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Does Pulmonary Rehabilitation improve the health of people in Kyrgyzstan living with lung disease caused by tuberculosis?

Submission date 28/08/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2019	**Overall study status** Completed	
Last Edited 10/10/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Chronic lung disease in low- and middle-income countries (LMICs) is associated with indoor air pollution, tobacco smoking and infections such as tuberculosis (TB). Chronic lung disease usually affects the most vulnerable in developing countries where people are unable to work from a younger age, compared with high income countries.

People living with post-TB lung disease are frequently disabled by their breathlessness. As a result, the individual experiences a reduced ability to perform daily activities, poor quality of life and social isolation. The disease is characterised by sudden flare-ups of symptoms, when symptoms become severe and the level of disability increases. Furthermore, medication in LMICs countries remains largely unavailable, expensive, and does not reverse the disability caused by TB.

Pulmonary Rehabilitation is a non-drug, low cost, high impact intervention that reverses the disability associated with chronic lung disease through education and exercise. It brings together health professionals from many disciplines, offering supervised exercise training and disease education. However, Pulmonary Rehabilitation is largely unavailable in developing countries. The project aims to develop culturally appropriate Pulmonary Rehabilitation and determine whether it is effective in improving the health of people living with lung disease caused by TB.

The aims of this project are to:
1. Adapt traditional Pulmonary Rehabilitation (PR) by incorporating music, singing and dancing as part of PR classes by patients and healthcare staff
2. Assess the impact of Pulmonary Rehabilitation on walking distance and quality of life for people living with post-TB lung disease in a randomised controlled trial
3. Explore differences in how patients respond to completing Pulmonary Rehabilitation

Who can participate?
In the first stage of the study, patients with chronic obstructive pulmonary disease (COPD) and healthcare staff who refer patients to PR programmes can take part.

In the second stage of the study people over 18 years old who suffer from tuberculosis can take part.

What does the study involve?
Patients and healthcare staff involved in Pulmonary Rehabilitation will discuss a new music, singing and dancing part to Pulmonary Rehabilitation to help make the service more culturally relevant to the people of Kyrgyzstan.

Participants with post-tuberculosis lung disorder will be randomly assigned to either Pulmonary Rehabilitation or a control group. The Pulmonary Rehabilitation programme will consist of 6 weeks of hospital-based education and exercises conducted twice weekly followed by a further 6 weeks of observation. The control group will consist of usual care. The study will assess whether Pulmonary Rehabilitation improves walking capacity, quality of life and symptom burden.

What are the possible benefits and risks of participating?
Pulmonary rehabilitation is not routinely available for people living with post-TB lung disease. We envisage participants benefiting from taking part in the intervention. Benefits may include improved fitness and reduced severity of symptoms such as breathlessness or chest tightness. There are no anticipated risks of participating.

Where is the study run from?
National Center of Cardiology and Internal Medicine named after Mirrakhimov, Kyrgyzstan

When is the study starting and how long is it expected to run for?
September 2019 to June 2022

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1

Study information

Scientific Title
Pulmonary Rehabilitation for people living with Post-TB lung disease in Kyrgyzstan: Global RECHARGE Kyrgyzstan

Acronym
Global RECHARGE Kyrgyzstan

Study objectives
Pulmonary Rehabilitation will improve exercise capacity and health-related quality of life for people living with post-TB lung disease in Kyrgyzstan

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 23/10/2019:
1. Approved 22/07/2019, Ethics Committee, National Centre of Cardiology and Internal Medicine (3 Togolok Moldo str, 720040, Bishkek, Kyrgyz Republic), ref: no. 17
2. Approved 16/09/2019, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, United Kingdom; +44 (0)1162522522; ethicsapp@leicester.ac.uk), ref: 22293

Previous ethics approval:
1. Approved 22/07/2019, Ethics Committee, National Centre of Cardiology and Internal Medicine (3 Togolok Moldo str, 720040, Bishkek, Kyrgyz Republic), ref: no. 17
2. Approval pending, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, UK; ethicsapp@leicester.ac.uk)

Study design
Randomised wait-list controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Post-TB lung disease

Interventions
This trial will consist of a mixed-methods approach and recruitment for each stage will be separate. The trial consists of two stages:

1. Focus groups will be conducted with adults with a diagnosis of post-TB lung disease and interviews will be conducted with potential referrers to Pulmonary Rehabilitation (healthcare staff).

2. A wait-list RCT of Pulmonary Rehabilitation versus usual care (control). Participants will be individually randomised (1:1) to the Pulmonary Rehabilitation programme or to a waiting list control. Due to the nature of Pulmonary Rehabilitation, it will not be possible for patients to be blinded to the allocation. All measures will be taken by a blinded assessor.

The intervention (Pulmonary Rehabilitation) will consist of a six-week programme, with sessions occurring twice weekly for at least two hours with approximately one hour for education and one hour for exercise, singing and dancing. It will be provided by a team of respiratory doctors, physiotherapists and nurses. The education component focuses on causes of breathlessness, coping techniques, the role of smoking, biomass smoke, TB and HIV, and the value of exercise. The standard programme of education will be supplemented by additional material on an individual basis or in small groups of people with post-TB lung disease. The exercise component consists of a combination of resistance and aerobic training using minimal equipment, individually adjusted over the course of six weeks. Classes will also include dedicated singing and dancing components which will be informed by patients as part of the trial. Pulmonary Rehabilitation will be provided in groups of up to 10 people with post-TB lung disease. The exercise regime will be individually prescribed to participants based on their exercise capacity. The regime is based on international guidance and will consist of the following:
1. Stretching/ flexibility exercises
2. Resistance training for upper and lower limbs including sit to stand, step-ups, bicep curls and pull-ups
3. Endurance exercises included walking and cycling on a stationary bike
4. Singing and dancing (informed by patients and health professionals)

The data gathered from stage 1 will inform the music, singing and dancing component of Pulmonary Rehabilitation and also the structure and content of the Pulmonary Rehabilitation classes. Outcomes will include a definition of the optimum music component including types of music and songs, dances, duration of the component, and how it is best delivered within the Pulmonary Rehabilitation programme.

The patients on the waiting list (control) arm will receive usual care and will be offered Pulmonary Rehabilitation after completing 12-week follow-up outcomes. There are currently no guidelines for the clinical management of Post-TB lung disease both locally and internationally. The usual care received by patients with post TB lung disease includes the following:
1. Frontal chest radiograph
2. Spirometry to screening for airway diseases
3. Optimised drug treatment
4. Advice to reduce exposures to risk factors e.g tobacco smoking, biomass smoke

Participants will in addition receive a leaflet with educational material about their lungs, which will be designed for this study together with patients. The information will cover the main needs of people living with post-TB lung disease and the importance of a healthy lifestyle including smoking cessation, exercises, diet, and self-management.

Intervention Type
Behavioural

Primary outcome measure
Walking distance (exercise capacity) on the Incremental Shuttle Walk Test (ISWT) at baseline and 6 weeks

Secondary outcome measures

1. Breathlessness is measured using the Medical Research Council (MRC) dyspneoa scale at 6 weeks
2. Symptom severity is measured using the COPD Assessment Test at 6 weeks
3. Health-related quality of life is measured using the Clinical COPD Questionnaire at 6 weeks
4. Economic impact is measured using the Work Productivity and Activity Impairment questionnaire at 6 weeks
5. Quality of life is measured using the EQ5D-5L questionnaire at 6 weeks
6. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale at 6 weeks
7. Physical activity is measured using accelerometry at 6 weeks
8. Pain is measured using the chest pain questionnaire at 6 weeks
9. Exercise capacity is measured using the Endurance Incremental Shuttle Walk Test at 6 weeks
10. Physical function is measured using the 5x Sit to Stand test at 6 weeks
11. End of study patient focus groups:
Participants allocated to the intervention group will be invited to participate in focus group discussions at the end of their Pulmonary Rehabilitation programme to learn about their experience of Pulmonary Rehabilitation. Focus groups will give an insight on views, experiences, opinions and recommendations which will be then helpful to inform design of future PR programmes. We anticipate conducting up to 6 focus groups with 2-10 participants in each. We will invite participants from the intervention group who completed the Pulmonary Rehabilitation programme and who dropped out of Pulmonary Rehabilitation to understand their experiences of the intervention. Focus group discussions will be audio-recorded, each lasting approximately 45-60 minutes, and will be conducted face-to-face by an interviewer and note taker (observer). Focus groups will be transcribed verbatim, with identifiable information removed.
12. End of study staff interviews:
Health care personnel involved in Pulmonary Rehabilitation will be invited to participate in interviews at the end of the study to discuss aspects of feasibility and acceptability, such as insights into barriers and facilitators to referral, uptake and completion of Pulmonary Rehabilitation. Interviews will be audio-recorded, each lasting approximately 30-45 minutes, and will be conducted face-to-face by an interviewer. Interviews will be transcribed verbatim, with identifiable information removed.
13. Book of testimonies collected throughout study:
Patients attending Pulmonary Rehabilitation will be asked to log their experience of the programme as they progress. This will be in the form of a Pulmonary Rehabilitation log book accessible to patients before, during and after sessions, as well as a dedicated patient evaluation form. Participants will be regularly prompted in order to gain the experiences of as many patients as possible. Patient satisfaction will also be recorded using a survey; staff involved in Pulmonary Rehabilitation will also receive the same evaluation form at the end of the study.

Overall study start date
01/04/2018

Completion date
30/06/2022

Eligibility

Key inclusion criteria

Stage 1 (patient):
1. Aged ≥18 years
2. Physician diagnosis of COPD

Stage 1 (staff):
1. Healthcare staff that would typically refer patients to a clinical PR programme, such as physicians & clinicians.

Stage 2:
1. Aged ≥18 years;
2. Definite diagnosis of a TB-negative patients with PTBLD lung disease
3. Previous TB treatment or finished treatment
4. Medical Research Council dyspnoea score grade 2 or higher

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
114

Total final enrolment
114

Key exclusion criteria
Stage 1 (patients):
1. Unable or unwilling to provide informed consent

Stage 2 (staff):
1. Unable or unwilling to provide informed consent

Stage 2:
1. Comorbidities such as severe or unstable cardiovascular, other internal diseases and locomotor difficulties that preclude exercise
2. Malignant disease such as lung cancer
3. Evidence of active TB on Chest X-ray or sputum tests within 1 month of assessment
4. Unable or unwilling to provide informed consent.

Date of first enrolment
12/10/2019

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Kyrgyzstan

Study participating centre
National Center of Cardiology and Internal Medicine named after Mirrakhimov
3 Togolok Moldo Street
Bishkek
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Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Results and Publications

Publication and dissemination plan

It is anticipated that the results from this study will be published in international journals and presented locally, nationally and internationally at appropriate meetings and conferences. All data that will be collected is anticipated to be published.

Updated 03/11/2021:
RECHARGE will be publicised through social media (Twitter @Global_RECHARGE), on a website (https://www.globalrecharge.org.uk/), conference abstracts and peer-reviewed journal articles.

Intention to publish date

30/09/2024

Individual participant data (IPD) sharing plan

For expressions of interest in collaborating, contributing research data to the database or for data access please contact the RECHARGE Scientific Committee by email at recharge@le.ac.uk. Please have a look at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7688060/

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	Qualitative results	04/02/2022	07/02/2022	Yes	No
Protocol article		21/02/2022	23/02/2022	Yes	No
Statistical Analysis Plan	version 1.0	09/10/2023	10/10/2023	No	No