

A trial to investigate the effect on overall health and functioning in patients with Lewy body dementia of memantine as an add-on treatment to a cholinesterase inhibitor

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Registration date 12/07/2022	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/02/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Dementia with Lewy bodies (DLB) and Parkinson's disease dementia (PDD) are related complex illnesses with a wide range of distressing symptoms. People with DLB/PDD have worse quality of life, more complex symptoms, higher care costs, and are more sensitive to medications than people with Alzheimer's disease (AD).

Acetylcholinesterase Inhibitors (AChEI) are commonly used medicines that can help people with DLB/PDD by improving day to day functioning and thinking abilities. Another drug which might help is memantine, used to treat moderate to severe confusion in AD. It may help to improve memory, awareness and the ability to perform daily functions; however, it is not clear if adding memantine to AChEI is beneficial for people with DLB/PDD.

The aim of this trial is to find out if adding memantine to AChEI improves overall health and functioning for people with DLB or PDD.

COBALT is a double-blind, placebo-controlled, randomised trial to assess the clinical and cost-effectiveness of memantine compared to placebo in patients on an AChEI with DLB (COBALT-DLB) and PDD (COBALT-PDD). There are two separate COBALT trials being carried out using the same protocol, one in the UK and one in Australia. We plan to recruit a total of 372 patients and their caregivers/informants. The UK trial will recruit 300 participants from 30 sites and the Australian trial will recruit 72 participants from up to 5 sites. UK and Australian data will be combined for analysis.

Who can participate?

Patients aged 55 years or older with DLB or PDD, and their caregivers/informants.

What does the study involve?

DLB/PDD patients aged ≥ 55 years with a Mini Mental State Examination score of ≥ 8 , on a stable dose of AChEI will be randomised 1:1 to memantine or placebo for 52 weeks. Both trials are identical in procedure and conduct, with the only variation being the disease group.

Participants and their caregiver/informant will complete assessments at baseline, 26 weeks (primary, secondary and exploratory outcomes) and 52 weeks (secondary and exploratory outcomes). During these visits assessments will be completed by the patient and their caregiver/informant.

What are the possible benefits and risks of participating?

Benefits:

The COBALT trial may help to improve treatment for people with DLB and PDD. The patients who participate in the trial may gain significant satisfaction from contributing and the regular contact from the local trial team.

Risks:

Memantine is well tolerated in patients with moderate to severe dementia in Alzheimer's Disease, with adverse events (AEs) reported in 10% of patients (comparable to placebo). The most frequently occurring adverse reactions are dizziness, headache, constipation, somnolence, and hypertension. Patients will undergo a titration phase in the first 4 weeks of their participation to assess how well they tolerate the IMP.

At some visits the questionnaires and memory testing may take 1-2 hours. Participants may find the questions tiring, tedious or embarrassing. Participants may choose not to answer any specific questions or do any test at any time.

We will ensure there are adequate rest breaks, however participants or their caregiver/informant can also request a break at any time. If the patient/caregiver requests an extended break, the assessments can be paused but must be resumed within 7 days of the initial visit.

Where is the study run from?

UK Trial - Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust (UK)

Australian Trial - The University of Melbourne (UoM)

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

March 2022 to March 2025

Who is funding the study?

NIHR Health Technology Assessment programme in the UK and National Health Medical Research Council in Australia.

Who is the main contact?

Sarah Dunn (UK), cobalt.study@ncl.ac.uk

Lesley Vidaurre (Australia), vidaurre.l@wehi.edu.au

Study website

<https://research.ncl.ac.uk/cobalttrial/>

Contact information

Type(s)

Public

Contact name

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Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

2021-003232-88

IRAS number

1004660

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

RES-20-041, IRAS 1004660, ERM ID 79783, CPMS 51602

Study information

Scientific Title

COMBining memantine And cholinesterase inhibitors in Lewy body dementia Treatment trial

Acronym

COBALT

Study objectives

What is the clinical and cost effectiveness of memantine compared to placebo in patients with DLB (COBALT-DLB) and PDD (COBALT-PDD) who are being treated with an acetylcholinesterase inhibitor (donepezil, rivastigmine or galantamine)?

Clinical effectiveness is determined using a global outcome scale - the Clinical Global Impression of Change (CGIC), 6 months after recruitment.

Cost effectiveness will be measured using health economic indicators, in particular the Client Services Receipt Inventory which has been adapted for use specifically for the COBALT trial and looks at the participant's use of health and social care services.

The secondary and exploratory objectives include determining whether active treatment with memantine vs. placebo leads to changes in:

1. Carer-based impression of global changes (using an adapted CGIC)
2. Cognitive function
3. Neuropsychiatric symptom frequency and severity
4. Quality of life and function for the patient
5. Quality of life for the care-giver
6. Long-term changes in global outcomes

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 04/07/2022, East of England - Essex Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)2071048227; essex.rec@hra.nhs.uk), ref: 22/EE/0075

2. Approved 24/05/2023, Royal Melbourne Hospital (Grattan Street, Parkville, 3050, Australia; +61 3 9342 8530; research@mh.org.au), ref: 2023.031

Study design

Interventional double-blind randomized parallel group placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Dementia with Lewy bodies (DLB) and Parkinson's disease dementia (PDD)

Interventions

Memantine will be the Investigational Medicinal Product (IMP) for the COBALT trials. Memantine is currently licensed for the treatment of moderate to severe dementia in Alzheimer's disease and is used off-licence in the UK for treatment of other dementias including DLB and PDD.

IMP: Memantine 10mg tablets and Memantine 5mg tablets (Oral capsules).

Placebo: Matched placebo tablets for memantine 5mg and 10 mg tablets will be manufactured and classed as an IMP for this trial (Oral capsules).

All participants will receive an initial 4-week titration pack with clear instructions stated in the participant diary (part 1) dose instructions table. This table must be completed by the local trial team and the participant must be in receipt of the diary prior to starting the IMP. The 4-week titration schedule will start at 5mg daily in a single dose, taken in the morning. Thereafter, the dose will be increased by 5mg every week. The target dose will be 20mg/day, taken in the morning but titration will be based on tolerability and response.

Potentially eligible patients will attend a screening visit during which consent will be obtained prior to any eligibility checks and the trial eligibility confirmation will be performed. This will include review of Liver and kidney function tests within the preceding 6 months. If no test results are available within this timeframe, a blood sample will be required to carry out these tests. A Mini Mental State Examination (MMSE) will be completed with the patient and a clinical diagnostic worksheet will be completed to confirm the patient's diagnosis (Dementia with Lewy Bodies or Parkinson's Disease Dementia). The patients will also be required to have a caregiver /informant in order to be eligible for the trial. The patient's caregiver/informant should be a person that is in regular contact with the patient, who knows the patient well and is able to attend the trial follow-up visits as required. The caregiver/informant will complete assessments relating to the patient and themselves during the scheduled trial visits. The caregiver/informant should be identified during the screening process and is required to consent to take part in the

COBALT trial.

Once the patient has been consented and confirmed eligible, they will be randomised as a participant in either the COBALT – DLB or COBALT – PDD module of the trial, depending on their diagnosis confirmed at screening. For each trial module, a central, secure, web-based randomisation system with concealed allocation (Sealed Envelope – UK; REDCap – Aus)) will assign participants to active or placebo treatment in a 1:1 ratio. All participants, their caregiver /informants and site staff will be blinded to the participants treatment allocation, meaning that they will not know if the participant is receiving active or placebo treatment.

The baseline assessments can be carried out once the participant has been consented, screened and randomised. This can occur at the same visit or can be scheduled for another day, within 14 days of the consent and screening visit. At baseline the primary, secondary, and exploratory outcome assessments will be conducted. IMP will be dispensed, along with the participant diary to record any adverse events, missed trial medication, visits to health care professionals and changes to concomitant medications. The participants and their caregiver/informant will also be given a participant safety card that includes information relating to their participation and emergency contact numbers for the trial team. Participants will be instructed to carry the card at all times and present it to any healthcare professional that they see during their COBALT trial participation.

Following the participants initial baseline visit a number of follow up visits are required.

Visit 5 (week 26) - These visits may occur at the local trial site, in the participant's home. The primary, secondary and exploratory outcome assessments will be conducted per protocol section 7.4.2. IMP will be dispensed, IMP adherence will be checked along with any side effects /Adverse Events and changes to the participant's concomitant medications.

Visit 7 (week 52)/Early Withdrawal - These visits may occur at the local trial site, in the participant's home. Secondary and exploratory outcomes will be conducted per protocol section 7.4.3. IMP adherence will be checked along with any side effects/Adverse Events and changes to the participant's concomitant medications.

Visit 2 (week 3), Visit 3 (week 8), Visit 4 (week 14) and Visit 6 (week 38) - These visits may occur at the local trial site, in the participant's home or by telephone/video call. IMP adherence will be checked along with any side effects/Adverse Events and changes to the participant's concomitant medications per protocol section 7.4.4. At visit 4 and visit 6 IMP will be dispensed to ensure a continued supply for the participant.

A Resolution Call will be made to participants at week 56 (Visit 8) to document any adverse events they have experienced following the Visit 7 (week 52)/Early Withdrawal visit per protocol section 7.4.5.

Participants are given the option to consent to a long-term follow up 12 months after the end of their participation in the trial. This can either be by review of the medical records or by speaking to someone from the local or central trial team, depending on what the participant agrees to. The purpose of this additional follow-up is to understand the long-term outcomes for patients with DLB and PDD following treatment with memantine.

At selected Australian trial sites, participant consent will be obtained to collect and store approximately 60mL of blood for future research including for example biomarker development, genomics, transcriptomics. Blood may be collected at up to 3 timepoints throughout the trial i.e. baseline, week 26 and week 52.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Memantine hydrochloride neuraxpharm 5 mg film-coated tablets, memantine Torrent 10 mg film-coated tablets

Primary outcome measure

Alzheimer's Disease Cooperative Study - Clinical Global Impression of Change (ADCS-CGIC) scale at 26 and 52 weeks post baseline

Secondary outcome measures

COBALT-DLB and COBALT-PDD

at baseline, 26 and 52 weeks:

1. Caregiver/Informant Impression of Change (C/I-CGIC)
2. Montreal Cognitive Assessment (MoCA)
3. Neuropsychiatric Inventory Plus (NPI+)
4. Quality of life: EuroQol EQ-5D 5 Level (EQ-5D-5L) - patient
5. Quality of life: EQ-5D-5L – proxy
6. Hospital and Anxiety Depression Scale (HADS)
7. Disability Assessment for Dementia (DAD)
8. Impact of memantine on motor function: The Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III (MDS UPDRS-III)
9. Epworth Sleepiness Scale (ESS)
10. Client Service Receipt Inventory (CSRI)
11. Zarit Burden Interview (ZBI) - Caregiver/informant
12. WHO Quality of Life - BREF

Overall study start date

15/03/2022

Completion date

31/03/2027

Eligibility**Key inclusion criteria**

Current inclusion criteria as of 21/12/2023:

1. Patients with a diagnosis or clinical features consistent with established consensus criteria for probable DLB or probable PDD
2. Aged ≥ 55 years
3. MMSE score ≥ 8 . Evidence of mild, moderate, or moderate to severe cognitive impairment on similar global cognitive scales previously completed by their clinical care team (e.g., Addenbrooke's Cognitive Examination, Mini-Addenbrooke's Cognitive Examination, Montreal Cognitive Assessment) can be used to pre-screen the patient, prior to approach.
4. Receiving a stable dose of AChEI for ≥ 12 weeks prior to baseline, with no expected plans for dose adjustment during the trial period; dose adjustment will be allowed during the trial, if clinically indicated, following discussion with PI and, if required, the central trial team
5. If receiving any antiparkinsonian treatment, antidepressants, anxiolytics, antipsychotics, or other drugs with significant psychotropic effects then dose must be stable for a minimum of 4 weeks prior to enrolment with no expected plans for dose adjustment during the trial period. Dose adjustment will be allowed during the trial if clinically indicated and will be documented. If a change in medication with psychotropic effects is required, this decision can be made by the treating clinician (e.g., starting an antidepressant in clinic) without consultation with the CI. In

some instances, the clinician may feel it is appropriate/relevant to discuss this with the PI prior to prescribing, for example, if the clinician feels that the medication change may have an impact on the trial and/or trial medication. Any changes should however be documented in the patient's concomitant medications electronic Case Report Form (eCRF).

6. Patients who lack capacity will be required to have a personal/professional nominated representative who is able to give informed consent on the patient's behalf

7. Females must be postmenopausal and not receiving IVF treatment or must have undergone permanent sterilisation. Permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause.

8. Patients with sufficient knowledge of the English language or support to understand the Patient Information Sheet and complete the trial assessments

Previous inclusion criteria:

1. Patients with a diagnosis or clinical features consistent with established consensus criteria for probable DLB or probable PDD.

2. Aged ≥ 50 .

3. MMSE score ≥ 8 .*

4. Receiving a stable dose of AChEI for ≥ 12 weeks prior to baseline, with no expected plans for dose adjustment during the trial period; dose adjustment will be allowed during the trial, if clinically indicated, following discussion with PI and, if required, the central trial team.

5. If receiving any antiparkinsonian treatment, antidepressants, anxiolytics, antipsychotics, or other drugs with significant psychotropic effects then dose must be stable for a minimum of 4 weeks prior to enrolment with no expected plans for dose adjustment during the trial period. †

6. Patients who lack capacity will be required to have a personal/professional nominated representative who is able to give informed consent on the patient's behalf.

7. 7. Females must be postmenopausal and not receiving IVF treatment or must have undergone permanent sterilisation††

8. Patients with sufficient knowledge of the English language or support to understand the Patient Information Sheet and complete the trial assessments

*Evidence of mild, moderate, or moderate to severe cognitive impairment on similar global cognitive scales previously completed by their clinical care team (e.g., Addenbrooke's Cognitive Examination, Mini-Addenbrooke's Cognitive Examination, Montreal Cognitive Assessment) can be used to pre-screen the patient, prior to approach.

†If a change in medication with psychotropic effects is required, this decision can be made by the treating clinician (e.g., starting an antidepressant in clinic) without consultation with the CI. In some instances, the clinician may feel it is appropriate/relevant to discuss this with the PI prior to prescribing, for example, if the clinician feels that the medication change may have an impact on the trial and/or trial medication. Any changes should however be documented in the patient's concomitant medications electronic Case Report Form (eCRF).

††Permanent sterilisation methods include hysterectomy, bilateral salpingectomy and bilateral oophorectomy. A postmenopausal state is defined as no menses for 12 months without an alternative medical cause.

Participant type(s)

Patient

Age group

Adult

Lower age limit

55 Years

Sex

Both

Target number of participants

372 (UK: 300, Australia: 72)

Key exclusion criteria

1. Atypical clinical features or course suggestive of an alternative dementia diagnosis.
2. Any clinically relevant concomitant disease that will affect ability to participate in the trial including, but not limited to, chronic renal disease stage 5, history of acute or chronic pancreatitis, epilepsy or former history of convulsions, patients with recent myocardial infarction (within last 6 months), uncompensated congestive heart failure (NYHA III-IV), or uncontrolled hypertension.
3. Patients with severe hepatic impairment based on known history and/or significant abnormalities identified in blood liver function tests (for example, levels in liver function tests that are 2-3 times higher than the upper limit of normal), which in the judgement of the local PI would exclude the patient from the trial.*
4. Patients taking memantine, amantadine, ketamine, or dextromethorphan.
5. Any neurological or major psychiatric diagnosis that may be contributing to cognitive impairment above and beyond that caused by the patients DLB or PDD.
6. Renally impaired patients with $\text{eGFR} < 35 \text{ mL/min/1.73m}^2$.†
7. Currently taking part in another clinical trial that would interfere with the outcomes of the COBALT trial.
8. If in the opinion of the investigator, the patient would be unable to comply with the trial procedures or has difficulty taking oral medications.
9. Patients without a reliable caregiver/informant.

*LFTs should be repeated if they were not carried out at screening and were abnormal in the last 6 months and/or, in the judgement of the local PI, are clinically relevant to check before deciding trial entry.

†U&Es should be repeated if they were not carried out at screening and were abnormal in the last 6 months and/or, in the judgement of the local PI, are clinically relevant to check before deciding trial entry. For example, a borderline $\text{eGFR} < 45 \text{ mL/min/1.73m}^2$.

Date of first enrolment

24/11/2022

Date of final enrolment

31/05/2026

Locations**Countries of recruitment**

Australia

England

Northern Ireland

Scotland

United Kingdom

Study participating centre

Walter and Eliza Hall Institute (WEHI)

1G, Royal Parade

Parkville

Australia

VIC 3052

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

Study participating centre

South London and Maudsley NHS Foundation Trust

Bethlem Royal Hospital

Monks Orchard Road

Beckenham

United Kingdom

BR3 3BX

Study participating centre

Cambridgeshire and Peterborough NHS Foundation Trust

Elizabeth House,

Fulbourn Hospital

Fulbourn

Cambridge

United Kingdom

CB21 5EF

Study participating centre

Essex Partnership University NHS Foundation Trust

The Lodge

Lodge Approach

Runwell
Wickford
United Kingdom
SS11 7XX

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
Southern Health NHS Foundation Trust
Tatchbury Mount Hospital
Calmore
Southampton
United Kingdom
SO40 2RZ

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
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United Kingdom
G51 4TF

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
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Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road

Exeter
United Kingdom
EX2 5AF

Study participating centre

North Bristol NHS Trust

Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre

Sheffield Health & Social Care NHS Foundation Trust

Fulwood House
Old Fulwood Road
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United Kingdom
S10 3TH

Study participating centre

Tees, Esk and Wear Valleys NHS Foundation Trust

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West Park Hospital
Edward Pease Way
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DL2 2TS

Study participating centre

Cornwall Partnership NHS Foundation Trust

Carew House
Beacon Technology Park
Dunmere Road
Bodmin
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PL31 2QN

Study participating centre

NHS Fife

Hayfield House
Hayfield Road
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KY2 5AH

Study participating centre**Nottinghamshire Healthcare NHS Foundation Trust**

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Porchester Road
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NG3 6AA

Study participating centre**NHS Lothian**

Waverley Gate
2-4 Waterloo Place
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EH1 3EG

Study participating centre**Surrey and Borders Partnership NHS Foundation Trust**

18 Mole Business Park
Randalls Road
Leatherhead
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KT22 7AD

Study participating centre**South West London and St George's Mental Health Trust**

Livingston House, 2-6 Queens Road, Teddington
London
United Kingdom
TW11 0LX

Study participating centre

University College London Hospitals NHS Foundation Trust
250 Euston Road
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Study participating centre
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Farm Villa
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Study participating centre
Oxford Health NHS Foundation Trust
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BT9 7AB

Study participating centre

Sherwood Forest Hospitals NHS Foundation Trust

Kings Mill Hospital
Mansfield Road
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NG17 4JL

Study participating centre

Northern Care Alliance NHS Foundation Trust

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BL9 7TD

Study participating centre

The Walton Centre NHS Foundation Trust

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United Kingdom
L9 7LJ

Study participating centre

Lancashire and South Cumbria NHS Foundation Trust

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United Kingdom
PR2 8DW

Study participating centre

Derbyshire Healthcare NHS Foundation Trust

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Kingsway
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DE22 3LZ

Study participating centre
United Lincolnshire Teaching Hospitals NHS Trust
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Lincoln
United Kingdom
LN2 5QY

Sponsor information

Organisation

Cumbria Northumberland Tyne and Wear NHS Foundation Trust

Sponsor details

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Newcastle upon Tyne
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NE3 3XT
+44 191 2467221
cntwsponsormanagement@cntw.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.cntw.nhs.uk/>

ROR

<https://ror.org/01ajv0n48>

Organisation

University of Melbourne

Sponsor details

Office of Research, Ethics and Integrity
Research, Innovation and Commercialisation
161 Barry St
Carlton Victoria
Melbourne
Australia

3010

-

Clinicaltrials-governance@unimelb.edu.au

Sponsor type

University/education

Website

<http://www.unimelb.edu.au/>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

National Health and Medical Research Council

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Results and Publications

Publication and dissemination plan

Peer reviewed scientific journals
Conference presentation
Publication on website
Submission to regulatory authorities
Data collection, validation and storage procedures will be harmonised between the UK and Australia trial teams, with an ethos of free data sharing between countries. Consent will be sought from all participants (at the point of trial enrolment) to transfer their de-identified data to the central trial team in the other country, for the purpose of data analysis and coding

Intention to publish date

01/04/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request. We will provide a contact in due course but this is likely to be the Chief Investigator, Professor John – Paul Taylor.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.0	29/06/2022	17/10/2022	No	No
HRA research summary	version 4.0	01/03/2023	28/06/2023	No	No
Participant information sheet			27/03/2024	No	Yes
Protocol file			11/07/2024	No	No