ISRCTN36391109 https://doi.org/10.1186/ISRCTN36391109

moreRESPECT: A study of an intervention aimed at improving the sexual health of people with severe mental illness

Submission date
10/07/2023

Recruitment status
Recruiting

Registration date
25/07/2023

Overall study status
Ongoing

Last Edited
19/03/2025

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

Background and study aims
People with severe mental illness (SMI) have significant needs in terms of physical health compared to the general population. Initiatives have commenced to address this; however, sexual health has been missed off the agenda. Like everyone else, positive sexual relationships are important for people with SMI, but this is rarely discussed in routine mental health care. Therefore, they can be unaware of important information such as where to get sexual health advice, how to reduce risk of sexually transmitted infections, contraceptive choices and finding relationships that are mutually respectful, not violent or abusive.

In a National Institute for Health and Care Research (NIHR)-funded feasibility study, this research team developed a 3-session support package that helped people with SMI to think about their own sexual health and provided useful information about how to improve their sexual health. Following the success of the feasibility study, this full trial will examine the effectiveness and cost-effectiveness of the intervention by recruiting 400 people with SMI from National Health Service (NHS) community mental health teams across England and Scotland.

Who can participate?
This study will recruit 400 participants with SMI from community mental health teams from NHS mental health services across England and Scotland.

What does the study involve?
People who agree to take part will be randomly allocated to either usual care (control arm) or usual care plus the moreRESPECT intervention (intervention arm). Data will be collected at baseline and then at 3-, 6-, 9- and 12 months post-randomisation. As part of a nested process evaluation, interviews with a small group of participants will also be conducted at 6 months post randomisation to find out how they found the support package and whether it worked better for some than others and in what circumstances.

What are the possible benefits and risks of participating?
We cannot promise that taking part in this study will help participants directly. However, some

people who took part in a previous study told us that they found taking part interesting, thought-provoking, and informative. The results of this study may help us find out how we can improve sexual health for people with a severe mental illness. Taking part will involve participants setting aside some time to meet with a member of the study team to complete the study's questionnaires. Participants in the sexual health information sessions group will also need to meet with a trained health professional three times. These may be face-to-face meetings or video call meetings. Participants safety and well-being are very important to us. Our team are trained to ensure participants comfort and minimise distress. We are aware that some participants may find some of the topics and questions about sex embarrassing. Some of the questions may also trigger upsetting memories. We will provide information for local and national support and will have a process to supporting those who may become upset or distressed.

Where is the study run from?
Glasgow Caledonian University (GCU) (UK)

When is the study starting and how long is it expected to run for?
September 2022 to September 2026

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

Who is the main contact?
morerespect-trial@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Liz Hughes

ORCID ID
http://orcid.org/0000-0002-4480-0806

Contact details
Glasgow Caledonian University (GCU), Cowcaddens Rd
Glasgow
United Kingdom
G4 0BA
+44 (0)141 331 8379
Elizabeth.hughes@gcu.ac.uk

Type(s)
Public

Contact name
Ms Laura Wiley

Contact details

York Trials Unit
Department of Health Sciences
University of York
ARRC Building
York
United Kingdom
YO10 5DD
+44 1904 321947
laura.wiley@york.ac.uk

Type(s)
Public

Contact name
Ms Laura Wiley

Contact details
York Trials Unit
Department of Health Sciences
University of York
ARRC Building
York
United Kingdom
YO10 5DD
+44 1904 321947
morerespect-trial@york.ac.uk

Type(s)
Public

Contact name
Dr Sam Brady

Contact details
York Trials Unit, Department of Health Sciences, University of York, ARRC Building
York
United Kingdom
YO10 5DD
+44 (0)1904 32(1926)
samantha.gascoyne@york.ac.uk

Type(s)
Public

Contact name
Mr Mo Hammouda

Contact details
York Trials Unit, Department of Health Sciences, University of York, ARRC Building
York
United Kingdom

YO10 5DD
+44 (0)1904 32(3905)
mo.hammouda@york.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309345

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56541, NIHR133865, IRAS 309345

Study information

Scientific Title
MoreRESPECT: A randomised controlled trial of a sexual health promotion intervention for people with severe mental illness delivered in community mental health settings

Acronym
MoreRESPECT

Study hypothesis
A bespoke sexual health intervention designed for people with severe mental illness reduces unprotected sexual acts and is cost-effective

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/07/2023, North West – Preston REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8143; preston.rec@hra.nhs.uk), ref: 23/NW/0157

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
https://www.morerespect.co.uk/

Condition
Sexual health promotion intervention for people with severe mental illness

Interventions
Participants will be randomly allocated to either the sexual health intervention group (in addition to usual care) or the usual care group. Data will be collected at the start of the participant's involvement (baseline) and then at 3, 6, 9 and 12 months after randomisation.

Intervention (Sexual health information sessions plus usual care): In addition to continuing with usual care and support that is usually available, participants will be invited to attend sexual health information sessions delivered by a trained health professional. This will comprise of 3 x 1 hour sessions delivered either face-to-face or via video call. Each time intervention participants meet with a health professional they will discuss things such as: understanding sexually transmitted infections; condoms and contraception; safer relationships, including assertiveness skills and negotiating skills relating to the type of sexual relationships they want to have.

Control (Usual Care): Participants will continue with their usual care and support that is usually available to them.

Intervention Type
Behavioural

Primary outcome measure
Number of unprotected sex acts (anal, vaginal, oral) are recorded using an adapted version (with permission) of the Sexual Risk Assessment Schedule (SERBAS) at baseline, 3, 6, 9 and 12 months

Secondary outcome measures
1. Knowledge about human immunodeficiency virus (HIV) and sexually transmitted infections is recorded using an adapted version (with permission) of the HIV-Knowledge Questionnaire (HIV-KQ) at baseline, 3, 6, 9 and 12 months
2. Perception of the risk of infection with a sexually transmitted infection (STI) is recorded using an adapted version of the Motivation to Engage in Safer Sex measure at baseline, 3, 6, 9 and 12 months
3. Attitudes towards the use of condoms as well as questions on self-efficacy in the use and negotiation of use of condoms are recorded using an adapted version (with permission) of the Condom Use Self-Efficacy Scale at baseline, 3, 6, 9 and 12 months
4. Engagement in risky or protective sexual behaviours is recorded using an adapted version (with permission) of the Behavioural Intentions for Safer Sex measure at baseline, 3, 6, 9 and 12 months
5. General questions about sexual health are recoded using items adapted from the National Survey of Sexual Attitudes and Lifestyle (NATSAL) questionnaire at baseline, 3, 6, 9 and 12 months
6. Health-related quality of life is measured using the EQ-5D-5L standardised instrument at baseline, 3, 6, 9 and 12 months
7. Quality of life for people with different mental health conditions is measured using the

Recovering Quality of Life (ReQoL) standardised instrument at baseline, 3, 6, 9 and 12 months
8. Heath care resource use, including medications, is captured using a bespoke resource use questionnaire at baseline, 3, 6, 9 and 12 months

Overall study start date
01/09/2022

Overall study end date
30/06/2026

Eligibility

Participant inclusion criteria
1. Adults aged > = 16 years
2. Diagnosed with a SMI*
3. In receipt of care from any form of adult community mental health service in each NHS site (outpatient clinics, day care, on caseload of community mental health team including assertive outreach; forensic, early intervention for psychosis, recovery colleges, depot clinics)
4. Willing and able to give informed consent to participate
*There is no agreed definition of SMI, so we will adopt a pragmatic and inclusive definition: a Psychiatrist assessed and documented (care record) primary diagnosis of schizophrenia schizoaffective disorder, or delusional/psychotic illness, or bipolar disorder, or major depression (with or without psychotic features), or severe anxiety, or personality disorder.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Participant exclusion criteria
1. Pose a current risk to others (e.g. research staff) including risks of sexual and/or physical violence;
2. A learning disability or other significant cognitive impairment;
3. Those known to be on the sex offenders register.

Recruitment start date
25/09/2023

Recruitment end date
31/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds and York Partnership NHS Foundation Trust
St. Marys House
St. Marys Road
Leeds
United Kingdom
LS7 3JX

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6ED

Study participating centre
Camden and Islington NHS Foundation Trust
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters Block B2
St Ann's Hospital
St Ann's Road
London
United Kingdom
N15 3TH

Study participating centre
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre
West Park Hospital
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Sheffield Health & Social Care NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
United Kingdom
S4 7QQ

Study participating centre
Musgrove Park Hospital
Musgrove Park
Taunton
United Kingdom
TA1 5DA

Study participating centre
Springfield University Hospital
Trinity Building, 15 Springfield Dr

London
United Kingdom
SW17 0YF

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
Berkshire Healthcare NHS Foundation Trust
London House
London Road
Bracknell
United Kingdom
RG12 2UT

Study participating centre
Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
United Kingdom
BA1 3QE

Sponsor information

Organisation
Glasgow Caledonian University

Sponsor details
Cowcaddens Rd
Glasgow
Scotland
United Kingdom

G4 0BA
-
Sharron.Dolan@gcu.ac.uk

Sponsor type
University/education

Website
https://www.gcu.ac.uk/

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
Results from this study will be written up and submitted to peer-reviewed journals, irrespective of the outcome, around one year after the overall trial end date. The findings will be presented at relevant national and international conferences. A summary of the trial results will be produced and made available to participants via a lay summary or blog that will be sent to every site to be distributed to those who participated.

Intention to publish date
01/09/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No