

# RADAR Trial: Testing the effects of reducing and discontinuing antipsychotic medication in people with long-term schizophrenia and similar conditions

<b>Submission date</b> 30/01/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/10/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Psychosis and schizophrenia are common and costly mental health problems. Psychosis is the name given to a group of mental conditions in which cause people to perceive or interpret things differently from those around them. One of the most common causes of psychosis is schizophrenia, a condition that causes a range of psychological symptoms, including hallucinations (hearing and/or seeing things) and delusions (believing something that is not true). One of the main treatment options for psychosis and schizophrenia is long-term treatment with antipsychotic medication, but many patients still find life difficult. Antipsychotic drugs can also have dangerous and unpleasant side effects. Finding alternatives to long-term drug treatment is a priority for patients and services. This study is testing the effects of gradually reducing antipsychotic medication in people with schizophrenia, psychosis or similar conditions in order to see if it can help improve day-to-day functioning and how it affects their chance of suffering a relapse (worsening of their condition).

### Who can participate?

Adults who have been diagnosed with schizophrenia, psychosis or a similar condition and are taking antipsychotic medication.

### What does the study involve?

Once a person agrees to take part, they are randomly selected to receive either the 'antipsychotic reduction programme' or 'maintenance treatment'. The 'antipsychotic reduction programme' involves reducing the participant's dose of antipsychotic medication gradually over several months. Participants are seen regularly by a psychiatrist to review and adjust their antipsychotic medication and to monitor their mental health. Some participants are recommended to try and stop their antipsychotic medication. Other participants are supported to maintain as low a dose as possible. Participants who are selected for 'maintenance treatment' are recommended to stay on roughly the same dose of antipsychotics throughout the study. Small adjustments can be made as required to reduce side effects or for other reasons. All

participants complete assessments at the start of the study and then again after 6, 12 and 24 months to assess their social functioning, symptoms and medication side effects. Some participants and clinicians involved in the study are also invited to be interviewed in more detail to explore how they found the antipsychotic reduction programme and their experience of being in the study.

**What are the possible benefits and risks of participating?**

As this is a trial of a new approach to antipsychotic treatment, it is not yet clear if participants will receive any direct benefit from taking part. Previous research suggests participants who receive support to reduce antipsychotics have improved social functioning, but it is not known whether this will be the case in the current study. Previous research has shown that some people may experience increased symptoms of psychosis or schizophrenia as their medication is lowered, and there may be an increased risk of having a relapse. Participants receiving the antipsychotic reduction programme will be monitored regularly to prevent this. If participants experience increased symptoms or relapse, they will be given additional treatment, as they would receive if they were having their usual care. The reduction of antipsychotic medication will be halted if necessary, and antipsychotics may be re-started if they have been stopped.

**Where is the study run from?**

1. North East London NHS Foundation Trust (UK)
2. East London NHS Foundation Trust (UK)
3. Camden and Islington NHS Foundation Trust (UK)
4. Barnet, Enfield & Haringey Mental Health Trust (UK)

**When is the study starting and how long is it expected to run for?**

January 2016 to March 2022

**Who is funding the study?**

National Institute for Health Research (UK)

**Who is the main contact?**

Dr Nadia Crellin

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## Contact information

**Type(s)**

Scientific

**Contact name**

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
2016-000709-36

**Integrated Research Application System (IRAS)**  
193921

**ClinicalTrials.gov (NCT)**  
NCT03559426

**Protocol serial number**  
31486, IRAS 193921

## **Study information**

### **Scientific Title**

Research into Antipsychotic Discontinuation and Reduction (RADAR): a randomised controlled trial

### **Acronym**

RADAR

### **Study objectives**

The aim of this study is to compare a gradual strategy of antipsychotic reduction and possible discontinuation with maintenance (continuous) treatment in people with schizophrenia or who have recurrent psychotic episodes.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

London-Brent Research Ethics Committee, 27/10/2016, ref: 16/LO/1507

### **Study design**

Randomised; Interventional; Design type: Treatment, Drug

### **Primary study design**

Interventional

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

Treatment

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

Schizophrenia

## **Interventions**

Consenting participants are randomly allocated to one of two groups.

Control group: Participants continue to receive antipsychotic treatment at the original dose.

Intervention group: Participants take part in the Antipsychotic Reduction and Discontinuation strategy. This involves having their antipsychotic medication gradually reduced and discontinued if possible. The reduction is flexible, and can be done slowly or more quickly over approximately 12 months, depending on experiences or circumstances. During this time participants see their psychiatrist roughly every 2 months to discuss how they are getting on and to review their medication.

Participants are followed up at 6 months, 1 year, and 2 years and will include an assessment of social functioning, symptoms and medication side effects.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Antipsychotic treatment

## **Primary outcome(s)**

Social functioning is measured by the Social Functioning Scale at baseline, 6, 12 and 24 months

Added 14/09/2022:

Also measured between 48-84 months from randomisation into the original trial

## **Key secondary outcome(s)**

1. Symptoms are measured by the Positive and Negative Syndrome Scale (PANSS) at baseline, 6, 12 and 24 months
2. Side effects as measured by the Modified Glasgow Antipsychotics Side-effects Scale (GASS) at baseline, 6, 12, and 24 months
3. Patient satisfaction as measured by the Client Satisfaction Questionnaire (CSQ 8) at baseline, 6, 12 and 24 months
4. Subjective quality of life as measured by the Manchester Short Assessment of quality of life (MANSA) at baseline, 6, 12 and 24 months
5. Neuropsychological function tests at baseline, 12 and 24 months
6. Medication adherence as measured by the Medication Adherence Rating Scale (MARS-5) at baseline, 6, 12 and 24 months
7. Relapse as measured by the relapse assessment schedule questionnaire at 6, 12 and 24 months
8. Health state as measured by the EQ-5D-5L at baseline, 6, 12 and 24 months
9. Wellbeing as measured by the ICECAP-A at baseline, 6, 12 and 24 months
10. Cost of health and social care as measured by the Client Service Receipt Inventory at baseline, 6, 12 and 24 months
11. Ability to work as measured by the Work Productivity and Activity Questionnaire at baseline, 6, 12 and 24 months
12. Economic data collected from patient records at baseline 12 and 24 months

13. Recovery as measured by the Questionnaire about the Process of Recovery (QPR) at baseline, 6, 12 and 24 months

14. Sexual experiences as measured by the Arizona Sexual Experiences Scale (ASEX) at baseline, 6, 12 and 24 months

Added 14/09/2022:

All outcome measures except the social cognition battery will also be measured between 48-84 months from randomisation into the original trial

**Completion date**

10/03/2022

## **Eligibility**

**Key inclusion criteria**

1. Aged over 18 years
2. A clinical and/or ICD10 diagnosis of schizophrenia, schizoaffective disorder, delusional disorder or other non-affective psychosis
3. More than one previous episode of relapse or psychotic exacerbation, or a single episode lasting more than one year
4. Taking antipsychotic medication

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

253

**Key exclusion criteria**

1. Participant lacks capacity to consent to the trial
2. Participant has insufficient command of spoken English to understand trial procedures
3. Participant subject to a Community Treatment Order (CTO) that includes a requirement to take antipsychotic medication
4. Clinician considers there will be a serious risk of harm to self or others
5. Participant has been admitted to hospital or had treatment from the Home Treatment or Crisis Team within the last month
6. Females who have a confirmed pregnancy
7. Females who are breast-feeding

- 8. Involvement in another IMP trial
- 9. No contraindications to continuing on antipsychotic medication

**Date of first enrolment**

24/03/2017

**Date of final enrolment**

31/01/2020

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**North East London NHS Foundation Trust**  
Research & Development Department  
1st floor, Maggie Lilley Suite  
Goodmayes Hospital  
Barley Lane  
Ilford  
United Kingdom  
IG3 8XJ

**Study participating centre**

**East London NHS Foundation Trust**  
Newham Centre for Mental Health  
London  
United Kingdom  
E13 8SP

**Study participating centre**

**Camden and Islington NHS Foundation Trust**  
Bloomsbury Building  
St Pancras Hospital  
4 St Pancras Way  
London  
United Kingdom  
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**Study participating centre**

**Barnet, Enfield and Haringey Mental Health Trust**  
St. Ann's Hospital  
St Ann's Road  
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N15 3TH

## Sponsor information

### Organisation

University College London

### ROR

<https://ror.org/02jx3x895>

### Organisation

North East London NHS Foundation Trust

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health 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 current 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>		28/09/2023	02/10/2023	Yes	No
<a href="#">Protocol article</a>	protocol	27/11/2019	27/10/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes