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PrimaryBreathe Feasibility Study

Submission date
30/10/2024

Recruitment status
Recruiting

Registration date
12/11/2024

Overall study status
Ongoing

Last Edited
19/12/2025

Condition category
Respiratory

[X] 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
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 a 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. This is a feasibility study to find out how feasible it is to implement in primary care and to work out the best approach to setting up the future main trial. This will be conducted across 6 general practices, with 60 patients in 2 regions of England. This study aims to determine the feasibility of conducting a study where participants are randomly assigned to different groups to test the effectiveness of a treatment by comparing it to a placebo (dummy) or standard treatment to determine intervention effectiveness and to implement the intervention in primary care. In later studies in the programme, this breathlessness treatment will be formally tested in general practices across England to check that it does help patients and carers.

Who can participate?
Patients living with persistent breathlessness, invited from participating GPs in England

What does the study involve?
The study involves randomly allocating consented patients to receive either the PrimaryBreathe treatment delivered by their GP or continue to receive routine care. The PrimaryBreathe treatment involves consented patients having two to three appointments with a trained Health Professional, who will teach them up to two techniques to help them with their breathlessness.

What are the possible benefits and risks of participating?
While it is possible that participants receiving the treatment in this research could benefit clinically, this is not the purpose of this study. There are no risks anticipated for participants 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.

When is the study starting and how long is it expected to run for?
September 2022 to Agust 2027

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Type(s)
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Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
343818

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 63126, NIHR Central Commissioning Facility (CCF) Grant Code: NIHR203682

Study information

Scientific Title
PrimaryBreathe programme: feasibility of evaluating a primary care intervention for chronic breathlessness

Acronym
PrimaryBreathe

Study objectives
It is feasible to undertake a trial to test the effectiveness of a Primary Care breathlessness intervention and implement it.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/09/2024, East Midlands - Leicester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048193; leicestersouth.rec@hra.nhs.uk), ref: 24/EM/0164

Study design
Randomized controlled study

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Supporting breathless

Interventions
Mixed-methods explanatory sequential design with two main components: Feasibility-Trial (FT) and Feasibility-Qualitative (FQ).

Recruitment:
The study will recruit 6 practices and 10 eligible patients from each practice. 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 control at a ratio of 1:1. Randomisation will be performed using a secure online platform (e.g., Sealed Envelope) with access available only to relevant member(s) of the study team with designated role-based permissions. Consented participants in the intervention arm will then be provided with the PrimaryBreathe treatment from a trained health professional participant.

All patient and health professional participants will be invited to complete questionnaires and some will be invited to take part in qualitative activities such as semi-structured interviews.

There are 5 types of participants in this study; health professionals delivering the intervention (a minimum of 6, at least 1 per site), patients (the largest group of 60), informal carers, general practice staff who are involved in the study administrative activities to some degree, and non-participating patients who decline to take part in the randomised part of the study, but that are willing to share their reasons with the study team. The latter three groups will only be invited to participate in FQ. Each of these participant types will be consented to in turn:

1. FT Health Professionals (HP)
The study will recruit 6 GP practices from the East of England Clinical Research Network (CRN or Regional Delivery Network, RRDN) and the Yorkshire & Humber CRN (or RRDN) regions. Each practice will identify at least one member of staff, 1-2 eligible HP(s), to deliver the PrimaryBreathe treatment to patient-participants. Each HP will receive an invitation pack consisting of covering text (for email), participant information sheet (PIS), consent form, and Data Collection Sheet (DCS). This will be sent electronically via email with an online link to all the documents and data entry forms. PIS and consent forms will focus on the intervention, its delivery to patients, completion of questionnaires and qualitative components. Please see the qualitative section towards the end of this question for more details of these.

If the HP agree to take part in the study they will be invited to complete the consent form and DCS online (this process will be managed by the study team).

Consented HP participants will complete PrimaryBreathe training (step 1 of the intervention) before delivering the intervention to patient participants (step 2 of the intervention). Training has 5 parts (A-E), partly completed in the HP's own time and partly through live online teaching sessions with health professionals from Cambridge Breathlessness Intervention Service (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 qualitative component of the study. Please see below for further details of how the treatment will be administered.

2. FT Patients
Practices will identify potentially eligible patients with an electronic record search or a 'soft search' (based on primary care staff knowledge of their patient caseloads), or a mixed approach. The identified patients will then be invited in batches, as appropriate, to take part in FT. The practice will send the identified patients an invitation pack consisting of a cover letter, PIS, consent form, reply slip, DCS and Chronic Respiratory Questionnaire mastery (CRQm). This will be sent either via post with a pre-paid return envelope or electronically via SMS with an online link to all the documents and data entry forms. PIS and consent form will focus on participation in the study outlining the randomisation to either intervention or control and the completion of questionnaires. The reply slip will enable patients who do not wish to take part to respond anonymously, indicating their reasons for declining the study. It will also provide an option for patients who do not wish to take part to indicate that they would be happy for a researcher to contact them to discuss further their reasons for deciding not to participate. This is a key part of understanding whether there is anything about the study and/or concept of breathlessness treatment that may be resulting in people not wishing to participate.

If the patient wishes to take part in the study they will be invited to complete the consent form, DCS and CRQm and return them to the study team in the pre-paid envelope provided or to complete them online (this process will be managed by the study team).

Following the participant's consent, the eligibility of the patient participant will be confirmed before them being randomised to intervention (PrimaryBreathe treatment) or control at a ratio of 1:1. The intervention arm involves patient participants receiving one-month PrimaryBreathe intervention, from a trained HP participant at their practice, along with medical optimisation of the underlying condition (OptiMed) and the control arm patient participants receive OptiMed alone. Intervention arm participants will usually attend a total number of between two to three consultations. Up to five consultations are permitted, as long as they occur within a six-week total period. During these consultations, the HP and patient participant will agree on 1-2 non-pharmacological techniques to use, based on the Breathing Thinking Functioning model, that are likely to help most with the patient's breathlessness.

As a critical factor to the success of the study, response rates will be closely monitored throughout and additional invitation batches will be sent from the GP practice as required to optimise uptake.

Patient participants in the intervention arm will also be invited to take part in FQ. The initial study invitation PIS will introduce these elements stating that additional information will be provided at the point of invitation to these components, and the participant is free to decide at that point whether to take part or not. A decision not to take part in the qualitative arm will not affect their participation in the main study. Please see the qualitative section towards the end of this question for more details on these components.

3. FQ 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 FQ. Carers will be approached indirectly; the patient participant will be invited to inform their carer about the study, if applicable and if they wish to. A follow-on qualitative study invitation pack will be addressed to the intervention patient participant, consisting of a cover letter, PIS and consent form. The invitation pack will

also include a separate invitation for the carer which will include a cover letter, PIS, consent form and DCS. This will be sent either via post with a pre-paid return envelope or electronically via SMS or email with an online link to all the documents and entry forms.

If the informal carer wishes to take part in the study they will be invited to complete the consent form and DCS and return them to the study team in the pre-paid envelope provided or to complete them online (this process will be managed by the study team). The informal carer can take part in this qualitative arm, even if the intervention participant they care for does not. Please see the qualitative section towards the end of this question for more details on these components.

4. FQ General Practice Staff
General practice staff who are involved in the administrative delivery of the study will be invited to take part in FQ. They will be sent an invitation pack consisting of covering text (for email), PIS, consent form and DCS. This will be sent electronically via email with an online link to all the documents and entry forms.

If the general practice staff wishes to take part in the study they will be invited to complete the consent form and DCS online (this process will be managed by the study team). Please see the qualitative section towards the end of this question for more details on these components.

5. FQ Non-Participating Patients
Patients who receive the study invitation from their practice, but decide not to take part are welcome to return a reply slip indicating this to the research team. The patients who decline to take part, offer reasons why they have decided not to take part, and provide their contact details agreeing that they are happy for a researcher to contact them to discuss their reasons with them, may be invited to participate in FQ. An invitation pack consisting of a cover 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 the documents and entry forms.

If the patient wishes to take part in FQ they will be invited to complete the consent form and DCS and return them to the study team in the pre-paid envelope provided or to complete them online (this process will be managed by the study team). Please see the qualitative section towards the end of this question for more details on these components.

Questionnaires:
All patient participants in FT will be asked to complete a series of questionnaires as part of their baseline measurement, prior to randomisation. These questionnaires will be self-administered either online or via post.

All patient participants will then be asked to complete follow-up 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 different timepoints: 1) after training and before they begin conducting PrimaryBreathe intervention appointments and 2) within 4 weeks of delivering their final planned intervention appointment.

Feasibility Qualitative (FQ):
The qualitative components of this study will explore how the PrimaryBreathe treatment is received and implemented at a practice level, and examine in some detail how practice staff and

patients experience the PrimaryBreathe treatment. Understanding how the treatment is perceived, received and reviewed is essential in developing a feasible and sustainable treatment programme, both for the planned main trial and potential national implementation.

PrimaryBreathe training (live teaching sessions led by CBIS staff) will be observed by a qualitative researcher.

Researcher field notes will be taken and the session may be audio-recorded. For consenting participants (patient and trained HP), a member of the research team will observe intervention consultation appointments. Consultation appointments will not be audio-recorded, 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 by the research team to take part in semi-structured interviews. Patients will attend 1-4 interviews over different timepoints. Semi-structured interviews will be audio-recorded.

Self-Management Website:
Patient participants (FT intervention arm) will be offered access to the PrimaryBreathe self-management website. A booklet (non-digital equivalent) will be available for patients who do not wish to or are unable to, use the website. HP participants will be provided with access to the self-management website. The self-management website (or booklet) is an optional intervention adjunct containing resources and useful strategies based on the Breathing Thinking Functioning model. Specific strategies and interactive content on the website can be used in a personalised manner during and/or following intervention consultations.

Additional physical resources (handheld fans and pedometer/step counter) will also be made available to patient-participants if they may benefit from these item(s).

Intervention Type
Behavioural

Primary outcome(s)
Quality of life of patients with chronic respiratory diseases measured using the Chronic Respiratory Questionnaire (CRQ) Mastery Scale at baseline and 8 weeks

Key secondary outcome(s))
1. Quality of life of patients with chronic respiratory diseases measured using Chronic Respiratory Questionnaire total score (CRQ-Total) at baseline, 4, 8, 12, 16, 20 and 24 weeks
2. Health and quality of life measured using the EuroQol EQ-5D-3L questionnaire at baseline, 4, 8, 12, 16, 20 and 24 weeks
3. Number of unplanned primary care attendances due to breathlessness measured using data collected in patient records at one timepoint
4. Number of emergency department attendances due to breathlessness measured using data collected in patient records at one timepoint
5. Healthcare resource use measured using the Healthcare Resource Utilisation Questionnaire (HRUQ) at baseline, 4, 8, 12, 16, 20 and 24 weeks
6. Shortness of breath measured using the Numerical rating scale for worst breathlessness in the last 24 hours (NRS-worst) at baseline, 4, 8, 12, 16, 20 and 24 weeks
7. Anxiety measured using the General Anxiety Disorder-7 (GAD-7) at baseline, 4, 8, 12, 16, 20 and 24 weeks

8. Patient Health Questionnaire-9 (PHQ-9) at baseline, 4, 8, 12, 16, 20 and 24 weeks
9. (For health professionals) Normalisation measure development questionnaire, adapted to include an assessment of self-confidence in the ability to deliver the intervention measured using the Normalization Process Theory Measure (NoMAD-adapted) questionnaire. The study team will issue the NOMAD-adapted questionnaire in electronic (self-administered) format to health professional participants for completion after they have completed their PrimaryBreathe core training and assessment and before delivering their first intervention consultation; and near the end of their planned intervention delivery period.

Completion date
31/08/2027

Eligibility

Key inclusion criteria
Feasibility-Trial (FT)

General practice site inclusion criteria:
1. Located in the East of England or the Yorkshire and Humber Clinical Research Network (CRN; or Regional Research Delivery Network, RRDN), AND
2. Practice uses either SystmOne or EMIS 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)

Health professional inclusion criteria:
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. Clinically qualified OR a Health and Wellbeing Coach AND
5. Able to provide informed consent

Patient inclusion criteria:
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 nine 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

Feasibility-Qualitative (FQ)

General practice staff inclusion criteria:
1. Health professional participant in Feasibility-Trial OR involved in the administrative delivery of Feasibility-Trial at a participating site through their professional role, AND
2. Able to provide informed consent, AND
3. Aged 18 years or over.

Patient inclusion criteria:
Patient participant in Feasibility-Trial intervention arm

Informal carer inclusion criteria:
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 Feasibility-Trial intervention arm.

Participant type(s)
Carer, Employee, Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Feasibility-Trial (FT)

General practice site exclusion criteria:
Participated in the Primarybreathe intervention co-design study.

Health professional exclusion criteria:
There are no exclusion criteria if all the inclusion criteria have been met.

Patient exclusion criteria:
1. Clinically considered by the site PI to be likely to be in the last three months of life, OR
2. Acute on chronic deterioration in breathlessness over preceding days or a small number of weeks, OR
3. Major surgery during the preceding four weeks or planned to occur within ten weeks after randomisation, OR
4. Site PI considers symptom-directed intervention to be inappropriate for the individual.

Feasibility-Qualitative (FQ)

General practice staff exclusion criteria:
There are no exclusion criteria if the inclusion criterion is met.

Patient exclusion criteria:
There are no exclusion criteria if the inclusion criterion is met.

Informal carer exclusion criteria
The patient participant does not consent to informal carer inclusion.

Date of first enrolment
06/01/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: East of England
Floor 4
Rouen Road
Norwich
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NR1 1QQ

Study participating centre
NIHR CRN: Yorkshire and Humber
8 Beech Hill Road
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S10 2SB

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
The datasets generated during and/or analysed during the current study are/will be available upon request. After the study, fully anonymised data may be made available to other researchers and organisations, with permission of the Chief Investigator, Dr Anna Spathis, primarybreathe@medschl.cam.ac.uk. Consent for this data sharing will have been obtained from study participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes