

Sexual health promotion in people with severe mental illness: the RESPECT feasibility RCT

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Declared competing interests of authors: Catherine Hewitt reports being a member of the National Institute for Health Research Health Technology Assessment Commissioning Board.

Published December 2019

DOI: 10.3310/hta23650

Scientific summary

RESPECT feasibility RCT

Health Technology Assessment 2019; Vol. 23: No. 65

DOI: 10.3310/hta23650

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Scientific summary

Background

People with serious mental illness have needs in relation to sexual health, but there is limited evidence regarding effective interventions to promote sexual health in this population.

Objectives

The overall aim of the project was to design a sexual health intervention for people with serious mental illness and to establish the feasibility and acceptability of undertaking a randomised controlled trial in order to establish key parameters to inform a future effectiveness trial. The main objectives were to:

- undertake a stakeholder consultation to inform the development of an intervention
- use intervention mapping to develop an evidence-informed and co-produced manualised sexual health promotion intervention
- assess the feasibility and acceptability of recruiting people with serious mental illness to a trial comparing the intervention with usual care (control)
- 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 intracluster correlation coefficients
- explore the feasibility of collecting cost-effectiveness data for a full randomised controlled trial
- develop an understanding of the sexual health needs of people with serious mental illness who use NHS mental health services, their use and uptake of sexual health services and to establish the barriers to accessing information and service provision.

Methods

Intervention development

The intervention was developed by a process called intervention mapping, which provided a framework on which to base development, including theory and stakeholder input in decision-making. Relevant manualised interventions were identified and key elements summarised. A number of stakeholder consultations were held to refine the content of a prototype manual. Feedback from each consultation was used to modify the intervention procedures and information packs. The intervention manual was co-developed by people with lived experience of a serious mental illness, people who cared for people with serious mental illness, mental health nurses, sexual health workers, drug and alcohol workers, and support workers.

Feasibility trial

Design, participants and setting

A two-armed randomised controlled, open feasibility study comparing usual care alone with usual care plus an adjunctive intervention designed to promote sexual health. Participants were adults aged ≥ 18 years with serious mental illness who were receiving care from six community mental health services in four UK cities (Leeds, Barnsley, London and Brighton).

Randomisation

To maintain allocation concealment, randomisation was performed by a secure, remote, telephone randomisation service based at York Trials Unit. An independent statistician at the University of York undertook the generation of the randomisation sequence. Randomisation was on a 1 : 1 basis using stratified block randomisation with stratification by centre and variable block sizes.

Interventions

Participants were randomised to receive one of the following:

- the intervention arm – treatment as usual plus the Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment (RESPECT) intervention, offered as three 1-hour sessions on sexual health (the intervention was delivered by a specifically trained mental health worker and was supported by a specifically devised manual and intervention pack)
- the control arm – treatment as usual only.

Main outcome measures

Feasibility was measured by establishing the percentage of people who were eligible, consented and retained in each arm of the trial, retention in the intervention, as well as the completeness of the data collection. Data were collected on knowledge, motivation to adopt safer sexual behaviour, sexual behaviour, sexual stigma, sexual health service use and quality of life. Data were collected at baseline and then at 3 months post randomisation (and at 6 months for the first 38 participants only, because of time constraints). A nested qualitative study was undertaken in order to qualitatively assess the feasibility and acceptability of the RESPECT study from the perspective of the participants themselves. In addition, feedback questionnaires were completed by some participants at the recruitment stage and at the end-of-study stage.

Secondary outcome measures

Sexual risk behaviour [Sexual Risk Behaviour Assessment Schedule (SERBAS)], knowledge about human immunodeficiency virus [knowledge about HIV questionnaire (HIV-KQ)], perception of infection risk, motivation to engage in safer sex, behavioural intentions for safer sex and attitude towards condom use were also measured. Participants' perceived stigma as a result of their mental health problem [Mental Illness Stigma Scale (MISS-Q)] and substance use was also measured [Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)]. Specific items from the National Survey of Sexual Attitudes and Lifestyle (Natsal) were also included. These were all assessed at baseline, 3 months and 6 months post randomisation using intention-to-treat analysis; only the first 38 people recruited were followed up at 6 months because the time constraints on data completion meant that the subsequent participants could only be followed up at 3 months. The economic analysis included intervention costing, calculation of NHS costs per patient, EuroQol-5 Dimensions, five-level version (EQ-5D-5L) results, health-related quality of life and assessment of the feasibility questionnaires, in preparation for a full, sufficiently powered randomised controlled trial.

Results

Intervention design

There was significant overlap between the RESPECT intervention content and that identified from a thematic analysis of the previous study intervention manuals. One aspect that the stakeholder and people with lived experience consultations highlighted as important was the inclusion of contraception more broadly than just a focus on condoms. In addition, people generally felt that the tone of the intervention should be positive and focus on 'health', 'being safer' and having 'positive intimate relationships'.

Feasibility trial

From a target of 100 participants, 72 people participated in the trial over an extended period of 12 months. Participants' average age was 44.8 years, ranging from 22 years to 66.1 years. There was almost an equal split of men (48.6%) and women (47.2%), with three participants stating that they were 'other'. The majority of the participants classed themselves as heterosexual (81.9%).

Primary outcomes

Fifty-two per cent of patients screened (72/138) were randomised into the feasibility trial: 36 participants to each of the trial arms. Of the 36 participants randomised to the intervention arm, 27 received the intervention (75.0%). The first session was attended by 25 participants (69.4%), the second was attended by 19 (52.8%) and the third was attended by 18 (50%). In addition to this, five participants had combined sessions, in which they covered the material from multiple sessions at one time. Twenty-five per cent ($n = 9$) of the participants did not receive any of the intervention sessions for various reasons: five had withdrawn from the intervention, two gave no reason for not attending sessions, one did not want to have a male interventionist and one had logistical issues arranging appointments. At 3 months, 59 out of the 72 participants completed follow-up questionnaires (81.9%) (intervention arm, $n = 30$; control arm, $n = 29$). At 6 months, 29 out of the 38 participants (comprising only the first 38 participants) completed questionnaires (76.3%) (intervention arm, $n = 13$; control arm, $n = 16$).

The qualitative interviews and exit feedback forms confirmed that both the trial design and the intervention had been acceptable to participants. Overall, the participants found the data collection process to be acceptable, although some reported that it was quite long and that there was some repetition between the outcome measures, suggesting that the case report forms could be streamlined to reduce their length and avoid repetition.

Secondary outcomes

The study was not powered to detect any statistically significant differences in outcomes between the intervention arm and the control arm at follow-up. Some trends in favour of the intervention were seen, but these cannot be considered to be robust given the small number of participants that were involved. These included some reduction in reports of condomless sex at 3 months, reduction in unprotected vaginal sex acts at 3 months and 6 months, a slight increase in human immunodeficiency virus knowledge score in the intervention arm compared with the control arm at 3 months, a higher mean score on the Condom Use Self-Efficacy Scale at 3 months in the intervention arm than the control arm and on the Behavioural Intentions to Safer Sex measure there was an increase in scores at 3 months for the intervention arm and the scores for those in the control arm were slightly lowered, suggesting that those in the intervention arm had increased intentions to have safer sex.

Health service resource use data had a very high completion rate and the EQ-5D-5L questionnaire had no missing data among respondents who continued in the trial. During study follow-up, those in the intervention arm showed more improvement in quality of life than those in the control arm; however, given the sample size, no statistically significant conclusions can be drawn. Overall, the economic analysis suggested a high questionnaire completion rate and a low level of item missingness in participants who stayed in the study; moreover, we did not find any unreasonable or out of range responses.

Conclusions

The RESPECT study is the first study related to sexual health promotion in people with a serious mental illness in the UK. The overall aim was to establish the acceptability and feasibility of an intervention to promote sexual health in people with serious mental illness (as defined by having psychosis, bipolar, or schizoaffective disorder and being on the caseload of a community mental health team). Originally, we had planned to recruit 100 participants to be able to adequately estimate standard deviations, allowing for 30% attrition. However, the actual attrition seen in the trial was less than anticipated, with 18.1% at 3 months and 23.7% at 6 months. Although this led to only 59 participants being retained at 3 months, fewer than we had intended, this still allowed us to make adequate estimates to inform a future trial. The qualitative study conducted with a subsample of participants confirmed that they found the study to be acceptable both in terms of the overall design and implementation. In addition, the intervention was also found to be acceptable. Some minor suggestions for changes to process and intervention were given and will be taken into account for any future study.

The results of the outcome measures at the follow-up time points suggest a positive direction in favour of the intervention; however, the study was underpowered to detect statistically significant differences and a larger fully powered study would be able to evaluate effectiveness of the intervention with more confidence. Successful strategies for recruitment have been identified.

Although there were no predetermined criteria regarding the feasibility parameters required for progression to a future definitive randomised controlled trial of the RESPECT intervention, this feasibility study has indicated that it is both acceptable and feasible to undertake a randomised controlled trial of sexual health promotion for people with serious mental illness, and participants valued the experience and the importance of the topic to their lives.

Implications for practice/health care

Previous studies have suggested that sexual health is a topic that is often avoided in mental health. However, the findings from the RESPECT study indicate that this topic is of interest to people with serious mental illness and that, for some, it is a priority. Although the sample may not be representative of people with serious mental illness (as participants self-selected to participate) the data indicate that some people have poor knowledge about sexual health risks, low perceptions of risk and motivation to engage in safer sex, and by self-report are engaging in condomless vaginal sex. While acknowledging that this is not a representative sample, these findings do confirm the results from studies undertaken in the USA and support the view that sexual health and relationships are important aspects of health for people with serious mental illness (just like the general population). In the RESPECT study, all participants were given male condoms and sachets of water-based lubrication as well as information about local sexual health services. These are relatively straightforward interventions, yet we know from surveys conducted in the UK that condoms are not provided as a matter of routine in mental health services. In addition, mental health staff appear to lack knowledge about local services. There is a need for mental health services to consider providing standard sexual health promotion information to all service users.

Recommendation for research

A fully powered trial would be able to establish the clinical effectiveness and cost-effectiveness of the RESPECT intervention. Further research into the relationship between mental health and sexual health is also required.

Trial registration

This trial is registered as ISRCTN15747739.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.819

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 14/172/01. The contractual start date was in February 2016. The draft report began editorial review in August 2018 and was accepted for publication in January 2019. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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