

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

<b>Submission date</b> 28/08/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/09/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/02/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 research 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?  
Dr Mark Orme  
mwo4@leicester.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Mark Orme

### ORCID ID

<https://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  
LE3 9QP  
+44 (0)1162583113  
mwo4@leicester.ac.uk

### Type(s)

Scientific

### Contact name

Dr Mark Orme

### ORCID ID

<https://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

LE3 9QP  
+44 (0)1162583113  
mwo4@leicester.ac.uk

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **ClinicalTrials.gov (NCT)**

Nil known

### **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 bioelectrical 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  $\geq 18$  years
2. Physician diagnosis of COPD
3. Spirometry confirmed COPD, based on GOLD criteria, with  $FEV_1/FVC < 0.7$ , and  $FEV_1 < 80\%$  predicted
4. Medical Research Council (MRC) dyspnoea score grade 2 or higher

Healthy controls:

1. Aged  $\geq 18$  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