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Does Pulmonary Rehabilitation improve the health of post tuberculosis patients living in Uganda?

Submission date
28/08/2019

Recruitment status
No longer recruiting

Registration date
12/09/2019

Overall study status
Completed

Last Edited
28/11/2023

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Chronic lung disease in low and middle-income countries (LMICs) is associated with fumes from cooking on open stoves, air pollution 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 hence increasing the burden of the disability in LMICs.

Sufferers 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, known as 'acute exacerbations,' when symptoms become severe and the level of disability increases. Furthermore, medication in developing countries remains largely unavailable, expensive, and does not reverse the disability caused by chronic lung disease.

Pulmonary Rehabilitation is a non-drug, low cost, high impact intervention that reverses the disability associated with chronic lung disease. It brings together health professionals from many disciplines, offering supervised exercise training and disease education. However, Pulmonary Rehabilitation is largely unavailable in developing countries like Uganda and this research seeks to fill this gap and address this unmet need.

The objective of this study is to assess the impact of Pulmonary Rehabilitation on walking distance and its economic benefit for symptomatic post-TB lung disease patients in Uganda.

Who can participate?
People living with post-TB lung disease in Uganda.

What does the study involve?
Participants with post-TB lung disease will be randomly assigned to either Pulmonary

Rehabilitation or a control group. The PR programme will consist of 6 weeks of hospital-based education and exercises conducted twice weekly. This will be followed by 6 weeks of home-based exercises.

The control group will consist of usual care for 12 weeks and will then be offered Pulmonary Rehabilitation at the end of their study participation. Participants in both groups will be asked to attend the clinic at 6 weeks and again at 12 weeks after randomisation for outcome assessments by the study team.

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?
Makerere University Lung Institute, Makerere University College of Health Sciences, Upper Mulago Hill, Kampala, Uganda, P.O. Box 7749.

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

Who is funding the study?
National Institute for Health Research.

Who is the main contact?
Dr Mark Orme, mwo4@leicester.ac.uk.

Contact information

Type(s)
Public

Contact name
Dr Mark Orme

ORCID ID
http://orcid.org/0000-0003-4678-6574

Contact details
Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre - Respiratory
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE39QP
01162583113
mwo4@leicester.ac.uk

Type(s)

Scientific

Contact name
Dr Mark Orme

ORCID ID
http://orcid.org/0000-0003-4678-6574

Contact details
Centre for Exercise and Rehabilitation Science
NIHR Leicester Biomedical Research Centre - Respiratory
Glenfield Hospital
Groby Road
Leicester
United Kingdom
LE39QP
01162583113
mwo4@leicester.ac.uk

Type(s)
Scientific

Contact name
Dr Winceslaus Katagira

ORCID ID
http://orcid.org/0000-0003-4622-191X

Contact details
Physician & Research Fellow
Makerere University Lung Institute
Mulago Hospital
Kampala
Uganda
256
+256782869980
wincegira@gmail.com

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 post tuberculosis patients living in Uganda: Global RECHARGE Uganda

Acronym
Global RECHARGE Uganda

Study objectives
Pulmonary Rehabilitation will improve the exercise capacity and health-related quality of life for post tuberculosis patients in Uganda.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/09/2019, Mulago Hospital Research and Ethics Committee, Mulago Hill, Kampala, Uganda; +256 0752-818584, evelynnamwase@gmail.com), ref: MHREC 1478
2. Approved 03/10/2019, University of Leicester Research Ethics Committee (University Rd, Leicester, LE1 7RH; +44 (0)1162522522; ethics@leicester.ac.uk). ref: 22349

Study design
Randomised wait-list controlled trial. 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.

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). 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. 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. PR will be provided in groups of up to 15 people with post-TB lung disease. The exercise regime will be individually prescribed to participants based around 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

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 patients with post TB lung disease receive includes the following:
1. Frontal chest radiograph
2. Spirometry to screening for airway diseases
As needed inhalational therapies for airway disease amenable to treatment
3. As needed antibiotic and systemic glucocorticoid therapy for infective exacerbations
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 the European Lung Foundation. The information will cover the different forms of chronic lung disease and the importance of a healthy lifestyle including smoking cessation, exercises, diet, and self-management.

Intervention Type
Behavioural

Primary outcome measure
Change in walking distance (exercise capacity) is measured using the Incremental Shuttle Walk Test (ISWT) at 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.

Overall study start date
01/04/2018

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Aged ≥ 18 years.
2. Willing and able to give consent to participate in the Pulmonary Rehabilitation and the follow-up schedule (signed or witnessed consent if the patient is illiterate).
3. Documented past history of smear positive PTB with treatment completed at least 6 months prior to study enrolment.
4. Negative Gene Xpert.
5. Medical Research Council dyspnoea grade of 2 or higher.
6. Able and willing to attend the full 12 weeks of Pulmonary Rehabilitation assessments.

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
114

Key exclusion criteria

1. Has co-morbidities that preclude exercise e.g known unstable cardiovascular disease, locomotor difficulties. No age or gender restrictions apply.
2. Unwilling to participate for any reason.
3. Has any condition (social or medical) which in the opinion of the investigator would make study participation unsafe.

Date of first enrolment
13/11/2020

Date of final enrolment
01/09/2021

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University Lung Institute
Makerere University College of Health Sciences
Upper Mulago Hill
Kampala
Uganda
P.O. Box 7749

Sponsor information

Organisation
University of Leicester

Sponsor details
University Road
Leicester
England
United Kingdom
LE1 7RH
0116 252 2522
smd8@leicester.ac.uk

Sponsor type
University/education

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Government

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

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.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/08/2021	12/08/2021	Yes	No
Statistical Analysis Plan	version 1.0	29/10/2023	22/11/2023	No	No