ISRCTN85689019 https://doi.org/10.1186/ISRCTN85689019

Is it possible to deliver Pulmonary Rehabilitation to people in India living with chronic obstructive lung disease?

Submission date
28/08/2019

Recruitment status
Stopped

Registration date
12/09/2019

Overall study status
Stopped

Last Edited
08/07/2022

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
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 people in developing countries, where people are unable to work from a younger age, and therefore increases 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 India and this research seeks to fill this gap and address the unmet needs.

The objective of this study is to develop and assess the feasibility and acceptability of a culturally appropriate Pulmonary Rehabilitation service in India.

Who can participate?
Individuals with a confirmed diagnosis of COPD.

What does the study involve?
Participants with COPD will be randomly assigned to either a Pulmonary Rehabilitation or control group (usual care). The Pulmonary Rehabilitation programme will consist of 8 weeks of disease-related education and exercises conducted twice weekly. Participants will be

encouraged to undertake exercise whilst at home too. Participants will be asked to attend the clinic at the time of entry into the trial (baseline), mid way through the Pulmonary Rehabilitation programme (4 weeks) and at the end of the programme (8 weeks).

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?
Symbiosis International (Deemed University) (India)

When is the study starting and how long is it expected to run for?
October 2019 to September 2020.

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

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 1

Study information

Scientific Title
Assess the feasibility and acceptability of a Pulmonary Rehabilitation (PR) programme incorporating yoga for people with COPD in India: Global RECHARGE India

Acronym
Global RECHARGE India

Study objectives
1. It is possible to develop a culturally adapted pulmonary rehabilitation programme specific to India using opinions from patients and health caregivers on aspects of yoga within pulmonary rehabilitation.
2. To develop a culturally adapted Pulmonary Rehabilitation programme that is feasible and acceptable according to patients and healthcare staff.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

A single-centre, qualitative study and feasibility randomised control trial. Participants will be individually randomised (1:1) to the Pulmonary Rehabilitation programme or to the control group (usual care). 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)
Other

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
Chronic obstructive pulmonary 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 COPD and interviews will be conducted with potential referrers to Pulmonary Rehabilitation (healthcare staff).

2. A feasibility RCT of Pulmonary Rehabilitation versus usual care (control). The intervention (Pulmonary Rehabilitation) will consist of an eight-week programme, with sessions occurring twice weekly for at least two hours with approximately one hour for education and one hour for exercise. The exercises will be guided by the data collected in the interviews and focus groups (stage 1). Pulmonary Rehabilitation will be provided by a team of respiratory doctors, physiotherapists, nurses and a yoga expert. The education component focuses on the awareness of COPD, the importance of PR, nutrition in COPD, smoking cessation and the prevention of indoor air pollution; the content will be largely guided by the focus groups in stage 1.

The exercise component consists of a combination of resistance and aerobic training, using minimal equipment, individually adjusted over the course of eight weeks. Pulmonary Rehabilitation will be provided in groups of up to 6 people with COPD. 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 and bicep curls
3. Endurance exercise included walking and cycling on a stationary bike.

The content of the programme will also include culturally appropriate yoga. These will be guided by the data gathered in stage 1.

The participants in the control arm will receive usual medical care. All participants, regardless of study arm, will receive the "Living with COPD: 5 steps to better lung health" brochure. This is an educational booklet containing information about lung health.

Intervention Type
Behavioural

Primary outcome measure
The primary aim of this study is to establish the feasibility of a future definitive trial; as such its aims are:
1. To inform the recruitment and timeline of a future fully-powered trial, by establishing the number of participants identified, approached, consented, randomised and completed.
2. To refine future trial procedures by establishing the acceptability and experience of the trial process to participants, including randomisation and completion of outcome measures.
3. To determine the optimal primary outcome measure in a future trial by assessing the performance of selected candidate primary outcome measures with respect to level of acceptability to participants (completion rates, perceived burden)
4. To inform estimation of sample size for a future trial by measuring data completeness at follow up (participant attrition), standard deviation of the likely primary outcome measure, and the variability of the comparator condition, treatment as usual.
5. To inform the measurement of health economic outcomes in a future trial through piloting the use of a tool for identifying resource use and costs associated with delivery of the intervention.
6. To further assess the acceptability of the treatment via qualitative interviews and focus groups and, based on input from trial participants and clinicians, to further refine and develop the intervention and the procedures for training, supervising and assessing the competence of intervention deliverers.

We will also evaluate whether the following continuation criteria have been met, prior to planning a future definitive trial:
1. Trial participation does not lead to serious negative consequences (unexpected serious adverse reaction) for our participants.
2. Any serious concerns about the acceptability and feasibility of the trial procedures can be rectified prior to a full trial.

Secondary outcome measures
Completed at baseline, and 4 weeks and 8 weeks post-baseline:
1. Anxiety and depression level, measured using Hospital Anxiety and Depression Scale (HADS).
2. Breathlessness, measured using Medical Research Council (MRC) Dyspnea scale.
3. Health status, measured using COPD Assessment Test (CAT) and Clinical COPD Questionnaire (CCQ).
4. Economic impact, measured using Work Productivity and Activity impairment (WPAI) Questionnaire Bodyweight, measured using scales.
5. Lung health, assessed by spirometry, impulse oscillometry and diffusing capacity for carbon monoxide.
6. Exercise capacity, measured by incremental shuttle walking test (ISWT) and the endurance

shuttle walking test (ESWT).
7. Physical activity, measured by ActiGraph wGT3x-BT accelerometer.
8. Strength, measured by quadriceps strength test and 5x sit-to-stand test.

Overall study start date
01/04/2018

Completion date
31/03/2021

Reason abandoned (if study stopped)
Participant recruitment suspended and the study closed during the coronavirus (SARS-CoV-2) pandemic

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. Age ≥18 years
2. Spirometry confirmed COPD, based on GOLD criteria, with FEV1/FVC<0/7, and FEV1<80% predicted.
3. Physician diagnosed COPD
4. Medical Research Council (MRC) dyspnoea score grade 2 or higher
5. Patients willing to participate and attend the PR program

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Stage 1: Up to 15 members of staff and 32 patients but this will be impacted by data saturation
Stage 2: As this is a feasibility trial, no formal sample size is required, yet we hope to recruit 70 patients

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. Co-morbidities or significant respiratory, cardiovascular, hepatic, renal, neurological, orthopaedic, neoplastic diseases that may hamper the participation of the patient and outcome of the program.
2. Active pulmonary Tuberculosis
3. COPD patients unable or unwilling to provide informed consent

Date of first enrolment
01/10/2020

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
India

Study participating centre
Symbiosis International (Deemed University)
Symbiosis Knowledge Village
Gram: Lavale, Tal: Mulshi
Pune
India
412115

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
31/03/2021

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