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The development of a new treatment for asthma aimed at improving the muscular control of breathing

Submission date
23/07/2025

Recruitment status
Recruiting

Registration date
01/08/2025

Overall study status
Ongoing

Last Edited
10/02/2026

Condition category
Respiratory

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Asthma is a condition which results in breathlessness because the airways become narrowed and swollen. Research has shown that one-third of people with asthma may experience breathlessness because of poor muscle coordination during breathing. If this is the case, it is important to provide breathing retraining to people with asthma who experience breathlessness, despite taking asthma medication. There is some evidence that breathing exercises can reduce breathlessness in people with asthma, but only by a small amount. The study team suggest that this is because these treatments do not teach people to change postural muscle patterns and because patients don't always understand how to improve their breathing. A physiotherapy treatment for joint pain has been developed, which teaches patients to reduce tension in postural muscles. Alongside this, computer software was developed that uses small cameras and uses this information to show breathing patterns as a patient breathes. This study aims to create a version of that treatment, called "Cognitive Muscular Therapy (CMT)", for people with asthma. After creating this intervention, it will be tested by 20 patients who have asthma but who still experience breathlessness despite taking asthma medication.

Who can participate?
Anyone over the age of 18 diagnosed with asthma and attended an asthma review clinic in the last 12 months. Participants should be regularly taking preventative asthma medications.

What does the study involve?
Every patient recruited into the study will receive between 7-8 weekly sessions of our new treatment at the University of Salford from an experienced NHS respiratory physiotherapist. Each treatment session will last 45-60 minutes. This treatment will include software to visualise the breathing pattern during normal breathing.

What are the possible benefits and risks of participating?
Participants will receive 7-8 sessions of the new treatment, which may reduce symptoms of breathlessness. The results of the study will help us to understand how to design a future larger study to test this new treatment for people with asthma. This is a very simple, straightforward

study. The physiotherapist will be using techniques which are used in routine clinical practice, and these will be complemented with our breathing visualisation system, which does not carry any risk. However, some people occasionally feel dizzy when receiving breathing retraining because of changes in their blood oxygen saturation level, and so the study team will monitor blood oxygenation to try to prevent this. However, if dizziness does occur, it will pass after a few minutes of sitting or lying.

Where is the study run from?
The University of Salford, UK

When is the study starting and how long is it expected to run for?
May 2025 to May 2027

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

Who is the main contact?
Professor Stephen Preece, s.preece@salford.ac.uk

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
346646

Central Portfolio Management System (CPMS)
63627

National Institute for Health and Care Research (NIHR)
207911

Study information

Scientific Title
Breathing REtraining for people with AsTHma and breathing pattern disorder (BREATH)

Acronym
BREATH

Study objectives
Objective 1: Through an iterative co-design approach, develop a new physiotherapist-led intervention which enables patients with asthma and breathing pattern disorder to improve the muscular control of breathing
Objective 2: Run a pilot study (case series) to evaluate the potential of the intervention to improve symptoms associated with asthma + breathing pattern disorder and improve breathing mechanics.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/05/2025, Black Country NHS Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 25/WM/0084

Study design
Non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory; Disease/Condition: Chronic lower respiratory diseases

Interventions

There are two phases to this study. Phase 1 focuses on intervention development with 10 participants, and phase 2 is an uncontrolled pilot study to explore the potential effectiveness of Cognitive Muscular Therapy (CMT) for people with asthma and breathing pattern disorder with 20 participants.

A version of the treatment will be created for people with asthma. Every patient recruited into the study will receive seven treatment sessions (lasting 45–60 minutes) of CMT at the University of Salford from an experienced NHS respiratory physiotherapist. This treatment will include software to show a patient their breathing pattern as they breathe. Patients and physiotherapists will be involved in a co-design process. This will involve the delivery of the treatment to 10 patients, gathering opinions on how it could be improved, and refining the new treatment. Once the treatment has been finalised, a physiotherapist will deliver it to 20 patients with asthma who experience breathlessness, despite taking medication. Questionnaire data on breathlessness, asthma control, and quality of life will be collected, along with laboratory measures of breathing function. Patients will also be interviewed to understand their experiences of the treatment.

Participant flow through the study:
Participant receives an invitation to join the study (phase 1 & 2)
Participant is sent the Participant Information Sheet or reads the sheet online (phase 1 & 2)
Participant completes online screening form or is screened over the phone (phase 1 & 2)
Research coordinator completes a 2nd screening over the phone to check eligibility (phase 1 & 2)
If eligible, participant completes 4 types of questionnaires: (phase 1 & 2)

1. Respiratory questionnaires: Self-evaluation of breathing questionnaire, Nijmegen questionnaire, Asthma Control questionnaire, Asthma quality of life questionnaire, Healthcare utilization and asthma exacerbations
2. General Functional and Daily Living Questionnaires: Generalised Anxiety and Depression Scale
3. Intervention Focused Questionnaires: Credibility and expectancy questionnaire, Breathing retraining engagement.
4. Sample Characteristic Questionnaires: Diversity and inclusion survey.

Participants attend a face-to-face workshop (Phase 1 only)
The participant attends for 7-8 treatment sessions at the University of Salford (Phase 1 & 2)
The participants complete the questionnaires again (Phase 1 & 2)
Participant attends a second face-to-face workshop (Phase 1 only)
Participant is interviewed about the new treatment (Phase 2 only)
Bias: Bias has been considered whilst designing this study:

1) Screening of participants will be completed by the research coordinator, not the physiotherapist.
2) Outcome measures will be collected and analysed by research staff, not physiotherapists.
3) Analysis will be completed using a computer program and not by hand.

The treatment sessions are summarised below:
Intervention Session 1: Understanding breathlessness: educational component
Intervention Session 2: General relaxation: Diaphragmatic/rib breathing & passive limb movements
Intervention Session 3: Postural deconstruction: Postural retraining
Intervention Session 4: Postural deconstruction: Postural retraining

Intervention Session 5: Postural deconstruction: Postural retraining
Intervention Session 6: Contextual triggers: Awareness training
Intervention Session 7: Functional integration: Relearning of functional tasks

Intervention Type
Behavioural

Primary outcome(s)
Breathing difficulty is measured using the Self Evaluation of Breathing Questionnaire (SEBQ) at baseline, 2 weeks and 3 months post-intervention

Key secondary outcome(s))
The following secondary outcome measures were assessed at baseline, 2 weeks and 3 months post-intervention (unless otherwise stated):
1. Hyperventilation symptoms are measured using the Nijmegen Questionnaire
2. Asthma control is measured using the Asthma Control Questionnaire (ACQ)
3. Asthma-related quality of life is measured using the Asthma Quality of Life Questionnaire (AQLQ)
4. Healthcare utilization and asthma exacerbations are measured using a custom questionnaire
5. Generalized anxiety and depression are measured using the Generalised Anxiety and Depression Scale (GAD-7)
6. Treatment credibility and expectancy are measured using the Credibility/Expectancy Questionnaire (CEQ) at 2 weeks post-intervention only
7. Engagement with breathing retraining is measured using a custom questionnaire at 2 weeks and 3 months post-intervention
8. Diversity and inclusion are measured using a custom Diversity and Inclusion Survey at baseline only

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Above 18 years old
2. GP diagnosis of asthma
3. Taking regular preventative asthma medications, e.g. steroid, LABA
4. Attended an asthma review clinic with a medical professional (GP, respiratory clinician, practice nurse) within the last 12 months (to ensure we exclude other causes of breathlessness)
5. Self-report that asthma symptoms are not well-controlled based on a score > 25 in the self-evaluation of breathing questionnaire despite taking medication. This will be taken to indicate an underlying breathing pattern disorder.
6. Ability to stand without any assistive device for at least 20 minutes (to ensure sufficient capacity to complete the intervention)
7. Speak and understand English sufficiently well to receive the intervention.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Dementia or other major cognitive impairment
2. BMI > 32 (as increased subcutaneous fat prevents use of breathing visualisation system)
3. Current smoker or smoked regularly within last 6 months
4. Respiratory comorbidity, including COPD, bronchiectasis, cystic fibrosis, pneumonia
5. Significant breathless from condition such as heart disease, cancer, pulmonary fibrosis
6. Any cardiorespiratory disease that requires medical intervention
7. Unable to cancel or postpone other physiotherapy treatment for breathing pattern disorder (during the period they are involved in the study).

Date of first enrolment
01/07/2025

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

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Sponsor information

Organisation
University of Salford

ROR
https://ror.org/01tmqtf75

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 will be stored in a publicly available repository.
o Location: https://salford.figshare.com/
o Type of Data: Questionnaire data from each of our outcomes
o Available: Anticipated July 2027 and will be available indefinitely
o We will provide a link in the scientific publications, which will allow anyone to download the data and use it without restriction.
o We have obtained consent from participants to share fully anonymised data.
o There should not be any ethical or legal restrictions on the sharing of questionnaire data.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	09/05/2025	30/07/2025	No	Yes
Participant information sheet	version 3	09/05/2025	30/07/2025	No	Yes
Participant information sheet	version 5	10/12/2025	10/02/2026	No	Yes
Protocol file	version 5	14/01/2026	10/02/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes