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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
31/03/2026

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 (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 300 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 December 2027

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
https://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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309345

Central Portfolio Management System (CPMS)
56541

National Institute for Health and Care Research (NIHR)
NIHR133865

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 objectives
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

Study type(s)
Prevention

Health condition(s) or problem(s) studied
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(s)
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

Key secondary outcome(s))
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

Completion date
31/12/2027

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key 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

Date of first enrolment
03/01/2024

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

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

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

Study participating centre
Camden and Islington NHS Foundation Trust
St Pancras Hospital
4 St Pancras Way
London
England
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
England
N15 3TH

Study participating centre
Fieldhead Hospital
Ouchthorpe Lane

Wakefield
England
WF1 3SP

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

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

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

Study participating centre
Musgrove Park Hospital
Musgrove Park
Taunton
England
TA1 5DA

Study participating centre
Springfield University Hospital
Trinity Building, 15 Springfield Dr
London
England
SW17 0YF

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

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

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

Study participating centre
Central and North West London NHS Foundation Trust
Trust Headquarters
350 Euston Road
Regents PLACE
London
England
NW1 3AX

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Gloucester
England
GL3 4AW

Study participating centre
Black Country Healthcare NHS Foundation Trust
Trafalgar House
47-49 King Street
Dudley
England
DY2 8PS

Study participating centre
Hertfordshire Partnership University NHS Foundation Trust
The Colonnades
Beaconsfield Close
Hatfield
England
AL10 8YE

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
County Hall
Martineau Lane
Norwich
England
NR1 2DH

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
Leatherhead
England
KT22 7AD

Study participating centre
Oxford Health NHS Foundation Trust
Littlemore Mental Health Centre
Sandford Road
Littlemore
Oxford
England
OX4 4XN

Study participating centre
Northamptonshire Healthcare NHS Foundation Trust
St Marys Hospital
77 London Road
Kettering
England
NN15 7PW

Study participating centre
Lincolnshire Partnership NHS Foundation Trust Hq
NHS Foundation Trust
Carholme Court
Long Leys Road
Lincoln
England
LN1 1FS

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

Study participating centre
West London NHS Trust
St Bernards Hospital
Ealing
London
England
UB1 3HW

Sponsor information

Organisation
Glasgow Caledonian University

ROR

https://ror.org/03dvm1235

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes