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Accessing sexual health care for people with severe mental illness

Submission date
07/03/2024

Recruitment status
No longer recruiting

Registration date
14/03/2024

Overall study status
Completed

Last Edited
25/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People with severe mental illness (e.g., schizophrenia) experience more physical illnesses compared to those who do not have mental illness. As a result, mental health services are increasingly offering service users regular health checks and healthy living advice. However, sexual health often remains overlooked. People with severe mental illness are LESS likely to attend sexual health services. Improved engagement with, and access to, sexual health services is essential for the treatment and prevention of sexual ill health. However, very little is known about why people with severe mental illness are less likely to access sexual health services. Therefore, this study will seek to identify the barriers to effective support and offer recommendations around sexual and reproductive health care in this group. To do this, the research team will talk directly to people with severe mental illness and sexual and reproductive health staff.

Who can participate?
Adults aged 18 years old and over with a current diagnosis of severe mental illness. For this study, severe mental illness will be defined as including all psychosis, schizophrenia and schizophrenia-related disorders, bipolar disorder and psychotic major depression. People who work in the sexual and reproductive health services.

What does the study involve?
Participants will be asked about their views and experiences of sexual and reproductive healthcare in private 1 to 1 interview, either in person, on an online video call or using the telephone.

What are the possible benefits and risks of participating?
There will be no direct benefits from taking part in this research. However, participants might value speaking with the researcher in the interview and value having the opportunity to share their experiences. They will also receive a £20 voucher as a thank you.

Participants will be asked questions about their experiences, their opinions and, if applicable, their views on the care that they have received, which they may find personal. They can take time to answer and do not have to answer questions that they do not want to. They can also

discuss any concerns at the end of the interview, and they will be asked if they would like their healthcare provider or case worker/support worker to be told so that they can provide further support.

Where is the study run from?
The study is run from the King's College London and the South London and Maudsley NHS Trust.

When is the study starting and how long is it expected to run for?
January 2024 to May 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
Dr Margaret Heslin, Margaret.heslin@kcl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
335538

Protocol serial number
NIHR205310, IRAS 335538, CPMS 61699

Study information

Scientific Title

Barriers and facilitators to accessing sexual health care for people with severe mental illness in England

Study objectives
Aim: To investigate the barriers and facilitators to accessing sexual and reproductive healthcare in people with severe mental illness from a service user and sexual and reproductive health providers' perspective.

Research Question: What are the barriers and facilitators to accessing sexual and reproductive healthcare in people with severe mental illness?

Study Objectives
There are two separate studies to answer two study objectives:
* Study 1 - To explore the barriers and facilitators to accessing sexual and reproductive healthcare in people with severe mental illness from a service user perspective.
* Study 2 - To explore the barriers and facilitators to accessing sexual and reproductive healthcare in people with severe mental illness from a sexual health providers' perspective.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/04/2024, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8290; gmeast.rec@hra.nhs.uk), ref: 24/NW/0092

Study design
National qualitative study using one-to-one semi-structured interviews and focus groups

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Sexual health in people with severe mental illness (schizophrenia and related disorders, bipolar disorder and psychotic major depression)

Interventions
The two objectives will be met using slightly different methodologies and are described below separately.

Study 1 - Service User Perspectives
A qualitative research study will be used to explore the research question from the perspective of service users, informed by their experience of accessing sexual and reproductive health services. Individual semi-structured in-depth one-to-one interviews will be undertaken with participants. Interviews will be facilitated by a topic guide to ensure that the interviews have a clear focus on the study objectives while allowing research participants to develop their areas /topics for discussion. Stratified purposive sampling will be used to recruit a diverse range of

people in terms of location, age, gender, gender identity, ethnicity, sexuality, disability and neurodiversity, with & without experience of sexual health services. The principal means of data collection will consist of recordings conducted in MS Teams interviews, transcribed verbatim. Transcripts will be analysed using reflexive thematic analysis.

Study 2 - Sexual and Reproductive Health Providers' Perspective
Focus groups will be used to explore the research question from the perspective of sexual and reproductive health providers, informed by their experience of providing sexual health services to people with severe mental illness. Focus groups will be facilitated by a topic guide and analysed as above.

Intervention Type
Other

Primary outcome(s)
1. Perspectives of service users, informed by their experience of accessing sexual and reproductive health services, measured using data collected from individual semi-structured in-depth one-to-one interviews conducted in MS Teams interviews, transcribed verbatim at one timepoint
2. Sexual and reproductive health providers' perspectives measured using data collected from focus groups at one timepoint

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/05/2025

Eligibility

Key inclusion criteria
Service users:
1. Aged 18 years old and over
2. Have received a formal diagnosis of SMI described above from a mental health professional
3. Have the ability to give informed consent

Staff:
1. Currently working in sexual or reproductive healthcare provision or have done so in the last 3 years
2. Have the ability to give informed consent

Participant type(s)
Health professional, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
44

Key exclusion criteria
Service users:
1. Not diagnosed with a severe mental illness
2. Aged under 18 years old
3. Are considered by the researcher(s) to be too unwell or distressed to participate in the study
4. Are unable to give informed consent to the study

Staff:
1. Are not currently working in sexual and reproductive healthcare provision or have not done so in the last 3 years
2. Are unable to give informed consent to the study

Date of first enrolment
07/06/2024

Date of final enrolment
22/04/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
De Cresginy Park
London
United Kingdom
SE5 8AF

Study participating centre
Maudsley and Bethlem Hospital School
Maudsley Hospital
Denmark Hill
London
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Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from margaret.heslin@kcl.ac.uk. The type of data that will be shared are anonymised transcripts of interviews, which will be available after the journal paper's publication. informed consent from participants was required and obtained. There are no ethical or legal restrictions.

IPD sharing plan summary
Available on request