

# Assessing approaches aimed at improving sexual functioning

<b>Submission date</b> 04/04/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/04/2018	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/08/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
v.leeson@imperial.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Verity Leeson

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## Additional identifiers

**Protocol serial number**  
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; NRESCcommittee.WestMidlands-Solihull@nhs.net), ref: 18/WM/0076

### **Study design**

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

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)

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

## Key secondary outcome(s)

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

## 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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

**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

## 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

### 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?
<a href="#">Results article</a>	results	01/09/2020	16/09/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Qualitative results of interviews exploring barriers to recruitment	22/08/2022	12/08/2022	Yes	No