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Pulmonary rehabilitation in low-resource settings for people with breathlessness due to lung conditions

Submission date
04/04/2024

Recruitment status
Recruiting

Registration date
11/04/2024

Overall study status
Ongoing

Last Edited
21/01/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Many people with chronic respiratory diseases (CRDs) such as chronic obstructive pulmonary disease, asthma, and post-tuberculosis damage have disabling symptoms, especially breathlessness, which affect their day-to-day activities. Breathlessness is uncomfortable and frightening, so people tend to avoid activities that make breathlessness worse. Then, because they are not doing any exercise, muscles weaken and they become 'unfit', which makes activities even harder. This increases anxiety and fear and affects quality of life, and depression is common. Pulmonary rehabilitation (PR) provides a supervised programme of exercise to reverse this vicious circle. PR combines endurance and muscle-strengthening exercises, with education about the causes and treatment of CRDs, and coping with breathlessness. At the end of the PR course, people with CRDs are less breathless and can do more, improving their quality of life. Previously, almost all PR trials have been performed in high-income countries, with well-equipped gyms and usually for people with one disease. In low- and middle-income countries (LMICs) and other low-resource settings, PR Centres often have less equipment and limited access to tests that allow accurate diagnosis of different types of CRD. Another problem is distance; travelling to a Centre 16 times in 8 weeks may be difficult in rural LMICs, so home-based PR may be useful. This trial aims to determine whether PR interventions provided in such settings effectively enhance exercise capacity, improve quality of life and provide efficacy among individuals with CRD when delivered at home versus traditional centre-based PR. Another focus is to ascertain the duration of benefits derived from PR, examining whether improvements are sustained over 6 months. The study further aims to assess the cost implications associated with PR interventions and gather insights from patients, PR therapists, and professionals to understand their perspectives and opinions regarding the PR services offered.

Who can participate?
Symptomatic adults aged 18 years old and over with CRD from four Centres (Bangladesh, India x2, Malaysia)

What does the study involve?
Participants will be allocated by chance to one of three groups:
1. Centre-PR: a programme of exercise and education twice a week for 8 weeks at a PR Centre
2. Home-PR: a programme of exercise and education twice a week for 8 weeks in their own homes, supervised remotely by video-call/telephone
3. Usual Care: usual clinical care. At the end of the trial, this group will be offered their choice of Centre-PR or Home-PR
Outcomes and expected benefits

Before and after the PR programme, exercise capacity, quality of life, breathlessness, anxiety and depression will be assessed to investigate the impact of PR, and again 6-months later to measure whether benefits are maintained. The use of healthcare resources will be measured to assess the cost implications for the health service, and if successful, how can this be rolled out in LMICs and other low-resource settings. Participants will be interviewed to find out what they think of the PR. The therapists will be asked about the practicalities of delivering PR in their Centre and at home and how they overcame any problems. Referring clinicians, health service managers and policymakers will be interviewed to understand how a service might be implemented and sustained in the four different settings.

Stakeholder and community engagement
Two members of the project team are people with CRD and the team will collaborate with community groups in each of the Centres throughout the trial. Proactive stakeholder engagement will ensure the findings influence professionals and policymakers.

What are the possible benefits and risks of participating?
Studies from high-income countries show that PR helps most people with certain lung diseases to feel less breathless, enables them to do more activities and improves their well-being. It is unknown whether PR will help people in low- and middle-income countries though our feasibility studies are encouraging.

The findings from the assessments will mean the PuRe trial will be able to show whether PR is a useful intervention in low- and middle-income countries. If the study shows that it enables people to do more activities and improves their well-being, governments and health services will be encouraged to provide the service. Although PR involves effort, the evidence from high-income countries and the feasibility study is that most people feel the effort is worthwhile because of the benefits. The safety of doing exercise has been tested carefully in high-income countries and there are no concerns even in people with severe breathlessness.

Where is the study run from?
The team includes people with CRD, clinicians, therapists, researchers, statisticians, health economists and health psychologists from the University of Edinburgh and the four Centres.

When is the study starting and how long is it expected to run for?
March 2024 to August 2027

Who is funding the study?
Medical Research Council

Who is the main contact?
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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Pulmonary rehabilitation delivered in low resource settings for people with chronic respiratory disease: a 3-arm assessor-blind randomised implementation trial

Acronym
PuRe

Study objectives
In people with chronic respiratory disease:
1. Compared to usual care, does Centre-PR or Home-PR improve functional exercise capacity (primary outcome) and quality of life (key secondary outcome) when delivered in LMICs?
2. Does supervised Home-PR achieve outcomes that are non-inferior to Centre-PR?
3. Is the impact of Centre-PR and/or Home PR sustained at 6-months?
4. Does Centre-PR or Home-PR lead to changes in healthcare utilisation, patient expense and work productivity over 6 months? What are the associated patient, healthcare, and societal costs?
5. Are Centre-PR or Home-PR programmes acceptable, feasible and implementable?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/07/2024, Edinburgh Medical School Research Ethics Committee (Teviot Place, Edinburgh, EH8 9AG, United Kingdom; -; EMREC@ed.ac.uk), ref: 24-EMREC-039

Study design
3-arm assessor-blind randomized implementation trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic respiratory disease

Interventions
This is a 3-arm individually randomised implementation trial. Randomisation will be carried out by research staff using a web-based randomisation service managed by the Edinburgh Clinical Trials Unit (ECTU). Participants will be randomised to either Centre-PR, Home-PR or Usual Care in the ratio 1:1:1, as shown below.

Patients will be randomly allocated to:
• Centre-pulmonary rehabilitation (PR): a programme of exercise and education twice a week for 8 weeks at a PR Centre
• Home-pulmonary rehabilitation: a programme of exercise and education twice a week for 8 weeks in their own homes, supervised remotely by video-call/telephone
• Usual Care: usual clinical care. At the end of the trial, this group will be offered their choice of Centre-PR or Home-PR

Before and after the PR programme patients will be assessed for exercise capacity, quality of life, breathlessness, anxiety and depression, to assess the impact of the intervention, and again 6 months later to measure whether the benefits are maintained.

The pulmonary rehabilitation will be delivered by trained therapists. The content of sessions will be defined in a detailed manual and local PR teams trained to deliver sessions in a standardised manner. Internationally recognised standards will be used for the exercise components of PR adapted for delivery in low-resource settings. Education resources (booklets, presentations, video clips etc) will build on those already used in the centres, be standardised for PuRe and adapted locally to ensure cultural and contextual relevance.

Sessions will be led by PR-trained therapists, with some content (e.g. psychological support, inhaler technique training, smoking cessation) delivered by other professionals according to the local skill mix.

Centre-PR will be delivered in groups (compliant with any social distancing requirements); in single-sex groups where this is culturally appropriate. Sessions will last up to two hours and include exercise components and group education.
Home-PR will include the same components as Centre-PR but supervision will be delivered remotely. Ideally, video links will be used to enable webinars for the education and supervision of several participants in a virtual group.

For Centre-PR, this will be delivered in a clinic setting either in a hospital, community clinic or satellite clinic.

Intervention Type
Behavioural

Primary outcome(s)
Functional exercise capacity is measured by the Endurance Shuttle Walking Test (ESWT) at baseline, post- PR and 6 months.

Key secondary outcome(s))
Quality of Life measured using the St Georges Respiratory Questionnaire (SGRQ) at baseline, post-PR and 6 months

Completion date
31/08/2027

Eligibility

Key inclusion criteria
1. Adults 18 years old (the age of majority in all the countries). No upper age limit.
2. Assessed by referring physician as having persistent and functionally limiting respiratory symptoms (mMRC 2) after optimisation of pharmacological therapy
3. Resident locally and willing to engage with either Centre-PR or Home-PR schedules if randomised to these groups
4. Willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. People with non-respiratory causes for the symptoms (stable co-morbidity may be included if clinically appropriate)
2. Active TB infection
3. Any condition that would increase risk (e.g. uncontrolled cardiac disease) interfere with PR (e.g. neurological disorders, severe arthritis, dementia), or be inappropriate (very severe frailty, end-of-life)
4. On-going, or completed PR (including other exercise programme) within the previous 18 months
5. Living in the same house as another participant
6. Unwilling or unable to provide informed consent

Date of first enrolment
01/09/2024

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
Algeria

Bangladesh

India

Malaysia

Study participating centre
Bangladesh Primary Care Respiratory Society
246 Haji Ismail Road
Khulna
Bangladesh
Bangladesh

Study participating centre
Christian Medical College
Ida Scudder Road
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632004

Study participating centre
King Edward Memorial Hospital Research Centre
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Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

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 non-publicly available repository. https://www.ed.ac.uk/information-services/research-support/research-data-service/after/data-repository

IPD sharing plan summary
Stored in non-publicly available repository