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PrimaryBreathe: designing a primary care version of a treatment for chronic breathlessness

Submission date
12/04/2023

Recruitment status
No longer recruiting

Registration date
03/05/2023

Overall study status
Completed

Last Edited
04/02/2026

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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 medicines. This approach needs to be adapted so it can be accessed by more people through their general practices (primary care).

Who can participate?
Patients, family or friend carers, general practice staff and researchers will work together in partnership to develop an acceptable primary care version of the treatment. We will be particularly careful to try to meet the needs of people from ethnic minority communities and people who do not use the internet.

What does the study involve?
The study has four phases. First, participants will talk with researchers, both individually and in groups, to give advice about the treatment and a related website that provides additional information (Phase A). Next, patients, carers and staff will agree the details of the treatment prototype in two workshops (Phase B). The treatment will then be delivered by general practice staff to patients (Phase C). Finally, we will talk with everyone who delivered or received the treatment to get feedback that can help us improve the treatment further (Phase D). Participants can choose whether they take part in one or more phases.

What are the possible benefits and risks of participating?
Benefits:
This study should help to improve the support provided to breathless people and their carers in the future. While it is possible that talking about the treatment in this research could lead to clinical benefit for people taking part in the study, this is not the purpose of this study. Healthcare professional participants will have remote access to ongoing general, and patient-

specific, support from Specialist Breathlessness Service staff, during the period of delivering the intervention.
Risks:
The breathlessness treatment is safe and will not involve taking new medicines. We understand that being breathless, caring for someone, or being a busy healthcare professional can make it harder to take part in research; we will make participating as convenient as possible, for example using phone/video calls rather than having to travel and keeping research conversations short. Talking about living with, or supporting someone with, breathlessness may be difficult or upsetting. Participants will never be under any pressure to answer questions or talk about topics they find preferable not to discuss.

Where is the study run from?
University of Cambridge (UK)

When is the study starting and how long is it expected to run for?
September 2022 to August 2025

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

Who is the main contact?
Dr Lindsey Berends, primarybreathe@medschl.cam.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lindsey Berends

Contact details
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Additional identifiers

Integrated Research Application System (IRAS)
323271

Central Portfolio Management System (CPMS)

55070

Study information

Scientific Title
PrimaryBreathe Intervention Co-design Study

Study objectives
This study uses a multiphase process to design, with patient, carer and professional stakeholders, a primary care intervention for chronic breathlessness. Without an iterative process of development and refinement, influenced by a range of stakeholders, interventions have less potential to be valuable, through failing to meet the needs of those receiving them.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2023, London - Stanmore REC (2nd Floor, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 207 104 8263; stanmore.rec@hra.nhs.uk), ref: 23/LO/0091

Primary study design
Interventional

Study design
Non-randomized; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic breathlessness

Interventions
This study will have four phases:
Phase A: Individual semi-structured interviews with patients with breathlessness, informal carers of patients with breathlessness and health professionals will be followed by mixed focus groups. These will explore the intervention resources, and participants' views on intervention principles, content and processes.
Phase B: Two virtual co-design workshops will generate the intervention prototype, informed by data from Phase A.
Phase C: The intervention prototype will be delivered within three general practices. Staff will receive the co-designed training and will then deliver the intervention to the patients and carers.
Phase D: Individual semi-structured interviews with all Phase C participants will allow further refinement of the intervention and a self-management website. The research team will create an electronic consultation guide for primary care staff and a detailed description of the intervention.

Intervention Type
Other

Primary outcome(s)
1. First version of an electronic consultation guide for health professionals delivering the intervention generated by a thematic analysis of qualitative data from participant interviews and focus groups;
2. Plain English version of the Breathing Thinking Functioning (BTF) model amended from the existing health professional version using qualitative data from participant interviews and focus groups;
3. Self-management website for use as an intervention adjunct, with associated paper-based resources for people without digital access, created by refining a researcher-generated website using qualitative data from participant interviews and focus groups.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/08/2025

Eligibility

Key inclusion criteria
Stakeholder Reference Group (SRG) members inclusion criteria:
1. Any member of the SRG who is a patient, carer, primary care health professional or specialist breathlessness service health professional
2. Aged 18+ years
3. Able to provide informed consent
4. Living or working in England

Patient and carer (family or friend) inclusion criteria:
1. Experience of chronic breathlessness in the last year, either personally or through a caring role
2. Patient registered with any of the three recruited general practices
3. Able to participate in one or more phases of the co-design research study
4. Able to provide informed consent
5. Aged 18+ years

Patients and carers who do not speak English are eligible; professional translation services will be available for written material, consent and research conversations.

Patient-carer dyads will be recruited when both a patient and their carer are interested in taking part. Equally, each can take part without the inclusion of the other.

Primary care health professional inclusion criteria:
1. Working clinically within any of the three recruited general practices
2. Interested in being trained to deliver a breathlessness intervention
3. Able to provide informed consent
4. Aged 18+ years

Participant type(s)
Mixed

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
47

Key exclusion criteria
1. Participant aged under 18 years
2. Participant cannot provide informed consent
3. Primary care health professionals working in a discipline that does not require health professional qualification (eg social prescriber)
4. Patients (and their carers) will not be approached to take part when considered by their clinical team to be likely to be in their last 3 months of life
5. Carers will be excluded if their patient has been recruited to the study and does not consent to carer inclusion; this will be explained sensitively

Date of first enrolment
01/05/2023

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
United Kingdom

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

Study participating centre

NIHR CRN Yorkshire and Humber
8 Beech Hill Road
Sheffield
England
S10 2SB

Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR203682

Results and Publications

Individual participant data (IPD) sharing plan
After the study, fully anonymised data (transcripts, data on participant characteristics and researcher fieldnotes) may be made available to other researchers and organisations, with permission of the Chief Investigator. Consent for this data sharing will have been obtained from study participants.
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IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			04/02/2026	No	No
HRA research summary			26/07/2023	No	No