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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

Registration date
07/02/2017

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
nadia.crellin@nelft.nhs.uk

Study website
https://www.ucl.ac.uk/psychiatry/antipsychotic-discontinuation-and-reduction

Contact information

Type(s)
Scientific

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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
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United Kingdom
NW1 0PE

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

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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