ISRCTN62842477 https://doi.org/10.1186/ISRCTN62842477

What are the physical activity levels, exercise capacity, nutritional status and lung function of people in Sri Lanka living with chronic obstructive lung disease?

Submission date
28/08/2019

Recruitment status
No longer recruiting

Registration date
12/09/2019

Overall study status
Completed

Last Edited
06/02/2023

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
Lung conditions are a major problem in Sri Lanka and many other low- and middle- income countries and little is known about the potentially broad range of negative impacts these conditions may have on the lives of patients. Most of the researcher in this area has come from high-income countries. In order for effective and culturally appropriate interventions to be created for adults living with COPD in Sri Lanka, further information is needed, including a detailed profiling of the nutritional status, exercise capacity, lung health and physical activity levels of this population. It is anticipated that the data gathered in this study will guide future interventions, including a culturally appropriate pulmonary rehabilitation intervention.

Who can participate?
People in Sri Lanka living with COPD

What does the study involve?
In a one-off visit lasting 60-90 minutes, the following assessments are performed: assessment of socio-demographic status, co-morbidities and medications; assessment of lung health and lung function; nutritional status assessed through measures of height, weight and body composition; disease burden and psychological well-being assessed through questionnaires; exercise capacity assessed using a walking test and physical function assessed using the sit to stand test. Physical activity levels are measured by wearing a device for 7 days during waking hours.

What are the possible benefits and risks of participating?
Benefits of participation are to contributing to new knowledge of the health status of patients living with COPD in Sri Lanka. There are no risks to participation.

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 May 2023

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

Protocol serial number
Version 1

Study information

Scientific Title
Cross-sectional assessment of people living with COPD in Sri Lanka who meet the criteria for attending a pulmonary rehabilitation programme: Global RECHARGE Sri Lanka

Acronym
Global RECHARGE Sri Lanka

Study objectives
There is limited information regards the nutritional status, physical activity levels, exercise capacity and lung function of people in Sri Lanka living with chronic obstructive pulmonary disease (COPD).

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 Ethics Committee (University of Leicester, University Road, Leicester, LE1 7RH, UK; Email: ethicsapp@leicester.ac.uk)

Study design
Single-centre observational (cross sectional) study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Assessment of socio-demographic status, co-morbidities and medications will be obtained through self-report measures. Assessment of lung health and lung function will occur, including spirometry. Nutritional status will be assessed through measures of height, weight, body composition (estimated through bioelectrial impedance analysis and skin fold thickness) and mid-upper arm circumference. Disease burden and psychological well-being will be assessed through self-report questionnaires. A questionnaire quantifying disease burden on work and activity

impairment will also be used (Work Productivity and Activity Impairment questionnaire). Exercise capacity will be assessed using the incremental shuttle walking test (ISWT) and physical function will be assessed using the 5x sit to stand test. Physical activity levels will be measured using the ActiGraph wGT3x-BT; participants will be asked to wear the device for 7 consecutive days during waking hours and removed during water-based activities.

Intervention Type
Other

Primary outcome(s)
Assessed at the research visit which is scheduled to occur only once:
1. Exercise capacity measured by the ISWT and lung function assessed through spirometry
2. Nutritional and dietary status assessed using measures of height, weight, body composition (bioelectrical impedance), mid-upper arm circumference and 7-day diet diary
3. Physical activity levels measured using accelerometers

Key secondary outcome(s))
Assessed at the research visit which is scheduled to occur only once:
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. Strength, measured by 5x sit-to-stand test

Completion date
01/05/2023

Eligibility

Key inclusion criteria
Patients:
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

Healthy controls:
1. Aged ≥18 years
2. No physician diagnosis of chronic respiratory disease

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Co-morbidities 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 PR programme
3. Unable or unwilling to provide informed consent

Date of first enrolment
01/04/2021

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
Sri Lanka

Study participating centre
Central Chest Clinic
Dr Danister De Silva Mawatha
Colombo
Sri Lanka
Sri Lanka

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