ISRCTN17004671 https://doi.org/10.1186/ISRCTN17004671

HoT – A phase III randomised trial to compare the rates of cancer returning in patients with low-risk differentiated thyroid cancer after a hemithyroidectomy and total thyroidectomy

Submission date
10/08/2021

Recruitment status
Recruiting

Registration date
22/02/2022

Overall study status
Ongoing

Last Edited
16/07/2025

Condition category
Cancer

[ ] 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
The rate of well-differentiated thyroid cancer (DTC) is increasing faster than any other tumour. The current standard treatment for low-risk DTC is surgical removal of the whole thyroid gland called total thyroidectomy (TT), followed by radioiodine treatment. More recently, surgeons have started performing hemithyroidectomy (HT) (removal of the cancerous half of the thyroid) as international guidelines changed and studies suggested patients may benefit from less extensive surgery, whilst maintaining excellent cure rates. HT patients may not require life-long hormone replacement therapy, calcium and vitamin D supplements, and radioiodine treatment. However, results from these studies are biased and conflicting. There is uncertainty surrounding the most appropriate surgery causing variations in practice between different teams and hospitals.

HoT is the first trial to directly compare TT versus HT in terms of the rate of cancer returning, impact on quality of life, surgery-related side-effects, need for thyroid hormone replacement therapy after surgery, health resources use and cost-effectiveness to the NHS.

Who can participate?
Individuals aged 16 years or over with a diagnosis of low-risk differentiated thyroid cancer.

What does the study involve?
There will be two groups of patients entering the trial with the same diagnoses and prognosis (i. e. risk of cancer returning):
- Group 1: Patients who have already had a hemithyroidectomy for thyroid problems and are then subsequently diagnosed with low-risk DTC will be randomly assigned (50:50 chance) to receive regular surveillance (follow-up only) OR have a second operation to remove the rest of their thyroid gland (two-stage total thyroidectomy).
- Group 2: Patients diagnosed with low-risk DTC but not undergone surgery, will be randomly assigned (50:50 chance) to have either the whole thyroid gland removed (single-stage total

thyroidectomy) or only part of the gland removed (a hemi-thyroidectomy).
All thyroid surgeries performed on the trial will be as per the standard of care at the treating hospital.
All patients on the trial will be followed up regularly for up to 6½ years. Patients will attend clinic visits for standard checks on their progress and health before surgery, sometime between 2 and 4 weeks after surgery, 6 months after surgery, then once a year for 6 years. These checks include clinical examinations, blood tests to check thyroid gland function and neck ultrasound scans. All patients will have an ultrasound scan of their neck every year. In several hospitals this scan is already part of routine care. For all patients, there is one extra ultrasound scan of their neck 6 months after surgery.
For research purposes patients will also be asked to complete four questionnaires about their health and well-being and a questionnaire to check voice function. Selected patients may be able to complete the questionnaires at home, using a web-based application ('app') that will send text (SMS) message alerts to their mobile phone/tablet. They can then complete these questionnaires on their mobile phone/tablet, rather than completing paper questionnaires at the hospital during clinic appointments. Using this 'app' is another part of the HoT trial, and is being performed using OpenClinica Participate. This 'app' allows electronic collection of information from trial patients allowing us to see if this approach is better and easier for patients than if they used paper questionnaires.
The first 30-50 patients recruited to the HoT study will be asked to use the 'app'. After this, patients will be randomly allocated (50:50 chance) to complete the well-being questionnaires either using the 'app' OR using paper forms. Patients who do not wish to take part in this study that evaluates the 'app' can instead use the paper version of the questionnaires throughout the trial or can switch from the web-based app to the paper questionnaires at any time if they wish.
After the initial 6½ years of follow-up long term follow up data on recurrences and mortality will be collected electronically from national registries and databases (e.g. NCRAS) for an additional 13 ½ years.
What are the possible benefits and risks of participating?

Patients will be treated as they would otherwise in routine care and receive the best treatment for their thyroid cancer whether they take part in this trial or not. By taking part in this trial, the patients will help us to understand more about treating patients, both in the UK and worldwide, with low-risk differentiated thyroid cancer and how best to treat them in the future. All patients taking part in the trial will have a neck ultrasound at their 6 month follow-up visit which may not always routinely be performed at all hospitals. Patients who have had a hemithyroidectomy before coming on to the trial and are then randomised to the surveillance arm will not need to have another surgery, avoiding the inconveniences of a second surgery along with the possible surgery-related complications. Patients who have a hemi-thyroidectomy as part of the trial may not need radioiodine ablation after (requires isolation in hospital) and may not need life-long thyroxine replacement therapy, which is likely to improve quality of life.

Both hemithyroidectomy and total-thyroidectomy procedures are performed routinely by surgeons as per standard of care and therefore do not pose any additional risks to patients beyond those associated with the surgeries. Both surgeries will be performed as per local site policy by qualified surgeons. A trial specific audit will be carried out on all recruiting hospitals to ensure both surgeries are being performed routinely there.

There is a small risk of the cancer recurring after both a hemithyroidectomy and a total thyroidectomy. Some studies have shown that the recurrence rate may be slightly higher in patients who have a hemithyroidectomy, however the difference was considered clinically small and overall survival was similar. Most recurrences happen within 3-5 years of initial treatment and whilst on the trial patients will be followed up annually for up to 6 and ½ years after the

surgery with routine thyroglobulin measurements and neck ultrasound to check for signs of recurrence. Once trial follow-up visits end the patient will be followed up as per standard practice at their treating hospital. A risk assessment of the trial has been carried out and a site monitoring plan will be developed based on this to ensure the trial is being carried out according to the protocol and Good Clinical Practice.

Where is the study run from?
Cancer Research UK & UCL Cancer Trials Centre, London

When is the study starting and how long is it expected to run for?
August 2020 to July 2031

Who is funding the study?
National Institute for Health Research (NIHR) (UK) will fund the trial up to the 6 ½ years of follow-up. The additional 13 ½ years of long-term follow-up data collection will be funded by UCL CTC. The nested sub-study testing the clinical utility of the web-based QoL app (software) will be funded by UCL CTC.

Who is the main contact?
ctc.hot@ucl.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-surgery-to-remove-the-whole-thyroid-or-part-of-the-thyroid-hot-trial

Contact information

Type(s)
Scientific

Contact name
Mrs Aniqa Tasnim

Contact details
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London
United Kingdom
W1T 4TJ
+44 (0)20 3108 4753
ctc.hot@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
294693

ClinicalTrials.gov number

NCT05604963

Secondary identifying numbers
CPMS 48988, NIHR128699, IRAS 294693

Study information

Scientific Title
Hemithyroidectomy or Total Thyroidectomy in 'low-risk' thyroid cancers

Acronym
HoT

Study objectives
The primary aim of the trial is to determine whether hemithyroidectomy is non-inferior to total thyroidectomy in low risk differentiated thyroid cancer, with regards to cancer recurrence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2021, London – Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, BS1 6PN, UK; +44 207 104 8105; Bromley.rec@hra.nhs.uk), ref: 21/LO/0292

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at https://www.youtube.com/watch?v=AfyV33J4GmY

Health condition(s) or problem(s) studied
Low risk thyroid cancers

Interventions
Patients will be identified via oncology multidisciplinary team meetings. There will be two sources of patients in the trial, with the same histological diagnoses and prognosis (i.e. recurrence risk):

- Group 1: Patients who have already had a hemithyroidectomy for thyroid problems and are then subsequently diagnosed with low risk DTC will be randomised 1:1 to undergo surveillance (follow-up only) only OR a second operation to remove the rest of their thyroid gland (two-stage total thyroidectomy).
- Group 2: Patients diagnosed with low risk DTC using cytology (Thy5) or core biopsy but no surgery performed will be randomised 1:1 to have either a hemi-thyroidectomy OR a single-stage total thyroidectomy.
All thyroid surgeries performed on the trial will be as per the standard of care at the treating hospital.

Intervention Type
Procedure/Surgery

Primary outcome measure
Recurrence rate at 3 years follow-up defined as thyroid cancer recurrence, metastatic disease or death from thyroid cancer (whichever occurs first), timed from date of surgery to 3 year follow up, analysed using Kaplan-Meier curves and Cox regression.

Secondary outcome measures
Current secondary outcome measures as of 16/07/2025:
1. Recurrence rate at 5-year follow-up defined as thyroid cancer recurrence, metastatic disease or death from thyroid cancer (whichever occurs first), timed from date of surgery to 5-year follow-up, analysed using Kaplan-Meier curves and Cox regression.
2. Anatomical site of recurrences measured using a frequency table and Fisher's exact test at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
3. Risk of loco-regional recurrence based on time to recurrence measured using Cox regression at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
4. Number and type of additional investigations and procedures after surgery measured using a frequency table and Fishers exact test at 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery
5. Surgical complications and severity, including voice function measured using CTCAE v5.0 and the highest grade of each event type for each patient. These will be compared using a frequency table and Fishers exact test where appropriate, measured prior to discharge post-surgery, 2-4 weeks, 6 months and 18 months from date of surgery. Voice function will also be measured using the Voice Handicap Index questionnaire (VHI-10) at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
6. Requirement for hormone replacement therapy defined as the percentage of patients who require this therapy will be compared between the trial arms using a chi-squared test of two proportions at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
7. Quality of life (QoL) measured using questionnaires: EORTC QLQ-C30, EORTC QLQ-THY35, EQ5D-5L; and FoP-Q-SF (Short Form of the Fear of Progression). These will be collected at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery. QoL will be analysed using repeated measures regression analyses.
8. Cost and health resource use will be measured as follows:
- Generic QoL measured using the EQ-5D-5L instrument at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
- Cancer specific QoL measured using the EORTC QLQ-C30 instrument at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
- Cancer site specific QoL measured using the EORTC QLQ-THY34 instrument at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of

surgery.
- Secondary care health resource use/costs collected using eCRFs completed at pre-randomisation, pre-surgery, post-surgery (prior to discharge & 2-4 weeks), and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery. Secondary care health resource use/costs will also be collected retrospectively for the study period from data in the Hospital Episodes Statistics linked to records in the NCRAS.
- Primary care and social care resource use/costs collected using an eCRF at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.

Exploratory outcome measure
1. Rate of rising thyroglobulin (Tg) in patients who have hemithyroidectomy and those who have non-ablation total-thyroidectomy. Tg, a standard blood measurement, will be performed at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery, and measured in the local laboratory using whichever standard assay they have.

Outcome measures associated with nested sub-study on OpenClinica Participate's web-based app
1. Percentage of patients who complete the questionnaire, at baseline (post-randomisation/pre-surgery), 2-4 weeks, 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
2. Percentage of questions completed (per patient) for each questionnaire
3. Timeliness of questionnaire completion via timestamp of form completion relative to the due date
4. Time taken to complete the questionnaire
5. Number of times a patient engages with the app
6. Number of prompts/reminders required before questionnaire completion

Previous secondary outcome measures:
1. Recurrence rate at 5-year follow-up defined as thyroid cancer recurrence, metastatic disease or death from thyroid cancer (whichever occurs first), timed from date of surgery to 5-year follow-up, analysed using Kaplan-Meier curves and Cox regression.
2. Anatomical site of recurrences measured using a frequency table and Fisher's exact test at 6, 18, 30, 42 , 54 , 66 and 78 months from date of surgery.
3. Risk of loco-regional recurrence based on time to recurrence measured using Cox regression at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
4. Number and type of additional investigations and procedures after surgery measured using a frequency table and Fishers exact test at 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery
5. Surgical complications and severity, including voice function measured using CTCAE v5.0 and the highest grade of each event type for each patient. These will be compared using a frequency table and Fishers exact test where appropriate, measured prior to discharge post-surgery, 2-4 weeks, 6 months and 18 months from date of surgery. Voice function will also be measured using the Voice Handicap Index questionnaire (VHI-10) at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
6. Requirement for hormone replacement therapy defined as the percentage of patients who require this therapy will be compared between the trial arms using a chi-squared test of two proportions at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
7. Quality of life (QoL) measured using questionnaires: EORTC QLQ-C30, EORTC QLQ-THY35, EQ5D-5L; and FoP-Q-SF (Short Form of the Fear of Progression). These will be collected at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery. QoL will be analysed using repeated measures regression analyses.
8. Cost and health resource use will be measured as follows:
- Generic QoL measured using the EQ-5D-5L instrument at baseline (post-randomisation/pre-

surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
- Cancer specific QoL measured using the EORTC QLQ-C30 instrument at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
- Cancer site specific QoL measured using the EORTC QLQ-THY34 instrument at baseline (post-randomisation/pre-surgery), 2-4 weeks and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
- Secondary care health resource use/costs collected using eCRFs completed at pre-randomisation, pre-surgery, post-surgery (prior to discharge & 2-4 weeks), and 6, 18, 30, 42, 54, 66 and 78 months from date of surgery. Secondary care health resource use/costs will also be collected retrospectively for the study period from data in the Hospital Episodes Statistics linked to records in the NCRAS.
- Primary care and social care resource use/costs collected using an eCRF at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.

Exploratory outcome measure
1. Rate of rising thyroglobulin (Tg) in patients who have hemithyroidectomy and those who have non-ablation total-thyroidectomy. Tg, a standard blood measurement, will be performed at 6, 18, 30, 42, 54, 66 and 78 months from date of surgery, and measured in the local laboratory using whichever standard assay they have.

Outcome measures associated with nested sub-study on Navio's web-based app
1. Percentage of patients who complete the questionnaire, at baseline (post-randomisation/pre-surgery), 2-4 weeks, 6, 18, 30, 42, 54, 66 and 78 months from date of surgery.
2. Percentage of questions completed (per patient) for each questionnaire
3. Timeliness of questionnaire completion via timestamp of form completion relative to the due date
4. Time taken to complete the questionnaire
5. Number of times a patient engages with the app
6. Number of prompts/reminders required before questionnaire completion

Overall study start date
01/08/2020

Completion date
31/07/2031

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 16/07/2025:
Group 1 (Hemithyroidectomy already performed prior to diagnosis)
1. Aged 16 or over
2. Papillary thyroid cancer (PTC):
2.1. pT1b-2 (≤4cm) irrespective of molecular genetic markers
2.2. R0 resection (clinically excised but microscopic R1 resected tumours at discretion of the local multidisciplinary team (MDT))
2.3. cN0 or pN0, pNX & pN1a (≤5 foci, no extranodal spread)
2.4. Confined to thyroid or minimal extrathyroidal extension
2.5. No higher risk histological variants on morphology (small foci allowed at the discretion of the local MDT)

2.6. No angioinvasion
2.7. Encapsulated follicular variant of PTC with capsular invasion only
2.8. Micro-PTC (≤1cm)
- multifocal
- unifocal with pN1a (≤5 foci; no extranodal spread)
3. Follicular thyroid cancer and oncocytic/Hurthle cell carcinoma:
3.1. pT1b-2 (≤4cm) irrespective of molecular genetic markers
- Minimally invasive, with capsular invasion +/- minimal (≤4 foci) vascular invasion (the latter is now called encapsulated angioinvasive and is at the discretion of the MDT)
3.2. Confined to thyroid or minimal extrathyroidal extension

Group 2 (Differentiated Thyroid Cancer on cytology/core biopsy, who has not had prior thyroid surgery yet)
1. Aged 16 or over
2. 'low risk' differentiated thyroid cancer confirmed by cytology or core biopsy.
3. cT1b-2 irrespective of molecular genetic markers
4. cN0
5. Contralateral lobe without suspicious nodule(s) (U2, or U3/U4 with Thy2 on FNAC)

Eligibility criteria for nested sub-study on OpenClinica Participate's web-based app (software):
1. Have a SMS enabled mobile phone or handheld tablet with web access
2. Are able to use the web-based app to complete the trial questionnaires without assistance

Previous key inclusion criteria:
Group 1 (Hemithyroidectomy already performed prior to diagnosis)
1. Aged 16 or over
2. Papillary thyroid cancer (PTC):
2.1. pT1b-2 (≤4cm) irrespective of molecular genetic markers
2.2. R0 resection (clinically excised but microscopic R1 resected tumours at discretion of the local multidisciplinary team (MDT))
2.3. cN0 or pN0, pNX & pN1a (≤5 foci, no extranodal spread)
2.4. Confined to thyroid or minimal extrathyroidal extension
2.5. No higher risk histological variants on morphology (small foci allowed at the discretion of the local MDT)
2.6. No angioinvasion
2.7. Encapsulated follicular variant of PTC with capsular invasion only
2.8. Micro-PTC (≤1cm)
- multifocal
- unifocal with pN1a (≤5 foci; no extranodal spread)
3. Follicular thyroid cancer and oncocytic/Hurthle cell carcinoma:
3.1. pT1b-2 (≤4cm) irrespective of molecular genetic markers
- Minimally invasive, with capsular invasion +/- minimal (≤4 foci) vascular invasion (the latter is now called encapsulated angioinvasive and is at the discretion of the MDT)
3.2. Confined to thyroid or minimal extrathyroidal extension

Group 2 (Differentiated Thyroid Cancer on cytology/core biopsy, who has not had prior thyroid surgery yet)
1. Aged 16 or over
2. 'low risk' differentiated thyroid cancer confirmed by cytology or core biopsy.
3. cT1b-2 irrespective of molecular genetic markers
4. cN0
5. Contralateral lobe without suspicious nodule(s) (U2, or U3/U4 with Thy2 on FNAC)

Eligibility criteria for nested sub-study on Navio's web-based app (software):
1. Have a SMS enabled mobile phone or handheld tablet with web access
2. Are able to use the web-based app to complete the trial questionnaires without assistance

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 456; UK Sample Size: 456

Key exclusion criteria
Group 1 (Hemithyroidectomy already performed prior to diagnosis):
1. Tumour > 4cm
2. Unifocal pT1a (< = 1cm) papillary thyroid cancer (PTC) and follicular thyroid cancer (FTC) (unless pN1a as listed in inclusion criteria)
3. Non-invasive encapsulated follicular variant of PTC
4. Anaplastic, poorly differentiated or medullary thyroid carcinoma
5. R2 resection
6. Gross extrathyroidal extension
7. pT4 or macroscopic tumour invasion of loco-regional tissues or structures
8. pN1a with > 5 foci or extranodal spread
9. pN1b
10. M1
11. Aggressive PTC with any of the following features:
- Widely invasive
- Poorly differentiated
- Anaplastic
- predominance of Tall cell, Columnar cell, Hobnail, Diffuse sclerosing and other higher risk variants
12. FTC and oncocytic/Hürthle cell cancer with any of the following features:
- Minimally invasive with extensive vascular invasion (now called encapsulated angioinvasive) (> 4 foci)
- Widely invasive
- Poorly differentiated
- Anaplastic

Group 2 (Differentiated thyroid cancer on cytology or after core biopsy, who has not had prior thyroid surgery yet)
1. M1

Date of first enrolment

13/12/2021

Date of final enrolment
31/07/2028

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
The Royal Marsden NHS Foundation Trust
Fulham Road
London
United Kingdom
SW3 6JJ

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Northwick Park Hospital
Watford Road

Harrow
United Kingdom
HA1 3UJ

Study participating centre
Lister Hospital
Chelsea Bridge Road
London
United Kingdom
SW1W 8RH

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane
Colney

Norwich
United Kingdom
NR4 7UY

Study participating centre
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Study participating centre
The Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Guy's & St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Cardiff & Vale University Lhb
Woodland House
Maes-y-coed Road
Cardiff
United Kingdom
CF14 4HH

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Royal Berkshire Hospital
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG1 5AN

Study participating centre
Taunton Hospital
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre

Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

Study participating centre
Gstt @ Royal Devon and Exeter
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

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

Study participating centre
Royal Derby Hospital
Uttoxeter Road
Derby

United Kingdom
DE22 3NE

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Northampton General Hospital
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
Ipswich Hospital
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Royal United Hospitals Bath NHS Foundation Trust
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Colchester District General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
WC1E 6BT

+44 2034 479995
ctc.sponsor@ucl.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Funder Name
National Institute for Health Research (NIHR) (UK)

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/01/2029

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (ctc.hot@ucl.ac.uk)

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