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Supported inspiratory muscle training for people with chronic obstructive pulmonary disease who have declined pulmonary rehabilitation

Submission date 10/12/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 18/12/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 19/01/2026	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pulmonary rehabilitation is recommended for people with Chronic Obstructive Pulmonary Disease (COPD). However, many people decline, putting them at higher risk of hospital admission. Supported Inspiratory muscle training (SIMT) may be an acceptable option to improve symptoms, enable future pulmonary rehabilitation and reduce health costs. Inspiratory Muscle training (IMT) involves breathing in through a mouthpiece on a hand-held device against enough resistance to strengthen the breathing muscles. Support for IMT is needed to help people keep motivated to do the training. A well-designed, full-scale study is needed to see if SIMT is worthwhile. The aim of this feasibility study (small scale test) is to check if SIMT is acceptable and test the study processes, to help design a full-scale trial.

Who can participate?
We will invite people aged 35 years and over with COPD who have declined the offer of pulmonary rehabilitation.

What does the study involve?
We aim to recruit 34 participants to take part for 9 months. Participants will be randomly allocated to either:
1. A training group being supported to receive SIMT and breathing exercises
2. A control group who will receive the same treatment as the training group but the setting on their training device will be too low to have an effect (sham training).
Training usually takes a few minutes and involves breathing in quickly and deeply through the training device five times (with rests and repeated until 30 breaths achieved). Training is twice a day, 5 days per week, supported with weekly visits for 2 months, then unsupported three times per week for the remaining 7 months. Support includes setting goals and giving feedback. Breathing exercises will encourage more efficient breathing and enhance the training. Participants will be asked to do a breathing test, wear an activity monitor for 5 days and complete six questionnaires at the first meeting and at the 2- and 9-month assessments. Staff

will be interviewed at the end of the study and 10- 15 participants doing the training at the 2- and 9-month assessments. At 9 months information will be collected about health service encounters and pulmonary rehabilitation enrolment.

What are the possible benefits and risks of participating?
Benefits:
There may be some improvement in symptoms, but we cannot promise anything. The next stage of the research might help other people with COPD and might save the NHS money.
Risks:
Use of a sham device. To address any disappointment where inspiratory muscle training is ineffective, breathing exercises are included in both groups and all participants are offered an inspiratory muscle trainer at the end of the study.
There may be some muscle soreness after the assessment and when first training. This is not expected to be severe and lasts no longer than a day. Muscle pain is minimised by starting the training at a very low level and building up.
Each session is short, but the number of sessions is twice a day, five times a week for the first 2 months and then three times per week in the follow-up period. This was deemed acceptable by Public Involvement groups and previous study participants. Burden is minimised by delivering assessments and interventions in the participants' own homes.

Where is the study run from?
The main centre for the study is Sheffield Teaching Hospitals NHS Foundation Trust and there will hopefully be at least one other site within South Yorkshire.

When is the study starting and how long is it expected to run for?
January 2026 to May 2028

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

Who is the main contact?
Cath O'Connor, cath.o'connor@nhs.net

Contact information

Type(s)
Public

Contact name
None Sarah Wilkinson

Contact details
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S5 7AT
+44 (0)114 271 1658 ext 11658
sarah.wilkinson71@nhs.net

Type(s)
Scientific, Principal investigator

Contact name
Ms Cath O'Connor

ORCID ID
https://orcid.org/0000-0001-6519-385X

Contact details
Sheffield Teaching Hospitals NHS Foundation Trust
Sheffield
United Kingdom
S5 7AT
+44 (0)114 271 1900
cath.o'connor@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
352426

Central Portfolio Management System (CPMS)
70267

National Institute for Health and Care Research (NIHR)
303582

Study information

Scientific Title
Supported inspiratory muscle training for people with chronic obstructive pulmonary disease who have declined pulmonary rehabilitation: a pilot randomised controlled trial and process evaluation

Acronym
SIMPLER Feasibility study Version 1

Study objectives
Objective 1. A pilot RCT (Workstream 1), assessing the feasibility of the study design in terms of:
1. Availability of healthcare data
2. Recruitment and dropout rates
3. Estimates of average values for relevant study results
4. Sample size calculation for a full scale RCT

Objective 2. A process evaluation (Workstream 2) to consider context and test theory in terms of:
1. Acceptability of the study design
2. Feasibility of delivering the intervention
3. Acceptability of the intervention
4. Fidelity of delivering the intervention

5. How the intervention needs adapting to help it work better in practice
6. Making sense of the results by combining information from the interviews with the other findings.

Objective 3. Refinement (Workstream 3) to integrate the above workstreams, engage stakeholders and refine the theory behind the study.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2025, East Midlands – Nottingham 1 Research Ethics Committee (-, -, -, United Kingdom; -; nottingham1.rec@hra.nhs.uk), ref: 25/EM/0210

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
This is a feasibility study involving mixed methods and consisting of a pilot Randomised Controlled Trial (RCT) and process evaluation. A feasibility study is a small study that acts like a test run for a larger study and helps us to design it better.

The pilot RCT:
If participants decide to take part, they will be selected to be in one of two groups by chance. This is called randomisation. The two groups are:
1. A group being supported to receive Supported Inspiratory Muscle Training and breathing exercises. This is called
the treatment group.
2. A sham training (control) group who get the same treatment as the training group but the breathing device will not be

effective. The group will still have support and will be taught breathing exercises to help better breathing. This is called the control group.
Participants won't be told which group that they are in as this can affect the results of the study. This is called "blinding".
Participants will be asked to do the training for a total of nine months. Participants in the control group, will be offered IMT at the end of the study (9 months after starting).

Intervention:
Treatment Group:
At each session we will support participants to breathe in a better way so that they get the most from the training. Training with the device usually takes less than five minutes and involves breathing in quickly and deeply through the device. Participants start with 5 deep breaths using the on a low (easier) setting. We progress training when participants feel they are ready to do more. Once they feel able to, we ask participants to repeat sets of five breaths with as much rest as they need in between and relaxed breathing exercises to help any breathlessness. We aim for participants to work up to doing a total of 30 breaths with rests after each set of five breaths.

For the first 2 months participants will be asked to do the training twice a day, five days per week with support once a week. For the remaining seven months participants will be asked to train on their own three times per week without support.

During the first 2 months participants will be supported by a trained member of staff once a week. The support is to help participants stick to the training plan as we know that it can be tricky to keep motivated. Supervised training (once a week for eight weeks) may be at home (Sheffield) or in a clinic (Site 2). During the supervised session participants will have a short health screen to check that it is safe to train (recorded in the clinical notes). They will also be asked if they have been feeling unwell, had any changes in medication or had a visit with a health professional, for example a GP or hospital doctor. The staff member will also collect electronic information off the training device at the weekly visits to check how participants are getting on.

Control Group:
The Control group receive the same support and training as the treatment group however the resistance set on the device is too low to be effective. Therefore the feedback given by staff as part of the support is limited.

Outcome Measures:
Pilot RCT outcomes:
As part of the study participants will be asked to do three assessments. These assessments happen at the beginning of the study, again after two-months and again at the end of the study (nine months after the start). The assessment will take about an hour and a half and can take place in the participants own home.

Demographic data (age, gender, race, index of deprivation (via postcode)), weight, height and spirometry are measured at the first assessment only. Spirometry checks how narrow the airways are and is used to classify the severity of COPD. For this test participants blow out as fast and as long and as hard as they can. Participants will have had this test before. The device used for this test is called a spirometer. To identify inclusivity and diversity of the research, voluntary data will also be collected on disability, gender reassignment, marriage or civil partnership, religion or belief and sexual orientation (via questionnaire).

A health check is conducted at the first assessment to check symptoms of deterioration and measuring blood pressure, breathing rate, heart rate, temperature and oxygen levels (on a small

device that clips to the finger or ear lobe). At the follow up assessments we will do a shortened version of the health check monitoring symptoms, oxygen levels and heart rate and rhythm - this is routine practice and will be recorded in the clinical notes.

At all three assessments we will assess breathing pattern, breathing tests, and completion of six short questionnaires. Participants will also be asked to wear a small activity monitor on the front of your thigh for five to seven days. The tests are described in more detail below:

The breathing tests (Baseline, 8-week and 9-month assessment):
The breathing tests take a few minutes but participants can rest in between each one so that they can get your breath back if they need to. The breathing test is called a Maximum Inspiratory Pressure (MIP) test. This tests how strong the breathing in muscles are. For this test participants breathe in as hard as they can five times after a normal breath out and five times after breathing out all the way. The Inspiratory Flow (how fast the breath in is) is measured at the same time. The device used for this test is the POWERbreathe KH2.

The activity monitor (baseline, 8-week and 9-month assessment):
The activity monitor is called an ActivPal. It is a small device that sticks on the front of the thigh. The monitor collects information on how active participants are. Participants will be asked to wear it for up to seven days. They can wear the device in bed and in the shower. If it is uncomfortable they can remove it and contact the researcher for advice.
The monitor will be dropped off and collected by the researcher.

The questionnaires (Baseline, 8-week and 9-month assessment):
The questionnaires will take about 30 minutes. They include two about breathing, two about mood, one about quality of life and one about what participants think about the study and the training.

At 9 months only:
• Rehab referral - collected by the rehab team
• Healthcare utilisation (GP appointments, Accident and Emergency (A&E) attendances, respiratory and all-cause hospitalisations and time until fit for discharge) - collected from electronic health records (via Sheffield Teaching Hospitals (STH) contract and honorary contract with Site 2 NHS Trust) between nine-months prior to baseline and 9-month follow up.

Process outcomes - assessed at end of study unless otherwise specified:
• Recruitment rate
• Retention
• Reasons for dropout
• Data completion rate
• Adherence with SIMT - download of data from IMT device by staff (weeks 1-8)/researcher (week 38).
• Fidelity - cancellations of supported sessions by staff or participant. Fidelity with the Motivational Interviewing principles and behaviour change techniques delivered with the participant - measured by recording the first two sessions for each staff member delivering the intervention.
• Feasibility of accessing outcome data from electronic health records (qualitative assessment).
• Acceptability of SIMT – Questionnaire at baseline, week 8 and 9 months
• Cost of the intervention

Participant Interviews (8-week and 9-month assessment only):
Participants in the treatment group will be invited to be interviewed about how they have found

the training and what they think about the study itself. This will happen at the end of the supervised training period (at two months after starting) and at the end of the study period (nine months after starting). The interview is expected to take about 30 minutes. The interview will be recorded and stored securely until it is destroyed.

Staff interviews (end of study):
2-6 staff will be interviewed at the end of the study to see how acceptable it was to deliver the intervention and follow
the study processes.

Sample:
34 participants will be recruited over 15 months (recruiting approximately 2-3 participants per month).

Allocation:
Once the participants have consented to being part of the study they will be allocated to the treatment group or the control group electronically.

Setting:
The study will take place in Sheffield and another NHS site within South Yorkshire. All assessments will take place in
the participant's own home. Supported sessions will take place in participants' homes in Sheffield and either at
home or in clinic at the second site. This reflects current variation in delivery of physiotherapy for people with
breathing problems.

Adverse events:
Adverse events will be reported as per the research protocol in line with GCP. It is anticipated that people with COPD will experience exacerbations of their condition and admission to hospital under usual circumstances.

Workstream 3 Refinement (MONTHS 39-45):
If the full-scale RCT is feasible, acceptable and financially viable then the intervention and RCT processes will be refined for a full scale multicentre RCT to evaluate clinical and cost effectiveness of Supported IMT.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment rate measured using the number of participants randomised per centre per month and the proportion of people enrolled of all those assessed for eligibility, at the end of the enrolment period

Key secondary outcome(s)
Secondary feasibility outcomes:
1. Retention (proportion of participants randomised who enrol and who complete the study with a valid PiMax outcome at 9-months post-randomisation)
2. Reasons for dropout from intervention or trial (qualitative data) measured throughout the study period

3. Data completion rates from clinical and patient-reported outcome measures measured at the end of the study period
4. Adherence with SIMT measured at weeks 1-8 and week 38
5. Feasibility of accessing health utilisation outcome data from electronic health records , evaluated at the end of the study period
6. Acceptability of SIMT measured using questionnaire at baseline, week 8 and 9 months.
7. Feasibility of delivering the intervention: visits/sessions cancelled, recording of first two sessions delivered by each HCP to evaluate fidelity with support for SIMT (motivational interview principles and behaviour change techniques), collated at the end of the study period.
8. Progression to full-scale RCT using a Red (not recommended), Amber (recommended with modifications), Green (recommended) system, with the following criteria:
Recruitment rate:
Red: <0.5 participants per centre per month
Amber: >=0.50 and < 1.1 participants per centre per month
Green: ≥1.1 participants per centre per month
Retention proportion at 9 months:
Red: <50% randomised participants
Amber: 50-79% randomised participants
Green: ≥80% randomised participants

Clinical outcomes – to be used as comparative outcome measures in the definitive trial and potentially inform sample size for the definitive trial:
1. Maximum Inspiratory Pressure (PiMax) measured in centimetres of water (cmH2O) from residual volume (RV) and functional residual capacity (FRC) using the POWERbreathe KH2 at baseline, 8 weeks and 9 months
2. Inspiratory flow measured from RV and FRC in litres per second (l/s) using the POWERbreathe KH2 at baseline, 8 weeks and 9 months
3. Disease-specific health status assessed using the validated, self-reported, 8-item COPD Assessment Test (CAT) questionnaire at baseline, 8 weeks and 9 months
4. Disease-specific quality of life measured using the summary score of the validated, self-report, 20-item Chronic Respiratory Disease Questionnaire (CRQ) at baseline, 8 weeks and 9 months
5. Breathlessness measured using the dyspnoea subscale of the CRQ at baseline, 8 weeks and 9 months
6. Generic health status measured using the EuroQol (EQ-5D-5L) at baseline, 8 weeks and 9 months
7. Depression measured using the validated, self-report, 9-item Patient Health Questionnaire (PHQ-9) at baseline, 8 weeks and 9 months
8. Anxiety measured using the validated, self-report, 7-item, Generalized Anxiety Disorder (GAD-7) questionnaire at baseline, 8 weeks and 9 months
9. Physical activity over 5 days from start of sham/treatment measured using the thigh-mounted activPAL monitor (PAL Technologies Ltd., Glasgow, UK) to capture energy expenditure, steps, step cadence (steps per minute), standing and sedentary time (sitting and lying) in minutes, number of sit to stands and metabolic equivalent task (MET) hours, measured at baseline, 8 weeks and 9 months
10. Breathing pattern assessed using the Breathing Pattern Assessment Tool (BPAT) at baseline, 8 weeks and 9 months
11. PR referral collected by liaison with the PR team, assessed at 9 months
12. Healthcare utilisation, GP appointments, Accident and Emergency (A&E) attendances, respiratory and all-cause hospitalisations and time until fit for discharge), collected from electronic health records (via Sheffield Teaching Hospitals) between 9 months prior to baseline and 9-month follow up.

HCP Weekly Supervision Cost Data will be collected to inform the study process of the definitive trial: mileage, travel time, band of clinician, duration of session, duration of research activity.

Completion date
31/05/2028

Eligibility

Key inclusion criteria
1. Stable COPD (no exacerbation needing antibiotics or steroids in the preceding past 4 weeks)
2. Aged 35 years and over
3. MRC breathlessness scale > = 3 (“walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own pace”)
4. Declined Pulmonary Rehabilitation (rehab)
5. Unable to attend rehab or discontinued rehab following their first or second session

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
35 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. History of spontaneous pneumothorax
2. Incomplete recovery from a traumatic pneumothorax
3. Asthma
4. Perforated eardrum
5. Unstable angina
6. Ventricular dysrhythmias
7. Cerebral event or myocardial infarction within the last two months
8. More than two sessions of PR within the last year
9. Oral antibiotics or steroids for exacerbation within the last four weeks
10. Pregnancy

Date of first enrolment

05/01/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Integrated Care Team Therapy
Firth Park Clinic, North Quadrant
Sheffield
England
S36 9QG

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

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