

# 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

<b>Submission date</b> 10/08/2021	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 22/02/2022	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/01/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

None Jeannie Chamberlain

### 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

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

294693

### ClinicalTrials.gov (NCT)

NCT05604963

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)

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.

### Key secondary outcome(s)

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

#### 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 years or over
2. Papillary thyroid cancer (PTC):
  - 2.1. pT1b-2 ( $\leq 4$ cm) 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 ( $\leq 5$  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 ( $\leq 1$ cm)
    - multifocal
    - unifocal with pN1a ( $\leq 5$  foci; no extranodal spread)
3. Follicular thyroid cancer and oncocytic/Hurthle cell carcinoma:
  - 3.1. pT1b-2 ( $\leq 4$ cm) irrespective of molecular genetic markers
    - Minimally invasive, with capsular invasion +/- minimal ( $\leq 4$  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 ( $\leq 4$ cm) 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 ( $\leq 5$  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 ( $\leq 1$ cm)
    - multifocal
    - unifocal with pN1a ( $\leq 5$  foci; no extranodal spread)
3. Follicular thyroid cancer and oncocytic/Hurthle cell carcinoma:
  - 3.1. pT1b-2 ( $\leq 4$ cm) irrespective of molecular genetic markers
    - Minimally invasive, with capsular invasion +/- minimal ( $\leq 4$  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

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

16 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**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

United Kingdom

England

Scotland

Wales

## Study participating centre

**The Royal Marsden NHS Foundation Trust**

Fulham Road

London

England

SW3 6JJ

## Study participating centre

**Leicester Royal Infirmary**

Infirmery Square

Leicester

England

LE1 5WW

## Study participating centre

**Queen Elizabeth Hospital**

Mindelsohn Way

Edgbaston

Birmingham

England

B15 2GW

## Study participating centre

**Northwick Park Hospital**

Watford Road

Harrow

England

HA1 3UJ

## Study participating centre

**Lister Hospital**  
Chelsea Bridge Road  
London  
England  
SW1W 8RH

**Study participating centre**  
**Nottingham City Hospital**  
Hucknall Road  
Nottingham  
England  
NG5 1PB

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

**Study participating centre**  
**Northern General Hospital**  
Northern General Hospital NHS Trust  
C Floor, Huntsman Building  
Herries Road  
Sheffield  
England  
S5 7AU

**Study participating centre**  
**Norfolk & Norwich University Hospital**  
Colney Lane  
Colney  
Norwich  
England  
NR4 7UY

**Study participating centre**  
**Gartnavel Royal Hospital**  
1055 Great Western Road

Glasgow  
Scotland  
G12 0XH

**Study participating centre**  
**The Royal Liverpool University Hospital**  
Prescot Street  
Liverpool  
England  
L7 8XP

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

**Study participating centre**  
**Queen Alexandra Hospital**  
Southwick Hill Road  
Cosham  
Portsmouth  
England  
PO6 3LY

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

**Study participating centre**  
**St George's Hospital**  
Blackshaw Road  
Tooting  
London  
England  
SW17 0QT

**Study participating centre**

**University Hospitals Bristol and Weston NHS Foundation Trust**

Trust Headquarters

Marlborough Street

Bristol

England

BS1 3NU

**Study participating centre**

**University College London Hospitals NHS Foundation Trust**

250 Euston Road

London

England

NW1 2PG

**Study participating centre**

**Taunton Hospital**

Musgrove Park Hospital

Taunton

England

TA1 5DA

**Study participating centre**

**Addenbrookes**

Addenbrookes Hospital

Hills Road

Cambridge

England

CB2 0QQ

**Study participating centre**

**Ninewells Hospital**

Ninewells Avenue

Dundee

Scotland

DD1 9SY

**Study participating centre**

**Luton and Dunstable University Hospital**

Lewsey Road  
Luton  
England  
LU4 0DZ

**Study participating centre**

**Gstt @ Royal Devon and Exeter**

Royal Devon & Exeter Hospital  
Barrack Road  
Exeter  
England  
EX2 5DW

**Study participating centre**

**Medway NHS Foundation Trust**

Medway Maritime Hospital  
Windmill Road  
Gillingham  
England  
ME7 5NY

**Study participating centre**

**Royal Derby Hospital**

Uttoxeter Road  
Derby  
England  
DE22 3NE

**Study participating centre**

**Aberdeen Royal Infirmary**

Foresterhill Road  
Aberdeen  
Scotland  
AB25 2ZN

**Study participating centre**

**Derriford Hospital**

Derriford Road  
Derriford  
Plymouth

England  
PL6 8DH

**Study participating centre**  
**Northampton General Hospital**  
Cliftonville  
Northampton  
England  
NN1 5BD

**Study participating centre**  
**Forth Valley Royal Hospital**  
Stirling Road  
Larbert  
Scotland  
FK5 4WR

**Study participating centre**  
**Ipswich Hospital**  
Heath Road  
Ipswich  
England  
IP4 5PD

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

**Study participating centre**  
**Colchester District General Hospital**  
Turner Road  
Colchester  
England  
CO4 5JL

**Study participating centre**

**Leighton Hospital**

Leighton  
Crewe  
England  
CW1 4QJ

**Study participating centre****Glan Clwd Hospital**

Ysbyty Glan Clwydd  
Bodelwyddan  
Rhyl  
Wales  
LL18 5UJ

**Study participating centre****Bedford Hospital**

Weller Wing  
Kempston Road  
Bedford  
England  
MK42 9DJ

**Sponsor information****Organisation**

University College London

**ROR**

<https://ror.org/02jx3x895>

**Funder(s)****Funder type**

Government

**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

### 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes