



Study Title:

The needs, preferences and challenges for developing Pulmonary Rehabilitation: Survey and qualitative insights among various stakeholders

Study Protocol

Study code:

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Background:

India has the largest number of deaths due to chronic respiratory diseases (CRD) in the world. Asthma, COPD, Bronchiectasis, Interstitial Lung Disease and Post-TB lung disease are the commonest causes of chronic respiratory diseases in India, and according to estimates, at any given point of time there are approximately 100 million such cases in India.(1) Apart from appropriate pharmacotherapy, which has a limited role in the management of chronic conditions, pulmonary rehabilitation (PR) is an extremely important component of the disease management strategy for chronic respiratory diseases because it improves quality of life, reduces suffering, reduces mortality and reduces economic loss.(2,3) Globally, the disease management guidelines advise incorporation of PR in the treatment of CRDs.(4,5) However PR services are largely underutilized, especially in India.(6) Several factors related to unavailability of services, skilled resources for delivery and lack of awareness about PR among various stakeholders contribute to this scenario.(7–10) Also, the PR guidelines are based on the evidences and healthcare systems in the developed countries which may not be applicable in low-resource settings. This study aims to understand the needs and views of stakeholders regarding PR to inform appropriate PR services, including PR delivery and PR referral processes. The study will include key stakeholders involved in the disease management viz., patients, prospective PR referrers and medical practitioners (doctors, physiotherapists) involved in the delivery of PR. The overall outcome of this research study will form the basis of strategizing ways to develop culturally adaptable PR services to improve utilization of PR facilities by the patients. This study is being initiated under the purview of the Global RECHARGE project (Global Health Research Group on Respiratory Rehabilitation, 17/63/20) as a part of collaboration with National Institute for Health Research (NIHR), United Kingdom through the University of Leicester, United Kingdom and Symbiosis International (Deemed) University, Pune.

We have conducted a formative research and patient and public involvement on the topic to understand better the needs of patients and the Indian healthcare system for CRD management and inform the full study design and methodological approaches. This study utilizes a mixed method approach with quantitative and qualitative dimensions based on a convergent parallel design.

Research Questions:

1. What challenges do people living with CRD have in managing their condition?
2. What is the willingness of people living with CRD to attend PR?
3. What should PR look like to be appealing to people living with CRD?
4. What are the challenges for health care personnel to refer to PR? What is needed to devise a suitable referral service for PR?
5. What factors do health care personnel consider important if referring to PR?

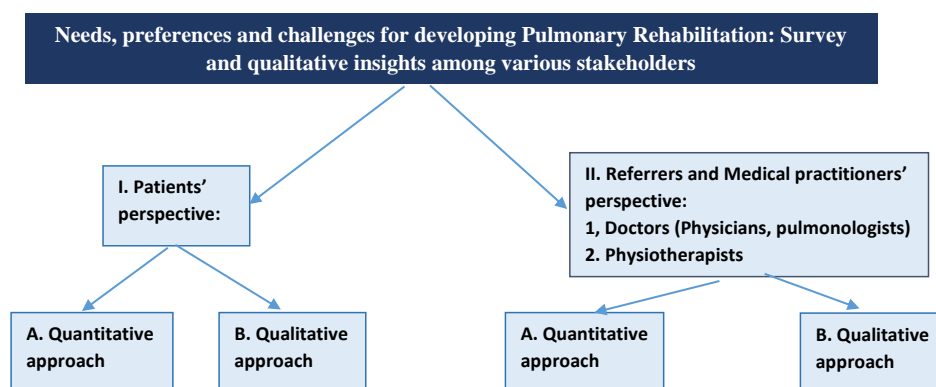
Objectives:

1. To determine the need for PR from people living with CRD.
2. To determine the preferred modes and structure of PR delivery of people living with CRD.
3. To obtain information on the model of PR care that is acceptable to patients.
4. To obtain information on the attitudes and beliefs of prospective PR referrers and medical practitioners who would deliver PR.
5. To obtain the views of these health care personnel on barriers to setting up a referral service for PR.

Study Details:

Mixed methods of quantitative and qualitative research approaches with convergent parallel design will be utilized to obtain a breadth and depth of responses.

1. STUDY METHODOLOGY



I. Patients:

Patients are the most important stakeholders in any healthcare service. This component of the study will capture the needs and requirements of CRD patients as regards to PR services. This will also help in understanding the patient perspective of the utilization of PR.

I.A. Quantitative Approach:

Study design: Cross-sectional observational study

Study setting: Pune city and urban outgrowths

Sample size: Minimum 100

Sampling strategy: Purposive sampling

Study population:

Inclusion criteria:

- Physician diagnosed chronic respiratory disease
- Patients must be willing to provide a written informed consent

Exclusion criteria:

- Patients not willing to participate in study

Research Tool: Interviewer administered questionnaire

Questionnaire will focus on following factors:

- Demographics
- Needs and requirements of PR among CRD patients
- Modes of delivery of PR to the patients
- Acceptable models of PR
- Willingness to participate in PR programs

Recruitment strategy and data collection:

The patients seeking care at Symbiosis University hospitals, Lavale will be invited to participate in the study. Given the risk of contagion from the COVID-19 pandemic, we will take a hierarchical approach to data collection: (1) data collection in person with all the required precautionary measures or (2) over telephonic/video calls or (3) online surveys. The participants will be given an idea about the study setting and the nature of the study. Verbal or written consents will be obtained as suited to the data collection procedures.

I.B. Qualitative approach:

The objective of the qualitative arm is to understand the views, experiences, perspectives, reasons and attitudes towards PR. The qualitative approach will surface the issues that may not be covered through quantitative methods using structured questionnaires as well as provide rich in-depth insights into the needs of patients and the optimal design and delivery of PR. The issues that surface through the qualitative approaches will directly inform service development and future research activities.

Study methodology: In-depth interviews

Sample size: Up to 20 patients

Sampling methodology: Convenient sampling

Patients invited for qualitative study will be different from the quantitative participants to remove contamination from the survey questions and response options.

I.B.4. Study Setting: Symbiosis University Hospitals and Research Centre and Symbiosis Medical College for Women, Lavale, Pune

I.B.5. Study Population:

Inclusion criteria:

- Physician diagnosed chronic respiratory diseases
- Patients must be willing to provide consent

Exclusion criteria:

- Patients not willing to participate in study
- Patients with hearing impairments (if unable or unwilling to attend a face-to-face visit)

- Patients with impairments related to articulation and speech (if only willing or able to attend face-to-face visit)

I.B.7. Recruitment strategy and data collection:

The patients seeking care at Symbiosis University hospitals, Lavale will be invited to participate in the study. Given the risk of contagion from the COVID-19 pandemic, we will take a hierarchical approach to data collection: (1) data collection in person with all the required precautionary measures or (2) over telephonic/video calls or (3) online surveys. The participants will be given an idea about the study setting and the nature of the study. Verbal or written consents will be obtained as suited to the data collection procedures. The participants will be given an idea about the study setting and the nature of the study. They will be briefed about the audio recordings of the proceedings and written consent will be obtained. The points to be discussed are enlisted in the schedule. These points have been derived based on formative research and literature. Each interview will have the same schedule and the interviewer will probe the patient as required. The facilitator will direct the discussion based on the patient's responses.

I. Referrers and Medical practitioner's perspective:

Referrers and Medical practitioners are the most important stakeholders in the service delivery as well as referrals that indirectly determine the patient uptake of PR. The referrers and medical practitioners include doctors, and physiotherapists. This will provide insight on the needs, requirements and to get an insight on the attitudes and beliefs around PR among referrers and medical practitioners involved in CRD care of patients. To understand their opinions on the preferred models of PR and modes of delivery of PR and perceived barriers on setting up and maintaining PR services.

II.A. Quantitative approach:

Study Methodology:

The quantitative arm of this study will be a *cross-sectional survey* for the referrers and medical practitioners.

Research tool: Self-administered questionnaire

Questionnaire will focus on following factors:

- Demographics
- Information about their roles in care of CRD patients
- Opinions about barriers, facilitators and needs around PR referrals, initiating and maintaining PR services
- Attitudes of Referrers and Medical practitioners will be captured based on willingness to refer patients to PR
- Perceptions about Pulmonary rehabilitation like worth of PR, belief in evidence of usefulness, cost effectiveness, opinions on how the PR programme should be delivered

Recruitment strategy and data collection for Referrers and Medical practitioners: The study will include physicians, pulmonologists, and physiotherapists from Pune city and

urban outgrowths. Given the risk of contagion from the COVID-19 pandemic, we will take a hierarchical approach to data collection: (1) data collection in person with all the required precautionary measures or (2) over telephonic/video calls or (3) online surveys. The participants will be given an idea about the study setting and the nature of the study. Verbal or written consents will be obtained as suited to the data collection procedures.

II.i.Doctors:

Sampling methodology: Purposive sampling

Sample size: Minimum 50

Inclusion criteria:

- Medical practitioners involved in practice of Respiratory medicine, Chest physicians, Surgeons involved in cardio-thoracic surgeries.
- Educational qualification of MBBS and MD/DNB/MS, with pulmonary / Respiratory practice

II.ii. Physiotherapists:

Sampling methodology: Purposive sampling

Sample size: Minimum 50

Inclusion criteria:

- Practising Physiotherapists in Multispecialty hospitals, small hospitals, clinics, etc
- Educational qualification with BPT / MPT

II.B. Qualitative

Based on grounded theory, the objective of the qualitative arm is to understand the reasons and attitudes that contribute to the current practices of rehab utilization. The qualitative approach will uncover issues that may not be covered through quantitative methods using structured questionnaires. The issues that surface through the qualitative approaches will inform service development.

The qualitative arm of the study aims to focus on understanding the barriers and facilitators to initiate and maintain the PR services. The in-depth discussions with the Referrers and Medical practitioners will also give an insight into the needs of referral pathways and accessibility to the PR services.

II.B.1. Study methodology: Semi-structured interviews will be conducted for referrers and Medical practitioners. Given the risk of contagion from the COVID-19 pandemic, we will take a hierarchical approach to data collection: (1) data collection in person with all the required precautionary measures or (2) over telephonic/video calls or (3) online surveys. The participants will be given an idea about the study setting and the nature of the study. Verbal or written consents will be obtained as suited to the data collection procedures.

I.B.2. Sample size:

Doctors: Up to 10

Physiotherapists: Up to 10

Since it is a qualitative interview, we will approach up to 10 doctors and physiotherapists respectively until the saturation point of information is achieved.

II.B.3. Sampling methodology: Purposive sampling

Healthcare providers invited for qualitative study will be different from the quantitative participants.

II.B.4. Study Setting: Pune city and urban outgrowths

Data management and Statistical methods

A. Quantitative:

Data management

The data will be entered in excel format and when available in batches.



Data will be collected and checked for completion and quality



Cases not passing the QA will be rechecked and re-entered



Clean data will be locked



Data analysis will be performed on SPSS (Version 23)

Commented [OMW1]: If helpful, we could create the survey on REDCap so you could enter data directly into data management system

Advantage – saves time for data entry for F2F administration
Disadvantage – no source verification records

Commented [OMW2]: Can be done through REDCap (automated)

Statistical Methods

Dataset for analysis: The entire study population who have completely filled the questionnaire will be included for analysis.

The demographic characteristics of the patients will be analysed using descriptive statistics. Continuous variable such as age, years in practice will be presented by mean, median, SD, 95% confidence interval of mean, range (minimum, maximum). Categorical variables will be presented by frequencies and percentages. Graphical presentation will be used for visual representation of the data.

B. Qualitative:

Qualitative data will be analysed 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 interview 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 data.

Ethical Considerations:

The study will be reviewed by the Independent Ethics committee of Symbiosis International University, Lavale, Pune which is registered with the Drug Controller General of India. The Independent Ethics committee at University of Leicester, UK will review the study.

Ethical Considerations will specifically be sought for approval to administer questionnaires and in depth interviews among all participants of the study including patients, doctors, and physiotherapists. There are no drug interventions in this study.

Details of payment to participants

In this study, a survey questionnaire regarding needs, perceptions and challenges around pulmonary rehabilitation services will be administered by investigators by meeting all eligible participants at their residence or convenient place of their preference or they will be contacted through telephonic calls. As they will not be invited to study centre for questionnaire interviews, they will not be paid for their participation. However, the participants (patients) called for qualitative interviews will be paid a monetary compensation of Rs. 500/- per visit towards their loss of wages and travel expenditure when they will be expected to visit the research centre. Participants may be provided with refreshment during their visits for qualitative interviews. Patients will not be paid in-kind for their participation. Break-up of payment is described below –

Nature of participation	No. of patients	No. of visits	Compensation per patient per visit (INR)
Qualitative interviews	20	1	500/-

Participants will sign a voucher against which s/he will be paid. All such vouchers will be verified and documented by project PI. Project team would notify the IEC about the payment to participants through periodic updates as applicable.

Publication Policy:

All data, results and intellectual property rights in the data and results derived from the study will be the property of the research group who may utilize the data in various ways, such as for submission to government regulatory authorities or international and national peer-reviewed journals, and presentations at national and international meetings and conferences.

The expected endpoints of the project:

- Insight on current Pulmonary rehabilitation needs around modes delivery of PR, models of PR, referral pathways
- Information on challenges and facilitators to implement and participate in the PR programmes for all the stakeholder
- The outcome of this research intends to set the backdrop for a need for preferred PR models and referral pathways among Referrers and Medical practitioners on Pulmonary Rehabilitation and also form the basis of strategizing ways to improve utilization of Pulmonary Rehabilitation facilities by the patients.

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