ISRCTN82850103 https://doi.org/10.1186/ISRCTN82850103

Choosing the right antidepressant for people with unipolar depression

Submission date
04/11/2022

Recruitment status
No longer recruiting

Registration date
07/11/2022

Overall study status
Completed

Last Edited
17/10/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Antidepressants are one of the available treatments for depression. There are many antidepressants that are licensed in the UK and any of them can be prescribed to you by your doctor. Matching antidepressant treatment to specific patients, however, is too often a matter of trial and error, with many factors influencing whether a treatment is suited to an individual. These factors may include clinical and demographic characteristics, how a person has responded to other treatments in the past, how severe their condition is and whether they have any other conditions they are being treated for.
This study aims to personalise treatment for people with depression. It uses a web-based decision support tool to predict which antidepressant works best for each individual patient, in comparison to usual care (i.e., when clinicians choose the antidepressant to prescribe based on their experience and clinical judgement).

Who can participate?
Patients aged between 18-74 years inclusive and diagnosed with a depressive disorder, who are willing to take an antidepressant but have not been treated with an antidepressant in the past 4 weeks

What does the study involve?
Participants will be invited to attend a study visit with a clinician, where they will be asked to sign a consent form and then asked some questions about their demographics and medical history. They will also be asked to answer a number of questionnaires before being allocated to either the group receiving standard care or the group using the PETRUSHKA tool. If a participant is assigned to the PETRUSHKA tool, they will be asked to express their preferences about some side effects and rank them based on how troublesome they would find them. At the end of the process, the PETRUSHKA tool will show them and their GP the three antidepressants that are most recommended for them (in ranking order), and the participant and their GP will be guided in the selection of the antidepressant to prescribe.

What are the possible benefits and risks of participating?
Participants will receive a treatment which may produce a reduction in depressive symptoms and an improvement in quality of life. However, this cannot be guaranteed. Participants will be

contributing to research which will help increase our knowledge of how depression treatment may be personalised, which may help improve future treatment of patients with depression. The researchers do not expect there to be any disadvantages or increased risk in taking part in this study. All the antidepressant medications that are prescribed are approved and routinely used as part of standard care in the NHS.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2018 to September 2023

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

Who is the main contact?
Prof. Andrea Cipriani, andrea.cipriani@psych.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Andrea Cipriani

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
286484

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 53582, IRAS 286484

Study information

Scientific Title
Personalise antidepressant treatment for unipolar depression combining individual choices, risks and big data

Acronym
PETRUSHKA

Study objectives
It is hypothesised that, in comparison with usual care, using the PETRUSHKA tool to prescribe an antidepressant in people with unipolar depression will be associated with more people still taking the prescribed antidepressant after 8 weeks and will also improve their depressive symptoms

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2022, South Central-Hampshire B Research Ethics Committee (2 Redmond Place London, E20 1JQ, UK; +44 (0)20 7104 8064; approvals@hrs.nhs.uk), ref: 22/SC/0240

Study design
Randomized; Interventional; Design type: Treatment, Drug, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unipolar depression

Interventions
The PETRUSHKA trial will be conducted in a primary care setting in the UK with participants being recruited by general practitioners (GPs) in GP practices. Secondary care settings will also be used to recruit a proportion of participants.

This is a two-arm, randomised, single-blind, superiority trial comparing the PETRUSHKA tool with standard care in patients with depression in the NHS.

Patients will be identified by their clinicians and screened for eligibility. Eligible patients will be provided with the patient information sheet to review and given the opportunity to ask questions. Those who wish to participate will be asked to complete an electronic informed

consent form. Once a patient has consented to the trial, the GP will use a randomisation tool to fairly decide whether the patient will be in one of two arms: the PETRUSHKA tool arm or standard care.

Once a patient has been randomised to an arm of the trial, they will be informed of the allocation. Following randomisation, the GP will collect data on demographics, medical history, and current medications and administer a set of baseline questionnaires which assess symptoms of depression, anxiety and suicidality.

For patients randomised to standard care, the GP will proceed in the usual way and prescribe the patient an antidepressant based solely on their clinical judgement.

For patients randomised to the PETRUSHKA tool, they will be asked to use the tool to rate common side effects associated with antidepressant treatments. Based on their preferences, patients will be shown a short list of antidepressants with details of the side effect profile and predicted efficacy of the treatment. The patient will then be asked to select the antidepressant they wish to be prescribed, based on the information provided. Patients will be able to ask their GP for support whilst using the tool as this is intended to be a collaborative decision-making process.

All patients, regardless of the arm they are randomised to, will be followed up for 52 weeks. The primary outcome will be assessed at 8 weeks. During the follow-up period, participants will be asked to complete a set of questionnaires which assess compliance with the prescribed medication, side effects, mood, anxiety and quality of life.

Intervention Type
Other

Primary outcome(s)
The number of participants who are still taking the allocated antidepressants after 8 weeks, collected by trained clinicians during the study visits and documented in the trial's case report forms

Key secondary outcome(s))
1. Self-rated depressive symptoms measured using the 9-item Patient Health questionnaire at baseline, weeks 2, 4, 6, 8,12, 16, 20 and 24
2. Depressive symptoms measured using the observer-rated 17-item Hamilton Depression Rating Scale at baseline, weeks 8 and 24
3. The number of participants who discontinue treatment at 8 weeks due to any cause, collected by trained clinicians during the study visits and documented in the trial's case report forms
4. The number of participants who discontinue treatment at 24 weeks due to any cause, collected by trained clinicians during the study visits and documented in the trial's case report forms
5. The number of participants who discontinue treatment at 8 weeks due to adverse events, collected by trained clinicians during the study visits and documented in the trial's case report forms
6. The number of participants who discontinue treatment at 24 weeks due to adverse events, collected by trained clinicians during the study visits and documented in the trial's case report forms
7. Self-rated anxiety symptoms measured using the 7-item Generalised Anxiety Disorder Assessment at baseline, weeks 2, 4, 6, 8, 12, 20 and 24

8. Observer-rated anxiety symptoms measured using the Hamilton Anxiety Rating Scale at baseline, week 8, and 24
9. The impact of depression on quality of life and capability wellbeing, measured using the EQ-5D-5L questionnaire at baseline, weeks 4, 8, 12 and 24
10. Risk of suicidality measured using the Columbia Suicide Severity Rating Scale at baseline and weeks 8 and 24
11. Functional outcome measured using the Work and Social Adjustment Scale at baseline, weeks 4, 8, 12 and 24
12. Health/social care costs of depression (direct and indirect) measured using the PECUNIA RUM at baseline, weeks 12 and 24

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the trial
2. Aged 18 -74 years
3. Clinical diagnosis of depressive disorder and for whom an antidepressant is clinically indicated
4. Participants willing to take antidepressant treatment, but have not been treated with antidepressants in the previous 4 weeks
5. Willing to meet any clinical requirements related to taking a specific medication
6. Able to read/understand and/or complete self-administered questionnaires online in English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Prescribed any antidepressant in the preceding 4 weeks
2. Current or historical diagnosis of ADHD, alcohol/substance use disorder, bipolar disorder, dementia, eating disorders, mania/hypomania, OCD, PTSD, psychosis/schizophrenia, treatment-resistant depression (having tried two or more antidepressants for the same depressive episode at adequate dose and time)
3. Diagnosis of arrhythmias (including Q-T prolongation, heart block), recent MI, poorly controlled epilepsy, acute porphyrias
4. Require urgent mental care or admission (including suicidal intent/plans)
5. Concurrently enrolled in another investigational medicinal product (IMP) trial or an

interventional trial about depression
6. Participants who are currently pregnant, planning pregnancy or lactating
7. Has a medical, social or other condition which, in the investigator's opinion, may make the participant unable to comply with all the trial requirements (e.g., terminal illness – motor neuron disease)

Date of first enrolment
14/11/2022

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Bicester Health Centre
The Health Centre
Coker Close
Bicester
United Kingdom
OX26 6AT

Study participating centre
Church Street Practice
Mably Way
Wantage
United Kingdom
OX12 9BN

Study participating centre
Eynsham Medical Group
Eynsham Medical Centre
Conduit Lane
Eynsham
Witney
United Kingdom
OX29 4QB

Study participating centre
Gosford Hill Medical Centre
167 Oxford Road
Gosford
Kidlington
United Kingdom
OX5 2NS

Study participating centre
The Univ of Nottingham Health Serv
Cripps Health Centre
University Park
Nottingham
United Kingdom
NG7 2QW

Study participating centre
The White Horse Medical Practice
Volunteer Way
Faringdon
United Kingdom
SN7 7YU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: RP-2017-08-ST2-006

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised data from this study will be available after the publication of the results of the trial and upon request from Prof. Andrea Cipriani (andrea.cipriani@psych.ox.ac.uk) as appropriate and after consultation/agreement with the NIHR. All contractual arrangements about the datasets will be managed by the Research Services of the University of Oxford.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes