ISRCTN14312425 https://doi.org/10.1186/ISRCTN14312425

A study to explore whether pulmonary rehabilitation in Uganda for adults with chronic respiratory disease is practical and acceptable to patients

Submission date
07/10/2015

Recruitment status
No longer recruiting

Registration date
21/10/2015

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In developing countries, long-term conditions which affect the lungs (chronic lung disease) and the airways are a growing problem. Infections which affect the lungs such as tuberculosis (TB) and HIV, along with tobacco smoking and unhealthy diet mean that around one in five adults in Africa suffer from chronic lung disease (CLD). People with CLD are likely to experience breathlessness and chest pain, especially when exerting themselves, and so sufferers tend to avoid exercise. This can lead to their lung conditions getting worse, causing disability that is both a source of suffering and strain on the health services. Medication can be used to help improve the symptoms of CLD however it does not stop the disease from getting worse in the long term. Many studies have shown that regular exercise can help to strengthen and tone the lungs so that they are able to take in more oxygen (increased lung capacity). The pulmonary rehabilitation (PR) programme has been designed to encourage people suffering from CLD to exercise and to educate them about how to best manage their condition. The PR is an inexpensive way of supporting patients to help each other and themselves, by using local health workers such as nurses, doctors, physiotherapists and clinic staff. The aim of this study is to find out whether the PR programme is an effective way to help people with CLD in Uganda, and whether it would be appropriate to organise a larger trial to test its benefits across East Africa.

Who can participate?
Adults who have been diagnosed with COPD or TB and are treated at Mulago Hospital (Uganda).

What does the study involve?
Participants are invited to take part in a pulmonary rehabilitation programme twice a week for six weeks. The programme involves a combination of exercises which are designed to improve strength, stamina and general fitness, and education sessions designed to teach about respiratory (breathing) diseases, why exercise is important and relaxation techniques. After the six week programme, and then again after a further six weeks, participants attend a follow-up appointment in which their general health is assessed by testing how they perform in physical

tests. Participants are also interviewed and asked to complete a number of questionnaires in order to find out if their quality of life has improved since taking part in the pulmonary rehabilitation programme.

What are the possible benefits and risks of participating?
A potential benefit is that taking part in this study will encourage patients to become more active rather than taking medications. This could help to improve their quality of life by improving symptoms such as chest pain, coughing up blood and night sweats. There are no risks of taking part in this study.

Where is the study run from?
Mulago Hospital (Uganda)

When is the study starting and how long is it expected to run for?
April 2015 to March 2016

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Ruper Jones
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
A development study to examine feasibility and acceptability of pulmonary rehabilitation in Uganda for adults with chronic respiratory disease

Study objectives
Pulmonary rehabilitation in Uganda for adults with chronic respiratory disease is feasible and acceptable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mulago Research Ethics Committee, 19/03/2015, ref: MREC 440

Study design
Single-centre mixed-methods feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Chronic Lung Disease

Interventions

This is a non-randomised feasibility study. Patients who fulfill the inclusion criteria will be invited to take part in a pulmonary rehabilitation programme (intervention) twice a week for six weeks, with follow-up at the end of the six week intervention and also six weeks after completion of the intervention. Follow-up includes data collection but no further intervention.

Pulmonary rehabilitation consists of a programme of exercises and health education, of one hour duration each . These take place on the same day, at Mulago Hospital, Kampala twice a week for six weeks. Each programme comprises 10-12 participants who fulfill the study eligibility criteria and have completed Baseline Assessment. During the PR programme each participant will be taken through a range of exercises supervised by a physiotherapist, and health education delivered by a physiotherapist and physician (see below).

Exercise programme
1. Includes resistance training (e.g. weights used for upper and lower limbs) and aerobic training: biceps Curl; sit to stand; pull ups; step ups; cycling and walking
2. Equipment – minimal for exercise so can be continued at home (e.g. weights are bottles filled with water)
3. Regime individually prescribed, monitored and increased as programme progresses

Education sessions
1. Causes of breathless (breathlessness is not harmful)
2. Coping and relaxation techniques
3. Role of exercise in building up strength and endurance
4. Effects of TB on lungs specifically and body in general
5. Treatment for TB
6. Pacing and activities of daily living
7. Cigarettes smoking and exposure to biomass smoke
8. Nutrition healthy eating
9. Chest infections and what to do if they get worse
10. HIV
11. What help and support is available
12. Maintaining the gains

Intervention Type
Behavioural

Primary outcome measure
The feasibility and acceptability of pulmonary rehabilitation programme is determined at baseline, 6 weeks (end of intervention) and 12 weeks (6 weeks after intervention completion) using the following measures:
1. Walking distance measured using the Incremental Shuttle Walking Test
2. Quality of life measured using the disease specific Clinical COPD and EQ-5D questionnaires
3. Breathlessness measured using the MRC Dyspnoea Scale, Spirometry, Oximetry and Biometrics
4. Functional ability measured using the Karnofsky Scale, Borg Score and sit to stand time
5. Participant experience measured using ethnographic observations, individual interviews and focus groups at baseline, during the pulmonary rehabilitation intervention and 12 weeks (6 weeks after intervention completion)

Secondary outcome measures
1. Chest pain is measured using a subset of questions from the Brief Pain Inventory at baseline, 6 weeks (end of intervention) and 12 weeks (6 weeks after intervention completion)

2. Haemoptysis is measured using a single question rating scale at baseline, 6 weeks (end of intervention) and 12 weeks (6 weeks after intervention completion)
3. Depression is measured using the PHQ-9 all measured at baseline, 6 weeks (end of intervention) and 12 weeks (6 weeks after intervention completion)

Overall study start date
24/04/2015

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Diagnosis of chronic obstructive pulmonary disease (COPD) or tuberculosis (TB)
3. Seen at Mulago Hospital as an inpatient or outpatient
4. Medical Research Council dyspnoea score grade 2 (MRC2) or higher
5. No unstable cardiovascular disease or locomotor difficulties that preclude exercise

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30-40

Total final enrolment
34

Key exclusion criteria
1. Smear positive TB for those with previous TB treatment
2. Unwilling or unable to attend a PR programme
3. Unable to provide informed consent.

Date of first enrolment
24/04/2015

Date of final enrolment
10/11/2015

Locations

Countries of recruitment
Uganda

Study participating centre
Mulago Hospital
Mulago Hill
Kampala
Uganda
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Sponsor information

Organisation
Plymouth University, Peninsula Schools of Medicine and Dentistry

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Sponsor type
University/education

Website
https://www.plymouth.ac.uk/your-university/about-us/university-structure/faculties/medicine-dentistry

ROR
https://ror.org/04dtfyh05

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The results of the feasibility development trial will be presented to local and national educational meetings in Africa and international conferences including the European Respiratory Society, International Union against TB and Lung Disease and the IPCRG (who have agreed for an oral presentation on this research at their 2016 conference. Papers will be submitted to peer reviewed open access journals and other high impact peer review journals (for example, Lancet Global Health).
A project website will be created and updated monthly on the University of Plymouth server, with links to other web platforms and social media. The website will be referred to in all project dissemination activities. Educational videos for lay people will be uploaded on the Plymouth and IPCRG websites, with free access to educational resources developed during the project.A press release will be developed with the assistance of the Plymouth University's press office. Local and national media campaigns will be used in Africa, particularly focussing on radio and television broadcasts.

Intention to publish date

31/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/12/2017	07/11/2023	Yes	No