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Does inspiratory muscle training with and without feedback alter breathing patterns and outcomes in people with a breathing pattern disorder?

Submission date
20/10/2025

Recruitment status
Recruiting

Registration date
21/10/2025

Overall study status
Ongoing

Last Edited
21/10/2025

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
The prevalence of breathing pattern disorders (BrPD) is suggested to be significant and can cause a variety of symptoms for individuals. Treatment for BrPD mainly focuses on breathing correction and re-training. Inspiratory muscle training (IMT) has been shown to improve outcomes such as inspiratory muscle strength, perceived breathlessness, exercise performance, and quality of life measures in other cohorts. However, the effect of IMT on BrPD is not known. This study will investigate whether a one-off intervention using IMT +/- biofeedback can improve breathing patterns. It will also investigate whether a home programme of IMT can improve breathing patterns and outcomes in individuals with a BrPD. There is no previous research documenting the effect of IMT on BrPD outcomes. This research will therefore expand current knowledge within this area.

Who can participate?
Adult patients with a breathing pattern disorder aged ≥18 and ≤65 years of age.

What does the study involve?
Four visits to the University of Kent and 6 weeks of home training with a breathing training device.

Visit one: Will involve questionnaire screening, blowing tests to measure lung function, sniff tests to measure air flow through the nose, breath testing to measure lung gases and breathing “in” tests to measure breathing muscle strength. A maximal effort exercise test on a stationary bicycle will be performed with a 5-minute warm-up and a continuous cycle with increasing workload until the participant is unable to keep cycling. Air breathed out will be measured via a facemask, worn throughout the whole test. Perceived exertion, heart rate, and oxygen levels will be monitored throughout the test. Blowing tests will be repeated at regular intervals for up to 30 minutes after the cycle test.

Visit two: Will involve attachment of ninety non-invasive reflective markers to the participant's torso. A sub-maximal exercise test on a stationary cycle, at low, moderate, and high intensity, will be performed. 3D-motion capture cameras will record chest movement at rest, during and after exercise. Participants' breathing will be recorded with a mobile phone immediately after the exercise test.

Once the participant has recovered from the cycle test, they will be instructed on how to use the breathing training device and have time to become familiar with it. Once participants have a correct technique, the sub-maximal exercise test and chest wall recordings will be repeated. A breathing training device will be loaned to the participant to use daily at home for 6 weeks. This will require two sets of thirty breaths daily. Each set should not take more than 5 minutes to complete. The research team will contact the participant weekly to review progress.

Visit three: Is a repeat of visit one, with the exclusion of post-exercise blowing tests.

Visit four: Participants will repeat the sub-maximal exercise test with 3D motion capture and video recording as outlined in visit two.

What are the possible benefits and risks of participating?
Participants will be informed of their breathing assessment and exercise test results. This will give participants a better understanding of their breathing. Participants will also receive training on how to improve their breathing pattern. It is currently unknown if IMT will improve BrPD outcomes.
Health and symptom questionnaires are designed to ensure that participants are suitable to participate in the study and to minimise risk. However, risks are associated with maximal effort exercise tests as they involve maximal exertion. Some people may feel dizzy or nauseated; this is a feature of all maximal exertion tests and should be short-lived. The participant will be reminded that they are in control of the test and can stop at any point. There may also be a risk of fatigue and muscle/joint soreness or injury, with both maximal and sub-maximal exercise testing. To minimise these risks, participants will undergo a warm-up as part of the exercise protocol. As with all physical exertion, there may be some cardiac risks, such as irregular heartbeat, chest pain, and sudden heart attack. Heart rate, peripheral oxygen saturation, and perceived exertion will be monitored throughout exercise testing. Testing will be stopped at any point if it is considered that participants are having difficulty breathing or are incurring any other form of distress.
If a participant's resting lung function appears reduced (less than 70% of predicted), they will not be able to participate in the study. Lung function will be closely monitored during and after the first exercise test, and if it falls below 10% of baseline levels, participants will be offered inhaled medication (Salbutamol) to reverse the reduction in lung function. This will be given via a standard inhaler. Alternatively, participants can use their own inhaler if they have one. Participants will be advised to remain in the laboratory until their lung function is within 10% of the baseline reading.

Because we are looking at breathing against resistance, participants may experience some shortness of breath or breathing muscle fatigue during testing and training. This should not last long and will improve at stopping the test or training session. The research team can show participants positioning and breathing exercises to settle breathing if required. The study will involve repeated deep breathing, which could result in some light-headedness. We will instruct participants on the correct breathing technique to help avoid this. Participants can, of course, stop the study at any time without reason at any point during the study.

There may also be a risk of skin irritation from the hypoallergenic tape that secures the markers onto the torso. Advice on how to manage this, should it occur, will be given by the research team.

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

When is the study starting and how long is it expected to run for?
May 2025 to December 2026.

Who is funding the study?
1. University of Kent, UK.
2. POWERbreathe International Ltd., UK.

Who is the main contact?
Kris Bahadur, kjb52@kent.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
UoK SERS REAG Ref No: 22_2025

Study information

Scientific Title
Does a one-off or a 6-week home programme of inspiratory muscle training with and without feedback alter breathing patterns and aerobic exercise parameters in people with a breathing pattern disorder?

Acronym
IMTinBrPD

Study objectives
1. To investigate if a one-off intervention using inspiratory muscle training +/- biofeedback can alter breathing patterns at rest and during light, moderate and high intensity exercise in individuals with a breathing pattern disorder.
2. To investigate whether a 6-week home programme of inspiratory muscle training can alter outcomes and breathing patterns at rest and during light, moderate and high intensity exercise in individuals with a breathing pattern disorder.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/05/2025, Sport, Exercise and Rehabilitation Sciences Research Ethics and Advisory Group (REAG) (University of Kent, Chipperfield Building, Canterbury, CT2 7PE, United Kingdom; + 44 (0)1227 816943; k.taylor-399@kent.ac.uk), ref: 22_2025

Study design
Single-centre interventional single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breathing pattern disorders

Interventions
1. Acute intervention of inspiratory muscle training +/- biofeedback.
2. A 6-week home training programme of inspiratory muscle training +/- biofeedback.

Following baseline screening and assessment (detailed in primary and secondary outcomes below) and including baseline optoelectronic plethysmography, participants will be randomly allocated to one of two groups using a computer-generated program:
1. Inspiratory muscle training alone
2. Inspiratory muscle training with biofeedback.

Acute (one-off) intervention:
All participants will be instructed on the use of the inspiratory muscle trainer as per their allocated group. Following instructions, optoelectronic plethysmography will be repeated at rest, during and after exercise. Observation of breathing post-exercise will also be made. Participants will then train at home for 6 weeks using the inspiratory muscle trainer, with weekly follow-up telephone or video call to review technique and progress their individualised programme. Initial training load will be set at 20% of their maximal inspiratory pressure and increased if appropriate in 10% increments. Participants will perform 2 x 30 breaths daily. Each set should take no longer than five minutes. Training load will be increased if participants are consistently (>5 days) and easily able to perform the training regime and demonstrate good technique. All baseline measures will be repeated at the end of the study.

Baseline is considered to be within 2 weeks before the start of the home training programme. The end of the study is considered to be within 2 weeks of completing the home training programme.

Intervention Type
Mixed

Primary outcome(s)
Breathing patterns were measured using optoelectronic plethysmography at baseline and the end of the study

Key secondary outcome(s))
The following secondary outcome measures were assessed at baseline and the end of the study:
1. Breathing pattern disorder was measured using the Nijmegen Questionnaire
2. The breathing pattern at rest was measured using the Breathing Pattern Assessment Tool
3. Upper airway dysfunction during exercise using the Exercise Induced Laryngeal Obstruction Dyspnoea Index
4. Breathing discomfort using the Self-Evaluation of Breathing Questionnaire
5. The physical and emotional components of breathlessness were measured using the Dyspnoea 12 index
6. Mood state was measured using the Brunel Mood Score
7. Lung function was measured using spirometry
8. Nasal air flow was measured using peak nasal flow recordings
9. Airway inflammation was measured using FeNO testing
10. Respiratory muscle strength was measured using maximal mouth inspiratory pressure
11. Performance was measured using VO2 max testing
12. Breathing pattern post-exercise was measured using a locally developed tool

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Ability to give written informed consent
2. Participants will be considered to have a breathing pattern disorder if:
2.1. Nijmegen Questionnaire score ≥23 or
2.2. Breathing Pattern Assessment Tool score ≥4 or
2.3. Exercise Induced Laryngeal Obstruction Dyspnea Index (EILODI) score ≥14 or
2.4. If a breathing dysfunction is identified on post-exercise observation
2.5. If no signs of exercise-induced bronchoconstriction on post-exercise spirometry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Conditions highlighted from the health questionnaire- Physical Activity Readiness Questionnaire (PAR-Q+). For example: musculoskeletal conditions or injury preventing exercise; active cancer or receiving cancer therapy; symptomatic or unstable cardiovascular disease; symptomatic or unstable metabolic disease; symptomatic or unstable respiratory disease; symptomatic or unstable neurological disease.
2. Sensitivity or allergy to OEP bi-adhesive tape
3. Sensitivity or allergy to inhaled salbutamol
4. Age <18 years or >65 years
5. Evidence of exercise-induced bronchoconstriction (EIB) on post-exercise spirometry defined by a >10% fall (from baseline) in FEV1 post exercise
6. Chest infection within the past 4 weeks, or any other illness within the past 2 weeks
7. Current musculoskeletal injury that would prevent exercise
8. Any contraindication or precaution to IMT (listed from the POWERbreathe K-Series K5 user manual)

Date of first enrolment
01/11/2025

Date of final enrolment
01/07/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Kent
Chipperfield Building
Canterbury
United Kingdom
CT2 7PE

Sponsor information

Organisation
University of Kent

ROR
https://ror.org/00xkeyj56

Organisation
POWERbreathe International Ltd.

Funder(s)

Funder type
University/education

Funder Name
University of Kent

Alternative Name(s)
The University of Kent

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
POWERbreathe International Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Kris Bahadur (kjb52@kent.ac.uk), Dr Jake Bowd (J.bowd@kent.ac.uk) or Professor John Dickinson (j.w.dickinson@kent.ac.uk). Data sets will be available following completion and publication of study results. All data sets available will be anonymised so that participant identification is not possible or deducible. Anonymised data may be used for presentations,

publications and other dissemination purposes, including availability to study funders. Anonymised data may also be used in secondary analysis or as part of meta-analyses and other relevant and legitimate scientific uses only, including future collaborative research projects. Written informed consent regarding participant data management will be gained from participants at study onset.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2		21/10/2025	No	Yes