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The neoGASTRIC trial: Avoiding routine gastric residual volume measurement in neonatal critical care

Submission date 25/01/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 08/02/2023	**Overall study status** Ongoing	
Last Edited 08/01/2025	**Condition category** Neonatal Diseases	

Plain English summary of protocol

Background and study aims

About one in seven babies born in the UK each year need specialist neonatal care in a hospital because they are born too early, are born very small or have a medical condition. Ensuring these babies have enough nutrition is a key part of their care.

Premature babies are fed milk every few hours through a soft plastic tube via their nose or mouth into their stomach, called a gastric tube. As premature babies stomachs and digestive systems are not yet ready for lots of milk, the amount of milk given each feed is increased slowly. Some doctors and nurses regularly check how much milk is left in a baby's stomach, called 'routinely measuring gastric residual volumes'. They check because they believe it will help them know how the baby is coping with the milk feeds and they also think it may help to identify a severe disease called necrotising enterocolitis (NEC). However, others think that measuring gastric volumes may be bad for babies and that it is inaccurate, uncomfortable for the baby and may actually be harmful.

The aim of the neoGASTRIC trial is to see if premature babies can safely get to full milk feeds quicker.

Who can participate?

All babies that are born 6 or more weeks early (before 34 weeks of pregnancy) who require tube feeding. The neoGASTRIC study is an opt-out study. Therefore all eligible babies will take part unless a parent does not wish their baby to participate or there is a medical reason why.

What does the study involve?

The neoGASTRIC trial will involve babies born more than 6 weeks early and will recruit about 7000 premature babies across the UK and Australia. Babies will be recruited from about 36 hospitals in the UK and 3-4 large hospitals in Australia, and will be recruited into one of two groups: to have no routine gastric residual volumes measured, or have gastric residual volumes measured regularly. This will be decided by chance, and babies will have an equal chance of being in either group. The two approaches being compared are already used in clinical practice

across the UK and Australia, so there is nothing new about either type of care. Babies will stay in the study until they reach full feeds, get discharged home, or when they reach 4 weeks past their due date (whichever one comes first)

The NeoGASTRIC trial will use an opt-out consent process, designed to be as simple as possible for families. This means that babies meeting the eligibility criteria will be automatically included in the trial unless parents opt-out. Parents will be informed about neoGASTRIC through posters and leaflets on the neonatal units and will have the option to opt-out at any point. This will make it easier for parents to be involved in the research and involve families who might not normally take part in research.

What are the possible benefits and risks of participating?
Both clinical approaches being studied are currently routinely practiced in the UK and Australia and so we do not believe there are any additional risks or benefits of taking part in neoGASTRIC. Not routinely measuring gastric residual volumes might lead to babies reaching full feeds quicker which might reduce the risk of infections – but we will only know this after we finish the neoGASTRIC study. We do not think there will be a greater risk of necrotising enterocolitis (NEC) from not routinely measuring gastric residual volumes because countries which do not routinely do this, such as France, have similar amounts of necrotising enterocolitis in the UK. Doctors and nurses will continue to look for necrotising enterocolitis through standard care and regular checks.

Where is the study run from?
The National Perinatal Epidemiology Unit, Clinical Trials Unit (NPEU CTU) at the University of Oxford, England, UK, in partnership with Monash University, Australia are coordinating and managing the study on behalf of the sponsor, Imperial College London.

When is the study starting and how long is it expected to run for?
September 2022 to October 2026

Who is funding the study?
The study is funded by the National Institute for Health and Care Research in the UK and the National Health and Medical Research Council in Australia.

Who is the main contact?
Chris Gale, Chief Investigator, Christopher.gale@imperial.ac.uk
Elizabeth Nuthall, Trial Manager, neogastric@npeu.ox.ac.uk

Study website
https://www.npeu.ox.ac.uk/neogastric

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

321050

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 321050, CPMS 54912

Study information

Scientific Title
Among babies born <34+0 gestational weeks does no routine measurement of gastric residual volume compared to routine (up to 6 hourly) measurement of gastric residual volumes lead to faster establishment of full enteral feeds without an increase in necrotising enterocolitis (NEC)?

Acronym
neoGASTRIC

Study objectives
The neoGASTRIC trial is taking place to determine whether avoiding the routine measurement of gastric residual volumes in preterm infants less than 34 weeks' gestation reduces the time taken for an infant to reach full enteral feeds without increasing harm, up until discharge home or 44+0 gestational weeks +days.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/02/2023, London Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8150; riverside.rec@hra.nhs.uk), ref: 23/LO/0060

Study design
Multi-centre randomized controlled trial

Primary study design
Other

Secondary study design

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
https://www.npeu.ox.ac.uk/neogastric/parents/parent-information-sheet

Health condition(s) or problem(s) studied
Preterm birth

Interventions
The neoGASTRIC study is an individually randomised, controlled, unmasked, trial comparing two parallel care pathways, with an internal pilot and process evaluation.
The two care pathways to be compared are:
1. No routine measurement of gastric residual volumes
2. Routine, up to 6-hourly, measurements of gastric residual volumes.
Both pathways represent standard clinical practice in different neonatal units in the UK and Australia.

Eligible infants will be identified by the neonatal teams in both the UK and Australia after admission. As both care pathways are standard neonatal practice, neoGASTRIC will use an opt-out consent approach.

The allocated pathway will be followed for as long as routine gastric residual measurement is standard local practice, until gastric feeding tubes are no longer required, the infant is discharged home or reaches 44+0 gestational weeks +days (whichever is sooner).

Updated 08/01/2025:
The allocated pathway will be followed for as long as routine gastric residual measurement is standard local practice, or until gastric feeding tubes are no longer required, or the infant is discharged home, or the infant reaches 44+0 gestational weeks +days

Randomisation of infants to either no routine measurement of gastric residual volumes or up to 6 hourly measurement of gastric residual volumes will be managed via a secure web-based randomisation facility hosted by the National Perinatal Epidemiology Unit Clinical Trials Unit (University of Oxford) with telephone backup available at all times (365 days per year).

Infants will be randomised using an online secure central randomisation service to ensure allocation concealment. The randomisation program will use a probabilistic minimisation algorithm and randomisation will use a 1:1 allocation ratio. To ensure balance between the randomised groups, minimisation criteria will include: hospital, multiple births and week of gestational age at birth.

Intervention Type
Procedure/Surgery

Primary outcome measure
Superiority outcome:
All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants' hospital notes/records.
1. neoGASTRIC main trial - superiority outcome
Time from birth to reach full milk feeds for 3 consecutive days (at least 145 ml/kg/day where this is considered full enteral feeds, or where breastfeeding and any additional milk is considered equivalent to full enteral feeds).
Also including,
2. neoGASTRIC Process Evaluation primary outcome: to evaluate pilot phase trial processes by analysing parent and staff responses from questionnaires and observing staff practices.
3. neoGASTRIC SWAT primary outcome: the parent did not opt out of infant's participation in the trial pre-randomisation.

Secondary outcome measures

Updated 08/01/2025: Secondary outcome measures as of 13/06/2023:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants' hospital notes/records.

Key secondary outcomes (non-inferiority outcome):
Necrotising enterocolitis (NEC), modified Bell's stage 2 or greater, evaluated by blinded endpoint review committee.

Other secondary outcomes (superiority outcomes):
1. Severe NEC, confirmed at surgery or leading to death
2. All-cause mortality
3. Focal intestinal perforation
4. Gastrointestinal surgery
5. Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth, evaluated by blinded endpoint review committee. To note: this is the same that has been used in previous trials (e.g. SIFT, ELFIN)
6. Duration of neonatal unit stay
7. Duration of any parenteral nutrition
8. Duration with a central venous line in situ
9. Weight standard deviation score
10. Head circumference standard deviation score
11. Duration of invasive ventilation
12. Chronic lung disease
13. Retinopathy of prematurity treated medically or surgically
14. Brain injury on imaging: intraventricular haemorrhage grade 3 or 4 and/or cystic periventricular leukomalacia
15. Any vomiting resulting in feeds being withheld, up to 14 days from randomisation
16. Number of days feeds withheld at least once, up to 14 days from randomisation
17. Total number of hours feeds withheld, up to 14 days from randomisation
18. Breastfeeding at discharge home or 44+0 gestational weeks+days (whichever is sooner)
19. Receiving maternal breastmilk at discharge home or 44+0 gestational weeks+days (whichever is sooner)

neoGASTRIC SWAT secondary outcome is to evaluate the quality of parental decision making by using descriptive statistics.

Previous secondary outcome measures as of 13/06/2023:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants hospital notes/records.

Non-inferiority outcome:
1. Necrotising enterocolitis (NEC), modified Bell's stage 2 or greater, evaluated by blinded endpoint review committee.
Other secondary outcomes - Superiority outcomes
2. Severe NEC, confirmed at surgery or leading to death

3. All-cause mortality
4. Focal intestinal perforation
5. Gastrointestinal surgery
6. Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth, evaluated by blinded endpoint review committee. To note: this is the same that has been used in previous trials (e.g. SIFT, ELFIN)
7. Duration of neonatal unit stay
8. Duration of any parenteral nutrition
9. Duration with a central venous line in situ
10. Weight standard deviation score
11. Head circumference standard deviation score
12. Duration of invasive ventilation
12. Chronic lung disease
13. Retinopathy of prematurity treated medically or surgically
14. Brain injury on imaging: intraventricular haemorrhage grade 3 or 4 and/or cystic periventricular leukomalacia
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17. Total number of hours feeds withheld, up to 14 days from randomisation
18. Breastfeeding at discharge home or 44+0 gestational weeks+days (whichever is sooner)
19. Receiving maternal breastmilk at discharge home or 44+0 gestational weeks+days (whichever is sooner)

neoGASTRIC SWAT secondary outcome is to evaluate the quality of parental decision making by using descriptive statistics.

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Original secondary outcome measures:

All outcomes will be measured up to discharge home or when the infant reaches 44+0 gestational weeks, whichever is sooner, unless otherwise stated. All data will be collected from infants hospital notes/records.

Non-inferiority outcome:
1. Necrotising enterocolitis (NEC), modified Bell's stage 2 or greater, evaluated by blinded endpoint review committee.
Other secondary outcomes - Superiority outcomes
2. Severe NEC, confirmed at surgery or leading to death
3. All-cause mortality
4. Focal intestinal perforation
5. Gastrointestinal surgery
6. Late-onset infection: microbiologically-confirmed or clinically suspected infection >72 hours after birth, evaluated by blinded endpoint review committee. To note: this is the same that has been used in previous trials (e.g. SIFT, ELFIN)
7. Duration of neonatal unit stay
8. Duration of any parenteral nutrition
9. Duration with a central venous line in situ
10. Weight standard deviation score
11. Head circumference standard deviation score
12. Duration of invasive ventilation
12. Chronic lung disease

13. Retinopathy of prematurity treated medically or surgically
14. Any vomiting resulting in feeds being withheld, measured up to 14 days from randomisation
15. Number of days feeds withheld at least once, measured up to 14 days from randomisation
16. Total number of hours feeds withheld, measured up to 14 days from randomisation
17. Breastfeeding at discharge home or 44+0 gestational weeks+days (whichever is sooner)
18. Receiving maternal breastmilk at discharge home or 44+0 gestational weeks+days (whichever is sooner)

neoGASTRIC SWAT secondary outcome is to evaluate the quality of parental decision making by using descriptive statistics.

Overall study start date
01/09/2022

Completion date
31/10/2026

Eligibility

Key inclusion criteria
Updated 08/01/2025: Corrected as of 03/04/2023:
1. Gestational age at birth less than 34+0 gestational weeks+days
2. Nasogastric or orogastric tube in place

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Previous inclusion criteria:
1. Gestational age at birth less than 34+0 gestational weeks+days
2. Nasogastric or orogastric tube in place
3. Baby receiving less than or equal to 15 ml/kg/day of milk

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
7040

Key exclusion criteria
Updated 08/01/2025:
Current exclusion criteria as of 03/04/2023:

1. Infant has received more than 15ml/kg/day of milk for more than 24 hours
2. Gastrointestinal surgical condition (including suspected necrotising enterocolitis and focal intestinal perforation) prior to randomisation
3. Major congenital abnormalities

4. No realistic prospect of survival
5. A parent has opted out of infant's participation in neoGASTRIC

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Previous exclusion criteria:

1. Infant has received more than 15ml/kg/day of milk for more than 24 hours
2. Gastrointestinal surgical condition prior to randomisation
3. Major congenital abnormalities
4. No realistic prospect of survival
5. A parent has opted out of infant’s participation in neoGASTRIC

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Original exclusion criteria:

1. Gastrointestinal surgical condition prior to randomisation
2. Major congenital abnormalities
3. No realistic prospect of survival
4. A parent has opted out of infant’s participation in neoGASTRIC

Date of first enrolment
01/04/2023

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
Australia

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent & Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Belfast Health and Social Care Trust
Trust Headquarters
A Floor - Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Liverpool Women's NHS Foundation Trust
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
Monkton Street
London
United Kingdom
SE11 4TX

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Imperial College Healthcare NHS Trust
St Marys Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Bedfordshire Hospitals NHS Foundation Trust
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital

Freeman Road
High Heaton
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NE7 7DN

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Portsmouth Hospitals University National Health Service Trust
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
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Herries Road
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United Kingdom
S5 7AU

Study participating centre

University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
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SO16 6YD

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
Swansea Bay University Local Health Board
One Talbot Gateway, Seaway Drive
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Baglan
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SA12 7BR

Study participating centre
Great Western Hospitals NHS Foundation Trust
Great Western Hospital
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SN3 6BB

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
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SY3 8XQ

Study participating centre

West Hertfordshire Teaching Hospitals NHS Trust
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Watford General Hospital
Vicarage Road
Watford
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WD18 0HB

Study participating centre
Monash Health
246 Clayton Road
Clayton
Victoria
Clayton
Australia
3168

Study participating centre
The Royal Women's Hospital
20 Flemington Road
Parkville
Victoria
Melbourne
Australia
3052

Study participating centre
Sydney Local Health District
Royal Prince Alfred Hospital
50 Missenden Road
Camperdown
NSW
Sydney
Australia
2050

Study participating centre
Women's and Children's Health Network
The Women's and Children's Hospital
72 King William Road
North Adelaide
South Australia
North Adelaide

Australia
5006

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road
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United Kingdom
SW17 0QT

Study participating centre
Betsi Cadwaladr University Lhb
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
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United Kingdom
LL57 2PW

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Hywel Dda Health Board
Hafan Derwen
St Davids Parc
Job's Well Road
Carmarthen
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SA31 3BB

Study participating centre
Aneurin Bevan University Lhb
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NP18 3XQ

Study participating centre
Cwm Taf University Health Board
Unit 3

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CF45 4SN

Study participating centre
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University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
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PL6 8DH

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
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EX2 5DW

Study participating centre
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Southmead Road
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Study participating centre
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Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
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Arrowe Park Road
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CH49 5PE

Study participating centre
Homerton Healthcare NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
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PE3 9GZ

Study participating centre

Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
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ME16 9QQ

Study participating centre
Bolton NHS Foundation Trust
The Royal Bolton Hospital
Minerva Road
Farnworth
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BL4 0JR

Study participating centre
Northern Lincolnshire and Goole NHS Foundation Trust
Diana Princess of Wales Hospital
Scartho Road
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DN33 2BA

Study participating centre
London North West University Healthcare NHS Trust
Northwick Park Hospital
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HA1 3UJ

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Sponsor information

Organisation
Imperial College London

Sponsor details
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+44 (0)20 7589 5111
rgit@imperial.ac.uk

Sponsor type
University/education

Website
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ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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

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 NIHR Collaborative Research Grant Scheme (NHMRC-NIHR)

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals, including publishing an account of the research project in the NIHR Journals Library.

Intention to publish date
30/12/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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 file	version 1.0	02/12/2022	05/04/2023	No	No
HRA research summary	version 3.0	19/04/2024	20/09/2023	No	No
Protocol file			08/01/2025	No	No