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Anti-depressants for depression in Huntington's disease

Submission date
22/09/2025

Recruitment status
Not yet recruiting

Registration date
02/10/2025

Overall study status
Ongoing

Last Edited
25/09/2025

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
Huntington's Disease (HD) is a condition that causes problems with movement and thinking, which get worse over time. Many people with HD also experience depression, which affects their quality of life and ability to do everyday activities. Treating depression well could help people with HD and their families feel better and may reduce the need for expensive healthcare. However, depression in HD may be different from depression in people without HD, so it is not clear how well antidepressants work for people with HD. This study aims to find out if a larger trial of antidepressants for depression in HD is possible and what is the best way to measure depression in people with HD.

Who can participate?
Adults who have Huntington's Disease and report mild or moderate symptoms of depression to their doctor may be able to take part.

What does the study involve?
Participants are randomly assigned to receive either a common antidepressant (Sertraline) or a dummy pill (placebo) for 6 months. They have assessments of depression and other HD symptoms at the start of the study and again after 6 months. The study also collects blood and a small sample of the fluid around the brain (using a lumbar puncture) to see if antidepressant treatment changes certain substances linked to inflammation. The study also looks at how many people are willing to join and stay in the study, and which depression measures work best.

What are the possible benefits and risks of participating?
Taking part may help researchers learn more about how to treat depression in HD, which could benefit participants and others in the future. Participants may or may not notice an improvement in their own symptoms. Risks include possible side effects from the medication, and discomfort or risks from blood tests and lumbar puncture. All procedures are explained and carried out by experienced staff.

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
The study is expected to start soon and runs for about 6 months for each participant.

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Duncan.Mclauchlan@wales.nhs.uk
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Study website
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/devise-hd

Contact information

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Scientific, Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1010717

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
02-TC-24-024

Study information

Scientific Title
Developing EVIdence for AntidepreSsant ChoicE to Treat Depression in Huntington's Disease

Acronym
DEVISE-HD

Study objectives
The primary objective is to determine the feasibility of a blinded, placebo-controlled trial of antidepressants in people with HD

This feasibility trial has three five secondary objectives:
1. Determine the minimal clinically important difference (MCID), ceiling and floor effects for established measures of depression in HD, to inform outcome selection for a future efficacy trial
2. Determine potential effect sizes in outcome of interest to inform power calculations for a future efficacy trial
3. Determine if there are differences on clinical and fluid biomarkers of disease progression with antidepressant treatment
4. Determine the percentage of participants who are registered in ENROLL
5. Determine the percentage of participants who are registered in HDClarity

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Double-blind randomized controlled feasibility trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Antidepressant treatment for depression in individuals with a confirmed genetic diagnosis of Huntington's Disease.

Interventions
Randomisation will take place online through a bespoke system built for the trial to maintain the blind.
Participants will be randomised to receive either 50mg of sertraline or Placebo daily for 6 months. Participants will take the IMP orally. Total follow up duration is 6 months for both arms.

Intervention Type
Drug

Pharmaceutical study type(s)
Dose response

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Sertraline

Primary outcome measure
Feasibility outcomes measured at 6 months post recruitment:
1. Recruitment
2. Retention
3. Data completeness
4. Medication adherence

Secondary outcome measures
1. Depression severity is measured using the Montgomery Asberg Depression Rating Scale (MADRS) at baseline, 8 weeks, and 6 months post randomisation
2. Depressive symptoms are measured using the Beck Depression Inventory-II (BDI-II) at baseline, 8 weeks, and 6 months post randomisation

3. Depressive symptoms are measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 8 weeks, and 6 months post randomisation
4. Problem behaviours are measured using the Problem Behaviour Assessment at baseline, 8 weeks, and 6 months post randomisation
5. Suicidal ideation and behaviour are measured using the Columbia Suicide Severity Rating Scale (C-SSRS) at baseline, 8 weeks, and 6 months post randomisation
6. Disability is measured using the WHO Disability Assessment Schedule 2.0 (WHODAS 2.0) at baseline, 8 weeks, and 6 months post randomisation
7. Perceived social support is measured using the MOS Social Support Survey at baseline, 8 weeks, and 6 months post randomisation
8. Clinical progression of Huntington's Disease is measured using the critical Unified Huntington's Disease Rating Scale (cUHDRS) at baseline and 6 months
9. Motor function is measured using the motor assessment component of the cUHDRS at baseline and 6 months
10. Functional ability is measured using the functional assessment component of the cUHDRS at baseline and 6 months
11. Cognitive function, including association between visual association and memory/thought processing and cognitive inhibition, is measured using the cognitive assessment components of the cUHDRS at baseline and 6 months

Overall study start date
01/07/2025

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Adult participants (age ≥ 18), with a confirmed positive genetic test of HD
2. Presenting with a new episode of depression, defined by patient report of low mood and PBAs depressed mood item (i.e. not experiencing depressive symptoms for at least 4 months before the new episode)
3. Presenting with depressive symptomatology defined by patient report of low mood and PBAs depressed mood item score >1 for both severity and frequency

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Currently taking an antidepressant medication or have taken antidepressants in the last six months (for any indication)
2. A previous reaction and/or contraindication to sertraline, and/or Sertraline found to be ineffective
3. Any brain illness/injury, other than HD that, or medication in the opinion of the principal investigator, is likely to contribute to depressive symptoms
4. Any participant with severe depression (PBAs severity >3) or suicidal ideation (due to higher risk of deterioration and suicide in this group).
5. Not able to give informed consent

Date of first enrolment
01/02/2026

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Cardiff and Vale NHS Trust
Cardigan House
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
The Uffculme Centre
52 Queensbridge Road
Moseley
Birmingham
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B13 8QY

Study participating centre
Betsi Cadwaladr University Lhb Colwyn Bay Office
Princes Park
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Sponsor information

Organisation
Cardiff University

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Sponsor type
University/education

Website
http://www.cardiff.ac.uk/

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)

Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-review journal and dissemination of lay friendly version of the results

Intention to publish date
30/09/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from the trial manager by emailing DEVISEHD@cardiff.ac.uk

IPD sharing plan summary
Available on request