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Feasibility and acceptability of pulmonary rehabilitation for people with chronic lung diseases in Malawi

Submission date	**Recruitment status**	[X] Prospectively registered
20/08/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/08/2021	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
23/05/2025	Respiratory	

Plain English summary of protocol

Background and study aims

Malawi has a substantial burden of chronic respiratory diseases (CRDs) which cause significant deaths and loss of economic productivity, affecting patients, families, and health systems alike. Pulmonary rehabilitation (PR) is a highly recommended non-drug intervention in the clinical management of people with CRDs. However, Malawi lacks published evidence on the implementation of PR for people with CRDs. This trial will test the feasibility and acceptability of a culturally appropriate hospital-based PR programme among adults with functionally limiting CRDs at Queen Elizabeth Central Hospital in Blantyre, Malawi.

Who can participate?

Both male and female adults (aged 18 years or older) with spirometry confirmed diagnosis of chronic respiratory disease (CRD) and functional limitation due to breathlessness reaching a score of ≥2 on the modified Medical Research Council (mMRC) dyspnoea scale

What does the study involve?

Eligible study participants will participate in a six-week, twice-weekly, supervised hospital-based pulmonary rehabilitation (PR) programme, with an additional weekly home-based non-supervised session. Assessment of participants' lung function, exercise tolerance, and health status will be conducted at both baseline (week 0) and end of the PR programme (week 6). In addition, semi-structured in-depth interviews with participants will be conducted before and after their participation in the PR programme.

What are the possible benefits and risks of participating?

Participation will help inform the design of a culturally appropriate pulmonary rehabilitation (PR) programme for people with chronic lung diseases (CRDs) in Malawi. Risks from participation are not anticipated.

Where is the study run from?

Malawi-Liverpool-Wellcome Trust Clinical Research Programme (Malawi)

When is the study starting and how long is it expected to run for?
September 2018 to December 2021

Who is funding the study?
1. National Institute for Health Research (NIHR) (UK)
2. Wellcome Trust (UK) [221465/Z/20/Z]
3. Royal Society of Tropical Medicine & Hygiene (RSTMH) (UK)
4. Academy of Medical Sciences Global Challenges Research Fund (GCRF) Networking Grant Scheme (GCRFNGR5\1242)
4. NIHR- Global Health Research Group on Respiratory Rehabilitation (Global RECHARGE) (17/63 /20) using UK aid from the UK Government to support global health research

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
P.07/19/2752, WT 221465/Z/20/Z

Study information

Scientific Title
Protocol for a single-centre mixed-methods pre-post single-arm feasibility trial of a culturally appropriate six-week pulmonary rehabilitation programme among adults with functionally limiting chronic respiratory diseases in Malawi

Study objectives
1. To co-design, with service users and stakeholders, a locally appropriate pulmonary rehabilitation programme for adult patients with functionally limiting chronic respiratory diseases in Malawi.
2. To examine participants' recruitment, retention, engagement, adverse events, drop-outs, loss to follow up, and patient acceptability.
3. To describe changes in lung function, exercise capacity and health status of participants after completing the PR programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 08/09/2019, University of Malawi College of Medicine Research and Ethics Committee (Mahatma Gandhi Road, Chimutu Building Room # 822, P/Bag 360 Chichiri, Blantyre 3, Malawi; +265) 01 871 911; comrec@medcol.mw), ref: P.07/19/2752
2. Approved 20/07/2021, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, United Kingdom; +44 (0)1162522522; ethicsapp@leicester.ac.uk), ref: 31574

Study design
Single-centre mixed-methods pre-post single-arm feasibility trial

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adults with functionally limiting chronic respiratory diseases in Malawi

Interventions
This is a single-centre mixed-methods pre-post single-arm feasibility trial of a culturally appropriate six-week pulmonary rehabilitation (PR) programme among adults with functionally limiting chronic respiratory diseases (CRDs) in Malawi. Twenty-five patients ≥18 years old, with a spirometry confirmed diagnosis of a chronic respiratory disease and breathlessness of ≥2 on the modified Medical Research Council dyspnoea scale, will be consecutively recruited at Queen Elizabeth Central Hospital (QECH). Their baseline lung function, exercise tolerance, and health status will be assessed using spirometry, incremental shuttle walk test and chronic obstructive pulmonary disease assessment test, respectively. Semi-structured in-depth interviews will explore their experiences of living with CRD and potential enablers and barriers to their PR uptake. Along with international PR guidelines, these data will inform culturally appropriate delivery of PR. We initially propose a six-week, twice-weekly, supervised centre-based PR programme, with an additional weekly home-based non-supervised session. Following programme completion (after six weeks), repeat assessments of lung function, exercise tolerance and health status will be conducted. Quantitative changes in clinical outcomes will be discussed in relation to published minimal clinically important differences. Follow-up semi-structured interviews will capture participants' perceived impact of the PR programme on their quality of life, enablers, and barriers to fully engaging with the programme, and allow iteration of its design.

Intervention Type
Behavioural

Primary outcome(s)
1. Input for a culturally appropriate pulmonary rehabilitation (PR) programme collected through semi-structured in-depth interviews at baseline (at week 0)
2. Participants' acceptability of the PR programme explored through semi-structured in-depth interviews at the end of the programme duration (at week 6)

Key secondary outcome(s))
1. Lung function (pre- and post-bronchodilator forced expiratory volume in one second (FEV1), forced vital capacity (FVC) and FEV1/FVC ratio) measured using spirometry at both baseline (at week 0) and end of the trial (at week 6)
2. Health status variables such as participants' perceived respiratory disability due to dyspnoea (using the modified Medical Research Council (mMRC) dyspnoea scale), health-related quality of life (using the chronic obstructive pulmonary disease assessment test (CAT)), subjective experience of fatigue (using the Checklist Individual Strength fatigue subscale (CIS-Fatigue)), and emotional health (using the Hospital Anxiety and Depression Scale (HADS)), at both baseline (at week 0) and end of the trial (at week 6)
3. Physical fitness variables such as exercise tolerance (using the incremental shuttle walk test (ISWT)), lower extremity muscular strength using five-repetition sit-to-stand test (5XSST) and hamstring flexibility measured using the chair sit-and-reach (CSR) test, at both baseline (at week 0) and end of the trial (at week 6)

Completion date
31/12/2021

Eligibility

Key inclusion criteria

1. Those aged 18 years or older
2. Those with a spirometry confirmed diagnosis of chronic respiratory disease (CRD)
3. Those with functional limitation due to breathlessness reaching a score of ≥2 on the modified Medical Research Council (mMRC) dyspnoea scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Those with significant cardiovascular, neurological, orthopaedic, cognitive, or any other condition that would compromise participation in the rehabilitation programme
2. Those with an active infection including tuberculosis (TB) and coronavirus disease 2019 (COVID-19)
3. Those with respiratory disease which is thought primarily to originate from recent COVID-19 infection
4. Those unable to provide informed consent

Date of first enrolment
01/10/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
Malawi

Study participating centre
Queen Elizabeth Central Hospital
Blantyre
Malawi
Post Office Box 95

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
National Institute for Health 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

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Royal Society of Tropical Medicine and Hygiene

Alternative Name(s)
The Royal Society of Tropical Medicine and Hygiene, RSTMH

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Anonymized datasets generated and/or analyzed during the current study will be stored /published in a publicly available database and repository. The case report forms (CRFs) for the study will be printed out so that participants' data collected by these will be stored in physical form. All CRFs with participants' data will be stored securely in a locked cabinet in the Physiotherapy Department at Queen Elizabeth Central Hospital. These will later be anonymized and digitally archived on a public online database similar to IMPALA's peer-reviewed 'Questionnaires for Lung Health across the Life Course' (https://github.com/jipp3r /IMPALA_QuestionSet), as a harmonized and shared data collection system of demographics,

baseline, and pulmonary rehabilitation (PR) outcomes for patients undergoing PR in Malawi. The management of the system will be supported by the Data Management Support Unit at the Malawi-Liverpool-Wellcome Trust Clinical Research Programme. Likewise, interview data will be anonymized at the time of translation and transcription (e.g, participants' identifiers such as names will be removed). All anonymized transcripts will be stored in a publicly available repository (https://doi.org/10.6084/m9.figshare.19165667).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/05/2025	23/05/2025	Yes	No
Protocol article		31/01/2022	05/10/2022	Yes	No
Dataset		13/02/2022	10/02/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results			05/10/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes