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A feasibility trial of community-based pulmonary rehabilitation for adults with chronic obstructive pulmonary disease (COPD) in India

Submission date 05/10/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 05/10/2021	**Overall study status** Completed	
Last Edited 30/04/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
India has the largest number of chronic obstructive pulmonary disease (COPD) cases in the world and ranks second in COPD mortality worldwide. COPD is a long-term inflammatory lung disease that causes difficulty breathing, cough, mucus (sputum) production and wheezing. It's often caused by long-term exposure to cigarette smoke. Since COPD is a progressive, non-curable condition, rehabilitation of the patient becomes the most plausible therapeutic intervention.

International guidelines recommend that pulmonary rehabilitation (PR) should be offered to adults living with COPD. PR reverses the disability associated with Chronic Respiratory Diseases (CRDs), which is supported by the highest level of evidence. The World Health Organization makes the case for the fundamental role of accessible and affordable rehabilitation and acknowledges an unmet need that is profound in low- and middle-income countries (LMICs) where demand greatly outweighs capacity.

Who can participate?
Adults aged between 18 and 65 years with a diagnosis of COPD and functional limitation due to breathlessness.

What does the study involve?
Eligible study participants will participate in a six-week, twice-weekly, supervised community-based pulmonary rehabilitation (PR) programme. Assessment of participants' lung function, exercise tolerance, and health status will be conducted. In addition, semi-structured in-depth interviews with participants will be conducted after their participation in the PR programme.

What are the possible benefits and risks of participating?
Participation will help inform the design of a culturally appropriate pulmonary rehabilitation (PR) programme for people with COPD in Jodhpur (India). Risks from participation are not anticipated.

Where is the study run from?
Indian Council of Medical Research – National Institute for Implementation Research on Non-Communicable Diseases (India)

When is the study starting and how long is it expected to run for?
October 2021 to March 2023

Who is funding the study?
National Institute for Health Research (NIHR) Global Health Research Group on Respiratory Rehabilitation (Global RECHARGE) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A single-arm feasibility trial of community-based pulmonary rehabilitation for adults with COPD in the slum areas of Jodhpur, Rajasthan

Study objectives
1. Determine the feasibility of conducting community-based PR for people living with COPD in residents of slum areas in Jodhpur, Rajasthan
2. Assess the acceptability of community-based PR among Indian adults living with COPD and healthcare staff involved in its delivery
3. Describe any changes in the health of the adults living with COPD following completion of PR
4. Assess the feasibility of a future trial and estimate the required sample size

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/08/2021, Institutional Ethics Committee & Health Research (ICMR-NIIRNCD Jodhpur (Rajasthan), India; +91 (0)11-27298472; membersecyniirncd@gmail.com), ref: IEC-ICMR NIIRNCD/2021/25/11
2. Approved 10/11/2021, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, United Kingdom; +44 (0)1162522522; ethicsapp@leicester.ac.uk), ref: 32024
3. Approved 26/10/2021, Institutional Human Ethics Committee & Health (Room no 116, first floor, Medical College, All India Institute of Medical Science, Basni, Phase-II, Jodhpur, Rajasthan-342005; +91 (0)291-2012984 ext: 3109; ethicscommitteeaiimsjdh@gmail.com), ref: ECR/866/Inst/RJ/2016/RR-19

Primary study design
Interventional

Study design
Single-centre mixed-methods single-arm non-randomized cohort feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
In addition to usual care, participants in the intervention arm will receive pulmonary rehabilitation (PR). PR will comprise the core elements of an evidence-based rehabilitation, a programme of exercises and health education will consist of a six-week programme offered to a group of up to 12 participants, with sessions occurring twice weekly for at least 2 h (approximately 1 h for education and 1 h for exercise). All staff delivering PR will be trained and assisted by a medical doctor (M.B.B.S) and by a Medical Social Worker. The venue will have a

maximum capacity of 6-8 patients per PR class and this will be continuously reviewed to ensure patient safety during COVID pandemic. The equipment required will be simple and include chairs, weights, and simple exercise equipment based on local availability and suitability.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility and the acceptability of the PR intervention measured using semi-structured in-depth interviews with participants at 6 weeks

Key secondary outcome(s)
1. Lung function measured using the following at baseline and 6 weeks:
1.1. Spirometry to calculate pre- and post-bronchodilator forced expiratory volume in one second [FEV1], forced vital capacity [FVC], and FEV1/FVC ratio
1.2. Questionnaires to calculate smoking status and number of COPD exacerbations in the last year
2. Health status measured using the following at baseline and 6 weeks:
2.1. Participant perceived respiratory disability due to dyspnea using the Medical Research Council (MRC) dyspnea scale
2.2. Health-related quality of life using the chronic obstructive pulmonary disease assessment test (CAT)
2.3. Economic impact using the Work Productivity and Activity Impairment (WPAI) questionnaire
2.4. Emotional health using the Hospital Anxiety and Depression Scale (HADS)
3. Physical fitness measured using the following at baseline and 6 weeks:
3.1. Exercise capacity using the incremental shuttle walk test (ISWT) and the endurance shuttle walking test (ESWT)
3.2. Lower extremity muscular strength using a five-repetition sit-to-stand test (5XSST)

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years
2. Spirometry confirmed diagnosis of chronic obstructive pulmonary disease (COPD)
3. Functional limitation due to breathlessness reaching a score of ≥2 on the Medical Research Council (MRC) dyspnea scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
9

Key exclusion criteria
1. Significant comorbidities such as cardiovascular, neurological, locomotor difficulties that preclude exercise, cognitive, malignant disease, or any other condition that would compromise participation in the rehabilitation programme
2. COVID-19 RT-PCR positive result within 3 days of assessment
3. Unable to provide informed consent.

Date of first enrolment
24/01/2022

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
India

Study participating centre
Indian Council of Medical Research – National Institute for Implementation Research on Non-Communicable Diseases.
New Pali Road
Air force Area
Jodhpur
India
342005

Study participating centre
All India Institute of Medical Sciences (AIIMS)
Basni Industrial Area
MIA 2nd Phase
Basni
Jodhpur
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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 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?
Protocol file	version 1	07/09/2020	01/03/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes