

What are the attitudes and opinions of healthcare staff and patients living with chronic obstructive lung disease in India regards pulmonary rehabilitation?

Submission date 28/08/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/01/2023	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

Lung conditions are a major problem in India and many other low- and middle- income countries. In other parts of the world, there is a health service called pulmonary rehabilitation (PR) which has been shown to be highly beneficial to people living with lung conditions. PR involved exercise, education and direct support from healthcare professionals. PR is not routinely provided for people living with lung conditions in India. This study aims to look at how ready the people living with lung conditions and healthcare professionals in Pune, India are for PR if it were made available as part of normal healthcare.

Who can participate?

People living with chronic obstructive lung disease (COPD) and doctors, physiotherapists and hospital administrators.

What does the study involve?

Completion of a short questionnaire.

What are the possible benefits and risks of participating?

Benefits of participation are to contribute to informing the need for and potential design of pulmonary rehabilitation in India. There are no risks to participation.

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?

September 2019 to February 2022

Who is funding the study?

National Institute for Health Research.

Who is the main contact?
Dr Mark Orme, mwo4@leicester.ac.uk.

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

Version 1

Study information

Scientific Title

The attitudes and opinions of healthcare staff and patients living with chronic obstructive lung disease regards the delivery of a clinical pulmonary rehabilitation programme: Global RECHARGE India

Acronym

Global RECHARGE India (Survey)

Study objectives

Despite being a common treatment for chronic lung disease in high income countries, Pulmonary Rehabilitation is not often implemented in low and middle income countries. Data is needed surrounding the perspectives and opinions of medical staff and patients living with chronic lung disease regards implementing and creating a clinical Pulmonary Rehabilitation service.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

A multi-centre observational, cross-sectional trial

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

COPD

Interventions

Eligible and interested patients, after providing written informed consent, will be given a brief questionnaire. The questionnaire will take no more than 5 minutes to complete and will be anonymous. We will collect no clinical data. The questionnaire asks patients to express their opinions as to what a 'good' pulmonary rehabilitation programme would look like for them.

Eligible and interested healthcare professionals, who provide written informed consent, will be given a brief questionnaire at their place of work about their beliefs about rehabilitation, their likelihood to refer patients and how they think this should /could be done. The questionnaire will take no more than 5 minutes to complete and will be anonymous. We will collect no personal data, except for the professional background and years of experience in managing people with chronic lung disease.

316 people living with COPD of which 15-24 will take part in focus groups

115 doctors of which 15-20 will take part in interviews

96 physiotherapists of which 15-20 will take part in interviews

42 hospital administrators of which 15-20 will take part in interviews

Intervention Type

Other

Primary outcome measure

The readiness of patients and healthcare professionals for Pulmonary Rehabilitation is measured using the questionnaire at the time of consent.

Secondary outcome measures

1. The need for Pulmonary Rehabilitation from patients with chronic lung disease is determined using the questionnaire at the time of consent.
2. The mode of Pulmonary Rehabilitation that is acceptable to patients is determined using the questionnaire at the time of consent.
3. The attitudes and beliefs of health care providers who would be potential referrers to Pulmonary Rehabilitation are determined using the questionnaire at the time of consent.
4. The views of health care personnel on the transfer of information and the mode of referral to the Pulmonary Rehabilitation service is determined using the questionnaire at the time of consent.
5. The need for Pulmonary Rehabilitation and individual preferred modes of delivery is determined using the questionnaire at the time of consent.

Overall study start date

01/04/2018

Completion date

01/02/2022

Eligibility

Key inclusion criteria

1. Diagnosed with chronic obstructive pulmonary disease
2. Healthcare professionals working with patients with chronic respiratory disease
3. Hospital administrators

Participant type(s)

Mixed

Age group

Adult

Sex

Both

Target number of participants

601

Total final enrolment

577

Key exclusion criteria

Anyone unable to provide written informed consent

Date of first enrolment

01/04/2021

Date of final enrolment

31/10/2021

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

Sponsor details

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Sponsor type

University/education

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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

Publication and dissemination plan

It is anticipated that the results from this study will be published 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

31/03/2023

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?
Protocol file	version 1	20/12/2020	12/01/2023	No	No