ISRCTN10521920 https://doi.org/10.1186/ISRCTN10521920

Is it possible to deliver pulmonary rehabilitation in a community setting to people in Sri Lanka living with chronic obstructive lung disease?

Submission date 28/08/2019	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2019	**Overall study status** Stopped	
Last Edited 08/07/2022	**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 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 Sri Lanka and this study seeks to fill this gap and address the unmet needs. The aim of this study is to develop and assess the feasibility and acceptability of a culturally appropriate pulmonary rehabilitation service in Sri Lanka.

Who can participate?
Patients aged 18 and over with COPD

What does the study involve?
Participants are randomly allocated to either a pulmonary rehabilitation group or a control group (usual care). The pulmonary rehabilitation programme consists of 6 weeks of disease-related education and exercises conducted twice weekly. Participants are encouraged to undertake exercise whilst at home too. Participants are asked to attend an appointment at the time of entry into the study (baseline) and at the end of the programme (6 weeks).

What are the possible benefits and risks of participating?
Pulmonary rehabilitation is not routinely available in Sri Lanka. It is envisaged that participants

will benefit 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?
Central Chest Clinic, Western District, Colombo, Sri Lanka

When is the study starting and how long is it expected to run for?
April 2018 to March 2021

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

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 community based pulmonary rehabilitation programme incorporating dancing for people with COPD in Colombo district in Sri Lanka: Global RECHARGE Sri Lanka

Acronym
Global RECHARGE Sri Lanka

Study objectives
To develop a culturally adapted community-based Pulmonary Rehabilitation programme that is feasible and acceptable according to patients and healthcare staff.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Faculty of Medical Sciences, University of Sri Jayewardenepura, Sri Lanka & University of Leicester, UK

Study design
Single-centre qualitative study and feasibility randomised control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease

Interventions

A feasibility RCT of Pulmonary Rehabilitation versus usual care (control). 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.

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, nurses and singing/dancing experts. The education component focus on causes of breathlessness, coping techniques, the role of smoking, biomass smoke, TB and HIV and the value of exercise. The exercise component consists of a combination of resistance and aerobic training, using minimal equipment, individually adjusted over the course of six weeks. Pulmonary Rehabilitation will be provided in groups of up to 10 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, bicep curls and pull ups
3. Endurance exercise included walking and cycling on a stationary bike

The content of the programme will also likely include culturally appropriate activities, such as singing and dancing. These will be guided by the data gathered in previous Global RECHARGE:Sri Lanka trials.

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 lungs.

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 Pulmonary Rehabilitation programmes. We anticipate that we will conduct up to 6 focus groups with 2-10 participants in each. Focus groups will involve a mix of participants from the intervention group who completed the Pulmonary Rehabilitation programme and those 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.

Staff interviews
Health care personnel involved in Pulmonary Rehabilitation will be invited to participate in interviews at the end of study to discuss aspects of feasibility and acceptability, such as insights into barriers and facilitators to referral, uptake and completion of Pulmonary Rehabilitation. We anticipate conducting up to 15 interviews. 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.

Book of testimonies
Patients attending Pulmonary Rehabilitation will be asked to log their experience of PR as they progress through the programme. 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.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility measures including:
1. Suitability of the inclusion criteria
2. Refusal rate
3. Uptake and completion of the study
4. Willingness of patients to be recruited and the willingness of healthcare professionals to refer to this study and future trials
5. Service provider and multi-disciplinary teams' willingness and ability to deliver the new PR programme
6. The practicality of delivering the intervention in the proposed setting
7. The time needed to collect and analyse the data
8. Test methods for the collection of data as well as data completeness and accuracy
9. The acceptability of the PR programme, assessed through focus groups
10. Compliance to the PR sessions
11. Adherence to home exercise assessed via a self-report exercise diary
12. The training and resource needed to deliver the intervention (ensuring readiness for a future multi-centre trial)

Key secondary outcome(s))
Measured at baseline and 6 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. Nutritional status, measured by body weight using scales, body composition using bioelectrical impedance and skinfold thickness, and 7-day diet diary
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. Physical function, measured by 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 Pulmonary Rehabilitation programme, such as physicians & clinicians.

Stage 2:
1. Aged ≥18 years
2. Physician diagnosis of COPD
3. Spirometry confirmed COPD, based on GOLD criteria, with FEV1/FVC <0.7, and FEV1<80% predicted
4. Medical Research Council (MRC) dyspnoea score grade 2 or higher

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Comorbidities such as severe or unstable cardiovascular, other internal diseases and locomotor difficulties that preclude exercise
2. Malignant disease or other serious illness which will interfere with participation in the Pulmonary Rehabilitation programme
3. Unable or unwilling to provide informed consent

Date of first enrolment
01/09/2020

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
United Kingdom

Sri Lanka

Study participating centre
Central Chest Clinic
Dr Danister De Silva Mawatha
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes