ISRCTN14831771 https://doi.org/10.1186/ISRCTN14831771

A feasibility trial of home-based pulmonary rehabilitation for adults with idiopathic pulmonary fibrosis in Delhi, India

Submission date 30/10/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 09/02/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/03/2024	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Idiopathic pulmonary fibrosis (IPF) is a condition in which the lungs become scarred and breathing becomes increasingly difficult. It often results in poor exercise tolerance, breathing difficulties, exertion, and reduced quality of life. Physicians are currently highlighting the increased cases and recognition of this disease in India. Treatment for IPF in India currently follows global trends of using antifibrotics. However, pulmonary rehabilitation is globally acknowledged in the management of IPF. Various methods exist for the delivery of pulmonary rehabilitation, including home-based programmes. At present, there is no evidence of the feasibility of conducting home-based pulmonary rehabilitation in adults with IPF living in India. The aim of this study is to find out whether it is feasible to deliver home-based pulmonary rehabilitation for adults with IPF in Delhi, India.

Who can participate?
Patients aged 18 years and above with a confirmed diagnosis of IPF, healthcare professionals who have at least 1 year of experience of working with IPF patients (including specialists, nurses and physiotherapists), and family caregivers who have and/or care for a family member diagnosed with IPF.

What does the study involve?
Participants will be interviewed to inform changes to the original SPACE for chronic obstructive pulmonary disease manual. The manual currently contains educational material and a home exercise programme. It incorporates an exercise regime that consists of a daily walking programme, and resistance training of the upper and lower limbs using free weights three times per week. However, due to the nature of this study, the precise details and content of the home-based pulmonary programme are unknown at this moment, as they will be heavily guided by the data collection. Nevertheless, the intervention will comprise of the core elements of evidence-based rehabilitation, a programme of exercises and health education.

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

Where is the study run from?
Metro Centre for Respiratory Diseases at Noida (India)

When is the study starting and how long is it expected to run for?
November 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?
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

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Version 1

Study information

Scientific Title
Protocol for a single-arm feasibility trial assessing home-based pulmonary rehabilitation for adults with idiopathic pulmonary fibrosis in Delhi, India

Study objectives
It will be feasible to deliver home-based pulmonary rehabilitation for adults with idiopathic pulmonary fibrosis (IPF) in Delhi, India.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2021, Metro Ethical Review Board (L 94 Sector 11, Noida, India; +91 (0) 852742866; msnoida@metrohospitals.com), ref: not applicable
Approved 05/10/2021, University of Leicester Ethics Committee (The University of Leicester, University Road, Leicester, LE1 7RH, UK; +44 (0)1162522522; ethicsapp@leicester.ac.uk), ref: 31989

Study design
Single-arm feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Idiopathic pulmonary fibrosis

Interventions
Healthcare professionals, family caregivers and adults living with IPF will be recruited by the Metro Centre for Respiratory Diseases (MCRD). Due to the nature of this trial, the precise details and content of the home-based PR programme are unknown at this moment, as they will be heavily guided by the qualitative data collection within WP1. However, the intervention will comprise of the core elements of evidence-based rehabilitation, a programme of exercises and health education.

Eligible participants will be informed verbally about the study by the PI and CRC. Literate participants will be asked to read the patient information sheet (PIS) about the study, written in English or translated in the local language. Illiterate participants will have the contents read out to them by a study staff member, in the presence of a witness who will be present during the whole process. Participants will have the opportunity to discuss the PIS with the study medical personnel. Once the study staff is satisfied that the participant has understood the PIS, and is interested in taking part in the study, they will be taken through the informed consent process. Participants will give consent before undergoing screening tests and procedures. At the time of recruitment, the patient’s severity of illness will be examined by a qualified doctor and lung functions will be assessed using a portable spirometer.

The original SPACE for COPD manual is divided into four stages and participants progress through the various educational topics. The manual currently contains educational material and a home exercise programme. Acquisition of skills is promoted through goal-setting strategies, coping planning and case studies. It incorporates an exercise regime that consists of a daily walking programme, and resistance training of the upper and lower limbs using free weights three times per week. The speed and duration of walking are prescribed based on results from the Endurance Shuttle Walk Test (ESWT) - see Secondary Outcome Measures for more information. The manual advises on training progression and includes an action plan for exacerbation management.

Calls will be conducted by healthcare professionals, PR staff and research staff throughout the intervention to participants to ensure they are progressing accordingly and answer any questions and queries.

Intervention Type
Behavioural

Primary outcome(s)
Measures to assess feasibility are provided below and include the comprehensive assessment of the feasibility of patient recruitment and the intervention delivery:
1. Feasibility of screening and recruiting participants, suitability of the inclusion criteria assessed through screening of patients records and data sources (week 0)
2. Number of eligible patients, number of patients screened, number of patients invited to take part, and the actual number of participants who consent to take part, assessed using study notes and screening log (week 0)
3. Number of patients who refuse, drop out and the reasons for refusing and dropping out, assessed using drop-out interview and information provided freely by the participants collected as field notes (week 6)
4. Operational experience of intervention delivery assessed using semi-structured in-depth interviews at week 0 and week 6
5. Service provider and multi-disciplinary teams' willingness and ability to deliver the intervention, assessed using semi-structured in-depth interviews at baseline with healthcare professionals (week 0 and week 6)
6. The practicality of delivering the intervention in the proposed setting, assessed using semi-structured in-depth interviews (week 0 and week 6)
7. The time needed to collect the data at both baseline and follow-up visit through the recording of the time from rehabilitation records needed for each measure (week 0 and week 6)
8. Data completeness and accuracy assessed with healthcare professional interviews rehabilitation records from the research team (week 6)
9. Adherence to home exercise assessed using interviews with patients and a self-report exercise diary (week 6)
10. The training and resources needed to deliver the intervention (ensuring readiness for a future much larger multi-center trial) assessed using semi-structured in-depth interviews and rehabilitation records (week 0 and week 6)
11. Description of unintended events using a data collection form with an adverse events log (week 6)

Key secondary outcome(s))
1. Socio-demographics assessed using questionnaires at baseline (Week 0)
2. Lung health assessed using spirometry data records, lung transfer factor, and smoking status questions at baseline (week 0)

3. Comorbidities assessed using questionnaires at baseline (week 0)
4. Treatments assessed using questionnaires at baseline (week 0)
5. Physical measurements such as blood pressure and temperature, assessed using appropriate equipment such as cuff, automated blood pressure monitor and thermometer at baseline (week 0)

Measured at baseline (at week 0) and the end of the trial (at week 6):
1. Perceived respiratory disability due to dyspnea assessed using the Medical Research Council (MRC) dyspnea scale
2. Health-related quality of life assessed using the chronic obstructive pulmonary disease assessment test (CAT)
3. Economic impact assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire
4. Quality of life assessed using King's Brief Interstitial Lung Disease (KBILD) and EuroQol Five Dimension Five Levels (EQ-5D-5L)
5. Psychological well being assessed using the Hospital Anxiety and Depression scale
6. Physical fitness variables such as:
6.1. Exercise capacity measured using the incremental shuttle walk test (ISWT) and the endurance shuttle walking test (ESWT)
6.2. Lower extremity muscular strength measured using a five-repetition sit-to-stand test (5XSST)

Completion date
30/03/2023

Eligibility

Key inclusion criteria
1. People eligible for inclusion in the home-based PR trial will be:
1.1. Aged ≥18 years
1.2. Confirmed diagnosis of IPF according to European Respiratory Society (ERS) and American Thoracic Society (ATS) guidelines
1.3. Willing to provide informed consent
2. Healthcare professionals who have at least 1 year of experience and work directly with IPF patients, including specialists, nurses and physiotherapists
3. Family caregivers who have and/or care for a family member diagnosed with IPF

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
30

Key exclusion criteria
Adults with comorbidities such as severe or unstable cardiovascular disease, other internal diseases and locomotor difficulties that preclude the exercise or malignant disease or other serious illness which will interfere with participation in the study, will be excluded. Individuals not eligible for the study will be recorded on a study screening log.

Date of first enrolment
10/11/2021

Date of final enrolment
01/02/2023

Locations

Countries of recruitment
India

Study participating centre
Metro Hospitals & Heart Institute
L-94 Sector 11
Noida
India
201301

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			12/02/2024	No	No