based on estimating attrition and standard deviation of the primary outcome. Assuming 30% of participants are lost to follow up (as in the SCIMITAR trial (Gilbody et al, 2015) with a sample size of 100, then the 95% confidence interval for this level of attrition will be the observed difference ±9 percentage points (i.e. between 21% and 39%; Hertzog, 2008). Hence an external pilot trial of 100 participants should ensure robust estimates of follow-up in this population. Furthermore, an external feasibility study of at least 70 measured subjects will provide robust estimates of the standard deviation of the outcome measure to inform the sample size calculation for the subsequent larger definitive fully powered trial (Teare, 2014).

34. Planned recruitment rate

It is expected that recruitment will be on average 16 patients per month. Should recruitment fall below the expected rate, we will meet with the sites to review progress and discuss any problems and take any necessary action in order to resolve any issues affecting recruitment. As well as the named teams/locations within each organisation for targeting the recruitment we have also identified other potential service locations within each organisation where we could increase the potential for recruitment.

35. Qualitative research

As well as obtaining data relating to the stated outcome measures, follow-up interviews will be conducted at six months post-randomisation. These will be undertaken by the RESPECT researchers as well as lived experience researchers who are part of the RESPECT steering group. The key aims of the qualitative interviews are to establish the acceptability and feasibility of the intervention itself, as well as the methodology and processes used throughout the trial. The qualitative process evaluation will run concurrently throughout the study. The qualitative study will aim to recruit a purposive sample of participants from both arms of the study. Approximately 20 participants will be recruited at the end of the intervention period; ten from the intervention and ten from the control group (which represents approximately 20% of people who will be recruited). We will attempt to recruit approximately equal numbers of males and females. We will also recruit approximately equal numbers from each site. In addition we will also be mindful of the demographic variance in the catchment areas for example; it is likely that Camden and Islington will be more ethnically diverse than Yorkshire.

The RESPECT researchers will be trained in qualitative interview techniques and will use interview topic guides in order to standardise procedures across all interviews. The interviewer will seek to establish satisfaction with the treatment received and perceived processes of change, including helpful aspects of the therapeutic process. This will complement the analysis of the quantitative data and identify ways in which the intervention may need to be modified in preparation for a definitive trial.

Additionally, the clinicians delivering the sexual health intervention at each site will be invited to participate in a focus group/debriefing session at the end of intervention

delivery. This will focus on delivery of the intervention, content of the intervention, barriers and solutions to delivery as well as sustainability and implementation across clinical practice.

All people who gave consent to be contacted will be sent a brief feedback questionnaire to complete and return to give feedback on how they found they recruitment process. In addition, all people entered into the study (who haven't officially withdrawn) will be sent an exit questionnaire to complete about their experiences of the study.

36. Interview format

The interviews will be by telephone. They will be semi-structured in nature and based around a topic guide. The topic guide will cover areas including characteristics of the setting, mode of delivery, satisfaction and acceptability of the intervention, aspects of the intervention that were helpful or unhelpful from the participant's perspective, intensity and duration of the intervention, the overall experience of the treatment and suggestions for improvement to the intervention. The topic guide will also cover processes related to trial methodology including views on the consenting process, randomisation, outcome measures used and other methodological factors.

37. Transcription and analysis of data

For the purpose of data analysis, all interviews will be recorded and transcribed; content analysis will be conducted independently by a minimum of two researchers and discrepancies in coding will be resolved through discussion until consensus is reached.

Analysis will be conducted using the framework approach. This deductive approach to qualitative analysis allows for a more structured approach to data collection based on pre-determined aims and objectives. Software (NVivo version 10) will be used to synthesize and code the data within a thematic matrix to enable elucidation of conceptual associations. Both pre-determined concepts used for developing the interview schedules as well as emergent themes arising from the data will inform the process of identifying the key thematic categories to be used in data coding, which will then be used to index and chart findings.

38. Data management

All data from the trial will be collected using paper-based forms (baseline booklet, intervention session forms; follow-up booklets). Researchers and clinicians will be responsible for ensuring the completeness and reliability of the data from their site, and then for transferring records to York Trials Unit. Data from paper forms will then be entered into a master database for the trial using either optical scanning techniques or entered manually.

39. Statistical Analysis

39.1 Quantitative analyses

The flow of participants through the trial will be detailed in a CONSORT flow diagram. The number of people screened, randomly assigned, receiving the intervention, completing the study protocol and providing outcome data will be summarised overall and by trial arm. The number of individuals withdrawing from the intervention and/or the trial and any reasons for withdrawal will be summarised by trial arm. To quantify the acceptability of the intervention the number of sessions attended will also be summarised. All data will be presented descriptively with no formal statistical analyses undertaken. For each data collection point and outcome measure, the number of non-responders will be calculated and completion rates compared. The potential impact of

therapist effects may be explored using ICC and the average caseload per therapist will be detailed.

40. Analysis of economic and quality of life data

The economic component of the study will be designed to assess the feasibility of conducting a cost-effectiveness analysis of a full trial. This will involve piloting a short questionnaire, analysing responses and calculating Quality Adjusted Life Years (QALY) changes using the EQ-5D. We would not expect to see significant changes between groups due to the small sample size in this feasibility trial.

A simple questionnaire will measure participants' use of health care and will be identified retrospectively by means of service use questions. The economic analysis will assess the feasibility of using such a questionnaire in this population. The questionnaire will ask about primary care, sexual health and family planning services. In the full trial resource use data will be multiplied by national average unit costs to calculate per participant costs in the 3 month period before the intervention and the 3 month period after receiving the sexual health intervention or TAU.

Quality of life will be measured by EQ-5D at baseline and each follow up time point. The use of EQ-5D enables the estimation of QALYs. Measuring health status using QALYs follows the recommendations of NICE[1] and enables the value for money afforded by treatments to be compared to a range of other health care interventions.

A full cost-effectiveness analysis will not be conducted in this feasibility trial. The economic component of this trial will examine the feasibility of conducting a full incremental cost-effectiveness analysis of sexual health intervention compared to TAU. This feasibility trial will inform the choice of appropriate effectiveness measure for the economic analysis and aid the identification of relevant resource use categories.

41. Compliance and withdrawal

41.1 Participant compliance

Participants will not be withdrawn on the basis of non-compliance with the intervention.

41.2 Loss to follow up

The RESPECT team will contact the participant's case manager or GP to identify any new contact details for a participant who we have lost contact with.

41.3 Withdrawal/ dropout of participants

Participants may withdraw from the study at any time without influencing their future care or treatment. Withdrawal may refer to the following situations:

- Where a participant wishes to withdraw from the study intervention, but is prepared to continue completing follow-up questionnaires (i.e. no intervention sessions are attended but the data is still collected). This is classed as 'Withdrawal from intervention'. This is pertinent only to the sexual health intervention arm of the study.
- Where a participant wishes to withdraw from completing any further follow-up interviews after completing their intervention sessions. This is classed as 'Withdrawal from follow-up'. This is applicable to both arms of the study.
- Where a participant wishes to withdraw from both the study intervention AND from completing any further follow-up interviews. This is classed as 'Full withdrawal'. This is applicable to both arms of the study.
- A person can be withdrawn without their consent from the intervention and/or the trial for reasons of risk or harm to self and/or others. This would only be actioned with evidence of serious and significant risk. In these instances the risk protocol will guide the interventionist and/or researcher in the appropriate action to be taken in conjunction with the lead research clinician and the duty worker in the organisation.

- We will ensure that the researchers are aware of the differences in types of withdrawal, and that they are explicit about whether participants wish to withdraw from the intervention, follow up, or both.

In either event, York Trials Unit will be informed.

42. Interim analyses

No interim analyses will be conducted.

43. Data Monitoring

The Chief Investigator will ensure that the study is appropriately monitored by ensuring that: all rights of the trial participants are adequately protected; that written informed consent is obtained; the trial data are accurate and complete; and that the conduct of the trial is in compliance with the protocol and its subsequent amendments, with GCP and applicable regulatory requirements.

44. Training

The intervention will be manual based, and the intervention manual will be adapted in accordance with the current trial. There will be a two day training session to introduce staff to the key-concepts and procedures involved in the intervention and research. In addition, we will create a private learning space within the University of Huddersfield online learning platform (UniLearn) for the interventionists. Within this secure space, interventionists will be able to access remotely and securely all the resources to support the delivery of the intervention as well as the manual, forms and exercises.

Once the trial commences, supervision will be provided on a regular on-going basis via monthly ‘supervision’ phone meetings with the CI. The clinician will also be able to contact the CI between scheduled sessions for advice and support.

45. Ethical considerations

45.1 Regulatory approvals

The proposed study will be conducted in accordance with the MRC Guidelines on Good Clinical Practice in Clinical Trials. Prior to undertaking the study, approval will be sought from the Health Regulatory Authority and local Research and Development department.

45.2 Informed consent

All eligible people with SMI will be provided with a PIS prior to giving consent. The information sheet will outline fully the potential benefits and risks of being involved in the trial. This information sheet will meet all the requirements of the HRA. Maintenance of confidentiality and compliance with the UK Data Protection Acts will be emphasised to all study participants. Participation in the study will be entirely voluntary and written consent will be sought. All data will be treated with the strictest confidence. Potential participants will be excluded from participating in the trial if it is felt they are lacking in capacity to consent as guided by the Mental Capacity Act.

45.3 Risks and anticipated benefits for trial participants and society

The main risk from participating in the study is embarrassment regarding collecting data about sexual behaviour, and if receiving the intervention, discussing sexual health and relationships. In order to minimise this, potential participants will be informed of the specific nature of the study prior to consent. The research will be undertaken in a sensitive way, maintaining awareness of the vulnerability of many of the participants.

In terms of benefits to society, should this new intervention prove clinically and cost effective in a larger, multi-site trial and should it be widely implemented, it would have a significant impact on the sexual health of people diagnosed with SMI. The aim is to design and trial a realistic intervention that can be readily delivered even in a climate of cuts for treatment services. The scope for implementation and impact is therefore great.

46. Safety and Adverse events

There are no anticipated risks in relation to either arm of the trial. However, the research team are aware that some people who have experienced sexual abuse and exploitation may find participating in this study distressing and may trigger difficult feelings.

Distress management – if a participant expresses any signs or reports any distress during any study related activity (e.g. meeting with a member of research team or during intervention delivery) an immediate halt will be implemented to the activity. Study specific guidance will be used to guide the researcher or interventionist for the management of this situation. Incidences of low level distress will be reviewed during scheduled supervision meetings. If a participant is referred to the local mental health team for management of their distress the CI (or delegated research clinician) will be informed within 24 hours.

Adverse events – If a participant becomes unwell during the course of the study (irrespective of condition) and needs to be admitted as an inpatient or other adverse event occurs (self-harm, suicide attempt, violence to others or victim of violence) this will be reported to the CI (or delegated clinician) immediately on receipt of this information, and the chair of the DMEC within 48 hours. The Chair of the DMEC will have the authority to terminate the trial should there be evidence that the study is causing harm.

All adverse events (AE) [serious and non-serious] will be reported to the Chief Investigator and reviewed by Professor Mike Lucock who is a clinical psychologist and experienced health researcher at the University of Huddersfield according to a Standard Operating Procedure (SOP) specific to this study. We are aware that judgements regarding relatedness can be difficult in this type of study, and therefore all serious adverse events (SAE) will be forwarded to the DMEC within 48 hours of the CI becoming aware of the event. Any event deemed by the team and the DMEC as ‘related’ to study treatment will be reported to the sponsor, ethics committee and TSC. Any non-serious AEs considered as ‘related’ to study treatment will also be forwarded to the DMEC.

47. Project management

47.1 Project Management Group (PMG)

A Project Management Group (PMG) comprising of Hughes, Nolan, Samuels, Watson, the Trial Co-ordinator, the statistician and research fellows will meet for one hour monthly (by an online meeting tool) to oversee the day to day running of the project and all its components.

47.2 Trial Management Group (TMG)

Regular meetings of a Trial Management Group (TMG) will take place to oversee the progress of the trial and review recruitment; the TMG will also be responsible for overseeing the qualitative components of the study. This group will include all co-applicants, collaborators, local principal investigators, representatives from the data management staff, trial statisticians and research staff. The trial will be managed on a day-to-day basis by the York Trials Unit team. The group will meet every two months by either face to face or by an online meeting tool. The group will provide timely reports on the progress, or completion, termination or discontinuation of the study to the ethics committees.

47.3 Trial Steering Committee (TSC)

The committee will consist of the principal investigators of the study (the co-applicants), an independent chair and at least two other independent members (including PPI team input and independent person with lived experience). The steering group will meet on at

least annual basis (at least twice during the study) to discuss progress of the trial, or more often as appropriate. The DMEC, research team and statisticians will report to the TSC as necessary. Meetings for the TSC will alternate between London and University of Huddersfield/York.

47.4 Data Monitoring and Ethics Committee (DMEC)

The committee will consist of independent experts (including independent statistician and mental health professionals, who are independent of the principal investigator and the study team. Its remit will be to monitor the trial data in particular quality control and quality assurance of the data collected and progress of the trial including adherence to the trial protocol. The committee will also examine and ensure that the dignity, rights, safety and wellbeing of all study participants are maintained at all stages of the trial. Data reports will be supplied, including any adverse events, and the committee will have access to summary data and documentation. The Chair of the DMEC will be informed of any adverse events that arise from the study or regarding participants during the study period, and they will be in a position to recommend suspension or ending the trial depending on the severity of the adverse event.

48. Input from Public Involvement Group

Active involvement of People with Lived Experience (PWLE) of SMI is essential for this study. Development of an acceptable and feasible complex intervention requires co-production with service users and clinicians as well as researchers (MRC, 2008). PWLE has been and will continue to be integrated into all stages of the study (design, development and training for intervention, decisions about outcome measures, recruitment, analysis, and dissemination. We have PWLE representation on the Trial Management Group (co-applicant Isaac Samuels). We have a group of 4 PWLE who are experienced researchers and trainers as well as having "lived experience" of mental health service use who will act as a PPI advisory group. A PPI consultation event on sexual health and SMI in April 2015 provided the opportunity to engage with a larger and

more diverse pool of people for the study. Additionally, the research team will have engaged the NHS service users in each site to participate in focus groups for the development of the intervention. A PWLE support protocol, clearly defining roles, responsibilities and remuneration (in line with INVOLVE guidance) has been developed. Nolan (London) and Prof Hughes (Huddersfield) will supervise the PWLE consultants and training and support will be provided through the University of Huddersfield.

49. Financing and insurance

This study is being co-ordinated and conducted by the University of Huddersfield, York Trials Unit (University of York) and University College, London. The research has been funded by the National Institute of Health Research Health Technology Research Programme.

NHS Indemnity will apply for patients treated within NHS sites. The University of Huddersfield, University College, London and the University of York will provide legal liability cover for their employed staff. Non-negligent harm will not be covered.

50. Reporting and dissemination

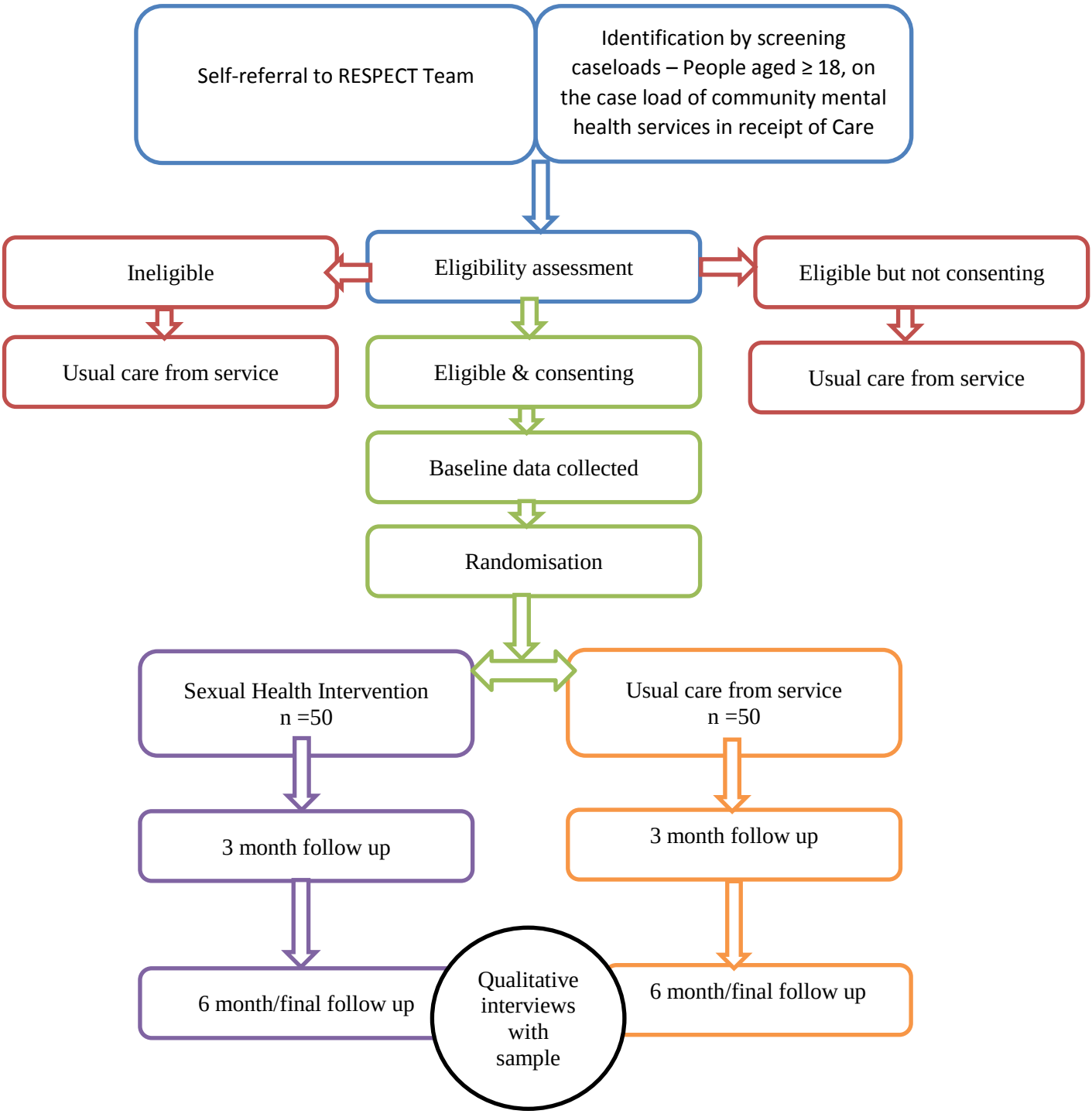
The results from this study will be submitted to the funders, peer-reviewed journals and presented at relevant meetings/conferences.

51. Project timetable

RESPECT Timeline	
Task	**Date**
Submit to NHS Ethics Committee	July 2016
Training intervention staff	Sept 2016

RESPECT Timeline	
Task	**Date**
In NHS Sites: promotion of study, training of CSOs, printing of study materials	Sept 2016
NHS Ethics and Site governance in place	Sept 2016
Recruitment and baseline data collection	Oct 2016 – March 2017
Follow up date collection	Dec 2016 – September 2017
Fidelity Monitoring	Oct 2016 – March 2017
Qualitative data collection: interviews with participants	March 2017
Staff focus group	May 2017
Data input and cleaning	Sept 2016 – Sept 2017
Quantitative Analysis	April 2017 – Nov 2017
Qualitative analysis	April 2017 – Nov 2017
End of Project Review meeting	Dec 2017
Write-up and outputs	Oct 2017 – Jan 2018

52. Appendix 1:Study flow diagram



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