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The RESPECT Study (Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment): a feasibility study of an intervention aimed at improving the sexual health of people with severe mental illness

Submission date
30/06/2016

Recruitment status
No longer recruiting

Registration date
05/07/2016

Overall study status
Completed

Last Edited
19/11/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims

People with serious mental illness (SMI) who experience long-term, relapsing mental health problems that require ongoing support from NHS mental health services, often have additional physical health problems. However, these needs are not always addressed for a number of reasons including lack of motivation, not reporting symptoms to their health workers, and what is known as "diagnostic over-shadowing", which means that physical ailments can be misinterpreted as a part of their mental illness (such as low energy levels and loss of appetite). As a response to these physical health needs, there is now a push for ways to help people with SMI access physical health care (including health checks at GP and assessment of physical health in mental health care). Despite this effort, one important area of health has been missed: sexual health. People with SMI, just like everyone else, hope to have safe and satisfying sexual relationships, and indeed this is an important part of building a life of recovery after a period of mental illness. However, the reality for people with SMI is often more bleak. Some people are more at risk of sexually acquired infections such as HIV and hepatitis B (and C), and more likely to face violence and exploitation in their relationships. An examination of published studies (a review) has looked at whether there are any ways of working that help promote sexual health and safer relationships. This review found that it was possible to get people involved in studies that focused on sexual relationships and sexual behaviour, and that some studies showed that there were positive changes in sexual behaviour after taking part in a specially focused group intervention. However, all the studies were done in the USA, and each was very different in how they were delivered. This has made it difficult to know what might help people with their sexual health and relationship needs here in the UK. Therefore, there is a need to develop an a package of care (intervention) that is relevant to the needs of people in the UK, and establish whether this is practical and whether it is acceptable and useful for people it is aimed at (feasibility

study). This type of study examines the practical issues in establishing such a study and therefore can iron out any of these problems before further funding is granted to do a much larger study.

Who can participate?
People aged 18 and over with severe mental illness

What does the study involve?
Participants are randomly allocated to receive usual care or the sexual health intervention plus usual care. Information is collected on how many people sign up to the study, how many 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, and use of sexual health services and GP services for family planning. A small group of people are interviewed about their experience of being part of the study.

What are the possible benefits and risks of participating?
A healthy sex life is just as important to people living with serious mental illness as it is for everyone else. Providing people with sessions about sexual health equips them with information about how to maintain their sexual health. The topic can be a little embarrassing to discuss and is therefore often avoided.

Where is the study run from?
1. Leeds and York Partnership NHS Foundation Trust
2. South West Yorkshire Partnership NHS Foundation Trust
3. Camden and Islington NHS Foundation Trust
4. Sussex Partnership NHS Foundation Trust
5. North East London NHS Foundation Trust

When is the study starting and how long is it expected to run for?
February 2016 to August 2018

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Dr Samantha Gascoyne (samantha.gascoyne@york.ac.uk)
2. Prof. Elizabeth Hughes (E.C.Hughes@hud.ac.uk)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 14/172/01; V2.0

Study information

Scientific 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

Acronym
RESPECT

Study objectives
To demonstrate the feasibility of recruiting people with severe mental illness (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.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1417201

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands –Derbt Research Ethics Committee, 30/09/2016, IRAS ID 21103, ref: REC 16/EM /0334

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Improving sexual health for those with severe mental illness

Interventions
Participants are randomised to receive either:
1. Usual care alone
2. Usual care plus a manualised sexual health intervention developed using Intervention Mapping derived from a synthesis of current evidence and co-produced with public involvement members with SMI and other key stakeholders

The main outcome is to establish the feasibility and acceptability of the intervention and the trial methodology. We will use a battery of quantitative outcome measures (to be specified in stage 1) related to sexual health knowledge, motivation, sexual behaviour, sexual stigma, violence in relationships, service use, and quality of life. In addition we will interview a sub-sample of participants in both arms to gather qualitative data on the acceptability of the outcome measures and the intervention itself. We include both arms as we are interested in whether the outcome measures in themselves led to greater interest in, and uptake of sexual health and family planning services and other related services, and whether involvement in the study has increased the likelihood of their conversations with their case manager being related to sexual health and relationship issues.

All data will be presented descriptively with no formal statistical analyses undertaken. Recruitment rates, attendance data, withdrawals and outcome completion rates will be compared between study arms at each stage of the trial.

The economic analysis will evaluate the feasibility and challenges of measuring costs and outcomes in the target population to inform the choice of effectiveness and resource use measures for the full-scale study.

Intervention Type
Behavioural

Primary outcome measure
The overall aim of the project is to establish the feasibility and acceptability of an evidence informed intervention to promote sexual health, and establish parameters for a future trial

Secondary outcome measures
1. To develop an understanding of sexual health needs of people with SMI who use NHS mental health services
2. To establish the use and uptake of sexual health services by people with SMI
3. To establish the barriers to accessing information and service provision
4. To establish treatment effectiveness through 3 and 6 month outcome quantitative data
5. To establish workforce capacity to undertake such an intervention in mental health services
6. To explore cost effectiveness in preparation for a large definitive randomised controlled trial
7. To develop recommendations for care pathways between mental health and sexual health service

Overall study start date
01/02/2016

Completion date
31/08/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/01/2018:
1. People on the case load of community mental health services
2. Aged 18 and over
3. Willing to provide written informed consent
4. Able to provide written informed consent

Previous inclusion criteria:
1. People on the case load of community mental health services
2. In receipt of Care Programme approach
3. Aged 18 and over
4. Willing to provide written informed consent
5. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
72

Key exclusion criteria
1. 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)
2. Severe physical illness that precludes them from active participation
3. Significant cognitive impairment (such as an organic brain disorder) as determined by psychiatrist or case notes
4. Non-English speaker (adapting the intervention is currently beyond the scope of this study)
5. Lacking capacity to consent (as guided by the Mental Capacity Act)
6. Unable or unwilling to give written informed consent

Date of first enrolment
01/01/2017

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds and York Partnership NHS Foundation Trust
United Kingdom
LS15 8ZB

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
United Kingdom
WF1 3SP

Study participating centre
Camden and Islington NHS Foundation Trust
United Kingdom
NW1 0PE

Study participating centre

Sussex Partnership NHS Foundation Trust
United Kingdom
BN13 3EP

Study participating centre
North East London NHS Foundation Trust
United Kingdom
RM13 8GQ

Sponsor information

Organisation
University of Huddersfield (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/05t1h8f27

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/08/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	20/12/2019	Yes	No
Results article	results	17/11/2020	19/11/2020	Yes	No
HRA research summary			26/07/2023	No	No