

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2019	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/07/2022	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

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Contact information

Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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
5. Bodyweight, measured using scales.
6. Lung health, assessed by spirometry, impulse oscillometry and diffusing capacity for carbon monoxide.
7. Exercise capacity, measured by incremental shuttle walking test (ISWT) and the endurance shuttle walking test (ESWT).
8. Physical activity, measured by ActiGraph wGT3x-BT accelerometer.
9. Strength, measured by quadriceps strength test and 5x sit-to-stand test.

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 $FEV_1/FVC < 0.7$, and $FEV_1 < 80\%$ 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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