A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in the slum area of Jodhpur, Rajasthan

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Abstract

Introduction India has the largest number of COPD cases in the world and ranks second in COPD mortality worldwide. 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), 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.

Methods and analysis Single-arm feasibility trial of community-based PR for people living with COPD in informal settlements in the Jodhpur Rajasthan**.**(N=40). The intervention will take place in in Rajiv colony, a low cost housing area and target patients living in housing schemes of this area.The Rajiv colony has 2485 households and a population of 17395. The colony is situated about 6 km north west of NIIRNCD. COPD cases will be identified from the colony by door to door survey. Screening tools (GOLD criteria) , spirometry and availability of prescriptions/hospital discharge summary will be used for confirmation of diagnosis. Confirmed cases will be invited to participate in the PR program. Recruitment will be stopped after enrolling 40 patients.

Suitable space will be rented for the purpose of intervention. The PR intervention will be carried out by nursing personnel after giving them prescribed training in PR. The primary outcome will be feasibility; with progression to a full trial based on recruitment (percentage of eligible patients who are recruited) and retention (percentage who complete the outcome assessment). Secondary outcome measures will include measures of exercise capacity, respiratory symptoms, psychological wellbeing and the economic burden of chronic respiratory disease; as well as qualitative evaluation through focus groups with patients and interviews with healthcare staff delivering PR.

Ethics and dissemination Ethical approval will be obtained from the ethics review committee of the National Institute for Implementation Research on Non-Communicable Diseases, India and All Indian Institute of Medical Sciences, Jodhpur, India and the University of Leicester, UK. The results of the trial will be disseminated through patient and public involvement events, local and international conference proceedings, and peer-reviewed journals.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is one of the most debilitating chronic respiratory illnesses. COPD is a progressive disease characterized by airflow obstruction and breathlessness. COPD is a major cause of morbidity and mortality throughout the world, corresponding to 6% of all deathsworldwide(1). Further, more than 90% of COPD deaths occur in low and middle-income countries(2).India has the largest number of chronic obstructive pulmonary disease (COPD) cases in the world (approximately 55.3 million) and India ranks second in COPD mortality worldwide(3, 4). COPD is a chronic, progressive disease of the airways and lung parenchyma, which often remains undiagnosed due to its subtle onset and delayed presentation, resembling the normal ageing process(5).

Chronic cough with sputum, breathlessness, physical inactivity and exercise intolerance resulting from dyspnoea or fatigue are common consequences of COPD. Symptoms of COPD progressively worsen and people can become breathless, even at rest. Daily activities often become difficult as the condition worsens, affecting their quality of life (6). The impact of COPD to the individual and to society makes the need for interventions to reverse the associated disability of paramount importance. Since COPD is a progressive, non-curable condition, rehabilitation of the patient becomes the most plausible therapeutic intervention.

Pulmonary Rehabilitation (PR) is a well-proven, internationally recommended, multidisciplinary intervention that aims to bring out lifestyle changes through exercise training, education, nutritional intervention and psychosocial support and this has been shown to significantly improve health related quality of life, exercise tolerance, breathlessness and fatigue(7-10). PR has been listed in the Indian Chest Association Guidelines (11) as an important intervention but there is no experience of delivery.

PR reverses the disability associated with CRDs, is supported by the highest level of evidence and is recommended in national and international guidelines (12). The World Health Organization makes the case for the fundamental role of accessible and affordable rehabilitation (13) and acknowledges an unmet need that is profound in LMICs where demand greatly outweighs capacity(14).

International guidelines recommend that PR should be routinely offered to patients with chronic respiratory disease who have persistent symptoms, limited activity, and/or are unable to adjust to illness(7, 10).PRis a low cost, high impact intervention that improves the quality of life, reduces suffering, reduces mortality and reduces economic loss, relieves dyspnoea and fatigue, improves exercise capacity, improves psychological and emotional function, and enhances an individual's self-management oftheir condition. Having realized the benefits of PR in COPD, Western countries have incorporated this as an important structural component of healthcare delivery services(15).Implementation of PR based as practiced in Western countries requires adaptation to the local health service, population and culture.

Conventionally, PR is a face-to-face structured program delivered over a period of 6-8 weeks in a hospital/clinic-based setting that needs multidisciplinary skilled staff, exercise equipment and space(7, 16). Despite the huge need, uptake and adherence to PR is restricted in India due to several factors like unavailability, inaccessibility and unaffordability.A low cost, community-based PR intervention is being provided in countries like UK, USA and Australia and supports patients for whom hospital-based PR programmers may not be accessible (17). There is a need for rolling it out in countries like India where universal health coverage is far below its expected roll out and cost of care in private sector is prohibitive for the patients from low socio-economic strata of the society. Among the residents of the slum areas of Jodhpur and in the low income group (LIG) housings, the ability to purchase health care is extremely restricted and access to health care in government provided free health care services is difficult due to disproportionately huge demand for the services.

In this project, we propose to carry out feasibility study of implementing a community-based low cost rehabilitation programmefor COPD patients. This will be administered at community setting with the help of trained nursing personnel. Therefore, the aim of this study is to devise an

appropriate community-based PR programme and then determine the feasibility and acceptability of this programme for adults living with COPD in the slum dwellers and residents of LIG colonies in the Jodhpur and assess the potential for a future trial of its effectiveness.

The objectives of the study are to:

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 COPDand healthcare staff involved in its delivery
3. Describe any changes in 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

METHODS AND ANALYSIS

Study design and registration

Single-arm feasibility trial of PR for adults living with COPDin informal settlements in Jodhpur with qualitative evaluation from PR deliverers and participants.The trial will be conducted, analyzed and reported according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (18) and will be registered viaInternational Standard Randomized Controlled Trial Number (ISRCTN).

Study setting:

Jodhpur is the second largest city in the Indian state of Rajasthan. Located in the north western part of the country. According to Census of 2011, the city has a population of 1,033,918. According to the Municipal Corporation, there are 217 slum areas having a population of 265 443 living in 46 364 households. For the purpose of this study Rajiv colony slum has been chosen, it has 2485 households and a population of 17395.No community based PR program was ever carried out in this area to the best of our knowledge.

Participants

Given the prevalence of COPD to be 4% in the adult population, 40 patients can be recruited by door to door survey of about 800 households. A suitable place will be rented for carrying out the project in the said area.

People eligible for inclusion in the trial will be: aged ≥18 years, will have a clinically confirmed diagnosis of COPD by a physician, confirmed COPD with spirometry based on GOLD criteria with $FEV_1/FVC<0.7$, and $FEV_1<80\%$ predicted, ≥1 exacerbation per year, mMRC grade ≥2 and willing to provide informed consent. Adults with co morbidities such as severe or unstable cardiovasculardiseases , other internal diseases and locomotor difficulties that preclude the exercise or malignant disease or other serious illness which will interfere with participation in the PR, will be excluded from the study. Individuals not eligible for the study will be recorded on a study screening log. Patients having RT-PCR positive report in 30daysfrom the day of survey will be excluded, and COPDwith active pulmonary tuberculosis will also be excluded. At present Covid 19 infection in Jodhpur is very low , so at the time of active intervention if the number of cases will be high then we will do RT PCR for Covid 19 testing as per guidelines.(i.e at the interval of 3 days or before starting new session.

Procedure

Each identified and confirmed case of COPD will be offered to be included in this trial and recruitment will be continued until desired sample size of 40 is achieved.

Eligible participants will be informed verbally about the study by the Principal investigator or the Research Associate. 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 staff and PR providers. 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, patient's severity of illness will be examined by a qualified doctor and lung functions will be assessed using portable spirometer. If still eligible

after the screening process, patients will be taken through another informed consent process. Information regarding the interest of participation in the studywillbe taken as field notes.

Experiences of the participants and PR deliverers regardingthe acceptability and feasibility of PR will be explored in interviews and focus groups. Participants who did not complete the PR will be asked to take part in a drop-outinterview andinformation provided freely by the participants will be collected as field notes.

Usual care

For usual care, patients will be free to continue to take treatment from hospitals or physicians of their choice. Any newly diagnosed patient will be referred to the AIIMS Jodhpurfor usual care. A co-investigator from the department of PulmonaryMedicine of AIIMS Jodhpur will ensure that all participants receive usual care and document the care received for each patient.

Intervention

In addition to usual care described above, participants in the intervention arm will receive PR. PR will comprise the core elements of an evidence based rehabilitation, a programme of exercises and health educationwill consist of a six-week programme offered to a group of up to 12 participants, with sessions occurring twice weekly for at least two hours (approximately one hour for education and one hour for exercise) (Table 1). Photos of PR from other low-resource settings are provided in Appendix A. 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 size of the facility will be big enough to ensure adequate distance of 6 feet between the participants and PR providers. Personal protective equipment, three layered surgical masks and hand hygiene facilities will be available to staff and participants at the venue. The venue will have adequate natural ventilation. The equipment required will be simple and include chairs, weights, and simple exercise equipment based on local availabilityand suitability.

Table 1: Structure and timetable for Pulmonary Rehabilitation

Components & duration	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6	
	Session 1	**Session 2**	**Session 3**	**Session 4**	**Session 5**	**Session 6**	**Session 7**	**Session 8**	**Session 9**	**Session 10**	**Session 11**	**Session 12**
Education	Avoidance of exacerbations	Chest clearance	Diet	Disease education	Energy conservation	Importance of exercise	Managing breathlessness	Pharmacy	Energy conservation, relaxation, meditation	Anxiety management	Maintaining the benefits of PR	Question and answer session
Upper body resistance training	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups	A minimum of: Bicep curls and Pull-ups
Lower body resistance training	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups	A minimum of: Sit-to-stand and Step-ups
Aerobic training	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of:Walking/ cycling	A minimum of:Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling	A minimum of: Walking/ cycling

A package consisting of printed material regarding the instructions to be followed as part of rehab will be provided to each enrolled patient in Hindi.

Diet: A dietician will assess the dietary pattern of the patient at base line and will educate the patient regarding modification of diet. Dietary assessment will be part of all follow up assessments. Dr. Pankaj Bhardwaj will look after of dietary assessment.

Change in living environment: the living environment of the patient will be evaluated at baseline using a check list and based on the findings, recommendations will be made for modification of the living environment in a pragmatic way considering the feasibility of making such modifications.

Quality control: Each intervention session will be monitored by the PI/co-investigator (s).

Warm-up and cool-down

Before starting exercises, participants will be taken through a group warm up session, followed by a cool down session at the end of exercises, each lasting 10-15 minutes. Both warm up and cool down will consist of stretching and flexibility exercises during which participants will perform both upper and lower body flexibility exercises, held for 10 to 15 seconds each (including stretching of major muscle groups such as the calves, hamstrings, quadriceps, and biceps, as well as range of motion exercises for the neck, shoulders, and trunk), 2 days/ week. The cool down session has the same activities of warm-up (Table 2) but performed at a slower pace. Warm up is aimed at readying the body for both the physical aspects of performance (increased blood flow and muscle temperature) and mental readiness for exercise whilst cool down session facilitates a smoother decline in temperature and blood flow.

Table 2: A list of warm up and cool down activities during PR session.

1. Marching on the spot, slowly bringing the feet off the floor for up to 1 minute
2. Heel digs: alternate heel digs in front of the body with toes pointing to the ceiling, add in a biceps curl (repeat 10-12 times)
3. Toe taps: Tap the toes to the floor in front of alternating legs at a comfortable distance. Heels stay off the ground. Repeat 10-12 times.
4. High knee marching – with opposite hand to opposite knee

5. Side bends: With arms relaxed by your side, leaning over to the right for 8 to 10 seconds and back to centre, then lean to the left for 8 to 10 seconds and back to the centre (repeat 8 times).
6. Arms stretched up, forwards and down
7. Alternate punching of arms forward
8. Seated or standing side taps to the floor with the foot – alternate legs
9. Seated or standing in upright posture, feet placed shoulder breadth apart – shoulder roll in both directions (clockwise and anti-clockwise)
10. Seated or standing in upright posture, feet placed shoulder breath apart, elbows bent with hands onto shoulder – elbows make circles in clockwise and anti-clockwise
11. Hamstring stretch: With right leg straight, place it in front of the body, heel pushed into the floor with toes pointing toward the ceiling. Slightly bend the left knee, place hands on the straight right leg and gently lean forward. Hold the stretch for 10-15 seconds then return to upright position. Repeat on left leg.
12. Quad stretch: While holding a chair or onto a wall, stand on your left leg and grab your right foot using your right hand, pulling it gently towards the ceiling. Hold the position for 10-15 seconds and return to upright position and repeat on the right leg.

Endurance training

Each participant will go through two stations of endurance exercise; a load adjustable stationary bike cycling and ground-based walking stations. We shall employ a high level of intensity of continuous exercise at each station for 10 minutes or until a Borg dyspnoea or fatigue score of 4 to 6 (moderate to [very] severe) is reached(19, 20). Participants who may have difficulty in sustaining continuous high-intensity exercise will have interspersed periods of rest or lower intensity exercise to maximize benefit of exercise training(12). The exercise regime will be individually prescribed to participants based around their performance in the incremental shuttle walk test (ISWT). Furthermore, the participant will be encouraged to walk at 85% of their maximal ISWT walking speed during the endurance shuttle walk test (ESWT)(21).

Strength training

Each participant will go through four stations of strength training, two stations for strengthening upper limb muscles (pull-ups and biceps curl) and two for strengthening lower limb muscles (sit-to-stand and step-up exercises). Each of the stations will include 3 sets of 8-12 repetitions. Participants will be asked to continue doing both endurance and resistance exercises at home, unsupervised.

Education sessions

A dedicated education session will be conducted at the start of each class, before starting the exercise regimes (12 sessions in total). Education topics will be:

- Anxiety management
- Avoidance of exacerbations
- Chest clearance
- Diet
- Disease education
- Energy conservation
- Exercise
- Maintaining the benefit after PR
- Managing breathlessness
- Pharmacy
- Questioning & Answering session
- Relaxation and meditation

Outcomes

Primary outcome

The primary outcome of the trial will bethe feasibility and the acceptability of the PR intervention.

Feasibility

Measures to assess feasibility are provided in Table 3 and include the comprehensive assessment of the feasibility of patient recruitment and the intervention delivery. This feasibility study is the next step towards a definitive evaluation of PR plus treatment as usual. Progression to a full trial will be based on a traffic light system whereby green indicates that it is feasible to proceed using

the current trial methodology, amber indicates that modifications to the methodology are needed, and red indicates that it is not feasible to proceed.

1, Recruitment (percentage of eligible patients who are recruited): Green ≥60%; Amber 59-25%; Red <25%

2, Follow-up (percentage who complete the outcome assessment): Green ≥70%; Amber 69-50%; Red <50%

Table 3: Primary outcome measures- Feasibility and operational experience assessment	
Feasibility of patient recruitment	**Data sources**
Feasibility of screening and recruiting participants	Interviews with the healthcare professionals, screening log
Suitability of the inclusion criteria	Interviews with the healthcare professionals, screening log
Number of eligible patients, number of patients screened, number of patients invited to take part, actual number of participants who consent to take part	Screening log
Number of patients who refuse, drop out and the reasons for refuse and drop out	Interviews with the patients, screening log
Operational experience of intervention delivery	
Service provider and multi-disciplinary teams' willingness and ability to deliver the PR	Interviews with healthcare professionals
The practicality of delivering the intervention in the proposed setting	Interviews with healthcare professionals and focus groups with participants
The time needed to collect the data Baseline visit- Time taken for each measure (each individual questionnaire and physical measure) Follow-up visit- Time taken for each measure (each individual questionnaire and physical measure)	Interviews with the healthcare professionals, Rehabilitation records
Data completeness and accuracy	Interviews with the healthcare professionals, Rehabilitation records, RedCap
Adherence to home exercise	Interviews with the patients and self-report exercise diary
The training and resources needed to deliver the intervention (ensuring readiness for a future much larger multi-center trial)	Interviews with the healthcare professionals and focus groups with participants, Rehabilitation records
Description of unintended events	Adverse events log, REDCap

Acceptability

The acceptability of the PR intervention among adults living with COPD and healthcare staff involved in its delivery will be assessed. Participants' experience of the PR, including any perceived benefits, challenges and changes they would make to the programme, will be explored in qualitative interviews and focus groups after their discharge assessment or withdrawal. The experience of healthcare professionals regarding the PR intervention, such as their confidence in deliveringtheprogramme, the components of PR, structure of PR, the patient adherence to the PRexercises and how their perceptions changed over the course of the trial, will be explored in qualitative interviews at the end of the trial.

Secondary outcomes

The secondary outcomes of this study are provided in Table 4. Comparison of secondary outcome measures of baseline and post intervention, will describe any changes in the health of the adults living with COPD following completion of PR.

Table 4: Secondary outcome measures

Outcome measures	**Baseline**	**Post-intervention**
Socio-demographics	**x**	
Lung health (spirometry data, smoking status, number of COPD exacerbations in the last year)	**x**	~~**X**~~
Co morbidities	**x**	
Treatments	**x**	**X**
Disease burden (MRC dyspnea grade, CAT, CCQ)	**x**	**X**
Economic impact of disease (WPAI)	**x**	**X**
Quality of life (EQ-5D-5L)	**x**	**X**
Psychological wellbeing (Hospital Anxiety and Depression scale)	**x**	**X**
Physical function (5x sit-to-stand test)	**x**	**X**
Exercise capacity (ISWT, ESWT)	**x**	**X**

MRC - Medical Research Council, CAT- COPD Assessment Test, CCQ - Clinical COPD Questionnaire, EQ-5D-5L - EuroQol Five Dimensions Five Levels, ISWT - Incremental Shuttle Walk Test, ESWT - Endurance Shuttle Walk Tests, WPAI – Work Productivity and Activity Impairment questionnaire

Sample size and recruitment target

This study is a feasibility trial that aims to provide data for an accurate estimation of the required sample size for future trials. Therefore, a formal sample size calculation is not required. We aim to recruit 40participants to the study.

Data collection

Single-arm feasibility trial

Data will be collected by trained researchers, following standard operating procedures during participants' study visits.

Qualitative evaluation of the PR intervention

Focus groups with patients

Participants allocated to the intervention group will be invited to participate in focus group discussions at the end of their PR programme. Focus groups will give an insight on views, experiences, opinions and recommendations which will inform future PR programmes. We anticipate conducting up to 5 focus groups until data saturation. Each focus group discussion will be conducted with 6-8 participants in each. In the event focus groups are not possible, we will conduct one-to-one interviews with patients.

Focus group discussions will be audio-recorded, expected to last approximately 45-90 minutes, and will be conducted a trained moderator and a note-taker~~)~~. Focus groups will be transcribed verbatim, with identifiable information removed and translated to English. Consent will be obtained from participants prior to their involvement in focus groups.

Interviews with PR staff

Health care personnel involved in delivering PR will be invited to participate in in-depth interviews at the end of the study to discuss aspects of feasibility and acceptability, such as insights into barriers and facilitators to attendance, logistical barriers of running a PR programme and their views of patients' experiences of the intervention. We anticipate conducting up to 10 interviews, each expected to last approximately 15-45 minutes. Interviews will be audio-

recorded and will be conducted face-to-face by a trained interviewer. Interviews will be transcribed verbatim, with identifiable information removed and translated to English.

Taking into account COVID guidelines, we will use a hierarchical approach for the qualitative data collection, dependent on resources and participant preference. The preferred approach would be to conduct face-to-face to focus groups for patients and face-to-face semi-structured interviews for PR staff. If face-to-face contact is not possible, video focus groups and interviews will take place, dependent on video/teleconferencing software resources. If this is not feasible, telephone interviews will be used.

Book of testimonies and evaluation form

Participants within PR will be asked to log their experience of PR as they progress through the programme. This will be in the form of a PR log book accessible to participants before, during and after sessions, as well as a dedicated evaluation form (Appendix B). Staff involved in PR will also receive the same evaluation form at the end of the study.

Baseline sample characteristics

Basic demographics including age, sex, religion, nationality, marital status, age of leaving full-time education, education level, ethnicity, employment status, monthly income, lung health, smoking status (packs per year), biomass fuel exposure, primary respiratory diagnosis, time since diagnosis in years, secondary respiratory diagnoses, family history of lung disease, co morbiditieswill be recorded at baseline.

Spirometry (post bronchodilator Forced Expiratory Volume in the first second (FEV_1),post bronchodilator Forced vital capacity (FVC), FEV_1/FVC ratio) will be conducted. If spirometry cannot be conducted we will use data from last 12 months available from medical notes. We will also collect the number of hospitalizations within the last 12 months, number of COPD exacerbations within the last 12 months,and currenttreatments as the baseline data prior to starting PR.

Secondary outcome measures

All secondary outcomes will be compared between the baseline visit and 6 week follow-up visit (within 7 days of completing their last PR session).

Exercise capacity

The incremental shuttle walking test requires the patient to walk up and down a 10-meter course, identified by two cones inset 0.5 m from either end to avoid the need for abrupt changes in direction. The speed at which the patient walks is dictated by an audio signal played on an audio device. Each participant will receive standardized instructions to: "Walk at a steady pace, aiming to turn around when you hear the signal. You should continue to walk until you feel that you are unable to maintain the required speed without becoming unduly breathless"(22). To ensure learning, a practice ISWT will be performed and the participant will receive encouragement from the physiotherapist throughout the test in an effort to increase the distance one can walk. The test is terminated when either 1) the patient indicates that they are unable to continue, 2) if the operator determines that the patient is not fit to continue, or 3) the operator assesses that the patient was unable to sustain the speed and cover the distance to the cone prior to the beep sounding. The minimal important difference (MID) is 36m(23).

The Endurance Shuttle Walk Test (ESWT) is a constant-load exercise test which measures the ability of the participant to sustain a given sub-maximal exercise capacity; the participant aims to walk at 85% of their maximal ISWT walking speed(21). The ESWT is frequently used as an exercise tolerance outcome measure for PR. The endpoint of the test is the time the participant walks at the constant endurance speed. The test consists of pre-recorded audio signals at different frequencies giving a total of 16 walking speeds. The ESWT is responsive to PR with an MID following a 6-week PR programmebetween 174 and 279 seconds(24).

Physical function

The Sit-To-Stand (STS) test is a commonly used functional performance measure of lower-limb strength(25). The five-repetition sit-to-stand test (FTSTS) measures the time taken to stand five times from a sitting position as rapidly as possible. The FTST is partly dependent on lower limb muscle function and balance, and is a common activity of daily living that measures performance such as time up and go, and gait speed(26). The FTSTS is reliable, valid and responsive to PR with an estimated MCID of 1.7 seconds(26).

Respiratory symptoms

The Medical Research Council (MRC) dyspnoea scale is a 5-point self-administered questionnaire based on the sensation of breathing difficulty experienced by the patient during daily life activities. Patients recognize their own level of respiratory fatigue used to measure functional dyspnea (27). The questionnaire is short, easy to use and has grades ranging from 1 (none) to 5 (almost compete incapacity), with high grades indicating high perceived respiratory disability(28). The MRC dyspnoea scale is responsive to PR with estimated MCID of 1 points(27, 29).

The Clinical COPD questionnaire (CCQ) is a simple 10-time validated Health related quality of life (HRQoL) questionnaire with good psychometric properties(30). It consists of 10 items, each scored between 0-6, divided into three domains (symptoms, functional, mental). The total score is calculated by summing the scores of the individual items and dividing by 10 (the number of individual items) giving a total score between 0-6 with higher scores representing worse HRQoL. The CCQ is responsive to PR with an estimated minimal important improvement of 0.4(31).

The COPD Assessment Test (CAT) is a validated, self-administered, short and simple questionnaire that measures HRQoL(32). The CAT consists of eight items, each scored between 0- and 5 scored with a range of 0- to 40; scores of 0-10, 11-20, 21-30, 31-40 representing mild, moderate, severe or very severe negative impact on HRQoL, respectively. The CAT is responsive to the effects of PR with an estimated minimal clinically important difference (MCID) of 2 points(33).

Psychological wellbeing

The Hospital Anxiety and Depression Scale (HADS) questionnaire is a validated, easy to use screening tool for anxiety and depression symptoms in a hospital outpatient setting (34). The self-report rating scale is composed of 14 items with two 7-item subscales (HADS-A and HADS-D), both ranging from 0- to 21 with higher scores indicating more severe distress. The HADS questionnaire is validated for screening for anxiety and depression from patients. The HADS is responsive to PR with estimated MCID of 2 points on each subscale (35).

Health Related Quality of Life

The Work Productivity and Activity Impairment (WPAI) questionnaire is a validated instrument to measure impairments in work and activities, both paid and unpaid. The WPAI self-administered questionnaire measures time missed from work, impairment of work and regular activities due to overall health and symptoms, during the past seven days(36). We have added two follow-up supplementary questions, following the WPAI format, to measure productivity with respect to regular household duties in low resource settings.

The European Quality of Life 5-Dimensions (EQ-5D-5L) questionnaire is a standardized questionnaire, developed to measure of health outcomes and defines health in terms of five dimensions: mobility, self-care, usual activities, pain or discomfort and anxiety or depression(37). The EQ-5D-5L will be used to calculate patient costs per quality adjusted life year (QALY). EQ-5D-5L is responsive to change following pulmonary rehabilitation, with a MCID of 0.05 (utility index) and 7.0 (visual analogue scale) (38).

Cost/benefit analysis

The cost of starting and running a PR program will include single and recurrent costs. Single payments will include the necessary costs needed to set up and run PR. Recurrent costs refer to any item with a life expectancy of ≤1 year (e.g. disposable materials)(39). The fixed costs will be captured prior to enrolling the first participant into the PR programme and the recurrent costs will be collected at the mid-stage of recruitment. The average fixed and recurrent costs will be calculated separately. Table 5 demonstrates the variables that will be used to calculate fixed and recurrent costs.

Table 5: The variables used to calculate fixed and recurrent costs (not an exhaustive list)

Fixed costs	**Recurrent costs**
Venue hire	Venue hire
Electrical equipment (laptop, printer, projector)	Staff time to conduct PR (assessment at baseline and discharge, conduct PR classes, telephone calls and data entry)
Equipment for PR (weights, treadmill, cycle ergo meter, country-specific equipment, step-up box, chairs)	Disposable equipment (for blood glucose monitor, spirometer mouthpieces, nose-clips, glyceryl trinitrate spray)
Equipment for shuttle walking tests (cones, licences, stop watches, tape measure, electrical equipment to play	Servicing costs (spirometer, PR equipment, specifically treadmills and cycle ergometers)

audio)	
Equipment for PR assessment (height stadiometer, weight scales, sphygmomanometer, pulse oximeter, spirometer, calibration syringe, country-specific equipment)	Miscellaneous (Oxygen cylinders, questionnaire licences, stationery (paper))
Additional safety equipment (blood glucose monitor, Oxygen cylinder holder)	
Miscellaneous (filing cabinets, storage units, questionnaire translations, questionnaire licences, staff uniform)	

Data management

Data collected during the study will be entered into a database using Research Electronic Data Capture (Redcap), which is a web-based platform (40, 41).Access to the database will be via a secure password protected web-interface. The participants will be identified by a study-specific identification code. Data will be validated using real-time data entry validation and electronic checks lead by the Independent Data Monitoring Committee (IDMC), established at the University of Leicester, UK.

Quantitative data analysis

The data will be analyzed using IBM SPSS Statistics for Windows. Data for baseline and follow-up time-points will be presented as descriptive statistics as appropriate. No inferential statistics will be performed due to the feasibility design of the trial.

Qualitative data analysis

Qualitative data will be analyzed using Thematic Analysis. This approach follows six distinct stages: familiarization with data; generating initial codes; searching for themes; reviewing themes; defining and naming themes and producing the report. The responsible investigator will carry out initial coding and a sample of focus group transcripts will be coded by a second member of the team to improve consistency and to enhance interpretive authenticity. Throughout

the data analysis, the team will meet to discuss and review emerging themes and search the accounts that provide contesting views of the same phenomena. Close attention will be paid to the complexity and interactions inherent in the focus group data.

Adverse events

All adverse events and serious adverse events will be recorded on an adverse event log, within study trial management paperwork, case report forms and REDCap.There will be no formal interim analysis of data due to the feasibility nature of the trial. The IDMC will review high level safety data. Adverse events will be monitored at least every month, and as needed on an ad hoc basis, to ensure the continuing safety of the participants. The Scientific Committee will determine the need to terminate the trial.Participant who experience any such event will be directed to the appropriate hospital and all the necessary care will be ensured and followed-up until the participant has resolved or stabilized.

Ethics and dissemination

Ethical approval will be obtained from the ethics review committee of NIIRNCD, Jodhpur, Rajasthan, AIIMS, Jodhpur, and the University of Leicester, UK. The results of the trial will be disseminated through patient and public involvement events, local and international conference proceedings, and peer-reviewed journals. Privacy and the confidentiality of all information and identities of participants will be strictly maintained and will not be disclosed when publishing the results of the study.

Compensation for travelling will be provided to all the participants. All study documents will be translated to Hindi toensure clear communication. Participation will be without compulsion and each participant has the right to withdraw at any time, without providing a reason. Consent form and data sheets will be securely stored in a separate locked cupboard. Study computers will be password protected. All the data will be stored safely up to 5 years and after 5 years consent form and data sheets will be disposed of appropriately. Study team and IDMC only will have access to final trial dataset. Data from the Global RECHARGE Core Dataset will be made available following the completion of this project and we are considering the best tools to use to

make this database available to the wider community. Any modifications of the protocol will be updated on trial registry (ISRCTN) and will be informed to the ethics review committee and the participants. Participants will be provided the provisions for re-consenting after any change of the approved protocol. It will be made clear in the publication of trial findings.

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Appendix A: Photos of PR from other low-resource settings (Uganda and Kyrgyzstan)

Appendix B: Pulmonary Rehabilitation Satisfaction Survey

Please tick the relevant column for your answer to each statement below:	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
I can do more of my daily activities since completing pulmonary rehabilitation.					
My levels of fitness have improved since beginning pulmonary rehabilitation.					
I have found pulmonary rehabilitation to be worthwhile.					
The information in the education talks was useful.					
Pulmonary rehabilitation has helped me to manage my lung condition more effectively.					
I would recommend this pulmonary rehabilitation course to others with a lung condition.					

- **What were the most useful aspects of the course?**

- **Is there anything you feel we could add to the course?**

- **Do you have a comment that that we could use for promotion of the program which would encourage other patients to participate?**

Human resources:

1. Project coordinator 1
2. Nursing staff 2
3. Physiotherapist 1
4. Administrative staff 1
5. Lab Technician 1 (FOR PERFORMIG SPIROMETRY)

Equipment:

1. Portable, digital spirometers (2)
2. Standard equipment for clinic: Stethoscopes, weighing scales, torch, etc.
3. Furniture, fittings and fixtures: chairs, tables, air conditioners, x-ray view box,
4. Logistics: Stationary, mobile phones, a laptop/desk top computer for record keeping

Budget

Items	Cost in INR
HR	
1. Research Coordinator	40,000 per month
2. Staff nurse/Dietician	35,000 per month
3. Yoga instructor	35 000 per month
4. Administrative staff	25,000 per month
5. Lab technician	20,000 per month
Equipment	
1. Portable spirometers	80,000 per unit

2. Standard equipment	10,000
3. Furniture, fittings, fixtures	150,000
4. Logistics	125,000
5. Room rent	25 000 per month
6. Travel/dissemination	
7. Publication cost	
8. Contingency*	20% of total budget
9. Overheads	10% of total budget
10. Incentives for the patients	Food vouchers INR 250 per patient per week

The contingency charges are for meeting the miscellaneous expenditures like

1. Telephone charges
2. Postal/courier charges
3. Stationary items like writing instruments, paper, file cover,
4. Local travel expenditure
5. Printing of questionnaire, consent form, patient information sheet etc.

A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in the Informal Settlements in Jodhpur Rajasthan

Part 1:

Home visit Survey

Serial No. _____ Zone_____ Locality_____Date_____

Select one respondent from each Household to fill up the first part

1) Name:

2) Address:

3) Contact Number:

4) Age:

5) Gender: (a) Male (b) Female

Part 2

Screening for COPD :

1. Is anyone in your home suffering from any respiratory illness since more than six months?
2. Name of patient:_____
3. Age of patient:_____
4. Sex :_____(0 male, 1 female)

5. Religion: _____

6.Age of living full time education: _____

7.Education level: _____

8.Ethnicity: _____

9.Employment status: _____

10.Monthly income: _____

11.Biomass fuel exposure:

	LPG	Kerosine oil	Coal	Wood	other
i)Daily					
ii) Less than daily					
iii) Occasionaly					
iv) Never					

a)Source of ventilation in the kitchen (active / used)

b) Exhaust / Chimney / Skylight / Extractor Hood / Cooking Canopy / Electric Chimney

c) Do you cook / cook? Yes No

12. Screening for COPD:

Symptom	never 0	Rearly 1	Occasionally 2	Often 3	Frequently 4	All the time 5	Total
1. How often do you cough?							
2. Do you have mucus in your chest which comes out with coughing?							
3. How often do you feel tightness in chest?							
4. How Often do you feel breathless while climbing stairs?							
5. Do you feel limited in doing activates of daily living due to lung condition?							
6.Do you have a sound sleep because of your lung condition?							
7.Do you feel drained and weak due to your lung condition?							

13.Did you consult a doctor for theabove symptoms?

Yes/no

14) Is prescription available : yes/no

15) If yes, sourse: Pvt. Practitioner/Pvt. hospital/Govt. hospital/ESI/Nursing home/RMP/OTHERS

16) Taking treatment: yes/no or As and when required.

17) Willing to undergo spirometry?

18) If no,why:……

19) Have you ever undergone spirometry test?

20) If yes: report,yes/no.

21) have you suffered from any major illness? If yes……

Information consent form

Name of the participant: Mr. / Mrs. .... By signing this form, I voluntarily agree to give an interview in this research and research work. I have been given full information about the study and I understand its nature. I have read the information given in Participant Information Paper / Information Consent Letter, and I understand that the information given by me will be kept confidential.

I have got an opportunity to ask questions about the study and am satisfied with the answer to all my questions. I understand that I am completely independent to participate in this study. I understand that I am free to separate from the study or not to answer any questions at any time. I understand that there is no penalty for participating in this study or withdrawing from this study. I have given a copy of this consent form.

Name of Participant:
_____

Signature of Participant: _____ Date: _____

Name of the person receiving consent: _____

Signature of the interviewer: _____ Date: _____

A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in slum areas of Jodhpur, Rajasthan

Participant information sheet (Pulmonary Rehabilitation trial [Staff- Qualitative])

Investigator details: Dr. Arun Kumar Sharma

You are invited to take part in a research project assessing the views of staff following community-based Pulmonary Rehabilitation for people with COPD.

Before you decide on whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before you decide whether or not you wish to take part. You are welcome to discuss this research project with others. Please contact us through the details aboveif there is anything that is not clear or if you would like more information.

What is the purpose of the study?

People living with COPD are frequently disabled by their breathlessness. As a result, the individual experiences a reduced ability to perform daily activities, poor quality of life and social isolation. Pulmonary Rehabilitation is a non-drug, low cost, high impact intervention that reverses the disability associated with chronic lung disease through education and exercise. Pulmonary Rehabilitation is not routinely offered to adults living in low and middle income countries. This project aims to test a community-based Pulmonary Rehabilitation programme in the North-East District of Delhi, India for adults living with COPD.

The views of healthcare staff that were involved with community-based Pulmonary Rehabilitation programme are important.

Why have I been chosen?

You have been chosen because you are a healthcare worker that has X years of experience and work directly with adults with COPD and have been involved with the home-based Pulmonary Rehabilitation programme.

Who is doing this research and why?
This research is being conducted by the NIIRNCD,Jodhpur and the University of Leicester, UK. This research is funded by the National Institute for Health Research, UK. Some data collected as part of this trial will contribute towards student projects which are supported through the University of Leicester.

What will I be asked to do?
Once you have provided written informed consent, you will participate in a recorded (audio or video) face-to-face interview with a researcher. In some circumstances, this may be conducted over the telephone or using audio technology.

Are there any exclusion criteria?
The exclusion criteria are presented below:

1. Unable or unwilling to provide informed consent
2. Less than X years of experience as a healthcare worker

Once I take part, can I change my mind?
After you have read this information and asked any questions you may have if you are happy to participate we will ask you to complete an Informed Consent Form. However if at any time, before, during or after the sessions you wish to withdraw from the study please just contact the main investigator. You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing. However, any data collected up to this point may still be kept for research purposes and included within the overall trial results.

Will I be asked to attend any sessions and where will these be?
You will be asked to attend { Rehabilitation centre } to provide written informed consent and participate in an interview.

How long will it take?
We anticipate the interview to last between 30 and 45 minutes. There will be some time before this to ensure you fully understand the study and if appropriate, sign the informed consent form.

Are there any disadvantages or risks in participating?
The risks of taking part in this study are minimal. There is a risk of a breach of confidentiality and privacy, however, all efforts will be made to ensure the risk of this occurring is reduced.

What are the possible benefits of taking part?
There may not be any direct benefit to participants who decide to take part. The study will inform future pulmonary rehabilitation services and research studies.

Is there anything I need to do before the sessions?
There is nothing you need to do before.

Data Protection Privacy Notice

University of Leicester will be using information/data collected from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

What personal information will be collected from me and how will it be used?

All information which is collected about you during the course of the research will be kept strictly confidential.

During the study, data collected about you will be labelled with a participant number, not your name. This number will be in place of any identifiable information. Only certain members of the study team directly involved in the study will be able to link your subject number to your name. An electronic recording of your interview will be stored on a secure password protected computer and the study documentation will stored in a secure, locked environment. Study data may also be looked at by the regulatory authorities to check that the study is being carried out correctly. The audio files will be transcribed with an external provider and a confidentiality agreement will be in place.

Your anonymised study data will also be shared with our research collaborators at the University of Leicester. You are free to withdraw from the study at any point without giving a reason. However if you do withdraw from the study we will need to use the information collected up until the time that you decided to withdraw from the study and your data may still be shared with our research collaborators.

The anonymised data collected from you as part of this trial may be used in future research studies; this will be overseen by Global RECHARGE and the University of Leicester.

What is the legal basis for processing my personal information?

Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as "sensitive data". The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

How long will my personal information be retained?

We will keep identifiable personal information about you for 5 years after the study has finished.

How will the anonymised data/results collected from me be used?

Data from the trial will be presented in reports, journal publications, conference papers and other academic outputs.

I have some more questions; whom should I contact?

If you require any further information, please do not hesitate to contact us on the details at the beginning of the information sheet.

National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

Study number:

Title of project: A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in slum areas of Jodhpur, Rajasthan.

Name of researcher: Dr.Arun KumarSharma,Director,NIIRNCD

INFORMED CONSENT FORM (Pulmonary Rehabilitation trial [Staff- Qualitative]**)**

Patient identification number: _____

Taking Part	**Please initial to confirm agreement**
The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the University of Leicester ethics committee and the NIIRNCD ethics committee.	----------
I have read and understood the participant information sheet(Pulmonary Rehabilitation trial [Staff- Qualitative]. Version number: 1.0) and this consent form.	----------
I have had an opportunity to ask questions about my participation.	----------
I understand that taking part in the project will involve participating in an interview that will be recorded (audio or video).	----------
I understand that personal information collected will include my name and date of birth. I understand I will be assigned a unique study identification number and my unique identification number and personal details will be stored on a secure enrolment log.	----------
I understand that the audio recordings taken during this interview will be converted to text but will remain anonymous.	----------
I understand that I am under no obligation to take part in the study, have the right to withdraw from this study at any stage for any reason, and will not be required to explain my reasons for withdrawing.	----------

Use of Information

I understand that responsible persons and employees of the ethics committee will have access to my personal data for strict control and to ensure the correct conduct of the study whilst ensuring strict confidentiality will be maintained. ----------

I understand this research is in collaboration with the University of Leicester, UK and all anonymised data will be shared.

I understand that all the personal information I provide will be processed in accordance with data protection legislation on the public task basis and will be treated in strict confidence unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others or for audit by regulatory authorities. ----------

I understand that information I provide will be used in publications, reports, web pages and other academic and research outputs. ----------

I understand that personal information collected about me that can identify me, such as my name, will not be shared beyond the study team. ----------

I agree that information I provide can be quoted anonymously in research outputs. ----------

I give permission for the anonymised data I provide to be deposited in the data archive governed by the {NIIRNCD} so that it can be made publicly available for future research at the end of the project. ----------

I understand that anonymised data collected as part of this study may be used in future research. ----------

Consent to Participate

I voluntarily agree to take part in this study. ----------

_____		_____		_____
Name of participant	[printed]	Signature		Date
_____		_____		_____
Researcher	[printed]	Signature		Date

National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in the slum area of Jodhpur, Rajasthan

Participant information sheet (Pulmonary Rehabilitation trial)

Investigator details: Dr. Arun Kumar Sharma, Director, NIIRNCD

You are invited to take part in a research project assessing a home-based exercise and education programme (known as home-based Pulmonary Rehabilitation) for people with IPF.

Before you decide on whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully before you decide whether or not you wish to take part. You are welcome to discuss this research project with others. Please contact us through the details above if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

People living with COPD are frequently disabled by their breathlessness. As a result, the individual experiences a reduced ability to perform daily activities, poor quality of life and social isolation. Pulmonary Rehabilitation is a non-drug, low cost, high impact intervention that reverses the disability associated with chronic lung disease through education and exercise. Pulmonary Rehabilitation is not routinely offered to adults living in low and middle income countries.

This project aims to test a community-based Pulmonary Rehabilitation programme in the Jodhpur, Rajasthan, India for adults living with COPD.

Why have I been chosen?

You have been chosen because you are an adult with COPD who has been identified as potentially eligible for the study. We are hoping to recruit approximately 40 individuals to this study.

Who is doing this research and why?

This research is being conducted by the NIIRNCD, Jodhpur and the University of Leicester, UK. This research is funded by the National Institute for Health Research, UK. Some data collected as part of this trial will contribute towards student projects which are supported through the University of Leicester.

What will I be asked to do?

First, we will see if you are suitable for the community-based Pulmonary Rehabilitation programme. The severity of your illness will be examined by a qualified doctor and you may be asked to take a simple lung function test. If you are still eligible after the screening process, you will be asked if you are willing to provide informed consent for the community-based Pulmonary Rehabilitation programme.

If you consent to the study, you will undertake the community-based Pulmonary Rehabilitation programme, an intervention that consists of exercise training and education. The exercise will have an element of strength and aerobic training and the educational content is designed to help you manage and understand your chronic lung disease. You will undertake this programme at a specialist facility and will be asked to undertake some exercise at home as part of the programme. The programme will be delivered twice a week for six weeks, with one hour of exercise and one hour of education per visit. The programme will be delivered by trained healthcare professionals.

After completion of Pulmonary Rehabilitation, you may be asked if you wish to attend a voluntary focus group. The purpose of this is to allow you to share your thoughts and

experiences of community-based Pulmonary Rehabilitation with the researchers. A focus group is a group discussion with other participants that have consented to the research trial. The focus group will be recorded (audio or video) and the information from this discussion will be typed up. You may be asked to attend an interview as opposed to a focus group discussion, and this may also occur over the telephone or using video-conferencing technology. If you no longer wish to participate in the community-based Pulmonary Rehabilitation programme, you may be invited to an interview to discuss the reasons why you dropped out of the study. This is voluntary and you will be asked to sign an informed consent form before participating in an interview.
During your research visits, you will be required to complete some walking tests, a test of functional strength and answer some questionnaires relating to your mood state, symptoms and quality of life. The researchers will also record some of your past medical history and your socio-demographic status. You will be asked to undergone Covid 19 RT PCR testing before starting each session and during screening.

Are there any exclusion criteria?
The exclusion criteria are presented below:

1. Unable or unwilling to provide informed consent
2. Aged less than 18 years of age
3. Have other medical conditions such as severe or unstable cardiovascular disease or any other condition that may affect participation in Pulmonary Rehabilitation.

If you are unable or unwilling to provide informed consent, you will also be excluded from the voluntary focus groups that will take place after Pulmonary Rehabilitation.

Once I take part, can I change my mind?
After you have read this information and asked any questions you may have if you are happy to participate we will ask you to complete an Informed Consent Form. However if at any time, before, during or after the sessions you wish to withdraw from the study please just contact the main investigator. You can withdraw at any time, for any reason and you will not be asked to explain your reasons for withdrawing. However, any data collected up to this point may still be kept for research purposes and included within the overall trial results.

Will I be asked to attend any sessions and where will these be?
You will be asked to visit study site located nearby area of Rajiv colony for your research visits. This will be at week 0 (when you consent to the study), and following your completion of community-based Pulmonary Rehabilitation, which is intended to be within week 6. The

Pulmonary Rehabilitation programme will be delivered at Study site.You may then be invited to a voluntary focus group after home-based Pulmonary Rehabilitation to discuss the programme.

How long will it take?

We anticipate each assessment will take between 1 and 2 hours. Each rehabilitation class will last 2 hours; one hour of education and one hour of exercise. The total Pulmonary Rehabilitation programme consists of 12 classes, ran over a consecutive six week period.

Are there any disadvantages or risks in participating?

The risks of taking part in this study are minimal. You may experience some muscle aching and general tiredness from starting Pulmonary Rehabilitation and performing the walking tests. This is usually mild and wears off after a couple of days. The staff supervising the classes will monitor you closely.

What are the possible benefits of taking part?

There may not be any direct benefit to participants who decide to take part. However it is hoped that home-based Pulmonary Rehabilitation will benefit patients in terms of improved muscle strength and exercise tolerance. The study will inform future pulmonary rehabilitation services therefore benefiting all patients.

Is there anything I need to do before the sessions?

Please ensure you are well hydrated and have eaten prior to the research visit; please refrain from eating food at least 30 minutes before.

Is there anything I need to bring with me?

Please ensure you wear or bring suitable shoes and clothing to exercise in. You may want to bring a water bottle.

Data Protection Privacy Notice

University of Leicester will be using information/data collected from you in order to undertake this study and will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly.

What personal information will be collected from me and how will it be used?

All information which is collected about you during the course of the research will be kept strictly confidential.

During the study, data collected about you will be labelled with a participant number, not your name. This number will be in place of any identifiable information. Only certain

members of the study team directly involved in the study will be able to link your subject number to your name. Your study data will be stored on paper (in a secure room) and on a computer database. The database is stored on a secure, web-based server software called REDCap (Research Electronic Data Capture) and is managed by the University of Leicester. This database is password protected.

These records will be kept separate from your medical records. You will not be named in any publications or reports about this research. Your medical records and study data may also be looked at by the regulatory authorities to check that the study is being carried out correctly.

Your anonymised study data will also be shared with our research collaborators at the University of Leicester. You are free to withdraw from the study at any point without giving a reason. However if you do withdraw from the study we will need to use the information collected up until the time that you decided to withdraw from the study and your data may still be shared with our research collaborators.

The anonymised data collected from you as part of this trial may be used in future research studies; this will be overseen by Global RECHARGE and the University of Leicester.

What is the legal basis for processing my personal information?
Under the General Data Protection Regulation (GDPR), some of the personal data which will be collected from you is categorised as "sensitive data". The processing of this data is necessary for scientific research in accordance with safeguards. This means that study has gone through an ethical committee to ensure that the appropriate safeguards are put in place with respect to the use of your personal data.

How long will my personal information be retained?
We will keep identifiable personal information about you for 5 years after the study has finished.

How will the anonymised data/results collected from me be used?
Data from the trial will be presented in reports, journal publications, conference papers and other academic outputs.

I have some more questions; whom should I contact?
If you require any further information, please do not hesitate to contact us on the details at the beginning of the information sheet.

National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

Study number:

Title of project:A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in slum areas of Jodhpur, Rajasthan.

Name of researcher: Dr.Arun Kumar Sharma, Director, NIIRNCD

INFORMED CONSENT FORM (Pulmonary Rehabilitation trial [Drop out interview]**)**

Patient identification number: _____

Taking Part	**Please initial to confirm agreement**
The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the University of Leicester ethics committee and the NIIRNCD ethics committee.	----------
I have read and understood the participant information sheet(Pulmonary Rehabilitation trial. Version number: 1.0) and this consent form.	----------
I have had an opportunity to ask questions about my participation.	----------
I understand that taking part in the project will involve participating in an interview that will be recorded (audio or video).	----------
I understand that personal information collected will include my name and date of birth. I understand I will be assigned a unique study identification number and my unique identification number and personal details will be stored on a secure enrolment log.	----------
I understand that the audio recordings taken during this interview will be converted to text but will remain anonymous.	----------
I understand that I am under no obligation to take part in the study, have the right to withdraw from this study at any stage for any reason, and will not be required to explain	----------

my reasons for withdrawing.

Use of Information

I understand that responsible persons and employees of the ethics committee will have access to my personal data for strict control and to ensure the correct conduct of the study whilst ensuring strict confidentiality will be maintained. ----------

I understand this research is in collaboration with the University of Leicester, UK and all anonymised data will be shared.

I understand that all the personal information I provide will be processed in accordance with data protection legislation on the public task basis and will be treated in strict confidence unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others or for audit by regulatory authorities. ----------

I understand that information I provide will be used in publications, reports, web pages and other academic and research outputs. ----------

I understand that personal information collected about me that can identify me, such as my name, will not be shared beyond the study team. ----------

I agree that information I provide can be quoted anonymously in research outputs. ----------

I give permission for the anonymised data I provide to be deposited in the data archive governed by the {NIIRNCD} so that it can be made publicly available for future research at the end of the project. ----------

I understand that anonymised data collected as part of this study may be used in future research. ----------

Consent to Participate

I voluntarily agree to take part in this study. ----------

Name of participant	[printed]	Signature	Date
Researcher	[printed]	Signature	Date

National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

Study number:

Title of project: A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in slum areas of Jodhpur, Rajasthan.

Name of researcher: Dr.Arun Kumar Sharma, Director, NIIRNCD

INFORMED CONSENT FORM (Participant focus groups-Post**)**

Patient identification number: _____

Taking Part	**Please initial to confirm agreement**
The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the University of Leicester ethics committee and the NIIRNCD ethics committee.	----------
I have read and understood the participant information sheet(Pulmonary Rehabilitation trial. Version number: 1.0) and this consent form.	----------
I have had an opportunity to ask questions about my participation.	----------
I understand that taking part in the project will involve participating in a focus group with other participants that will be recorded (audio or video).	----------
I understand that personal information collected will include my name, date of birth and medical history. I understand I will be assigned a unique study identification number and my unique identification number and personal details will be stored on a secure enrolment log.	----------
I understand that the audio recordings taken during this focus group will be converted to text but will remain anonymous.	----------
I understand that I am under no obligation to take part in the study, have the right to withdraw from this study at any stage for any reason, and will not be required to explain my reasons for withdrawing.	----------

Use of Information

I understand that responsible persons and employees of the ethics committee will have access to my personal data for strict control and to ensure the correct conduct of the study whilst ensuring strict confidentiality will be maintained. ----------

I understand this research is in collaboration with the University of Leicester, UK and all anonymised data will be shared. ----------

I understand that all the personal information I provide will be processed in accordance with data protection legislation on the public task basis and will be treated in strict confidence unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others or for audit by regulatory authorities. ----------

I understand that information I provide will be used in publications, reports, web pages and other academic and research outputs. ----------

I understand that personal information collected about me that can identify me, such as my name, will not be shared beyond the study team. ----------

I agree that information I provide can be quoted anonymously in research outputs. ----------

I give permission for the anonymised data I provide to be deposited in the data archive governed by the NIIRNCD so that it can be made publicly available for future research at the end of the project. ----------

I understand that anonymised data collected as part of this study may be used in future research. ----------

Consent to Participate

I voluntarily agree to take part in this study. ----------

_____		_____	_____
Name of participant	[printed]	Signature	Date
_____		_____	_____
Researcher	[printed]	Signature	Date

National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

Study number:

Title of project:A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in slum areas of Jodhpur, Rajasthan

Name of researcher: Dr.Arun Kumar Sharma,Director,NIIRNCD

INFORMED CONSENT FORM (Pulmonary Rehabilitation trial**)**

Patient identification number: _____

Taking Part	**Please initial to confirm agreement**
The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the University of Leicester ethics committee and the NIIRNCDethics committee.	----------
I have read and understood the participant information sheet(Pulmonary Rehabilitation trial. Version number: 1.0) and this consent form.	----------
I have had an opportunity to ask questions about my participation.	----------
I understand that personal information collected will include my name, date of birth and medical history. I understand I will be assigned a unique study identification number and my unique identification number and personal details will be stored on a secure enrolment log.	----------
I understand that I am under no obligation to take part in the study, have the right to withdraw from this study at any stage for any reason, and will not be required to explain my reasons for withdrawing.	----------
I understand that during the study period I may need to adhere to rules and requirements.	----------
I understand that depending on my health, the researcher has the right to exclude me from the study.	----------
I understand that I am required to inform the research team about prescriptions and recommendations I have received from other doctors	----------

I understand that relevant sections of my medical notes may be looked at by individuals from the research team and ethics committee ----------

Use of Information

I understand that responsible persons and employees of the ethics committee will have access to my personal data for strict control and to ensure the correct conduct of the study whilst ensuring strict confidentiality will be maintained. ----------

I understand this research is in collaboration with the University of Leicester, UK and all anonymised data will be shared. ----------

I understand that all the personal information I provide will be processed in accordance with data protection legislation on the public task basis and will be treated in strict confidence unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others or for audit by regulatory authorities. ----------

I understand that information I provide will be used in publications, reports, web pages and other academic and research outputs. ----------

I understand that personal information collected about me that can identify me, such as my name, will not be shared beyond the study team. ----------

I agree that information I provide can be quoted anonymously in research outputs. ----------

I give permission for the anonymised data I provide to be deposited in the data archive governed by the {NIIRNCD} so that it can be made publicly available for future research at the end of the project. ----------

I understand that anonymised data collected as part of this study may be used in future research. ----------

Consent to Participate

I voluntarily agree to take part in this study. ----------

Name of participant	[printed]	Signature	Date
Researcher	[printed]	Signature	Date

National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur

Study number:

Title of project: A Single-arm Feasibility Trial of Community-based Pulmonary Rehabilitation for Adults with COPD in slum areas of Jodhpur, Rajasthan

Name of researcher: Dr.Arun KumarSharma,Director,NIIRNCD

INFORMED CONSENT FORM (Pulmonary Rehabilitation trial [screening]**)**

Patient identification number: _____

Taking Part	**Please initial to confirm agreement**
The purpose and details of this study have been explained to me. I understand that this study is designed to further scientific knowledge and that all procedures have been approved by the University of Leicester ethics committee and the {NIIRNCD} ethics committee.	----------
I have read and understood the participant information sheet(Pulmonary Rehabilitation trial. Version number: 1.0) and this consent form.	----------
I understand that this consent form applies to the screening aspect of the study, and I may or may not be eligible to participate following this screening process.	----------
I have had an opportunity to ask questions about my participation.	----------
I understand that personal information collected will include my name, date of birth and medical history. I understand I will be assigned a unique study identification number and my unique identification number and personal details will be stored on a secure enrolment log.	----------
I understand that I am under no obligation to take part in the study, have the right to withdraw from this study at any stage for any reason, and will not be required to explain my reasons for withdrawing.	----------
I understand that during the study period I may need to adhere to rules and requirements.	----------
I understand that depending on my health, the researcher has the right to exclude me from the study.	----------
I understand that I am required to inform the research team about prescriptions and recommendations I have received from other doctors	----------

I understand that relevant sections of my medical notes may be looked at by individuals from the research team and ethics committee ----------

Use of Information

I understand that responsible persons and employees of the ethics committee will have access to my personal data for strict control and to ensure the correct conduct of the study whilst ensuring strict confidentiality will be maintained. ----------

I understand this research is in collaboration with the University of Leicester, UK and all anonymised data will be shared. ----------

I understand that all the personal information I provide will be processed in accordance with data protection legislation on the public task basis and will be treated in strict confidence unless (under the statutory obligations of the agencies which the researchers are working with), it is judged that confidentiality will have to be breached for the safety of the participant or others or for audit by regulatory authorities. ----------

I understand that information I provide will be used in publications, reports, web pages and other academic and research outputs. ----------

I understand that personal information collected about me that can identify me, such as my name, will not be shared beyond the study team. ----------

I agree that information I provide can be quoted anonymously in research outputs. ----------

I give permission for the anonymised data I provide to be deposited in the data archive governed by the {NIIRNCD} so that it can be made publicly available for future research at the end of the project. ----------

I understand that anonymised data collected as part of this study may be used in future research. ----------

Consent to Participate

I voluntarily agree to take part in this study. ----------

_____		_____		_____	
Name of participant	[printed]	Signature		Date	
_____		_____		_____	
Researcher	[printed]	Signature		Date	