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Is pulmonary rehabilitation possible for patients with chronic obstructive pulmonary disease in a low resource setting in Jaffna, Sri Lanka?

Submission date
05/03/2021

Recruitment status
No longer recruiting

Registration date
16/04/2021

Overall study status
Completed

Last Edited
09/08/2022

Condition category
Respiratory

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

Plain English Summary
Background and study aims
Chronic obstructive pulmonary disease (COPD) is the name for a group of lung conditions that cause breathing difficulties.
The burden of Chronic Obstructive Pulmonary Disease (COPD) has been increasing worldwide over the last few decades. It is a major cause of illness and death. According to the World Health Organization, 5% of global deaths in 2015 were due to COPD.
COPD increases the risk for other diseases and has effects like weight loss, nutritional abnormalities and muscle problems. In addition, decreased exercise performance, low physical activity and, impaired quality of life are adverse effects.
International guidelines for the management of COPD strongly recommend Pulmonary Rehabilitation (PR), which involves exercise and education at its core. At the moment there are no formal PR services in Sri Lanka, as with many low resources settings with limited facilities or expertise to conduct PR. Hence, this study aimed to implement a PR program in a low resource setting and to find out if it is feasible to deliver a trial of PR for people living with COPD in Jaffna, Sri Lanka.

Who can participate?
Adult patients with COPD.

What does the study involve?
Participants either had treatment as usual or a six-week programme, with sessions occurring twice weekly with approximately one hour for education and one hour for exercise.

What are the possible benefits and risks of participating?
None

Where is the study run from?
University of Jaffna (Sri Lanka)

When is the study starting and how long is it expected to run for?
June 2019 to March 2020

Who is funding the study?
1. University of Jaffna (Sri Lanka)
2. The National Institute for Health Research (UK).

Who is the main contact?
Dr Mathanki Sooriyakanthan, smathanki@univ.jfn.ac.lk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Feasibility trial of pulmonary rehabilitation on patients with Chronic Obstructive Pulmonary Disease in a low resource setting in Jaffna, Sri Lanka

Study hypothesis
It will be feasible to conduct a trial of pulmonary rehabilitation in a low resource setting for people living with COPD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2019, Faculty of Medical Sciences REC (University of Sri Jayewardenepura, Sri Lanka; +94-11-2758588; erc.fms.usjp@gmail.com), ref: 35/18

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

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

Condition

Chronic obstructive pulmonary disease

Interventions
The intervention (Pulmonary Rehabilitation) consisted of a six-week programme, with sessions occurring twice weekly with approximately one hour for education and one hour for exercise. Pulmonary Rehabilitation was provided by the trained investigator and assisted by other staff at the department. The education component was focused on exercise, diet, disease education, medication, managing breathlessness, chest clearance, relaxation, energy conservation and avoidance of exacerbations.
Pulmonary Rehabilitation was provided in groups of up to 6 COPD patients. The exercise program consisted of stretching, aerobic and strength training exercises, using minimal equipment, individually adjusted over the course of six weeks. The aerobic exercise was 30 minutes of continuous walking. Strength training exercises consisted of bicep curls, pull ups, sitting to standing and step ups. Each of these strength training exercises were performed with hand weights.
The participants in the control arm received usual pharmacotherapy alone.

Intervention Type
Behavioural

Primary outcome measure
Feasibility measures including:
1. Suitability of inclusion criteria measured using the reasons for not being eligible, reasons for declining, reasons for not completing the exercise program by 9 months
2. Refusal rate measured using number of eligible patients identified and number of patients consented to participate in the study by 9 months
3. Uptake and completion of the study measured number of patients enrolled into the study and number of patients completed 6 weeks program during 9 months
4. Compliance to PR sessions measured using number of patients enrolled in PR sessions and number completed 6 weeks program including post assessment during 9 months
5. Adherence to home exercise assessed via a self-report exercise diary assessed via a self-report exercise diary for 6 weeks

Secondary outcome measures
Measured at baseline and at 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. Lung health, assessed by spirometry
5. Exercise capacity, measured by Incremental Shuttle Walk Test (ISWT) and Six Minute Walk Test (6MWT)

Overall study start date
10/06/2019

Overall study end date
13/03/2020

Eligibility

Participant inclusion criteria
Physician diagnosis of COPD based on symptoms and spirometry confirmed based on GOLD criteria, with FEV1/FVC <0.7, and FEV1<80% predicted.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50-60

Total final enrolment
54

Participant exclusion criteria
1. Unable or unwilling to provide informed consent
2. Comorbidities such as severe or unstable cardiovascular disease or other lung diseases
3. Stroke, Peripheral neuropathies or any other internal diseases and locomotor difficulties that limit the exercise performance
4. Significant hearing impairment

Recruitment start date
15/06/2019

Recruitment end date
10/03/2020

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Department of Physiology
Faculty of Medicine
University of Jaffna
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Sponsor information

Organisation
University of Jaffna

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Sponsor type
Government

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http://www.jfn.ac.lk/

ROR
https://ror.org/02fwjgw17

Funder(s)

Funder type
University/education

Funder Name
University of Jaffna

Alternative Name(s)
UoJ

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sri Lanka

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
The researchers will publish the results from this study 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
30/04/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Results article		08/08/2022	09/08/2022	Yes	No