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Assessing approaches aimed at improving sexual functioning

Submission date	**Recruitment status**	[X] Prospectively registered
04/04/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/04/2018	Stopped	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/08/2022	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Schizophrenia is a severe mental health condition that affects almost a quarter of a million people in the UK. The illness usually starts in early adult life and can have a major impact on a person's quality of life and social functioning. Antipsychotic medication provides effective treatment for most people with the condition, but these drugs have a range of side effects which can impair a person's quality of life. At least half of people who take antipsychotic medication for schizophrenia experience sexual dysfunction. Sexual dysfunction may have a considerable impact on a person's quality of life, particularly for people with psychosis who are more likely to experience relationship problems and social isolation resulting from poor mental health and stigmatisation. Previous studies of switching a person's antipsychotic medication have demonstrated beneficial effects. However, there is uncertainty about how effective switching antipsychotic medication is. This study will provide clinicians and patients with the evidence they need to know whether to use this approach to manage sexual dysfunction associated with use of antipsychotic drugs. The aim of this study is to investigate whether, among people with schizophrenia and related psychoses who experience sexual dysfunction associated with the use of antipsychotic medication, if switching their antipsychotic medication to one with a lower reported association with sexual side effects improves sexual functioning.

Who can participate?
Patients aged 18 or over with schizophrenia and related psychosis

What does the study involve?
Participants are randomly allocated to either switch (change antipsychotic) or no-switch (continue on current antipsychotic). Those allocated to switch are prescribed one of a choice of three antipsychotics. In addition, all study participants receive two sessions of advice and support delivered by a trained doctor or nurse to address sexual problems. Patients are followed up for 6 months to measure sexual dysfunction.

What are the possible benefits and risks of participating?
It is possible that sexual problems will improve in some of the participants in the study. The information from this study should improve understanding of sexual problems associated with antipsychotic medication. It is not anticipated that participants will have a negative response to

the advice and support sessions. Participants allocated to the switch group may experience side effects changing to a new antipsychotic medication.

Where is the study run from?
1. Central and North West London NHS Foundation Trust (UK)
2. Leeds and Yorkshire Partnership NHS Foundation Trust (UK)
3. Northumberland Tyne and Wear NHS Foundation Trust (UK)
4. South West Yorkshire Partnership NHS Foundation Trust (UK)
5. Tees Esk and Wear NHS Foundation Trust (UK)
6. West London NHS Mental Health Trust (UK)

When is the study starting and how long is it expected to run for?
May 2018 to October 2021

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

Who is the main contact?
Dr Verity Leeson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
37678

Study information

Scientific Title
Management of sexual dysfunction associated with antipsychotic drugs

Acronym
REMEDY

Study objectives
Schizophrenia is a severe mental health condition that affects almost a quarter of a million people in the UK. The illness usually starts in early adult life and can have a major impact on a person's quality of life and social functioning. Antipsychotic medication provides effective treatment for most people with the condition, but these drugs have a range of side effects which can impair a person's quality of life. At least half of people who take antipsychotic medication for schizophrenia experience sexual dysfunction. Sexual dysfunction may have a considerable impact on a person's quality of life, particularly for people with psychosis who are more likely to experience relationship problems and social isolation resulting from poor mental health and stigmatisation. Previous studies of switching a person's antipsychotic medication have demonstrated beneficial effects. However, there is uncertainty about how effective switching antipsychotic medication is. This study will provide clinicians and patients with the evidence they need to know whether to use this approach to manage sexual dysfunction associated with use of antipsychotic drugs.

The aim of the study is to investigate whether, among people with schizophrenia and related psychoses who experience sexual dysfunction associated with the use of antipsychotic medication, if switching their antipsychotic medication to one with a lower reported association with sexual side effects improves sexual functioning.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/08/2018, West Midlands Solihull Research Ethics Committee (The Old Chapel Royal Standard Place, Nottingham, NG1 6FS; +442071048104; NRESCommittee.WestMidlands-Solihull@nhs.net), ref: 18/WM/0076

Study design
Randomised; Interventional; Design type: Treatment, Drug, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Antipsychotic-Induced Sexual Dysfunction

Interventions
Participants will be randomised on a 1:1 allocation ratio using a remote web-based randomisation system to either enhanced standard care plus a switch in antipsychotic medication or enhanced standard care alone.

Enhanced standard care
All study participants will be offered two sessions of enhanced standard care comprising usual treatment plus brief advice and support to discuss their sexual health and functioning.

Antipsychotic switch
In addition to enhanced standard care, those in the “switch” arm of the trial will be offered a change in their current antipsychotic medication to a choice of three antipsychotics with a lower tendency to cause sexual dysfunction: aripiprazole, quetiapine and olanzapine.

Patients will be recruited from NHS community mental health services and followed up for 6 months.

Intervention Type
Other

Primary outcome measure
Patient reported sexual dysfunction measured using the Arizona Sexual Experience scale (ASEX) at baseline, 3 and 6 months. Primary outcome at 6 months.

Secondary outcome measures
1. Sexual behaviour measured using questions from the National Survey of Sexual Attitudes and Lifestyles (NATSAL) at baseline and 6 months
2. Researcher-rated sexual functioning measured using the Clinical Global Impression for Sexual Functioning at 6 months
3. Mental health measured using the total score on the Positive and Negative Syndrome Scale (PANSS) at baseline and 6 months
4. Side effects of medication measured using the Antipsychotic Non-Neurological Side Effects Scale (ANNSERS) at baseline and 6 months
5. Medication adherence measured using the Brief Adherence Rating Scale (BARS) at baseline and 6 months
6. Quality of life measured using the European Quality of Life-5 Dimensions (EQ-5D-5L) 40 and the Recovering Quality of Life (REQOL) questionnaire at baseline and 6 months
7. Resource use measured using the Adult Service Use Schedule (AD-SUS) at baseline and 6 months

Overall study start date
01/05/2018

Completion date

31/10/2021

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Men or women aged 18 or over
2. A clinical diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder or psychosis not otherwise specified, as defined by DSM-IV
3. Sexual dysfunction associated with antipsychotic medication for whom reducing the dose of their current antipsychotic was either not effective or not appropriate
4. Assessed by their clinical team as not having an underlying physical condition that is responsible for their sexual dysfunction

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 232; UK Sample Size: 232

Total final enrolment
10

Key exclusion criteria
1. Acutely psychotic or have been so within the last 3 months
2. Unable to speak sufficient English to complete the baseline assessment
3. Currently prescribed clozapine as this medication is restricted to those with treatment resistant psychosis
4. Current sexual problems started prior to their taking antipsychotic medication
5. Currently taking part in another clinical trial

Date of first enrolment
01/08/2018

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Central and North West London NHS Foundation Trust (lead centre)
15-21 Headstone Drive
Harrow
United Kingdom
HA3 5QX

Study participating centre
Leeds and Yorkshire Partnership NHS Foundation Trust
2150, Thorpe Park
Leeds
United Kingdom
LS15 8ZB

Study participating centre
Northumberland Tyne and Wear NHS Foundation Trust
Wolfson Research Centre
Institute of Neuroscience
Campus for Ageing and Vitality
Westgate Road
Newcastle Upon Tyne
United Kingdom
NE4 5PL

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Fieldhead
Ouchithorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre
Tees Esk and Wear NHS Foundation Trust
Flatts Lane Centre
Normanby Road

United Kingdom
TS6 0SZ

Study participating centre
West London NHS Mental Health Trust
Clinical Trials Facility
Lakeside Mental Health Unit
West Middlesex University Hospital Site
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Sponsor information

Organisation
Imperial College Healthcare NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 16/95/01

Results and Publications

Publication and dissemination plan

The trialists will publish their results in the Health Technology Assessment Journal (March 2021) and widely read high-quality peer-reviewed open access journals. The results of the study will be presented at leading conferences for psychiatrists and mental health pharmacists. In addition, should the intervention demonstrate benefit for patients they will host an interactive free-to-access webinar on managing sexual dysfunction associated with use of antipsychotic medication for people with schizophrenia and related psychoses.

Intention to publish date

01/03/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made 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?
Results article	results	01/09/2020	16/09/2020	Yes	No
Other publications	Qualitative results of interviews exploring barriers to recruitment	22/08/2022	12/08/2022	Yes	No
HRA research summary			28/06/2023	No	No