

Evaluating a primary care intervention for chronic breathlessness

Submission date 19/02/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 24/02/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 21/08/2026	Condition category Respiratory	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Breathlessness affects the daily lives of one in ten people with long-term health conditions, like lung or heart disease. Doctors and nurses often feel they cannot help when breathlessness persists despite treating the underlying condition. However, a few specialist teams have developed effective ways to support breathless people, for example, with breathing or relaxation techniques. The treatment is safe and does not involve taking new medicine. This approach needs to be adapted so it can be accessed by more people through general practices. The five-year PrimaryBreathe programme has already completed a co-design study, where patients, family or friend carers, general practice staff and researchers from Cambridge and Hull worked together to develop an acceptable primary care version of the treatment. A feasibility study has also been conducted to find out how feasible it is to implement in primary care. We are now in a position to begin the main Trial, to assess the clinical effectiveness and estimate the cost-effectiveness of the PrimaryBreathe intervention.

Who can participate?

Adult patients living with persistent breathlessness, invited from participating general practices in England.

What does the study involve?

The study involves randomising consented patients to either receive the PrimaryBreathe treatment delivered by their GP Practice or continue to receive routine care. The PrimaryBreathe treatment involves consented patients having 2-3 appointments with a trained Health Professional, who will teach them up to 2 techniques to help them with their breathlessness.

What are the possible benefits and risks of participating?

The aim is for participants receiving the treatment in this research to benefit clinically, but this will be assessed by conducting the trial. No risks are anticipated for participants in taking part. The breathlessness treatment is safe and will not involve taking new medicines.

Where is the study run from?

The University of Cambridge, Primary Care Unit, UK.

When is the study starting and how long is it expected to run for?
April 2026 to February 2027.

Who is funding the study?
The National Institute for Health and Care Research (NIHR), UK.

Who is the main contact?
primarybreathe@medschl.cam.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)

357644

Central Portfolio Management System (CPMS)

67990

National Institute for Health and Care Research (NIHR)

Study information

Scientific Title

PrimaryBreathe trial: Evaluating a primary care intervention for chronic breathlessness – a randomised controlled trial.

Acronym

PrimaryBreathe Trial

Study objectives

- a. To assess the clinical effectiveness of the PrimaryBreathe intervention.
- b. To estimate the cost-effectiveness of the intervention.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 23/01/2026, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 0207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 25/EE/0261

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: General Practice, Primary sub-specialty: General Practice; Health Category: Cardiovascular, Respiratory; Disease/Condition: Symptoms and signs involving the circulatory and respiratory systems

Interventions

Mixed-methods explanatory sequential design with two main components: Randomised Controlled Trial (RCT) and Qualitative Parallel Process Evaluation (QPPE).

Recruitment:

This study will recruit approximately 33 practices and 10 eligible patients from each to the RCT. Participants will provide written informed consent either online or via post. Following this, each participant's eligibility will be confirmed before they are randomised to intervention (PrimaryBreathe treatment) or routine care (control). After randomisation, patients in both arms will be checked for medical optimisation of the underlying long-term condition(s) causing chronic breathlessness, using disease-specific checklists (OptiMed). The intervention arm involves participants receiving the PrimaryBreathe intervention as well as OptiMed; those in the control arm receive OptiMed alone. Consented participants in the intervention arm will be provided with the PrimaryBreathe treatment from a trained health-professional participant. All patient and health professional participants will be invited to complete questionnaires. The qualitative parallel process evaluation (QPPE) will involve approximately eight diverse general practices taking part in the RCT. There are six types of participants in the trial: health professionals delivering the intervention (a minimum of 33, at least one per site), patients (the largest group of 330), informal carers, non-participating patients who decline to take part in the RCT but are willing to share their reasons with the research team, general practice staff involved in administrative activities, and Cambridge Breathlessness Intervention Service (CBIS) staff. The latter four groups will be invited to participate in QPPE only. Each of these participant types will be consented in turn.

1. RCT Health Professionals (HP)

This study will recruit approximately 33 GP practices from at least four of the 12 RRDN regions of England. Each practice will identify at least one member of staff, one to two eligible HPs, to deliver the PrimaryBreathe treatment to patient participants. Each HP will receive an invitation pack consisting of covering text (for email), a participant information sheet (PIS), consent form, and Data Collection Sheet (DCS). This will be sent electronically via email with an online link to all documents and data entry forms. The PIS and consent form will focus on the intervention, its delivery to patients, the completion of questionnaires, and QPPE. Please see the QPPE section towards the end of this question for more details. If the HP agrees to take part in the RCT, they will be invited to complete the consent form and DCS online (managed by the research team). Consented HP participants will complete PrimaryBreathe training (step 1 of the intervention) before delivering the intervention to patient participants (step 2). Training has three parts, completed partly in the HP's own time and partly through live online teaching sessions with health professionals from CBIS. Participants will need to complete and pass an assessment. In total, training takes approximately 2.5 hours. The online training sessions may be audio-recorded and field notes taken as part of the QPPE. Please see below for further details of how the treatment will be administered.

2. RCT Patients

Practices will identify potentially eligible patients with an electronic record search or a 'soft search' (based on primary care staff knowledge of their caseloads), or a mixed method. Identified patients will then be invited in batches, as appropriate, to take part in the RCT. Patients can also be approached in person (e.g. during planned visits). The practice will send the identified patients an invitation pack consisting of a covering letter, PIS, consent form, reply slip, and DCS. This will be sent either via post with a pre-paid return envelope or electronically via SMS with an online link to all documents and data entry forms. The PIS and consent form will focus on participation in the trial, including randomisation to intervention or control, and completion of questionnaires. The reply slip will enable patients who do not wish to take part to respond anonymously, indicating their reasons for declining. It will also allow patients who do

not wish to take part to indicate that they are willing to be contacted by a researcher to discuss their reasons. This is important for understanding whether aspects of the trial or the concept of breathlessness treatment may be discouraging participation. If the patient wishes to take part in the trial, they will be invited to complete the consent form and DCS and return them to the research team in the pre-paid envelope or complete them online (this process will be managed by the research team). Following participant consent, the eligibility of the patient participant will be confirmed before randomisation to intervention (PrimaryBreathe treatment) or control. The intervention arm involves patient participants receiving a onemonth PrimaryBreathe intervention from a trained HP participant at their practice, along with medical optimisation of the underlying condition (OptiMed), while control arm participants receive OptiMed alone. Intervention arm participants will usually attend between two and three consultations; up to five are permitted as long as they occur within a sixweek period. During these consultations, the HP and patient participant will agree on 1–2 nonpharmacological techniques—based on the Breathing, Thinking, Functioning model—considered most likely to help with the patient’s breathlessness. As response rates are critical to the success of the study, they will be closely monitored throughout, and additional invitation batches will be sent from the GP practice as needed to optimise uptake. Patient participants in the intervention arm will also be invited to take part in QPPE. The initial trial invitation PIS will introduce these elements, explaining that further information will be provided at the point of invitation and that participation is optional. Declining QPPE will not affect participation in the main trial. Please see the QPPE section towards the end of this question for more details of these components.

QPPE Informal Carers

Informal carers (family or friends) of a patient participant in the intervention arm will be invited, alongside the patient participant, to take part in QPPE. Carers will be approached indirectly: the patient participant will be invited to inform their carer about the QPPE study, if applicable and if they wish to. A followon QPPE study invitation pack will be addressed to the intervention patient participant, consisting of a covering letter, PIS, and consent form. The invitation pack will also include a separate invitation for the carer, containing a covering letter, PIS, consent form, and DCS. This will be sent either via post with a prepaid return envelope or electronically via SMS or email with an online link to all documents and entry forms. If the informal carer wishes to take part in the QPPE study, they will be invited to complete the consent form and DCS and return them to the research team in the prepaid envelope provided or complete them online (this process will be managed by the research team). The informal carer can take part in the QPPE even if the intervention participant they care for does not. Please see the QPPE section towards the end of this question for more details of these components.

QPPE Non-Participating Patients

Patients who receive the trial invitation from their practice but decide not to take part are welcome to return a reply slip indicating this to the research team. Patients who decline participation, provide reasons for doing so, and give their contact details agreeing to be contacted by a researcher to discuss these reasons may be invited to participate in QPPE. An invitation pack consisting of a covering letter, PIS, consent form, and DCS will be sent either via post with a pre-paid return envelope or electronically via SMS or email with an online link to all documents and entry forms. If the patient wishes to take part in QPPE, they will be invited to complete the consent form and DCS and return them to the research team in the pre-paid envelope provided or complete them online (this process will be managed by the research team). Please see the QPPE section towards the end of this question for more details of these components.

QPPE General Practice Staff

General practice staff involved in the administrative delivery of the trial will be invited to take

part in QPPE. They will be sent an invitation pack consisting of covering text (for email), PIS, consent form, and DCS, delivered electronically via email with an online link to all documents and entry forms. If the general practice staff member wishes to participate in the QPPE study, they will be invited to complete the consent form and DCS online (this process will be managed by the research team). Please see the QPPE section towards the end of this question for more details of these components.

QPPE CBIS Staff

CBIS staff involved in the trial will be invited to take part in QPPE. They will receive an invitation pack consisting of covering text (for email), PIS, consent form, and DCS, sent electronically via email with an online link to all documents and entry forms. If the CBIS staff member wishes to participate in the QPPE study, they will be invited to complete the consent form and DCS online (this process will be managed by the research team). Please see the QPPE section towards the end of this question for more details of these components.

Questionnaires:

All patient participants in the RCT will be asked to complete a set of questionnaires as part of their baseline measurement, prior to randomisation. These questionnaires will be selfadministered either online or via post. All patient participants will then be asked to complete followup questionnaires at 4 weeks, 8 weeks, 12 weeks, 16 weeks, 20 weeks, and 24 weeks. HP participants will be asked to complete a NOMAD questionnaire online at two timepoints: (1) after training and before they begin conducting PrimaryBreathe intervention appointments, and (2) within 4 weeks of delivering their final planned intervention appointment.

QPPE

The QPPE components of this trial will explore how the PrimaryBreathe treatment is received and implemented at the practice level, and examine how practice staff and patients experience the treatment. Understanding how the treatment is perceived, received, and reviewed is essential for assessing the programme, both for the main trial and for potential national implementation. PrimaryBreathe training (live teaching sessions led by CBIS staff) will be observed by a qualitative researcher. Field notes will be taken and the session may be audiorecorded. For consenting participants (patients and trained HPs), a member of the research team will observe intervention consultation appointments. These appointments will not be audiorecorded, but field notes will be taken. Observations will only take place for appointments held in person at the practice. Individuals from each participant group will be invited to take part in semistructured interviews. Patients will attend 1–4 interviews at different timepoints. All semistructured interviews will be audiorecorded.

SelfManagement Website:

Patient participants in the RCT intervention arm will be offered access to the PrimaryBreathe selfmanagement website. A booklet (nondigital equivalent) will be available for patients who do not wish to, or are unable to, use the website. HP participants will also be provided with access to the selfmanagement website. The website (or booklet) is an optional adjunct to the intervention, containing resources and strategies based on the Breathing, Thinking, Functioning model. Specific strategies and interactive content can be used in a personalised manner during and/or after intervention consultations. Additional physical resources (handheld fans and pedometers/step counters) will also be made available to patient participants if they may benefit from these items.

Intervention Type

Other

Primary outcome(s)

1. Mastery of breathlessness measured using the Chronic Respiratory Questionnaire (CRQ) Mastery Scale at baseline and 8 weeks

Key secondary outcome(s)

1. Quality of life measured using the Chronic Respiratory Questionnaire total score (CRQ-Total) at baseline, 4 weeks, 8 weeks and 24 weeks after randomisation

2. Quality of life measured using the Health questionnaire and quality of life measure (EQ-5D-3L) at baseline, 8 weeks and 24 weeks after randomisation

3. Healthcare resource utilisation, via the numbers of unplanned primary care attendances, and the number of emergency department attendances due to breathlessness, measured using questionnaires at baseline and every 4 weeks until 24 weeks after randomisation

4. Healthcare resource utilisation measured using the Healthcare Resource Utilisation Questionnaire (HRUQ) at baseline, 8 weeks, 12 weeks and 24 weeks after randomisation

5. Worst breathlessness in the last 24 hours measured using a Numerical Rating Scale for worst breathlessness in the last 24 hours (NRS-worst) at baseline, 8 weeks and 24 weeks after randomisation

6. Anxiety and depression measured using the General Anxiety Disorder-7 (GAD-7) and the Patient Health Questionnaire-9 (PHQ-9) at baseline, 8 weeks and 24 weeks after randomisation

7. (For health professionals) Assessment of self-confidence in the ability to deliver the intervention measured using the adapted Normalisation measure development questionnaire (NoMAD-adapted) at 2 time points: pre- and post-intervention delivery

Completion date

28/02/2027

Eligibility

Key inclusion criteria

General practice site eligibility

1. Located in England's Regional Research Delivery Network (RRDN) regions
2. Practice uses either SystmOne or EMIS (also known as Optum) electronic medical record software, AND
3. At least one eligible health professional working clinically in the practice is interested in delivering the intervention, AND
4. One General Practitioner (GP) at the practice is willing to oversee the study as site Principal Investigator (PI).

Trial participants

Health professional eligibility

1. Working clinically within a participating general practice, AND
2. Interested in delivering the intervention, AND
3. Considered by the site PI to have sufficient skill and enthusiasm to be suitable to deliver the intervention after training, AND
4. Registered health professional OR a Health and Wellbeing Coach.

Patient eligibility

1. Registered at a participating general practice, AND
2. Aged 18 years or over, AND
3. Able to give informed consent, AND
4. Experiencing chronic breathlessness on exertion or at rest for at least 8 weeks with one or more of the index long term conditions (LTCs), diagnosed in primary or secondary care, being a major contributor to the patient's experience of chronic breathlessness, AND
5. Modified MRC scale self-assessment score of 2-4.

Qualitative parallel process evaluation participants

General practice staff eligibility

1. Health professional participant in the trial OR involved in the administrative delivery of the trial at a participating site through their professional role, AND
2. Able to provide informed consent, AND
3. Aged 18 years or over.

Patient eligibility

1. Patient participant in the trial intervention arm

Carer eligibility

1. Aged 18 years or over, AND
2. Able to provide informed consent, AND
3. Identified as a family member or friend giving support (unpaid/family carer) by a patient participant in the trial intervention arm.

Patient non-participant eligibility

1. Invited to participate as patient participant in the trial, AND
2. Notified trial team they did not want to participate, AND
3. Able to provide informed consent, AND
4. Aged 18 years or over.

CBIS staff eligibility

1. CBIS staff involved in the delivery of the intervention training, AND
2. Able to provide informed consent, AND
3. Aged 18 years or over.

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

110 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

General practice site eligibility

1. Participated in the PrimaryBreathe intervention co-design study or the PrimaryBreathe feasibility study

Trial participants

1. Health professional eligibility

2. Working exclusively as a Health Care Assistant with no other registered profession(s)

Patient eligibility

1. Likely to be in the last three months of life, OR

2. Known acute or chronic deterioration in breathlessness over preceding days or a small number of weeks, OR

3. Known ICU admission in the three months prior to recruitment, OR

4. Known major surgery during the preceding four weeks or scheduled within the next three months after recruitment, OR

5. A symptom-directed intervention is inappropriate for the individual, for example, they do not have the cognitive capacity to benefit and/or engage with study interventions, OR

6. Considered unable to complete study measures, OR

7. Patient is housebound

Qualitative parallel process evaluation participants

General practice staff eligibility

1. Not meeting the key exclusion criteria

Patient eligibility

1. Not meeting the key exclusion criteria

Carer eligibility

1. Patient participant does not agree to carer inclusion

Patient non-participant eligibility

1. Not meeting the key exclusion criteria

CBIS staff eligibility

1. Not meeting the key exclusion criteria

Date of first enrolment

01/04/2026

Date of final enrolment

30/12/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Norwich

Norfolk & Norwich University Hosp'
Colney Lane
Colney
Norwich
England
NR4 7UY

Study participating centre

Leicester Royal Infirmary

Infirmary Square
Leicester
England
LE1 5WW

Study participating centre

Freeman Road Hospital

Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

Study participating centre

St James' S University Hospital

Beckett Street
Leeds
England
LS9 7TF

Study participating centre

Manchester Royal Infirmary

Oxford Road
Manchester
England
M13 9WL

Study participating centre
New Cross Hospital Royal Wolverhampton
Wolverhampton Road
Heath Town
Wolverhampton
England
WV10 0QP

Study participating centre
The Royal London Hospital
80 Newark Street
London
England
E1 2ES

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
England
GU2 7XX

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
England
SE1 7EH

Study participating centre
Bristol Royal Infirmary
Marlborough Street

Bristol
England
BS2 8HW

Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

Royal Devon University NHS Ft
Barrack Road
Exeter
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EX2 5DW

Sponsor information

Organisation

University of Cambridge

ROR

<https://ror.org/013meh722>

Organisation

Cambridgeshire and Peterborough Integrated Care Board

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date