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Reducing chronic breathlessness in adults by following a self-guided, internet-based supportive intervention

Submission date 04/04/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/04/2024	**Overall study status** Ongoing	
Last Edited 27/06/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Some health conditions make breathing difficult and uncomfortable. When this happens every day, it is called chronic breathlessness. Over 3 million people living with heart and lung disease have chronic breathlessness in the UK. Breathlessness is very difficult for patients themselves and their families, resulting in disability and feelings of fear, distress, and isolation. Due to a lack of supportive breathlessness services many patients frequently attend hospital Accident and Emergency (A&E) departments seeking help. Given the ongoing challenges faced by the NHS in the UK, such as long waiting times, staff shortages, and increased demand for services because of the COVID-19 pandemic, there is an urgent need to develop new ways to support those living with chronic breathlessness. One potential solution is to offer support online, as it is estimated that 7 out of every 10 people with chronic breathlessness in the UK are internet users. With the help of patients and NIHR funding the research team led by Dr Charles Reilly, developed an online breathlessness supportive website called SELF-BREATHE. SELF-BREATHE provides information and self-management tools such as breathing exercises, that patients can do at home. SELF-BREATHE has been tested as part of its development. SELF-BREATHE is acceptable and valued by patients. However, it is unknown whether SELF-BREATHE improves patients' breathlessness and their lives. This study aims to test if using SELF-BREATHE for six weeks improves patients' breathlessness, their quality of life and whether SELF-BREATHE should be offered within the NHS and see if patients opt to continue to use SELF-BREATHE after six weeks and what benefits this may have for patients.

Who can participate?

People aged 18 years old and over living with chronic breathlessness

What does the study involve?

Each person will be randomly chosen by a computer to continue with their usual care or their usual care plus access to SELF-BREATHE. All study participants will complete questionnaires at the start of the study, thereafter at seven and twelve weeks after randomisation. These questionnaires will ask patients about their breathlessness and its effect on their lives and planned and unplanned hospital visits. At the end of the study, we will compare answers to

these questionnaires between the two groups at seven and 12 weeks. This will inform the team if SELF-BREATHE improved patients' breathlessness and reduced their need for unplanned hospital visits e.g., A&E attendances due to breathlessness.

What are the possible benefits and risks of participating?
The possible benefits for those allocated to the intervention arm using SELF-BREATHE include help with their breathlessness, but the research team cannot promise that this will happen. The purpose of the study is to see if there are any benefits to using SELF-BREATHE. Importantly, the information, the research team get from this study will help improve the future treatment of people with chronic breathlessness. The main benefit of taking part in this study for an individual is to help improve the care for future patients. Involvement in this study will help the study team answer the question: does using SELF-BREATHE for 6 weeks improve people's breathlessness?

For those that agree to take part in this study, there will be additional time involved to follow the SELF-BREATHE programme (logging on 2-3 times a week over six weeks) if allocated to the SELF-BREATHE arm of the study and complete the research questionnaires. For all participants in the study, this will involve three research assessments over 12 weeks. To minimise inconvenience, these research assessments will be scheduled at a time most convenient for participants.

Where is the study run from?
King's College Hospital NHS Foundation Trust

When is the study starting and how long is it expected to run for?
December 2023 to July 2028

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

Who is the main contact?
Dr Charles Reilly, charles.reilly@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334979

ClinicalTrials.gov number
NCT06326957

Secondary identifying numbers
V1 15/01/2024, CPMS 60966, IRAS 334979

Study information

Scientific Title
A multicentre, randomised controlled trial comparing usual NHS care to a self-guided internet-based intervention (SELF-BREATHE) plus usual NHS care to reduce breathlessness in adults living with chronic breathlessness

Acronym
mRCT SELF-BREATHE

Study objectives
We hypothesise that using SELF-BREATHE plus usual NHS care (intervention) for six weeks will reduce worst breathlessness over the last 24 hours, quantified on 0-10 numerical rating scale (NRS) in patients living with chronic breathlessness compared to those receiving usual NHS care (Control)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/03/2024, London – Bromley Research Ethics Committee (Temple Quay House, 2 The Square, Bristol Research Ethics Committee Centre, London, BS1 6PN, United Kingdom; +44 (0)207 104 8118; bromley.rec@hra.nhs.uk), ref: 24/LO/0142

Study design
Statistician blind multicentre parallel-group two-arm randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Adults living with chronic breathlessness due to malignant and non-malignant diseases

Interventions
Intervention arm: SELF-BREATHE

SELF-BREATHE is a complex, theoretically informed intervention developed with patients following the IDEAS and MRC frameworks. Participants allocated to the intervention group (SELF-BREATHE) will continue to receive their usual NHS care and they will also be given a username and password, which provides unlimited access to SELF-BREATHE. SELF-BREATHE has seven core components, delivered via multi-model media i.e., animations, written text, audio files, pictures, and instructional videos.

1. Patient education about chronic breathlessness and self-management.
2. Self-monitoring of breathlessness; breathlessness severity, distress due to breathlessness, and the impact of breathlessness on life, with real-time algorithm-based automated feedback.
3. Breathing exercises and techniques to improve breathlessness self-management e.g., breathing control exercises, pursed-lipped breathing, and body positions to relieve breathlessness.
4. Breathlessness self-management planning: patients can formulate a personalised breathlessness crisis plan, which will include the breathlessness management techniques used at points of breathlessness crisis e.g., breathing control.
5. Improving physical activity: advice on how to increase daily activity levels, self-directed and self-monitored home exercise programme of bed, chair and standing-based exercises.
6. Personalised Goal Setting: self-guided support for patients to set personalised goals and track achievement and success.
7. Ask the expert: inbuilt messaging service where patients can ask a question or get advice about any specific aspect of SELF-BREATHE (minimal response time of 48 hours).

Intervention Type
Behavioural

Primary outcome measure
Patient-rated intensity of worst breathlessness over the previous 24 hours measured using a validated 11-point (0-10) Numerical Rating Scale (NRS), where 0 = no breathlessness, and 10 = worst imaginable breathlessness at baseline (T1), 7 weeks (T2) and 12 weeks (T3) post-randomisation

Secondary outcome measures
The following secondary outcome measures are assessed at baseline (T1), 7 weeks (T2) and 12 weeks (T3) post-randomisation:

1. Distress and severity of breathlessness in the previous 24 hours measured using a 0–10 Numerical Rating Scale (NRS) at rest, and on exertion
2. Self-efficacy for managing breathlessness measured using a 0-10 Numerical Rating Scale (NRS)
3. Breathlessness measured using Dyspnoea 12 which quantifies 12 descriptors that incorporate the physical and affective aspects of dyspnoea
4. Functional impact of breathlessness on activities of daily living measured using the London Chest Activity of Daily Living Scale (LCADL)
5. Health-related quality of life (HRQL) measured using the Chronic Respiratory Disease Questionnaire (CRQ), a 20-item validated questionnaire across 4 domains: dyspnoea, fatigue, emotion and mastery
6. Health status in advanced disease measured using the EQ-5D-5L and EQ-VAS (visual analogue scale). The EQ-5D-5L consists of five dimensions and estimates responses into a single health index score, which typically ranges from 0 (equivalent to death) to 1 (equivalent to full health).
7. Cognitive and emotional representations of illness measured using the Brief Illness Perception Questionnaire (Brief IPQ)
8. Patients' cognitive and behavioural responses to their symptoms measured using the Cognitive Behavioural Responses Questionnaire (CBRQ) (Short version)
9. Willingness to accept breathlessness measured using the Acceptance scale, a 9-item subscale measuring pain willingness, taken from the Chronic Pain and Acceptance questionnaire. Participants will be asked to rate each item as it applies to them on a 7-point Likert Scale (0 = Never true to 6 = always true); where a higher score will indicate greater acceptance.
10. Heath service use measured using the Client Service Receipt Inventory (CSRI), an established and validated user self-reported outcome measure in chronic breathlessness and will be used to quantify GP contacts, planned and unplanned hospital and emergency department attendances as the main cost drivers associated with chronic breathlessness and associated cost

The following secondary outcome measures are assessed at 7 and 12 weeks (data collection window +/- 10 days) post-randomization:
1. SELF-BREATHE-specific outcomes measured using the SELF-BREATHE acceptability questionnaire: based on the theoretical framework of acceptability (affective attitude, burden, perceived effectiveness, intervention coherence and self-efficacy).
2. Individuals' experiences of using and perceived benefits of SELF-BREATHE for participants randomised into the intervention arm (SELF-BREATHE) will be measured in two semi-structured qualitative post-interventional interviews at 7 and 12 weeks (data collection window +/- 10 days) post-randomization

Overall study start date
14/12/2023

Completion date
31/07/2028

Eligibility

Key inclusion criteria
1. Adults ≥ 18 years of age
2. Chronic Breathlessness at rest and/or exertion
3. Chronic Breathlessness (CB) defined as breathlessness that persists (> 3 months) despite pharmacological treatment of the underlying disease including, but not limited to; cancer, chronic obstructive pulmonary disease (COPD), interstitial lung disease (ILD), bronchiectasis, chronic fibrotic lung disease following SARS-CoV2 infection

4. Medical Research Council (MRC) dyspnea score ≥ 2 (MRC 2= short of breath when hurrying on the level or walking up a slight hill
5. Access to a computer, tablet, or smartphone with internet access
6. Able to provide informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
246

Key exclusion criteria
1. Breathlessness of unknown cause
2. Primary diagnosis of chronic hyperventilation syndrome
3. Currently participating in a rehabilitation programme e.g., pulmonary/cardiac rehabilitation (patients that have completed PR > 4 weeks will be eligible).

Date of first enrolment
05/07/2024

Date of final enrolment
30/11/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kings College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
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ME16 9QQ

Study participating centre
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Study participating centre
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Study participating centre
University Hospitals Sussex NHS Foundation Trust
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Sponsor information

Organisation
King's College Hospital NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.kch.nhs.uk/

ROR
https://ror.org/01n0k5m85

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/08/2029

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	15/01/2024	10/04/2024	No	Yes