

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

Submission date 30/01/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/10/2023	Condition category 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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Study website

<https://www.ucl.ac.uk/psychiatry/antipsychotic-discontinuation-and-reduction>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2016-000709-36

IRAS number

193921

ClinicalTrials.gov number

NCT03559426

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/01/2016

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 218; UK Sample Size: 218

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

England

United Kingdom

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

NW1 0PE

Study participating centre

Barnet, Enfield and Haringey Mental Health Trust

St. Ann's Hospital

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Sponsor information

Organisation

University College London

Sponsor details

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Sponsor type

University/education

ROR

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

Organisation

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Sponsor type

Hospital/treatment centre

Website

<http://www.nelft.nhs.uk/>

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

Publication and dissemination plan

Results will be written up for publication in high level scientific peer reviewed journals, and presented at academic conferences.

Intention to publish date

01/01/2023

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?
Protocol article	protocol	27/11/2019	27/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		28/09/2023	02/10/2023	Yes	No