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Development and pilot testing of health worker delivered theory of planned behaviour based educational intervention for behaviour change in chronic respiratory disease patients: A feasibility study in southern Indian rural community

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Declaration

I confirm that this thesis presented for the degree of Doctor of Philosophy of Population Health Sciences, has

1. i) been composed entirely by myself
2. ii) been solely the result of my own work
3. iii) not been submitted for any other degree or professional qualification

Biswajit Paul

Abstract

Introduction

Chronic respiratory diseases (CRDs) are one of the major causes of mortality and morbidity worldwide. Low- and middle-income countries (LMICs) account for 80% of the total burden of CRDs and mortality. CRDs are the second most common cause of all deaths in India and contributed to almost 30% of all deaths and DALYs due to CRDs globally in 2019. Most of these chronic diseases including CRDs are related to risk behaviours and therefore modifying health behaviours are crucial in improving chronic diseases outcomes, with the potential to reduce the enormous morbidity and mortality associated with such diseases. The Theory of Planned Behaviour (TPB) had been used extensively, mostly in western countries and in affluent populations to predict health behaviour or deliver interventions to change health behaviour. The research in my thesis was designed to test the feasibility of implementing a TPB-based health intervention in changing health behaviour, using health care workers (HCWs), in a rural, low literacy population.

Aim and Objectives

The aim of my research project was to develop and pilot test HCW-delivered TPB-based health intervention for behaviour change in patients with chronic respiratory disease (CRD) using current evidence in practice and drawing on past experience of delivering culturally sensitive health programmes adapted for low health literacy communities. The objectives were – 1) To examine the effect of TPB-based interventions in chronic diseases in low health literacy settings through a systematic review of literature 2) To develop a culturally acceptable and locally adaptable TPB-based intervention model for behaviour change in patients with chronic respiratory disease 3) To examine through a feasibility study, whether successful outcomes of TBP-based interventions found in the literature could be reproduced in a low-resource setting, and identify the implementation challenges in these settings.

Methods

My research methods were informed by the new UK Medical Research Council (MRC) guidance and update 2019 for developing and evaluating complex interventions; they included identifying evidence, developing/identifying a theory, modelling processes and outcomes (intervention development), feasibility testing, evaluation and implementation (dissemination of findings)**.** The research work proceeded in four phases –

1. I began studying the existing evidence through a systematic review of literature, following Cochrane review methods. The review examined the feasibility and effectiveness of TPB-based interventions on chronic disease patients to change health behaviour, particularly in low health literate populations of LMICs. I used a Population, Intervention, Comparison, Outcome and Study design (PICOS) search strategy and duplicate screening, data extraction and Cochrane Collaboration tool for quality assessment. Narrative synthesis was conducted due to heterogeneity of studies.
2. In the second phase I conducted formative qualitative research in my target population to examine prevailing attitudes, subjective norms perceived behavioural control and underlying beliefs related to CRDs – while exploring the experiences of those living with the disease. Qualitative data were collected between September and December 2018 through eight focus group discussions (FGDs), five in-depth interviews and four key-informant interviews from patients and community members. Community engagement and awareness-raising was undertaken prior to the study and all interviews and discussions were recorded with permission. Inductive coding was used to thematically analyse the results.
3. In the third phase, I developed the intervention by modelling processes and outcomes. A TPB-based evaluation questionnaire was developed with guidance from the results of the formative research, it was validated by pilot testing, content validity and reliability. Development of the methods and intervention took account of cultural sensitivity and the local customs. The intervention was refined using the Template for Intervention Description and Replication (TIDieR) checklist and guide.
4. In the final phase I tested the intervention for its feasibility and effectiveness using a cluster randomised design. Four of the 18 clusters from the ‘community

development block' (administrative unit of government in the local community) where our hospital is situated, were chosen for the intervention with two in the intervention arm and two in the control. 100 patients with confirmed CRD (asthma, COPD, bronchiectasis, post tuberculosis lung disease) were recruited in each arm of the study. Patients in both arms were provided with free inhalers with spacers, training on breathing exercises and some basic education materials on CRDs. In the intervention arm, patients received TPB-based educational intervention using culturally acceptable media and methods; some created with suggestions from patients and community members. The TPB constructs (attitude towards behaviour, subjective norms, perceived behavioural control and intention) were evaluated at baseline and at the end of the intervention period - health behaviour and clinical outcomes were also measured.

Results

1. My systematic review's search strategy produced 4284 studies of which four were included for narrative synthesis. Among the four studies, the intervention period was between four months to one year, they were from LMIC settings, and all were conducted in urban populations. The review findings suggested TPB-based psychological theory could be effectively applied in these LMIC settings and suggested interventions based on TBP theory were feasible – although only a few such studies were identified and interventions were typically of a shorter duration (~4-5 months). TPB-based interventions were undertaken for chronic diseases including osteoarthritis, diabetes mellitus and cardiovascular diseases (myocardial infarction), but no such study was identified for chronic respiratory disease. Two of the studies specifically described formative research before undertaking a TPB-based intervention.
2. The formative qualitative research elicited important beliefs, perceptions, attitudes, norms and behaviours prevailing in this local community. There was generally poor understanding of the diseases or their causation; health seeking behaviour commonly involved conventional health services, but many sought treatment directly from pharmacies for symptomatic relief and/or alternative/traditional health providers; common treatment modalities were oral medicines for symptom relief in less severe conditions (contrary to accepted

practice) and use of injections and nebulisations for emergencies and relief of severe symptoms. Prevailing risk behaviours for CRD included smoking and use of biomass fuel, which were common in the community, the former particularly among males and latter in households – for cooking. The use of inhalers was infrequent and inadequate, mainly for immediate and symptomatic relief. There was no awareness or practice of respiratory exercises among patients with CRD; health providers typically gave no advice on the topic, and associated facilities were rarely accessed by participants.

3. The evaluation questionnaire (Appendix 13) developed for baseline and post-intervention assessment had four sections – identifying information, socio-demographic information, the TPB questionnaire and the HBM questionnaire. The TPB questionnaire had a total of 61 questions with 31 questions on intention, attitude, subjective norm and perceived behavioural control and the rest on their underlying beliefs. The screening questionnaire for health care workers (HCWs), the Clinical Assessment and Review form and the TPB intervention were designed and developed as part of my project (embedded within a larger feasibility trial). The TPB intervention comprised motivational videos, 'ask your doctor' videos about asthma and COPD, a calendar showing steps of inhaler use and breathing exercises, puppet shows answering frequently asked questions in form of a play, a school painting competition on CRDs and engaging the patients and the public through interaction with doctors and other health providers.
4. The two objectives of this phase were: pilot testing the intervention for its feasibility and implementation challenges; and evaluation of the effectiveness of the TPB intervention. The overall screening rate by the HCWs was 52.8%, the confirmation rate among the screened participants was 91.3% and all the confirmed patients of CRD could be recruited. The early dropout rate was 4.5% (after recruitment and before start of intervention) and the final completion rate at the end of one year of intervention was 89%. Health workers involved in the project were capable of all key project elements, including screening, health education and follow-up. There was significant improvement in the constructs of TPB (attitudes, subjective norms, perceived behavioural control) and in CRD-

related health behaviour at the end of intervention period - however this was seen in both intervention and control arm. There was significant improvement in adherence to inhalers (from 78% to 94%, $p<0.001$) and in symptoms (cough, phlegm and breathlessness) post intervention. Episodes of exacerbations decreased dramatically ($p<.001$) and lung function remained static or improved in 69.6% of the patients.

Conclusion

This TPB-based intervention was developed using evidence from systematic review of existing literature, and through eliciting the salient beliefs and prevailing TPB constructs by conducting formative qualitative research. This research study has established the feasibility of such an intervention and its usefulness in changing health outcomes for CRD patients, utilising HCWs in resource poor, low health literacy population settings. Although the intervention was effective in improving health behaviour and clinical outcomes, no significant difference between the intervention and control was observed. It was, however, a feasibility study, and not powered to demonstrate differences between key outcomes. Further, part of the intervention was similar in both arms, impacting on health behaviours. Improving capability was a more important first step and needs to be supplemented by motivation through TPB interventions, perhaps for a longer duration and on a sustainable scale over time to show differences between two arms. The study also establishes the feasibility of TPB-based interventions for changing health behaviour and puts a case for a definitive trial for further evaluation, with the potential to inform policy on adopting behaviour change interventions for improving outcomes in chronic respiratory disease patients, specifically in LMICs.

Lay Summary

Chronic respiratory diseases (CRDs) are a global health problem, affecting people in high income as well as low-income countries alike. The numbers of such affected people and deaths due to these diseases are enormous in low- and middle-income countries in comparison to developed countries. Ignorance about disease manifestations, poor accessibility, affordability to health care and prevalence of risk behaviours all contribute to such burden. Health behaviour plays an important role in initiation and progression of CRDs, and through behaviour change can these diseases be controlled. Among the different psychological theories for behaviour change, Theory of Planned Behaviour (TPB) has been used widely and has been reported to be successful in predicting behaviour through intention by changing the attitude towards behaviour, social norms and perceived control and their underlying beliefs. Most of such studies have been done in high income countries and in well-educated population. This research study was undertaken with an aim to examine the feasibility and usefulness of developing and pilot testing an intervention, applying theory of planned behaviour, in chronic respiratory disease patients in a poor, low health literate population, using local health care workers to deliver it.

Current evidence about TPB-based intervention was gathered using a systematic review. Four studies, all from LMICs on chronic disease patients, established that TPB-based interventions are possible and also are useful in changing TPB constructs and clinical outcomes. In two studies, formative research was helpful before implementing such an intervention. Eight focus group discussions, five in-depth interviews and four key informant interviews were conducted among patients of CRDs and the different community members to explore their experiences of living with the diseases and the prevailing beliefs and practices. Risk behaviours like use of biomass fuel (firewood, leaves, dung cakes) for cooking and smoking handmade cigarettes among men was common. Stigma and social exclusion for such patients was present in the community. Health seeking for respiratory symptoms was restricted to local pharmacies, use of inhalers was limited and breathing exercises to improve symptoms was uncommon. The systematic review and the qualitative research informed me in developing the TPB intervention which included provision of inhalers, training for use

of inhalers and spacers, breathing exercises, motivational videos, ask your doctor videos about asthma and COPD and puppet shows. The community trial was conducted with an intervention and control group. The intervention was successfully carried out with good response to recruitment and few drop-outs at the end of one year. Health workers were useful in intervention delivery and capable of screening, health education and follow-up. At the end of the intervention period, improvement in attitude, subjective norms and perceived control was noted, in both the arms, and a significant improvement in symptoms, adherence to inhaler use and clinical outcomes was also observed. This study was not designed to estimate the difference in outcomes; however it established the feasibility of TPB based behaviour change interventions in chronic respiratory disease patients of resource poor LMIC settings.

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Publications

1. **Paul B**, Isaac R, R. H, Jebaraj P, S. M, Das D, et al. (2021) Development of an educational intervention to reduce the burden of adult chronic lung disease in rural India: Inputs from a qualitative study. PLoS ONE 16(7): e0254534. https://doi.org/10.1371/journal.pone.0254534
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Presentations

1. Poster – Chronic Respiratory Disease and Lung Cancer: Development and pilot testing of an Educational intervention in a southern Indian rural community (RESPIRE Annual Scientific Meeting (ASM), 29-30 May, 2018, Porto, Portugal)
2. Poster – Chronic Respiratory Disease and Lung Cancer: Development and pilot testing of an Educational intervention in a southern Indian rural community (9th IPCRG World Conference, 31 May- 2 June, 2018, Porto, Portugal)
3. Poster – Theory of Planned Behaviour (TPB) based evaluation tool for Chronic Respiratory Disease (CRD) Patients: Development and Implementation (RESPIRE ASM, 10-12 September 2019, Kuala Lumpur, Malaysia)
4. Oral and poster – Development of a complex intervention to improve knowledge, attitude and promote behaviour change for chronic respiratory disease (CRD) patients in low and middle-income countries (LMIC) (RESPIRE ASM, 10-12 September 2019, Kuala Lumpur, Malaysia)
5. Oral – Improving health behaviour in patients with chronic respiratory disease using theory of planned behaviour-based educational intervention: Development and Pilot testing in rural south India (RESPIRE ASM Three Minute Thesis-style Presentation, RESPIRE ASM 24-25 November, 2020, Virtual/Online)
6. Oral (TAPAS presentation) – Improving patient behaviour and community awareness about asthma and COPD: role of health care workers in a rural setting of a LMIC – learnings from the field (10th IPCRG World Conference 28-30 May, Dublin, Ireland held virtually from 6-8 May 2021 from Dublin, Ireland)
7. Oral – Development and pilot testing of theory of planned behaviour based intervention for behaviour change in chronic respiratory disease patients: A study in southern Indian rural community (3-minute thesis presentation at CPHS Seminar, University of Edinburgh, held on 14 June 2021)
8. Poster with narration – Qualitative study informs the development of educational intervention for behaviour change to reduce adult chronic lung

disease in rural India (ERS Congress, 2021 held virtually from 5-8 September, 2021)

9. Poster with narration – Behaviour change in chronic respiratory disease patients through health care worker delivered theory of planned behaviour-based educational intervention: results from a pilot feasibility study (ERS Congress, 2021 held virtually from 5-8 September, 2021)
10. Oral – Engaging patients and communities for the CRD care (International Conference at Goa for RESPIRE dissemination held on 4-5 April 2022)
11. Oral – Review of prevalence and challenges of care for CRD in India and other LMIC (International Conference at Goa for RESPIRE dissemination held on 4-5 April 2022)
12. Oral – CME for network of lung medicine practitioners in Vellore district (International Conference at Goa for RESPIRE dissemination held on 4-5 April 2022)
13. Poster – Community based pulmonary rehabilitation among chronic respiratory disease patients using peer volunteers: A feasibility study in rural south India (11th IPCRG World Conference, 5-7 May 2022, Malaga, Spain)
14. Oral – Pulmonary rehabilitation using peer volunteers in a rural Indian setting: A feasibility study (ERS Congress, 4-6 September 2022, Barcelona, Spain)

Acronyms

ACOS	Asthma-COPD Overlap Syndrome
AIDS	Acquired Immuno-Deficiency Syndrome
ANOVA	Analysis of Variance
ASHA	Accredited Social Health Activist
ASIR	Age Specific Incidence Rate
ASM	Annual Scientific Meeting
ASPR	Age Specific Prevalence Rate
BMC	BioMed Central
BMI	Body Mass Index
BOLD	Burden of Obstructive Lung Disease (study)
CA	Control Arm
CAC	Community Advisory Committee
CD	Compact Disc
CDB	Community Development Block
CDC	Centres for Disease Control and Prevention
CMC	Christian Medical College
CME	Continuing Medical Education
CMNND	Communicable, Maternal, Neonatal and Nutritional Diseases
CONSORT	Consolidated Standard for Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus disease
CRD	Chronic Respiratory Disease
CVD	Cardiovascular Disease
DALY	Disability Adjusted Life Year

EAPC	Estimated Daily Percentage Change
ECHRS	European Community Respiratory Health Survey
ERS	European Respiratory Society
ETL	Epidemiological Transition Level
FCV	Family Care Volunteer
FGD	Focus Group Discussion
GARD	Global Alliance Against Chronic Respiratory Diseases
GBD	Global Burden of Disease
GMF	Global Monitoring Framework
HA	Health Aide
HAP	Household Air Pollution
HBM	Health Belief Model
HCP	Health Care Providers
HCW	Health Care Worker
HIC	High Income Countries
HIV	Human Immunodeficiency Virus
HRQoL	Health Related Quality of Life
IA	Intervention Arm
IDI	In-depth Interview
ILD	Interstitial Lung Disease
IPCRG	International Primary Care Respiratory Group
IRB	Institutional Review Board
KII	Key Informant Interview
LMIC	Low-and-Middle Income Country
MeSH	Medical Subject Headings

MRC	Medical Research Council
NCD	Non-Communicable Disease
NPCDCS	National Programme for prevention and control of Cancer, Diabetes, Cardiovascular Diseases and Stroke
OPD	Outpatient Department
PBC	Perceived Behavioural Control
PhD	Doctor of Philosophy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PRISMA-P	Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols
PROSPERO	International prospective register of systematic reviews
PSU	Peripheral Service Unit
PTLD	Post Tuberculosis Lung Disease
RESPIRE	Global Health Research Unit on Respiratory Health
RCO	Rural Community Officer
RUHSA	Rural unit for Health and Social Affairs
SARS	Severe Acute Respiratory Syndrome (SARS)
SCT	Social Cognitive Theory
SDG	Sustainable Development Goal
SDI	Socio-demographic Index
SES	Socio-economic status
SGRQ	St. George's Respiratory Questionnaire
SR	Systematic Review
TAI	Test of Adherence to Inhalers
TIDieR	Template for Intervention Description and Replication

TTM	Transtheoretical model
TPB	Theory of Planned Behaviour
UI	Uncertainty Interval
UK	United Kingdom
USNCHS	United States National Centre for Health Statistics
WHA	World Health Assembly
WHO	World Health Organisation
YLD	Years of Life lost due to Disability
YLL	Years of Life Lost (due to premature death)

Glossary

Age standardised rates (ASIR and ASPR) Age standardised incidence rate and Age standardised prevalence rate

An age-standardized rate is a weighted average of the age-specific rates, where the weights are the proportions of a standard population in the corresponding age groups. The potential confounding effect of age is removed when comparing age-standardized rates computed using the same standard population. Both ASIR and ASPR are calculated per 100 000 population.

AIDS: Acquired Immunodeficiency Syndrome

Disease due to infection with the human immunodeficiency virus (HIV).

Asthma

Asthma is a long-term condition affecting children and adults caused by airflow obstruction. The air passages in the lungs become narrow due to inflammation and tightening of the muscles around the small airways. Bronchial obstruction is usually reversible and between asthma episodes the flow of air through the airways is usually good.

CMNND: Communicable, Maternal, Neonatal and Nutritional Diseases

CMNND group is one of the three major groups for causes of deaths and disabilities under GBD study. This aggregate cause contains seven Level 2 causes: HIV/AIDS and sexually transmitted infections, respiratory infections and tuberculosis, enteric infections, neglected tropical diseases and malaria, other infectious diseases, maternal and neonatal disorders, and nutritional deficiencies.

COPD: Chronic obstructive pulmonary disease

Chronic obstructive pulmonary disease (COPD) is a common, preventable and treatable chronic lung disease which affects men and women worldwide. It is a chronic inflammatory lung disease that causes obstructed airflow from the lungs.

COVID-19: Coronavirus disease (2019)

COVID-19 is an infectious disease caused by the SARS-CoV-2 virus. Most people infected with the virus will experience mild to moderate respiratory illness but some will become seriously ill and require medical attention. Older people and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer are more likely to develop serious illness.

CVD: Cardiovascular disease

Cardiovascular disease covers a wide array of disorders, including diseases of the cardiac muscle and of the vascular system supplying the heart, brain, and other vital organs. The most common manifestations of CVD are ischemic heart disease, congestive heart failure, and stroke.

DALY: Disability Adjusted Life Years

DALY is a measure of the gap in healthy years of life lived by a population as compared with a normative standard. More formally, DALYs are a time based measure which adds together years of life lost due to premature mortality with the equivalent number of years of life lived with disability or illness. One DALY represents the loss of the equivalent of one year of full health.

Epidemiological transition

The process whereby major communicable diseases and conditions of poverty (e.g., malnutrition) are progressively replaced by non-communicable diseases such as cancers and CVD.

ETL states: Epidemiological Transition Level states

ETL state groups were defined on the basis of the ratio of DALYs from communicable, maternal, neonatal, and nutritional diseases (CMNNDs) to those from non-communicable diseases (NCDs) and injuries combined in 2016, with a lower ratio indicating higher ETL: low ETL (ratio 0·56–0·75), lower-middle ETL (0·41–0·55), higher-middle ETL (0·31–0·40), and high ETL (<0·31). Epidemiological transition ratios of the states of India have a significant inverse

relation with the Socio-demographic Index (SDI) calculated by GBD based on income, education, and fertility levels, suggesting broad correspondence between the ETL state groups and socio- demographic development levels.

GARD: Global Alliance Against Chronic Respiratory Diseases

The Global Alliance Against Chronic Respiratory Diseases (GARD) is a voluntary alliance of national and international organizations, institutions, and agencies committed to the vision of "a world where all people breathe freely."[1,2] Its goal is to reduce the global burden of chronic respiratory disease (CRD).

GBD: Global Burden of Disease

GBD is a comprehensive demographic and epidemiological framework to estimate health gaps for an extensive set of disease and injury causes, and for major risk factors, using all available mortality and health data and methods to ensure internal consistency and comparability of estimates. It is the most comprehensive worldwide observational epidemiological study to date and offers a powerful resource to understand the changing health challenges facing people across the world in the 21st century.

GBD levels for causes

GBD classifies causes in a hierarchy of four levels. Diseases and injuries were organised into a levelled cause hierarchy from the three broadest causes of death and disability at Level 1 to the most specific causes at Level 4.

Level 1 causes are aggregates of non-communicable diseases; injuries; and a category combining infectious diseases, maternal and neonatal disorders, and nutritional deficiencies. There are three level 1 causes.

At Level 2, there are 22 disease and injury aggregate groupings such as respiratory infections and tuberculosis, cardiovascular diseases, and transport injuries.

Level 3 includes specific causes such as tuberculosis, stroke, and road injuries. In some cases, these Level 3 causes are the most detailed classification, whereas for others a more detailed category is specified at Level 4. There are 174 level 3 causes.

Examples of Level 4 causes include latent tuberculosis infection, ischaemic stroke, and pedestrian road injuries. There are 301 Level 4 causes (including 131 Level 3 causes that are not further disaggregated at Level 4.

GBD super-region(s)

The GBD regional classification system created super regions based on two criteria - epidemiological similarity and geographic closeness. There are seven GBD super-regions – South-East Asia, East Asia and Oceania; South Asia; North Africa and Middle East; sun-Saharan Africa; Latin American and Caribbean; Central Europe, Eastern Europe and Central Asia; High Income

GMF: Global Monitoring Framework

Following the Political Declaration on Noncommunicable Diseases (NCDs) adopted by the UN General Assembly in 2011, WHO developed a global monitoring framework to enable global tracking of progress in preventing and controlling major noncommunicable diseases – cardiovascular disease, cancer, chronic lung diseases and diabetes – and their key risk factors. The framework is comprised of nine global targets and 25 indicators aimed at combatting global mortality from the four main NCDs, accelerating action against the leading risk factors for NCDs and strengthening national health system responses.

H1N1 flu

The H1N1 flu, commonly known as swine flu, is primarily caused by the H1N1 strain of the flu (influenza) virus. H1N1 is a type of influenza A virus, and H1N1 is one of several flu virus strains that can cause the seasonal flu. Symptoms of the H1N1 flu are the same as those of the seasonal flu. This virus is a combination of viruses from pigs, birds and humans that causes disease in humans.

HIC: High income Country

HIC is a category in the World Bank income grouping of countries used for countries with Gross National Income (GNI) per capita of $13,205 or more calculated using the World Bank Atlas method in 2021.

HIV: Human Immunodeficiency Virus

HIV is an acronym for the Human Immunodeficiency Virus, the cause of AIDS (acquired immunodeficiency syndrome).

LMIC: Low- and middle-income Country

A category in the World Bank income grouping of countries used for countries with Gross National Income (GNI) per capita of less than $13,205 calculated using the World Bank Atlas method in 2021.

Risk Factor

A risk factor is an attribute or exposure which is causally associated with an increased probability of a disease or injury.

SARS: Severe Acute Respiratory Syndrome

SARS is a viral respiratory disease caused by a SARS-associated coronavirus. SARS is an airborne virus and can spread through small droplets of saliva in a similar way to the cold and influenza. It was the first severe and readily transmissible new disease to emerge in the 21st century and showed a clear capacity to spread along the routes of international air travel.

SDI: Socio-demographic Index

SDI is is a composite indicator of a country's lag – distributed income per capita, average years of schooling, and the fertility rate in females under the age of 25 years

Sensitivity analysis

Systematic investigation of the effects on estimates or outcomes of changes in data or parameter inputs or assumptions.

Standard Population

A population structure that is used to provide a constant age or covariate distribution, so that the age- and sex-specific rates within different populations can be applied to it and can be compared without confounding by the different age or covariate distributions of the populations.

STI: Sexually transmitted infection

An infection that can be transferred from one person to another through sexual contact. Among the sexually transmitted infections (STIs) are HIV/AIDS, chlamydia, genital herpes, gonorrhea and syphilis. The term "sexually transmitted infection (STI)" corresponds to the older term "sexually transmitted disease (STD)".

Uncertainty analysis and Uncertainty Interval (UI)

Estimation of range or distribution of uncertainty in estimates based on an assessment of the uncertainty or confidence intervals for all data and parameter inputs. Uncertainty intervals (UI) should ideally include all sources of uncertainty, including those arising from systematic biases and measurement error. In contrast, generally reported confidence intervals are based solely on the variation observed in sample data.

YLD: Years of healthy life lost due to disability (YLD)

The component of the DALY that measures lost years of healthy life through living in health states of less than full health. YLDs expressed per 100 000 population. One YLD represents the equivalent of one full year of healthy life lost due to disability or ill-health.

YLL: Years of Life Lost

The component of the DALY that measures years of life lost due to premature mortality. YLLs expressed per 100 000 population. YLLs are calculated from the number of deaths multiplied by a global standard life expectancy at the age at which death occurs.

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12. Screening questionnaire
13. Evaluation questionnaire including TPB section
14. St. George's Respiratory Questionnaire
15. Test of Adherence to Inhalers (TAI) questionnaire (Tamil)
16. Clinical Assessment and Review Form
17. Calendar of steps of inhaler use and respiratory exercises

Chapter 1

Introduction

"The lives of too many people in the world are being blighted and cut short by chronic diseases such as heart disease, stroke, cancer, chronic respiratory diseases and diabetes." – Dr LEE Jong-Wook, the late Director-General of WHO

1.1 Chronic Respiratory Diseases, symptoms and risk factors

1.1.1 Chronic Respiratory Diseases

The World Health Organisation (WHO) defines chronic respiratory diseases (CRDs) as chronic diseases of the airways and other structures of the lung[1]. CRDs are diseases of lungs and airways which cause shortness of breath and lead to long term respiratory problems and complications. These are a group of diseases which do not have a cure but are preventable or can be controlled with treatment. Various forms of treatment which dilate the airways and improve shortness of breath can help control the symptoms and improve quality of life[2]. Chronic obstructive pulmonary disease (COPD) and asthma, are most common[3-4]. Other common CRDs include occupational lung diseases like pneumoconiosis, bronchiectasis, interstitial lung disease (ILD), post tuberculosis lung disease (PTLD) and pulmonary hypertension[1, 3-5].

1.1.2 Symptoms

CRD is an umbrella term of a group of respiratory diseases, and the symptoms of each vary from the others. Breathlessness, which is described as shortness of breath or difficulty in breathing is one of the common and distressing symptom described by patients with CRDs. Patients struggle to breathe and breathlessness can occur at rest or with activity. Other symptoms include wheeze, cough with or without sputum production, chest tightness and chest pain, haemoptysis, fatigue and weight loss. COPD causes limitations in lung air flow and is characterised by breathlessness or a 'need for air', excessive sputum production and a chronic cough[2]. The common symptoms of asthma include recurrent attacks of breathlessness and wheezing which vary in severity and frequency from person to person. Symptoms may show diurnal and seasonal variations and may become worse with physical activity[2]. The symptoms of bronchiectasis resembles those with COPD with presence of cough on most days

and tenacious sputum production often one or more exacerbations/year and frequent hospitalisations[6]. Chronic respiratory symptoms such as cough, phlegm, shortness of breath, chest tightness and wheeze, are the important markers of CRD that contribute to significant hospitalization, reduced lung function, poor health related quality of life[7].

Although the gamut of diseases within CRDs have commonality in symptoms, there are subtle differences which distinguish them and hence influence health behaviour and outcomes. COPD is characterised by gradual increase in breathlessness which increases from dyspnoea on exertion to dyspnoea at rest, if left untreated and commonly involves adults and persons exposed to smoke or respiratory irritants over many years. However, asthma commonly affects children and young adults, is seasonal and/or diurnal in nature, often self-limiting and characterised by wheezing or noisy breathing in addition to dyspnoea. These differences lead to different health behaviours in patients affected; patients with asthma may use inhalers/medications only during acute exacerbations while patients with COPD seek treatment quite late into their disease.

1.1.3 Risk factors and their contribution to CRDs

The common risk factors for the CRDs include tobacco smoking (including second-hand smoke), indoor air pollution due to cooking with biomass fuels (wood, crop waste and animal dung), outdoor air pollution and risk occupations involving working in dusty environments; these are preventable or modifiable. Some risk factors like age and heredity also contribute, but are non-modifiable.

Tobacco smoking and second-hand smoke killed 1.5 million people with chronic respiratory diseases in 2017 besides 1.2 million additional deaths due to cancer of trachea, bronchus and lung[8]. Tobacco smoking is the leading cause of COPD worldwide and the risk is particularly high in individuals who start smoking or are exposed to second hand smoke at an early age. Smoking also exacerbates asthma leading to activity limitation, workdays lost and disability. Tobacco smoke, which contains more than 7000 chemicals and 69 known carcinogenic substances, is dangerous form of indoor air pollution where it can linger up to 5 hours while remaining invisible[7]. There is no safe level of exposure to second-hand smoke and the only elimination of smoking from indoor environments is a major public health imperative[9].

Indoor air pollution due to use of solid fuels (such as wood, crop waste, charcoal, coal and animal dung) and kerosene in open fires and inefficient stoves is one of the major risk factors for chronic respiratory diseases, particularly in poor, and in low-and-middle income countries (LMICs)[9-11]. Indoor air pollutants can cause or aggravate asthma and COPD. Around three billion people use biomass fuel, coal and kerosene for cooking throughout the world which produces high levels of household air pollution and health damaging pollutants. Exposure is particularly high among women and small children because of time spent in the house and proximity to the fireplace. In 2019, 91.5 million disability adjusted life years (DALYs) lost globally were attributable to household air pollution (HAP)[10]. Of the 3.8 million people who die prematurely every year from illness attributable to indoor air pollution, 20% die from COPD alone and another 35% from respiratory illness and lung cancer[10]. About 25% of all deaths from COPD among adults in LMICs are due to exposure to household air pollution. The estimated cumulative total of premature deaths from household indoor air pollution will be 9.8 million, by 2030, based on modelling data[12]. Women exposed to household air pollution have twice the risk of suffering from COPD; similarly exposure also doubles the risk of developing COPD among men who are smokers[10].

Outdoor air pollution is a major environmental health problem, in both cities and rural areas resulting in 4.2 million premature deaths worldwide per year in 2016, primarily due to cardiovascular and respiratory disease and cancer. Of these, 91% of premature deaths occurred in LMICs, and the greatest number in WHO south-east Asia region and the western pacific region. Of total deaths in 2016, 18% were due to COPD and acute respiratory infections, while 6%were due to lung cancer[13]. The mortality due to outdoor air pollution in CRD patients are mainly due to fine particulate matter, mainly of size 2.5 microns and less, which cause maximum damage.

Occupational risks for developing CRDs are related to work place environment and long exposure to such environments. Once the disease process has begun, the person continues to be at risk for many years, even after the exposure ceases. In addition, once these conditions have developed, they are usually chronic and may worsen, even when further exposure to risk factors is avoided. WHO has estimated that in 2000, workplace risk factors were responsible for 13% of COPD, 11% of asthma and 9% of lung cancer worldwide. WHO also estimated that in 2000, an estimated 386,000

deaths and nearly 6.6 million disability adjusted life years (DALYs) were attributable to occupational airborne particulates in the working environment[9, 14-15].

Figure 1.1 Disability-adjusted life years (DALYs) (in millions) attributable to various risk factors, by level of socioeconomic development and sex, 2000

	High mortality developing country		Low mortality developing country		Developed country	
	Males	Females	Males	Females	Males	Females
Total DALYs	421	412	223	185	118	97
	(% of total)	(% of total)	(% of total)	(% of total)	(% of total)	(% of total)
Tobacco	3.4	0.6	6.2	1.3	17.1	6.2
Indoor smoke from solid fuels	3.7	3.6	1.5	2.3	0.2	0.3
Urban air pollution	0.4	0.3	1.0	0.9	0.6	0.5
Occupational airborne particulates	0.1	<0.1	0.87	0.1	0.4	0.1

Source: 9

1.2 Epidemiology, burden of disease and socio-economic impact of chronic respiratory diseases (CRDs)

1.2.1 Epidemiology of chronic respiratory diseases

Chronic respiratory diseases are major global health problems concerning both high-income countries and the resource poor LMICs. Chronic respiratory diseases including COPD, asthma, sarcoidosis, ILD, bronchiectasis and PTLD impose considerable socio-economic burden on individuals, families and societies, yet they are underestimated and under recognised and, until recently, typically neglected compared to other non-communicable diseases like cardiovascular diseases (CVD), cancer or diabetes[16,17]. CRDs have a long latency period and once developed, continue to progress with age. They are more often seen in adults and elderly age groups, except for asthma which has an early age of onset[18]. Risk factors like tobacco smoke, environmental exposure (indoor and outdoor air pollution, allergens), occupational exposure, diet and physical inactivity also contribute to the disease burden. Therefore, an aging world population and an increased exposure to risk factors will only increase the burden and make it a more challenging health problem for all the regions of the world. For men, smoking accounts for the highest proportion

of disability (measured in terms of disability adjusted life years, DALYs) attributable to CRDs in all Global Burden of Disease (GBD) super-regions[18]. However, for women, the leading risk factor for disability varied by region: household air pollution from solid fuel use in south Asia and sub-Saharan Africa, exposure to ambient particulate matter in the southeast Asia, east Asia, and Oceania and the north Africa and Middle East super-regions, and smoking in all other super-regions[18]. The epidemiology and the burden of CRDs vary considerable in different parts of the world and understanding the trends can be useful for prevention and control of CRDs.

Accumulating global evidence point towards CRDs being major causes for mortality and morbidity worldwide within the gamut of chronic diseases[17–21]. Evidence from the above literature also shows that developing countries account for 80% of the total burden of CRDs and mortality. Health utilisation costs, health related quality of life, severity and hospitalizations due to CRDs like COPD and asthma are higher in populations with a lower social standing and economic capability[22].

Studies on trends in CRDs and GBD studies[17–18,23] show that globally the total number of CRD cases increased from 389.7 million in 1990 to 544.9 million in 2017, a change of 39.5% over 27 years. Deaths due to CRDs in 2017 increased by 18% since 1990, while total disability adjusted life years (DALYs) increased by 13.3%. However, when accounting for ageing and population growth, declines were observed in age-standardised prevalence (14·3% decrease), age-standardised death rates (42·6%), and age-standardised DALY rates (38·2%). Age-standardised incidence rates (ASIR) and age-standardised prevalence rates (ASPR) have shown a decreasing trend, with an average decrease of 0.33% during the same period. ASIR decreased from 1990 to 2005 and subsequently increased from 2005 to 2017. The same trend is also being observed in ASPR with a dip in 2005. The ASIR for CRDs like COPD, pneumoconiosis and asthma decreased while ASIR for ILD and sarcoidosis increased during the period from 2005-2017. The incidence trend of asthma affected the lowest incidence rate of CRDs in 2005.

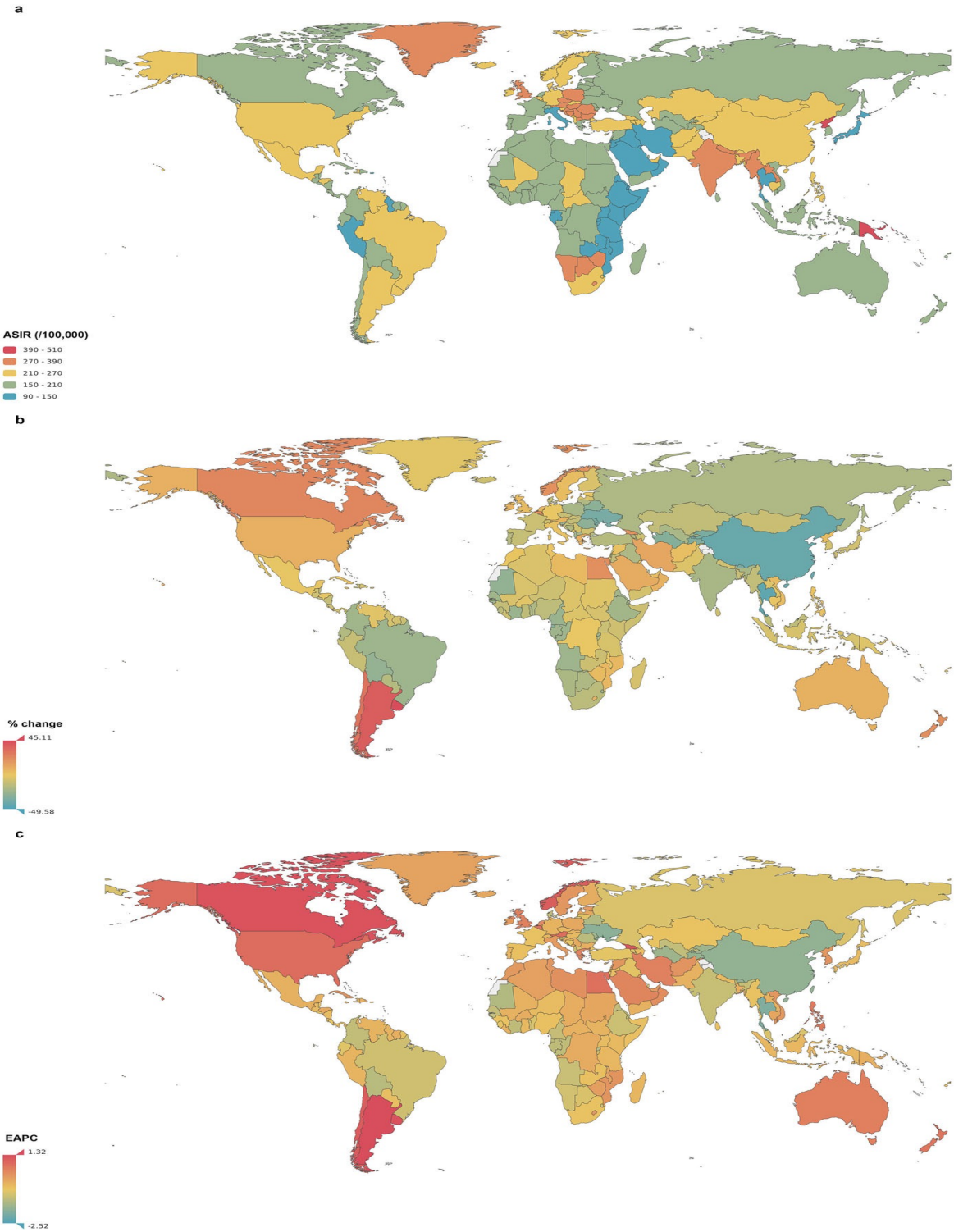
Distribution by gender shows that ASPR decreased from 1990 to 2005 in both sexes, which subsequently showed an increasing trend in females from 2005-2017 but showed a decreasing trend in males during the same period. The ASIR was higher in

males than in females till 2014, whereas the ASPR of CRDs were higher in females than in males, attributed to a higher prevalence rate of COPD and asthma in females. Analysis of age distribution of CRDs have revealed that the incidence of CRDs increase with age, except for asthma, and exhibited a strong increase elderly people above age 90 years. The age-sex specific prevalence varied among different CRDs. Asthma prevalence peaked at 5-9 years of age for boys and girls; it was higher in boys than in girls till 9 years of age and from age 10 onwards, asthma prevalence was higher in females. The prevalence of COPD in both sexes increased consistently from adulthood to old age. ILD and pulmonary sarcoidosis were more prevalent in males than in females. The overall prevalence of and burden from CRDs are going to increase in future as WHO estimates that worldwide 2 billion people are expected to be 60 years of age, or older, by 2050 accounting for 22% of the world population.

The spatial and geographical distribution of CRDs revealed that prevalence showed wide variability across GBD super-regions, with the highest prevalence among both males and females in high-income regions, and the lowest prevalence in sub-Saharan Africa and south Asia. The age-sex-specific prevalence of each chronic respiratory disease in 2017 was also highly variable geographically. Mortality rates from chronic respiratory diseases were greatest in south Asia and lowest in sub-Saharan Africa, also across both sexes. Deaths attributable to CRDs were most frequent in south-Asia super region, i.e., 81.2 deaths (75.4-86.3) per 100,000 individuals in 2017, and least in sub-Saharan Africa at 15.5 deaths (14·4–17·0) per 100,000 Individuals. Although absolute prevalence was lower in south Asia than in most other super-regions, years of life lost (YLLs) due to CRDs across the subcontinent were the highest in the world.

Among individual CRDs, COPD with a global prevalence 3.9% and asthma with a global prevalence of 3.6% were the two most common CRDs worldwide. In 2017, COPD was the most prevalent among CRDs accounting for 55.1% of CRD prevalence among men and 54.8% among women globally. COPD was the most common cause of mortality attributable to CRDs worldwide and across all GBD super-regions while asthma was the second most common cause of deaths in all but three GBD super-regions. Death rates due to interstitial lung disease and pulmonary sarcoidosis were greater than those due to pneumoconiosis in all super-regions. The global incidence of COPD in both sexes in different countries and territories is depicted in Figure 1.

Figure 1.2 The global incidence of chronic obstructive pulmonary disease (COPD) for both sexes in 195 countries and territories. a The age- standardized incidence rate (ASIR) of COPD for both sexes combined in 2017. b The relative percentage change in the ASIR of COPD for both sexes between 1990 and 2017. c The estimated annual percentage change (EAPC) in the ASIR of COPD for both sexes from 1990 to 2017. COPD, chronic obstructive pulmonary disease; ASIR, age-standardized incidence rate; EAPC, estimated annual percentage change



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1.2.2 Burden of chronic respiratory diseases

1.2.2.1 Global Burden of chronic respiratory diseases

In 2019, 455 million (95% uncertainty interval [UI] 417 – 499) people had chronic respiratory diseases with a prevalence rate of 5789.2 (95% UI 5290.7 – 6418.1) per 100,000 population[24]. The total number of new cases of CRDs diagnosed in 2019 was 77.6 million with an incidence rate of 1001.6 per 100,000 population. CRDs were the third leading cause of all deaths in 2019; they were seventh leading cause for years of life lost due to premature death (YLLs), 11th leading cause of years of life lost due to disability (YLDs) and 10th leading cause of disability-adjusted life years (DALYs) in 2019. CRDs accounted for 7.03 percent (95% UI 6.36% – 7.51%) of all deaths, with 3.97 million (95% UI 3.58-4.30) deaths recorded in 2019 globally[24,25]. In total, chronic respiratory diseases accounted for 51·3 (UI 45.9–55·5) deaths per 100000 individuals in 2019, 66.7 (UI 60.5–73.1) per 100000 males and 39·7 (UI 33.2–44.7) per 100 000 females; showing a higher proportion of deaths in males from CRDs in 2019. They were responsible for 71·1 million (95% UI 64·7–77·0) YLLs, 32·4 million (26·1–38·5) YLDs and 104 million (95% UI 94.8–112) DALYs in 2019. The change in rank of the CRDs, almost over 20-year period, both in terms of mortality and morbidity (DALYs lost) have been depicted in Figure 2 and Figure 3, respectively. Both continue to show an upward trend with the burden due to absolute number of deaths and DALYs from CRDs increasing from 1990 through 2019.

Figure 1.3 Global rank of CRDs in 2019 in comparison to 1990 levels – mortality (level 2 causes)

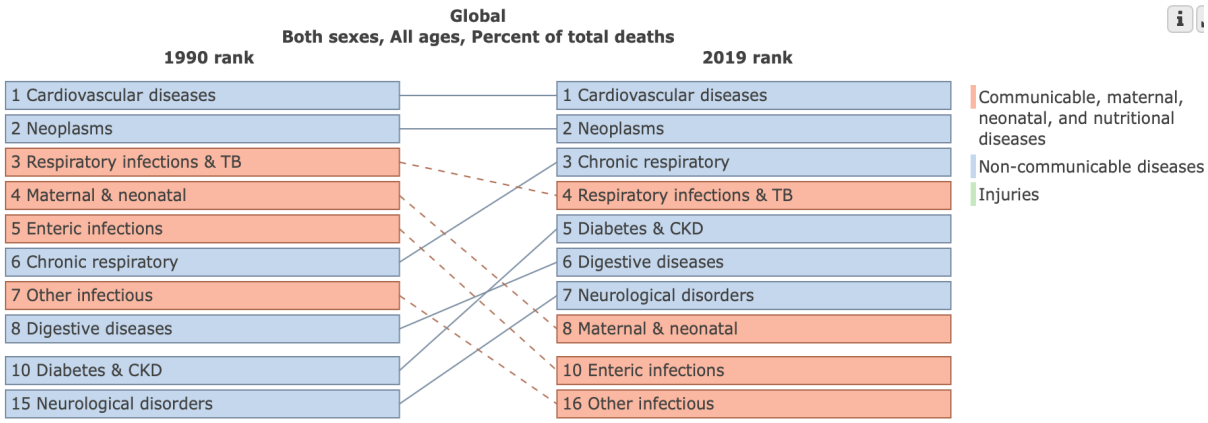

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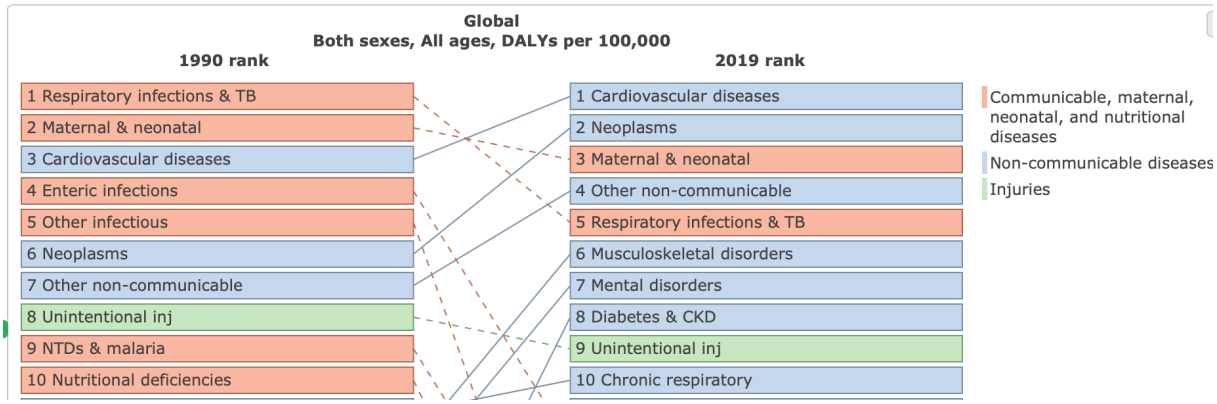
Figure 1.4 Global rank of CRDs in 2019 in comparison to 1990 levels – DALYs (level 2 causes)



Source: 25

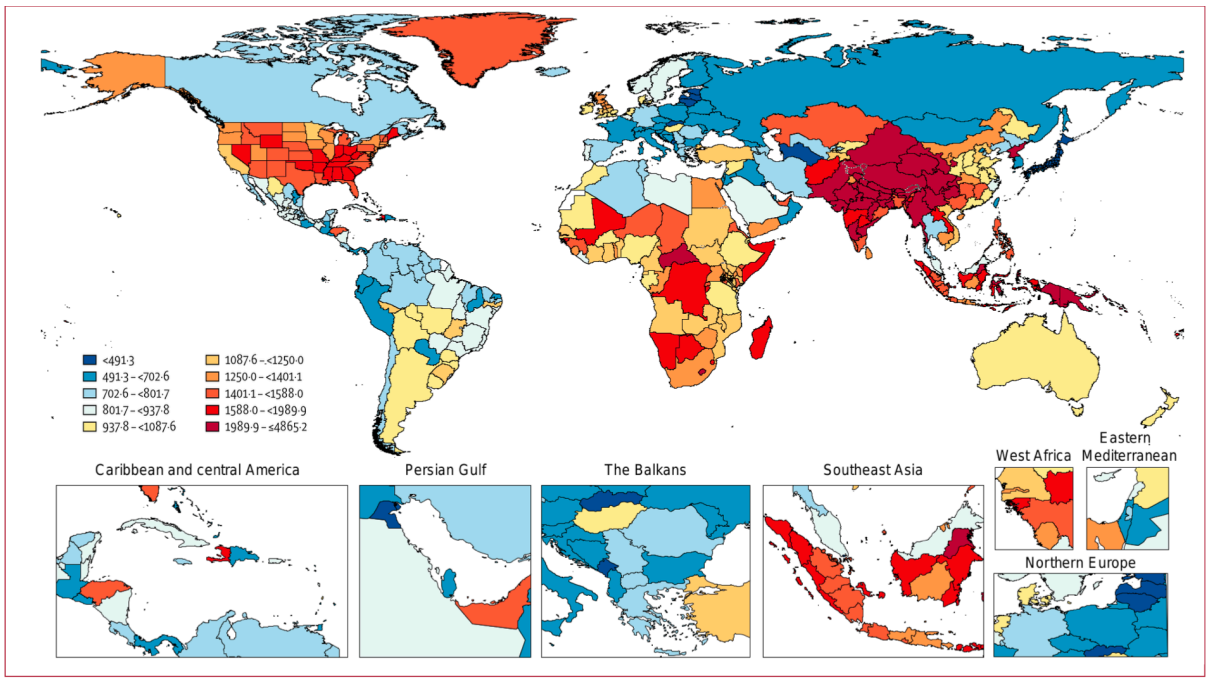
COPD and Asthma are two common CRDs and responsible for most of the mortality and morbidity burden due to these diseases. In 2019 COPD is the third leading cause of death globally[25]. As per WHO Global Alliance Against Chronic Respiratory Diseases (GARD) action plan 2008-2013, World Health Statistics 2008 estimated that by 2030 COPD will be the third leading cause of death globally[26]. However, the progress in ranking and contribution to burden of disease had been sooner than anticipated. As per the GBD 2020 estimates[24-25], there were 212 million (UI 200-225) cases of COPD worldwide in 2019 with 2638.2 cases (95% UI 2492.2-2796.1) per 100,000 population; prevalence in males was 2828.1 (95% UI 2677.6-2990.5) per 100,000 male population while in females it was slightly lower at 2487.1 (95% UI 2346.5-2640.6) per 100,000 female population. The number of new cases of COPD detected in 2019 were 16.2 million (95% UI 15.2-17.2) globally. The percentage change in prevalence and incidence of COPD in 2019 from 1990 estimates were 20.8% and 22.3% respectively, showing an upward trend. Total number of deaths attributed to COPD in 2019 were 3.28 million (95% UI 2.90-3.57) worldwide with males contributing to 1.88 million (95% UI 1.70-2.07) and females 1.40 million (95% UI 1.14-1.60) deaths. COPD resulted in 74·4 million (95% UI 68·2–80·2) global DALYs and 71·9% (67·9–75·4) of total chronic respiratory disease DALYs in 2019. COPD ranked third among the level 3 causes for global deaths and sixth for DALYs in 2019, from sixth and eleventh respectively, in 1990. Smoking, ambient particulate matter in air, occupational particulate matter, gases and fumes, and household air pollution from solid fuels were the top four risk factors for COPD globally.

Asthma is the most common non-communicable disease in children while most deaths occur in adults. There were 262 million (95% UI 224-309) people with asthma on 2019 of which 136 million (95% UI 117-158) were females and 127 million (95% UI 107-153) were males. The new cases of asthma diagnosed in 2019 were 37 million (95% UI 29.6-45.9) with almost equal male-female proportion. The number of deaths from asthma were low at 0.461 million (95% UI 0.367-0.559), as compared to COPD. High body mass index, smoking and occupational allergens for asthma were the three top risk factors, globally. Asthma was responsible for 21·6 million (95% UI 17·1–27·0) DALYs in 2019, which was 20·8% (17·5–24·7) of total DALYs from CRDs. Death rates from asthma were highest in countries of low and middle socio-demographic index (SDI), while prevalence was highest in high SDI countries.

1.2.2.2 Burden in LMICs and south Asia

Although the prevalence rates of CRDs are higher in high income countries, the LMICs bear a disproportionately higher burden of mortality and morbidity from CRDs including COPD, asthma, bronchiectasis and PTLD. LMICs contribute to more than 90% of global mortality due to COPD and 80% of asthma mortality[27]. The GBD study 2019 undertaken by Institute of Health Metrics and Evaluation shows that high income (HI) super-region account for only 15% of the global mortality and morbidity calculated in terms of total number of deaths and DALYs respectively, 85% of the burden being distributed in all other super-regions, including the LMICs[25]. LMICs account for 62·6% of the global burden of COPD and lung cancer, and this share is likely to increase sharply over coming decades due to ageing populations and if tobacco and air pollution control are less successful[28]. Southeast Asia, east Asia, Oceania and the south Asia super-regions contribute to 70% and 64% of total global mortality and DALYs, respectively[25]. In south Asia, although crude prevalence is lower than that in most other super-regions, morbidity and mortality attributable to chronic respiratory diseases are the highest in the world. South Asia super region including the Indian sub-continent contributes to one-third of the total deaths and DALYs due to CRDs globally; it ranks first in the contribution to DALYs and second in total deaths among all GBD super-regions in 2019.

Figure 1.5 Age-standardised DALY rates (per 100 000) by location, both sexes combined, 2019



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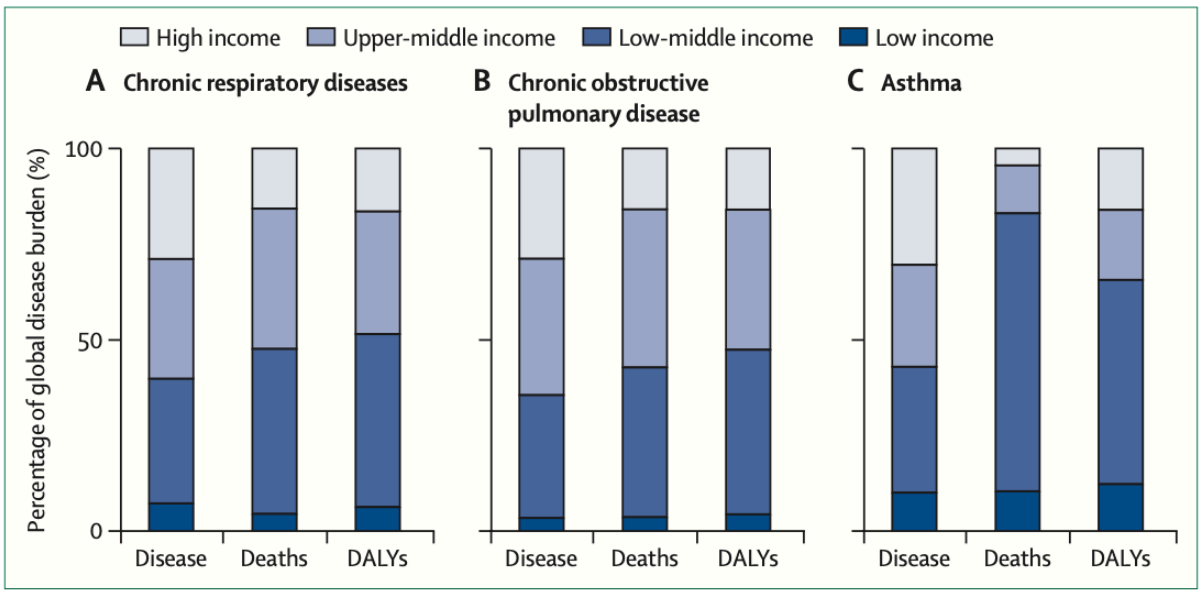
Asthma and COPD are responsible for substantial burden of CRDs in LMICs. Asthma is the most common CRD globally with 262 million people suffering from it in 2019; of these 96% of global asthma-related deaths and 84% of global asthma-related DALYs were contributed by LMICs[29]. COPD is the world's third most common cause of mortality and about nine-tenths of all deaths due to COPD occur in LMICs. GBD 2019 study estimates that LMICs contribute to 71% of the global COPD burden, 84% of global COPD deaths, and 84% of the global COPD DALYs[29]. Tobacco smoke remains an important risk factor for COPD, but more importantly in LMICs biomass fuel use for cooking also contributes to COPD, especially in women, with a third to fifth of cases of COPD occurring in people who have never smoked. Most of the deaths in south-Asia region are premature deaths due to asthma and COPD and contributing to DALYs, being aggravated by factors like environmental pollutants, indoor air pollution and occupational allergens and dusty working environments. Factors like poor access to care, underdiagnosis and low availability and higher cost of inhalers compared to oral medications act synergistically to increase vulnerability and exposure to risk factors, especially for asthma. Poor socio-economic status, exposure to biomass fuels, history of childhood respiratory infections, history of tuberculosis, high levels of under-

diagnosis and misdiagnosis of the disease and lack of appropriate clinical care are some of the factors specific to LMICs which lead to a higher morbidity and mortality from COPD[29-30].

Figure 1.6 Distribution of the global burden of disease, deaths, and DALYs from (A) chronic respiratory diseases, (B) chronic obstructive pulmonary disease, and (C) asthma, by World Bank-defined country income strata, using Global Burden of Disease 2019 estimates



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1.2.2.3 Epidemiology and Burden of disease in India

India is the largest country of the Indian sub-continent which comprises of the south Asia GBD super-region. It is the seventh largest country of the world in terms of land area and the second largest in terms of population, with 2% of the land area and 17% of the global population. India has a population of 1.34 billion living in 29 states and seven union territories. According to the GBD study on chronic respiratory diseases in India[31], CRDs are a major public health problem carrying a substantial burden of global CRDs, an increasing trend in the prevalence of COPD, higher magnitude of DALYs lost per case and the highest burden of DALYs within the country being contributed by the low epidemiological transition level (ETL) states. High ETL states have low ratios and are more developed than low ETL states, which also broadly corresponds to higher SDI as calculated by GBD study for high ETL states.

GBD studies with specific focus on India and across the Indian states[31–32], published in the Lancet in 2017 provide picture of the burden of CRDs in India and the variations within the states, an account of which is as follows – CRDs accounted for 10·9% (95% UI 10·0–12·0) of the total deaths and 6·4% (95% UI 5·8–7·0) of the total DALYs in India in 2016, as compared with 9·6% (95% UI 8·2–10·5) and 4·5% (95% UI 4·0–4·9), respectively, in 1990. India contributed to 32% of the total global DALYs due to CRDs in 2016. COPD and asthma were the predominant CRDs, contributing to 75·6% and 20% of the total DALYs, respectively, in 2016. COPD was the second leading cause of disease burden in India after Ischaemic Heart Disease contributing 8·7% (95% UI 7·8–9·5) of the total deaths and 4·8% (95% UI 4·3–5·3) of the total DALYs. The proportions of deaths and DALYs were similar among men and women for COPD, asthma, and interstitial lung disease except for pneumoconiosis where it was significantly higher in men than in women.

The number of COPD cases in India was 55·3 million (95% UI 53·1–57·6) in 2016, as compared to 28·1 million (95% UI 27·0–29·2) in 1990. The crude prevalence of COPD in India in 2016 was 4·2% which was an increase of 29·2% from 3·3 % in 1990. In all ETL state groups, the crude prevalence increased significantly from 1990 to 2016. The crude prevalence of COPD was highest in the high ETL state group, whereas age-standardised prevalence was highest in the low ETL state group. The age-specific prevalence of COPD increased with age and rapidly after the age of 30 years, with a greater increase in men than in women. The crude case-fatality rate of COPD in India in 2016 was 1·53% (95% UI 1·44–1·63). The crude asthma case-fatality rate in India was 0·48% in 2016, a reduction from the rate of 0.89% in 1990. Asthma prevalence dropped after 9 years of age and increased after the age of 25 years, reaching the highest prevalence in the 75–79 years age group, both among men and women.

In 2016, 53·7% (95% UI 43·1–65·0) of all DALYs due to COPD were attributed to air pollution, 25·4% (19·5–31·7) to tobacco use, and 16·5% (14·1–19·2) to occupational risks, making these the leading risk factors for COPD. Among the components of these groups of risk factors, 33·6% (21·7–46·7) of COPD DALYs could be attributed to ambient air pollution, 25·8% (16·9–39·8) to household air pollution, and 21·0% (15·4–27·1) to smoking. The age-standardised prevalence of COPD in India was 1·5 times the global average prevalence in 2016. The age standardised DALYs per person in

India were 1·7 times and 2.4 times the global average, respectively for COPD and asthma in 2016.

In 2019, CRDs were the second most common cause of deaths in India after cardiovascular diseases, the fourth most common contributor to DALYs and the third most common cause of death and disability combined; they contributed to almost 30% of all deaths and DALYs due to CRDs globally[25]. The number of COPD deaths in India increased from 624 000 (508 000–741 000) in 1990 to 898 444 (691 584–1 058 389) in 2019[25]. Total number of asthma deaths in 2019 was 198 798 (129 621–271 915), compared to 149 454 (90 390–227 979) in 1990[25].

1.2.2.4 Challenges in reducing burden of disease and CRD management in India

The total number of deaths and DALYs from CRDs per year had shown an increasing trend from 1990 to 2019 and are going to increase if the risk factors of ambient air pollution, household air pollution due to biomass fuels and smoking are not controlled; the ageing population of India is also going to contribute to this increasing burden of CRDs[31]. A peculiar characteristic of CRD burden in India is that a substantial share of COPD cases (COPD accounts for 75% of DALYs due to CRDs) occur in people who have never smoked[33] and other factors not related to smoking played a role. Studies in India[33–35] have listed several factors such as outdoor air pollution from particulate matter, indoor air pollution from biomass fuels, occupational exposure to crop dust, dust from mines, chemicals, poor socioeconomic status, poor nutrition, overcrowding, and residence in urban slums as being associated with CRDs in this country. Some of the other factors contributing to this burden of diseases, specifically for COPD in India, are underdiagnosis of COPD due to lack of spirometry and dependence on symptoms for diagnosis, symptomatic people being late in seeking care because of low awareness of the disease, inhalational devices being perceived as stigma in rural areas and infrequently used devices, as also people seeking care from non-formal health practitioners of alternative medicines and faith healers leading to aggravation and advancement of the disease[31, 36-37]. Further, women are less symptomatic than men in the early stages of COPD combined with their less common health seeking behaviour pose additional challenges to diagnosis. Poor management of asthma, poor utilization of protocols and tools for asthma, limited use of inhaled medications, and

the existence of several misconceptions and misbeliefs in the community seem to be the likely contributing factors to the high DALY rate per person with asthma in India[31, 39–41]. There is misclassification between COPD and asthma due to overlap of symptoms, and further an asthma – COPD overlap syndrome (ACOS) has also been described in which patients have mixed features of asthma and COPD with air flow limitation[42], which make diagnosis and management challenging in primary and secondary care settings across the country. The management of CRDs, as with other chronic diseases, require long term therapy involving prolonged period of treatment, repeated hospital visits and follow-up which results in patients dropping out or discontinuing therapy. This results to poor compliance to treatment adding to increased morbidity and mortality for the disease.

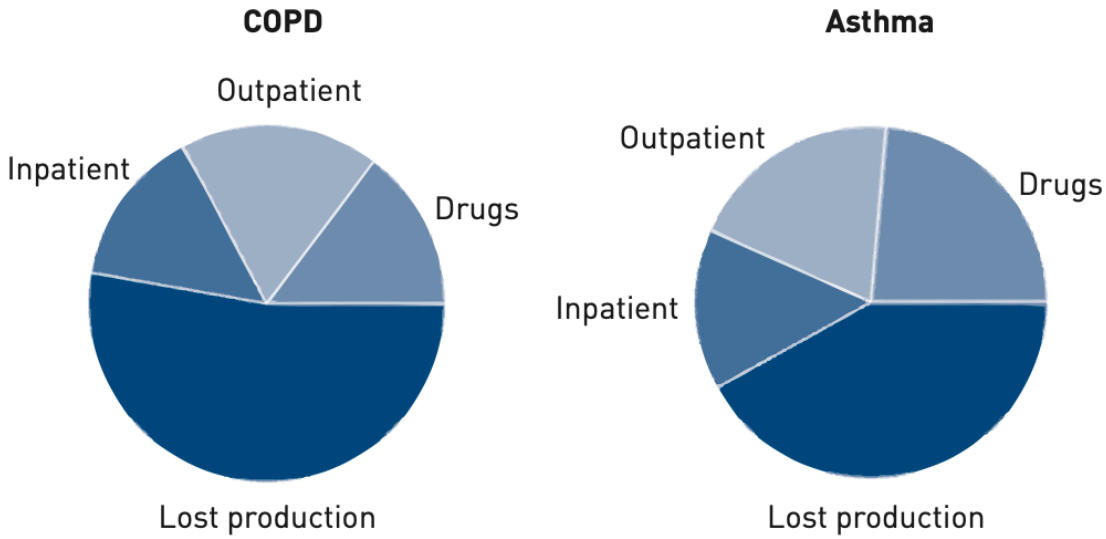
Health behaviour is the underpinning element which can modify or influence many of the risk factors and challenges to management of CRDs; be it exposure to risk factors, health seeking from practitioners of alternate medicine and faith healers, late presentation to formal health care system, use of inhalational devices, continuation and compliance to treatment and follow-up[43-44]. The determinants of health behaviour like awareness about disease and its outcomes, attitude towards the behaviour, societal factors and health system factors also need to be modified to create an enabling environment to make healthy options a default choice. Health behaviour can be the integral component for health and well-being in people with CRDs and in reducing the morbidity and mortality from the disease.

1.2.3 Socio-economic impact of chronic respiratory diseases

The socio-economic impact of CRDs can be attributed to the long duration of illness, severity of the disease, hospitalisations and medical costs, decrease in work productivity and loss of workdays which affect individuals as well as the economy. The total estimated costs incurred from respiratory illness in United Kingdom (UK) in 2014 was 11.1 billion pounds, as reported by British Lung Foundation, including both treatment (direct costs) and wider loss to economy (indirect costs); the most expensive respiratory diseases being asthma (costs – 3 billion pounds) and COPD (costs – 1.7 billion pounds) in the UK[45]. According to the report published in the European Lung white book on the economic burden of lung disease[46], the total cost of respiratory

disease in the 28 countries of the European Union amounts to more than €380 billion annually which includes €55 billion on direct primary and hospital health care costs, €42 billion on costs lost to production and €280 billion on monetised value of DALYs lost. The annual costs of health care and lost productivity due to COPD and asthma amounts to €48.4 billion and €33.9 billion respectively, annually. The costs of drugs and devices, the cost of outpatient treatment and the costs due to hospitalisations make up the direct costs whereas loss to production due to absence or poor work capacity leads to indirect costs, excluding the costs incurred due to premature deaths or disability. The direct cost of COPD is 6% of total healthcare spending in the European Union and accounts for 56% of the total cost of treating respiratory diseases.

Figure 1.7 Distribution of direct and indirect costs by category for chronic obstructive pulmonary disease (COPD) and asthma



Source: 44

A study by Brakema et al[47] on the socio-economic burden of chronic lung disease on low-resource settings as a part of FRESH AIR study, reported that the median overall work impairment due to CRDs was 30% and decreased productivity (presenteeism) was 20%, although the absenteeism was relatively low. A study conducted on quality of life and economic burden of respiratory disease in Asia-Pacific by De Yun Wang et al[46] involved six countries including India and reported that the mean annual cost for patients with a respiratory disease was US $4191 per patient while it was US $7315

per patient for those who reported impairment at work. Patients were impaired, on an average, for one-third of their time for work and it resulted in 36% loss in productivity. Patients with diagnosis of asthma or COPD had higher visits to emergency department; patients with COPD had highest direct medical costs among respiratory diseases.

1.3 Current policy on chronic respiratory diseases

1.3.1 WHO policy and approach on CRDs

The initial recognition of the huge burden of CRDs first came at the turn of the millennium when the fifty-third World Health Assembly (WHA) requested the Director-General of WHO to continue giving priority to the prevention and control of noncommunicable diseases (NCDs), including chronic respiratory diseases and passed a resolution for action. Resolution 53.17 (May 2000) called for special emphasis on developing countries and "to coordinate, in collaboration with the international community, global partnerships and alliances for resource mobilization, advocacy, capacity building and collaborative research" for prevention and control of NCDs including CRDs[26]. An alliance of nations called Global Alliance against Chronic Respiratory Diseases or GARD was formed to spearhead the course of action which had its first meeting at WHO headquarters, Geneva, Switzerland on 18-19 Jan, 2005[49]. Following the resolution of the WHA in 2000, WHO came up with a report "Preventing chronic diseases: a vital investment"[50] (2005) and the publication "Global surveillance, prevention and control of chronic respiratory diseases: a comprehensive approach" (2007) further raised awareness of the huge impact of chronic respiratory diseases worldwide; it highlighted the risk factors as well as ways to prevent and treat these diseases. The Action Plan for the Global Strategy for Prevention and Control of Noncommunicable Diseases 2008-2013, endorsed by WHA in 2008, includes chronic respiratory diseases in its scope of action, together with cancer, diabetes and cardiovascular diseases, and addresses their main risk factors – tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol. In 2013, the WHA endorsed the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020 which gave WHO, international partners and the member States a road map and menu of policy options which, when implemented collectively between 2013 and 2020,

will contribute to progress on nine global NCD targets to be attained in 2025, including a 25% relative reduction in premature mortality from NCDs by 2025[51]. The WHA 2013, also adopted the comprehensive global monitoring framework (GMF) for the prevention and control of NCDs[52]. The GMF includes a set of nine targets and 25 indicators to monitor trends and assess progress made in the implementation of national strategies and plans on NCDs, including CRDs. The GMF focusses on four main NCDs – cardiovascular disease, cancer, chronic lung diseases and diabetes which kill three in five people worldwide with a target of 25% relative reduction in risk of premature mortality from these four diseases by 2025, with a baseline of 2010.

1.3.2 Sustainable development goals and CRDs

Sustainable development goal (SDG) 3 is 'to ensure healthy lives and promote well-being for all at all ages. Target 4 of the SDG 3 states 'by 2030 (relative to 2015 levels) reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being'. NCDs are the leading cause of deaths and ill health worldwide accounting for seven of the ten deaths between ages 30 and 70 years and CRDs are one of the big four among cardiovascular diseases, chronic respiratory diseases, cancer and diabetes. Large reduction in the deaths and disabilities caused by CRDs are required along with others in the big four for achieving the SGD 3.4 through a combination of prevention, early detection and treatment[53]. Specific to CRDs this includes reduction in tobacco use and household air pollution, low- dose inhaled corticosteroids and bronchodilators for asthma and selected patients with COPD and availability of quality of care to treat acute exacerbations of asthma and COPD at first level and regional hospitals[53-57]. This is also emphasised by target 3.8 of goal 3 which states 'achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all'. If we are to achieve the SDG target 3.4 by 2030, reduction in burden of disease due to CRDs are essential.

1.3.3 Policy on CRDs in India

India has been a country which has traditionally being fighting off communicable, maternal, neonatal, and nutritional diseases (CMNNDs). With improvement in

standard of living, better health facilities and food security, burden from CMNNDs have started declining but it also led to an epidemic of non-communicable diseases (NCDs) thrust upon the nation facilitated by an and higher life expectancy and changes in lifestyle. Fighting this double burden of disease requires a quick reassessment in policy and a clear action plan to tackle the ever-increasing burden due to NCDs. The National Health Policy 2002 emphasised on strengthening health infrastructure, public private partnership, integrating alternate systems of medicine into national framework and consolidating gains made so far, mainly by controlling communicable diseases. The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke was launched in 2010 and there was no CRD component in the program; later a small component which involves only referrals of suspected cases to the district hospitals was added[58]. Components, such as health promotion, early diagnosis, and management, were lost in the mix of other non-communicable diseases such as cardiovascular disease and diabetes. There had been calls for a national programme on the control of COPD and other CRDs in India, as well as primary health care reforms to so that these diseases can receive attention commensurate with their contribution to the disease burden[59-60]. A task force of India's health ministry proposed in 2014 that health promotion activities, screening, and management guidelines for COPD, asthma, and pneumoconiosis be included in the service packages of primary health care, in addition to other non-communicable diseases[61]. The latest National Health Policy 2017 incorporates screening for COPD, and for oral, breast and cervical cancer in addition to existing screen for diabetes and hypertension[62]. However, at present there is no separate policy or national program for prevention and control of CRDs in the country.

1.4 Research gaps and need for the study

Awareness level of CRDs in the general population is low and not enough importance is given to the disease or its symptoms until it becomes severe enough to affect their activities of daily living or their work capacity. Use of clean fuel (gas) not yet adapted or not used regularly and smoking of bidis still continues, specifically in poor rural areas. Lack of awareness also leads to underestimate of disease prevalence and progression of the disease because of late presentation and delay in seeking care

from the formal health care system. Patients usually seek care initially from traditional healers or local medical shops or from practitioners of alternate medicines like Homeopathy, Unani or Siddha, most of whom do not recognise the disease as a separate clinical entity. Misdiagnosis and underdiagnosis of the disease is common. Evidence-based treatment guidelines are available but are not followed and there is inadequate availability and use of inhalational drugs and devices. Stigma of the disease and of inhalers prevent use, hinder follow-up and promote discontinuation of treatment.

CRD is a major public health problem globally and is more serious health concern for India which contributes to 30% of global deaths and DALYs due to CRD . Currently, there is no specific government program or policy on prevention and control of CRDs in India. At present, not much evidence is available through research on CRDs in India. There are a few prevalence studies done by independent researchers and provide regional data[63-66]. There are no pan-India prevalence studies on CRD. The only pan India data regarding the burden of CRDs has been published recently in 2018, as a part of global burden of disease (GBD) study, 2016 in the Lancet[31] which describes the estimates of burden of CRDs at the national and sub-national (state) level, accessing all available data sources and assessing their scope and quality for inclusion.

Although health behaviour is an underpinning factor for human health and well-being and in better control of chronic diseases[43], it has not been explored as an option for reduction of symptoms, and in long term, for reduction of morbidity and mortality due to CRDs in LMICs. CRDs are life style diseases and health behaviour plays an important role in shaping the disease course or its outcomes. In the resource poor and low literacy settings of LMICs, intervention for health behaviour change may be used as an effective method for prevention and control of CRDs. There is no specific policy or program on CRDs or on COPD or asthma in India and the therefore no active screening program for CRDs at the primary or secondary care level. When the severity of symptoms increase and the patients seek health care advice, they usually land up in tertiary care centres via referral and usually have advanced disease by the time they are diagnosed in the tertiary setting.

In my experience as a primary care physician I saw lots of patients coming to the OPD with respiratory symptoms of acute breathlessness, wheezing, dyspnoea on exertion (during work or while walking) which was progressive with emergency visits to hospital and in-patient admissions due to exacerbations. Over the years the thought was always in my mind that why the patients land up in this condition and why don't they access healthcare during the initial symptoms or continue to comply with treatment advised. Why do they behave in such a manner, what are the barriers to seeking early access to health care and treatment compliance and how can this health behaviour be modified towards achieving better health outcomes.

Behaviour change intervention is one way of connecting people to the health system for better access and compliance to treatment[43-44]. Making them aware of the risk factors, and complications from the disease and the benefits of early diagnosis and treatment can help improve health seeking behaviour and compliance to treatment and follow-up. This can lead to avoidance of risk factors and change in lifestyle, better control of symptoms, reduction in complications and eventually reduction in morbidity and mortality from the disease with the better quality of life for the individuals.

1.5 Why use theory-based intervention and why choose theory of planned behaviour?

1.5.1 Why use theory-based intervention?

The MRC guidance on developing complex interventions emphasises that development of an intervention should be informed by theory[67-68], as this is more likely to result in an effective intervention than a purely empirical approach; this also allows in the replication of the model by researchers in future. For developing a complex intervention for behaviour change it is important to develop a theoretical understanding of the likely process of change, by drawing on existing evidence and theory, supplemented by stakeholder engagement and formative research like interviews and discussions with those targeted by the intervention or involved in its development or delivery. Using theory for developing interventions can lead to more powerful effects in behaviour change than those developed without theory, as is the evidence from several systematic reviews[69-70]. Theories can help identify the needs of a program before developing it. They also provide an understanding of various approaches that

may be required to reach people and organisations and make an impact on them[71-72]. There are number of theories informing behaviour change, some of the earliest and most commonly used ones are health belief model, the theory of planned behaviour, the transtheoretical model and social cognitive theory of behaviour change. Newer models like social ecological model and the behaviour change wheel theory are recently being used explaining health behaviour or developing behavioural interventions.

1.5.2 Why use theory of planned behaviour (TPB)?

TPB assumes best predictor of health behaviour is behavioural intention, which in turn is determined by attitude towards the behaviour, subjective norms and perceived behavioural control and the beliefs underlying these constructs; thus TPB links beliefs with the person's behaviour. TPB has been used extensively in interventions for behaviour change like smoking, drinking, exercise, mammography and contraceptive use in HIV[73-75] and in chronic diseases like obesity, schizophrenia, diabetes and cardiovascular disease[76-78]. The TPB-based interventions work and have been found to be effective (mean effect size = 0.5) in changing health behaviour[79].

Although TPB-based interventions for behaviour change had been successfully applied for changing dietary pattern, physical activity and chronic diseases like diabetes, but there were no such studies for CRDs; specifically in LMICs and none from India. I hypothesised that TPB-based interventions for behaviour change can also be applied for risk reduction and compliance to treatment in patients with CRDs, thereby controlling symptoms and preventing morbidity and mortality from the disease, in the long run. However it was important to develop a behaviour change intervention in a way that would be feasible, acceptable to the local community and effective in changing health behaviour in CRD patients.

The decision for choosing TPB as the appropriate behaviour change theory was based on the following reasons –

a) It is established that TPB based interventions were effective in changing health behaviours and they have been used in influencing a wide range of health behaviours from screening of breast cancer to maintenance of exercise and compliance in schizophrenia[80-82].

b) Prior experience of working with health belief model (HBM) have led us to realise the fact the merely providing knowledge and creating awareness about the diseases does not actually transform into the desired health behaviour, there are barriers in the society in form of individual attitudes, beliefs and norms which needs to be appraised and TPB specifically addresses all these aspects, so appropriate enough to be used for behaviour change intervention.

c) One of the reasons for adopting this theory is the setting where the intervention is to be applied – rural low socio-economic and low health literacy setting where there is diverse interplay of factors where TPB seems to be a good fit in addressing such issues. The population in these settings have their own set of beliefs related to the social milieu that they live in, cultural practices and health behaviour; TPB helps to know specifically about these social norms, their capability and control over these factors and their attitude towards the behaviour – all of which are paramount for designing health interventions for behaviour change[83]. There are other behavioural theories like transtheoretical model and social cognitive model which provides for changing individual health behaviour but they also require collective self-actualisation and self-liberation and more of individual capability to realize and adopt the change; this community setting of resource poor, low literate population is not so well developed to use them at present. Other models like social ecological models which work at multiple levels may not be feasible to implement within the scope of PhD.

d) Last but not the least is the feasibility and sustainability of the intervention and, the equity which the intervention will deliver to the community. Having our own health care workers who come from the local community aided by a network of social and medical personnel will be helpful in delivering and maintaining the health behaviour in the community – a model used and found suitable for low resource settings[84] moreover, addressing the beliefs and norms which act as barriers can bring about social equity, reducing disparities in health and social well-being

1.6 Context of research – the RUHSA community and the health system

1.6.1 Setting of the study (geo-socio-cultural background for the intervention)

The study was conducted in KV Kuppam (Figure 1.8c) Community development block (an administrative unit of a district with about 100,000 population in India) which is one

of the twenty-one blocks of the Vellore district (Figure 1.8b). in the state of Tamil Nadu (Figure 1.8a), which is located in southern part of India. The health and community development activities of this block are managed by the Rural Unit for Health and Social Affairs (RUHSA) Department of Christian Medical College (CMC), Vellore, one of the top two medical schools in India with a focus on service, education and research. The strength of RUHSA is its involvement in community development programmes and chronic disease management programmes for more than 5 decades; there is strong community linkage through a range of mechanisms including community health workers like Family Care Volunteers (FCVs), health aides and Rural Community Officers (RCOs) as well as community nurses / nurse practitioners.

Figure 1.8 Maps depicting Tamil Nadu (a), Vellore district (b) and K V Kuppam Block (c) sequentially

The K V Kuppam block is located around 16 miles north-west of Vellore town which is the field practice area of the RUHSA department. It has a population of 128,000 as per the latest census conducted by RUHSA in 2015. It is a 100% rural area. Majority of the block residents follow Hindu religion and about 3% belong to other religions, including Muslims and Christians. Most of the inhabitants in the block subsist on agriculture and linked occupations. There is a recent trend among young men in the rural areas to migrate to the nearby urban towns and cities to work as labourers or get into alternate professions. Some of the other occupations are weaving, poultry farming, rope making, dairy farming and “Beedi” (country cigarettes) making. The overall literacy rate is 64%; male literacy rate is 73.4% and female literacy rate is 57.4% with a large proportion of literates below middle level of schooling. The general socio-economic status of the population is from lower to lower middle.

1.6.2 Health system under RUHSA and application of TPB model for behaviour change intervention

The K V Kuppam block is divided into 18 peripheral service units (PSUs) for provision of primary health services to the community (Photo 3). Each PSU caters to a population of about 7, 000 and helps in reaching out to the people in the entire block. A team comprising of a doctor, nurse, rural community officer (RCO-Social worker), health aides and family care volunteer visits each PSU once a month and conducts half-a-day clinic while a nurse-led clinic and community house visits are organised once a week under each PSU.

RUHSA has extensive experience in providing health education to the community in a range of health topics, including cervical cancer screening, over the last ten years. In terms of psychological models the programme has drawn initially on the Theory of Health Belief Model for behavioural change and has used a range of novel media and community-oriented techniques to overcome problems of low health literacy[84]. Further qualitative research at RUHSA has identified, in its poor, rural target populations, cultural norms, subjective norms and beliefs, perceived attitude influencing behavioural change. In RUHSA's programmes HCWs are responsible for imparting culturally appropriate health education; despite this, barriers are encountered, and RESPIRE offers the opportunity to further refine our interventions, drawing further on psychological and social-cognitive theory. The Theory of planned behaviour (TPB) has been found in other settings to predict if an individual engages in a wide variety of different health behaviours including exercise, undergoing a health check-up, being screened for breast and colorectal cancers[66, 85].

This research incorporated TPB elements in RUHSA HCW-delivered interventions to address risk factor reduction, and medication/pathway compliance in chronic respiratory diseases. My PhD research study was designed to develop a TPB-based intervention for behaviour change and pilot test it for feasibility in a resource poor, low-literacy, rural setting of an LMIC and examine the effectiveness of this intervention.

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Chapter 2

Overview of the research project

2.1 Aims and Objectives

The aim of my PhD research project is to develop and pilot test a health care worker (HCW)-delivered theory of planned behaviour (TPB)-based health intervention for behaviour change in patients with chronic respiratory disease (CRD) using current evidence in practice and drawing on past experience of delivering culturally sensitive health programmes adapted for low health literacy communities.

Objectives of my PhD are:

- to interpret the effect of TPB based interventions in chronic diseases in low health literacy settings through a systematic review of literature
- to develop a culturally acceptable and locally adaptable TPB based intervention model for behaviour change in patients with chronic respiratory disease (CRD)
- to examine through a feasibility study, whether successful outcomes of TBP-based interventions found in the literature could be reproduced in a low-resource setting, and identify the implementation challenges in these settings

2.1.1 Aims and objectives of the systematic review (Project 1)

The aim of the systematic review is to evaluate the impact and effectiveness of TPB based interventions for behaviour change among chronic disease patients in low health literacy settings

Objectives of the systematic review:

- to determine the feasibility and fidelity of TPB based interventions in low health literacy settings of LMICs
- to determine the impact of TPB based interventions for behaviour change among chronic disease patients on:
    - Health outcomes (improvement of symptoms, quality of life)
    - Individual behaviour outcomes (preventive behaviours, lifestyle changes, adherence to therapy/medications, regularity of follow-up/treatment, care seeking)

    - TPB constructs like attitude towards behaviour, subjective norms and perceived behavioural control
- to describe the TPB interventions in terms of their development methods, types of intervention used, time frame/modes of delivery and the settings of such delivery (urban, rural, male, female, socio-economic status (SES))

2.1.2 Aim and objectives of qualitative research (Project 2)

The aim of my qualitative research was to understand the social and cultural context of the CRD related health behaviour from the patients, caregivers and the community, and to gain an insight into attitudes, social norms, perceived behavioural control and underlying beliefs governing such behaviour. This qualitative study was part of formative research to inform the design of a feasible TPB-based intervention in rural, low health literacy region of India.

Objectives of the qualitative research –

- to explore the beliefs, perception and practices of patients, family members and the community towards CRD-related health behaviour
- to construct the experiences of patients with CRD and their caregivers in the socio-cultural context and understand their attitude, social norms, perceived control, and barriers and facilitators to health behaviour

2.1.3 Aims and objectives of intervention development and description (Project 3)

The aim of this project was to develop a culturally acceptable educational intervention based on the psychological theory of planned behaviour and informed by UK Medical Research Council (MRC) complex intervention development and evaluation guidance, for behaviour change in patients with CRD in a rural low health-literacy population

The objectives of the intervention development were:

- to design a TPB-based educational intervention for behaviour change in patients with CRD using the MRC complex intervention development and evaluation guidance
- to develop the intervention to make it socio-culturally acceptable and adaptable to the local community

- to describe the intervention in the context of the setting, rationale, methods and materials using the template for intervention description and replication (TIDieR) reporting guidelines

2.1.4 Aims and objectives of pilot testing of the intervention and its evaluation (Project 4)

The aim of this phase of my PhD project was piloting the educational intervention I'd developed, through a trial on confirmed CRD patients of rural low health-literacy community to test its feasibility and understand implementation challenges. It also aimed to examine the impact of the intervention on the constructs of TPB and on health behaviour.

The objectives of intervention testing were:

- to evaluate the TPB-based intervention for its feasibility and identify the implementation challenges
- to analyse the effect of the intervention on attitude, social norms, perceived power and intention related to the health behaviour
- to measure the effectiveness of the intervention on behaviour change and health outcomes at the end of the intervention period

2.2 Outline of the PhD research and overview of the methodology

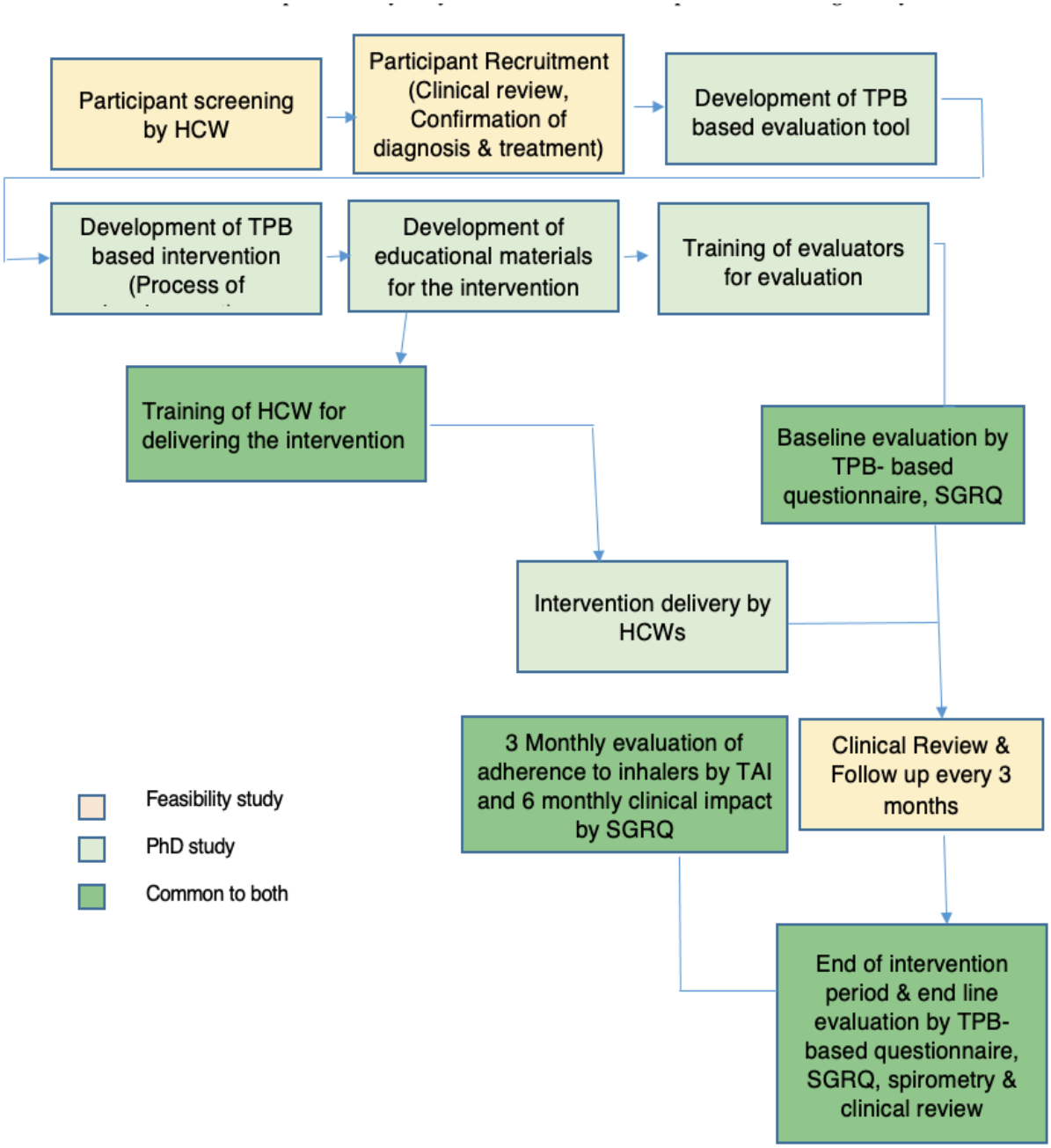
2.2.1 Introduction

This section provides an overview of the PhD research describing why it was conceived and how it was planned and implemented. It briefly summarises the various methods that were used as a part of research and why they were used for this study.

My PhD study of intervention development and feasibility testing was embedded in a larger NIHR Global Health Research Unit on Respiratory Health (RESPIRE) feasibility study titled 'Prevention, detection and treatment of adult lung disease (including lung cancer) in a poor, rural population in Tamil Nadu: feasibility study'. Some components of my PhD were common with the larger feasibility study and some components were stand alone to it but both the components were essential for the completion of my PhD and feasibility study. My PhD study was facilitated by the larger RESPIRE feasibility study in terms of provision of personnel like the research officer project coordinator

and respiratory therapist, equipment like spirometry and tools like protocol for diagnosis and treatment of CRDs using international evidence-based guidelines. The parts of my PhD which were distinct from the RESPIRE study were the TPB evaluation questionnaire, the TPB intervention, all educational materials, media and methods used for delivering the TPB educational intervention as well as trained evaluators and health care workers (HCWs) for baseline/endline evaluation and education, follow-up and referrals of patients, respectively. The distinct and the combined parts of my PhD and RESPIRE feasibility study is depicted in the schematic diagram, in Figure 2.1.

Fig. 2.1 The flow diagram of PhD activities/methods embedded in a larger RESPIRE feasibility project

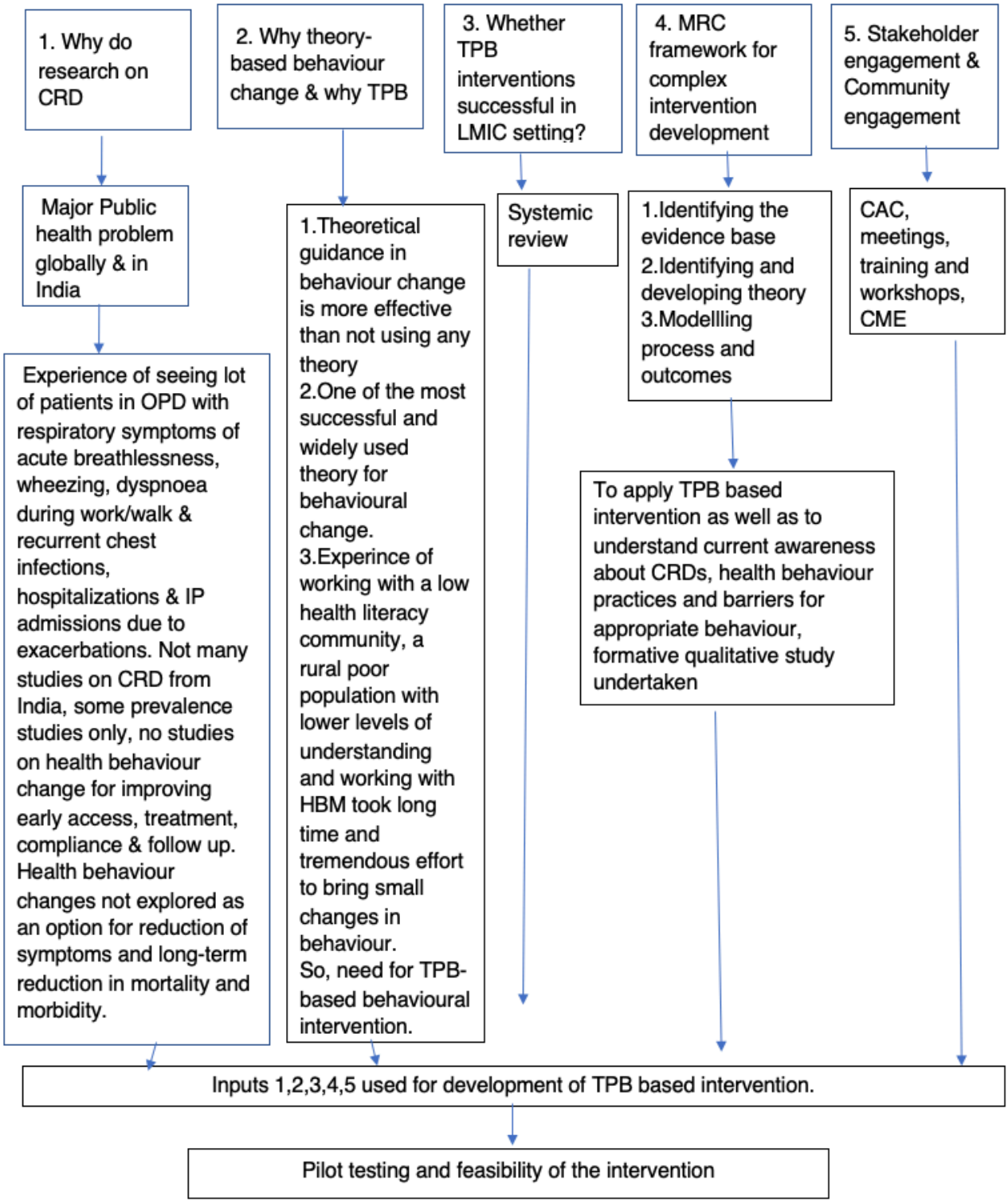


HCW – Health Care Worker TPB – Theory of Planned Behaviour SGRQ – St. George's Respiratory Questionnaire TAI – Test of Adherence to Inhalers

The aim was to develop and pilot test a theory of planned behaviour (TPB) based intervention for behaviour change in CRD patients in a low-health-literacy setting of a LMIC. Planning a research project involving health intervention for behaviour change

is like planning of a health programme or service; the first step of the planning cycle[1] is 'situational analysis' which involves assessing the present situation to get a perspective of problems and the gaps that need to be addressed. An intervention to effect behaviour change depends on several factors and is complex in nature, and therefore I used the new UK Medical Research Council (MRC) guidance and update 2019 for developing and evaluating complex interventions[2,3]. This guidance involves identifying the evidence base, identifying or developing a theory and modelling processes and outcomes. Therefore, it was important to identify the research gaps and collate current evidence, study the context and the community where intervention need to be delivered and use a theory which would be appropriate and beneficial for behaviour change. The schematic diagram in figure 2.2 depicts the methodology used to develop and test this intervention for behaviour change.

Fig. 2.2 Flow diagram depicting the development and testing of the TPB-based intervention



CAC – community Advisory Committee CME – Continuing Medical Education

2.2.2 Knowledge gap and need for CRD study

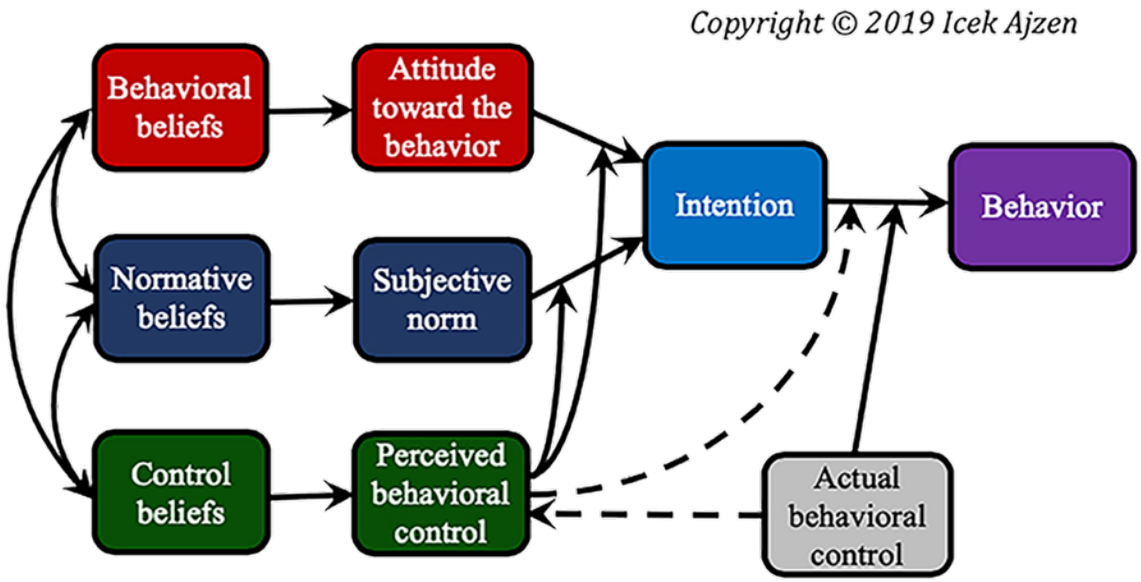
CRDs are a global problem with the majority of the mortality-morbidity burden being borne by low- and middle-income countries (LMICs). However, at the global level, the prioritisation of CRDs as a major public health problem and contributor to the global burden of diseases was recognised late, only by the turn of the millennium (2000) and thereafter efforts were undertaken by the World Health Organisation (WHO) by constitution of the Global Alliance Against Chronic Respiratory Diseases (GARD)and formation of the Global Monitoring Framework (GMF) for NCDs. Even then there is no specific target for CRDs in the GMFs, like the other NCDs in the 'big four' (as detailed in my introduction section). Similarly at the country level, the national programme for NCDs do not mention CRDs specifically, and there is no specific policy or programme on CRDs in India. True prevalence of CRDs in our country is not known, we do have some isolated research data but no country wide studies on prevalence of CRDs. Risk factors are known but no research on risk factors specific to geographical locations or types of population and which ones need to be targeted. For all chronic diseases including CRDs, adherence to treatment and disease appropriate health behaviour is a problem which results in failure of health services or health programmes. Research is required to examine factors responsible for such behaviour and how they can be modified to improve adherence and disease appropriate behaviour.

Creating awareness and providing information is the important first step but is not enough in itself; behavioural factors are crucial, regardless of target population characteristics (e.g., western, affluent, rural, low health literacy etc). It has been said that health behaviour change is our greatest hope for reducing the burden of preventable disease and death around the world. The challenge of understanding and improving health behaviour is central for health policy today and is "one of the most complex tasks yet confronted by science[4]. There is no research on the role of health behaviour or behavioural interventions in CRDs, in our country. Health behaviour is pivotal for successful implementation of any programme or policy; conversely, appropriate health behaviour creates health service demand from the population and stimulates policy change at the highest level.

2.2.3 Theory-based behaviour change and selection of TPB as theoretical framework

Several systematic reviews have shown that using theory in developing interventions can result in more powerful effects than interventions developed without theory[5, 6]. A better understanding of the role of theory can result in producing effective, sustained behaviour change. And the stage has changed from one that is primarily local and country-specific to one that is both global and local, in which we increasingly see the world as interconnected.

Figure 2.3. The theory of planned behaviour



The TPB was proposed by Icek Ajzen[7, 8] in 1985 and linked beliefs to intention which was considered the immediate antecedent to behaviour. There are three main constructs of the TPB – namely the attitude towards the health behaviour, the subjective norms and the perceived behavioural control. Together they can predict intention to perform behaviours, intention being considered the strongest predictor of actual behaviour. It is the attitude of a person toward the health behaviour which makes it likely or unlikely for her/him to perform the behaviour; such an attitude comes from the behavioural beliefs of the person and the outcome of such beliefs in the context of the environment and individual preferences which drives her/him to such behaviour. Similarly, subjective norms are social parameters, or boundaries, which influence a person's behaviour. The society or the community to which she/he belongs

have some norms regarding any health behaviour which can make it easy or difficult for a person to comply with it and the individuals in a society commonly believe that societal norms are the boundaries within which they must act. A person's own sense of control or perceived control is partially influenced by her/his attitude and societal norms as well as individual traits, preferences and capability to perform that health behaviour; therefore, the control beliefs and the person's perceived power influence the ability to perform the behaviour. All the above three constructs of TPB influence the intention of a person to perform the health behaviour, considered to be the strongest predictor of performing the actual behaviour.

There are different psychological theories for behaviour change and applying them in context can give the desired outcome(s). There had been some previous experience in our setting of using the health belief model, but desired outcomes were partial and took long time to achieve. Understanding people's perceptions and knowing their beliefs, attitude and intention in the context of the community where they live was of utmost importance for changing health behaviour. In this context and with the evidence that theory of planned behaviour has been used extensively in predicting behaviour change and to some extent, recently in developing behavioural interventions successfully, the TPB was chosen as an appropriate theory for designing the current intervention. The detailed rationale for choosing TPB as the appropriate theory for developing the intervention can be found in the introduction section.

2.2.4 Systematic review – Are TPB based interventions successful in LMIC setting and how should they be implemented?

As per the guidelines of updated MRC guidance on complex intervention development and evaluation 2019, intervention development involves collating current evidence and identification of a theory for intervention development. In the context of our rural, low-health literacy community and the need for behavioural interventions for CRD patients, I also needed to know whether TPB based interventions work in these challenging contexts - were they feasible to implement and were they effective? TPB had been widely used and reported to be effective in high income settings where the populations were typically educated, aware of consequences of respiratory-related behaviours and had good access to quality health care settings[9-12]. But could these approaches be

replicated in LMIC settings, or do they require change in approach and application? The best way to find out was to do a systematic review which could answer all these questions.

The protocol for the systematic review was developed using the PRISMA-P guidelines and the guidance from Cochrane's Handbook for Systematic Reviews of Interventions[13]. The systematic review (SR) followed methods of data analysis and reporting as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines[14]. The PICO criteria were used for describing the review question. The systematic review describes the feasibility and fidelity of TPB based interventions from LMIC settings and was used as an evidence base to guide in development of my intervention. The protocol is available on PROSPERO, registration number: CRD42018104890 and the procedures in the Cochrane Handbook for Systematic Reviews of Interventions. Searches were run in August-September 2018 and updated in March 2019, four papers were finally selected for review and a narrative synthesis was conducted to arrive at the results. The protocol for the systematic review was published in BMC *Systematic Reviews*. This was followed by the completion of the systematic review.

2.2.5 Qualitative study – formative research into local community health behaviour

For developing an intervention to change health behaviour among CRD patients, it was important to know about the current behaviour in practice, and the related attitudes, social norms, lived experiences and the facilitators or barriers to such behaviour. This was made possible by my qualitative study using the TPB framework to develop the topic guide and using focus group discussions, in-depth interviews and key informant interviews with CRD patients, care givers and key community members, respectively. Thematic analysis was used to arrive at the results. The qualitative study provided rich information about the awareness, risk behaviours, physical and psychological challenges of CRD patients, and the social norms, stigma and barriers to appropriate health behaviour besides financial and health system challenges. The inputs form this study helped me in identifying gaps wherein interventions could be useful and in design and delivery of the intervention (addressing low awareness, risk behaviour, stigma about disease and inhaler use in public, lack of information about

breathing exercises from health providers, etc). This qualitative study has been published in PLOS ONE and attached to appendices.

2.2.6 Inputs from stakeholder engagement

The stakeholder engagement started before the beginning of intervention and continued through and after the intervention period to actively engage the patients and the community, the health providers and practitioners, the project team members and the administrative and government officials and policy makers. The community engagement was done through community meetings and formation of a Community Advisory Group (CAG); the administrators were updated through quarterly and annual reports and annual meetings, whereas dissemination of project information and science among government officials and health practitioners was done through workshops and continuing medical education (CME) sessions. Inputs from the CAG group and community meetings were helpful in deciding how the intervention was planned (involving community and self-help groups to raise awareness about CRD, using specific CRD related videos and culturally acceptable media to disseminate CRD related education to low-literate population).

2.2.7 Intervention development and its components

The evidence from the systematic review, the inputs from the qualitative study and the stakeholder engagement programme helped in developing the theory of planned behaviour-based intervention using updated MRC complex intervention development and evaluation framework. This intervention used the TPB constructs to address gaps in awareness, risk behaviour, attitudes, subjective norms, perceived control and barriers with an aim to modify CRD related health behaviour among the patients and gain support of such behaviour in the community. The components of the educational intervention were patient and community education, training and demonstrations for inhaler use and breathing exercises, motivational short films to explain TPB constructs and live puppet shows and information videos addressing patient queries on specific CRDs.

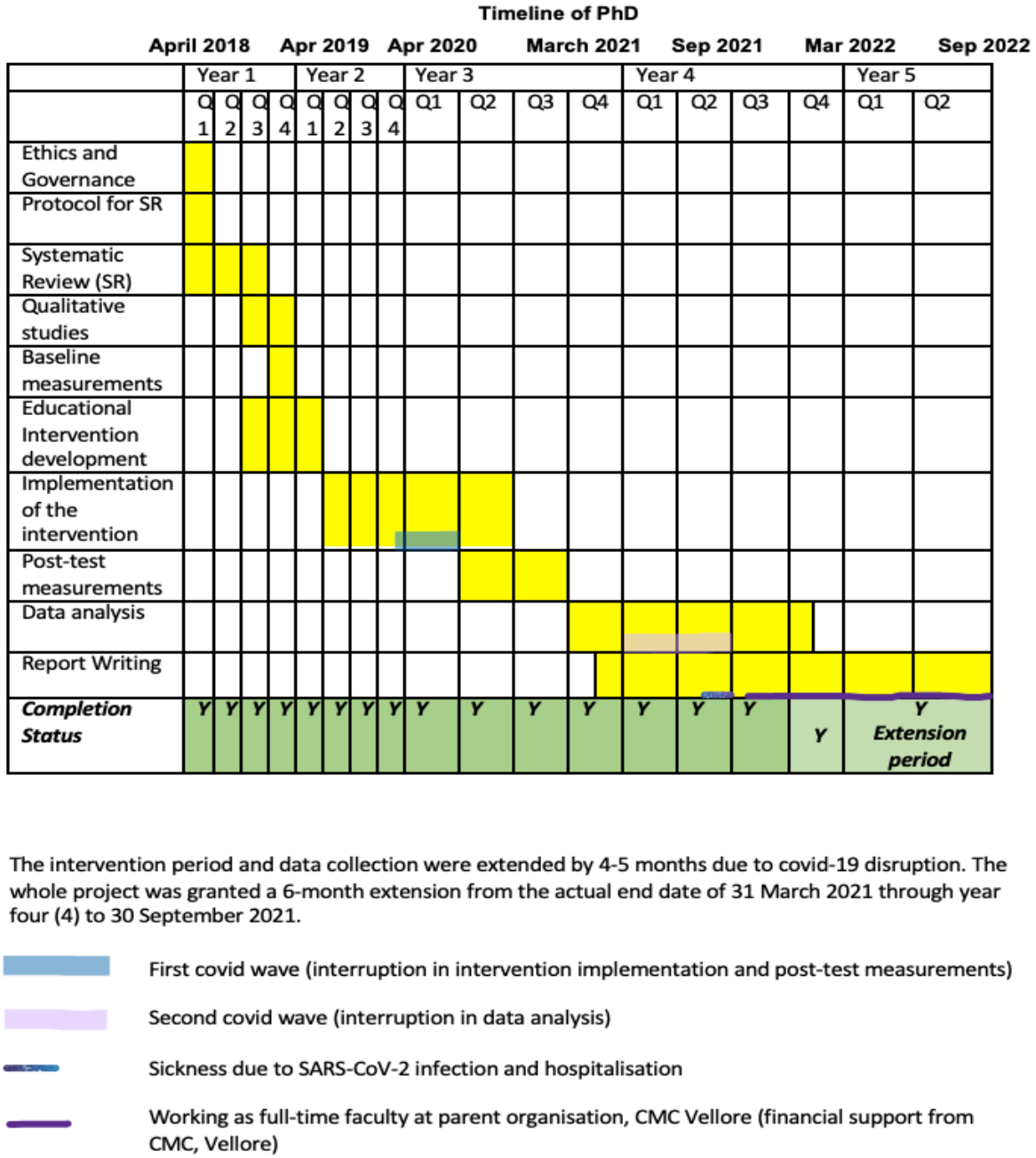
2.2.8 Testing of the intervention for its feasibility and its effectiveness

The final step was to pilot the intervention for its feasibility and test its's effectiveness in changing behaviour in CRD patients. The feasibility study took the form of a cluster randomised community trial where the intervention and control arms had two clusters each, with an anticipated 100 patients of CRD in each arm. The patients in the intervention arm were provided with the TPB-based educational package while in the control arm were provided usual health education based on health belief model (HBM). Protocol based management involving spirometry and treatment (GINA/GOLD guidelines) and provision of inhalers with spacers were provided for each patient. A baseline and an end-line evaluation were done for each patient using a validated evaluation questionnaire with a TPB section. The data obtained was analysed at the end of the intervention period to arrive at the results.

2.3 Timeline of the project

This PhD research proceeded as per the timeline depicted in Figure 2.4 below. The project was scheduled to be completed in three years' time but was extended by six months due to the covid-19 pandemic.

Figure 2.4 Timeline of the PhD research project



2.4 Triangulation in research

Triangulation is the method used in research for enriching data, add clarity to findings and bring about credibility and validity of research findings[15, 16]. It enriches data by adding findings from different datasets and presenting different aspects of the same research problem. It helps in examining the phenomenon of interest from different angles and helps in in confirming hypothesis where one dataset confirms findings of

another dataset. It also helps in bringing clarity to the findings in a research by generating data using different methods, as questions left unanswered in one method may be answered using a different method as happens in mixed methods research. Qualitative data may supplement quantitative data and vice-versa. Credibility denotes trustworthiness of findings or how 'believable' a study is; validity implies the extent to which the study correctly replicates or evaluates the concept or the research ideas being explored[17]. Thus, triangulation brings value to research and improves findings.

Triangulation in research can done in different ways. Norman Denzin (1970) identified four types of triangulation[18] – data triangulation, methodological triangulation, theory triangulation and investigator triangulation. In my PhD research I have used the first three types of triangulation and fourth one to a limited extent in my qualitative research.

2.4.1 Data triangulation

This refers to using multiple sources of data in research and using it to compare and cross check the findings. In my qualitative research study, I used focus group discussions (FGDs), in-depth interviews (IDIs) and key informant interviews (KIIs) with patients, care givers and key community members, respectively to obtain information on awareness, perceptions and practice of health behaviour related to CRD and to elicit social norms and opinions prevalent the community. Data triangulation helped in validating some findings (poor awareness to CRD, risk behaviours like not using inhalers or performing breathing exercises), while debating over some (use of biomass fuel – unaware vs financial constraint) and enriching information.

2.4.2 Methodological triangulation

This refers to using different methods to study a single problem. This is typically employed to compare quantitative data with qualitative methods, it is used to establish the degree of compatibility between information obtained through different strategies[19]. Qualitative and quantitative methods may be used simultaneously or sequentially to add to research findings or come to a conclusion. In my PhD study, I used narrative synthesis in systematic review of TPB-based interventions to collate current evidence on feasibility, fidelity and types and modes of interventions used in chronic disease patients in low health literacy settings of LMICs. I used qualitative methods with thematic analysis to gather information on awareness, perceptions,

attitudes, subjective norms, beliefs and health behaviour of patients and in the local community before developing and testing the intervention. I used feedback and suggestions from stakeholder engagement meetings to design and develop components of my intervention to make them more effective. I also used quantitative methods of data collection to test feasibility of the intervention and to assess attitudes, subjective norms, perceived power, intention and health behaviour in the same population before and after pilot-testing the intervention.

2.4.3. Theory triangulation

This implies use of multiple theoretical perspectives in conducting the research or interpreting the results. This helps in interpreting the phenomenon or conducting the research, more robust. In my PhD study, I have used theoretical frameworks – theory of planned behaviour (TPB) and the updated MRC guidance/framework on developing and evaluating complex Interventions. Both these theoretical frameworks emphasise on collating current evidence in practice. The MRC theory also states identifying a theory as the first step to develop a complex intervention which led to identification of TPB. TPB states doing formative research as an essential step for developing TPB-based interventions. Thus, both the theoretical frameworks have facilitated intervention development.

2.4.4 Investigator triangulation

This involves using several researchers for the study. Since this is PhD research, it was not possible to have multiple investigators. However being embedded in the larger feasibility study, aspects of the research was supervised by my supervisors. In the qualitative study, I had to use an independent researcher to conduct, transcribe and translate the FGDs, IDIs and KKIs and produce the transcripts as I was not well versed with the vernacular language of the local population. She also helped in initial reading of transcripts to generate the codes along with me. So my language limitation became strength of my qualitative study as two researchers were initially involved in coding.

2.5 Positionality and Reflexivity

Positionality and reflexivity are two important aspects to consider while doing research as they explain the position and the views of the researcher and the influences thereof on research design, execution and outcomes. Positionality is an individual's world view

because of her/his values and beliefs and the position that the individual takes in research and its social and political context[20-22]. An individual's world view or 'where the researcher is coming from' involves ontological assumptions (an individual's beliefs about the nature of social reality and what is knowable about the world), epistemological assumptions (an individual's beliefs about the nature of knowledge) and assumptions about human nature and agency (individual's assumptions about the way we interact with our environment and relate to it)[23-26]. These are affected by values and beliefs shaped from socio-cultural environment, political allegiance, social class, religion, ethnicity, gender, sexuality, geographical location, status and so on[25-27]. Positionality may be identified by locating the researcher about the subject under research, the research participants, and the research process and context[22]. Reflexivity is the concept whereby researchers acknowledge and disclose their selves in the context of research, seeking to understand their position and their influence on it[28]. Reflexivity starts by identifying preconceptions brought into the project by the researcher, representing previous personal and professional experiences, pre-study beliefs about how things are and what is to be investigated, motivation and qualifications for exploration of the field, and perspectives and theoretical foundations related to education and interests[20]. In other words, reflexivity informs positionality.

I am a primary health care professional and a public health researcher working in an academic institute with roles of primary care physician, educator, administrator and community health researcher, primarily in implementation research. I have had medical training as well as training in research ethics and good clinical practice. I work as a primary care provider in a rural setup with a community which is low-literate, primarily agrarian, of Asian ethnicity and with a low to lower-middle socio-economic class. I belong to Asian ethnicity, of male gender with a heterosexual predisposition and have been working this this community for almost 10 years. Communication with the community members and patients who come to the hospital is mostly verbal in the vernacular language with limited pictorial handouts. The type of patients seen in the hospital vary with both non-communicable and communicable diseases presenting on a daily basis in the out-patients department with in-patient and emergency department (ED) patients predominantly being non-communicable like cardiovascular events,

chronic respiratory disease exacerbations and complications of diabetes and hypertension.

The type of patient profile seen at our hospital, with a substantial proportion of patients visiting outpatient with respiratory symptoms and frequent exacerbations of CRD patients visiting our ED with breathlessness, stimulated the current research topic with an aim to improve the quality of life of such patients, through research. My research participants were the patients with chronic respiratory disease, belonging to the local community as described above with good representation of the vulnerable population[29] like rural, poor, female gender, low social class. The context of the research came from the idea/hypothesis of improving the health and well-being through behaviour change for such chronic disease (CRD) patients using a newer psychological theory tested successfully in high income countries but yet to be tried for behaviour change intervention in LMICs. Since this was a novel setting with a different population profile, I thought it was important to further my research through community engagement and feedback to bring out the potential barriers and build an appropriate intervention. Of course, my current position as a medical practitioner and community health researcher did give me some prior idea, but I wanted to validate and value-add some more with community engagement, which I thought gave me best results, social acceptability and sustainability to this research besides making it feasible to implement and useful to the community.

During the formative qualitative research and community engagement process, I found it a useful eye-opener; patient and public involvement was essential for guiding research; it unveiled current attitudes, life experiences due to the disease and community norms previously unknown to me, or plainly covered from my horizon because of my medical knowledge, social class and my capacity as care-provider rather as a care-seeker. However the interactions were very exciting and satisfying because of their myriad nature and the richness of the information gathered and at times heart-wrenching because of the painful experiences shared by CRD patients. I was, though, received well, perhaps because of my position, by the interviewees and they responded well to my questions. Since I interviewed only key-informants with a higher social status, I believe the answers were true and not influenced by my position. For the focus group discussions (FGDs), I was only involved as an observer, in a

couple of sessions, while a social scientist with a sociology background, belonging to the same community, responsible for conducting the FGDs. I was involved in all other community engagement activities.

Being a medical practitioner, having a position of interacting with patients on a daily basis and experience of working in the community for many years, my inclination for biomedical terms was natural and reflected in development of some of the themes, as in, causation, health behaviour and treatment seeking. However I went about with an open mind to capture participants' perspectives, experiences and emotions during the process of interviews and discussions. The process of reading of the transcripts was an enriching experience of delving into the participants' world and understanding their views. Overall, I had an enriching experience during the PhD research, not only academically but also in life values and social interactions.

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Chapter 3

Project 1 – A Systematic Review of Theory of planned Behaviour interventions for chronic diseases in low health-literacy settings

3.1 Introduction

Chronic diseases are conditions which persist over a long period of time or have long lasting effects; in some cases they may develop over time. Because of their long-lasting nature and long-term effects, they are responsible for lot of morbidity and mortality in individuals inflicted with them. The duration of chronic diseases has been defined as more than 3 months to more than a year in various definitions of chronic disease given by various organisations including United States National Centre for Health Statistics (USNCHS) and Centres for Disease Control and Prevention (CDC)[1]. Different conditions have been included by different organisations and definitions vary[2-5] but there is no denying the fact that chronic diseases affect all age groups and all regions of the world. Chronic diseases including noncommunicable diseases are associated mainly with older age groups and cause most of the premature deaths (~85%) in low- and middle-income countries[6]. In this systematic review (SR), we have used the definition of chronic diseases used by World Health Organization[3] and have included major chronic diseases causing multi-morbidity and mortality. Chronic diseases are usually of longer duration; require prolonged treatment, repeated hospital visits and follow-up; and involve specific health behaviours for prevention or control. Health behaviour is the underpinning component which can modify or influence many of the risk factors, lead to better management of chronic diseases and improve compliance to treatment[7], thereby reducing the enormous morbidity and mortality associated with such diseases.

Health behaviour relates to actions taken by individuals which affect their health and wellbeing[8]. In fact, in everyday life, we perform a lot of actions which affect our health, either positively or negatively. A simple behaviour like adequate sleep and maintaining sleep time can affect health, as much as behaviours like low physical activity or smoking. Health behaviour is an integral part of our lives and affect our health because of the actions we perform[8]. Health behaviour refers to any behaviour that impacts on people's physical and mental health and quality of life[9]. It is defined by Gochman, 1997

as “personal attributes such as beliefs, expectations, motives, values, perceptions, and other cognitive elements; personality characteristics, including affective and emotional states and traits; and overt behaviour patterns, actions, and habits that relate to health maintenance, to health restoration, and to health improvement”[10]. Behaviour can be a set of actions that a person does in response to an external or internal stimulus or event; these actions may be overt and directly measurable or covert but results in a change[11]. Health behaviour is dynamic and tends to change over time and therefore interact to affect human health both ways.

Human behaviour influences health; researchers have suggested that human behaviour underlies more than 50% of the illness[12-13]. Population health is affected by three types of behaviour – behaviours that relate to disease prevention, behaviours that comprise care seeking and adherence to treatment, and behaviours that contribute to healthcare delivery[9]. Behaviours not only initiate change in health status but can also maintain it if continued for long period or is transformed into a habit[14]. Tobacco use, unhealthy diet, physical inactivity and the harmful use of alcohol – considered the main risk factors for four main non-communicable diseases – cardiovascular, respiratory, diabetes and cancer[15] are all related to human behaviour and are therefore modifiable and/or preventable. Low- and middle-income countries (LMICs), which traditionally were burdened with infectious diseases, now face the double burden of both infectious and non-communicable diseases due to the increased prevalence of smoking, alcohol consumption, unhealthy diet and obesity[16]. Not only non-communicable diseases, but even infectious diseases like HIV/AIDS require health behaviour change like use of condoms to reduce or to completely prevent disease[17]. Recently the COVID-19 pandemic has shown to the world that human behaviours like use of face mask, social distancing, handwashing and vaccination are important even for infectious diseases in disease prevention and pandemic response[18]. Health behaviours are important in managing chronic conditions and behaviours like care seeking and adherence to treatment are paramount in chronic disease patients for early diagnosis, control of symptoms and prevention/mitigation of complications. Health behaviours needed for medication adherence include obtaining the medications using one’s own resources; accurately self-administering medications over time; and recognizing and reporting any adverse

outcomes and going for a regular follow-up visit as desired by health provider. People who successfully manage chronic conditions manage negative emotions associated with chronic conditions and fulfil responsibilities to their concomitant life roles[19-20]. Healthcare professionals need to better understand how health behaviour change is made and their role in facilitating and supporting change. Changing behaviours of health care professionals so that they implement evidence-based guidelines and provide required information about treatment implications to patients can contribute to effectiveness and quality of care of health care delivery[21-22]. Recent times have seen a dramatic rise in public interest and professional endeavours in preventing disability and death through changes in lifestyle and participation in screening programs. Much of this interest in disease prevention, early detection self-management and adherence to treatment for control of disease has been stimulated by the epidemiological transition from infectious to chronic diseases as leading causes of death, the aging of the population, rapidly escalating health care costs, and data linking individual behaviours to increased risk of morbidity and mortality. Health behaviours are an inseparable part of human health and well-being and play a major role in health promotion, disease prevention, adherence to medications, disease control and quality of health care delivery; however, their role in prevention and control of chronic diseases cannot be overemphasised[23-25].

Behaviour change can be targeted at individual, organisational, community, and population levels, and any intervention delivered at one level can impact other levels. Interventions that target several levels simultaneously and consistently are most effective in changing health behaviour[26-27]. Changing health behaviour warrants an understanding of the existing health behaviour and transformation of this knowledge into effective strategies for behaviour improvement. Basic behavioural research is vital in developing theories, and these must be tested iteratively in real-world contexts[28]. Theories provide the concepts and a systematic view of events to explain a health behaviour or a phenomenon. Theory has been defined by Kerlinger as “a set of interrelated constructs (concepts), definitions, and propositions that present a systematic view of phenomena by specifying relations among variables, with the purpose of explaining and predicting phenomena”[29]. An understanding of theories of behaviour change is important to design interventions that yield desirable changes

along with a capability to use them skilfully in research and practice[30]. Since resources are always limited, it is essential that the interventions should be evidence informed and use theories which can best predict the change in each setting. MRC emphasizes use of a theory in intervention design; theory improve intervention effectiveness and allow replication[31]. Theories help to identify what one needs to know before developing an intervention program and strategize how to reach to people to make an impact on them. Well formulated and empirically validated theories are valuable for designing and evaluating the effects of behaviour change interventions[32-33]. Interventions based on theoretical framework are more effective in changing health related behaviour than non-theory based interventions[34]. Systematic reviews have shown that using theory in crafting interventions can lead to more powerful effects than interventions developed without theory[35-36].

Quite a few behaviour-change theories have been used for changing health behaviour in individuals, either for predicting such behaviour or developing interventions based on a particular theory to change health behaviour. Among the different theoretical frameworks that have been used in the past, those used more often were Health Belief Model (Hochbaum and Rosenstock, 1950), Social Cognitive Theory (Bandura 1986), Transtheoretical Model (Prochaska 1984) and Theory of Planned Behaviour (Ajzen and Fishbein 1980)[37-38]. The Health Belief Model (HBM) emphasises on providing information and improving knowledge of the participants so that they identify and appreciate susceptibility and severity of the disease, perceive the barriers and the benefits and can act based on all the information provided about the disease. Basically, HBM theorises that adequate knowledge translate to appropriate behaviour. However, knowledge does not always translate to action as desired and may take a long time for the behaviour to be adopted[39-41]. Indeed, this has been the lesson learnt from the ongoing cervical cancer screening program at my medical centre for the last 15 years.

The Social Cognitive Theory (SCT) by Bandura states that human behaviour is a product of dynamic interplay of personal, behavioural and environmental influences but it focuses on people's potential abilities to alter and construct environments to suit purposes they devise for themselves[42]. SCT also emphasises on the human capacity for collective action. Thus SCT emphasises on individual human capability to perform

a health behaviour as well as collective ability to control environment and social factors to influence behaviour. This type of ability and self-efficacy may be possible from well educated, health-literate and a knowledgeable population in developed countries where most of these theories were tested, but may not be suitable or feasible to a low health-literate and resource poor low economic capability population. Transtheoretical Model (TTM) of Prochaska which relies more stages of change in individuals and focusses on individual's ability to go through these stages to change behaviour. TTM reviews provide mixed evidence and suggest that TTM-guided interventions do not always change health behaviours. Moving people from one early non-behavioural stage to another is not equivalent to behaviour change, and interventions that alter stages of change (or intentions) may or may not yield behaviour change[43].

The Theory of Planned Behaviour (TPB) by Ajzen states that behaviour is an outcome of individual beliefs related to that behaviour which determines the attitude towards the behaviour, the subjective norms prevalent for that behaviour and the perceived behavioural control which lead to an intention to perform that behaviour, intention being the most important determinant and immediate antecedent to a particular health behaviour. TPB assumes a causal chain that links beliefs (behavioural, normative and control beliefs) to behavioural intentions and behaviours via attitudes, subjective norms, and perceived behavioural control. The TPB provides a systematic method to identify those issues that are most important to a person's decisions about performing specific behaviours. Because many important beliefs and attitudes are changeable, they are ideal targets for subsequent interventions. One of the important strengths of TPB is its specificity of the intended behaviour which is also central to the TPB theoretical framework. TPB is well supported by existing data from laboratory experiments, field studies, and health behaviour interventions[43]. TPB is a widely used and effective theory for behaviour change in individuals and have been used in a wide range of settings for predicting health behaviour or developing interventions for behaviour change[38]. TPB has been used successfully to predict and explain behaviour change in a variety of behavioural domains, from safer sex to consumer behaviour, choice of travel, physical activity, type of diet and drug use[44-47]. More recently, TPB has been used increasingly as a behavioural framework for designing and evaluating behaviour change interventions and their outcomes[48-50].

Most of the studies done on TPB have come from the western world and the settings were more of wealthy population with ample of resources available to them; most of the predictive TPB studies have been on the affluent, young and fit individuals[51-53]. Although some researchers have designated the TPB as 'Western' and fit for well-educated population[54], there have been ample arguments in its favour to apply it cross-culturally and to investigate and understand the behaviour from the perspective of the study population[55-56]. It is important to study beliefs underlying these constructs that must be specific to the behaviour and population being investigated. Therefore, it was essential to conduct this systematic review (SR) on chronic disease patients in low resource and low health literacy settings, i.e., TPB based behavioural interventions in low- and middle-income countries to determine the effectiveness of such interventions in these populations and test the feasibility of such interventions in these settings. Besides this SR was conducted to inform me about developing and implementing such an intervention in my country. The objectives of the systematic review were –

- to determine the feasibility and fidelity of TPB based interventions in low health literacy settings of LMICs
- to determine the impact of TPB based interventions for behaviour change among chronic disease patients on:
    - ⇒ Health outcomes (improvement of symptoms, quality of life)
    - ⇒ Individual behaviour outcomes (preventive behaviours, lifestyle changes, adherence to therapy/medications, regularity of follow-up/treatment, care seeking)
    - ⇒ TPB constructs like attitude towards behaviour, subjective norms and perceived behavioural control
- to describe the TPB interventions in terms of their development methods, types of intervention used, time frame/modes of delivery and the settings of such delivery (urban, rural, male, female, socio-economic status (SES))

3.2 Methods

3.2.1 Protocol and registration

This SR followed methods of data analysis and reporting as per the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines[55]. A protocol for this SR was developed prior to conducting this review, in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P)[58] and guidance from the Cochrane Handbook for Systematic Reviews of Interventions guidelines for developing a protocol[59]. This protocol is registered with the University of York Centre for Reviews and Dissemination International prospective register of systematic reviews PROSPERO (an international database of prospectively registered systematic reviews in health and social care) database and can be accessed online (registration number: CRD42018104890) and have been published by Paul et al in BMC Systematic Reviews[60].

3.2.2 Types of studies

Randomised controlled trials, clustered randomised community trials and quasi-experimental studies / non-randomised trials[61] were included. Studies comparing the intervention with a comparison group including placebo, treatment as usual / standard care or comparison with a different intervention than in the designated intervention group, were included. Studies with more than one intervention group, or within subjects across time (i.e. controlled before and after studies) were included.

Case–control studies, cohort studies, cross-sectional studies, reviews, case reports, case series and animal studies were excluded. Studies on health behaviour change which do not mention Theory of planned behaviour (TPB) or at least two constructs of TPB among four (attitude towards health behaviour, subjective norms, perceived behavioural control and intention) or other psychological theories were not included. Studies undertaken on healthy individuals with a purely health promotion focus were not considered in this review.

Studies published in any language were accepted to improve the range and diversity of TPB based interventions, in different settings. Since this review looked at studies specific to low- and middle-income countries (LMICs), the decision to include any language publication was taken to consciously include a larger number of possible

studies. Also an initial web search in English language studies did not give encouraging results, hence the decision.

3.2.3 Types of participants

Participants were adults, of 18 years of age or more and who have had chronic disease (s)[3]. Chronic diseases including cardiovascular diseases, cancers, chronic respiratory diseases, diabetes, hypertension, obesity, chronic mental illness like Alzheimer's disease, chronic bone or joint disease like osteoarthritis, and HIV/AIDS were considered for this systematic review. Healthy population and pregnant women were excluded.

3.2.4 Types of interventions and control/comparator

Health or educational interventions using the constructs of TPB (attitude towards the behaviour, subjective norms, perceived behavioural control and intention) to change health behaviour (lifestyle/preventive behaviours/adherence to medications/health seeking behaviour) were considered for this review. Interventions using underlying beliefs to the TPB constructs – behavioural beliefs, normative beliefs and control beliefs and terms like evaluation of outcomes, motivation to comply and perceived power were also included, as was informed from a scoping review of literature. As mentioned earlier, interventions based on TPB were included if at least two of the constructs and/or underlying beliefs were used. TPB interventions on individuals or on groups, either hospital or community based were included. Interventions applied on patients with chronic diseases (defined above) and on LMIC countries with low literate or low health literacy populations were included for this review. Health literacy has been defined as "the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions"[62] and influence health behaviours and outcomes[63-65]. Health literacy in low- or middle-income countries (LMICs) is lower than that measured in the USA and other high-income countries (HICs), because by definition, general income and education of people in LMIC will be lower as a whole as well[64-68]. Population belonging to (LMIC) as defined by World Bank 2017 per capita income was included for the selection[69]. The reason behind this selection was to use it as a proxy for population with low

literacy, healthcare and income/socio-economic status, i.e. low health literacy and health resource.

The control or the comparator was (1) health or educational intervention not based on any psychological theory, (2) health education based on psychological theory other than TPB or (3) treatment as usual without any education. For controlled before and after studies the same group used as control with usual health education or no education with treatment followed by TPB-based intervention were included.

3.2.5 Outcomes

The primary outcome that was required for the inclusion of studies was change in health behaviour following the intervention; health behaviour included preventive behaviours, lifestyle changes, adherence to treatment and care seeking. Adherence has been defined by the World Health Organization (WHO) as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider"[70].

Other key study elements included in this SR were study setting, constructs of TPB which influenced health behaviour change, time-frame of such interventions, feasibility and fidelity of the intervention, i.e. recruitment rates, integrity of the intervention, completion and follow-up rates and adherence to time frame. Other important elements were the mode of delivery of the intervention, type of health providers implementing the intervention and satisfaction among patients to the intervention. These study characteristics helped in informing the researchers for building an intervention, appropriate for a LMIC setting, which could be feasible and effective.

3.2.6 Information sources and search strategy

A total of 11 electronic databases were searched for relevant studies. They were MEDLINE, Embase, Cochrane Library, PsychINFO, Web of Science, Scopus, CINAHL, ProQuest databases (ProQuest Sociology and ProQuest Social Sciences), Global Index Medicus, Bibliography of Asian Studies and IndMED.

Each database was searched from year 1980 to 2019. Search terms used keywords, truncation and MeSH terms as appropriate for each database's indexing reference; appropriate syntax, with parentheses, boolean operators and field codes were used for searching records from databases[71]. The search was stratified into five categories:

theory of planned behaviour, trials, health behaviour or adherence, chronic disease and low and middle income countries. Search terms were chosen based on previous research, theory and practice. The first category used TPB/TRA and related terms to search for studies based on it, as it was the central to the review objective. The second category used trials which included terms like randomised and non-randomised trials, longitudinal studies and feasibility studies. The third category was health behaviour or adherence which was the primary objective of the review and used keywords like behaviour change, health seeking behaviour, adherence or compliance. The fourth category specified on chronicity of the disease or condition and used chronic disease and chronic respiratory diseases. The fifth and final category searched for studies from low and middle income countries and used search terms like low income, underserved population, less developed, developing countries and specific country names or regions. A full electronic search of the databases search is attached. Web based search using titles and phrases were also done in addition to database search.

3.2.7 Study selection and data collection process

The databases were searched for relevant studies, and all such records were exported to the EndNote Library for screening, deduplication and overall management of the records. Search for records, export to Endnote and deduplication was done by me. Final records in the end note were all screened by me by their titles and abstracts and by a second reviewer to assure correctness and avoid missing out relevant records. First screen by done by titles and the second screen by reviewing the abstracts as per the pre-established inclusion criteria (Table 1). Any disagreement was resolved by discussion and was finally guided by my supervisors. A similar process was followed for screening of full-text studies. Multiple publications of the same study utilising the same data set was taken as one study. The full-text article for a particular study title or abstract not freely available was requested through our library resources. Studies were included if they were available till the cut-off date of March 2019. A review for newer studies was once more done through a web based search in March 2020. All full text articles were reviewed by me and a second reviewer using the inclusion and exclusion criteria in table 3.1 and studies were selected and matched. All studies included were matched between two the reviewers and confirmed by my supervisors and finally went into synthesis.

Table 3.1. Inclusion and exclusion criteria for screening

Sl. No.	Characteristic	Criteria for inclusion/exclusion
1.	Population	The selected population should be adults above 18 years of age, either males or females or mixed population and should not be Caucasian. If any population <18 years of age is defined as adult as per the country's classification, then it will be accepted.
2.	Disease / Condition	Any chronic disease or condition is acceptable for inclusion since the search criteria involves population with any chronic disease while excluding research studies involving healthy population or pregnant women. Thus, globally recognised terminologies of disease classification are used, i.e., non-communicable diseases like cardiovascular disease, stroke, diabetes, hypertension, obesity, chronic bone or joint disease like osteoarthritis, chronic mental illness and cancer are included along with people suffering from HIV/AIDS
3.	Intervention	Studies which have used Theory of planned behaviour (TPB) based educational or health intervention for health behaviour change (HBC) will be included; studies using multiple theories for HBC will be included provided there are measurable outcomes effected by TPB. Studies considering at least two of main constructs of TPB will be considered. The constructs of TPB are attitude towards health behaviour, subjective norms and perceived behavioural control; of course, underlying beliefs and intention to act will also be considered for inclusion.
4.	Control /Comparator	Comparison will include health or educational intervention for behaviour change not based on any psychological theory or health education using behavioural theories

		other than TPB. Individuals or groups getting treatment as usual without any structured health education are also eligible as controls.
5.	Study design	Only interventional studies measuring effect after a period of intervention will be included; this include clinical trials, randomised and non-randomised trails, cluster randomised and community trails, before and after studies and longitudinal and feasibility studies with TPB intervention. Surveys, case studies, case control and cohort studies will not be included as well as animal studies.
6.	Setting	Population belonging to low- and middle-income countries (LMIC) as defined by World Bank 2017 per capita income is included for the selection. The reason behind this selection is to use it as a proxy for population with low literacy, healthcare and income/socio-economic status, i.e. low health literacy and health resource.
7.	Outcomes	Any measurable change in knowledge, attitude and health behaviour specific to a chronic disease condition will be evaluated which will include measurable difference in disease awareness, frequency and/or duration of exercises, drug adherence and self-care.

3.2.8 Data items, summary measures, synthesis and analysis of results

The data extraction form was adapted from the Cochrane Collaboration data collection form of randomised controlled trials (RCTs) and non-randomised studies (NRS)[72]. Data extraction was performed by me and rechecked by a second reviewer and finally reviewed by my supervisors. Detailed descriptive information from each intervention including the name of the included study with author(s), place and year of study; study design features (e.g., data collection points, inclusion of a control group or not); socio-demographic characteristics including age and gender, education/literacy levels were reported in table 2. For assessing the effect of the interventions, the name of the

outcome measure(s), reported value(s) for intervention effectiveness (i.e. p value, effect size) and based on prior research that provided a narrative commentary on study design methods that may influence the generalisability of study effects were obtained. Outcomes were considered to be statistically significant if the quantitative effects on the basis of $p < .05$[73], was reported. For combining and reporting the results of narrative synthesis, I inspected each study's methods and outcomes and categorised them in accordance with the following key themes: study setting, feasibility and fidelity of the intervention, effectiveness of the study, methods of health education/intervention delivery, health providers for study implementation and outcomes (change in knowledge, attitude, behaviour or adherence, i.e. increase knowledge, improve attitudes or change in health behaviour or quality of life). A summary of these findings are presented in table 3. A meta-analyses was not conducted as substantial heterogeneity was found for construct measurement and operationalisation (e.g., improvement of healthy lifestyle vs improvement in quality of life). No additional subgroup or sensitivity analyses were conducted, as only a small number studies were finally chosen.

3.2.9 Risk of bias within and across studies

Risk of bias for all potential studies was evaluated using the Cochrane Collaboration's tools for assessing the risk of bias. For randomised controlled trials (RCTs), revised Cochrane risk-of-bias tool for randomised trials (RoB 2) was used[61]. For non-randomised studies like quasi-experimental studies, the risk of bias in non-randomised studies of interventions (ROBINS-I) tool was used[74]. As per the guidelines in the Cochrane Handbook of Systematic Reviews of Interventions[72], the studies were assessed as per standard criteria and labelled as 'low', 'some concerns' or 'high' risk of bias. The tool includes domains for assessing risk of bias and detects bias arising from the randomization process, due to deviations from intended interventions, due to missing outcome data, due to measurement of the outcome and bias in selection of the reported result. Each domain is coded as high, low or some concerns for the relative risk of bias and an overall judgement is accumulated.

3.3 Results

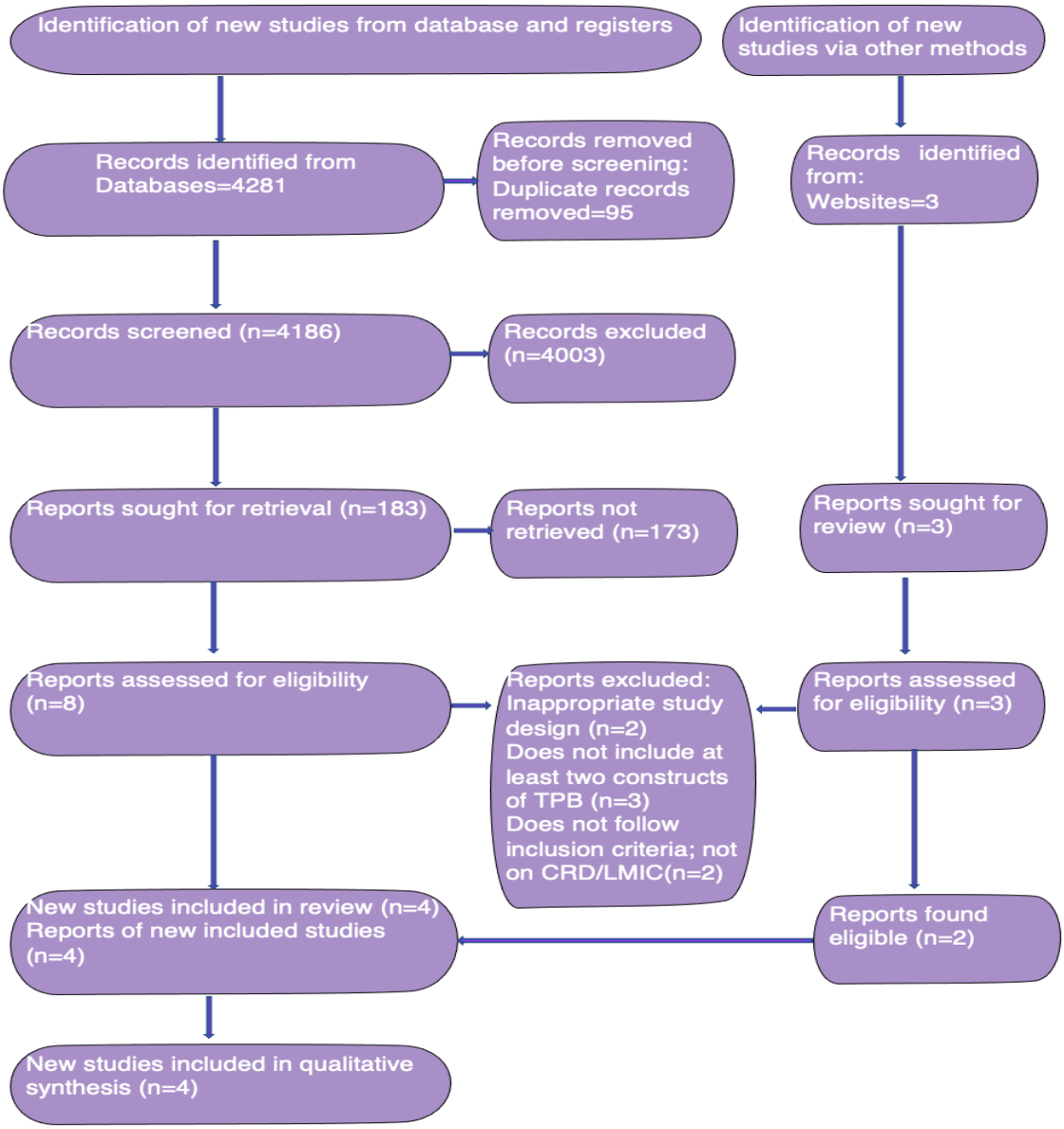
3.3.1 Descriptive results

A total of 4281 titles and abstracts were reviewed (3697 from ProQuest Sociology; 257 from Scopus; 237 from Cochrane; 41 from EMBASE; 24 from MEDLINE; 9 from Web of Science; 7 from Global Health; 4 from CINAHL; 2 from Psych INFO). Three articles was identified by web search, one during scoping review and two later after database search. After removal of duplicates (n = 95), 4186 titles and abstracts remained. Of these, 4003 were identified as irrelevant and were excluded. A total of 186 articles were identified as relevant and underwent a further detailed screening for full-text printing eligibility; of these, 11 met the criteria for a standardised independent full-text screening by two authors.

From the 11 articles, authors agreed upon seven articles to be excluded because they did not meet the inclusion criteria on at least one level. There was complete agreement between two authors including me and with the supervisors for inclusion of four studies for narrative synthesis. The PRISMA flow diagram for this systematic review is presented in Figure 1. Three articles[75-77] did not use TPB for changing behaviour; of these one[75] used coping and action planning and the second[76] used Gollwitzer's Implementation Intention Theory to change intention to behaviour for medication adherence while the third[77] study used TPB questionnaire for evaluation of eating behaviour, one component of evaluation of clinical outcomes and health behaviour, but did not use TPB for health intervention. Two studies[78-79] used TPB but were cross-sectional studies and did not fulfil the inclusion criteria for interventions, and hence were excluded. In one study[80] the participants were healthy individuals and the intervention was for health promotion, rather than being on patients of chronic disease; hence was excluded. The last study[81] that was not included for the final synthesis was not from a LMIC. Of the three articles identified by manual web search, one was a conference abstract of an ongoing study and was not included in final synthesis, the other two included in the eleven studies that underwent full text screening. The above process of screening and selection based on inclusion criteria, finally resulted in four studies being selected for analysis and narrative synthesis. The process is depicted

in Figure 1 as per Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) 2020 updated statement[82].

Figure 3.1. The PRISMA 2020 flow diagram



3.3.2 Study characteristics

Study characteristics are detailed in Table 3.2. The title of the study, name of the authors who conducted the study, the year, the design, study duration and sample characteristics are described. Across the four studies[83-86], 408 participants took part, which included 227 females and 181 males. Only one study reported economic status[81]. Education was reported by all four studies; three[83,85,86] of them also reported

marital status and employment status of the participants. The interventions were delivered to a range of chronic disease participants including cardiovascular disease patients with previous myocardial infarction (n = 2), diabetes (n = 1) and knee and hip osteoarthritis (n = 1). Study designs adapted include three randomised control trials (RCTs)[83,85,86] and one non-randomised (quasi-experimental) trial[84]. All the studies were from LMICs as per World Bank definition[69], in-fact they were from a single country. All of them used intervention and control groups; TPB-based educational intervention was given in all studies and routine education was given to the control groups in three studies[83,85,86] while it was not clear in one[84].

Table 3.2 Descriptive information of the four included studies

Name of the study; Authors	Place of study; year of study	Study design; Duration	Sample characteristics
A theory of planned behavior-based intervention to improve quality of life in patients with knee/hip osteoarthritis: a randomized controlled trial Saffari M, Emami Meybodi MK, Sanaeinasab H, Karami A, Pakpour AH, Koenig HG.	Tehran, Iran 2016	Randomised controlled trial with intervention (I) and control groups (C) I- TPB based intervention C – routine treatment; no educational intervention May – September 2016; total 5 months duration	n=120 (I=60; C=60) Mean age=55.8±8.9 years Gender: Females=91 (75.8%) Education: Illiterate/elementary=68 (56.7%); high school/secondary=27 (22.5%); university=25 (20.8%) Economic status: good=12 (10%); not good, not bad=90 (75%); bad 18 (15%) Married=112 (93.3%) Employed= 10 (8.3%)
The Effect of Educational Program Based on Belief, Attitude, Subjective Norm, and Enabling Factors Model	Fasa City, Iran	Randomised clinical trial with intervention and control groups	n=108 (I=54; C=54)

on Changing the Metabolic Indices in Elderly Patients with Type II Diabetes Askari A, Jeihooni AK, Kashfi SM, Marzban A, Khiyali Z.	2016	I – Educational intervention including two constructs of TPB and some other components; training sessions (two/week), a total of eight sessions; physical activity (walking for 3 times a week of 20-minute duration each) C – Not clear; coordination performed with medical staff at centre Duration – Not specified; one month of intervention and endline evaluation after 3 months	Mean age: I=66.45±3.40 years; C=67.11±3.25 years Gender: Females (I=36 (66.66%); C=34 (62.97%)) Education: Illiterate/primary school (I=14 (25.8%); C=17 (31.5%)); High school/secondary (I=34 (63%; C=30 (55.5%)); College (I=6 (11.3%); C=7 (13%)
Effect of Educational Program on Lifestyle of Myocardial Infarction Patients in Iranian Population Ali Khan Jeihooni, Zhila Fereidouni, Pouyan Afzali Harshini, Esmaeil	Fasa city, Iran 2016-17	Quasi-experimental trial with intervention and control groups I – Educational intervention based on TPB C – Routine health education by nurses	n=100 (I=50; C=50) Mean age: I=52.80±6.71 years; C=51.65±6.90 years Gender: Females (I=19 (38%); C=20 (40%))

Kavi, Hajar Haghshenas, Leila Akbari		Duration – June 2016 to May 2017; 1 year	Education: Illiterate/elementary (I=5 (10%); C=5 (10%)); Junior High school/high school (I=33 (66%; C=35 (70%)); College (I=12 (24%); C=10 (20%) Married: I=45 (90%); C=43 (86%) Employed: (I=29 (58%); C=28 (56%))
Impact of Educational Intervention Based on Theory of Planned Behaviour on Lifestyle Change of Patients with Myocardial Infarction Karimy T, Saffari M, Sanaeinasab H, Khalagi K, Hassan-Abadi M	Bandar Abbas, Iran 2014	Controlled clinical trial with intervention and control groups I – TPB based educational intervention C – No educational intervention, routine nursing advise on discharge Duration – not defined; Intervention period of 1 month and the evaluation at 1 month and 3 months after the completion of intervention	n=80 (I-40; C=40) Mean age 51.5+7.07 years Gender: Females n=27 (33.75%) Education: Illiterate/elementary (I=18 (45%); C=17 (42.5%)); Middle school/high school (I=13 (32.5%; C=14 (35%)); University (I=9 (22.5%); C=9 (22.5%) Married: I=35 (87.5%); C=34 (85%) Employed: (I=10 (25%); C=12 (30%))

3.3.3 Results from systematic review

The name of the authors who conducted the study, the study settings, the feasibility and fidelity of the studies, the effectiveness of the studies in terms of outcomes achieved, mode of delivery, methods used and health providers involved in intervention delivery are summarised in Table 3.3. Studies selected for inclusion were published between 2014 and 2017.

Table 3.3 Summary of findings – feasibility and outcome measures

Authors	Study Setting	Feasibility and fidelity	Effectiveness / Outcomes achieved	Intervention description – methods used, mode of delivery and health providers involved
Saffari M et al	1. Hospital based study 2. Urban setting (city)	Feasibility - yes 1. Recruitment rates - 82.2%. 2. Integrity of intervention delivery - Present Structured intervention with specific activities with timeline; follow up done for 3 months after intervention 3. Completion rates 89.2% 4. Completion within stipulated time - yes Fidelity – yes (very good) Intervention was completed Overall dropout rate - 10.8%	Objectives achieved 1. Significant Improvement in quality of life measured through three different scales within intervention group and between intervention and control groups 2. Significant Improvement in some clinical outcomes within intervention group and between intervention and control groups 3. Significant improvement in	Educational intervention was given over 7 group sessions (groups of 8-10), each about 60-90 minutes; Lectures and interactions, brainstorming, group discussion, role play, listing by participants about their control beliefs, educational film, CD-ROM and booklet about preventive lifestyles and adherence to treatment Face to face with direct interaction of the trainer with

		(completion rate in intervention arm=88.3%; in control arm=90%	all five TPB constructs within intervention group and between intervention and control groups	the participants in multiple sessions Health provider - Trainer - no specifics given
Askari A et al	1. Community based study (participants chosen from list at diabetic centre and available at community during selection; place of training/educational sessions – not mentioned; follow-up at homes by telephone)	Feasibility – yes (excellent) 1. Recruitment rates - 100% 2. Integrity of intervention delivery - Present; Intervention was provided through 8 sessions over a 1 month period and follow-up was done at 4 weeks and 8 weeks after intervention through telephonic calls. Training was for 70 minutes per session and given through lecture, Q&A and group discussion. 3. Completion rates - 100%	Objectives achieved; 1. Significant improvement in TPB constructs - (attitude and subjective norms) and behaviour (nutrition and jogging) within intervention arm and between two groups 2. Significant improvement in biochemical indices (laboratory outcomes) within the intervention arm and between groups	Training in 8 sessions (2/week), each of 70 min. duration: Lectures, question & answer (Q&A) sessions and group discussions. Some images or visual content was also provided. Pamphlets were given to families and relatives Hybrid - Face to face training sessions with telephonic follow-up Researchers

	2. Urban setting (city)	4. Completion within stipulated time - yes Fidelity – yes (excellent) All participants selected in the study completed the study with no dropouts		
Ali Khan Jeihooni et al	1. Community based (patients were selected from the hospital list of admitted MI patients and chosen from the community during selection) 2. Urban setting (city)	Feasibility - yes 1. Recruitment rates – not mentioned 2. Integrity of intervention delivery - present; structured educations sessions (one per week for 8 weeks covering TPB constructs and nutrition: each of the five groups received same education for 8 sessions 3. Completion rates 100% (all completed) 4. Completion	Objectives achieved 1. Significant improvement in all 5 TPB constructs - (attitude, subjective norms, perceived behavioural control, intention and behaviour/lifestyle within intervention arm and between two groups after intervention period 2. The TPB constructs (attitude, subjective norms and perceived behavioural	Eight sessions (one/week) of 55-60 minute duration for participants divided into 5 groups of 10 each Group discussion, educational movies, role playing, answering questions of participants on common beliefs; one lecture session by a cardiologist; group discussion and step by step teaching to adopt a healthy lifestyle

		within stipulated time - yes; time frame was adhered to Fidelity – yes (excellent) All participants were available for endline evaluation and went through the intervention, no dropouts	control) contributed to 39.6% of intention to change lifestyle.	Face to face with direct interaction of the educator and nutritionist with the participants in multiple sessions Educational intervention - Educator Nutrition advise by - Nutritionist 1 session by an cardiologist (on subjective norms)
Karimy T et al	1. Community based study (patients were selected from the hospital list of admitted MI patients and	Feasibility – yes 1. Recruitment rates - not mentioned (participants were replaced if refused to consent to achieve sample size) 2. Integrity of intervention delivery – present; structured sessions for	All objectives were achieved 1. Significant improvement in healthy lifestyle in intervention group following intervention.	Four 50-minute sessions (one/week) in three groups of 10-15 participants Group discussions, film screenings, Q&A sessions

chosen from the community during selection) 2. Urban setting (city)	all participants in three groups with same content; methods used were same; instructor for these sessions not mentioned (same or different) 3. Completion rates - 86.25% 4. Completion within stipulated time - yes, completed within time frame Fidelity – yes (very good) The overall dropout rate was 13.75%. The completion rate for intervention arm was 90% and for control arm was 82.5%	2. Improvement in TPB constructs of attitude, subjective norms, perceived behavioural control and intention in the test group as compared to control group.	Face to face with direct interaction of the instructor and nutritionist with the participants in multiple sessions Educational intervention - Instructor Nutrition advise by - Nutritionist

3.3.4 Risk-of-bias assessment

Risk-of-bias assessment for the three randomised controlled studies is presented in Table 3.4. The quality assessment done using Cochrane's RoB 2.0 tool demonstrated some concerns / unclear risk of bias for two studies[83-84] and high risk of bias in one study[86]. In the study by Saffari M et al[83], all the domains had low risk of bias except for the randomisation process where the method of random allocation sequence was unknown but did not give rise to any baseline differences; therefore the quality of that domain was determined as some concerns which affected the overall quality of the study. In the study by Askari A et al[85], there were two domains with some concerns – the randomisation process where information on random allocation sequence was unavailable, and, the effect of adhering to intervention raised some concerns as there was no information about the co-interventions, overall quality determined as some concerns. Study by Karimi T et al[86] had high risk of bias as there was alternation during random sequence generation and there was some concerns in the selection of the reported result, with overall judgement as high risk of bias.

Table 3.4 Risk of bias for randomised studies using Cochrane's risk of bias tool version 2018 (Rob 2.0)

Study	Randomisation process	Effect of assignment to intervention	Effect of adhering to intervention	Missing outcome data	Measurement of outcome data	Selection of reported result	Overall risk of bias
Saffari M et al[81]	[b] Method not disclosed	[a] Participants and personnel unaware and appropriate analysis used	Participants and personnel were unaware, no information on co-interventions but outcome unaffected; participants adhered to assigned intervention and appropriate analysis used	[a] Outcome data for all participants not available but results not biased by missing outcome data	[a] Appropriate method of measuring outcome and outcome wouldn't have differed; assessors aware but outcome not influenced by knowledge of intervention received	[a] Trial analysed as per pre-specified plan; numerical result assessed unlikely to be have been selected from multiple outcomes and multiple analysis	Some concerns
Askari A et al[82]	[b] Method not disclosed	[a] Participants unaware, personnel aware but no deviation from intended intervention and appropriate analysis used	[b] Participants unaware, personnel aware, no information on co-interventions but outcome unaffected; participants	[a] Outcome data for all participants available	[a] Appropriate method of measuring outcome and outcome wouldn't have differed; assessors unaware of	[a] Trial analysed as per pre-specified plan; numerical result assessed unlikely to be have been selected from multiple outcomes	Some concerns

			adhered to assigned intervention and appropriate analysis used		intervention received	and multiple analysis	
Karimy T et al[84]	[c] Assignment between groups as per alternation	[a] Participants unaware, personnel – no information but no deviation from intended intervention and appropriate analysis used	[a] Participants unaware, personnel – no information; co-intervention balanced and outcome unaffected and participants adhered to assigned intervention	[a] Outcome data for all participants not available but results not biased by missing outcome data	[a] Appropriate method of measuring outcome and outcome wouldn't have differed; assessors unaware of intervention received	[a] No information on pre-specified plan but numerical result assessed unlikely to be have been selected from multiple outcomes and multiple analysis	High risk

[a] Low risk of bias [b] Some concerns [c] High risk of bias

Risk of bias for the non-randomised (quasi-experimental) study is presented in Table 3.5. The outcome accessors were probably aware of the intervention received by the study participants and could have influenced the outcomes, although there was no systematic errors in measurement of the outcome related to intervention received. The overall risk of bias was moderate for this study.

Overall, out of four studies one had high risk of bias and three others had some concerns/moderate risk of bias.

Table 3.5 Risk of bias for non-randomised studies using Cochrane's risk of bias tool (Robbins-I)

Study	Confounding	Selection of participants	Classification of interventions	Deviation from intended interventions	Missing outcome data	Measurement of outcomes	Reporting of results	Overall risk of bias
Jeihooni A K et al[83]	[a] No potential of confounding effect	[a] Selection of participants not based on participants characteristics observed after start of intervention; follow-up and start of intervention coincide for most participants	[a] Intervention groups were clearly defined and recorded at the start of the intervention;	[a] No deviations from intended intervention beyond expected in usual practice	[a] Outcome data available for all participants	[b] Outcome measure could have been influenced by knowledge of intervention received and assessors were aware of intervention but methods of outcome assessment comparable across groups and there were no systematic errors in measurement	[a] Reported effect estimate unlikely to be selected on basis of multiple outcomes or multiple analyses and sungroups	Moderate risk of bias

[a] Low risk of bias [b] Moderate [c] Serious [d] Critical [e] No information

3.4 Discussion

This systematic review was conducted as part of the updated MRC guidance (2019) on complex intervention development and evaluation[87], which seeks to develop an intervention by identifying a theory and generating an evidence base. The TPB framework has increasingly been used for developing and evaluating behaviour change interventions[88] and for designing interventions for improving treatment adherence, avoidance of risk behaviours and advancing follow-up to improve health outcomes[89-90]. Through this systematic review, I sought to gather evidence on feasibility of TPB interventions in low-resource, low literacy settings and to inform its effectiveness using the available resources (methods, modes of delivery and health personnel), in such settings. Studies that met the inclusion criteria were reviewed for quality so that recommendations for those in the process of designing and evaluating studies could be made.

3.4.1 Study setting, design and delivery

One of the objectives of this SR was to describe the study settings and the way the intervention was delivered. All the studies were from a single country, within the purview of the LMIC definition of World Bank[69], and were conducted among the urban population residing in cities. While one study was hospital based[83], all others were community based studies[84-86]. These were interventional or quasi-experimental studies with intervention and control groups wherein the intervention was designed on TPB constructs to change attitude towards behaviour, subjective norms, perceived behavioural control, intention and behaviour; one study additionally looked at improving clinical outcomes and quality of life. Mode of intervention delivery was similar in all studies with group education being the preferred option, education was given face to face in all studies with one study opting for a hybrid option[84]. The studies were not typically very precise in describing the health providers who delivered the intervention, with terms like trainer[83], researcher[84], educator[85] and instructor[86] being used for those providing the education; there was no mention of whether they were part of the health system or their roles within the health care network. One study[85] specified a cardiologist and nutritionist as those providing one of the sessions of health education, but this was the exception. Different media and methods were used for

providing the educational interventions, the common being group discussions, educational videos or films, Q&A sessions and brain storming; other methods used were booklets, CDs, educational movies and role playing.

These studies provide an insight about the study setting and the delivery. Although all the studies were on urban populations, a significant proportion had low educational levels. They do not provide any information about rurality of setting, and study designs didn't describe the use of cluster randomisation designs. The methods and media of the intervention were usually quite clearly elucidated in the studies - however the providers and their roles were not quite clear.

3.4.2 Feasibility and fidelity of the interventions

This SR was conducted to assess the feasibility (i.e., the impact an intervention has on its end user and the resources required to successfully implement the intervention[91]) and the fidelity (i.e., the degree to which an intervention has been delivered as intended[92]) of the interventions. Feasibility basically looks at whether an intervention is appropriate, can be implemented in a particular setting and whether it is relevant and sustainable. I looked at recruitment rates, the integrity of intervention delivery, the completion rates and the timescale of completion to evaluate the feasibility of the studies. Two studies have high recruitment rates[83-84], in others[85-86] the recruitment rates are not mentioned but sample sizes had been achieved as desired in the studies. The integrity of the intervention delivery was assessed by whether there was a structured method to intervention, its implementation and whether it reached the intended participants. All the studies had a structured intervention and a time schedule was followed for its delivery to the participants in the intervention arm, the media and methods were clearly described and all were completed within the stipulated time-frame. The controls had either standard education as per routine practice or had no education during the intervention period; some was given educational materials at the end of the intervention period to maintain research ethics[83]. Two studies had 100% completion rates[84,85] and other two[83,86] had completion rates close to 90%, demonstration the acceptability among the participants and the fidelity of the intervention. Overall, the interventions demonstrated feasibility

and the fidelity and provided researchers with insights to develop and deliver such interventions in these settings.

3.4.3 Impact of the interventions

All the four studies demonstrated the effectiveness of the interventions in terms of improvement in TPB constructs, measured quantitatively through mean changes and their significance ($p<0.05$). Three studies[83,85,86] showed significant improvement ($p<0.05$) in all five TPB constructs following intervention while one[84] showed significant improvement in attitude, subjective norms and behaviour. There was significant improvement in health behaviour (nutrition, exercise-jogging, lifestyle), clinical outcomes and quality of life ($p<0.05$) following the intervention and one study[85] showed that TPB constructs were responsible for 39.6% change in intention towards healthy lifestyle. All the studies demonstrated that desired outcomes could be achieved implementing TPB based interventions, in diverse chronic conditions ranging from cardiovascular disease to diabetes and osteoarthritis. The total study duration varied from five months to a year, but the period of intervention was one month for each of these studies, with the evaluation being done three months after the completion of intervention. The impact of the intervention was effective over a short duration, but there was no information about its effect on long term or the effect of an intervention carried out over a longer period.

3.4.4 Methodological quality of studies

Three studies were randomised controlled trials and one was of a quasi-experimental design, suggesting that robust study designs were used for testing the interventions and therefore the outcomes were reliable and may be replicated in similar settings.

Assessing the quality of studies, among the three RCTs two had some concerns, as allocation sequence during the randomisation process was not mentioned while the third had high risk of bias as the participants were assigned by alternation, which make it predictable and subject to bias. Reporting of the intervention in the selected studies as per Consolidated Standard for Reporting Trials (CONSORT) 2010 updated guidelines[93] was not done except for one study[83] out of the four selected. Reporting trials as per CONSORT guidelines improves the methodological rigour, reporting

quality and prevents bias while allowing researchers to study and replicate such trials in other settings.

Prior to this systematic review, there was little specific information on the change in health behaviour brought about by TPB-based interventions in chronic diseases and their applicability in different settings — in particular, LMICs. Three other systematic reviews on TPB-based interventions have been conducted earlier. Systematic review by Wendy Hardeman et al.[94] conducted in 2001 examined TPB interventions to change health behaviour on any population where TPB has been applied without any mention of chronic diseases. It mainly measured process and outcome variables and to predict intention and behaviour. Antonia Rich et al.[95] examined, in 2015, the role of TPB in predicting adherence in people with a chronic conditions. Their research suggested that TPB made a useful contribution to our understanding of adherence in chronic illness; it measured the types of adherence behaviours and the effects of the TPB constructs on adherence behaviour. However, it did not examine the settings in which the interventions were delivered or had any reference to health literacy and excluded studies with populations considered to be at risk of chronic disease (e.g., sedentary adults). Steinmetz et al.[96] in 2016, incorporated a three-level meta-analysis to establish that interventions based on TPB were effective in changing behaviour. The mean effect size was 0.50 for antecedent variables (behavioural, normative, and control beliefs, attitude, subjective norm, perceived behavioural control and intention); types of conditions were not specified.

The current systematic review examined studies from the LMIC settings to provided valuable inputs about the feasibility, impact and methods of intervention delivery. It also underlined the need for conducting more such studies as currently the limited number of studies do not provide complete information for development and implementation of such interventions in a diverse array of chronic conditions.

3.5 Strengths and Limitations

This systematic review included studies with robust study designs, the outcomes were described quantitatively with estimates and strength of significance (p values) and interventions were well described. This is the first systematic review to provide information on feasibility, effectiveness and methods of implementing TPB intervention

in chronic disease patients in low-health literacy settings. This SR used PRISMA-P guidelines to develop the protocol[58] and register it at PROSPERO, and used PRISMA 2020 guidance on reporting[82] with two reviewers screening titles, abstracts and full papers. However, the number of included studies was low, and it did not provide diversity of information I'd hoped for about different kinds of population characteristics or study settings as all the studies were from a single country and from urban background. None of the studies met high quality criteria, as none had an overall low risk of bias, but three studies could be considered to be of moderate quality with some concerns or moderate risk of bias.

3.6 Conclusion

While TPB is effective in changing health behaviour, there was little evidence of feasibility and applicability of such interventions in different settings, particularly in LMICs. This systematic review provides evidence of effectiveness of TPB interventions as well as their feasibility in such settings. This provides some insights on developing and implementing TPB based interventions with regards to setting, time frame, media and methods. Such interventions are limited in LMICs, where health behaviour change can be an effective and economic tool for fighting chronic diseases, therefore more such studies are required to gather definitive evidence and prove their feasibility and utility in LMICs.

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Chapter 4

Project 2 – Qualitative research for developing the TPB based intervention

In the previous chapter I presented evidence on the use of the social-cognitive theory, i.e., the theory of planned behaviour (TPB) in designing interventions, particularly in low health literacy and low resource settings of low and middle income countries (LMICs), for behaviour change among chronic disease patients. Through my systematic review, I found that although such designs were successfully used over the years in many high-income countries, the use of such interventions using TPB for changing health behaviour were limited and used infrequently. Those that used TPB based interventions in LMIC settings were successful in modifying health behaviour and in improving outcomes; but they were used in only a small number of chronic conditions only and no such TPB intervention was used in chronic respiratory diseases.

4.1 Aims and Objectives

The aim of my qualitative study was to understand the social and cultural context of CRD-related health behaviour in patients, caregivers and the community, and to gain an insight into attitudes, social norms, perceived behavioural control and underlying beliefs governing such behaviour. This qualitative study was part of formative research to inform the design of a feasible TPB-based intervention in rural, low health literacy regions of India.

Objectives of this thesis component:

1. To explore the beliefs, perceptions and practices of patients, family members and the community towards CRD-related health behaviour
2. To construct the experiences of patients with CRD and their caregivers in the socio-cultural context and understand their attitudes, social norms, perceived control, and barriers and facilitators to health behaviour

4.2 Background for the qualitative research

The primary aim of my PhD research project was to develop and pilot test a health intervention for behaviour change in patients with chronic respiratory disease to improve health behaviour and outcomes. Since it was a complex intervention, I was informed by the Medical Research Council (MRC) updated guidance (2019) on developing and evaluating complex interventions[1,2]. Complex interventions[1, 3-7] have several interacting components which may act independently or interdependently to produce an outcome; a single component cannot be considered to have caused an outcome. The complexity comes from the difficulty of standardising the design and delivery of the interventions in the local context and in the length and complexity off the causal chains linking intervention with outcome. Complex interventions are often used in health service, public health practice and in areas of social policy; they include educational and behaviour change components. The key elements include development of the intervention, feasibility or pilot testing, evaluation of the intervention and implementation in form of dissemination, surveillance and follow-up.

The MRC updated guidance on complex intervention development informs about use of a theoretical framework to develop an intervention. The theory that was identified as most appropriate for developing the behaviour change intervention in my research project was the Theory of Planned Behaviour (TPB); the reasons for choosing this theoretical framework are mentioned in Chapter one. To summarise it here, TPB has been proven to be effective in changing health behaviour in chronic diseases[8-9] whereas usual education or education based on health belief model, which we had been using for many years in our health practice has not been beneficial or provided little value while taking many years. Taking feasibility into account and the socio-cultural context of the participants, TPB was considered as appropriate theoretical basis for developing the intervention (more elaboration in chapter 1, page 61-62). TPB links individual beliefs to the health behaviour and focuses on theoretical constructs concerned with individual motivational factors as determinants of the likelihood of performing a specific behaviour[10-11]. As per TPB, the best predictor of the behaviour is behavioural intention, which in turn is a function of attitude towards the behaviour and social normative perceptions towards it. Perceived control over performance of a behaviour is the third construct which basically considers external conditions which

influence capability of an individual, thereby influencing intention to act; it also directly influence health behaviour[10].

Once it was decided that the TPB will be used as the theoretical basis for developing my intervention, identifying the current evidence and practice was achieved through the literature review on chronic respiratory diseases (CRDs) and the systematic review on the effectiveness and feasibility of TPB-based interventions in LMICs. Systematic reviews on TPB interventions advised formative research for intervention development. Literature on TPB[10-12] informed me that before developing an intervention, it is important to do formative research in the community to understand the salient beliefs underlying attitudes towards health behaviour, subjective norms and perceived behaviour control as well as intention and behavioural practice. Icek Aizen[11] in his guidance on developing a TPB based intervention, indicates that the importance of formative research and eliciting accessible beliefs underlying the constructs of TPB. It is the corresponding set of beliefs which guide the attitudes, subjective norms and perceived behavioural control of people and ultimately influence their behaviour. These are the salient beliefs or those beliefs which are readily accessible in peoples' memories; qualitative research is required for identifying behavioural, normative and control beliefs of the specific behaviour that is targeted for change. Interventions which modulates these beliefs, either by transforming or promoting them, has a stronger influence on changing health behaviour.

Behavioural, normative and control beliefs among individuals vary from behaviour to behaviour[10]. For example, behavioural beliefs about getting a mammogram (belief that it will be painful) will be different from doing exercise for losing weight (belief that it will be easy to perform). Relevant underlying beliefs may vary even for similar behaviours, e.g., using an inhaler by an elderly, frail, illiterate and financially poor patient (belief that an inhaler will be costly and difficult to use) versus using an inhaler by an young, economically productive and educated young patient (belief that inhaler will keep symptoms under control and help lead a normal active life). Even the underlying beliefs of a particular behaviour may differ in individuals from different populations. Fishbein (2000)[12]; Fishbein and Capella (2006)[13] has emphasized that identifying correct beliefs relevant to the behaviour or/and to the population is important rather than an investigator sitting in the office and developing the measures of TPB

constructs. Therefore, an essential step in developing a TPB based intervention is to conduct interviews with the population being studied to elicit information about the behaviour, normative and control beliefs for the targeted behaviour and the population. Once these are identified, appropriate measures of TPB constructs are designed and quantitative surveys using those measures can be conducted and analysed to arrive at beliefs which best explain intention and health behaviour. Thus, the basis for conducting my formative qualitative research was to provide inputs for developing the behaviour change intervention for chronic respiratory disease (CRD) patients underpinning the constructs of TPB essential for effecting the change. It was also important to get information about current awareness of CRD, risk behaviours prevalent in the community, current health behaviours in CRD disease, their experiences through the disease influencing them to follow such behaviour and the environmental facilitators and barriers to such behaviour. My intention was to develop an intervention which could address these and therefore result in behaviour change.

4.3 Methods

There were two main objectives of qualitative research project. The first was eliciting beliefs and exploring participants' perceptions and practices; the second was to construct the experiences of the patients and caregivers in their socio-cultural context to understand their attitudes, social norms, perceived control, and barriers and facilitators to health behaviour. The Theory of Planned Behaviour was used as a framework to develop the topic guides as this was most appropriate for the objectives of the study. For each of the constructs or the domains and the underlying beliefs for each domain, questions were framed as a guide to explore that domain. The focus group discussions (FGDs) were specifically directed for patients with the disease and started by exploring their perceptions towards the disease they have; it was followed by asking them their experiences of living with the disease and how they were influenced by social norms, their attitudes and their perceived control over the conditions. They were also interviewed on their beliefs related to the disease and its behaviour.

4.3.1 Ethics and permissions

Ethics approval for this study was obtained from the scientific and ethics committee of Christian Medical College, Vellore, India known as the Institutional Review Board (IRB) of CMC Vellore vide IRB min no. 11381. It also required approval the Health Ministry's Screening Committee of Medical Research with proposal id 2018-0706; as it was a part of the grant obtained from University of Edinburgh; this was as a part of Indian regulatory policy on externally funded research proposals.

4.3.2 Setting and study design

The setting for the study was the K V Kuppam community development block (an administrative unit of the government with a population between 80,000 – 120, 000). The details of the study area and its population can be found in the introduction chapter, under the heading context of research – the RUHSA community and the health system. To summarise, it was a completely rural area with low socio-economic and low-literacy population. The RUHSA hospital provides secondary level care; the whole area was divided into 18 clusters for providing primary care and carrying out community development activities. A network of voluntary health care workers connected the population with the RUHSA health system and community development programs. This qualitative study included eight FGDs done with patients of CRDs to capture their current practises and life experiences, five in-depth interviews (IDIs) with caregivers of CRD patients to know about their views and understand about family support, and four key informant interviews (KIIs) from the key community members to get the community opinion about the disease and its health behaviour. These were enough to achieve data saturation and obtain information about respiratory health behaviour; salient beliefs, attitudes, societal norms, barriers and facilitators related to such behaviour was also comprehended through this qualitative study.

Community engagement was initiated with key community members including panchayat (local government) leaders, teachers, village leaders and self-help group members (small self-reliant, financially independent local women groups involved in income generation and community influencers) to apprise them about the CRD program, the content and process of research and gather their views and opinions towards it. It helped us in strengthening the relationship with the community and carrying out the study.

Pilot qualitative studies (FGDs) were also conducted to help me refine the topic guide and the determine the participant composition. I conducted two focus group discussions among patients with CRDs in two villages, different from the ones which I finally chose for my qualitative study. One was a male and the other was an all-female group, but both the groups had people above 18 years till 65 years of age. These focus groups made me realise that division by gender is not enough, age division is also required to capture the diverse opinions and attitude towards their disease and health behaviour. It also helped me in fine tuning the questions and understand the way of navigating the discussion as a moderator.

A total of eight FGDs were conducted, four among either gender and among two age groups – less than 50 years and more than or equal to 50 years from four clusters selected among eighteen within the K V Kuppam block. The participants of the FGD were patients with CRDs, a list of which was obtained from the hospital database and the outreach centres' database, including patients who were on regular oral medications for CRDs. Division by gender and age group was necessary to make the groups homogeneous. Gender captured the differences in health behaviour due to diverse work environment and cultural practises among males and females while age grouping was done as attitude and perceived control about respiratory health behaviour varied with age.

FGDs were conducted with the patients supported by our piloting experience that group dynamics made them comfortable enough to express their opinions, experiences and beliefs about their disease and associated health behaviour; a homogenous group of patients with similar life experiences made them open up about their innermost feelings and helped them articulate their thoughts in a familiar, non-threatening environment. There was stigma associated with CRDs and its related health behaviours (like inhaler use) in my clinical experience of treating such patients, they usually did not express their thoughts or reveal their experiences unless there was a lengthy consultation, unbiased attitude and attentive listening. Each person need to be handled very sensitively, with a lot of time invested. The FGDs helped in two ways – firstly, participants were of the same age and gender group and from the same village where all inhabitants typically knew one another; this helped in providing a comforting environment and thereby convey their living experiences, emotions and

free opinions. Secondly, most of the members opened up to discuss their issues and problems related to their disease when one or two among the group initiated the discussions; they added to the experiences and opinions and sometimes provided non-verbal cues to others' opinions, thereby providing rich information during the discussions in quick time. FGDs are easier to conduct, are useful for researchers working within timelines, a rapid and resource efficient way of gathering information about complex relationships and avails a large amount of data within a limited timeframe [14-16]. FGDs are also used for enhanced disclosure, especially evident when sensitive issues are under discussion – in particular painful or emotionally intense experiences such as a stigmatising illness – wherein individuals typically offer considerable detail about such aspects of their lives, specifically when their contributions are reinforced and their concerns legitimated by other group members[17-18]. To supplement and corroborate the information from the viewpoint of caregivers of CRD patients and to include a community perspective, I conducted five in-depth interviews and four key informant interviews with them respectively. Initial piloting and division by age and sex to maintain homogeneity of groups gave us enough numbers of participants and enough focus groups to reach data saturation[19-21]. The findings from FGDs were complemented by in-depth interviews and key-informant interviews.

4.3.3 Development of Topic guides and conduct of the qualitative study

Topic guides were developed for FGD, IDIs and KIIS to guide the discussions and avoid missing relevant topics. FGD guides were prepared based on themes resonating with the constructs of TPB; there were suitable prompts for symptoms of disease, risk factors and health behaviours, attitudes, experience of living with the disease, social norms, the influence of peers, family members and the community and their belief in themselves and dependence on others for performing the behaviour. The key behaviours that we looked for included use of inhalers and spacers for symptom control, breathing exercises, use of biomass fuel, smoking and risk occupations among the patients with CRDs. Topic guides were prepared in English, translated to local vernacular language (Tamil) and back translated to English to retain its context and the meaning. It was piloted in a non-study village and the guides were refined for the current study.

A social scientist in our research team conducted the FGDs in the local language—she was the facilitator assisted by an observer who took notes and captured interactions within and between participants and the facilitator. Focus group discussions were conducted with the eight groups of patients in their respective villages at a place ensuring confidentiality. The focus groups with homogenous composition in terms of age, disease and gender and belonging to the same village helped the participants to volunteer opinions and attitudes about their disease experiences and provided us with enriching information about CRD perception and health behaviour. Photographs 4.1 and 4.2 shows a female and a male group involved in focus group FGD.

IDIs explored the experiences of the caregivers and their views on caring and living with the patient with a CRD. KIIs gathered community perceptions and opinions about CRD. The key informants had specific knowledge about and influence in the community. They were either local leaders or administrators in the community and comprised of block (administrative unit of local government) development officer, panchayat (local government) member, block medical officer and head of high school. They were chosen based on their experience and knowledge of the community and/or the health problem. The social scientist steered the IDIs whereas the key informant interviews were undertaken by the principal investigator (PI), a clinician with experience in CRDs. IDIs were conducted at home and KII at the workplace of participants.

All interactions were face-to-face. An audio-recorder was used to record the FGDs and the interviews. The length of the FGDs was 60–90 minutes while most of the interviews were about 30–45 minutes in duration.

Photograph 4.1 A focus group (with females>50 years of age) in progress

Photograph 4.2 A focus group (with males >50 years of age) in progress

4.3.4 Analysis of qualitative data

The FGDs and interviews were audiotaped along with field notes that were taken during the process. All of them were initially transcribed in verbatim and translated into English. Analysis was conducted using a thematic analysis framework. An inductive coding frame was developed collaboratively between the investigator (self) and the social scientist to allow the themes to emerge from the content of the raw data. This was done by reading the transcripts and listening to audio. This was then discussed with my supervisors. In doing so I was cognisant of my perspectives on the problem, and my natural inclination to impose a biomedical framework on the data which reflected in development of some of the themes, as in, causation, health behaviour and treatment seeking. However, I went about with an open mind to capture participants' perspectives, experiences and emotions during the process of interviews and discussions.

While the topic guides were informed by the theory of planned behaviour, the analysis was done by inductive coding so that newer themes and subthemes can be captured, beyond the TPB framework. It resulted in me capturing some surprisingly newer aspects of patient behaviour like the psychological aspects of living with the disease and the psycho-social environment that they fight with, in addition to physical aspects of the disease and its health behaviour. The process of reading of the transcripts was an enriching experience of delving into the participants' world and understanding their views. The interpretation was obtained by looking into the viewpoints of different stakeholders in their context. Nevertheless, the final result was an outcome of an iterative process of reading and re-reading the transcripts and understanding it in the context of participants' environment and own knowledge.

Initially data from two FGDs, one KII and IDI each were coded separately by me and social scientist and quality checked by my supervisors. Data from the transcripts were charted into a matrix using Microsoft excel, adjacent to appropriate codes; any emerging codes were also added to the matrix. Subsequently themes and sub themes were developed by analysing the text and finding commonalities and differences within and between the codes. Descriptive accounts of the data was written based on the chart developed. As part of the analysis, similarities and differences were explored between the different data collection methods and different community members'

accounts. Such interrogation of the descriptive accounts was used to generate an explanatory account of the data. The final document, with the themes and the narration, was reviewed by my supervisors.

4.4 Results

The participant characteristics for the FGDs , the IDIs and the KIIs are presented in table 4.1.

Table 4.1 The participant characteristics for the qualitative studies

Study type	Participant Characteristics
Focus Group Discussions	
FGD 1 (village 1)	Females <50 years (7 participants)
FGD 2 (village 2)	Males ≥50 years (7 participants)
FGD 3 (village 5)	Females <50 years (6 participants)
FGD 4 (village 6)	Males ≥50 years (6 participants)
FGD 5 (village 7)	Females ≥50 years (6 participants)
FGD 6 (village 8)	Males <50 years (7 participants)
FGD 7 (village 3)	Females ≥50 years (6 participants)
FGD 8 (village 4)	Males <50 years (6 participants)
In-depth Interviews	
IDI 1	Male, 59 years (Husband)
IDI 2	Male, 56 years (Husband)
IDI 3	Male, 39 years (Son)
IDI 4	Female, 31 years (Daughter)
IDI 5	Female, 62 years (Wife)
Key Informant Interviews	
KII 1	Male, 50 years (Block Development Officer)
KII 2	Male, 40 years (Block Medical Officer)
KII 3	Male, 45 years (Panchayat (local government) member)
KII 4	Female, 60 years (School Principal)

Three major themes emerged from the thematic analysis of the FGDs, supplemented by IDIs and KIIs. The corroboration of the narratives by patients, caregivers and key

community members were captured by quoting the participants in verbatim (though translated to English thereafter) and some of the quotes used in this section have been used in the paper[22] published in PLOS One, with permission of author(s), under open access Creative Commons Attribution License.

4.4.1 Theme 1 Understanding of chronic lung disease and associated health behaviour

4.4.1.1 Sub-theme 1 Perception about their disease condition and their causation

The participants (patients of CRDs) did not perceive their condition as a separate disease entity, rather recognised it through the symptoms, that they had. They however recognised that their symptoms continued for a long duration and was difficult to manage.

'I have breathing problem. I have cold and chest pain'. (R4, FGD3)

'I have this wheezing (moochu prachnay) for 10 years'. (R4, FGD4)

The participants knew that their symptoms get worse during the cold season, on exposure to dust or smoke and cold weather or rain.

'Due to dust (tuci), rainy season (malai kalam), if it' s heavy rainfall disease will become severe. . . ' (R1, FGD1)

Mostly respondents knew that smoking was not good for their health and many believed that it caused the breathing problems. Some of the respondents believed that the disease was spread from others, going in proximity with asthma patients or eating food with them. Most of them did not know that household air pollution caused by using biomass fuels (firewood, dung cakes, hay, leaves and the like) for cooking was the cause of their disease. Even the female groups more than 50 years of age defended wood-fire cooking and said that it had been there for ages.

'One day unfortunately I ate remaining food of asthma patient, so I too get the problem'. (R4, FGD3)

'No [do not get the disease by cooking with firewood]. In olden days we used to cook in firewood only.' (R1, FGD 3)

'Yes (using firewood for cooking and boiling water at home'. (R2, FGD4) (all others in the group say yes in unison).

The low awareness level about the disease and its causation was also substantiated from the interviews with key community members.

'If we ask the people in the society, they will tell what problem they have, the symptoms like breathing difficulty (muchi kastam) but they do not know the name of the disease'. (KI-3)

4.4.1.2 Sub-theme 2 Treatment seeking for chronic respiratory disease

Patients sought treatment for their symptoms, on as-and-when required basis, usually seeking treatment from modern medicine (Western medicine or Allopathy), although sometimes relying on traditional system of medicines (Ayurveda or Siddha) with a belief of getting cured. They initially sought relief of their symptoms by taking medicines over the counter from local medical store (pharmacies are known as medical stores in this region where medicines are stored and distributed with or without prescription) or at best visiting some local practitioner or clinic and only engaged with mainstream health care services providing modern medicine, at a later stage. Engaging with the health care system also depended on their perception of severity of their symptoms or the seasonality.

'…I feel difficulty in breathing that time I will take (medicines) and also buy in the medical shop'. (R1, FGD5)

[Go for] only allopathy' . (R1, FGD2); 'No, not going for other treatment, we all following only allopathy.' (R6, FGD5)

'Yes, I went to Siddha and Ayurveda, but I do not want that now, I like to continue Allopathy medicine only.' (R1, FGD3); 'Visit RUHSA and government hospital.' (R3, FGD2);

'Patients are not going to the hospital at their initial stage of the disease; after getting severe they go to hospital; At the beginning they will go to local doctors, it became severe they will visit RUHSA; . . .(go to) medical shops or local doctors in the beginning.' (KI 3)

'Not using medicine regularly, only at winter season.' (R5, FGD1);

'No, not taking [treatment] continuously; whenever I had cough and cold I will buy medicine in the medical shop and use it. I will not go to hospital.' (R6, FGD5)

4.4.1.3 Sub-theme 3 Health behaviour related to chronic respiratory disease

Their chronic respiratory disease related health behaviour that were revealed during the discussions with patients were long standing habits of smoking (hand rolled cigarettes, known as bidis locally), usually among men and use of biomass fuel for cooking as a cultural practice and convenience, at their homes.

'Smoking causes the disease. . .smoking for more than five years; using firewood at home-. . .don' t have gas facility.' (R2, FGD 2);

'...like to cook food by using firewood only, it is tasty...R1, FGD3 (others nod their head in agreement)

'[using firewood] because cost of cylinder is increased' [Rs 1000 per cylinder;, 1£ ~ Rs 100] (R1, FGD 5);

'While going for coolie work, we will collect firewood. It' s free of cost, so we are using it.' (R2, FGD 6)

They also spoke about using tablets (mattirai – local language) for their disease/symptoms and sometimes getting injections (uci- local language) and nebulisations (avi- local language) during severe breathlessness, as a common practice. A few patients spoke about using inhalers for their respiratory problem, however the use was infrequent and limited to breathlessness and/or seasonality. Inhalers were not available at government health centres.

The availability of inhalers was restricted to pharmacies with out of pocket expenses for the patients.

'[I take] tablets (mattirai) provided by government hospital [for my breathing difficulty]. ' (R2, FGD 2);

'[I take] tablet (mattirai) and injection (uci) [for my respiratory problem].' (R2, FGD 4)

'Using inhaler (puff) is good, it gives sudden relief to me.' (R1, FGD2);

'Using puff during the winter season' …I 'm satisfied about using puff, but only two minutes control.' (R1, FGD8)

'…they need good treatment, in government side there is no supply of inhalers…' KII2, Block Medical Officer

The patients during the FGDs revealed that they were not aware of any breathing exercises that they need to do as a part of their disease management; they had not been advised as such by health providers, they were unaware of its benefits and do not practise any breathing exercise.

'No (do not know about any respiratory exercises, not taught by anyone'. (R5, FGD6) (others agree by nodding their heads)

'Nobody is doing exercise' (R2, FGD1)

'No (do not know about any respiratory exercises), not taught by anyone R5, FGD6N

'No (nobody taught any chest exercises) R3, FGD5 (Everyone in the group nod their head.

4.4.2 Theme 2 Lived experiences with the disease

4.4.2.1 Sub-theme 1 Health related experiences from CRD

Patients described their health-related experiences of living with CRD as physically disabling, at times a struggle for survival (just to breath in air) and an overpowering sense of helplessness.

'Not able to breath properly and not able to do any small work.' (R5, FGD1)

'If I am affected by cold and cough, wheezing problem becomes severe. I'm unable to sleep at night.' (R6, FGD5)

'I'm also feeling the same thing, I am not able to speak and if simply sitting also I will get wheezing…' R3, FGD8)

'. . . she finds difficulty in breathing. . . doctor will give nebulisation (aavi) to the patient and will prescribe medicine. Then we will bring the patient to home and give medicines with hot water. . .If she eats something cold she will have severe breathing

problems. So we provide her chapati, ginger tea. . .; During winter and rainy seasons, I won't allow her to work out of the house because during winter she will suffer a lot. ' (IDI 4)

4.4.2.2 Sub-theme 2 Social interactions and experiences due to the disease

The social impact of their disease as narrated by the patients and their caregivers was painful, a separate struggle in the society/community and something which made them sad and depressed. They felt humiliated and let down by the community around them.

'Everybody is seeing me as someone different and sometimes they tease me.' (R3, FGD1)

'If I cook food, my relations and neighbours will hesitate to eat and if I give water they will not drink; those situations affect me very much; I looked after. . . cared my husband ' s elder brother ' s daughter. . . (pauses and starts speaking with a heavy voice). As soon as they came to know [about] my respiratory disease he will not allow her daughter to my house and stop talking to me. (while saying this she started crying). ' (R2, FGD 1)

'Some people feel sympathy upon me and few of them think that when I am going to die.' (R3, FGD6)

'…feel sad and find it difficult.' (R4, FGD2)

4.4.3 Theme 3 Social norms, attitude and other factors influencing health behaviour

4.4.3.1 Sub-theme 1 Family and community influence on health behaviour

Family and community were important influencers to health behaviour of the CRD patients. Family, for most of the respondents, acted as a support system and provided them with courage and capability to move on with their disease and their life. However the experience with community members was unpleasant and unsupportive – they had to face lot of disrespect and apathy from society because of their disease and use of inhaler, which acted as barriers difficult to navigate.

The participants during the FGDs revealed that family acts as pillar of support for them, helping them to get the treatment, take them to hospital, help them with their activities, provide financial support at times and encourage them towards healthy practices.

There was enough family support for the CRD patients, as was described by the caregivers during the in-depth interviews.

'Family members encourage and take care; I am taken to hospital [by family members].' (R1, FGD1)

'…Family members ask me to take puff regularly.' (R1, FGD8)

'My wife advised me to eat all the fruits and vegetables, [she said] don't ignore anything, nothing will happen to you.' (R2, FGD 4)

"I will support her in all the ways, accompanying her to hospital; yes, of course (influenced by spouse), she is expecting love and care from me and I have to take her for continuous treatment; all the members in the family [are] supporting [her] to improve her health condition.' IDI2

The patients did not want to reveal their disease to their neighbours or other community members, did not use inhalers in public and not use it at all if they have to go to their relatives' home to attend any function. Stigma towards the disease and towards inhaler use and a feeling of being ridiculed by community, made them to hide their disease or prevent them from following the appropriate behaviour.

Nobody knows about I'm using puff' (R1, FGD8)

'Don't know what the neighbours think. . .will use in my house, they might not know my problems. If I go for any function that time I will face difficulty.' (R1, FGD 1)

'Not interested to reveal their problems in front of the others because of stigma. They will find difficult to share with others.' (KI 4, Head Government Girls High School)

'Many know the respiratory problem but they are not ready to use puff (inhaler) [openly]. . . that means in public.' (KI 3, Panchayat member)

4.4.3.2 Sub-theme 2 Patient's attitude towards disease and health behaviour

Patients during the FGDs spoke about the disease being difficult for them and affected their lives but many had a positive attitude of "getting better of the disease", fighting it and hoped that one day they could lead normal life in their family and the society.

'[I want] to take care of my health and to take care of my family members.' (R3, FGD 4)

'I'd like live and lead a healthy life.' (R3, FGD2); "To live long without depending on others.' (R1, FGD3)

4.4.3.3 Sub-theme 3 Other societal influences

There were some barriers and a few facilitators to health behaviour of the patients with CRDs. Barriers were financial, temporal, societal and health system related.

'Both time and money is a major factor. Sometimes there is nobody to accompany to go to the hospital.' (R5, FGD 7)

'Yes [I use puff], but not using now because, I don't have sufficient money to buy inhaler [puff].' (R1, FGD 6)

'If she needs to attend funeral ceremony (few important unavoidable occasions) cannot continue treatment at that time, do not want others to know about it.' (IDI 4)

'They are not following due to family problem, some people have job problem. Some people are smokers, drinkers, we cannot believe and cannot expect they take treatment regularly; They need good treatment, in government side there is no supply of inhalers: . . .need to get permission from higher officials. . .' (KI 2, BMO)

There were positive reinforcement influences like subsidised gas connections, government schemes of financial support through work and preventing open burning of waste. These were highlighted by the key informants which could lead to a better health behaviour.

'Government has given gas connection; They are earning 200 to 300 rupees per day (through 100 days' work under MGNREGA) and they can buy gas (at subsidised rates). . . They (waste collectors) will collect the waste things at home in the morning at 7.O clock. . .every day. . . instead of burning should be given to them; They collect and segregate at one particular place and put in the separate pit.' (KI 1, BDO)

Some of the suggestions provided by the participants were to establish local clinics in the community, provision of subsidised treatment for encouraging health behaviour and inhaler use, provision of psychological support to CRD patients and establishing a separate respiratory clinic for such patients.

'…free medicines and organise medical camp once in a month at the panchayat (local community)' . (R1, FGD 8). . .(others nod their head in agreement)

'. . .so, the wheezing problem is very serious disease, so you should arrange counsellors for counselling the patient for regular treatment and follow up.' (IDI 1)

'To give separate care and start unit for respiratory problem.' (KI 3, Panchayat Leader)

4.5 Discussion

4.5.1 Principal findings

The qualitative study using the TPB framework and thematic analysis indicated that there was no clear perception towards the disease or its causation; health seeking behaviour was commonly from modern medicine (allopathy) but involved local and traditional methods of treatment as well. Treatment seeking was initially from pharmacies for symptomatic relief; common treatment modalities were oral medicines for symptom relief in less severe conditions and use of injections and nebulisations for emergencies and relief of severe symptoms.

Prevailing risk behaviours for CRD included smoking and use of biomass fuel, which were common in the community, former among the males and latter in households for cooking. The use of inhalers was infrequent and occasional, mainly for immediate symptomatic relief and patients commonly used oral medicines as these were prescribed by doctors at government hospitals or local clinics. There was no knowledge or practice of respiratory exercises among patients of CRD and no such information was received from the health providers or such facilities accessed by patients.

4.5.2 Strengths and limitations of the study

The study had several strengths. The variety in responses, the differences and similarities in opinions to various situations and experiences were well captured by creating homogenous groups based on gender and age categories. The richness and validity of the data was enabled by triangulation[23] of findings achieved by using different methods of data collection, coding and quality checks by the team and obtaining information from different groups of participants. Providing a rich account of data and its confirmability also added to its quality. FGDs involving community members without disease could have provided a richer narrative of community perspective of the CRD in addition to the information obtained from KIIs. Interviews with different levels of health care providers could have provided more information about health system barriers, which in our study was limited to only one health provider. There may have been some social desirability bias[24] operating during the FGDs and KIIs, due to the typically long periods of health service in the community and good rapport thereof, but it would be limited to specific questions and individuals. The discussions and the interviews were led by a social scientist with experience in qualitative research and interpretation included discussions with the multidisciplinary team.

4.5.3 Study interpretation and discussion in light of published literature

The patients found it very difficult to live with the disease, both physically and psychologically. Physically, the disease was responsible for them not being able to work, with some participants unable to sleep or breathe normally during exacerbations of symptoms. This situation was complicated by patients feeling depressed, sad and unwanted because of the stigma due to the disease or use of inhalers, social exclusion and sense of apathy from the community.

This study also revealed that use of inhalers was not the norm in the community and patients who used them avoided doing so publicly. There was good family support with most of the patients finding physical, financial and psychological assistance from their immediate family members. Patients' preference was typically towards better quality of life and an aspiration to live independently and be of service to their family.

Some of the hurdles to access modern medical treatment were insufficient time, money, physical support, family problems or unavailability of inhalers in government hospitals. Some of the suggestions given by key community members were to start a special respiratory clinic and to have a counsellor for CRD patients which they thought would be beneficial to the patients and improve health behaviour.

The narration from the patients, the caregivers and the key community members suggested quite a few risk behaviours of CRDs prevailing in the community. Such behaviours were common due to inadequate awareness among the patients and public, lack of resources, tardiness of access to modern health systems and cultural practices and taboos. Since my aim was to develop an intervention which can change health behaviour in CRD patients to control the disease and improve outcomes, it was important to identify such risk behaviours and the dynamics of the behaviours which could be potential target points for building on the intervention. Should such negative influences be modified or removed, or positive ones strengthened, or a new set of influencers created, changing health behaviour to promote respiratory health might be possible.

A risk behaviour approach capturing the prominent behaviours, actions putting the patients at risk or aggravating their current disease and circumstances leading to such behaviour would be a useful step towards building up my intervention. Looking at the above outputs from the study, there were four current behaviours among CRD patients which put them at risk from respiratory conditions; they require thorough analysis of the influencers (knowledge, attitude, social norms and capability – financial, physical, psychological) and corresponding beliefs which lead to such behaviours.

First was health seeking behaviour among the CRD patients – though patients usually sought treatment from modern medicine (Allopathy), they self-treated themselves by visiting the local medical shops (pharmacies) even without consulting a physician or visiting a hospital; and obtaining medicines to relieve symptoms on as-and-when basis. It's likely that gaps in understanding about the disease, its natural course, complications arising due to non-treatment or inadequate treatment were responsible for such behaviour. Their belief that taking medicines to relieve symptoms was enough to deal with the disease stems from their lack of knowledge about long term

consequences or failure to recognise it as a separate disease entity - different from symptoms like fever which subside and sometimes resolve on taking medicines (e.g., paracetamol for fever in viral upper respiratory infection) from local pharmacies – this is a common practice among patients in this community. This behaviour stems from their recognition of the symptoms of CRDs as common cold, failing to recognise them as a separate disease entity and their belief that the disease was curable. Misconceptions like disease was transmissible and could spread by close contact or food were also present. Seeking treatment from modern medicine and visiting a qualified doctor or a hospital early, helps in improving diagnosis, accessing evidence-based treatment and maintaining regularity, all of which are proven methods for controlling disease and reducing morbidity and mortality from CRDs in the long term[25-27]. As is discussed in my published paper, gaps in understanding of the disease and prevailing beliefs due to incomplete knowledge affect health seeking behaviour, awareness being linked to health behaviour change[22].

The second key risk behaviour was indoor air pollution from use of biomass fuel for cooking at homes. This was a common cultural practice and social norms dictated its use at many homes. The common use of biomass fuel in the community was either because they did not recognise it as a risk factor for their disease or they did not consider it to be serious enough to affect them. None of the respondents in the FGDs mentioned smoke from biomass fuel as the cause of CRDs, did not relate it to their symptoms and believed it to be harmless - especially the female groups of age more than 50 years, who were convinced that firewood use for cooking was not a cause for CRD. However, patients from male groups and female groups with age less than 50 years offered different perspectives of using biomass fuel for cooking. Those included ease of collection of firewood – easy availability and free of cost, could be collected while returning from work, and financial compulsion as gas cylinders were costly and not affordable even if they had a gas connection. Indoor air pollution due to biomass fuel use had been established as a major risk factor for CRDs, with high exposure among women and children, especially in poor, and in LMIC countries[25, 28-29].

The third risk behaviour among the CRD patients was use of oral medications for treatment of CRD and infrequent, if at all, use of inhalers. Inhalational therapy for control of symptoms is far more effective in management of patients with CRDs like

COPD and asthma; international strategy documents and guidelines as well as several published papers have recommended use of inhalational route due to direct delivery into target site of action while minimising side effects[30-35].

Several factors contributed to use of oral medicines rather than inhalers for CRD. Many of the CRD patients were unaware of inhalers as a mode of treatment and continued to use oral medicines. Patients visiting government primary health centres or local private hospitals were usually prescribed oral medications for their respiratory symptoms. There was no initiative from the health system on promoting use of inhalers, as primary care physicians commonly prescribed oral medications for CRD patients, inhalers being unavailable in government primary health centres whereas oral medications were provided free of cost.

Some patients who did use inhalers, did not know how and when to use them. They used as per their convenience, either when their symptoms were aggravated, usually in winter or when they had enough money to buy them. They were unaware of the benefits of regular and continuous use of inhalers for control of their symptoms. The use of inhalers was also limited by financial constraints, as the patients found it hard enough to afford them themselves on a regular basis. The irregular and infrequent use of inhalers was also attributed to stigma associated with its use leading to public knowledge of their disease in the community. So inhaler use in those few who used them was limited to their homes and was stopped if they had to go out in public.

The fourth risk behaviour of concern was the limited awareness about breathing exercises as a non-pharmacological treatment for CRD for control of symptoms and improvement in quality of life. There was no practice either of any breathing exercises by CRD patients. CRD patients during their restricted contact with modern system of medicine and hospitals, had limited information from health providers about breathing exercises and were unaware of its benefits. Not only the lack of awareness prevented them from performing any breathing exercises but also there were no pulmonary rehabilitation or exercise training centres in the rural community, the nearest one being in Christian Medical College and Hospital, Vellore – a tertiary care centre 25 kilometres from the community. Randomised controlled trials have shown that comprehensive pulmonary rehabilitation (PR) program with evaluation, physical exercise, self-

management awareness, nutritional intake and psychological support has decreased symptoms, improved exercise tolerance and physical activity thereby improving health-related quality of life (HRQOL) and reducing health care utilization[36-37]. Breathing exercises are an essential component of comprehensive PR program and help to improve functional exercise capacity and physical quality of life[22, 38].

Besides the four main risk behaviours, recognition of CRD as a separate disease entity, similar to other chronic diseases like hypertension or diabetes, was lacking. There was lot of stigma for CRD patients and social support was limited only to immediate family members or care-givers. This led to lot of psychological distress among patients and further inhibited any health promoting behaviour. Social recognition and appreciation can work as motivators for health behaviour change.

Implications for policy and practice – A change at the policy level towards CRD focussing on investment to address financial barriers, education and health awareness, as well as implementation and availability of inhalers for use at primary care level can lead to significant change in perception of CRD in the community and behavioural practices among patients. These are often considered as 'upstream' factors or factors at the base of "the health impact pyramid"[39] which are difficult to achieve and require political will and government policy. They are, nevertheless, most effective and ultimately reach broader segments of society. Concerted efforts at the level of primary care practices and a better communication between patients and the HCPs can allay fears and misconceptions towards the disease, provide precise health information and promote healthy behaviour. Engaging the community with culturally acceptable and locally available media and methods, improving their awareness and acceptance of CRD prevention and treatment through educational interventions, building trust by improving interactions with the community through community-based health providers can result in immediate impact and outcomes.

This study helped in identifying gaps wherein intervention could be useful, providing direction in its design and delivery. the intervention included culturally acceptable and easy to understand media and methods for improving awareness about CRD and related health behaviour. This was not limited to patients alone but was for dissemination in the community and the caregivers to help reduce stigma and

generate social support. Detailed information about health practices related to CRD was given to the patients by the health care providers to plug the gap of limited or misinformation about behaviour practices; this was reinforced by training and demonstrations of health practices (inhaler use and breathing exercises). Inhalers were made available to all participating in the intervention and the community was engaged throughout the intervention period with appropriate health messages being delivered. Belief in themselves to perform health behaviour, along with community support might contribute to better health outcomes, thereby improving quality of life among the patients of CRD.

4.6 Conclusion

To conclude, the qualitative study has provided me with key information about the prevailing behaviours, practices, attitudes, social norms and extent of capability among the CRD patients. The prevailing health behaviours and the underlying beliefs underpinned the intervention for behaviour change. The gaps identified were used for my intervention design and delivery targeting not only the patients with CRDs but also the caregivers, the family members and the local community, all of whom were influencers of health behaviour. Thus the qualitative study informed me for TPB intervention development which is described in detail in the next chapter.

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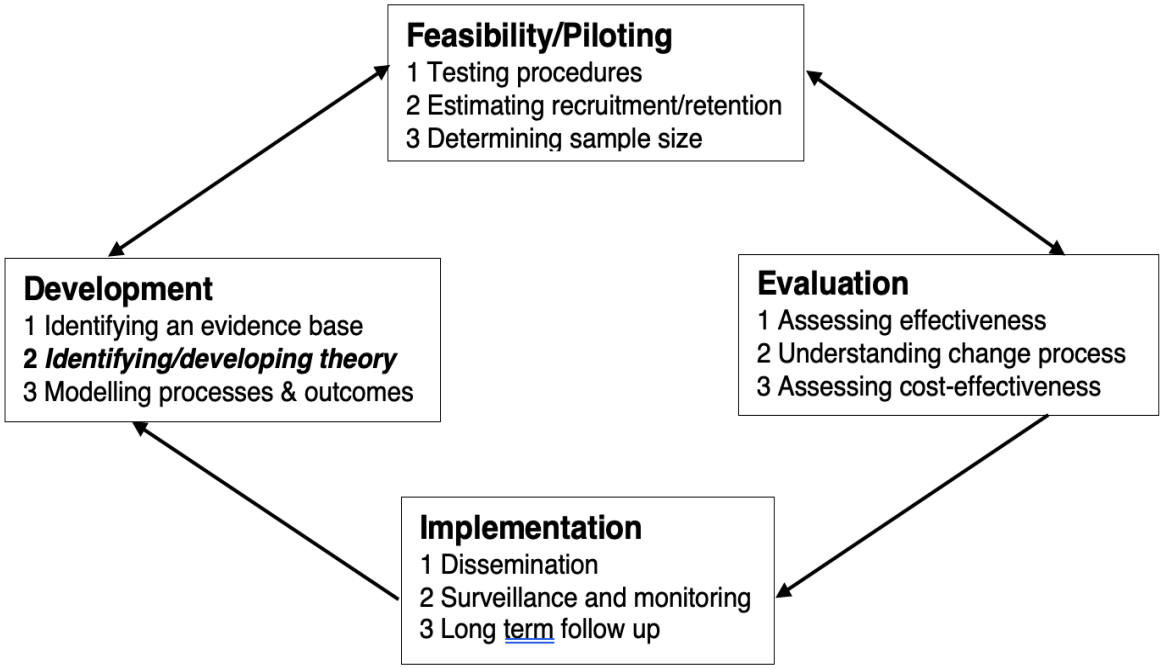
Chapter 5

Project 3 – Intervention development and description

In the previous two chapters I have systematically searched for evidence on TPB based interventions, their feasibility and applicability in low health literacy populations in resource poor LMIC settings (through a systematic review) and explored current beliefs, practices, lived experiences, opinions, barriers and facilitators to health behaviour in chronic respiratory disease (CRD) patients in the local community (through qualitative formative research). In this chapter, I present my work on the development of the intervention, informed by systematic review (SR) and qualitative research and its assessment of the change in TPB constructs and behaviour using an evaluation questionnaire. This chapter describes the theory behind the intervention development, the process of questionnaire development and the intervention development and delivery methods.

The development of the TPB-intervention was guided by the updated MRC guidance (2019) on complex intervention development and evaluation[1], which seeks to incorporate theory, generate an evidence base and model processes and outcomes. The intervention development was accompanied by the development of an evaluation questionnaire to assess the effectiveness of the intervention in changing TPB constructs (attitudes towards behaviour, subjective norms, perceived behavioural control) and health behaviour related to CRD. As per UK MRC guidance, there are four key elements or phases in intervention development and evaluation which includes development of a theory-based intervention, feasibility testing of the developed intervention, assessment of the effectiveness (in terms of outcomes and economic viability) and implementation of the intervention through monitoring, follow-up and dissemination. The key elements of the MRC complex intervention development and evaluation are depicted in Figure 5.1. The different phases of intervention development have been described in detail; similarly the different phases of development of the evaluation tool have also been described.

Figure 5.1 Key elements of the development and evaluation process



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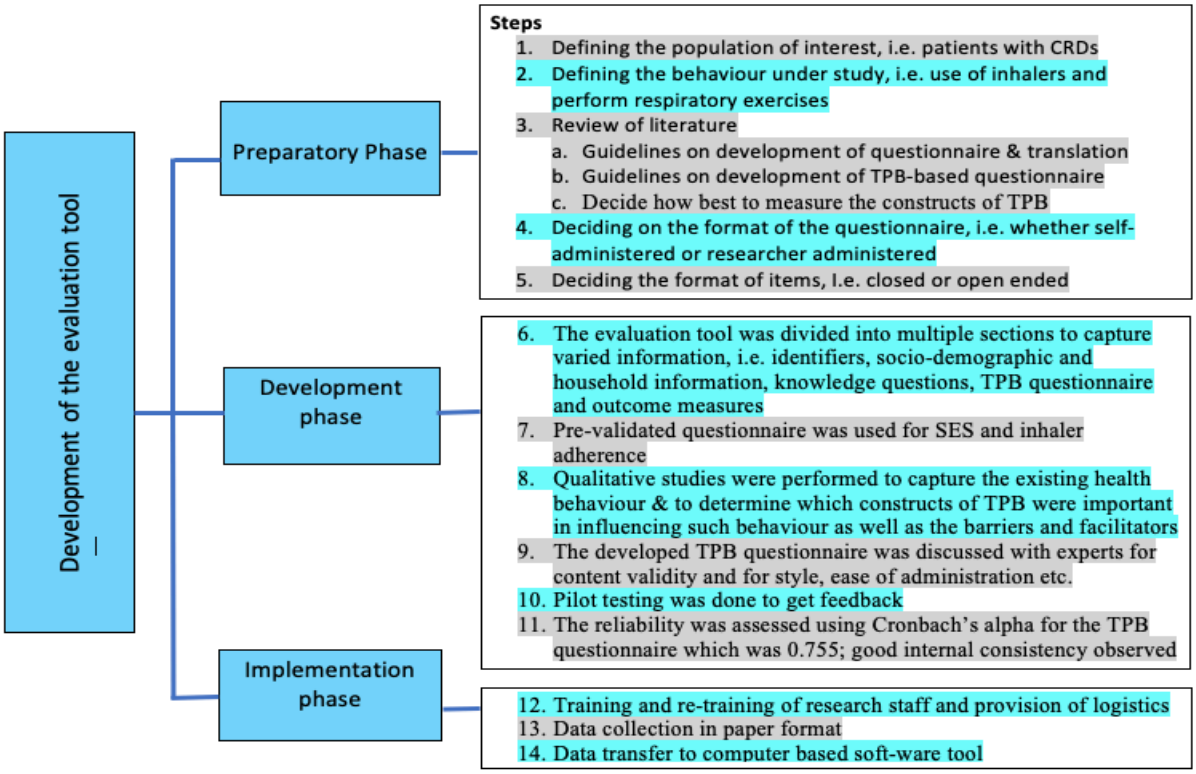
5.1 Development and validation of TPB based evaluation tool (evaluation questionnaire)

To quantify the desired objectives and to determine whether my TPB based intervention worked, an evaluation tool was necessary which could measure not only the changes in TPB constructs (attitudes, subjective norms, perceived behavioural control, intention and behaviour) but also pick up sociodemographic variables and risk behaviours in relation to CRDs. The development of such a tool (the evaluation questionnaire) involved three phases; the preparatory phase, the development phase, and the implementation phase, as depicted in Figure 5.2. All the three phases were important and interlinked to one another. The development of the evaluation questionnaire took place systematically, one phase leading to the other and ultimately led to the development of a refined, pretested and validated questionnaire. The questionnaire was used at baseline and at the end of the intervention period on the same CRD patients, to evaluate the changes in TPB constructs and their underlying beliefs, health behaviour related to CRD, socio-demographic details and risk

behaviours. The development of the evaluation questionnaire was informed by Tsang et al[2].

Figure 5.2 Process of questionnaire development



Development of questionnaire adapted from Tsang et al[2]

5.1.1 The preparatory phase

This phase involved basic groundwork and collection of information about availability of any existing evaluation tool, means and methods of developing an evaluation tool and development of a basic framework for such a tool. Activities under this preparation phase included:

i) Review of literature (research articles, published papers, books, blogs, websites)

- To gather information and find guidelines for developments of new questionnaires
- Guidelines on translation of questionnaires to native language
- Information and guidance for development of the TPB based questionnaire, especially in LMICs with lower health literacy
- To look out for existing questionnaires on TPB based intervention evaluation

- Detailed review of the constructs of the psychological theory to develop a template for my TPB questionnaire

ii) deciding on the format of the questionnaire

- Whether self-administered or researcher administered

iii) Deciding on the format of the items in the questionnaire

- Whether close-ended or open-ended

After thorough review of literature and discussion with my supervisors, I chose to develop an evaluation questionnaire which was to be administered by the researcher or her/his representative and would be semi-structured. The reason for choosing a researcher administered questionnaire was that most of the study population were illiterate or had low literacy levels and would not be able to read or comprehend the meaning of the questions asked. It was decided that independent evaluators who were not part of the research project were to be trained in the process of questionnaire administration and would explain the questions and clear any doubts raised by participants, while filling up the questionnaires; moreover, it would minimise bias. It was also decided that to overcome the barriers due to low-literacy, some pictorial aids would be used by the evaluators besides using colloquial (vernacular) language, as used by the participants. Although it was a semi-structured questionnaire, most of the questions were in structured form to elicit accurate responses to the quantitative variables; some questions (such as relationship to head of the household or type of occupation) were open ended.

5.1.2 The development phase

5.1.2.1 Questionnaire development

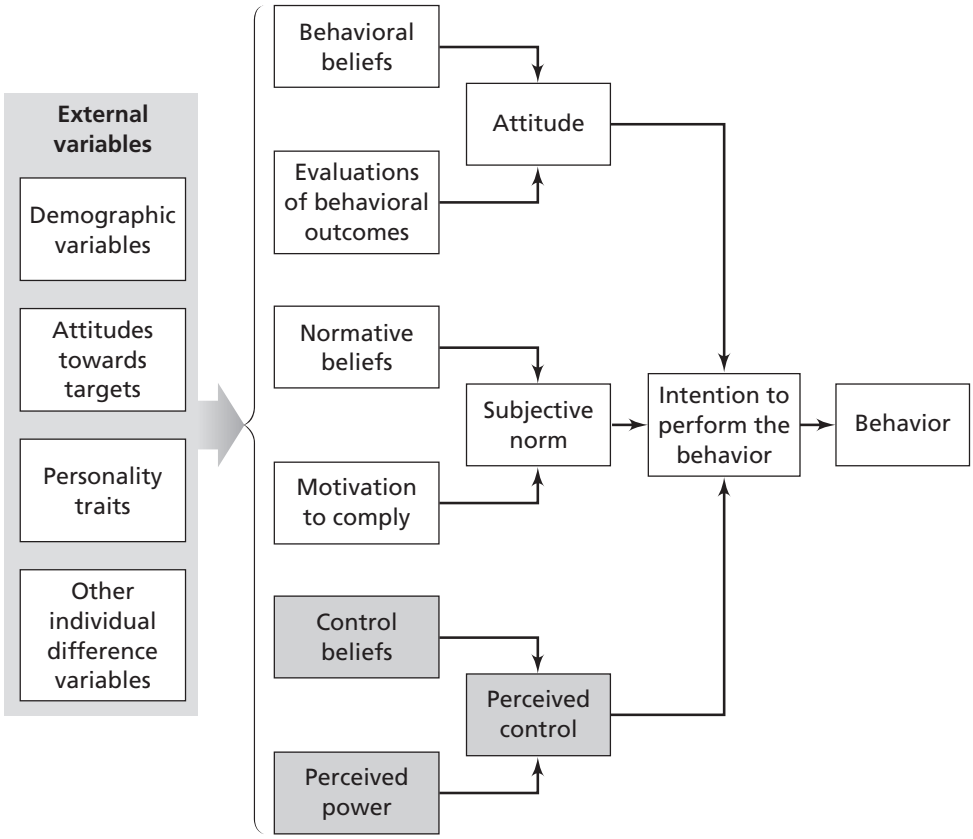
This involved the entire process of developing the evaluation tool and its validation. The evaluation questionnaire was divided into different sections to capture different information; some were prepared from scratch with insights from articles, published papers and available literature, while for some sections pre-validated and pre-tested questionnaires were available and assembled. For others (like the TPB based questionnaire), guidelines were followed, and much formative groundwork was undertaken. The section on identifying information had details of the participant and

address, contact number, height and weight and type and duration of the disease. The second section had socio-demographic information about the participant which included age, sex, religion, caste, marital status, type of family, number of rooms and family members. It also included a validated and widely used, structured socio-economic status (SES) scale known as the Uday Pareek scale for SES[3]. This scale is used exclusively to determine the socio-economic capability of people living in rural areas - this scale was chosen given the rurality of my study population. It has nine domains which assess the socioeconomic status of the individual (i.e., caste, occupation, house, land, education, social participation, farm power, material possessions, and family members). The TPB questionnaire had a 61 questions with 30 questions on intention, attitudes, subjective norms and perceived behavioural control; the rest examined underlying beliefs.

5.1.2.1.1 TPB based questionnaire

Guidelines for development of TPB questionnaires[4-6] indicated that formative research was necessary in examining the behaviour in the population of interest to formulate a questionnaire. Qualitative studies involving FGDs, in-depth interviews and key informant interviews were conducted to collect information about the beliefs associated with attitudes, subjective norms and perceived behavioural control in relation to health seeking behaviour, oral medications, inhaler use and follow-up among patients, caregivers and the general population. Identifying the accessible behaviour as well as behavioural, normative and control beliefs helped in framing a TPB questionnaire. The details governing the theory of planned behaviour are depicted in Figure 5.3. The TPB questionnaire section of the evaluation questionnaire is presented in box 5.1.

Figure 5.3 The Theory of Planned Behaviour



Source: 4

Considering the low literacy levels and the age of the respondents, it was decided to have a researcher-administered questionnaire which would be read out, with recoding of responses. It was also decided that it would be manually completed and later transferred into a computer-based program by the data entry operator. Considering the objectives of the evaluation tool and the constructs of TPB, appropriate items were developed and included in the questionnaire. The entire questionnaire was initially developed in English.

5.1.2.2 Translation

The final version of the English questionnaire was translated to a Tamil version as that is the native language of the respondents. This was colloquial Tamil common to that area as dialects of a language vary in our country, from region to region. The translation team had 2 members, both of whom were native Tamil speakers albeit well versed in English. The translated Tamil questionnaire was independently back-translated into English by the second translator so as to maintain the content, context and meaning of the questions. This was verified by myself and my supervisor.

Box 5.1 The questions used in the TPB evaluation questionnaire

Example: How is the weather today?

1. Too Cold 2.Cold 3. Moderate 4.Hot 5.Too hot

Behavioural Intention (Perceived likelihood of performing the behaviour)

Sl. no		1 Extremely Unlikely	2 Quite unlikely	3 Not sure	4 Quite likely	5 Extremely Likely	NA
1.	To continue treatment as instructed by your doctor even when you feel well						
2.	To take oral medications dailylong-term if recommended						
3.	To take inhalers daily for long period of time if recommended						
4.	(If smoker)To stop smoking within the next three months if your doctor advise so						
5.	(If using biomass fuel) To stop using biomass fuel (firewood/cowdung cakes/ leaves or straw /kerosene) for cooking and change to cleaner option (gas) within the next three months, if your doctor advise so						
6	To seek medical help immediately if you get wheezing or breathlessness						
7	To do all the investigations (blood, x-ray, spirometry, lung scan) recommended by doctor						
8	To do respiratory health exercises if therapist/doctor advise						

Attitude related to CRD

For my disease condition

Sl. No.		1 Extremely Foolish	2 Quite Foolish	3 Not sure	4 Quite Wise	5 Extremely Wise
1	Taking oral medicines daily is					
2.	Regular use of inhalers long-term is					
3.	Learning correct technique of use of inhaler is					
4.	Daily performance of respiratory health exercises to reduce breathlessness is					
5.	Doing blood investigations, x-ray and lung scan is					
6.	Using Siddha/Ayurveda/unani/other AYUSH treatment is					
7.	Doing a breath test (spirometry) early in the disease stage is					
8.	Stopping smoking to reduce the symptom is					
9.	Stopping use of biomass fuel at home to reduce the symptoms is					

Subjective norm

		1 Completely disagree	2 Somewhat disagree	3 Do not disagree or agree	4 Somewhat Agree	5 Completely Agree
1.	My family thinks that for my respiratory illness, I should use allopathic oral medicines only					
2.	My doctor thinks inhalers/rota-halers is better than using oral medicines					
3.	Neighbours think that my disease will spread to others					
4	In my community/village, most people look down upon people using inhalers in public					
5.	My family think that I cannot lead a normal social life because of my illness					
6	My doctor thinks that smoking bidis/cigarettes is responsible for my lung disease					
7.	In my community/village, most people do not think biomass fuels (like firewood/cowdung cakes/ leaves or straw /kerosene) cause lung disease					

Perceived Behavioural control

		1 Not at all sure	2 Not quite sure	3 Neither sure or unsure	4 Quite sure	5 Completely sure
1	I am confident that I can take my inhalers and medicines regularly					
2	I can do my breathing exercises daily at least for 20 minutes					
3	I am sure of eating a nutritious meal at least once every day to improve my symptoms					
4	I am confident that I will be able to follow the correct technique of inhaler use					
5	How sure are you that you can stop smoking in the next three months					
6	How sure are you that you can purchase your inhalers for regular use					
7	How sure are you that you can get all the investigations done for your disease even if you have to go to CMC/VELLORE GVMC					

Beliefs related to the constructs (Indirect measures of the constructs)

a. Beliefs Related to attitude (behavioural beliefs and outcome evaluation)

[the individual's beliefs about outcomes or attributes of performing the behavior]

	Behavioural Beliefs	1 Completely disagree	2 Somewhat disagree	3 Neither disagree or agree	4 Somewhat agree	5 Completely agree
1	Taking my prescribed oral medications (inhalers/medicines) for my lung condition will make me symptom free (reduce my breathlessness, wheezing, cough and expectoration)					
2	Regular use of inhalers/rota-halers will make me symptom free (reduce my breathlessness, wheezing, cough and expectoration)					
3	Performing the respiratory exercises will decrease my breathing difficulty					
4	Stigmatizing to use inhalers/rota-halers in public					
5	Taking nutritious food daily can improve my respiratory health					

Outcome evaluation

		1 Extremely low	2 Somewh at low	3 Not low or high	4 Somewh at high	5 Extremely high
1	Scope of myself remaining free of respiratory symptoms is					
2	Likelihood of suffering from the complications of the respiratory disease is					
3	Myself to be able to keep better control of my symptoms is					
4	Myself to be able to use inhalers in public is					
5	Myself to be able to keep healthy is					

a. Beliefs related to subjective norm (normative beliefs and motivation to comply)
[whether important referent individuals approve or disapprove of performing the behavior, weighted by his or her motivation to comply with those referents.]

	Normative Beliefs	1 Definitely should not	2 Maybe should not	3 Not sure	4 Maybe should	5 Definitely Should
1	My family (spouse/children/parents) thinks that I_____ use inhalers					
2	My family thinks that I _____ go for regular medical check up					
3	My doctor thinks that I _____ do breath tests (spirometry), blood tests and lung scan for my lung disease					
4	a) My doctor thinks I _____ stop smoking					
	b) My doctor thinks I _____ stop using biomass fuels					
5	My doctor thinks I _____ do breathing exercises for my respiratory disease					

Motivation to comply

		1 Strongly disagree	2 Somewhat Disagree	3 Neither disagre e or agree	4 Some what agree	5 Strongly agree
1	When it is a matter of inhaler use I want to do what my family thinks I should do					
2	When it is a matter of regular medical check-up I want to do what my family thinks I should do					
3	I should do my breath tests, blood tests and lung scan if my doctor thinks so					
4	a) If my doctor thinks I should stop smoking, I should do it					
	b) If my doctor thinks I should stop using biomass fuel, I should do it					
5	If my doctor thinks I should do breathing exercises, then I should do it					

C. Beliefs related to perceived behavioural control (control beliefs and power of control factors) [factors outside individual control that may affect intentions and behaviors]

	Control Beliefs	1 Highly unlikely	2 Somewhat likely	3 Not sure	4 Somewh at likely	5 Highly likely
1	I can arrange enough money for my medications					
2	I will manage time for doing the respiratory exercises					
3	My family responsibilities will not get in my way for regular medical check-up					
4	Once in three months respiratory clinics in my community will help me to comply with the treatment					
5	If correct technique of inhaler use is demonstrated, I will be able to perform it					

Power of control factors

		1 Complet ely disagree	2 Somewh at disagree	3 Neither disagree or agree	4 Somewha t agree	5 Completely agree
1	Having money will enable me to continue my medications					
2	Performing respiratory exercises will decrease my breathlessness					
3	Access to regular assessment and treatment recommendation for my lung disease will help me to lead a symptom free life					
4	Having access to special respiratory clinics will ensure compliance to medications					
5	Demonstration will help me to use the inhaler correctly					

5.1.2.3 Validation

5.1.2.3.1 Content validity

The drafts of the questionnaires were circulated among experts (included experts in TPB like Icek Ajzen, Karen Glanz, Daniel E. Montano, Danuta Kasprzyk, Amudha Poobalam and my supervisors) to get their opinion and feedback about the content and relevance to the purpose. Icek Ajzen started the theory of reasoned action (1980) with Fishbein, and subsequently theory of planned behaviour, while Karen Glanz, Daniel E. Montano, Danuta Kasprzyk are well known authors of the book Health Behaviour and Health Education – Theory, research and Practice; Amudha Poobalam is a qualitative researcher in University of Aberdeen. The reason for contacting them was to seek guidance in correctly developing the TPB based questionnaire and the intervention and for checking the content my TPB evaluation questionnaire for its validity.

Three out of five experts replied to me. They gave feedback related to the readability, consistency of style and formatting and the clarity of the language used and ease of administration to the respondents and the consensus views were incorporated and agreed to at the end. Ajzen suggested about using his website[5] to get a host of information on the development of TPB questionnaire. One of the changes made was to use a 5-point Likert scale instead of 7-point (which was usually used), as 7 point-scale was considered too complex given the literacy levels of the respondents.

5.1.2.3.2 Pilot testing

The questionnaire was ready for pilot testing. Before administering, the research staff (evaluators) were appraised about the theory and the items of the questionnaire and what each section sought to capture. After administering it to the respondents, feedback was obtained about the feasibility, consistency of style and formatting, clarity of local language used, ability to understand the items, length of the questionnaire and ability to compete it. The following changes were made to the questionnaire based on the feedback from the respondents:

- There was a problem in understanding the scales, so a commonly understood example with a similar type of scale was initially administered (such as, how is

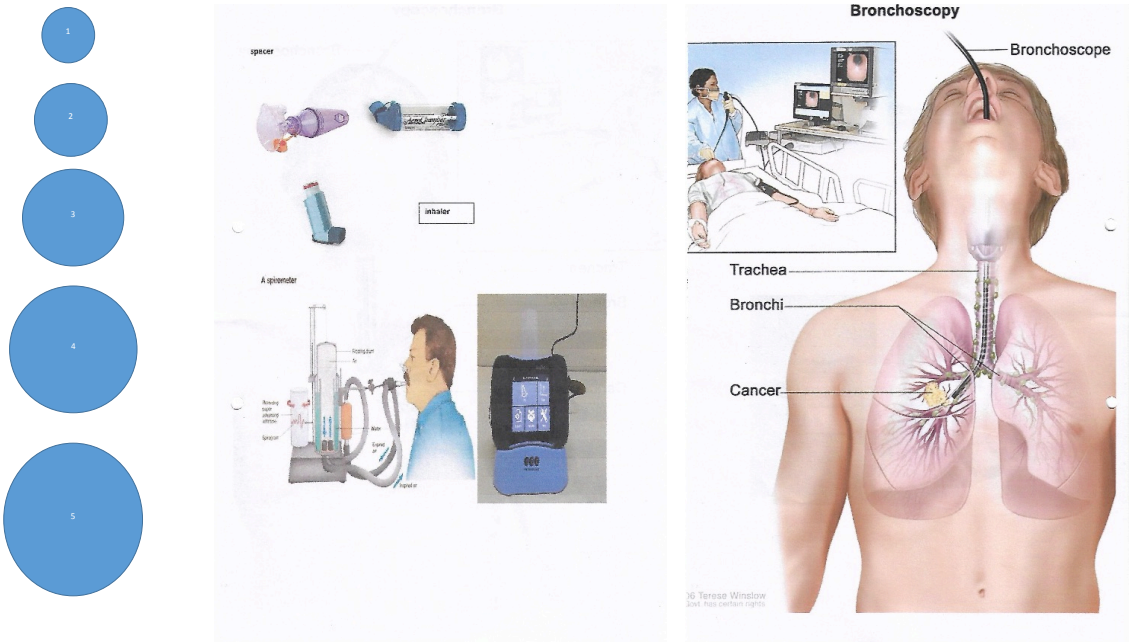
the weather today? With options of too hot, hot, moderate, cold, too cold) to them for their understanding before the actual administration of the questions

- Some pictorials were also used to make their response to questions easier
- The respondents felt the questionnaire was a bit lengthy but opined that it was necessary
- They were able to complete the entire questionnaire in 45-60 mins
- Some of the literary Tamil words were replaced by colloquial Tamil words which made the understanding easy to the participants

5.1.2.3.3 Reliability

The internal consistency was tested by using Cronbach's alpha[7-8] for the TPB questionnaire which was 0.755 and considered to be of good internal consistency among the items in the questionnaire.

Figure 5.4 The tools used during using administration of evaluation questionnaire to participants to make the questionnaire more understandable



5.1.3 Implementation Phase

This phase involved the preparation and actual administration of the evaluation tool to the study population. This involved the following activities -

- Training and re-training of the research staff (evaluators) in each item and way of administration of the questions

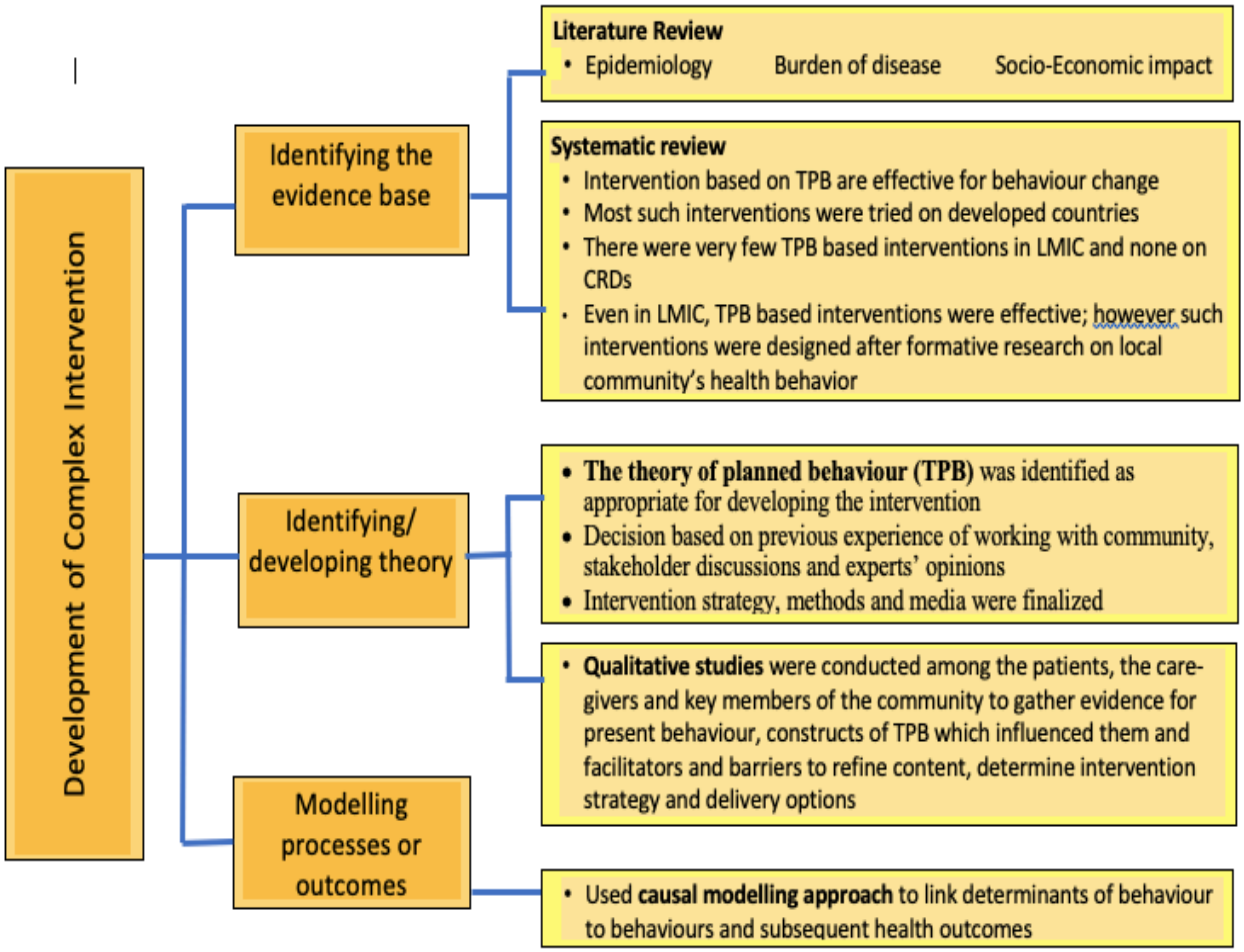
- Printing of the evaluation tool
- Provision of pictorial tools to the evaluators
- Provision of a separate room for privacy and holding attention
- Establishing a mechanism (with shared understanding amongst the whole team) about of activities from health check-up to questionnaire administration

The whole process of development and implementation of the evaluation tool took around 6 months and was developed between October 2018 to March 2019.

5.2 Development of the TPB-based intervention

The TPB-based intervention was developed as per UK MRC updated guidance on complex intervention development and evaluation[1]. The process for development of the intervention was adapted from Smith et al[10] and described as per my intervention parameters. The first phase is the development of the complex intervention, which involved identifying the current evidence on the magnitude and distribution of burden of CRDs globally and regionally and the risk factors associated with it. This was followed by gathering evidence on applicability and effectiveness of the theory of planned behaviour in low resource settings of low-and-middle-income countries (LMICs), though a systematic review (SR). This SR informed me about need for a formative research to understand salient beliefs and behaviour of the community and develop an intervention to appropriately change the TPB constructs – attitude, subjective norms and perceived control and the CRD related health behaviour. The steps of development of this intervention is depicted in Figure 5.5.

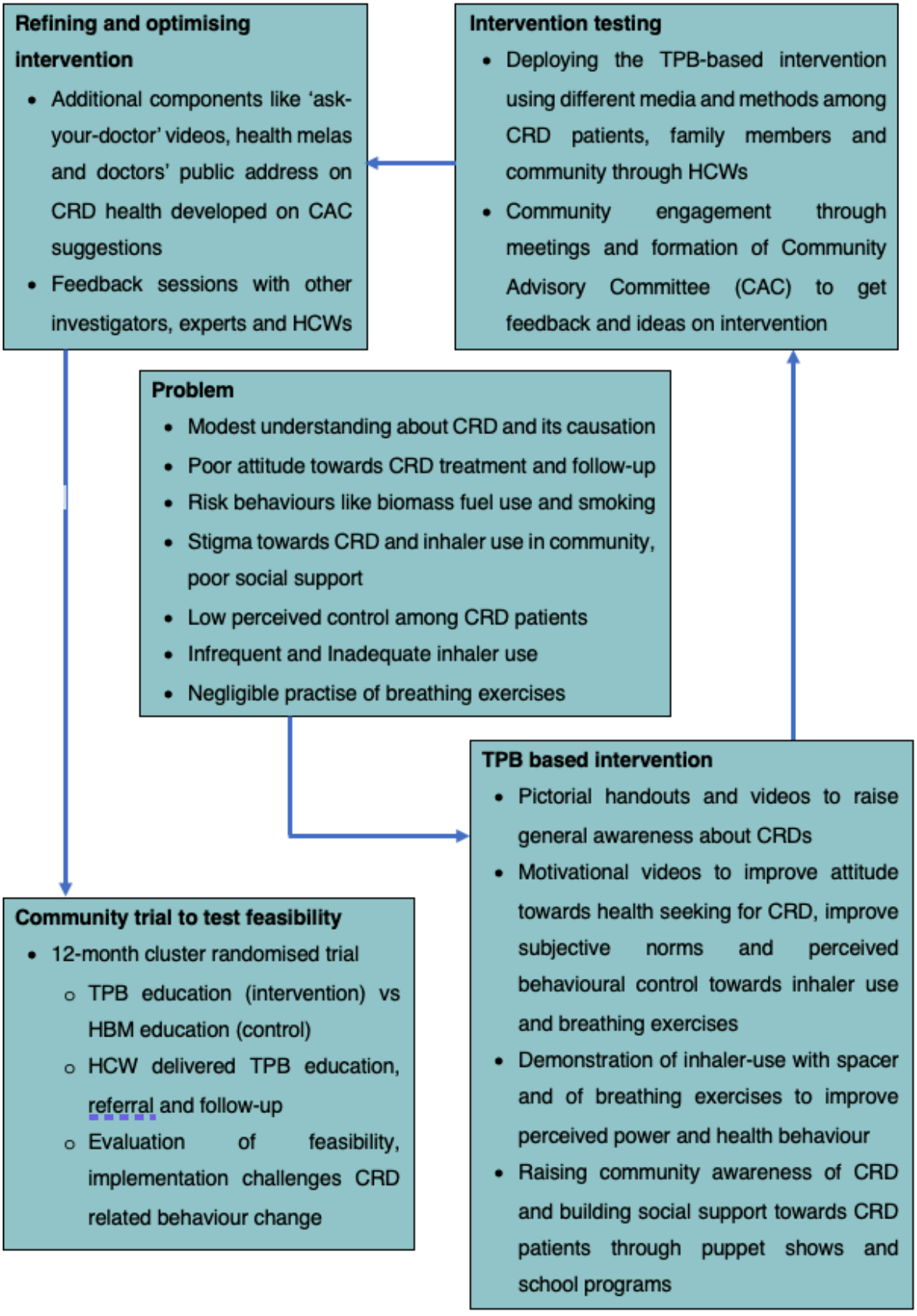
Figure 5.5 Steps in development phase of complex Intervention



Source: 1

The intervention development and implementation was an iterative process, as the intervention developed from the initial inputs of my systematic review and formative qualitative research needed to be refined based on the feedback of the stakeholders including the patients and the public, the health care workers delivering the intervention and the researchers working with the project. The process of intervention development and implementation is described in figure 5.6.

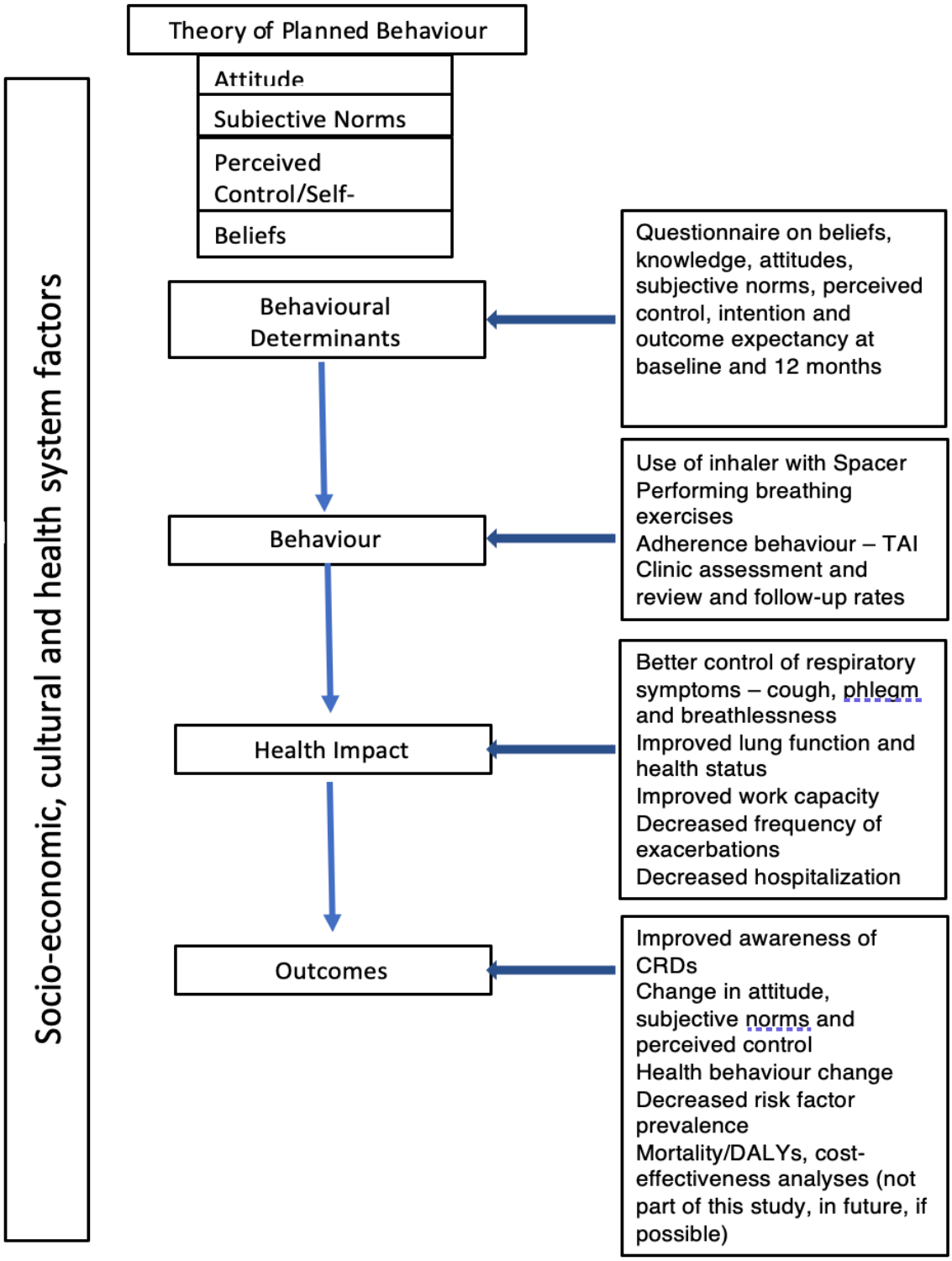
Figure 5.6 Intervention development and implementation



Source: 9

Using a causal modelling approach, the determinants of behaviour change were linked to behaviour and subsequent health outcomes. The causal modelling pathways for my intervention is depicted in Figure 5.7.

Figure 5.7 Hypothesised causal pathways and measures for evaluation for TPB-based intervention



5.3 Process evaluation of the intervention

5.3.1 Logic model of the intervention

A logic model of the intervention was developed to look into the different aspects of the intervention with regards to inputs, processes, outputs and outcomes. It provided an understanding of the overall inputs to outcomes and benefits in timescale. The logic model is described in table 5.1.

Table 5.1 Logic model of TPB-based intervention

Intervention inputs	Intervention processes and activities	Outputs	Immediate outcomes	Intermediate outcomes	Long term outcomes
Funding for the intervention project	Preparation and approval of budget and securing funding	Quarterly financial reports generated. Annual reports Risk registers			
Research Staff for organisation, coordination and implementation of research activities	Staff recruitment – Research Officer, Project coordinator, Field coordinator, Research Coordinator and HCP (HA)	Rolling out of research activities Quarterly and annual reporting	Conduction and completion of the research project		
Facilitation of action group meetings between researchers and project staff	Action group decides priorities and oversees actions	Periodic meetings to decide course of action and prioritise activities	Conduction of appropriate activities and maintaining timeline		
Stakeholder engagement and community engagement	Meetings with key community members (panchayat leaders, SHG members, teachers and HCW) for appraisal of the problem and actions to be taken. Brainstorming session with Government officials and Health Providers of the region Continuing Medical education on updated diagnosis and treatment of CRDs among health providers	Community meetings Formation of Community advisory group SE meeting for brainstorming session CME for doctors	Strengthening of rapport in the community Community endorsement of the research team and willingness to participate in the research project. Suggestions to improve CRD behaviour and adherence. Better diagnosis and management of CRD	Acceptance of CRD patients and of inhaler use in the community. Increased awareness about CRD symptoms, risk factors and treatment leading to regularity in treatment and follow-up. Adherence to inhalers Use of correct inhaler technique by patients Better control of symptoms in CRD patients	Improvement in quality of life in patients with CRDs Reduction in mortality and morbidity among patients with CRDs Social inclusion and recognition of the CRD patients in the community Improvement in mental health status Economic development due to more active contribution to the workforce and as a result of reduction of healthcare costs
Training materials and modules Training of staff for respective roles (induction and intermediate and advanced)	Development of training modules for HCWs Education through modules on CRDs, communication and hands-on training on data collection methods at different points of time	Training modules on CRD screening, symptoms, risk factors and treatment Scheduled trainings for HCWs on data collection and patient communication	Better communication with patients about CRDs Identification of suspected CRD patients by HCWs and referring them for diagnosis and treatment at the hospital Improved patient motivation and awareness about CRD treatment	More active life and work capability in patients with CRDs Reduction in the exacerbations (severe breathlessness episodes) and in hospitalizations due to the disease	Change in government policy towards CRD for better protocol-based management and availability of drugs and devices

Survey needs, health and behavioural practices of CRD patients Measurements of impact and health behaviour	Conducting qualitative research to describe lived experiences comprising existing behavioural practices and attitudes, subjective norms, perceived power of their actions and facilitators and barriers to behaviour related to CRDs. Development of survey questionnaires based on qualitative feedback and psychological TPB theory. Literature search and finalization of tools for outcome evaluation	Development of topic guides for FGDs, IDIs and KIIs for the qualitative research Qualitative research informs the development of TPB-based intervention. Baseline and end line survey questionnaires SGRQ as impact evaluation questionnaire TAI as evaluation tool for adherence behaviour	TPB-based intervention targets health awareness and behaviour among patients of CRDs and the rural community Diagnosis and treatment of patients of CRD as per protocol Use of inhalers and spacers by the CRD patients Respiratory exercises performed by the CRD patients.	De-stigmatisation of the disease and more community support for CRD patients Use of inhalers supported and established as normal health behaviour in the community.	
Protocol for diagnosis, treatment and follow-up of CRD patients and standardisation of treatment	Review protocol development for CRD diagnosis and treatment, and follow-up the patients for clinical assessment periodically Diagnostic facilities upgraded e.g., spirometry and x-ray	Clinical Review Forms for diagnosis and follow-up, optimisation of treatment and measurement of clinical outcomes			
Availability and access to recommended drugs and devices Educational materials, trainings and demonstrations for CRD patients	Indent and stocking of medicines and medical devices Complex intervention development (informed by TPB, qualitative feedback and experience with the community) with multiple components (education, standardised treatment, training of inhaler use with spacer and demonstrations of respiratory exercises) and points of action (patient, caregivers and community)	Medicines, inhalers and spacers were stocked and supplied as per prescription Leaflets General Awareness video TPB video Patient doctor Q&A videos for asthma and COPD Pictorial handouts/calendar for inhaler use and exercises at home. Puppet shows in the community about CRDs and treatment availability			

HCW (HA) – Health Care Workers (Health Aide); CRD – Chronic respiratory disease; FGD – Focus group discussion; IDI – In-depth Interview; KII – Key Informant Interview; SGRQ – St. Georges Respiratory Questionnaire; TAI – Test of Adherence to Inhalers

5.3.2 Stakeholder and community engagement and feedback

One of the important aspects of this research, and a central learning attribute for me, was the stakeholder and community engagement; the patient and public involvement as partners in this research provided me with novel insights and enriched the research. This section describes the stakeholder engagement and community engagement activities and the outcomes which not only contributed to the development of the intervention but were also helpful for its implementation. Engaging with the stakeholders throughout helped in keeping their perspective central – it also kept them informed and interested and facilitated the intervention delivery, even if some mid-intervention changes had to be made due to unexpected circumstances.

5.3.2.1 Stakeholder engagement (SE) in research

A stakeholder can be anyone who is interested in the research, is affected by it, or can affect or influence the research. For example, a doctor or clinician or public health specialist interested in respiratory disease research might be stakeholders in this kind of project. Patients suffering from respiratory diseases and the community where patients live and who can be affected by such research are also stakeholders. Similarly, government officials, the funders or the policy makers who can accelerate or stop such research are also stakeholders. Overall, each of the individuals or groups influence or get influenced in their own way and are stakeholders. Therefore, it is important to engage them from the beginning, through and to the end of the research project to maintain a continuity and provide meaning to the research and a sense of fulfilment for the stakeholders. It is also an iterative process which should be continued into service delivery and future research for meaningful and successful implementation of health problems' solutions.

Stakeholders have been defined as 'individuals, organisations or communities which have a direct interest in the process and outcomes of a project, research or policy endeavour"[10]. A stakeholder can be an individual or a group in a research project or a programme that has an interest in the proposed change and can influence or impact the success of that change. Concannon et al[11] conceptualised the **7Ps** framework to identify stakeholders in the project entitled Patient-Centered Outcomes Research and

Comparative Effectiveness Research – it was undertaken in the USA. The 7Ps are patients and the public, providers, purchasers, payers, public policy-makers and policy advocates working in the non-governmental sector, product makers, and principal investigators[12]. There are usually multiple stakeholders in a single research project and identifying and prioritising them are important for engagement and ultimately the success of the research. The National Health service (NHS), United Kingdom (UK) has provided a **9C**s framework for identifying stakeholders[13]. This helps to ensure all relevant stakeholders are included. They are -

Commissioners: those who pay the organisation to do things

Customers: those who acquire and use the organisation's products

Collaborators: those with whom the organisation works to develop and deliver products

Contributors: those from whom the organisation acquires content for products

Channels: those who provide the organisation with a route to a market or customer

Commentators: those whose opinions of the organisation are heard by customers and others

Consumers: those who are served by our customers: ie patients, families, users

Champions: those who believe in and will actively promote the project

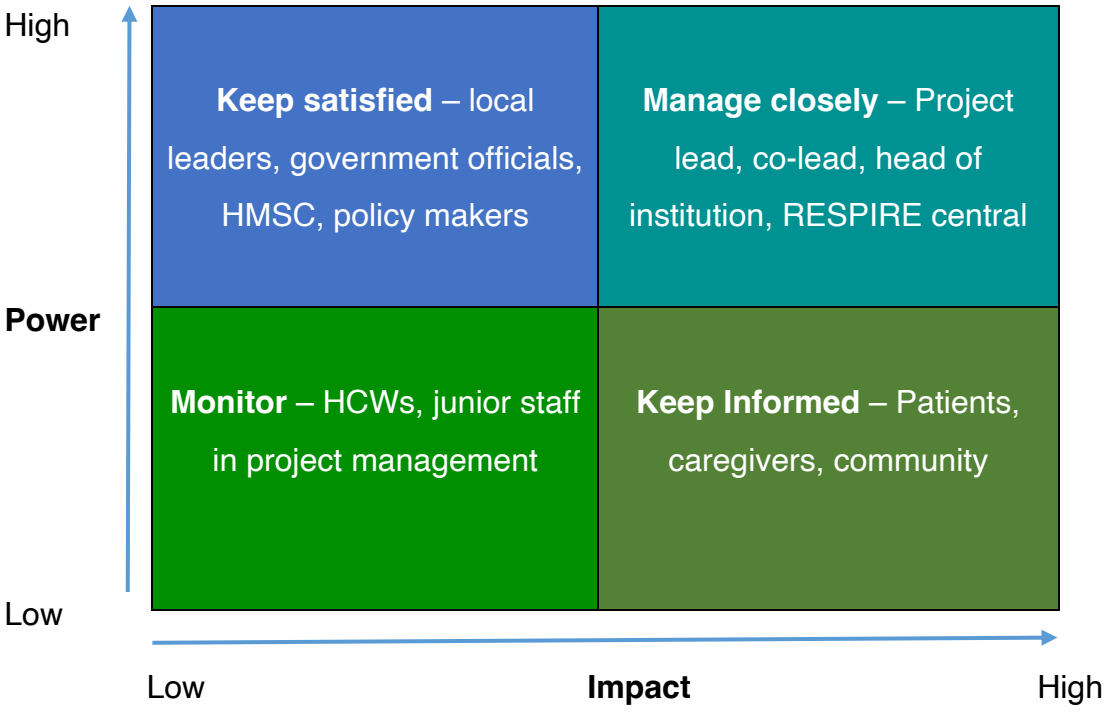
Competitors: those working in the same area who offer similar or alternative services.

Stakeholder engagement has been defined by Deverka et al[10] as "an iterative process of actively soliciting the knowledge, experience, judgment and values of individuals selected to represent a broad range of direct interest in a particular issue, for the dual purposes of: creating a shared understanding; making relevant, transparent and effective decisions". Stakeholder engagement is, in essence, building relationships based on mutual understanding and trust, thereby enabling and facilitating change. It is based on building sustainable relations with individuals or groups who are affected by what we do or can contribute to what we do. It relies on a commitment to engage, listen, respond and communicate openly and honestly with stakeholders. Knowing the perceptions and opinions of stakeholders, being honest with them, keeping them well

informed and consulting with them all along helps in building trust are essential for stakeholder engagement and makes implementation of the research/service effective.

The Academy of Research and Improvement of the Solent NHS Trust has come up with a guide to stakeholder engagement[14], which informs about four key steps to effectively engage stakeholders – 1. Identification 2. Prioritising 3. Developing an engagement and communication plan and 4. Facilitating patient and public involvement. Identification of stakeholders is done by listing everyone who will be affected by the research or service, or have power or influence over it or have an interest in its outcome. This is followed by prioritisation of the stakeholders classified by the power of their influence and interest/impact of the project on them by using the power-impact matrix as given in Figure 5.8. Prioritisation is important to formulate an engagement and communication plan which may be different for each set of stakeholders.

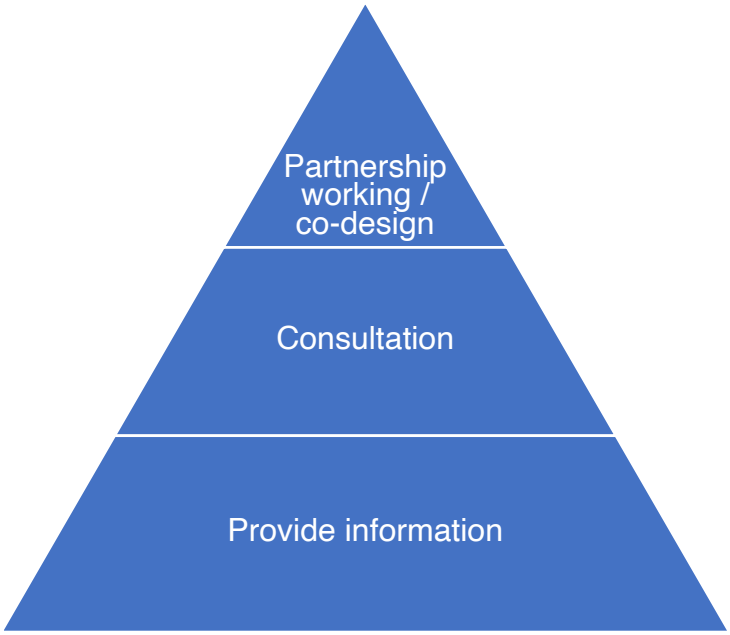
Figure 5.8 Power-Impact matrix to prioritise stakeholders



Patient and public involvement (otherwise known as community engagement) is an important aspect of research; patients are the most affected by the research and therefore they need to be empowered and engaged for better access, acceptability and effectiveness of research. Community engagement is a part of stakeholder

engagement and it can be undertaken at three levels as depicted in Figure 5.9. The lowest level/involvement is providing information about the research project already completed. The next level is consultation with them in the form of a survey or feedback using focus groups or forming a committee to obtain ideas. The highest level is partnership working or co-design which is the joint working between patients/community groups and the research staff to explore, identify and implement improvement activities. This helps in developing ownership and implementing in a way that actually benefits the end-users/patients and the community.

Figure 5.9. Levels of patient and public involvement



5.3.2.2 Stakeholder engagement /community engagement in my PhD / RESPIRE feasibility project

Since my PhD research is an embedded research in the main RESPIRE feasibility project titled 'Prevention, detection and treatment of adult lung disease including lung cancer in a poor, rural population in Tamil Nadu: feasibility study', stakeholder and community engagement was part of both the projects.

Stakeholder engagement was a new concept for me to which I was introduced during our induction week at Edinburgh between 26-30 March 2018, just before the start of the PhD program from 1st April 2018. The importance of stakeholder engagement and patient and public involvement (PPI) in a research project was elucidated by faculty from the University of Edinburgh (UoE). I also attended a PPI meeting conducted by

faculty members, subsequently on 4th April, 2018 and learned about the experiences of researchers who had engaged with patient groups. In the research projects that I had worked on previously, the local community would be informed in the beginning and at end of the project; at the beginning to obtain assistance and acceptability for the project implementation and at the end to disseminate the finding and thank them. But the initial sessions during the after the induction week, made me realise that SE was much more than that and PPI is really important for research. After the initial ideas that I obtained, as I went back to India to start my research, I along with my India supervisor and primary investigator (PI) of the feasibility project planned our SE program. We carried out SE with various groups, whom we identified (Figure 1) and carried out SE activities in the following way:

5.3.2.2.1 Patients with CRD, care givers and community members (high impact, low power)

It was clear in my mind that the primary stakeholders were the patients, their caregivers and the community; they would all experience direct impact of the intervention. We wanted to know what were their opinions about CRD and its related health behaviours in their local community where we were planning the intervention and what they wanted out of it. Four out of eighteen clusters were randomly selected for intervention delivery and patients and public from these areas were engaged to learn from them as well as to empower them. The first program for patient and public involvement was scheduled on 3rd September 2018 where patients with CRD, self-help group (SHG) members, key persons from the community (including village leaders, retired teachers, panchayat (local government) leaders and community health workers of the local community) were invited to attend the meeting. A SHG is a small committee or group of 10-20 women from the local community or village who come together for small savings and micro credit, joint income generation and social activities. A total of 57 participants were registered for this meeting. This first engagement was mainly to provide information to them about the CRD and the importance of starting structured prevention, detection, treatment and follow-up through a research program. A further aim was to get a first impression of public opinion about the disease occurrence in the local community and whether they considered such a program would be useful to them. The SHG members agreed that

there were people in their villages who had cough and breathlessness for many years and the panchayat leaders were very supportive of our initiative and felt that the community would be benefitted. Photograph 5.1 depicts a moment from the community meeting.

Photograph 5.1 India supervisor addressing the first community meeting at RUHSA

The next engagement with the patients and public of the local community was on 15 October 2018 – it took place in two different villages from the study area (Latteri and Vaduganthangal). There were eight participants at Latteri and 10 participants at Vaduganthangal which included members of the public, SHG members, panchayat members and leaders and health care workers of that community. These discussions took place before we were to undertake formative qualitative research for intervention development into the study area. Photograph 5.2 depicts a village level community meeting with key community members. The aim of these public meetings was to learn about public perception of CRD and associated barriers and how our research programme might be implemented to be useful in that context.

Photograph 5.2 Investigator addressing key community members

The following points came to the fore during the discussions –

- The communities do have people with chronic respiratory symptoms and indeed it is a problem that they see often
- A lot of people have breathing problems in rural villages but they do not know where to get treatment
- Awareness about CRDs is low among patients and in the community, highlighting the need for strategies to raise awareness; people stop medicines when symptoms subside and do not appreciate that treatment should be continued
- Patients do not take early treatment due to family and job issues and end up visiting hospital at later stages leading to hospitalisation
- There is no proper diagnosis and treatment available for such diseases and it would be desirable to have it
- Ideally programmes should be at the village level at convenient times and at an affordable cost

- They also asked about a separate clinic for patients with respiratory diseases

This discussion gave us an understanding about the current scenario of CRD in our local rural community and helped to refine ideas about implementation of the intervention program.

After our initial formative research and preparation for the pilot intervention study, we formed a Community Advisory Committee (CAC) out of the patients and the public group from the intervention villages of the study, with an aim of getting opinions about the intervention, using this feedback to refine our intervention. There were 30 members in the CAC, 14 from Kilalathur village and 16 from Kilmutkur village. We had three meetings with CAC running through the intervention period. The first and second meetings happened in the month of July 2019 just after the educational intervention had started and patient recruitment was ongoing. The educational intervention included general awareness videos about CRD, theory of planned behaviour (TPB) based videos depicting the correct attitude towards respiratory health behaviour, changing societal norms towards acceptance of CRD and inhaler use and tapping into the power of self-efficacy to change lives. Also included were puppet shows – a form of folk culture to depict stories or provide health messages through talking and singing puppets, controlled by puppeteer. The frequently asked questions about CRD and its health behaviour were depicted by puppet shows to clarify concerns among the patients, their relatives and the community where they live.

Box 5.1. The examples of changes to intervention following suggestions of Community Advisory Committee (CAC)

- Ask-your-doctor videos i.e., specific videos for asthma and COPD were created with interaction sessions between a patient and a doctor to answer all their concerns and queries related to the disease and its health behaviour
- HCWs were specifically instructed check the use of inhaler and spacer and train CRD patients on steps of inhaler use, and demonstrate breathing exercises during their house visits or health education sessions (on basis of the feedback that some patients were unable to use / did not know how to use inhalers with spacer)
- TPB videos for motivating patients and general awareness videos on CRD were played after inviting the patients, their family members and the community members to generate awareness, reduce stigma and create supportive environment for treatment and inhaler use (post the feedback on lack of awareness and social support for CRD and prevailing stigma on inhaler use)

The committee members provided the following feedback:

- Some of the committee members have watched the videos and the puppet shows and they said that they were informative, and they learnt that they should avoid smoking and using firewood (biomass fuel) at home for cooking. They understood the need of using inhalers and doing breathing exercises daily; and the importance of encouraging patients to go to hospital and get treatment as neighbours and fellow community members.

  "*I have seen the video in the evening near Kilmuttukur village bus stand. The video was played outside the RUHSA building in Kilmuttukur. The video explained about breathing problem, how it comes and what to do. Like treatment. It was good."* – CAC member 6, Kilmutkur village

  "*The puppet show is very useful. The Puppet show message creates awareness in the community by informing them the ways to prevent, what are the causes and treatment to respiratory diseases. It is very attractive and everyone is listening to the puppet show.*" – CAC member 5, Kikalathur (Sethuvandai)
- They suggested that providing CRD education to SHG members might be effective as they can share this knowledge within their groups and further spread the message to each and every family in the community. This could help in bringing change and reducing stigma.

  "If we educate the SHG, then the families are educated through these women. That itself will bring a change in the society." – CAC member 6, Kilmutkur village

  "Like that if you focus on the SHG then you can reach out and reduce the stigma in respiratory diseases." – CAC member 5, Kilalathur village
- With regards to educating patients and creating awareness in the community, the CAC suggested that videos on specific disease should be shown in the village; they also suggested rallies or even a walkathon to generate interest and make people more aware about CRD.

  "*We can do a walking rally. It will create awareness. We can put some pictures and talk in the mic.*" – CAC member 9, Kilmutkur

- Members also advised that those who have breathing problems are reluctant to tell others about it or take treatment for it. Some of them refuse to consider it a disease.

  "*I have come and told them that I have this disease. But others won't come out and tell you that they have this disease because others will think so low of us, so they don't want to tell it out*." – CAC member 11, Kilalathur

  "*Few of them are feeling shy to tell they are having breathing disease and not taking medicine*." – CAC member 8, Kilmutkur

  "*They feel shy and they also feel that the community will keep them aside if everyone comes to know that they have this disease. People are proud to say that they have BP and sugar but not asthma*." – CAC member 1, Kilalathur
- Some members suggested that patients should have enough capacity and confidence on their own to tell others about disease, use inhalers and get treatment from hospital – that is, only their own self-belief only can make them stronger and provide them with a better life.

  "if they think that they are kept away in the community then they won't be able to get any treatment and they will end up in a very bad situation. They should only throw everything out and come for treatment." – CAC member 3, Kilalathur

  "If they have a feeling that they are kept away from the community then they won't get any benefit. Look at me. I have come out. My mother in law also has the disease. Both of us are getting benefited from this project." – CAC member 11, Kilalathur
- One member observed that some patients with CRD were not able to use inhalers because they do not have enough strength in their hands to use it.
- The CAC members also met with patients in their community and encouraged them to continue their treatment and follow-up; they also reported that some patients do not know how to use inhalers and some patients still could not use inhaler when a spacer device was added.

  "Some of them are not able to inhale the medicine provided through the pump. They are taking medicine…" – CAC member 8

  "…She is taking medicine only. She hasn't used the inhaler itself. She doesn't know how to use the inhaler. – CAC member 9

The suggestions from the CAC were useful in understanding the barriers to health behaviour for CRD and also helped us to identify areas which should be strengthened. The following components of TPB intervention were introduced or strengthened –

a) specific videos for asthma and COPD were created with interaction sessions between a patient and a doctor to answer all their concerns about taking treatment.

b) the HCWs (trained and retrained periodically) were specifically instructed to train CRD patients on steps of inhaler use and demonstrate breathing exercises during their house visits or health education sessions.

c) TPB videos for motivating patients and general awareness videos on CRD were played after inviting the patients, their family members and the community members to generate awareness, reduce stigma and create supportive environment for treatment and inhaler use.

5.3.2.2.2 Project lead, co-lead, head of institution, RESPIRE central (high impact, high power)

Several rounds of meetings were held by the project lead and co-lead with the project team members for planning, implementation of the intervention and for monitoring the progress of the research project. I had several rounds of discussion with my supervisors during the creation and piloting of my TPB based evaluation tool, as well as during development of the intervention.

Permission was obtained from the head of the institution for carrying out my PhD research and ethical clearance was obtained from the Institutional review board (IRB) of the CMC. Reports of all activities carried out by me and the RUHSA team with regards to the project were send to the RESPIRE central team in form of quarterly reports and also as annual reports. Similarly financial reports were also sent quarterly. If any change in the agreed plan of activities was required due to any reason, a prior proposal was sent to RESPIRE central team and only after approval of such proposal were the new set of activities carried out. One interesting example arose during the

COVID-19 pandemic; we had to stop our educational activities related to the intervention and then send a proposal of modification of education using small groups, social distancing, use of face masks and covid appropriate behaviour while conducting the activities. After this was approved, we started using this modified approach. Similarly remote consultation and review of CRD patients during the pandemic was undertaken after approval of such measures by RESPIRE central team.

5.3.2.2.3 HCWs, junior staff in project management (low impact and low power)

Although this group have low power and impact on the research, they are vital for carrying out the activities related to research. For performing the activities as designed during planning by the lead and team, it was important to convey it them properly. So team meetings were held for the junior staff in the research. These included the HCWs, the project officer, the field coordinator and data management team in the hope that all of them understood their respective activities and carried them out accordingly. Small meetings were held by me with the field coordinator and the project coordinator for micro-planning the activities on a daily, weekly and monthly basis – these meeting helped in fixing targets. The TPB based intervention activities (i.e., providing health education, using video shows, inhaler training and exercise demonstration) were carried out by the HCWs; so they were trained and re-trained using training modules for standardisation in delivery of such activities. Similarly evaluators were also trained for comprehending and delivering the TPB evaluation tool to CRD patients using standardised questionnaires and pictorial tools.

5.3.2.2.4 Local leaders and practitioners, government officials, HMSC, policy makers (High power and low impact)

Local community and government leaders were appraised of the research project before and during the implementation of the research periodically as mentioned previously. Since the research was part of an international collaboration and obtained foreign funding, as per the law of our country, I applied for approval of my PhD research from the government of India through the Health Ministry's Screening Committee (HMSC) under the Indian Council of Medical Research (ICMR). Only after obtaining such approval did I proceed with participant recruitment. I also needed to send an annual report at the end of the year in a designated proforma of the ICMR detailing the activities carried out in the previous year. In the very beginning in 1st

December 2018, we conducted a workshop on “Community based Chronic lung disease care for rural communities in India”. Physicians and primary care practitioners who treated patients with CRD, along with state and district officials were invited to that workshop. The government officials and the policy makers were informed at the outset about the project; they also provided inputs about the current government policy and practice in the state for CRD treatment. The brainstorming session also involved physicians who gave their opinions about prevention, diagnosis and treatment of CRD. A Continuing Medical Education (CME) programme titled “Challenges of managing chronic lung disease in general practise” was conducted on 19th December, 2019 for the local practitioners and physicians from government and private sector managing CRD patients in the Vellore district. An international conference titled “Prevention, detection and treatment of adult lung disease in resource limited settings in India” was conducted between 4-5 April, 2022 involving policy makers from national and state levels, RESPIRE central researchers and administrators from Edinburgh, pulmonologists, researchers and administrators from our institution to disseminate the findings of the research projects and build a consensus towards health care policy for chronic respiratory diseases.

5.4 Intervention description

5.4.1 Intervention development and implementation as per MRC guidance

The intervention description below follows the updated MRC guidance and the details of the four phases of my TPB intervention has been described in table 5.2.

Table 5.2 Different phases of intervention development and implementation as per MRC guidance

1. Development (of complex intervention)	
1.1 Identifying the evidence base	1. Literature review on the epidemiology and burden of chronic respiratory diseases 2. Identified existing systematic reviews on the effectiveness of use of a psychological theory 'theory of planned behaviour' and use of such theory on behaviour change in chronic diseases; most of which happened to be in the developed world with studies being conducted in the high-income countries. 3. Conducted a systematic review to collate evidence on the use and role of the theory of planned behaviour-based interventions in chronic diseases in low resource setting of low- and middle-income (LMIC) countries.
1.2 Identifying/developing theory	1. Using the previous experience of working with the community and the stakeholders and discussion with experts to decide on the theory, behaviour change techniques and intervention strategies 2. Qualitative studies with the patients, the caregivers and key members of the community as well as discussions with different

	sections of the community to refine content, determine intervention strategy and delivery options
1.3 Modelling process and outcomes	Used causal modelling approach to link determinants of behaviour to behaviours and subsequent health outcomes
2. Assessing feasibility and piloting methods	
2.1 Testing procedures for acceptability, compliance, and intervention delivery	1. Testing components of acceptability, feasibility, compliance and implementation challenges
	2. Full intervention was tested in a pilot feasibility study of one year duration
2.2 Estimating recruitment and retention	1. Recruitment was done directly from the community with confirmed patients of CRDs, being identified earlier by HCWs using a screening questionnaire with a checklist of symptoms, previous diagnosis and medications use
	2. Using best practices and support with educational intervention for retention of trial participants
2.3 Determining sample size	Pilot-feasibility studies do not require exact calculation of sample size, however a sample size of 80 was considered to provide enough power to evaluate the outcomes; 100 patients were recruited in each arm

3. Evaluation	
1.a Assessing feasibility and implementation challenges 1.b Assessing effectiveness	1. Cluster randomised community trial for testing feasibility was conducted for a period of 1 year 2. Feasibility was assessed through screening and referral rates for physician assessment, recruitment rates, treatment acceptability and follow-up rates, variation within clusters, missing data, integrity of intervention delivery and completion rates 3. Primary outcome change in attitude towards behaviour, subjective norms, perceived behaviour control and behaviour change for inhaler use, practice of breathing exercises and adherence to inhaler at 1 year, data on secondary outcomes along hypothesized causal pathway also collected 3. Control group get usual HBM based educational intervention, intervention group get TPB based educational package designed to support treatment adherence
2. Understanding change process	1. Intervention fidelity assessed using adherence to time to complete, recruitment and completion rates

	2. The baseline and final data analysis to help understand TPB driven health behaviour change
3.. Assessing cost-effectiveness	*Not a part of this research, can be explored in future*
4. Implementation	
1. Dissemination	Peer reviewed publications, conference presentations, public engagement activities, making available tools used to develop and deliver intervention
2. Surveillance and monitoring	Accessed routinely collected health data. Routine and periodic follow-ups and health data collection for evaluation; analysed outcome data could inform additional definitive trials.
3. Long term follow-up	To continue as part of the service delivery (Respiratory Wellness Clinic on weekly basis) and continuing community engagement and health education

Source 1

5.4.2 Intervention description as per Template for Intervention Description and Replication (TIDieR) checklist and guide

The development and evaluation of an intervention could not be complete without description of the intervention as per the reporting items of the template for intervention description and replication (TIDieR)[15]. It provides useful information to the researchers to replicate or build on the research findings in different settings. My intervention is described through the TIDieR checklist in table 5.3 and informed my intervention development.

Table 5.3 The TIDieR (Template for Intervention Description and Replication) Checklist

Item number	Item
	BRIEF NAME
1.	*Provide the name or a phrase that describes the intervention*. Development and pilot testing of health worker delivered theory of planned behaviour based educational intervention for behaviour change in chronic respiratory disease patients: A feasibility study in southern Indian rural community
	WHY
2.	*Describe any rationale, theory, or goal of the elements essential to the intervention.* The complex intervention is based on the theory of planned behaviour and proposes behavioural change in CRD patients to improve health. The morbidity and mortality in the CRD patients is high, typically in the low and middle income countries (LMICs) because of lack of awareness about the disease, low accessibility and delay in seeking treatment, and lack of adherence and follow-on for those taking treatment. This TPB based intervention explores the underlying beliefs of TPB constructs to enhance capability and increase motivation among the CRD patients to improve health behaviour.
	WHAT

3. *Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (eg online appendix, URL).*

The intervention included the following –

i. Provision of inhalers with spacers and training on inhaler use
ii. Training on breathing exercises
iii. A calendar pictorially depicting the steps of inhaler use with a spacer on one side and breathing exercises on the other – this was meant to help the patients perform these activities themselves, correctly at home
iv. Demonstration of inhaler-use with spacer and of breathing exercises by the health aides (HCWs) at peripheral health centres
v. Playing of videos on general awareness on CRDs
vi. Motivational videos based on TPB constructs – attitude towards health behaviour, subjective norms and perceived behavioural control
vii. Puppet shows (theatre) answering frequently asked questions (FAQs) of people related to CRDs in a theatrical and culturally acceptable form
viii. Health melas putting all the educational materials together for a whole day in peripheral health centre for public and patients viewing
ix. School painting and debate competitions to raise awareness about CRDs and their treatment
x. Awareness rally for dissemination of CRD mindfulness in the community
xi. Doctors' public address to create awareness and promote positive attitude towards treatment and follow-up of CRDs

4. **WHO PROVIDED**

Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.

This was primarily a health care worker (HCW) delivered intervention. The screening and referral of CRD patients were done by them. The pulmonary

function test using spirometry was performed by a respiratory therapist. The diagnosis and treatment was managed by a trained primary care physician and confirmed by a pulmonologist. The different educational components of the theory of planned behaviour (TPB) intervention were delivered by the HCW's in the intervention arm, who also followed up the patients periodically and evaluated the impact of the intervention using a St. Georges Respiratory questionnaire (SGRQ) and their adherence using a test of adherence to inhalers (TAI) questionnaire.

5. HOW

For each category of intervention provider (eg psychologist, nursing assistant), describe their expertise, background and any specific training given.

The health care worker is a health volunteer with 12 years or more of formal education, These workers are responsible for imparting culturally appropriate health education and get feedback from the community in her cluster. For this research the chosen HCWs, known as health aides locally were imparted training on CRDs through module based training sessions which was imparted in the beginning and also periodically throughout the intervention period. They were also trained on gathering data from using a screening questionnaire and follow-up CRD patients using SGRQ and TAI questionnaires. They had training on steps of inhaler use, breathing exercises to improve symptoms of breathlessness and on imparting TPB-based health education.

The respiratory therapist was a professional with a degree, however she was trained again before this research programme specifically on correct techniques of performing spirometry on patients and interpret the results obtained as usable or unusable for interpretation by a doctor. The primary care physicians were trained through three workshops/continuing medical education (CME) to interpret and diagnose type of CRD using spirometer reports and categorise them as per severity using Global Initiative Against Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines and offer treatment, appropriate for each patient.

6. WHERE

Describe the modes of delivery (eg face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.

Most of the TPB-based educational intervention was designed face-to-face and most of it was delivered face-to-face. There was direct interaction of the CRD patients with the HCWs, respiratory therapist and the physician. Except during the complete lockdown imposed by local government during the covid-19 pandemic, when face to face interactions were prohibited, the progress of patients was reviewed online by telephonic interviews and medications were provided through community mobile services near their homes.

7. WHEN and HOW MUCH

Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.

The educational intervention was implemented in the community setting. The TPB based education to the patients, their families and the public was delivered at the outreach centres of our hospital located in the same community. Besides, a community building accessible to the participants or a common open space in the community were used for video shows or puppet shows. The HCWs also visited the houses of the participants during the evaluation.

8. *Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.*

The motivational video on TPB was of 20 minutes duration, it was designed to captivate people and hold their attention span and used stories to visualise the successful outcomes of the constructs. The ask-your-doctor videos on asthma and COPD were around an hour long. All these videos were shown to the CRD patients, their family members and the local community in the intervention villages. The puppet show was an hour long event where a stage

was prepared and three puppets talk with one another in to ask and clarify the general queries on CRD related behaviour.

Distribution of various educational intervention sessions in the intervention clusters

Educational Intervention Sessions	Intervention cluster 1	Interventions cluster 2
Video Shows	75	58
Puppet Shows	14	11
Health Mela	2	2

TAILORING

9. *If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.*

The educational component of the intervention was planned to be given to the patients in their community to cover all the patients, their families and the local communities at least once in three months. This was later changed from a periodic activity to a continuous process and the intervention clusters were mapped to provide TPB education to the entire community, including the patients and their localities. The patients were expected to come for clinical reviews and follow-up once in three months and a total of four times during the one-year intervention period.

MODIFICATIONS

10.‡ *If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).*

HOW WELL

Although the intervention was not modified in terms of its content, the way it was delivered and the frequency of delivery was changed. This was a feasibility study, and I was open to changes that might be required for improving its effect among the patients and the public. After the initial three months of educational intervention, the response to follow-up and clinical reviews were not quite encouraging and therefore it was decided to change

the intervention delivery from once every three months to a continuous activity and a comprehensive plan was drawn to map and cover the entire community systematically. The TPB based education was given subsequently according to this plan, which resulted in better coverage, acceptance and response from the patients.

11. ***Planned:*** *If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.*

The planned fidelity of the intervention was related to training of the HCWs delivering the intervention, the delivery of the intervention and the receipt of the intervention.

The HCWs had training sessions on the screening questionnaire, general awareness of CRDs, TPB educational materials (dissemination and delivery), inhaler use with spacer and breathing exercises, TAI and SGRQ training for data collection. Training of independent evaluators on the evaluation questionnaire (TPB based) and a series of review meetings throughout the project period were planned for maintaining the quality and integrity of the intervention delivery. A master chart for different educational programmes was developed to ensure desired coverage of all sections and areas in the intervention clusters. Two intervention clusters were divided into 23 areas and 41 sub-areas for the educational purpose. Handbills, video shows and puppet shows targeted study participants, their families and the community members of their locality. Training on inhaler technique and respiratory exercises was given to the patients using pictorial charts by the HCWs. It was planned that the education will motivate the patients to accept and adopt the health behaviour and adhere to it. The follow-up and clinical review of the patients were planned every three months.

12.‡ ***Actual:*** *If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.*

The following activities took place during the intervention, which highlight the fidelity and feasibility of the intervention.

Training and review meetings during the project

Sl. No.	Description	Frequency
1.	Health aides (HCWs) training on screening questionnaire and CRD awareness	6
2.	HCWs training on health education (dissemination and delivery)	8
3.	HCWs training on handouts, inhaler use and breathing exercises demonstration	5
4.	Health aides (HCWs) training on TAI and SGRQ	15
5.	Training of evaluators	7
6.	Review meetings with project team	37

Distribution of various educational intervention sessions in the intervention clusters

Educational Sessions	Intervention	Intervention cluster 1	Interventions cluste
Video Shows		75	58
Puppet Shows		14	11
Health Mela		2	2

Across the four clusters (PSUs), 219 participants were invited to come for eligibility testing and take part in the study. Of these 19 were not eligible; 17 did not have a confirmed CRD diagnosis, one was not able to perform spirometry and one belonged to a cluster not chosen for trial. All 200 had consented to take part in the trial at the time of initial visit to RUHSA hospital for clinical review and spirometry; 191 patients could be recruited and allocated to IA and CA and 178 completed the intervention. The early acceptability rate was 95.5% (191/200) for the trial and The completion rate at the end of the trial period was 89% (178/200).

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Chapter 6

Project 4 – Pilot testing of the TPB intervention and its evaluation

This chapter describes in detail the implementation of the TPB intervention describing not only the methodology used in implementing this project but also essential co-factors including training of the health care providers and evaluators, TPB-based education to patients and community using various media and methods and evaluation process for assessment of outcomes. Finally, it also interprets the results of this the intervention in the context of feasibility of the pilot and the effectiveness of the TPB intervention.

6.1 Background

Promoting human health, preventing disease and keeping people free of disease has been a constant endeavour in human health. Improvements in medical science and technology have led to treatment of many diseases which earlier could have led to death or severe morbidity (e.g., tuberculosis, HIV/AIDS, streptococcal pneumonia or valvular heart disease). Similarly better knowledge about determinants of disease, has led to better health promotion and prevention activities (e.g., vaccines for prevention of childhood killer diseases, eradication of smallpox or polio). But there are still other diseases which can not be cured but may be treated or prevented. Health has so many aspects to it, and it is not just absence of disease or infirmity. The WHO has defined health in 1948 as “a state of complete physical, mental and social wellbeing and not merely an absence of disease or infirmity”[1]. Health involves not only the human body but also the social, psychological and behavioural aspects of human being.

Among the top ten causes of mortality globally, seven belong to the non-communicable or chronic diseases category[2]. Most of the countries of the world are fighting from the chronic disease pandemic, while there are parts of the world, specifically in the LMICs which are tackling the double burden of both communicable and chronic diseases. The most common chronic diseases like heart disease, stroke, cancer, chronic respiratory diseases and diabetes are lifestyle diseases and are influenced by human behaviour. Behavioural factors like tobacco use, healthy diet, physical activity and alcohol consumption are among the prominent contributors of mortality[3]. Besides mortality and morbidity due to chronic diseases are also influenced

by compliance to treatment, which as per various studies is about 50% in developed countries, with a far lesser compliance rates in LMICs[4-6]. The growing burden of chronic diseases and increasing elderly population worldwide, makes it crucial to look into human behaviour in an attempt to promote health and manage the burden of chronic diseases.

Human behaviour is an integral part of human health and many problems seen today are linked directly or indirectly to human behaviour. Behaviour has links to debilitating diseases, chronic diseases (cardiovascular disease, cancer, chronic respiratory disease, obesity), global pandemics (SARS, H1N1, COVID-19), mental health problems, addictions, social, financial and criminal problems. Partaking in relevant behaviours regularly can result in better health and wellbeing, positive mental health, better functioning in the workplace, in interpersonal relationships, and better management of chronic diseases[7]. The value of developing strategies to change behaviour of targeted population groups, in individuals and in communities to promote desirable outcomes is increasingly being recognised by governments, organisations and professionals. Although legislation and regulations like smoking bans in public places, taxes on cigarettes and alcohol, seat belt use etc. have been used successfully, these are not always feasible or acceptable and therefore other approaches to behaviour change are required. Governments and organisations have used funding to gather evidence on behaviour change and to inform policy and develop effective behaviour change strategies for solving health and social problems[8-10]. Behaviour change research has since expanded from evidence-based practice that began in fields like medicine[11] and allied health[12] to gradually encompass other domains.

The science of behaviour change relies on behavioural/psychological theories and formative research to predict, understand and change behaviour. Interventions based on theories provide information about how the intervention work and processes involved in behaviour change to effect outcomes. Theory informs which aspects of interventions are responsible for, and likely to facilitate, behaviour change and the various individual, social, and environmental conditions that may alter intervention effects[13-14]. Developing interventions based on theory provides the evidence base that change behaviour, explain how such interventions work and how they can be

implemented and made feasible in real life settings. Systematic reviews have shown that theory-based interventions are more effective in changing health related behaviour than those developed without theory[15-17].

The theory of planned behaviour (TPB)[18-20] is a behavioural theory which focus on theoretical constructs concerned with individual motivational factors and capability as determinants of likelihood of performing a specific behaviour. In other words, it states that an individual will adopt a new behaviour if s/he has the motivation as well as the capability to do so; the motivation may be self-motivation based on person's attitude towards the behaviour or due to social norms. To state simply, the human behaviour is predicted by intention to perform the behaviour and perceived behavioural control (PCB) whereas intention is guided by attitude towards the behaviour, i.e., how favourable or unfavourable attitude the individual holds towards behaviour, subjective norms, i.e., views of significant others towards such behaviour and PCB, i.e., the extent to which the individual perceives performing the behaviour as easy or difficult or under her/his control. Behavioural, normative and control beliefs of individuals form their attitude, subjective norm and PBC, respectively. Beliefs about the likely consequences and experiences resulting from performance of the behaviour are behavioural beliefs, while beliefs about the expectations and behaviours of significant social referents result in normative beliefs and beliefs about factors that may facilitate or impede performance of the behaviour form control beliefs. TPB links beliefs of an individual to the formation of an intention to perform a behaviour, although performance of actual behaviour depends on behavioural control, i.e., individuals should have skills and resources to carry out their intention. TPB has been used successfully to explain and predict behaviour in multiple domain s like physical activity, safer sex in HIV/AIDS patients, nutritional behaviour and drug use[21-24]. Increasingly TPB is being used to design and evaluate interventions for behaviour change[25-27], but these are mostly reported from developed countries with literate populations and adequate resources available. Few studies have examined use of TPB in chronic conditions[28], and I could not find any intervention for behaviour change for chronic respiratory diseases through my systematic review, neither from developed world nor from LMICs, at the time of developing my intervention. Most recently a study published in April 2021 used TPB to improve asthma control and medication adherence among

asthma patients in Turkey[29]. Development of my TPB based intervention in the context of a low-literate, resource poor and rural population of an LMIC setting required pilot testing for evidence regarding its feasibility and its effectiveness in real world setting.

6.2 Aim and objectives

The aim of this phase of my PhD project was piloting the developed educational intervention through a trial on confirmed CRD patients of rural low health-literacy community and test for its feasibility and its effectiveness. It also aimed to examine the impact of this TPB-based educational intervention on the constructs of TPB and health behaviour.

Objectives of intervention testing were –

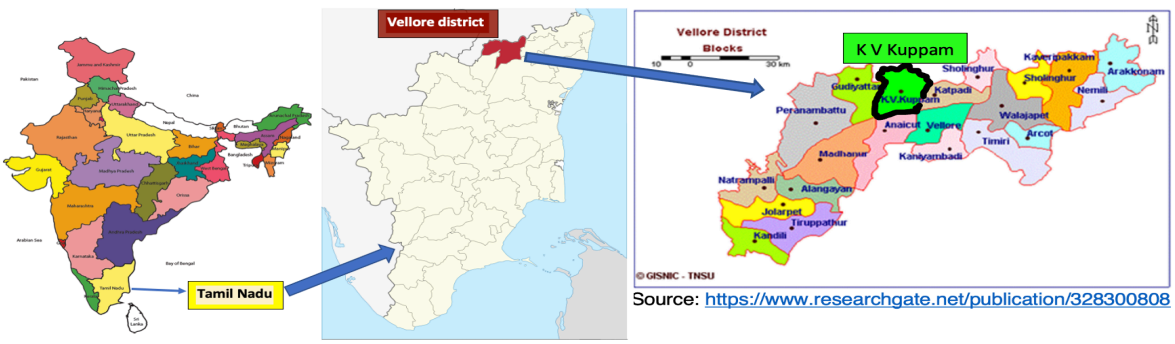
- To evaluate the TPB-based intervention for its feasibility (in terms of screening and referral for physician assessment, recruitment rates, treatment acceptability and follow-up rates, variation within clusters, missing data, integrity of intervention delivery and completion rates) and identify the implementation challenges in low resource settings
- To analyse the effect of the intervention on attitude, social norms, perceived power and intention related to the health behaviour
- To measure the effectiveness of the intervention on behaviour change and health outcomes at the end of the intervention period

6.3 Study setting

The pilot testing of the intervention was conducted in the K V Kuppam block of the Vellore district in the state of Tamil Nadu. For administrative purposes and ease of governance, the country is divided into states, states into districts and districts into subdistricts known as community development blocks (CDBs) or talukas or tehsils. India has 28 states and 8 union territories[30], the state of Tamil Nadu is one of the five southern states in India and has 38 districts[31], and the Vellore district had 20 CDBs[32]. On 15 August 2019, the Vellore district was trifurcated into Vellore, Ranipet and Tirupattur districts[33]. The newly formed Vellore district has 6 taluks or CDB including the K V Kuppam block[34]. Each CDB has on an average 80,000-120,000 population which may vary from block to block. Each block is managed by a government official,

known as block development officer (BDO) for administration. Health is a state responsibility in India which means that state governments are required to implement policies in their own way even though health policy guidelines are formulated by the central government. Health administration and reporting also goes through state governments to the centre. There are variations in health infrastructure, personnel and policy implementation from state to state. State of Tamil Nadu is considered as one of states with best public health facilities and administration, providing quality health services at an affordable cost, especially to the rural people. It is considered as a role model of public health care delivery system in India in resource limited setttings[35]. In spite of this model, there are major gaps. For example, spirometry for diagnosis of CRDs is not available at primary or secondary level, oral medications are used for treatment of CRDs and inhalers are not available except in the tertiary level medical college and hospitals; there is no protocol based management in place or an attempt to actively engage and change respiratory health behaviour among CRD patients at primary-secondary level. The position of RUHSA in K V Kuppam block is unique in the sense that it has been providing services to the people for the last 44 years, not only in terms of health care but also in creating opportunities for their social and economic development and in improving overall quality of life. It has a good rapport with people and conversely people have a high degree of confidence in RUHSA to provide high quality care. RUHSA also works closely in full cooperation with government health facilities of the area. More details about the study area and its population have been described in the Introduction chapter, under the heading context of research – the RUHSA community and the health system.

Figure 6.1 Maps depicting Tamil Nadu, Vellore district and K V Kuppam block



Source: https://www.researchgate.net/publication/328300808

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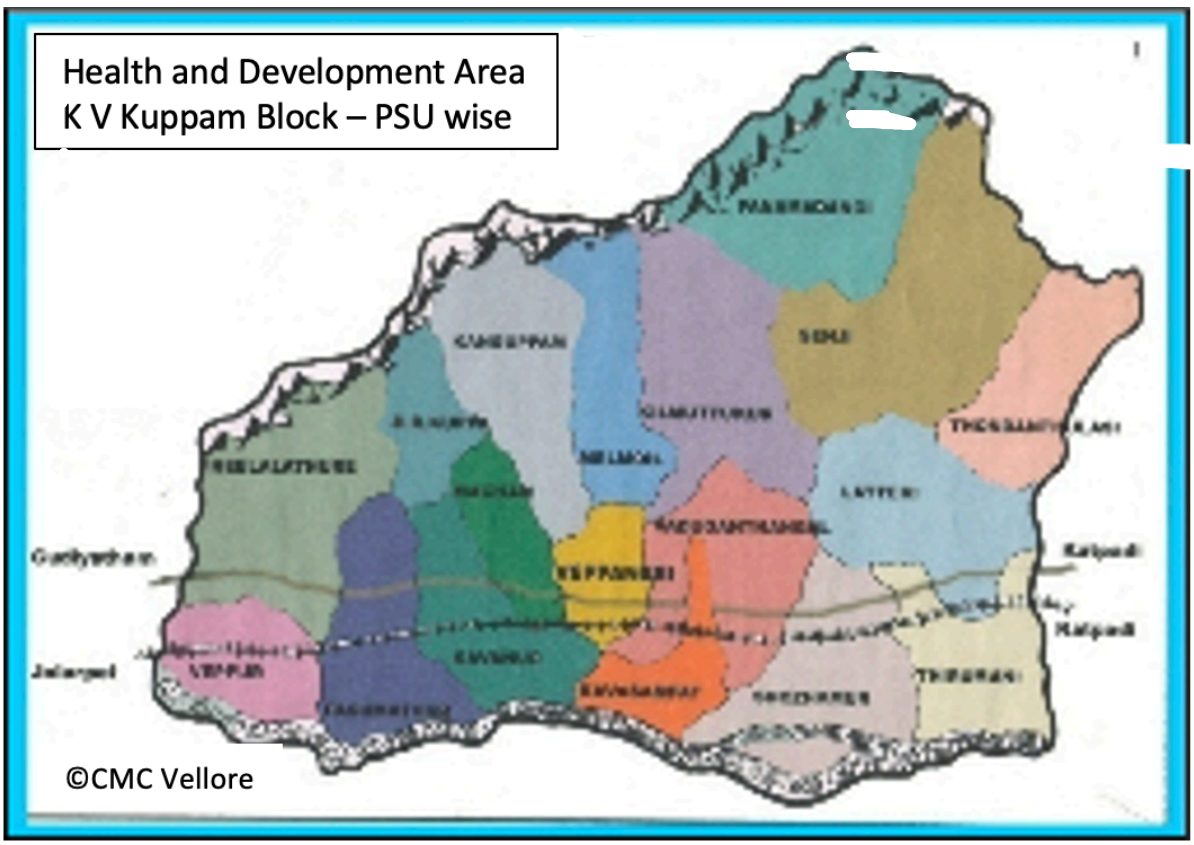
Rural Unit of health and Social Affairs (RUHSA) was established in 1977 in the K V Kuppam of Vellore district by Christian Medical College Vellore to provide quality health care facilities and promote community development activities in the block. At present it provides secondary care services through its 75 bedded base hospital including outpatient and inpatient services. It has its own semi-automated laboratory and pharmacy services, x-ray facilities, level 2 nursery, 24X7 emergency department and ambulance services for emergency referrals to CMC main hospital. Besides general health check-up services, treatment of common diseases, ante-natal care and delivery, nutritional counselling and immunisation services, specialist clinics for otorhinolaryngology, ophthalmology, dental, orthopaedics, obstetrics and gynaecology, elderly and diabetes are run by the RUHSA. Special clinics run at varying frequency ranging from five days a week to once a month depending on needs of the people of this community. For delivering effective primary care services, the whole block is divided into 18 clusters, known as peripheral service units (PSUs), with a population between 7000-8000 and each having an outreach centre. Figure 2 depicts the PSUs within the K V Kuppam block.

Figure 6.2. Map depicting K V Kuppam block with its clusters (PSUs)



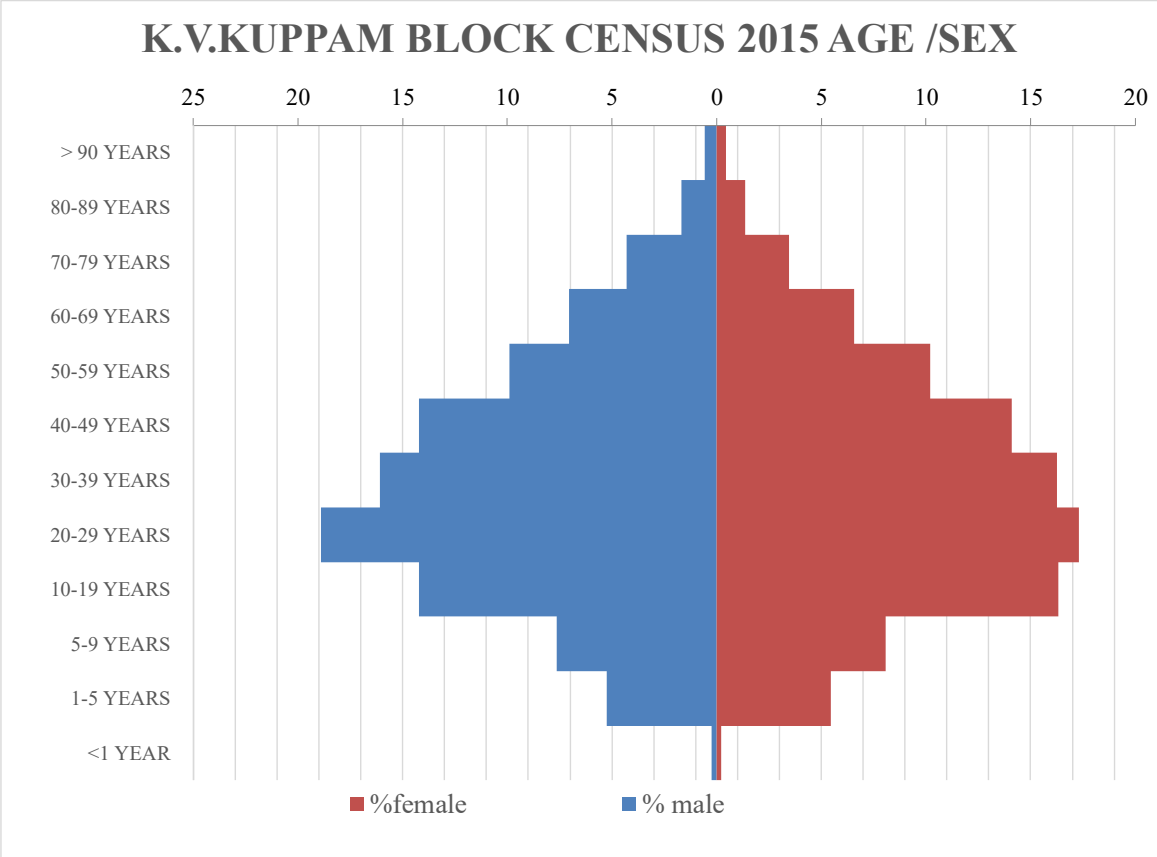
Source: RUHSA Department, CMC Vellore

Primary health care services are provided through these 18 outreach centres located throughout the block by a monthly doctor run clinic and bi-monthly nurse practitioner led clinics and house visits to the area. They are supported by various community health workers like family care volunteers (FCVs – local women with 6-10 years of formal education and looking after ~150 households of their village reporting vital events to and communicating health information from RUHSA), health aides (HAs – Local women with 12-15 years of formal education overseeing work of FCVs and part of primary health care team of RUHSA) and rural community officers (RCOs) at the community level. Registration of vital events like births, deaths and marriages, enumeration of childhood immunisation and providing essential health information are the activities performed by FCVs and guided and verified by the HAs. RCOs are a link between people and the RUHSA health system – advising on health opportunities available and new treatment facilities or specialised clinics as and when added to RUHSA health care system. They work closely with panchayat leaders (elected people's representatives of local government) to inform and garner support from the community about these initiatives or newer research projects in which they may be benefitted, besides helping them to inform and avail government social security schemes and financial initiates. RUHSA is also involved in community development activities like community based rehabilitation program for mentally and physically challenged, formation and guidance to women self-help groups (SHGs) for economic and social empowerment, economic upliftment of marginal farmers through farmers club, youth clubs to engage rural youth in sports and career guidance, care of neglected poor elders through elderly day care centres and providing vocational training to local youth for income generation through community college training. K V Kuppam block also have five government primary health centres including block primary health centre at Vaduganthangal. There is a good and harmonious relationship between RUHSA and the government health system. Additionally, RUHSA is also involved in teaching, training and research activities, primarily focussing on implementation research to solve local health problems of the people.

K V Kuppam is a completely rural block with a population of 138, 033 as per last census (2015) conducted by RUHSA. People of different faiths co-exist together,

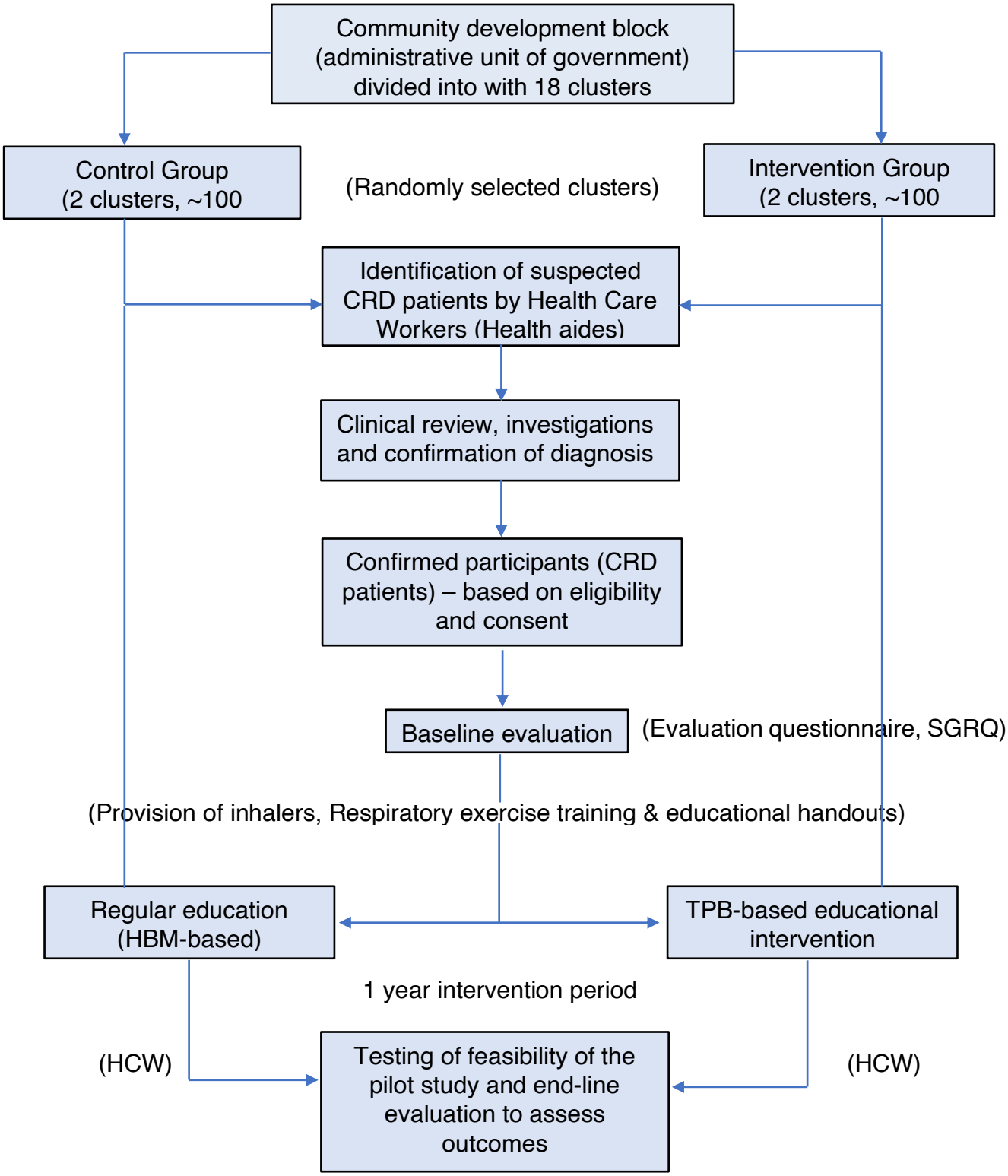
however majority are Hindus (97%) and rest are Christians and Muslims. The overall literacy rate is 64% with male literacy being 73.4% and female literacy being 57.4%. It is an agrarian community with agriculture / farming being the main occupation; other occupations are linked to farming. Some of the other occupations being poultry farming, weaving, dairy farms and beedi (country cigarettes) rolling. There is a recent trend of youth going to nearby cities to work under service and manufacturing sector. The age-sex population pyramid of the K V Kuppam block depicts that youth and the productive age group dominate the age-sex structure as depicted in fig. 6.3.

Figure 6.3 Age-sex population pyramid of K V Kuppam block (2015)



Source: RUHSA Department, CMC Vellore

6.4 Overview of the community-based cluster randomised control trial



CRD – Chronic respiratory disease; TPB – Theory of planned behaviour; HBM – Health Belief Model

6.5 Methods

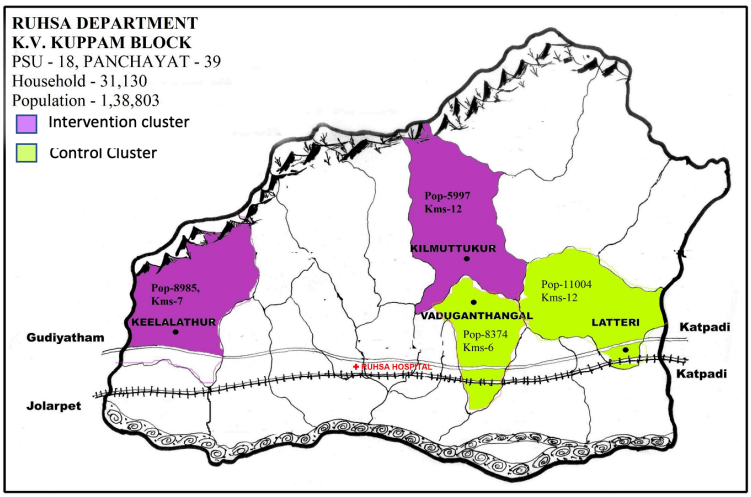
6.5.1 Study design

A cluster randomised controlled trial design was used to test the feasibility of the developed intervention in the real-life conditions and in a setting where CRD patients normally access health service. This trial was conducted as a piece of implementation research to see if it works and how well it works in current settings. The purpose of implementation research is to maximise adoption, appropriate use, and sustainability of effective clinical practices in real world clinical settings[36]. This trial used experimental pre-post design with a control group and cluster randomisation.

6.5.2 Cluster allocation

Out of the 18 clusters (known as peripheral service unit (PSUs)) of the block 4 PSUs were randomly selected to participate in the trial. Out of these, two PSUs were chosen in the intervention arm (IA) and two PSUs in the control arm (CA), again by random assignment. Figure 6.4 depicts the KV Kuppam block with the chosen PSUs, there distances from the centre and the population for each PSU. All the PSUs were similar in terms of geographic type, occupational practises, population characteristics, socio-economic status and literacy, with the assumption that randomisation of clusters would equally distribute the characteristics and nullify any variations. One of the PSUs in the intervention arm was far away from the hospital and had some difficult to reach areas. Measurements of both treatment and control conditions occurred pre- and post-intervention, with differential improvement between the groups attributed to the intervention.

Figure 6.4. K V Kuppam Block with the selected PSUs for feasibility trial



6.5.3 Allocation concealment

This was a feasibility trial – a piece of implementation research to establish the processes in the current settings. Therefore, a pragmatic approach to concealment of allocation was undertaken. Allocation concealment to the participants was done by informing all the participants across the clusters, that they would receive an educational package about chronic respiratory disease by HCWs in the community; they were not aware specifically about TPB or HBM package that they received. However, there was a possibility of some cross communication between participants of IA and CA through intermixing or having relationships with families in the other arm. The HCWs, known as the health aides (HA) in our area, who delivered the educational package were unaware of the type of intervention they provided and the training for each group was different. However, all the health aides came for reporting simultaneously and there could have been exchanges about the type of education (the social dynamics being close knit and interactive), there was a chance that the HAs of the CA delivered some of the education from the IA due to enthusiasm. This was a community-based implementation trial with a pragmatic approach, therefore complete concealment was not possible under these circumstances. The evaluators/assessors used during baseline and endline assessment were not related to the ongoing trial and were unaware of the participants into IA and CA.

6.5.4 Study participants

The study population included all patients who had a confirmed diagnosis of chronic respiratory diseases and resided in the K V Kuppam block. Participants for this trial included adult patients, both males and females, 18 years of age or older, and who had confirmed chronic respiratory disease i.e., one among asthma, chronic obstructive pulmonary disease (COPD), bronchiectasis, post tuberculosis lung disease (PTLD) or interstitial lung disease. All the patients were required to be permanent residents of the K V Kuppam block, the criteria being they should be residing for at least one year prior to their selection. Pregnant women, those not willing to be a part of the study, people who had heart diseases and patients too ill or infirm to participate were excluded from the study.

6.5.5 Sample size

As per Whitehead et al[37], the size of a pilot-feasibility trial should be related to the size of the future definitive trial. They recommended pilot trial sample sizes for each treatment arm of 75, 25, 15, and 10 for standardised effect sizes that are extra small (0.1), small (0.2), medium (0.5), or large (0.8), respectively, for a trial designed with 90% power and two-sided 5% significance. Since this was a pilot-feasibility study and was done to assess feasibility and design parameters for a full trial, statistician from University of Edinburgh estimated that a sample of 80 patients should provide sufficient data to estimate, with a 95% confidence interval, the important design parameters for the full trial. These comprised of control rate (the extent to which pre- and post-intervention measures change in the control group), range of plausible intervention effects for three chosen primary outcomes (awareness, prevalence of risk factors and compliance to treatment pathways i.e., inhaler use and continuation of respiratory exercises) an estimation of the intraclass corelation coefficient and rates of missing data. It is not possible to give a formal, statistically justified sample size based on outcomes for a pilot study (such sample size calculations are developed for later phase confirmatory trials, usually in which a single hypothesis is under investigation, and the sample size then controls the type 1 (false positive) and type 2 (false negative rates) to a given level, and hence estimates a single quantity e.g., a treatment effect to a required degree of precision). This pilot study was aimed at evaluating at least the 6 quantities stated above and estimating the range of plausible values of these important design parameters for the full trial. Expecting dropout rate of about 20%, the final sample size was calculated as 100 in each arm.

6.5.6 Study Instruments

The following study instruments were used –

a. **Screening questionnaire (appendix 12)** – The screening questionnaire was used by HCWs for listing suspected CRD patients from the community within the PSUs chosen for the trial. The screening questionnaire consisted of selected questions taken from the Burden of Obstructive Lung Disease study (BOLD) questionnaire and the European Community Respiratory Health Survey (ECRHS) II questionnaire for covering respiratory symptoms and their characteristics related

to COPD and asthma. This was supplemented by questions about use of medications, the type of medications and the duration of usage.

b. **Baseline and end-line evaluation questionnaires (Appendix 13)** – The baseline evaluation questionnaire comprised four sections – identifying information, socio-demographic information including socio-economic status scale for rural areas, theory of planned behaviour (TPB) questionnaire and the health belief model (HBM) questionnaire. The TPB questionnaire was based on the constructs of TPB and included sections on health behaviours (smoking, use of biomass fuel, risk occupation, inhaler use and breathing exercises), intention, attitude towards health behaviour, subjective norms and perceived behavioural control. Details of development of TPB questionnaire are included in the previous chapter. The end-line evaluation questionnaire captured the same details on TPB and HBM components while omitting socio-demographic details as these were already available, the same person being approached at the end of one year. The HBM questionnaire included questions assessing knowledge and reported sources of health information; it included sections on perceived susceptibility, perceived severity, perceived benefits, perceived barriers and cues to action.

c. **Clinical assessment and review forms (Appendix 16)** – The clinical assessment and review forms were created for initial clinical assessment of patients with CRD and subsequent clinical review of their progress. They collect information on history of symptoms, past history, family history, social and treatment history relevant to CRD, investigations relevant to CRD and assessment of the severity and control of COPD or asthma based on GOLD and GINA guidelines respectively; the final section being treatment recommendation and date for next follow-up visit.

d. **St. Georges Respiratory Questionnaire (Appendix 14)** – The St. Georges Respiratory Questionnaire (SGRQ) was used to measure the impact on overall health, daily life and perceived well-being of the patients. It consisted of questions on three components – symptoms related to the disease, activities which cause or are limited by breathlessness and impact (social or psychological) resulting from the disease, divided into two parts with the latter two components belonging to part two. The local vernacular version (Tamil) of the SGRQ was used with

permission from St George's, University of London (St George's Hospital Medical School).

e. **Test of Adherence to Inhalers questionnaire (Appendix 15)** – The Test of Adherence to Inhalers (TAI) is a questionnaire designed specifically to measure adherence to inhalers in adult patients with asthma or COPD. It is a 12-item questionnaire with value ranges from 1-5 and can be used in clinical settings or during patient interactions.

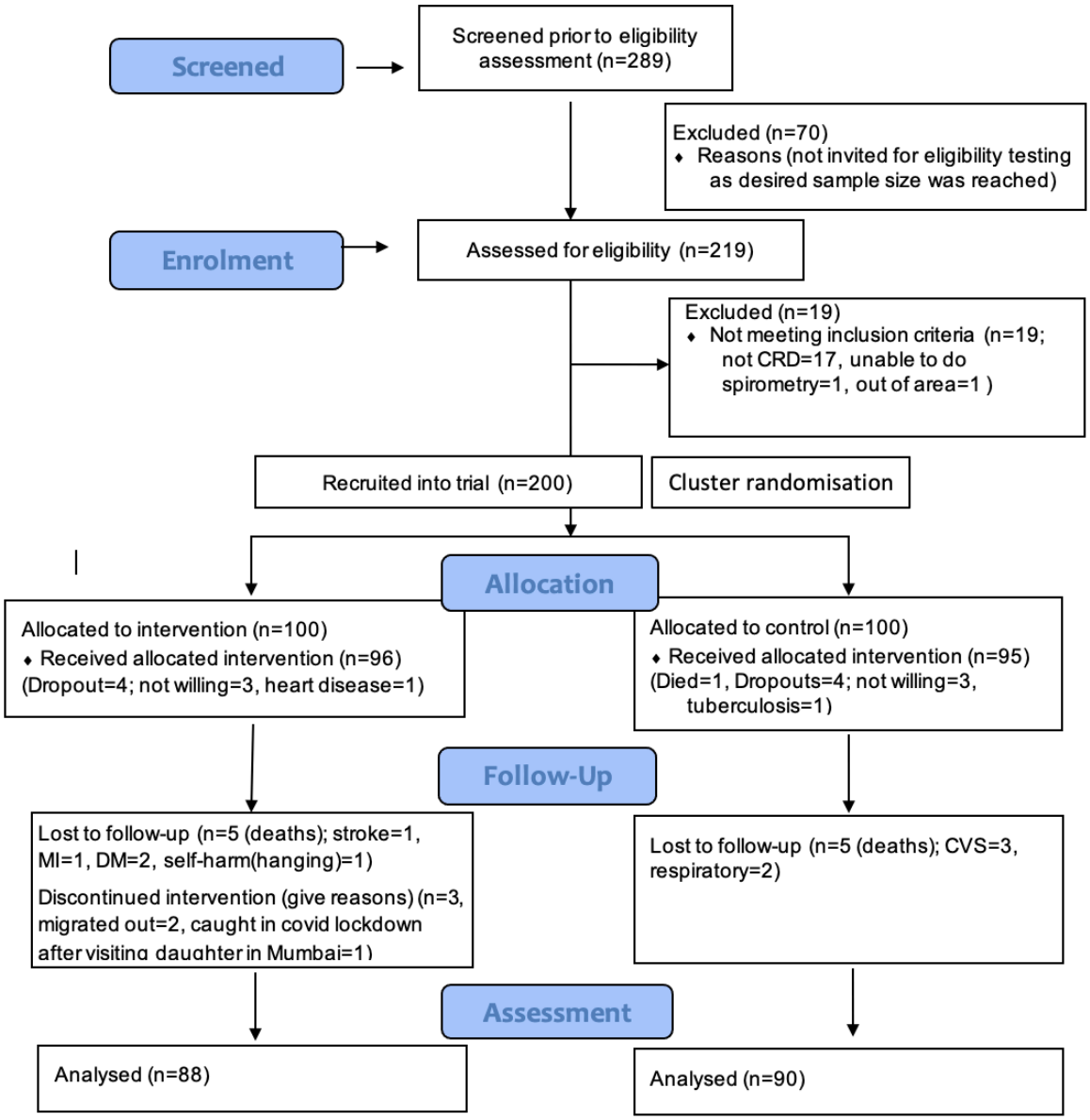
6.5.7 Study process

Initially a list of suspected patients of CRD was prepared. A register of listed chronic disease patients taking medications from the outreach health centres of the selected PSUs was used to list-out patients taking medications for CRD like oral salbutamol (albuterol) and deriphyllin (a combination of etophylline and theophylline), drugs commonly used in this low resource and low-literacy rural setting. The health aides (HCWs) asked such patients about other patients in their village with similar respiratory symptoms and made house visits in their area to prepare a list of suspected CRD patients. All such patients were screened using a screening questionnaire (Appendix 12) and if any symptom was listed positive in the questionnaire, those patients were considered screen positive and required to visit RUHSA hospital for further review and diagnosis. The four chosen PSUs were Kikalathur, Kilmutkur, Latteri and Vaduganthangal as shown in figure 6.4. of which the first two are intervention and last two are control clusters. One cluster was managed by one health aide (HCW) with a total of four working for the intervention trial throughout the duration of the project. Adequate training was provided to the HCWs on CRDs, communication with the patients and use of screening questionnaire, follow-up of patients and use of SGRQ and TAI questionnaires. Similarly, assessors who were blinded to the intervention or control patients were also trained for using the evaluation questionnaire (Appendix 13).

The suspected patients who were screen-positive were invited to take part in the study and were asked to visit the RUHSA hospital for clinical review and confirmation of diagnosis. Patients were invited from all the four clusters of both intervention and control arm and were assessed for eligibility after taking their consent till the required sample size was reached. The Consolidated Standards of Reporting Trials

(CONSORT) flow chart for randomised pilot-feasibility trials38 is used to show the flow of the participants through the study (Figure 6.5).

Figure 6.5 Consolidated Standards of Reporting Trials flow diagram for randomised pilot feasibility trials



Source: 38

The participants who came to the hospital, were first given information about the study and asked for consent to participate. Detailed information about the study and the requirements from the participant thereof were provided using the participant information sheet and the patient gave his or her consent after understanding the risks and benefits from the study (Appendix 11). The consent taken was thus informed

written consent which the participant either signed or put thumb impression in presence of a witness. The process of getting the consent was sometimes immediate (within an hour) and sometimes stretched for days (about a week). Each participant was scheduled for a total of two visits including the day of the consent to complete the clinical review, confirm the diagnosis and starting of treatment. The screening for potential CRD patients by HCWs and the participant recruitment which included clinical review, diagnosis and treatment were part of the larger feasibility trial in which my PhD was embedded.

After the consent was taken, initial clinical assessment was done using the "Clinical Assessment and Review form" (Appendix 16; Clinical Assessment and Review Form) which included identifying information, detailed history of the patient about symptoms and medications, investigations like chest x-ray and spirometry, final diagnosis, assessment of patients' severity based on Global Initiative for Chronic Obstructive Lung Disease (GOLD) or Global Initiative for Asthma (GINA) guidelines, treatment and follow up. Photograph 6.1 depicts the study physician interacting with a participant during clinical review.

Photograph 6.1 Physician interviewing a participant during clinical review

This protocol-based management developed as a part of the larger feasibility study, was inserted as a computerised form into RUHSA clinical services as a special form (Clinical Assessment and Review Form, Appendix 16) which was password protected and used only by the study physician recruited for the feasibility study. The primary Investigator (PI) and co-investigators (co-Is) also had access to that form. At the end of the study period, it became a part of the routine health services provided by RUHSA via a special respiratory clinic known as Respiratory Wellness Clinic and was known as RUHSA RESPIRE clinical form. Clinical examination, chest x-ray and spirometry were done during the first visit and a provisional diagnosis was made by the study physician in consultation with PI or co-I. All the reports along with the findings from the 'clinical assessment and review form' were sent to the pulmonologist by e-mail who gave the final diagnosis. Treatment was initiated based on the diagnosis as per the GOLD or GINA guidelines. Baseline evaluation of the participants recruited onto the study was done using an evaluation questionnaire (Appendix 13) which included sections like identifying information, socio-demographic information, the TPB questionnaire and knowledge questionnaire based on health belief model (HBM). St. George's Respiratory Questionnaire (SGRQ) (Appendix 14) was also used at baseline for evaluating the disease status and impact; it was used as a part of the bigger feasibility study. The questionnaire was used again at the end of the 12-month intervention period; the SGRQ was used at 6 months and at 12 months (end of intervention); a test of adherence to inhalers (TAI) questionnaire (Appendix 15) was used at 3 months, 6 months, 9 months and 12 months intervals to know the adherence to inhalers among them. All the questionnaires were used for participants in both the control and the intervention clusters. The evaluation questionnaire used at baseline and end-line was administered by trained evaluators who had degrees in social science, were part of RUHSA training and evaluation team and had no relationship with the study. Photograph 6.2 shows an interview with a participant for filling up an evaluation questionnaire by an evaluator. TAI questionnaires were paper based and SGRQ was in electronic form administered to the participants by HCWs using handheld tablet computers. Photographs 6.3 shows the administration SGRQ questionnaire by a health aide (HCW).

Photograph 6.2 An evaluation questionnaire being filled up

Photograph 6.3 SGRQ questionnaire administered to a participant by a health aide (HCW)

All the participants were told about their diagnosis; they were advised to avoid risk behaviours by the physician, prescribed inhalers and a spacer was given to all. There was training on inhaler use by a respiratory therapist at the hospital and respiratory exercises training and demonstration was done by the physiotherapist. All the participants also received a pictorial handout containing detailed information about CRD. The participants in the intervention arm additionally obtained a calendar (Appendix 17) with pictorial depiction of steps of inhaler use on one side and respiratory exercises on other side to help them continue with correct technique of inhaler use and perform the respiratory exercises. All were asked to come for review every 3 months to clinically assess them for their symptoms and check their use of inhalers. The evaluation questionnaire was developed as a part of my PhD study and TAI was selected for testing inhaler adherence. The SGRQ was selected for evaluation of clinical symptoms and impact of the disease and was part of the bigger feasibility project into which my PhD was embedded.

6.5.8 TPB intervention

The additional TPB based intervention exclusive to the IA for participant and community engagement through use of various media and methods consisted of the following –

i. a calendar pictorially depicting the steps of inhaler use with a spacer on one side and breathing exercises on the other – this was designed to help patients perform these activities themselves, correctly at home
ii. demonstration of inhaler-use with spacer and of breathing exercises by the health aides (HCWs) at peripheral health centres
iii. playing of videos on general awareness on CRDs
iv. motivational videos based on TPB constructs – attitude towards health behaviour, subjective norms and perceived behavioural control
v. Puppet shows (theatre) answering frequently asked questions (FAQs) of people related to CRDs in a theatrical and culturally acceptable form
vi. ‘Ask-your-doctor’ videos on asthma and COPD with specific questions and answers to the concerns of patients
vii. Health melas putting all the educational materials together for a whole day in peripheral health centre for public and patients viewing

viii. School painting and debate competitions to raise awareness about CRDs and their treatment

ix. Doctors' public address to create awareness and promote positive attitude towards treatment and follow-up of CRDs

The photographs below show some of the above activities including inhaler training, Puppet shows and health melas.

Photograph 6.4 Inhaler training

Photograph 6.5 Health Mela

Photograph 6.6 Puppet show

6.5.9 Analysis

This was a pilot-feasibility trial, which aimed to establish the feasibility of conducting the intervention using health care workers; concurrently it also measured the effectiveness of the TPB intervention in terms of the change in its constructs and in respiratory health behaviour at the end of the intervention period. Analysis of feasibility was done in terms of screening and referral for physician assessment, recruitment rates, treatment acceptability and follow-up rates, variation within clusters, missing data, integrity of intervention delivery and completion rates using frequencies, proportions and percentages. Baseline demographic data were summarised using frequencies and descriptive statistics, and the arms (TPB vs. HBM) were compared using a t-test/Mann–Whitney U-test or Fisher's exact test for continuous and categorical variables, respectively.

For measuring the effectiveness of the TPB intervention on this rural low-literacy population in LMIC settings, mean differences and ANOVAs were used. Analysis was carried out between and within two groups (intervention and control) involving four experimental conditions. Analysis was performed to compare the participants who received the TPB educational intervention, i.e., intervention arm with those who received health belief model (HBM) education (control arm). Comparison within and between the groups and conducted at two time points (baseline, i.e., before the beginning of intervention and at end line, i.e., after completion of the intervention). The repeated measure factor was the two time points, baseline and end line whereas the between subject factor was the experimental condition, i.e., intervention or control group. Paired sample t-tests were performed within the groups at two time points whereas independent sample t-tests were used for between-group comparisons; a difference in difference (for mean differences within groups at two time points) was used to compare the difference between the two groups. These tests evaluated the effects of the intervention on the constructs within the theory of planned behaviour and on the health behaviour itself. A 2x2 mixed analysis of variance (ANOVA) was used to evaluate the effect of the intervention on the two groups at the end of the intervention period. The basic statistical analysis had been done by me – but I acknowledge the contribution of the biostatistics department of Christian Medical College Vellore in analysing data and performing higher statistical analysis to arrive at my results.

6.6 Results

6.6.1 Objective 1

To evaluate the TPB-based intervention for its feasibility (in terms of screening and referral for physician assessment, recruitment rates, treatment acceptability and follow-up rates, variation within clusters, missing data, integrity of intervention delivery and completion rates) and identify the implementation challenges in low resource settings

The trial included a total of 200 participants (patients with CRDs) with 100 each in IA and in CA. Each arm had two clusters (each with approximately 7000-8000 population) from which the participants were screened from the community. A minimum of 50 participants in each cluster were required for the trial to proceed. Each cluster had one health aide (HCW) who was assigned the job of screening and referral of suspected CRD patients. The screening rate by the HCWs, the patients referred and the confirmation rates are given in table 6.1.

Table 6.1 Screening and referral of suspected CRD patients by the HCWs

Cluster name	Participants screened (a)	Screen positive patients (b)	Patients referred for clinical review (c)	Confirmed patients (d)	Screening rate* (b/a)	Confirmation rate** (d/c)
Kilalathur	173	124	55	50	71.7%	90.9%
Kilmutkur	101	53	53	50	52.5%	94.3%
Latteri	118	58	57	50	49.2%	87.7%
Vaduganthangal	155	54	54	50	34.8%	92.6%
Total	547	289	219	200	52.8%	91.3%

*Screening rate is the proportion of participants fulfilling criteria of screening questionnaire to the number of participants approached

**Confirmation rate is the proportion of confirmed patients to the number of participants reviewed with spirometry and clinical review form

Across the four clusters (PSUs), 219 participants were invited to come for eligibility testing and take part in the study. Of these 19 were not eligible; 17 did not have a confirmed CRD diagnosis, one was not able to perform spirometry and one belonged to a cluster not chosen for trial. All 200 had consented to take part in the trial at the time of initial visit to RUHSA hospital for clinical review and spirometry. The time taken for recruitment of 200 participants into the trial was almost 6 months (23 weeks); the rate of recruitment was 8.7 (8-9 participants) per week. Initiation of treatment and introduction to educational intervention required a second visit to the hospital; 191 patients could be recruited and allocated to IA and CA. Of these nine patients, one died before the start of the intervention, one each was diagnosed with tuberculosis and heart disease and therefore had to be excluded, and six of them refused to take part in the intervention. The early acceptability rate was 95.5% (191/200) for the trial. At the end of the intervention period, only 178 participants could be followed up. Of these 13 participants were lost to follow up during the intervention – their data could not be included in analysis. Ten had died, two had migrated out of the designated clusters and one was caught-up in COVID-19 induced lockdown in another part of the country. Overall, 22 participants could not make it to the end of the intervention period of which the death rate was 5.5% (11/200) and the dropout rate was 5.5% (11/200). The completion rate at the end of the trial period was 89% (178/200).

The extent of variation within the clusters, i.e., intraclass corelation coefficient (ICC) was found to be 0.21 (0.03, 0.35), 0.17 (0.06, 0.38) and 0.21 (0.10, 0.38) for attitude, intention and behaviour, respectively. The integrity of intervention delivery was maintained by the continuation of intervention delivery by the HCWs throughout the intervention period, the quality of the intervention delivered due to training and re-training of HCWs and the systematic coverage of the intervention area to include all patients, family members and the whole community. The integrity of the intervention was ensured by holding training sessions for health aides on screening questionnaire, general awareness on CRDs, TPB educational materials (dissemination and delivery), inhaler use with spacer and breathing exercises, TAI and SGRQ training for data collection, training of evaluators on evaluation questionnaire and a series of review meetings throughout the project period. Table 6.2 shows the frequencies of the above conducted during the trial. A master chart for different educational programmes was

developed to ensure desired coverage of all sections and areas in the intervention clusters. Two intervention clusters were divided into 23 areas and 41 sub-areas for the educational purpose. Handbills, video shows and puppet show targeted study participants, their family and the community members of their locality. Training on inhaler technique and respiratory exercises was given to the patients using pictorial charts by the HCWs. Table 6.3 presents the educational sessions based on TPB and delivered by the HCWs in the intervention clusters throughout the intervention period. Besides these, school painting and debate competitions on CRD, and doctors' public address to raise CRD awareness were organised by the health aides (HCWs) in the intervention areas. Training of HCWs is depicted in photograph 6.7.

Table 6.2 Training and review meetings during the project

Sl. No.	Description	Frequency
1.	Health aides (HCWs) training on screening questionnaire and CRD awareness	6
2.	HCWs training on health education (dissemination and delivery)	8
3.	HCWs training on handouts, inhaler use and breathing exercises demonstration	5
4.	Health aides (HCWs) training on TAI and SGRQ	15
5.	Training of evaluators	7
6.	Review meetings with project team	37

Table 6.3 Distribution of various educational intervention sessions in the intervention clusters

Educational Intervention Sessions	Intervention cluster 1	Interventions cluster 2
Video Shows	75	58
Puppet Shows	14	11
Health Mela	2	2

Photograph 6.7 Training of Health Aides (HCWs)

The fidelity of the intervention was maintained in three ways throughout the trial period – 1) Week by week scheduling of the activities of HCWs with regards to TPB education in the community and among the participants; similar scheduling was done for follow-up of the participants by the HCWs which was checked during review meetings - actual activities and area coverage was compared with the scheduled activities and plan. 2) The field coordinator was responsible for supervision of the activities of the HCWs and went physically to the local community (as per the schedule) to observe and ensure that the activities take place as designed. Evidence was gathered by taking photographs of such activities and reporting to investigator(s) during the review meetings. 3) The medical officers, including me who did clinical review and follow-up treatment, engaged with the patients during their visits to the hospital to find out whether TPB education, training and follow-ups were done by HCWs and whether they performed the desired health behaviour.

Interviews with health aides (HAs) carried out at the end of intervention period to get their feedback about their role and about the intervention (the process evaluation) produced the following results:

They were well trained during the trial period about CRDs and that helped them in their understanding of the disease and conveying the same to the patients

"Initially, they taught us the risk factors, causes and what problems will be there for patients with breathing difficulty. They also trained us on what chronic respiratory diseases are and when all they should go see the doctor. …and then puppet show, video, we were all trained for educating the patients. They also trained us in how to take the inhaler…" HA 3

"They trained us for one month and each training was for half a day. They taught us how to talk to the patients. What all questions to ask the patients? Like those they gave us training. Then we went to the village to do the screening. They also taught us how to use the tab. (tablet PC) … HA4

They thought that the educational intervention provided by them and using the video shows and the puppet shows were useful to the patients

"We also advised them to use LPG gas and avoid cooking in open Chula inside their home. We have also told them to reduce smoking little by little. And to avoid smoking inside home as their family members will also be affected by the smoke and get the disease. I think whatever we have said they are doing… Ha ha (Laughing) HA1

"We also have shown a general education video that they should not smoke or should wear mask while working in dusty work environment and we also showed doctor-patient education video…. but this was doctor and patient interaction, and it was about their breathing problem. The doctor is saying that when blue medicine should be used and when pink medicine should be used. The doctor also gives a clear explanation that during pregnancy also we should take inhaler and he assures that there are no side effects. It is like patient asking questions and doctor is giving the answer. So, they can relate to their disease, and they said it was helpful and understandable." HA2

The intervention was useful in removing stigma about the disease and inhaler use; people have stated using the inhalers voluntarily and the family members and community support them

"…But after seeing all these educations through video they all started taking inhaler. They are aware that inhaler will improve their lung and they are even taking it outside, before they were ashamed to carry their medicine, but now they are not." HA2

They felt that at the end of the intervention period the patients and the community have appreciated the project, accepted the intervention and have been benefitted by it.

"… she initially thought that she is having heart issue but during the screening survey she had problems for respiratory issue. She came to RUHSA got properly diagnosed and took regular treatment and is now good. She actually had COPD and she referred one more patient…She is also getting better now." HA3

They believed they were responsible for bringing such a change through their constant effort of delivering the intervention

"I have recruited 50 patients in this project. Initially, the patients didn't come or were not interested. But now as the project was going, everyone are getting involved and it's like a social work for us to identify them and send them for treatment. They are saying that you're working in RUHSA and you arer helping us. Thank you. They are also thankful that we got them inhaler free of cost. I am also happy hearing it…" HA4

"I think it some 80% change in patients would be from us" HA2

They appreciated the research project and felt that the intervention during the trial period had been useful for the community and their relationship with the community had improved.

"This project is very good only sir. But there are more patients than this 50. We should be treating all the patients with respiratory disease…" HA4

"Relationship is improved sir. They are calling and asking me when to go see the doctor, is the doctor available in RUHSA, can we join our friends who are having breathing problem in this project, like these they are asking me. Initially they were not

willing to share or join the project but after taking the inhaler, they are asking if the project is still going on." HA2

The effectiveness of the TPB based intervention was measured by the change/ improvement it brought on the constructs of TPB and underlying beliefs governing them. It was also measured by the change in behaviour and the clinical outcomes at the end of the intervention period. Table 6.4 shows that baseline characteristics of the participants in both the arms (IA and CA) were similar as were the characteristics of all participants in the trial. The number of asthma and COPD patients in each arm was almost equally distributed, so as their body mass index, age, gender and other characteristics. Representation by gender favours female distribution and by age slightly favours younger population with age less than 60 years (<60=53.3% and ≥60=46.7%). Three quarters of the younger population within age 60 years were females (74.5% and 75% respectively for IA and CA) while above 60 years shows a male preponderance. The majority of the asthma patients were females in either arm (85.4% and 75.5% in IA and CA respectively) with COPD predominantly diagnosed among males (64.3% and 77.8% in IA and CA respectively).

6.6.2 Objective 2

To analyse the effect of the intervention on attitude, social norms, perceived power and intention related to the health behaviour

Table 6.4 Baseline characteristics of the participants

Variable		**Control Arm, n=90 (%)**	**Intervention Arm, n=88 (%)**	**Total n=178(%)**
Age in years, Mean (SD)		55.7 (13.8)	57.2 (13.2)	56.40 (13.48)
Gender	Females	53 (58.9)	54 (61.4)	107 (60.1)
	Males	37 (41.1)	34 (38.6)	71 (39.9)
Religion	Hindu	81 (90)	85 (96.6)	166 (93.3)
	Christian	8 (8.9)	3 (3.4)	11 (6.2)
	Muslim	1 (1.1)	0 (0)	1 (0.6)

Marital Status	Currently married	70 (77.8)	71 (80.7)	141 (79.2)
	Widowed	14 (15.6)	16 ((18.2)	30 (16.9)
	Separated	2 (2.2)	0 (0)	2 (1.1)
	Single	4 (4.4)	1 (1.1)	5 (2.8)
Type of Family	Nuclear	64 (71.1)	61 (69.3)	125 (70.2)
	Extended	14 (15.6)	19 (21.6)	33 (18.5)
	Joint	12 (13.3)	8 (9.1)	20 (11.2)
Education	No formal education	40 (44.4)	43 (48.9)	83 (46.6)
	Up to middle school	45 (50)	40 (45.5)	85 (47.8)
	High school and above	5 (5.6)	5 (5.6)	10 (5.6)
SE class	Lower	23 (25.6)	33 (37.5)	56 (31.5)
	Lower middle			
	Middle	61 (67.8)	51 (58)	112 (62.9)
		6 (6.7)	4 (4.5)	10 (5.6)
BMI	Mean (SD)	24.2 (5.4)	24.3 (5.7)	24.3 (5.5)
Disease type	Asthma	49	42	91
	COPD	37	42	79
	ACOS	1	1	2
	Others (COPD with Bronchiectasis, PTLD)	3	3	6

BMI = Body mass index SE = Socio-economic

Fig. 6.5 shows that the five major risk behaviours evaluated during this study were equally distributed in both the arms at the beginning of the intervention period. There were few current smokers, but more than two-thirds of the participants used biomass fuels as their primary fuel for cooking needs. Use of any type of inhalers, in any

frequency was also low, with about a quarter of the participants using it; breathing exercises were almost unknown to the participants (6.7%).

Table 6.5 Risk behaviours at baseline

Variable		Control Arm, n=90 (%)	Intervention Arm, n=88 (%)	Total n=178 (%)
Current smoker	Yes	11 (12.2)	7 (8)	18 (10.1)
	No	79 (87.8)	81 (92)	160 (89.9)
Biomass fuel	Yes	62 (68.9)	60 (68.2)	122 (68.5)
use	No	28 (31.1)	28 (31.8)	56 (31.5)
Risk	Yes	10 (11.1)	9 (10.2)	19 (10.7)
occupation	No	80 (88.9)	79 (89.8)	159 (89.3)
Breathing	Yes	5 (5.6)	7 (8)	12 (6.7)
exercises	No	85 (94.4)	81 (92)	166 (93.3)
Current Inhaler	Yes	20 (22.2)	26 (29.5)	46 (25.8)
Use	No	70(77.8)	62 (70.5)	132 (74.2)

The results below in table 6.6 show that there was no change in corresponding beliefs related to attitude, subjective norm and perceived behavioural control respectively, at the end of the intervention period except for change seen in the behavioural beliefs in the control arm.

Table 6.6 Effect of the intervention on the behavioural, normative and control beliefs

	Control	Intervention	Difference in Difference of means (95% CI)
	Mean (SD)	**Mean (SD)**	
Behavioural beliefs			
Baseline	54.90 (18.75)	50.57 (18.250	
Endline	63.41 (15.53)	54.68 (19.970	-4.4 (-11.6, 2.8)
Mean difference (95% CI)	-8.5 (-13.6, -3.4) *	-4.1 (-9.8, 1.6)	
Normative beliefs			
Baseline	84.96 (24.48)	80.69 (28.14)	
Endline	82.43 (25.30)	86.35 (30.46)	8.2 (-3.3, 19.7)
Mean difference (95% CI)	2.5 (-4.8, 9.8)	-5.7 (-14.4, 3.1)	
Control Beliefs			
Baseline	81.42 (22.75)	79.65 (23.84)	
Endline	79.54 (19.98)	83.51 (21.74)	5.7 (-3.0, 14.5)
Mean difference (95% CI)	1.9 (-4.4, 8.2)	-3.9 (-10.7, 2.9)	

*Significant at 0.05 level

There was a significant improvement in attitudes, subjective norm and perceived behavioural control at the end of the intervention period. No change in intention was observed but there was a significant improvement in composite respiratory health behaviour (combining the five respiratory health behaviours evaluated for this study, as shown in table 6.8) at the end of the intervention period. The improvement in the constructs of TPB brought about by the intervention was observed in both the IA and the CA.

Table 6.7 Effect of the intervention on TPB constructs

TPB constructs (total score)	Control Mean (SD)	Intervention Mean (SD)	Difference in Difference of means (95% CI)	p value
Attitude (45)				
Baseline	30.99 (2.83)	30.30 (3.16)	0.29 (-1.1, 1.6)	0.431
Endline	35.73 (2.97)	35.33 (4.51)		
Mean difference (95% CI)	-4.7 (-5.6, -3.9) **	-5.0 (-6.2, -3.9) **		
Subjective Norm (35)				
Baseline	17.83 (3.48)	17.83 (3.49)	-0.82 (-2.4, 0.7)	0.509
Endline	22.08 (3.90)	21.25 (3.70)		
Mean difference (95% CI)	-4.2 (-5.3, -3.2) **	-3.4 (-4.5, -2.4) **		
Perceived Behavioural Control (35)				
Baseline				
Endline	12.42 (2.87)	13.16 (3.44)	0.29 (-1.6, 2.2)	0.476
	24.58 (4.60)	25.60 (6.33)		
Mean difference (95% CI)	-12.2 (-13.3, -11.0) **	-12.4 (-13.9, -10.9) **		
Intention (40)				
Baseline	23.98 (2.60)	23.29 (3.02)	0.4 (-1.0, 1.7)	0.361
Endline	23.71 (3.20)	23.10 (4.60)		

Mean difference (95% CI)	0.43 (0.45, -0.46)	0.08 (0.5, -1.0)		
Behaviour (5)				
Baseline	2.36 (0.89)	2.51 (0.87)		0.442
Endline	3.58 (0.94)	3.82 (1.05)	0.08 (-0.3, 0.4)	
Mean difference (95% CI)	-1.2 (-1.5, -0.95) **	-1.3 (-1.6, -1.0) **		

**Significant at 0.001 level

6.6.3 Objective 3

To measure the effectiveness of the intervention on behaviour change and health outcomes at the end of the intervention period

Table 6.8 depicts that individual health behaviours i.e., biomass fuel use, use of inhalers with spacers and breathing exercises to improve lung function, all improved significantly at the end of intervention period. There was a decrease in the proportion of people continuing with risk occupation in the intervention arm as compared to control arm, though this was not statistically significant. This is also depicted in table 6.9 where the mixed ANOVA analysis showed that the TPB constructs except intention have improved over time but there is no difference between the groups (non-significant interaction between time and condition (the conditions being the TPB intervention and HBM education). A small effect size with Cohen's d of 0.11, 0.22, 0.19 and 0.24 are observed for attitude, subjective norm, perceived behavioural control and behaviour respectively.

Table 6.8 Effect of the intervention on respiratory health behaviours

	Control arm			**Intervention arm**		
Variable	**Baseline**	**End-line**	**P value**	**Baseline**	**End-line**	**P value**
Non smokers	79	78	0.82	81	82	0.77
Not using biomass fuel	28	64	**<0.001**	28	60	**<0.001**
Not in risk occupation	80	73	0.14	**79**	**82**	0.42
Performing breathing exercises	5	29	**<0.001**	7	42	**<0.001**
Using inhalers	20	78	**<0.001**	26	70	**<0.001**

Table 6.9 Mean scores of direct and indirect measures at baseline and endline following intervention and significance of 2x2 ANOVA's

TPB beliefs and constructs	Baseline (t1)		Endline (t2)		Probabilities			Interaction effect size
	Control Mean (SD)	Intervention Mean (SD)	Control Mean (SD)	Intervention Mean (SD)	Time	Group	Interaction	Cohen's d
Behavioural Beliefs	54.90 (18.75)	50.57 (18.25)	63.41 (15.53)	54.68 (19.97)	0.0	0.12	0.23	0.48
Normative beliefs	84.96 (24.48)	80.69 (28.14)	82.43 (25.30)	86.35 (30.46)	0.50	0.28	0.16	0.14
Control Beliefs	81.42 (22.75)	79.65 (23.84)	79.54 (19.98)	83.51 (21.74)	0.54	0.61	0.19	0.19
Attitude	30.99 (2.83)	30.30 (3.16)	35.73 (2.97)	35.33 (4.51)	0.0	0.12	0.67	0.11
Subjective Norm	17.83 (3.48)	17.83 (3.49)	22.08 (3.90)	21.25 (3.70)	0.0	0.99	0.29	0.22
Perceived Control	12.42 (2.87)	13.16 (3.44)	24.58 (4.60)	25.60 (6.33)	0.0	0.12	0.77	0.19

Intention	23.98 (2.60)	23.29 (3.02)	23.71 (3.20)	23.10 (4.60)	0.49	0.10	0.87	0.15
Behaviour	2.36 (0.89)	2.51 (0.87)	3.58 (0.94)	3.82 (1.05)	0.0	0.24	0.63	0.24

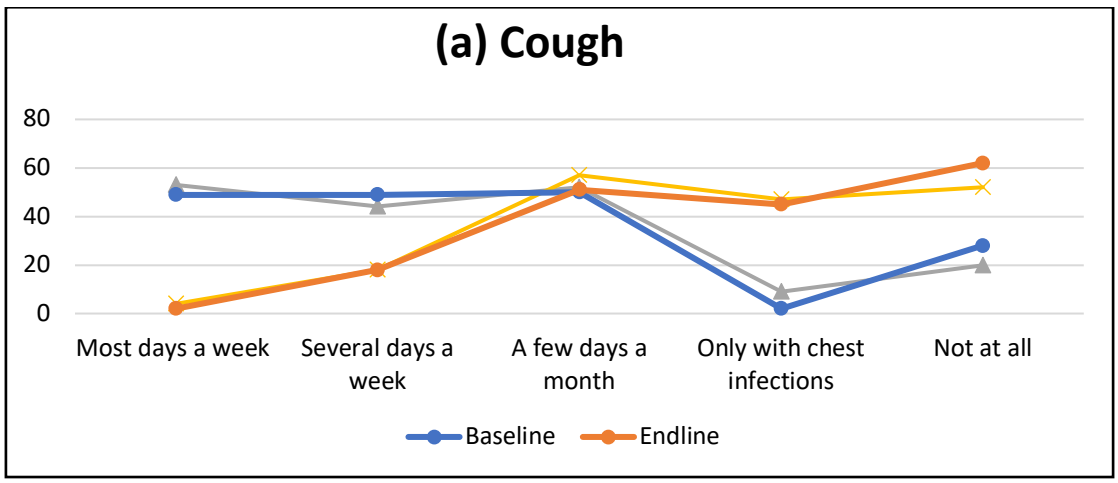
Adherence to inhalers was tested at three monthly intervals starting at 3 months after first provision to participants. There was significant improvement in adherence level over time; adherence was considered to be good if the participants scored 5 in each of the ten questions (score of 50 out of 50) asked to them using the TAI questionnaire.

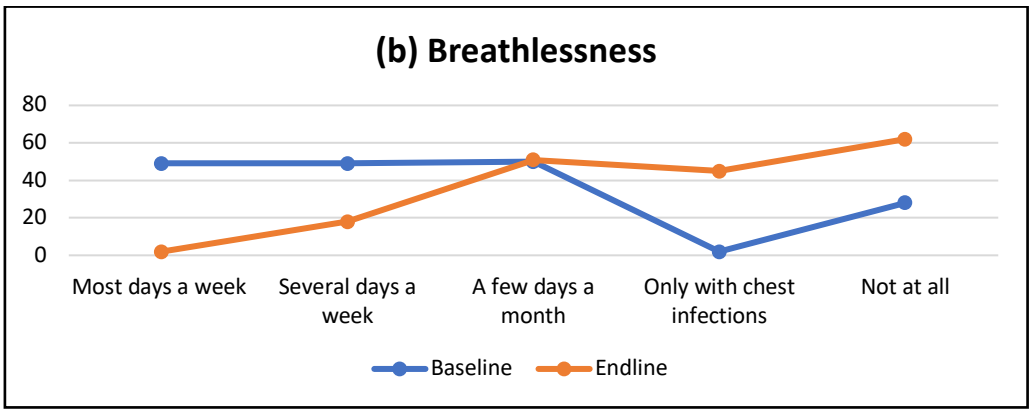
Table 6.10 Adherence to inhalers during follow up period (1year of intervention)

Adherence level	**Time points of adherence assessment**				**Chi-square (p value)**
	3 months (n=186) Frequency (%)	**6 months (n=173)** Frequency (%)	**9 months (n=113)** Frequency (%)	**12 months (n=125)** Frequency (%)	
Good	78 (41.9)	83 (48)	71(62.8)	94 (75.2)	46.193
Intermediate	50 (26.9)	29 (16)	18 (15.9)	8 (6.4)	**(p<0.00001)**
Low	58 (31.2)	61 (35)	24 (21.2)	23 (18.4)	

The participants (patients with CRD) reported a significant improvement in symptoms and ($p<0.001$) and remarkable decrease in exacerbations at the end of the intervention period; there was also improvement or no worsening in lung function in more than two thirds (69.6%) of patients at the end of intervention period.

Figure 6.6 (a, b, c) Symptoms in CRD patients after 1 year of intervention





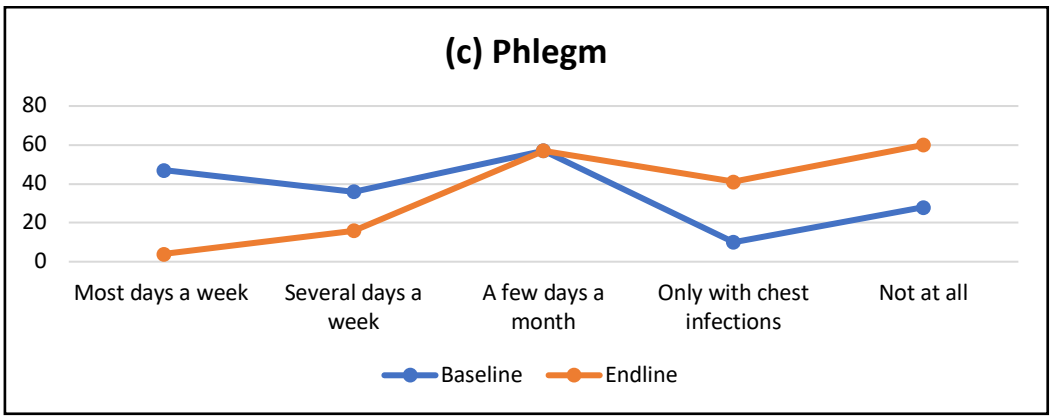


Table 6.11 Exacerbation episodes among CRD patients (n=178)

Exacerbations	Baseline	End line	Chi square and p value
Present	74	39	X^2=15.88
Absent	104	139	**P<0.001**

Table 6.12 Pulmonary function of CRD patients after intervention (n=178)

Baseline PFT			End-line PFT	
Small airway obstruction		**Large airway obstruction**		
Mild	15(7.1%)	19(9%)	Improved	59(33.1%)
Moderate	6(2.9%)	5(2.4%)	Same status	65(36.5%)
Moderately Severe	22(10.5%)	52(24.8%)	Worse	38(21.3%)
Severe	114(54.3%)	48(22.9%)	Missing spirometry	16 (9.0%)

6.7 Discussion

6.7.1 Main results

The theory of planned behaviour was used for the first time, to my knowledge, for behaviour change in CRD patients, using HCWs for intervention delivery, screening, referral and follow-up, in a poor, rural, low literacy setting of an LMIC. So, it was important to establish the feasibility of such an intervention, so that further definitive trials can be planned. The results of this pilot-feasibility study were promising with the outcomes establishing that such a study was feasible in the current setting and definitive trials could be planned in future. The results of this feasibility study in terms of effectiveness of TPB educational intervention in changing the constructs within the TPB behaviour change model were encouraging and clinical outcomes showed a remarkable improvement in patients' symptoms, although this a pilot-feasibility study and not powered to calculate a change in TPB or clinical outcomes. I was able to establish that recruitment of CRD patients from the community was possible with the involvement of trained HCWs; the screening, diagnosis , treatment, educational intervention and follow-up were possible with the help of trained health personnel; adherence to treatment and completion rates were good enough and the feasibility trial could be completed in time; it was acceptable to the participants, community members and the research team; and finally TPB constructs and behavioural outcomes improved after the intervention.

6.7.2 Strengths, challenges and limitations

6.7.2.1 Strengths

There were many strengths of this research study. First, the development and feasibility testing of this intervention trial was informed by UK Medical Research Council (MRC) guidance (2008) and update 2019 for developing and evaluating complex intervention[49-50]. Current scientific evidence was examined using a systematic review and the results used for informing intervention development. The process of intervention development, feasibility testing, evaluation and implementation were followed and therefore a robust framework guided the whole process. Second, it used a sound theoretical framework[7] for intervention development: the theory of planned behaviour guided the intervention development, its implementation, and its

evaluation. A relevant theory more likely ends up in an effective intervention than an empirical approach[51]. Third, an extensive formative research in form of qualitative studies on patients, caregivers and community members helped in detecting the salient beliefs, attitudes, subjective norms, capability and practises resulting in careful assessment and development of an appropriate intervention. Fourth, the study was completed within the allotted time and with a good retention rate (in spite of COVID-19 pandemic), shows the reliability and acceptance of the study.

6.7.2.2 Challenges

There were numerous challenges faced throughout the feasibility trial. During the training of health care workers, a single round of training was not sufficient to bring the requisite confidence, correct message delivery and acceptable skill levels in them. Since they were responsible for screening, TPB education delivery and follow-up with SGRQ and TAI questionnaires multiple training rounds were necessary to bring them to a sufficiently high level, as well as some additional training was required before SGRQ and TAI questionnaires as these were administered periodically. Quite of few rounds of brainstorming with the HCWs and research team along with Community Advisory (included members from the community) had to be untaken to develop the correct messages and use the appropriate media which could influence / captivate participants and their social environment. There were challenges in conducting the FGDs and community engagement events like video shows and puppet shows as timings did not match. To overcome this situation, the timings were changed to evening when participants were available at their homes (came back from work or caregivers were available). The COVID-19 pandemic posed a serious challenge to the whole study, due to complete lockdowns which severely restricted human contact. Community engagement and education principally was based on human contact and face-to-face participation, which had to be stopped for about three months and then restarted following social distancing, covid norms on hygiene and with small gatherings in open spaces: masks and hand sanitizers had to be procured for HCWs and participants, some remote consultation had to be done and even inhalers and drugs were distributed in the community to the participants. spirometry had to be stopped and then restarted after a gap following the GINA and the ERS guidelines.

6.7.2.3 Limitations

Instead of choosing the clusters randomly for the trial, it would have been better to choose them purposefully in the first stage based on the distances from the hospital and the terrain, so that intervention and control clusters were far away from each other, equally distant and of similar terrain, all of which influenced mobility and at times, contamination. In a community-based trial, it is difficult to control contamination - some would happen through people interaction but mostly happened due to overenthusiasm of the HCWs of control arm to do the same for their clusters. Since this is implementation research, a step wedge design would be suitable as it would provide opportunity to the control clusters to go into the intervention over a period and therefore cover all population with the services provided. If we are to show the difference between TPB and HBM model, i.e., IA and CA, in a trial we need to calculate a sample size for a specific parameter with minimally acceptable difference or effect size (e.g., difference in inhaler use by 10%), to provide enough power to show the change. Such sample size calculation or power calculation had not been done in this trial and it was not able to show any difference between arms, although it showed improvement with time. This was a feasibility study undertaken to test whether this intervention can be implemented, and yes, it had shown that it was feasible in this setting.

6.7.3 Discussion of results in light of published literature

Feasibility of recruitment using health care workers (HCWs) – In relation to my first objective, it was well established that patient recruitment through use of health aides (HCWs) was feasible; it was not too much of a burden or too difficult a process for them. They could be trained to use the screening questionnaire and were able to screen patients from the community. There was a variation in the screening rates among the health aides (HCWs) for different clusters, which was quite pragmatic because of the geography and variation within clusters and individual capability of HCWs notwithstanding the same training given to all. The variation in screening positivity ranged from little over one third to almost up to two thirds of the participants screened in the community, with the overall screen positivity rate at little above the halfway mark. This study has informed that about double the number of people with any respiratory symptoms need to be screened at community level to obtain a

sufficient pool of participants for eligibility testing. The confirmation rate of CRD patients among the screen positive patients was quite high with nine out of ten confirmed as a CRD patient, giving the initial impression of the questionnaire being quite effective in picking up suspected CRD patients and could be used for screening. None of the screen positive participants who were invited to come to the hospital for eligibility testing / diagnosis refused.

Recruitment period – The initial recruitment period decided for this trial was three months. However it took almost double that time to complete recruitment for 200 participants. The reasons for longer period were – i) minimum two visits 2 weeks apart, one for investigations and second for initiation of treatment after arriving at the diagnosis; sometimes 2 weeks extended up to four weeks as participants had to find time to come to the hospital a second time as per their convenience after they were informed about their diagnosis and invited to come for treatment and intervention. It was a pragmatic approach to the trial, so I learnt that this was be the minimum time requirement and could recruit around 9 participants per week. Ii) the second reason was the TPB-based intervention was still under development and we did not want to start treatment without starting educational intervention simultaneously, as it was necessary for evaluating the effectiveness of the intervention.

Follow-up and dropout rates – There was a time gap between testing for eligibility (confirmed diagnosis of CRD) and starting of the treatment and intervention. The start of treatment followed by initiation of educational intervention required a second visit by the patient after one to two weeks of their first visit for diagnosis; nine patients dropped out during this per period – one died soon after diagnosis was made, two were subsequently diagnosed with concurrent heart disease and tuberculosis for which they had to be excluded and six (three from each arm) refused to take part further in the trial citing unavailability of time. The early dropout rate was thus 4.5% and 95.5% of the patients could be retained fat the time of initiation of intervention. The time gap was essential as all investigations including chest x-ray and spirometry along with patient's history were forwarded to the pulmonologist remotely, who reverted back with the confirmation of diagnosis, as per the protocol. During this trial period, primary care physicians could be trained for interpreting spirometry to arrive at

a diagnosis; therefore the process of recruitment could be expediated during a future definitive trial.

Most of the participants lost to follow-up (10/13) between the beginning and the end of the intervention period were due to deaths related to co-morbidities. These were CRD patients suffering from multi-morbidity and most of the deaths were attributed to cardiovascular disease or diabetes. The overall completion rate of 89% (88% in IA and 90% in CA) proved that the intervention trial was quite feasible in this setting.

Integrity of the intervention – The integrity of intervention delivery was maintained by numerous training sessions for the HCWs at appropriate time points, training for the evaluators and blinding them to the trial and systematic patient and public involvement by engagement with the community through various media and methods. These were necessary for acceptance of the intervention, continuation of treatment and follow-up. Training and education of the HCWs before they could deliver the education to patients and the community was important to improve their knowledge, to develop their skills, to raise their own understanding and awareness about CRD, thereby changing their own beliefs and empowering them with the capacity to deliver the correct message and get themselves fully committed to the task as agents for changing health behaviour. Training provided capacity building for them to deliver the educational intervention and follow-up patients in the community as per protocol. This also improved their acceptance of the programme. Staff for the trial could be recruited and / or trained for trial management and the trial could be completed as per the protocol, aided by several review meetings of the staff with the investigators.

Acceptability of the intervention – The second important aspect in feasibility testing of an intervention trial is acceptability. The acceptability to this trial could be established by the fact that the clusters we randomly selected and the participants from those clusters agreed to take part in this trial. In fact, all the screened participants who were invited to come for eligibility testing and recruitment to the trial agreed and came to the hospital. Most of the participants had switched to using inhalers with spacers, doing breathing exercises and using clean fuels for cooking at the end of the intervention period (Table 6.5 and 6.8), which supported their acceptance to the intervention. Speaking with patients and the community members through the

Community Advisory Group (CAG) (mentioned in detail under stakeholder and community engagement), they responded positively and spoke how the intervention helped them in knowing about symptoms, using inhalers, risk behaviour and most importantly in removing the social stigma associated with the disease and inhaler use. Most of the patients were quite satisfied after using the inhalers with spacers and performing the breathing exercises which made them symptom free and reduced there hospital visits due to exacerbations, as expressed by the health aides in their feedback and narrated by the patients during the clinical reviews. Overall, the responses from the patients and community corroborated their acceptance to the intervention.

The acceptance of health providers, mainly the health aides (HCWs) was ascertained by the qualitative interviews with the health aides (HCWs) wherein they had narrated about their training, their improvement in understanding about CRDs, usefulness of the intervention to the patients and the community and the vital role that they have played in bringing a change in behaviour, reducing stigma and bringing social acceptance. They were satisfied with their role and at the end of the intervention period they advocated for expanding this intervention to all areas in the community for benefit of CRD patients. They could be used successfully in implementing the intervention is evidence of their acceptance and strength of the trial.

Feasibility and acceptability are two important parameters to establish in a pilot feasibility trial[38-40]. Recruitment, adherence to intervention, retention, response rates to questionnaires, follow-up rates, ICCs in cluster trials, time to completion and practicability of delivering the intervention in the current setting are some of the features which establish feasibility for a further definitive trial. Factors like acceptability of intervention to users, representative recruitment and engagement, willingness of participants and health care providers to go through the trial and describes the acceptability to the trial. My trial addressed all of these features covered and results showed that the intervention was both feasible and acceptable in the current setting.

The baseline characteristics of participants showed that there was no difference between the IA and the CA in relationship to their socio-demographic characteristics, their BMI and the disease type. Both the arms were well represented in terms of the vulnerable populations[41-42], ie rural, elderly, females and the poor. It was a community based cluster randomised trial in a low resource setting and well represented the

commonalities of the region. The predominant representation of females among the study participants might be due to a slightly favourable female to male ratio of the region; also it suggested that females being more exposed to biomass fuel at home were at increased risk for CRDs.

Effect of TPB intervention on TPB constructs – My second objective was to evaluate the effect of the TPB-based intervention on the beliefs and constructs of theory of planned behaviour. The TPB proposed by Ajzen[18,42] hypothesized that intention to perform a behaviour was the immediate antecedent to actual behaviour; intention is a function of attitude towards the behaviour, subjective norms and perceived behavioural control and these follow respectively from behavioural beliefs (beliefs about behaviour's likely consequences), normative beliefs (normative expectations of significant others) and control beliefs (presence of factors that control behavioural performance). My TPB-based intervention had not shown any significant changes (statistical significance) in these beliefs, either in IA or the CA or between the groups, at the end of intervention period, though there had been small improvements in all three beliefs in the IA. Whether these small improvements were sufficient enough to cause a change in health behaviour and in clinical outcomes (without being statistically significant) needs to be tested further.

There was significant improvement in attitudes, subjective norm and perceived behavioural control at the end of intervention period, in both the IA and the CA. This was evident from the confidence intervals and the probability (p) values from paired t-tests (table 6.7) and the p-values against time in the 2X2 ANOVAs (table 6.9). Similarly the composite behaviour score also improved significantly at the end of the intervention period which implied a change in health behaviour pattens of the participants. However, the intention did not change significantly at the end of the intervention period, in either arm, although behaviour changed appreciably. This could be explained by the fact that the participants' intention to change behaviour were not realised previously, as they did not have any resources or capability at their disposal. This gap between intention and behaviour was bridged by provision of inhalers with spacers free of cost, to all participants, in both the arms, along with some training and skill development to use inhalers with spacers, breathing exercises and some educational materials given to all, at the hospital during recruitment. This empowered

them to procure their inhalers as and when they needed, use them correctly due to their training, realise the benefits of breathing exercises and inhaler use on their symptoms and therefore continue follow up. This capability and the ability to change their own health behaviour was amply demonstrated by improvement in use of inhalers, performance of breathing exercises and use of clean fuels for cooking, and corroborated by almost doubling of their perceived behavioural control scores, seen in both the arms. Perceived behavioural control represents the extent of external obstacles which people need to overcome to attain the desired behaviour, while intention to act depends on information, intelligence, skills and abilities and other internal factors which enable health behaviour[43-44]. Perceived behavioural control influences health behaviour directly as well as indirectly through intention. Even without any change in intention, the health behaviour had changed significantly and so had the perceived behavioural control, in my feasibility trial.

Effect on health behaviours – The individual health behaviours – using clean fuel for cooking, breathing exercises to improve pulmonary function and use of inhalers with spacers for controlling symptoms have improved significantly, in both the arms, at the end of the intervention; this led to the overall improvement in the behaviour score. Though there has been a significant change in constructs of TPB and in behaviour within the groups (arms) at the end of the intervention period, no such difference in TPB constructs and in behaviour was observed between the groups at the end of intervention (Table 6.9), as shown by probabilities with respect to time, group and interaction in 2X2 ANOVA table. There was a significant change (in TPB constructs and behaviour) with time in each arm, ignoring the type of intervention (time probability); there was no change observed between groups, ignoring the time (group probability) and there was no effect of the intervention with time between the groups (interaction probability).The interaction of the TPB intervention and time between the two arms is insignificant, or there were no changes due to TPB intervention as compared to HBM intervention over time, between the two groups. There were probably several reasons for not observing the difference between groups at the end of the intervention period – first, this was a feasibility study trying to establish feasibility of conducting the trial in a low resource, low-literacy setting and gather information related to a future definitive trial. Published literature suggest that a feasibility study

supports the development of future RCT, but information on potential safety and effectiveness may be collected[38-39, 45]. Second, the study was not conducted using a particular outcome measure (e.g., attitude or behaviour-inhaler use) to estimate the desired sample size with enough power to detect that change between the two groups; since the study was not powered enough, estimating the difference between groups might not been possible. Third, the comparison was not between TPB intervention (in IA) and no education or placebo (in CA), it was between TPB intervention and HBM education which was ongoing in the community for many years. Fourth, as discussed earlier, part of the intervention like availability of inhalers and exercise training was common to both arms due to ethical considerations, and therefore change was visible initially in both the arms because of improvement of capability and availability of resources and difference purely due to educational intervention could not be observed, at this point in time. Fifth, educational interventions to change and maintain health behaviour may take sustained efforts over many years[46] with study design to detect a significant change, and therefore more time may be required for such a discernible change based on pure TPB educational intervention, with baseline behaviour optimised for both arms.

The small improvements in the TPB constructs and behaviour shown by effect sizes (cohen's d ranging from 0.11 to 0.24) have been reported for this feasibility trial even though the difference between the two arms were non-significant ($p>0.05$ for interaction probability). This was important as a further definitive trial is planned as small effect sizes can have large consequences[45], in the current feasibility trial there was significant improvement in clinical outcomes among CRD patients. Although p-value establishes whether an intervention is effective and effect size demonstrates how much effective is an intervention, it might seem ineffectual to report effect sizes when the p-value is non-significant, as in the current study. However considering the effect of the consequences and small sample size of the feasibility study, these might be extremely useful while planning a definitive trial.

The clinical outcomes following the intervention had improved for most of the patients as well as adherence to inhaler use. The improvement in adherence to inhaler use was steady and was maximum at the end of the intervention period. The validated that patients accepted the use of inhalers; perhaps the decrease in symptoms – cough,

phlegm and breathlessness, the reinforcement of inhaler use and its technique by HCWs and acceptance in the community to inhaler use, all contributed to it. There was also a significant decrease in exacerbations among the CRD patients following the intervention as well as improvement in pulmonary function. Inhaler use with spacer, breathing exercises and decrease in use of biomass fuel for cooking might have resulted in improvement in pulmonary function or prevented worsening of it in majority of the patients reviewed at the end of the intervention period. Overall the clinical outcomes proved to be very appropiate indicators of the feasibility of intervention and its and usefulness.

6.8 Conclusions

The health care worker delivered TPB based intervention used in this feasibility trial provided us with the data to proceed for a future definitive trial. It had provided evidence that it is feasible and acceptable in this setting and to the community; planning for a future definitive trial is possible. We now know that recruitment of patients from the community is possible, enough CRD patients are available to be recruited by screening and subsequent confirmation using health care workers in this low resource setting, trained HCWs are vital for adherence to treatment and follow up, training and education of HCWs should not be a one-time activity and needs continuity better results. In other word, Recruitment is possible and can be accomplished by HCWs – recruitment and follow-up activities aren't too much of a burden for them. This trial also demonstrated that the intervention is acceptable to the community and community engagement is vital for the success and usefulness of the trial. Initial estimates of screening rates, overall recruitment rates, completion rates, ICCs and effect sizes have been obtained and will be useful during designing of a future definitive trial.

One of the important learnings form this research study was the importance of community engagement and involvement of patient and public in research. Involving the patients and the community in decision making, creating awareness and empowering them, and engaging them for their own health is paramount in behaviour change models. Patient empowerment through creating awareness and changing beliefs about appropriate health behaviour and essentially through availability of

resources, improving capability through training and skill development are important predictors of behaviour change, initially, rather than the type of health intervention. Similarly engaging the community and family members to provide social support strengthens the capability of performing desired behaviour. These two together, in turn, can create demand for availability of health services and policy change. Policy changes relate with upstream factors in health impact pyramid[47] which have greatest population health impact.

Using theory of planned behaviour in behaviour change models is important[7, 44], as it investigates the current believes, attitude, social norms, capability and current practises which act as barriers or facilitators for respiratory health behaviour. Doing formative research informs the researcher about developing an intervention which can break the barriers and strengthen good practices; it specifically explains where an intervention is needed, and which beliefs and practices need to be modified. However, behaviour change is an extended process that requires sufficient time and sustained effort, training and varied approach based on local socio-cultural context to bring the desired change.

Using healthcare workers in resource poor settings can be a 'game changer' in respiratory health services; it can lead to early diagnosis and treatment, early referrals and sustaining health behaviour and follow up. In countries like India where accessibility to doctors is low, specifically in the rural areas, healthcare workers can strengthen the health services; and already existing cadre of HCWs known as Accredited Social Health Activists (ASHAs)[48] the government health system throughout the country can be tapped into for this purpose.

This intervention had been able to bring a behaviour change in the study population, and a change in the attitude, subjective norms and perceived behavioural control over a period of one year and was beneficial to the participants as was reflected in the clinical outcomes.

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Chapter 7

Implications of this research and conclusions

7.1. Summary of findings and discussion

The aim of this PhD research was to develop and pilot-test a theory driven intervention for behaviour change in chronic respiratory disease patients using health care workers in a low literacy, resource poor setting of a low- and middle-income country (LMIC) to assess its feasibility and implementation challenges, as well as changes in outcome measures. In this research project, my intervention development and testing was informed by the updated UK Medical Research Council (MRC) guidance (2019) on complex intervention development and evaluation[1] and used the Theory of Planned Behaviour (TPB) theoretical framework[2-3] for developing and implementing the intervention.

Intervention development started with examining the current evidence by conducting a systematic review (SR) and narrative synthesis on TPB-based interventions among chronic disease patients, particularly in low health literacy settings of LMICs. This SR informed that only a limited number of TPB based interventions were available, only four studies had been conducted to-date, all were from a single LMIC and on low literacy urban population; none of the studies were on chronic respiratory disease. Through this SR I learnt that implementing TPB interventions in LMIC settings was feasible; it required well designed and detailed intervention and formative qualitative research. The interventions were effective through use of structured education and time frame as well as various media and methods relevant to the population under study. This systematic review provided evidence of effectiveness of TPB interventions as well as their feasibility in LMIC settings, though the evidence was moderate in quality in most of the studies[4-6] and low in one of them[7].

Informed by my systematic review and existing literature on TPB-based interventions[2-3], I conducted formative qualitative research to elicit the salient beliefs and the corresponding attitudes, subjective norms, perceived behavioural control among the patients and the community, as well as their behavioural practices related to chronic respiratory disease. I learnt from my qualitative research that awareness about the

disease was low; there was no clear perception towards the disease or its causation and patients initially avoided accessing established health care system, being ignorant of its complications or severity. Use of inhalers for relief and maintenance in chronic respiratory disease (CRD) patients was uncommon and breathing exercises to help improve upon symptoms were rarely prescribed or practised. The patients' experiences of living with the disease were physically disabling (due to breathlessness) and emotionally challenging with lot of stigma associated with the disease and inhaler use. I learnt about the underlying beliefs and practices which contributed to current health behaviour in CRD patients.

The systematic review and qualitative study informed me in developing the TPB intervention targeting poor, low health literate population in a LMIC setting. Building into the learnings, I developed an evaluation questionnaire with TPB questions assessing the attitude towards the behaviour, subjective norms, perceived behavioural control and their underlying beliefs, as well as intention and health behaviour towards CRD. This questionnaire was validated and pilot tested before administration on the patients. The intervention was developed by modelling processes and outcomes and intended to unravel the barriers around practice by empowering and motivating the patients through provision of inhalers, training on breathing exercises and using various media and methods (videos, puppet shows, school program, health melas) for awareness and motivation. Challenges in patient recruitment, in treatment and follow up was evaluated through review meetings; public and patient engagement was done to improve uptake and acceptance to the intervention. The description of the intervention was done through the template for intervention description and replication (TIDieR) checklist and guide[8].

The final part of my PhD research was based on pilot testing and evaluation of this TPB based intervention for its feasibility and its effectiveness. The results of this pilot-feasibility study were promising with the outcomes pointing that such a study was feasible in the current setting and definitive trials could be planned in future. The completion rates were healthy with low dropouts. Health workers were capable of screening, health education and follow-up. A structured TPB based educational intervention using various methods and media was accepted and appreciated by patients and the public There was significant improvement in the constructs of TPB -

attitude, subjective norms, perceived behavioural control and in CRD related health behaviour at the end of intervention period, however this was seen in both intervention and control arm. This pilot-feasibility study was not powered to calculate a change in TPB or clinical outcomes, rather to test the feasibility of intervention, which it was able to demonstrate. The community-based feasibility trial was reported as per Consolidated Standards of Reporting Trials (CONSORT)[9].

7.2 New knowledge gained from this research

This research has shown that a theory-driven behaviour change intervention in a low health literate, rural and resource poor population can be implemented. This is a first attempt, to my knowledge, to implement an intervention for behaviour change among patients with chronic respiratory diseases (CRDs). Although TPB-based interventionsve been used successfully in changing health behaviour in other chronic diseases like cardiovascular diseases[6-7] and diabetes[5], they've not so far been tried in CRDs – using health care workers (HCWs). The use of HCWs to screen, refer, educate and follow up chronic respiratory disease patients has not been used in the past; it provides an opportunity in resource poor settings to screen for CRDs in population and improve the detection and early diagnosis. Existing healthcare workers in government settings can be trained to perform these activities without additional burden to the health system. Improving the capability of CRD patients and enabling factors (provision of inhalers and training for their use, breathing exercises) are important determinants of behaviour change in the initial phase which can be sustained through health education.

Based on my work I consider TPB based interventions to be feasible in most settings if developed appropriately, taking account of current beliefs, attitudes, social norms and barriers/facilitators for preventive behaviours. My work also emphasises the importance of formative research in developing TPB based interventions as essential in developing it. However, my work also illustrates the challenges in implementing population based complex interventions and the importance of patient and public involvement in research. Educating patients about CRDs, including treatment, was challenging in our setting – this arose from factors including low health literacy, social prejudice about the disease and its related health behaviour and unavailability of

appropriate healthcare facilities. Recruiting patients for this research and continuing their follow up was labour-intensive; it took many months and a lot of effort by healthcare workers. Nevertheless, this informs us that health education is not a one-time activity but, rather, a continuous process involving multiple methods and media. Similarly, training of the health workers at the beginning and throughout the study duration was important; it maintained the integrity of the interventions and the quality of evidence gathered. Informing the patient and the public through community engagement is a worthwhile investment; not only does it lead to a better acceptance of the intervention but also provides insights into challenges and their solutions. Since patients live with the disease, they are well aware of its problems; they are particularly responsive to simple solutions which are practical and don't impose too great a financial burden. In this research study, we offered question and answer sessions with the doctor specifically on asthma and COPD – this appeared to help in clearing many of the doubts that patients have about this disease, including the benefits in using the prescribed treatments; this led us to develop the specific 'ask-your-doctor' video for them. It was through their suggestion that we started the respiratory wellness clinic for chronic respiratory disease patients on a weekly basis - this facilitated training of doctors and other healthcare personnel associated with this clinic, thereby improving quality of care in the health services we offer at RUHSA. This offered an example of patient and public involvement and partnership in research which translated into health care service.

7.3 Strengths and limitations of my research

This was a challenging project – development and implementation of theory-based interventions in resource-constrained, low-literacy settings requires persistence, and an acceptance that key study elements such as intervention integrity and adherence won't be perfect – the challenge is to deliver interventions to the highest possible standard. There are, nevertheless, several strengths to my study. It drew on the MRC updated guidance[1] framework for developing and evaluating complex interventions. The MRC guidance is a widely used and accepted framework and helps researchers to recognise and adopt appropriate methods to improve the quality of research and maximise the impact of interventions. Using the MRC guidance I developed and tested

the feasibility of this intervention in the context of a LMIC setting on a resource limited, rural and low literate population – this hasn't. to my knowledge, been previously attempted in India. This rigorous framework should help maximise the policy impact for CRDs in India and other LMICs.

In this research I also used an established psychological theory – the Theory of Planned Behaviour for the behaviour change intervention. This is also a very well accepted and effective theory for predicting behaviour and developing behaviour change interventions. However the context /setting was novel as it was applied for the first time in CRD patients and in a LMIC, low-literacy setting. Using this theory helped me to elicit salient behavioural, normative and control beliefs among the patients; attitudes towards the behaviours, subjective norms, perceived behavioural control, prevalent health behaviour of CRD patients. Further, the experience of living with the disease (including the facilitators and barriers to prevention and seeking of appropriate health care) were elicited. All these factors were critical in identifying gaps and developing an appropriate intervention which was culturally acceptable and technically feasible. Using HCWs drawn from the patients' own communities resulted in better acceptance among people and higher diffusion of the educational intervention. Understanding the socio-cultural context, with the assistance of psychological (TPB) theory led to the use of appropriate media and methods for education - like use of question and answer sessions between the doctor and the patient, use of pictorial calendars for training and use of puppet shows for the predominantly low literate population.

This was a mixed methods study which used qualitative aspects and quantitative assessments – using mixed methods carries with it the potential to enrich study outputs and improve the quality of the research. Quantitative methods provided the estimates of the outcomes and qualitative methods provided a more granular understanding of strategies to implement my challenging intervention and arrive at the study's outcomes. Overall both were important in developing and implementing this intervention. Qualitative formative research led to gap analysis of behaviours related to CRD in the community; the quantitative study informed me about the feasibility of the intervention to close these gaps and change health behaviour.

Patient and public involvement / community engagement was critical – It was one of the core strengths of this programme of research; in fact it was a great learning point for me to involve patients and public as partners in research, and I found this aspect of the work especially rewarding. Community engagement from the beginning of the research and throughout was responsible for development of the desired intervention, and its successful implementation. Key community members, patients and public were consulted about the research program and its impact on their lives. CRD patients' experiences were explored and a Community Advisory Committee (CAC) was formed to obtain suggestions throughout the research programme. It was on their suggestion that the research project was converted into a routine primary care service delivery programme at our hospital. To me, this was an example of the translational potential of the work, and, as a researcher, I found this 'sustainability' element of the work most satisfying.

In terms of stakeholder engagement, key policy makers at the state and district level along with physicians and primary care practitioners who treated patients with CRD were invited for a 'brainstorming' session, unravelling the existing challenges in prevention, diagnosis and treatment of CRD and current policy of the government, at the beginning of this research project. It was followed by a continuing medical education programme for training the local practitioners and physicians from government and private sector managing CRD patients in the Vellore district. All stakeholders including the administrators and the RESPIRE central team were apprised of the research and its progress through quarterly reporting. Health care workers and junior staff involved in the project were trained and their performance monitored through review meetings.

In terms of disseminating my findings, to get expert input and balanced interpretation of findings throughout my PhD, I presented my findings at different points in time through Annual Scientific Meeting (ASM) of the RESPIRE network, through poster and oral presentations at conferences and through publications in journals[10-11]. I attended three RESPIRE ASMs, two International Primary Care Respiratory Group (IPCRG) conferences and two European Respiratory Society (ERS) international congresses to present my findings through poster/oral presentations; the input from international researchers during these presentations was invaluable. A final international

conference titled “Prevention, detection and treatment of adult lung disease in resource limited settings in India” was conducted between 4-5 April, 2022 involving policy makers from national and state levels, RESPIRE central researchers and administrators from Edinburgh, pulmonologists, researchers and administrators from our institution to disseminate the findings of the research projects and build a consensus towards health care policy for chronic respiratory diseases.

The research programme has some important limitations, from which I have learned a great deal. There was a degree of contamination of the intervention – extremely difficult to avoid in these challenging settings. it was partly due to diffusion of ideas and exchange of thoughts between the HCWs of the control and the intervention arms and partly due to diffusion among the patients between the two groups. Patients had relatives in other clusters and study information and materials were disseminated inadvertently though enthusiastic patients during family visits. Although it was a cluster (which should minimise contamination), some amount of contamination is inevitable among participants - it could be further minimised by adopting a step wedge cluster design, reducing the impact of information sharing between study subjects – and HCWs.

There was a gap in community engagement and delivery of the TPB educational intervention – it was around two months, due to COVID-19 pandemic and its associated lockdowns. The education had a staggered start as there were still restrictions and a partial lockdown was continuing. However, we were able to restart and continue education in small groups in open spaces following the regulations of social distancing and hygiene.

7.4 Implications for research, policy and practice

There are limited studies of TPB based interventions in chronic disease patients in LMIC settings, and none at all on CRDs. This study establishes the feasibility of TPB interventions in CRD patients, informs researchers on challenges of implementing such an intervention in the context of these settings and emphasises the importance of patient and public involvement. This research provides a template to implement TPB interventions in resource poor settings and in LMICs – ideally other researchers might learn from the challenges (and potential solutions) I faced in this work. Since

this was a pilot feasibility study, further definitive trials with clinical, quality of life and other key endpoints, are required to refine the intervention and validate the results. I hope to obtain funding to address this next step.

This study identified barriers, gaps and challenges in CRD control - both in the community and within the health system. Nevertheless, it provided a framework for improving health behaviour, and showed how these gaps can be addressed by education, community engagement, evidence based diagnosis and treatment - and using HCWs from the local community to improve health behaviour.

Research can have a direct impact on clinical services; my project led to improved quality of care through availability of spirometry for diagnosis and use of evidence based protocols using Global Initiative for Asthma (GINA) and Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for treatment in the local community. Using similar methods to improve quality and scope of healthcare can be useful for practice in primary care.

CRDs are the second most common cause of mortality in our country; however we lack a policy specifically focusing on chronic respiratory diseases, although they are a part of larger NCD programme. My research is a step towards providing evidence to policymakers on building a consensus for policy and advocacy for CRDs in India. Building a policy towards, for example, availability of spirometry for diagnosis, inhalers and spacers for treatment and use of protocols for CRD patient management could have a very important positive impact on CRD burden in India. Further, integrating these approaches into primary care could improve access, acceptability and confidence in health systems and reduce morbidity and mortality from chronic respiratory diseases.

7.5 Conclusion

This was a theoretically based complex intervention in a challenging setting translating the constructs of TPB into actionable measures for changing health behaviour. It was attempted for the first time in a rural low literate population where in the challenges of educating the patient and the community and motivating them to adopt appropriate respiratory health behaviours had to be undertaken with lot of innovative methods

which were transformative and culturally acceptable. However, the community engagement that was undertaken during this research project evolved as one of the strengths of this study and provided us with new insights into behaviour change communication. The primary aim of this research study was to test the feasibility of the intervention in terms of its uptake, integrity of the intervention delivery and acceptance – I feel I achieved these aims, albeit with a lot of challenges along the way.

TPB is a good psychological theory for behaviour change which proved useful in a resource-poor low health literate population using formative research to identify salient health behaviours and barriers and facilitators of such behaviour. However, it has its own limitations and does not cover all levels or aspects where intervention can be more effective in designing behaviour change. For making intervention successful and effective in a time bound way and attain sustainability, some components of newer models need to be incorporated. Components like political will, economic viability and policy frameworks related to the disease and its health behaviour, as used in social - ecological model are important drivers of behaviour change. Similarly physical and psychological opportunity to individuals to perform a behaviour and providing means to improve capability can accelerate behaviour change in individuals and populations, as advocated by the theory of behaviour change wheel. Thus, scope of behaviour change can be improved by incorporating the critical components of psychological theories; although each theory directs behaviour change in a particular way, a more broader approach may be useful for effective behaviour change.

The use of health care workers in delivering the interventions in low resource settings was also a newer approach and it was, I believe, successfully demonstrated through the research project. In settings where resources are limited, and health providers are hard to access, HCWs are a vital resource in the delivery of health interventions. There was substantial improvement in all study subjects in health behaviour in terms of inhaler use, breathing exercises, symptom reduction and improvement in pulmonary function. As I've discussed the absence of differences in clinical outcomes between the two arms was not a key concern, because the study was not powered to capture these differences – rather, it was a feasibility study for testing the implementation of the intervention. Improving the capability of the patients in both the arms, through

provision of free inhalers, training for inhaler use and breathing exercises with some education provided at baseline, was a feature of research – without doubt, there was some contamination of trial arms due to the free exchange of ideas and discussion among study patients and HCWs.

I believe my study sets the scene for further research in the form of definitive trials to validate the findings and show the differences in outcomes of this TPB based intervention. This will require adequate powering of the study and the use of study designs which minimise contamination, while maximising intervention integrity and outcome validity. It has been my privilege to work with some of the most vulnerable communities in India in this project. At present they are, largely, denied access to services which would reduce the burden they suffer from CRDs. Findings from my study add to a growing body of evidence that solutions needn't be costly – rather, holistic, evidence-based interventions, delivered through primary care, can significantly improve the lives of these patients. It's vital that further research is undertaken in these settings – and that findings can influence governments and policy makers in addressing the burden of chronic respiratory disease.

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Dear Biswajit,

RE: NIHR Global Health Research Unit on Respiratory Health (RESPIRE) PhD studentship

Thank you for attending the interview for an NIHR Global Health Research Unit on Respiratory Health PhD studentship based at The University of Edinburgh. I am delighted to offer you a studentship award.

Title of research project: *Lung cancer and chronic respiratory disease: Development and pilot testing of an intervention in a southern Indian rural community (Funding Ref:* 16/136/109*)*
Start date: *1 April 2018*
Length of programme: 3 *years*
Type of attendance/Registration: *full-time*
Location: *Usher Institute for Population Health Sciences and Informatics, The University of Edinburgh*
Supervisors *(Edinburgh)*: *Professor David Weller and Professor Liz Grant; (India): Professor Rita Isaac*

The offer is unconditional on the successful completion of The University of Edinburgh Population Health Sciences PhD programme application process.

As you have secured a studentship award, RESPIRE funding will cover your UoE tuition fees based on the following agreed rates for three years (Year 1: £14,600; Year 2: £15,500; Year 3: £18,000) in addition to a stipend each year based on RCUK rates (currently £14,553) pro-rata during your time in the UK, and associated consumable/research costs. The total cost for fees, stipend and consumables is not to exceed £93,000 over the course of the PhD. If you have any problems with the application process, please contact Melissa Goodbourn (0131 650 4617;) in the first instance.

Please reply to Melissa Goodbourn confirming, as soon as possible, whether you intend to accept this offer of a studentship.

Congratulations on your successful application and we look forward to hearing from you.

Yours sincerely

Professor Igor Rudan

Professor Igor Rudan, MD, DSc, PhD, MPH, HonMFPH
Chair in International Health and Molecular Medicine
Joint Director, Centre for Global Health Research and
WHO Collaborating Centre for Population Health Research and Training
Director of Research, The Usher Institute
Editor-in-Chief, "Journal of Global Health"
College of Medicine and Veterinary Medicine
The University of Edinburgh, Scotland, UK

Email:
Tel: +44 (0)131 650 3210

www.ed.ac.uk/usher/respire
@RESPIREGlobal
RESPIRE@ed.ac.uk

Professor Aziz Sheikh
Usher Institute, University of Edinburgh
Old Medical School
Doorway 3, Teviot Place
Edinburgh
EH8 9AG

4 July 2018

CONFIDENTIAL
Biswajit Paul
58-6B2, Abc Quarters
Christian Medical College Hospital Campus
Vellore
Tamilnadu
India, 632004

Dear Biswajit

RE: NIHR Global Health Research Unit on Respiratory Health (RESPIRE) PhD studentship
Amendment to your RESPIRE funding award letter of 15 February 2018

I am writing to inform you of an amendment to the above letter of award for your PhD studentship. The UoE tuition fees outlined in this letter were: Year 1: £14,600; Year 2: £15,500; Year 3: £18,000.

The tuition fee for Year 3 is incorrect, and your tuition fees should be amended to: Year 1: £14,600; Year 2: £15,500; Year 3: £16,400. All other terms and conditions of your award remain unaffected.

I hope this gives you enough information, but please do contact Rachael Atherton (0131 651 5142;) if you have any questions.

Yours sincerely

Professor Igor Rudan

Professor Igor Rudan, MD, DSc, PhD, MPH, HonMFPH
Chair in International Health and Molecular Medicine
Joint Director, Centre for Global Health Research and
WHO Collaborating Centre for Population Health Research and Training
Director of Research, The Usher Institute
Editor-in-Chief, "Journal of Global Health"
College of Medicine and Veterinary Medicine
The University of Edinburgh, Scotland, UK
Email:
Tel: +44 (0)131 650 3210

THE UNIVERSITY of EDINBURGH

Research Governance
The University of Edinburgh
Queen's Medical Research Institute
47 Little France Crescent
Edinburgh EH16 4TJ
United Kingdom

Tel +44 (0) 131 242 9100

resgov@accord.scot

12th October 2018

Dear Professor Sheihk,

Study Title: RESPIRE - Prevention, detection and treatment of adult lung diseases including lung cancer in a poor, rural population in Tamil Nadu: feasibility study

The University of Edinburgh agrees in principle to act as Sponsor for this project.

Sponsorship is subject to you receiving a favourable ethical opinion from an authorised ethics committee in the countries involved in the study.

Our Sponsor review has determined the project to be low risk and we confirm that a UK based ethical opinion is not required.

As Chief Investigator, you must ensure that the study does not commence until all applicable approvals have been obtained. Following receipt of all relevant approvals, you should ensure that any substantial amendments are reviewed and authorised by the Sponsor prior to submission for applicable approvals.

Yours sincerely,

Chris Coner

Research Governance Coordinator
University of Edinburgh
The Queen's Medical Research Institute
47 Little France Crescent
Edinburgh, EH16 4TJ

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Ethics Committee Registration No: ECR/326/INST/TN/2013 Re Reg-2016 Issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. of India

Dr. George Thomas, M.B.B.S., D. Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. L. Jeyaseelan, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., MA (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

September 21, 2018

Dr Biswajit Paul,
Professor,
Department of RUHSA,
Christian Medical College,
Vellore – 632 002.

Sub: External Research Grant: New Proposal: RESPIRE:
Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community
Dr Biswajit Paul, Employment Number:33299, Professor, RUHSA, Dr. David Weller, James Mackenzie Professor of General Practice, Dean International, E/SE Asia & Australasia, Co-Director, Centre for Population Health Sciences University of Edinburgh Edinburgh, Dr Liz Grant Personal Chair of Global Health and Development, Centre for Global Health Research University of Edinburgh Edinburgh, Dr Rita Isaac, RUHSA.

Ref: IRB: 11383 (OTHER) dated: 27.06.2018

Dear Dr Biswajit Paul,

The Institutional Review Board (**Silver**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community" on June 27th 2018.

The Committee reviewed the following documents:

1. IRB Application format
2. Patient Information Sheet and Informed Consent Form (English and Tamil)
3. Budget
4. Cvs of Drs. Biswajit Paul, David Weller, Liz Grant, Rita Isaac
5. No. of documents 1 – 4.

The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting held on June 27th 2017 at 9.45 am in the New IRB Room, Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Silver, Office of Research, I Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788 E-mail: research@cmcvellore.ac.in

Name	Qualification	Designation	Affiliation
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB, Chennai	External, Clinician
Rev. Dr. T. Arul Dhas	MSc, BD, DPC, PhD(Edin)	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Additional Vice Principal (Research), Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore.	Internal, Clinician
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Clinician
Dr. L. Jeyaseelan	MSc, PhD, FSMS, FRSS	Professor & Head, Biostatistics, Secretary (Research Committee), IRB, CMC, Vellore	Internal, Statistician
Dr. Jacob John	MBBS, MD, MPH	Professor, Community Medicine, CMC, Vellore	Internal, Clinician
Dr. Ashish Goel	MBBS, MD, DM	Professor, Hepatology, CMC, Vellore	Internal, Clinician
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMC, Vellore	Internal, Basic Medical Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert

Ethics Committee Silver, Office of Research, I Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788 E-mail: research@cmcvellore.ac.in

Dr. Prasanna Samuel	MSc, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Mrs. Ilavarasi Jesudoss	M Sc (Nursing)	Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Suceena Alexander	MBBS, MD, DM	Associate Professor, Nephrology, CMC, Vellore	Internal, Clinician
Dr. Shirley David	MSc, PhD	Professor, Head of Fundamentals Nursing Department, College of Nursing, CMC, Vellore	Internal, Nurse
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Administrative Committee's approval is to be obtained for opening the account-head, employing any personnel or purchasing any equipment. The investigator also needs to present to Administrative Committee, the terms and condition of the Funding agency for approval.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board
Christian Medical College, Vellore - 632 002.

IRB: 11383 (OTHER) dated: 27.06.2018

Ethics Committee Silver, Office of Research, I Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788 E-mail: research@cmcvellore.ac.in

MINUTES of the Administrative Committee (AC) meeting

Date: 04.10.2018

140-i/10/18: Approval of budget for the project– Principal

The Administrative Committee approval is sought for the following projects. After discussion, it was

RESOLVED to recommend to the Director / Executive Committee to approve the following projects as per the details given below:

Principal Investigator	Name of the project	Funding Agency	Research /Ethics Committee	Details
Dr. Rita Isaac, -RUHSA	Prevention, detection and treatment of adult lung disease including lung cancer in a poor, rural population in Tamil Nadu: feasibility study	NIHR Global Health Research Unit on Respiratory Health (RESPIRE), University of Edinburg	IRB No. 11381, dt. 27.06.2018	Appendix-II
Dr. Biswajit Paul, -RUHSA	Development and pilot testing of Theory of Planned Behavior based educational intervention to improve knowledge, attitude and health behavior in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community.	RESPIRE (NIHR Global Health Research Unit on Respiratory Health (RESPIRE), University of Edinburgh	IRB Min. No. 11383 dt. 27.06.2018	Appendix-III
Dr. BhavyaBalasubramanya, -RUHSA	Revised Budget: Impact Assessment of Rural Unit for Health and Social Affairs (RUHSA)'s Initiatives on Women's Empowerment. Previous AC Min. No. 73-n/6/18 dt. 01.06.2018	INSEAD Singapore	IRB No. 11256 dt. 28.03.2018	Appendix-IV
Dr. Sathish Kumar T., -Child Health II	A phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group study to Evaluate the safety and efficacy of Denosumab in Pediatric subjects with Glucocorticoid-induced Osteoporosis.	Amgen Technology Pvt. Ltd.,	IRB No. 10766 dt. 19.07.2017	Appendix-V
Dr. Ashish Jacob Mathew, -Clinical Immunology and Rheumatology	Multi-institutional network programme on systemic lupus erythematosus (SLE)-understanding the diversity on SLE	Dept. of Biotechnolgoy (DBT)	IRB No. 10653 dt. 28.03.2018	Appendix-VI

Appendix -III

Externally Funded Research Proposal
AC Approval

Principal Investigator: Dr. Biswajit Paul
Name: Dr. Biswajit Paul
Designation: Professor
Department: RUHSA
Full Title of Project:Development and pilot testing of Theory of Planned Behavior based educational intervention to improve knowledge, attitude and health behavior in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community
Short Running Title: TPB-RESPIRE
Name of funding Agency:RESPIRE (NIHR Global Health Research Unit on Respiratory Health)
Duration of the project: 3 Years
IRB Min No: 11383 dated: 27/06/2018 Animal Ethics Min No: -
Grant No: -
Institutional Account No: Yet to be created
Total budget approved in principle (£46500).

Budget Category :

Designation	No.	Duration Months	Qualification Required	External Salary Scale £	External Salary ScaleINR	Salary Scale	To Be appointed/Budget Savings
A. Personnel							
Stipend for 3rd year @ 1000 pounds / month		3rd year		12000	1143960		
Research Coordinator	1	1 Year		2800	266925		To be appointed
B. Consultation and Honorarium							
Health Aides (Honorarium + Travel)	2	3 years		2160	205913		
C. Travel							
International Travel + Subsistence		3 years		19410	1850355		
Local Travel + investigator + team		3 years		1300	123929		
D. Operational Cost							
Community engagement		3 years		850	81030		
Training for Health Aides		2 years		300	28599		
Translation				100	9533		
Stationary				300	28599		
Development of education materials				2700	257391		
Hardware/Softw are				2450	233558		
Contingencies				930	88657		
Data Management				1200	114396		
E. Equipment: -List equipment required to be purchased to implement this project							
Item(s)						**Amount sanctione**	**Amount sanctioned INR**

	d £	
-	-	-
F. Administrative Cost :		
Item(s)	**Amount sanctioned £**	**Amount sanctioned INR**
Overhead		
Total Amount sanctioned for the pilot phase	£ 46500	**Rs.4432845**

*** No Overheads- Justification letter to be included**
*** Only for Pharmaceutical Study**

Name: Dr. Biswajit Paul,

Signature:
Principal Investigator

Dated: Appendix -IV

Externally Funded Research Proposal AC Approval

Principal Investigator: Dr. BhavyaBalasubramanya Guide : Dr. Rita Isaac, Professor
Name: Dr. BhavyaBalasubramanya
Designation : Assistant Professor II

Department : RUHSA
Full Title of Project : Impact Assessment of Rural Unit for Health and Social Affairs (RUHSA)'s Initiatives on Women's Empowerment
Short Running Title:WoEMP
Name of funding Agency : INSEAD Singapore
Duration of the project: 3 Months
IRB Min No: 11256 dated 28.03.2018 Animal Ethics Min No: -
Grant No: -
Institutional Account No: Yet to be created

Budget Sanctioned :

1. Staff

Designation	No.	Qualification Required	External Salary Scale(Payment made through Self Help Group)	Salary Scale	To Be appointed/Budget Savings
Project Coordinator	1	Existing Staff (Training Officer 20% effort)	Rs. 16000pmx3 Months		Budget saving
Field Worker	3	12^{th} Pass	Rs. 16000pm x3 Months + 3% for SHG (Rs. 4320).		To be appointed
Trainers	3	Any UG Degree	Rs. 20833pmx2 Months		To be appointed

2. Equipment: -

Item(s)	Amount sanctioned(Rs.)
a. -	Rs.
b. -	Rs.

3. Other expenses :

Item(s)	
A Campaign Material	Rs.10000
B Transportation cost	Rs.53000
C Experimental Participant cost	Rs.60000
D Workshop Room Rent / Food	Rs. 55000
E Indirect Model Video	Rs. 32900
Overheads: (10%) (Applicable to all study)*	NA
Goods Service Tax (18%)*	NA
Total Amount	**Rs.532,220**

*** No Overheads- Justification letter to be included**

*** Only for Pharmaceutical Study**

Name:

Signature:
Principal Investigator

Regarding HMSC Decision

icmr@cdac.in

Fri 12-04-2019 12:45

To:Biswajit Paul <drbpaul@cmcvellore.ac.in>;

Dear DR. BISWAJIT PAUL,

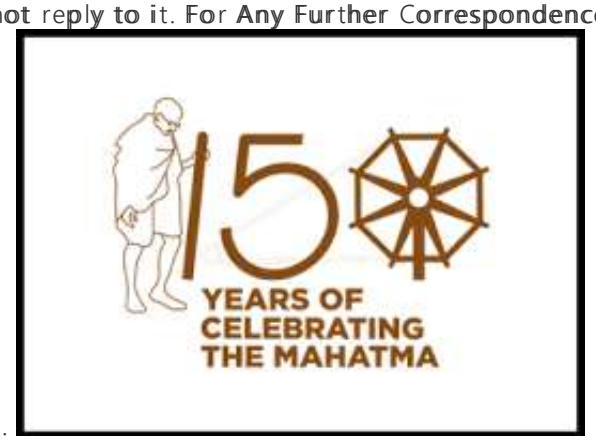
The proposal with proposal id **2018-0706** entitled **DEVELOPMENT AND PILOT TESTING** OF **THEORY OF PLANNED BEHAVIOUR** BASED **EDUCATIONAL INTERVENTION TO IMPROVE KNOWLEDGE, ATTITUDE AND HEALTH BEHAVIOUR IN PEOPLE WITH CHRONIC RESPIRATORY DISEASE: A STUDY IN SOUTHERN INDIAN RURAL COMMUNITY,** was considered during the HMSC meeting held on 13-03-2019 and the decision of the HMSC is as follows:

Approved .

You may now take necessary action at your end to initiate the project and let us know the date of initiation of the project. You are requested to kindly ensure submission of progress report of the project to ICMR.

You are also requested to upload the duly filled in and signed DST project summary sheet and DST check list by logging into your account at http://www.icmrextramural.in/ICMR/ for onward transmission to DST by ICMR.
For any further queries please contact the coordinator, ICMR at 011-26589492

With Regards
ICMR Team.

This is a system generated mail.Please do not reply to it. For Any Further Correspondence please contact only at 

"hmscihdicmr@gmail.com / 011-26589492 ".

Theory of planned behaviour based interventions and health behaviour change in chronic diseases among low health-literacy population: protocol for systematic review

Biswajit Paul, Richard Kirubakaran, David Weller

Citation

Biswajit Paul, Richard Kirubakaran, David Weller. Theory of planned behaviour based interventions and health behaviour change in chronic diseases among low health-literacy population: protocol for systematic review. PROSPERO 2018 CRD42018104890 Available from: http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42018104890

Review question

Can the theory of planned behaviour based interventions be used on patients with chronic diseases in low health literacy settings to change health behaviour?

Searches

The following databases will be searched for relevant studies: MEDLINE, EMBASE, Cochrane Library, PsycINFO, Web of Science, Scopus, CINAHL, ProQuest databases (ProQuest Sociology, ProQuest Social Sciences), Global Index Medicus, JSTOR, Bibliography of Asian Studies and IndMed. We will also search the grey literature through OpenGrey and The Grey Literature Report.

The search was conducted in July-August 2018; the publication period for the search was restricted to 1980 to 2018 and there was no language restrictions.

Types of study to be included

The following study types will be considered for inclusion: randomized controlled trials, quasi-randomized controlled trials and controlled before and after studies. Case-control studies, cohort studies, reviews, case reports, case series and animal studies will be excluded.

Condition or domain being studied

The review looks into the health behaviour of patients with chronic diseases. Since health behaviour like adherence and care seeking are important for symptom free periods, reduction of complications and long term benefits like quality of life and since they pose a serious challenge for the health system, this review looks into theory of planned behaviour (TPB) to see if interventions based on this theory can change health behaviour in low health literacy and low income population groups. This review also will look into the type of interventions used, the specific constructs of TPB that were most helpful, the time period of such interventions and the personnel who administered such interventions.

Participants/population

Participants will include adults over 18 years of age and who have any chronic disease. Healthy population and pregnant women will be excluded for the review.

Intervention(s), exposure(s)

Any educational or health intervention used on individuals or groups which have documented the use of the constructs of theory of planned behaviour i.e. attitude towards the behaviour, subjective norms and perceived behavioural control for changing health behaviour.

Comparator(s)/control

The control groups will have either any health education or treatment as usual without any education. The same group used as control before the administration of TPB based intervention also also be included.

Context

Chronic diseases mostly affect adults and the elderly.

Main outcome(s)

Health behaviour change -

a) Adherence to treatment

b) Care seeking behaviour

Additional outcome(s)

a) TPB constructs influencing health behaviour change

b) Types of interventions

c) Time period of interventions

d) Mode of delivery of intervention

e) Providers of such intervention

Data extraction (selection and coding)

A data extraction form will be developed and standardized and it will be piloted and revised before the start of the review. Data extraction will be performed by two independent reviewers and any discrepancies will be resolved by discussion; if still disagreement persists it will be arbitrated by a third reviewer.

Risk of bias (quality) assessment

Quality and risk of bias for all potential studies will be evaluated using the Cochrane Collaboration's Tool for Assessing the risk of Bias. As per the guidelines in the Cochrane Handbook of Systematic Reviews of Interventions, the studies will be assessed as per standard criteria and will be labelled as 'low', 'unclear' or 'high' risk of bias. For non-randomised trials, we will use the ROBINS-I tool for evaluating the risk of bias.

Two independent researchers will be involved in quality and risk of bias assessment and any disagreement will be resolved through discussion; if no mutual agreement is reached an adjudicator will make the final decision.

Strategy for data synthesis

All the characteristics of included studies will be presented in a tabular form with the description of study design, type of disease, type of intervention used, no. of groups involved, outcomes and methods of assessment and risk of bias in each study. We will do a narrative synthesis of the studies to draw the conclusions. Whether or not we will do a pooled quantitative estimation (meta-analysis) will depend on the type and homogenity of the studies.

Analysis of subgroups or subsets

A sub-group analysis is planned on types of interventions and modes of delivery

Contact details for further information

Biswajit Paul
b.paul-3@sms.ed.ac.uk

Organisational affiliation of the review

University of Edinburgh, UK and Christian Medical College Vellore, India
universityofedinburgh.co.uk

cmcvellore.ac.in

Review team members and their organisational affiliations

Dr Biswajit Paul. University of Edinburgh, UK and Christian Medical College, Vellore
Mr Richard Kirubakaran. Christian Medical College,Vellore
Professor David Weller. University of Edinburgh

Anticipated or actual start date

01 May 2018

Anticipated completion date
31 December 2018

Funding sources/sponsors
No specific funding for this systematic review is received. It was part of the dissertation for the award of PhD in Global Health degree at the University of Edinburgh. The PhD course was supported by NIHR Global Health Research Unit on Respiratory Health (RESPIRE).

Conflicts of interest

Language
English

Country
India, Scotland

Stage of review
Review_Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Chronic Disease; Health Behavior; Health Literacy; Humans; Vulnerable Populations

Date of registration in PROSPERO
17 September 2018

Date of publication of this version
17 September 2018

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

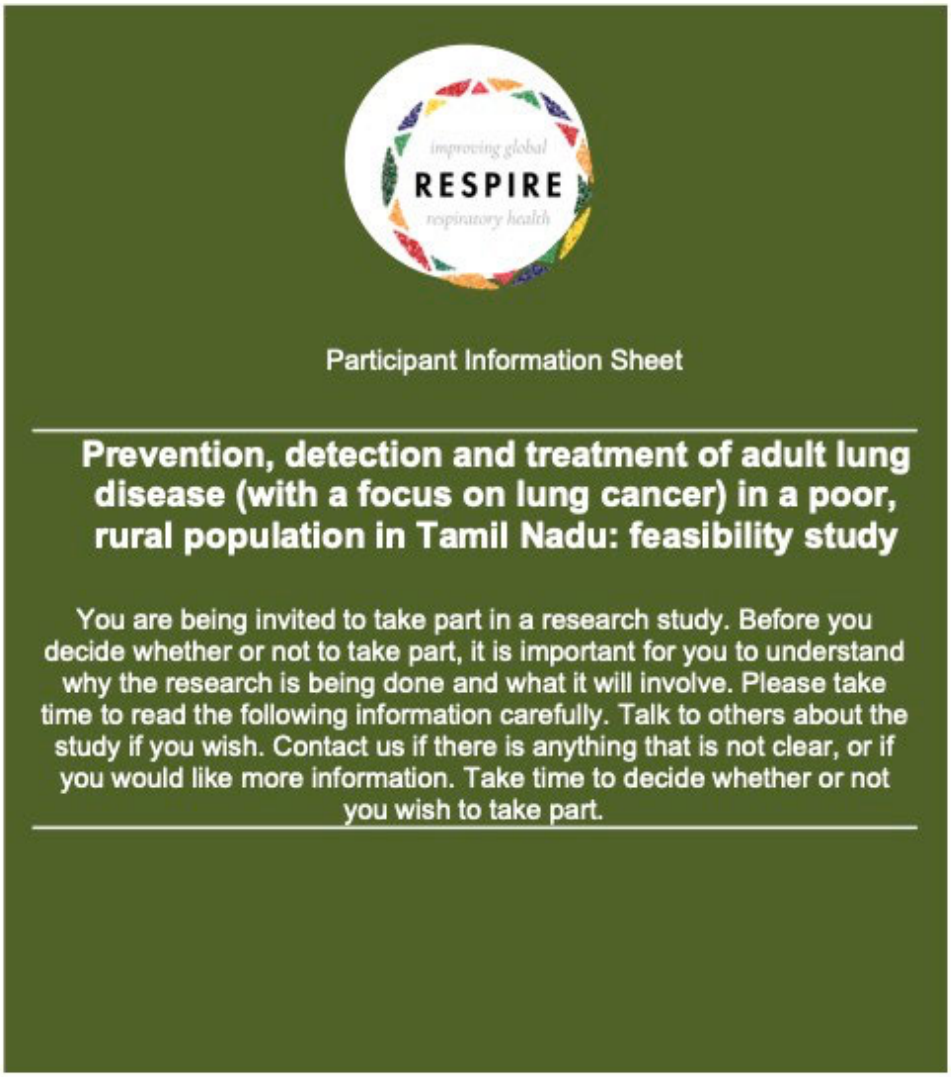
Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Versions
17 September 2018

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Participant Information Sheet and Consent Form



What is the purpose of the study?

Chronic respiratory diseases (CRDs) like asthma and COPD are important public health problems throughout the world and more so in the developing countries. CRDs lead to large number of deaths and disability. Although the respiratory symptoms are common, CRDs are not often diagnosed and

An NIHR Global Health Research Unit on Respiratory Health (RESPIRE) at the University of Edinburgh project.
www.ed.ac.uk/usher/respire
This research was commissioned by the National Institute of Health Research using Official Development Assistance (ODA) funding.
The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.
Funded by NHS National Institute for Health Research

when diagnosed people do not follow the medications and inhalers on a regular basis which leads to worsening of symptoms and poor health.

We are doing this research to understand the factors that facilitate a health behaviour reducing the exposure to risk factors that causes CRDs and comply with the recommended treatment options and demonstrate to patients how they can keep themselves symptom free, reduce the complications of the disease and have a better quality of life. Theory of planned behaviour (TPB) based patient education have shown to cause improvement in health behaviour among people and have led to healthier lifestyles. The TPB based educational intervention that can be delivered by Health Care Worker will be developed by RUHSA, CMC and will be tested in a sample of participants and compare with standard health belief model education in controls. This study will help in knowing whether the TPB based educational intervention delivered by Health Care Worker (HCW) can be successfully implemented among rural population and will be better than the standard health belief model based education to bring about a change in the awareness levels, respiratory disease related behaviour in terms of risk reduction, timely investigation, regular medicine/inhaler use and follow up that will lead to better health outcomes. This study will also help us to know CRD related awareness levels of the people with CRDs in terms of its causes, risk factors, preventive measures, signs and symptoms, complications and treatment options. At the end of the study, this intervention will be tested in larger sample of study participants and will provide a basis for implementing it in similar settings worldwide.

Why have I been invited to take part?

You have been asked to take part as you have been diagnosed with CRD (will mention his/her lung disease) at RUHSA clinic.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

If you agree to participate in this study, you will be required to spend time with the investigator or her/his representatives, the trained health workers and provide general information about yourself and your family and share information related to CRD risk factors and signs& symptoms of your disease. You will also be required to participate in education sessions in groups along with other people who have CRDs wherein a variety of information and demonstrations will be given through different media like puppet shows, videos, plays and narrations providing you with knowledge and avenues to follow correct and regular treatment for CRDs. You will be required to participate in these sessions every three months for a period of one year.

There are no costs associated with your participation. You will be reimbursed half day wages and travel expenses in actuals that may be incurred by you for your visit to the hospital.

Is there anything I need to do or avoid?

There are no special precautions / requirements for participants. You do not need to fast, you're your medications or avoid alcohol.

What are the possible benefits of taking part?

The direct benefits are

- You will be provided with a special educational package which will help them in better managing their disease, reduce their symptoms and improve their health status.
- You will get all the investigations done free of cost, subsidized treatment from the RUHSA hospital and will be followed up with the help of health care worker to make sure they are complying with the treatment.

What are the possible disadvantages of taking part?

By taking part in the study you will have to spend time (1-2 hours) with the health care worker and respond to questions related to socio-economic background and respiratory health. You also need to spend time in groups, attending educational sessions, once in three months for a period of one year to improve your health behaviour related to CRD.

Apart from the time to be spent, there are no other possible disadvantages of taking part in this study.

What if there are any problems?

If you have a concern about any aspect of this study please contact Dr Rita Isaac or Dr Biswajit Paul at the RUHSA hospital or in these telephone numbers - Tel: 04171-246251; Mob: 9300031305 who will do their best to answer your questions

No potential risks to the participants are expected. The proposed research aims to improve the health of patients with CRD and no significant risk is anticipated in the conduct of the study.

What will happen if I don't want to carry on with the study

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study.

If you withdraw,

- You will no longer be attending further research clinics or taking part in any educational sessions
- If you wish that all your data be destroyed, we will extract your data and destroy it, if this is what you request
- Withdrawal for the study will not affect your usual treatment at this hospital in any way.

What happens when the study is finished?

The known Chronic lung diseases patients will be initiated on appropriate treatment and motivated to continue the treatment from the health center of your choice or at RUHSA hospital or CMC main hospital, if so required.

- Their personal data will be anonymised, conceal their identifying information and will be analysed and reports prepared as a part of the study.
- The data will be retained at the centre at least for a period of 3 years
- The data may be shared with our con-investigators and sponsors
- Treatment for the participant will continue as usual
- The data may be used for further studies in the future

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

- Study researchers will ask your permission to access your medical records to carry out this research project.
- Data may be used anonymously in future studies. The ethics committee will be asked for approval for use of the data in present or in future at the beginning of study, during the ethics approval of the project.
- Since the study will take place in India, the data will be stored at the Indian site and shared with our UK co-investigators and sponsors.
- The information will be kept secure by keeping it in a pass-coded database with limited access and using unique identification codes for each participant; the identifying information will be anonymised
- Our statistical team located in our institute has responsibility for looking after the data.
- In order to monitor and audit the study we will ask your consent for responsible representatives from our sponsor(s), the University of Edinburgh, to access your medical records and data collected during the study, where it is relevant to you taking part in this research. The Sponsor(s) is/are responsible for overall management of the study and providing insurance and indemnity.

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

What will happen to the results of the study?

This study will be written up as publication and may also be part of conference proceedings. (publication, conference presentation).

You will not be identifiable in any published results

Who is organising and funding the research?

This study has been organised by the NIHR Global Health Research Unit on Respiratory Health (RESPIRE) and sponsored by University of Edinburgh

RESPIRE is being funded by NIHR, UK

Who has reviewed the study?

The study proposal has been reviewed by the Institutional Review Board, Christian Medical College,Vellore, Tamil Nadu, India.

Ethical approval from the University of Edinburgh has been applied.

We have submitted a 'Stakeholders engagement proposal' to RESPIRE for funding. As part of that proposal we have proposed to involve patients and public to contribute to development of a population based CRD management model.

Researcher Contact Details

If you have any further questions or doubts regarding the study at any time, you can contact the Principal Investigator, Dr. Rita Isaac or her representatives at any time at RUHSA Department, Christian Medical College, Vellore, Tamil Nadu.

Contact Information: Dr Rita Isaac; Dr. Biswajit Paul

Tel: 04171-246251; Mob: 9300031305

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact Dr Biju George, Convenor, Institutional Review Committee, Christian Medical College, Vellore at - biju@cmcvellore.ac.in

Complaints

If you wish to make a complaint about the study please contact:

Dr Biju George, Convenor, Institutional Review Committee, Christian Medical College, Vellore at biju@cmcvellore.ac.in

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Participant ID:		Centre ID (if applicable)	

CONSENT FORM

Prevention, detection and treatment of adult lung disease (with a focus on lung cancer) in a poor, rural population in Tamil Nadu: feasibility study

Please **initial** box

1. I confirm that I have read and understand the information sheet (17 Sept 2018 and Version Number 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care and/or legal rights being affected. ☐
3. (If appropriate) I give permission for the research team to access my medical records for the purposes of this research study ☐
4. (If appropriate) I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from the NHS organisation or other regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
5. (If appropriate) I give permission for my personal information (including name, address, date of birth, telephone number and consent form) to be passed to the Christian Medical College, Vellore and the University of Edinburgh for administration of the study ☐
6. (If appropriate) I agree to my interview being audio/video recorded. Yes ☐ No ☐
7. (If appropriate) I agree to my audio/video recorded interview being transcribed by a third party contractor. Yes ☐ No ☐
8. (If appropriate) I agree to my identifiable data and/or tissue being used for future ethically approved studies Yes ☐ No ☐
9. (If appropriate) I agree to my anonymised data and/or tissue being used in future studies Yes ☐ No ☐
10. (If appropriate) I agree to my General Practitioner being informed of my participation in the study ☐
11. I agree to take part in the above study ☐

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Participant ID:		**Centre ID (if applicable)**	

Name of Person Giving Consent	Date	Signature
Name of Person Receiving Consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record

An NIHR Global Health Research Unit on Respiratory Health (RESPIRE) at the University of Edinburgh project.
www.ed.ac.uk/usher/respire
This research was commissioned by the National Institute of Health Research using Official Development Assistance (ODA) funding.
The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Participant Information Sheet

We invite you to take part in a research study that will help in knowing about the awareness levels, the attitude and the behavior among adults with chronic respiratory diseases (CRDs) like chronic obstructive pulmonary disease and asthma in rural Indian population. CRDs are major public health problems in developing countries and lead to large number of deaths and disability. Although the respiratory symptoms are common, CRDs are not often diagnosed and when diagnosed people do not follow the medications and inhalers on a regular basis which leads to worsening of symptoms and poor health. People behave in a particular way either because of lack of awareness about the disease or its complications; due to current prevailing subjective norms in the society or because of some problems or barriers which prevents them from following healthy practices. All these will be explored through a psychological theory – specifically known as the theory of planned behavior and the inputs will be utilized to develop a special respiratory package, i.e. an educational intervention which will be delivered by the trained health care workers. This study will help in knowing whether an educational intervention in form of Health Care Worker (HCW) delivered special respiratory package can be successfully implemented to these settings to bring about a change in the awareness levels, respiratory behavior of people in terms of regular medicine intake, inhaler use and follow up and provide better health outcomes. At the end of the study this intervention will be tested and will provide a basis for implementing it in similar settings worldwide.

If you take part what will you have to do?

If you agree to participate in this study, you will be required to spend time with the investigator or his/her representatives, the trained health workers and provide general information about yourself and your family and share information related to CRD risk factors and symptoms. You will also be required to participate in groups along with other people who have CRDs wherein a variety of information and demonstrations will be given through different media like puppet shows, videos, plays and narrations providing you with knowledge and avenues to follow correct and regular treatment for CRDs. You will be required to participate in these sessions every three months for a period of one year.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

Are there any study related risks?

There are no anticipated risks related to your participation in the study.

Benefits from the study

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

The participants will be provided with a special educational package which will help them in better managing their disease, reduce their symptoms and improve their health status. They will also be provided with subsidized treatment from the RUHSA hospital and will be encouraged to continue with the process as advised during the special respiratory package.

What happens after the study is over?

The study will help in understanding the awareness levels of the patients with CRDs and how the educational intervention influences their knowledge, behavior and respiratory outcomes. Those who got the special respiratory package will continue to follow what they have learnt and those who got the normal package will be motivated to change over to the special respiratory package to improve their respiratory behavior and outcomes.

Costs: There are no costs associated with participation.

Payment: This educational package will be delivered in your community in the RUHSA peripheral centres and you will not incur travel costs. You will be reimbursed half day wages and travel expenses in actuals that may be incurred by you for your visit.

Will your personal details be kept confidential?

All the personal information will be kept confidential. All identifying information will be removed when the data is analyzed and shared with the investigators.

If you have any further questions or doubts regarding the study at any time, you can contact the Principal Investigator, Dr. Paul or his/her representatives at any time at RUHSA Department, Christian Medical College, Vellore, Tamil Nadu.

Contact Information: Dr Biswajit Paul

Tel: 04171-246251; Mob: 9300031305

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Consent Form

PARTICIPANT'S STATEMENT:
I have read/heard the content of this consent form and have discussed with Dr Isaac or her representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

I understand that I will be informed of any new findings developed during the course of this research study that may affect my willingness to stay in this research study.

I understand that my participation is voluntary. I understand that I may refuse to participate in this study. I also understand that if, for any reason, I wish to discontinue participation in this study at any time, I will be free to do so, and this will have no effect on my future care or treatment by my physicians in this hospital. I have been fully informed of the above-described study with its risks and benefits, and I hereby consent to the procedures set forth above.

I understand that as a participant in this study my identity and my medical records and data relating to this research study will be kept confidential, except as required by law, and except for inspections by Indian governmental regulatory agencies and the study sponsor.

_____ _____

Date Participant's Signature

Or, Thumb Impression _____

I have fully explained to _____ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

_____ _____

Date Principal Investigator or Representative's Signature

Signature or thumb impression of the Witness:

Date: / /

Title of the Research Project: Development and pilot testing of Theory of Planned Behaviour based educational intervention to improve knowledge, attitude and health behaviour in people with Chronic Respiratory Disease: A study in Southern Indian Rural Community

Principal Investigator: Dr Biswajit Paul

Name & Address of the Witness:

Screening questionnaire for health aides (HCWS)

Name	Age	Sex	Area	Address	Phone No	Symptoms: 1. Chronic Cough 2. Wheezing (Noisy Breathing) 3. Breathing Difficulty 4. Chest Tightness 5. Mucus Production 6.Allergy	Duration	Medications: 1.Salbutamol 2.Deriphyllin 3.Montelukast 4.Asthalin C Pap	Risk Factors: 1.History of Smoking 2.Second hand smoking /Passive smoking 3.Tobacco Usage(Eg: Hans) 4.Chula For Cooking 5.Industry Work(Mining) 6.Pesticides Spraying 7.Beedi Rolling 8.Bricklin Worker	Any Previous history of Medical Diagnosis

Screening Questionnaire for health care workers (HCWs) using CRD SYMPTOMS checklist

(Adapted from BOLD and ECHRS questionnaires with permission by the RESPIRE working group)

I. Known COPD or Asthma 1. Yes 2. No

II. Screening potential participants

	Section 2.1: Cough			
1	Q1007	Do you usually cough when you don't have a cold? *[If **no**, skip to Q1008]*	❑ Yes ❑ No	01 02
2	Q1007A	Are there months in which you cough on most days?	❑ Yes ❑ No	01 02
3	Q1007B	Do you cough on most days for as much as three months each year?	❑ Yes ❑ No	01 02
4	Q1007C	For how many years have you had this cough?	❑ Less than 2 years ❑ 2-5 years ❑ More than 5 years	01 02 03
	Section 2.2: Phlegm			
5	Q1008	Do you usually bring up phlegm from your chest, or do you usually have phlegm in your chest that is difficult to bring up when you don't have a cold? [If **no**, skip to Q1009]	❑ Yes ❑ No	01 02
6	Q1008A	Are there months in which you have this phlegm on most days?	❑ Yes ❑ No	01 02
7	Q1008B	Do you bring up this phlegm on most days for as much as three months each year?	❑ Yes ❑ No	01 02
8	Q1008C	For how many years have you had this phlegm?	❑ Less than 2 years ❑ 2-5 years ❑ More than 5 years	01 02 03
	Section 2.3: Wheezing/Whistling			
9	Q1009	Have you had wheezing or whistling in your chest at any time in the last 12 months? *[If **no**, skip to Q1010]*	❑ Yes ❑ No	01 02
10	Q1009A	In the last 12 months, have you had this wheezing or whistling only when you have a cold?	❑ Yes ❑ No	01 02

11	Q1009B	In the last 12 months, have you ever had an attack of wheezing or whistling that has made you feel short of breath?	❑ Yes 01 ❑ No 02
Section 2.4: Breathlessness (Questions from ECRHS II)			
12	Q1010	Do you ever have trouble/difficulty with your breathing? *[If **no**, skip Q1010A -, Q1012D]*	❑ Yes 01 ❑ No 02
13	Q1010A	Do you have this trouble?	❑ Continuously so that your breathing is never, quite right? 01 ❑ Repeatedly, but it always gets completely better? 02 ❑ Only rarely? 03
14	Q1012	Are you troubled by shortness of breath when hurrying on the level or walking up a slight hill?	❑ Yes 01 ❑ No 02
15	Q1012A	Do you have to walk slower than people of your age on level ground because of shortness of breath?	❑ Yes 01 ❑ No 02 ❑ Does not apply 03
16	Q1012B	Do you ever have to stop for breath when walking at your own pace on level ground?	❑ Yes 01 ❑ No 02 ❑ Does not apply 03
17	Q1012C	Do you ever have to stop for breath after walking about 100 yards (or after a few minutes) on level ground?	❑ Yes 01 ❑ No 02 ❑ Does not apply 03
18	Q1012D	Are you too short of breath to leave the house or short of breath on dressing or undressing?	❑ Yes 01 ❑ No 02 ❑ Does not apply 03

Evaluation questionnaire including TPB section

Section A Identifying Information

Section B Socio-demographic Information
Household Information
Pareek's SES scale

Section C TPB questionnaire

Section D HBM questionnaire

RESPIRE FEASIBILITY STUDY PROFORMA

Date: _____/_____/ **2019**

Section A: Identifying Information

Hospital No: ☐☐) ☐☐☐ ☐☐☐

1. Name of the respondent_____
2. Father/husband name(husband name for married women)

   _____
3. Name of the Head of the Household_____
4. Family Index No._____
5. Address:
   a. House No._____
   b. Street Name. _____
   c. Name of the locality_____
   d. Village

      Name_____PSU:_____
   e. Accessible Mobile No. _ _ _ _ _ _ _ _ _ _
   f. Living in the same house since how many years _____ years (completed)
6. Height (in cm) ___ ___ ___
7. Weight (in kg) ___ ___ ___
8. Chronic lung Disease diagnosed _____
9. Duration of disease? _____ years
10. Spirometry done earlier [ ] YES [ ]NO

    If yes, date of spirometry done _____

Section B: Socio-demographic Information

11. Age __ __
12. Sex [ ] Male [ ] Female [ ] Transgender [ ] Do not want to disclose
13. Religion: [ ] Hindu [ ] Muslim \

    [ ] Christian [ ] Any other, mention_____
14. Caste: _____
15. Marital Status:[ ]Currently Married []Widowed [ ]Divorced

[ ] Separated [ ] Deserted [ ] Single

16. Type of Family: [ ] Nuclear [ ] Extended [ ] Joint

17. No. of family members: [ ] Adults [ ] Child/children(<18 years)

18. No. of living rooms in the house __ __

19. **SES status – Uday Pareek Scale updated 2017 (for rural areas)**

Components	Score	Components	Score
Caste		**Social participation**	
Scheduled caste	1	None	0
Lower caste	2	Member of one organization	1
Artisan caste	3	Member of more than one organization	2
Agriculture caste	4	Office holder in such an organization	3
Prestige caste	5	Wide public leader	4
Dominant caste	6	**House**	
Occupation		No house	0
None	0	Hut	1
Labourer	1	Kutcha house	2
Caste occupation	2	Mixed house	3
Business	3	Pucca house	4
Independent profession	4	Mansion	5
Cultivation	5	**Farm house**	
Service	6	No draught animals	1
Education		1-2 draught animals	2
Illiterate	0	3-4 draught animals	4
Can read only	1	5-6 draught animals	6
Can read and write	2	**Material possessions**	
Primary	3	Bullock cart	0
Middle	4	Cycle	1
High school	5	Radio	2
Graduate	6	Chairs	3
And above	7	Mobile phone	4
Land		Television	5

No land	0	Refrigerator	6
Less than 1 acre	1	**Family type**	
1-5 acre	2	Single/nuclear	1
5-10 acre	3	Joint	2
10-15 acre	4	Extended	3
15-20 acre	5	Size upto 5	2
20 and above	6	Any other distinctive features	2

Section C: TPB questionnaire

CRD Related Behaviour

1. Have you ever smoked [ ] Yes [ ] No (if No skip to Q.No:7)
2. Currently do you smoke [ ] Yes [ ] No
3. What do you smoke? [Multiple responses possible]

[ ] Cigarette [ ] Bidi [ ] Hookah

[ ] Cigar [ ] Pipe/Chute [ ] Other, specify _____

4. How often do you smoke? [ ] Daily [ ] No. of days per week [ ] No. of days per month
5. No. smoked per day __ __ __
6. No. of years of smoking __ __ (Include previous smoking history)
7. Do you use the following type of fuel (biomass fuel) for cooking at home? (if no skip to Question No. 8.

(firewood/leaves or straw, bark/dung cakes/saw dust/diesel/kerosene)

[ ] Never [ ] Sometimes [ ] Most of the time [ ] All the time

If biomass fuel used,

7a. Is food cooked on a stove, a chullah or an open fire?

[ ] Stove [ ] Chullah [ ] Open fire

7b.Is the cooking usually done in the house, in a separate building, or outdoors?

[ ] In the house [ ] In a separate building [ ] Outdoors

8.If in an occupation at risk for CRD (quarry worker/cement factory/ sugarcane field worker/loading and unloading clay/ brick kiln worker, other specify……), do you use protective measures?

[ ] Yes [ ] No (if NO skip to Q.No 9)

8a. If yes, specify _____

9. Are you doing any respiratory health exercises to improve your disease? [ ] Yes [ ] No
10. What investigations for your lung condition have you done in the past? [Multiple responses possible]

[ ] None [ ] CBC (blood count) [ ] CXR [ ] SPUTUM test

[ ] MRI/CT CHEST/THORAX [ ] Bronchoscopy

11. What is the treatment you are currently taking? [Multiple responses possible]

[ ] None [ ] Oral allopathic medications [ ] inhalers [ ] AYUSH oral medications

11a. If on medications, list all the medications

[ ] Salbutamol [ ] Deriphylline [ ] Steroids [ ] Asthalin inhaler

[ ] Seroflo inhaler [ ] Ventolin Rotahaler [ ] Duolin [ ] Formoterol

[ ] Duova inhaler [ ] Others _____

Example: How was the weather today?

1. **Too Cold 2.Cold 3. Moderate 4.Hot 5.Too hot**

Behavioural Intention

Perceived likelihood of performing the behaviour

Sl. no		1 Extremely Unlikely	2 Quite unlikely	3 Not sure	4 Quite likely	5 Extremely Likely	NA
1.	To continue treatment as instructed by your doctor even when you feel well						
2.	To take oral medications dailylong-term if recommended						
3.	To take inhalers daily for long period of time if recommended						
4.	(If smoker)To stop smoking within the next three months if your doctor advise so						
5.	(If using biomass fuel) To stop using biomass fuel (firewood/cowdung cakes/ leaves or straw /kerosene) for cooking and change to cleaner option (gas) within the next three months, if your doctor advise so						
6	To seek medical help immediately if you get wheezing or breathlessness						
7	To do all the investigations (blood, x-ray, spirometry, lung scan) recommended by doctor						

8	To do respiratory health exercises if therapist/doctor advise						

Attitude related to CRD

For my disease condition

Sl. No.		1 Extremely Foolish	2 Quite Foolish	3 Not sure	4 Quite Wise	5 Extremely Wise
1	Taking oral medicines daily is					
2.	Regular use of inhalers long-termis					
3.	Learning correct technique of use of inhaler is					
4.	Daily performance of respiratory health exercises to reduce breathlessness is					
5.	Doing blood investigations, x-ray and lung scan is					
6.	Using Siddha/Ayurveda/unani/other AYUSH treatment is					
7.	Doing a breath test (spirometry) early in the disease stage is					
8.	Stopping smoking to reduce the symptom is					
9.	Stopping use of biomass fuel at home to reduce the symptoms is					

Subjective norm

		1 Completely disagree	2 Somewhat disagree	3 Do not disagree or agree	4 Somewhat Agree	5 Completely Agree
1.	My family thinks that for my respiratory illness, I should use allopathic oral medicines only					
2.	My doctor thinks inhalers/rota-halers is better than using oral medicines					
3.	Neighbours think that my disease will spread to others					

4	In my community/village, most people look down upon people using inhalers in public					
5.	My family think that I cannot lead a normal social life because of my illness					
6	My doctor thinks that smoking bidis/cigarettes is responsible for my lung disease					
7.	In my community/village, most people do not think biomass fuels (like firewood/cowdung cakes/ leaves or straw /kerosene) cause lung disease					

Perceived Behavioural control

		1 Not at all sure	**2 Not quite sure**	**3 Neither sure or unsure**	**4 Quite sure**	**5 Completely sure**
1	I am confident that I can take my inhalers and medicines regularly					
2	I can do my breathing exercises daily at least for 20 minutes					
3	I am sure of eating a nutritious meal at least once every day to improve my symptoms					
4	I am confident that I will be able to follow the correct technique of inhaler use					
5	How sure are you that you can stop smoking in the next three months					
6	How sure are you that you can purchase your inhalers for regular use					
7	How sure are you that you can get all the investigations done for your disease even if you have to go to CMC/VELLORE GVMC					

Beliefs related to the constructs (Indirect measures of the constructs)

a. Beliefs Related to attitude (behavioural beliefs and outcome evaluation)
[the individual's beliefs about outcomes or attributes of performing the behavior]

	Behavioural Beliefs	1 Completely disagree	2 Somewhat disagree	3 Neither disagree or agree	4 Somewhat agree	5 Completely agree
1	Taking my prescribed oral medications (inhalers/medicines) for my lung condition will make me symptom free (reduce my breathlessness, wheezing, cough and expectoration)					
2	Regular use of inhalers/rota-halers will make me symptom free (reduce my breathlessness, wheezing, cough and expectoration)					
3	Performing the respiratory exercises will decrease my breathing difficulty					
4	Stigmatizing to use inhalers/rota-halers in public					
5	Taking nutritious food daily can improve my respiratory health					

Outcome evaluation

		1 Extremely low	2 Somewhat low	3 Not low or high	4 Somewhat high	5 Extremely high
1	Scope of myself remaining free of respiratory symptoms is					
2	Likelihood of suffering from the complications of the respiratory disease is					
3	Myself to be able to keep better control of my symptoms is					
4	Myself to be able to use inhalers in public is					
5	Myself to be able to keep healthy is					

b. Beliefs related to subjective norm (normative beliefs and motivation to comply)
[whether important referent individuals approve or disapprove of performing the behavior, weighted by his or her motivation to comply with those referents.]

	Normative Beliefs	1 Definitely should not	2 Maybe should not	3 Not sure	4 Maybe should	5 Definitely Should
1	My family (spouse/children/parents) thinks that I_____ use inhalers					
2	My family thinks that I _____ go for regular medical check up					
3	My doctor thinks that I _____ do breath tests (spirometry), blood tests and lung scan for my lung disease					
4	a) My doctor thinks I _____ stop smoking					
	b) My doctor thinks I _____ stop using biomass fuels					
5	My doctor thinks I _____ do breathing exercises for my respiratory disease					

Motivation to comply

		1 Strongly disagree	2 Somewhat Disagree	3 Neither disagree or agree	4 Somewhat agree	5 Strongly agree
1	When it is a matter of inhaler use I want to do what my family thinks I should do					
2	When it is a matter of regular medical check-up I want to do what my family thinks I should do					
3	I should do my breath tests, blood tests and lung scan if my doctor thinks so					
4	a) If my doctor thinks I should stop smoking, I should do it					

	b) If my doctor thinks I should stop using biomass fuel, I should do it					
5	If my doctor thinks I should do breathing exercises, then I should do it					

C. Beliefs related to perceived behavioural control (control beliefs and power of control factors) [factors outside individual control that may affect intentions and behaviors]

	Control Beliefs	**1 Highly unlikely**	**2 Somewhat likely**	**3 Not sure**	**4 Somewhat likely**	**5 Highly likely**
1	I can arrange enough money for my medications					
2	I will manage time for doing the respiratory exercises					
3	My family responsibilities will not get in my way for regular medical check-up					
4	Once in three months respiratory clinics in my community will help me to comply with the treatment					
5	If correct technique of inhaler use is demonstrated, I will be able to perform it					

Power of control factors

		1 Completely disagree	**2 Somewhat disagree**	**3 Neither disagree or agree**	**4 Somewhat agree**	**5 Completely agree**
1	Having money will enable me to continue my medications					
2	Performing respiratory exercises will decrease my breathlessness					
3	Access to regular assessment and treatment recommendation for my lung disease will help me to lead a symptom free life					
4	Having access to special respiratory clinics will ensure compliance to medications					

5	Demonstration will help me to use the inhaler correctly					

Section D: HBM Questionnaire

Perceived susceptibility [Belief about the chances of experiencing a risk or getting a condition or disease]

1. What do you think is the cause of your lung disease?

   _____

   _____
2. Do you think the disease is spread from others? [0] Yes [1] No
3. Do you think it is inherited? [ ] Yes [ ] No

(In Sec.A Question .8 if it is Asthma Yes -1 and No -0 and if it is COPD & Others Yes - 0 and No - 1)

4. Is your disease common in your village? [1] Yes [0] No
5. Can your lung disease be cured? [0] Yes [1] No
6. Do you think your lung disease could have been prevented? [1] Yes [0] No

   6a. If yes, how? _____

Perceived severity [Belief about how serious a condition and its sequelae are]

1. What do you think about your illness? [Respond choosing the options below]
2. My symptoms will reduce with treatment [1] Yes [0] No
3. My symptoms will persist lifelong despite treatment [0] Yes [1] No
4. My symptoms can become worse as I become older despite treatment

   [0] Yes [1] No
5. I may develop complications like coughing out blood [1] Yes [0] No
6. I may lose weight and become lean [1] Yes [0] No

Perceived benefits [Belief in efficacy of the advised action to reduce risk or seriousness of impact]

1. Persons who totally stop / avoid smoking tobacco products can prevent this disease or improve their symptoms considerably

   [2] Agree [1] Unsure [0] Disagree

2. If biomass fuel use is avoided and instead clean fuels like LPG or electric stove are used, the symptoms will improve in those who have chronic lung disease

   [2] Agree [1] Unsure [0] Disagree

3. People in dusty occupation or environment if they change their jobs or use personal protection gear like face masks can improve their symptoms

   [2] Agree [1] Unsure [0] Disagree

4. Early diagnosis and treatment can control the symptoms

   [2] Agree [1] Unsure [0] Disagree

5. Taking inhalers / rota-halers / nebulization routinely and as directed by the doctor, will be helpful in relieving all respiratory symptoms

   [2] Agree [1] Unsure [0] Disagree

6. Inhalers are used on long term as directed by the doctor will prevent complications in future

   [2] Agree [1] Unsure [0] Disagree

Perceived barriers [Belief about the tangible and psychological costs of the advised action]

1. Stigmatising disease [0] Yes [1] No
2. Not able to get the correct advise on treatment [0] Yes [1] No
3. Treatment I received from the doctors has not relieved my symptoms

   [0] Yes [1] No

4. Family does not approve of taking inhalers [0] Yes [1] No
5. Inhalers are not affordable [0] Yes [1] No
6. Inhalers does not help my condition [0] Yes [1] No

Cues to action [Strategies to activate “readiness”]

1. Where do you get your information regarding disease and treatment [Multiple responses possible]

   [ ] TV [ ] Doctors

   [ ] Health workers [ ] Newspaper

[ ] Neighbours and friends [ ] Pamphlets

[ ] Health education mela or programme [ ] Hospital posters

[ ] Others _____

2. Will reminder system through SMS help you to come for regular check-up?

   [1] Yes [0] No

3. Will home visits by health workers/health aides to educate help you to follow the treatment correctly?

   [1] Yes [0] No

4. Do you mark the next check up on your calendar as a reminder?

   [1] Yes [0] No

5. Can education by health workers/health aides help you to understand about the disease?

   [1] Yes [0] No

செயின்ட் ஜார்ஜின் சுவாசிப்புப் பிரச்சனைகளின் வினாப்பட்டியல் (SGRQ)

எப்படி உங்கள் சுவாசிப்பு உங்களை தொல்லைப்படுத்துகின்றது மேலும் அது எப்படி உங்கள் வாழ்க்கையைப் பாதிக்கின்றது என்பதை மேலும் அதிகம் நமக்கு கற்றுக்கொடுக்க குறிப்பிடும் வகையில் இந்த வினாப்பட்டியல் வடிவமைக்கப்பட்டுள்ளது.
மருத்துவர்களும் செவிலியர்களும் உங்கள் பிரச்சனைகள் என்ன என்று நினைப்பதை விட, உங்கள் நோயின் எந்தக் கூறுகள் மிக அதிகப் பிரச்சனைகளுக்குக் காரணமாக உள்ளன என்பதைக் கண்டறியவே நாங்கள் இதனைப் பயன்படுத்துகிறோம்.

தயவு செய்து கவனமாக நெறிமுறைகளைப் படிக்கவும், ஏதேனும் உங்களுக்குப் புரியவில்லை என்றால் கேட்கவும்.
உங்கள் பதில்களைத் தீர்மானிக்க அதிகம் (அதிக நேரம்) செலவிடாதீர்கள்.

மீதமுள்ள வினாப்பட்டியலை முடிக்கும் முன்:

தயவு செய்து உங்களின் தற்போதைய ஆரோக்கியத்தை எப்படி விளக்குவீர்கள்.அதை ஒரு கட்டத்தில் டிக் என்ற குறியிட்டு காட்டுக:	மிக நன்று	நன்று	சுமார்	மோசம்	மிக மோசம்
	☐	☐	☐	☐	☐

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தொடரும்...

செயின்ட் ஜார்ஜின் சுவாசிப்புப் பிரச்சனைகளின் வினாப்பட்டியல்
பகுதி 1

சென்ற 3 மாதங்களில் ***எந்த அளவுக்கு உங்களுக்கு மார்புப் பிரச்சனை இருந்து வந்தது என்பதை விளக்கும் கேள்விகள்.***

தயவு செய்து *ஒவ்வொரு கேள்விக்கும் ஒரு கட்டத்தில்* குறியிடவும்(✓):

	ஒரு வாரத்தில் அதிக நாட்கள்	ஒரு வாரத்தில் பல நாட்கள்	ஒரு மாதத்தில் ஒரு சில நாட்கள்	மார்புக் கிருமியால் தொற்றி ஒற்றுதல் மட்டும்	இல்லவே இல்லை
1. சென்ற 3 மாதங்களில் நான் இருமினேன்:	☐	☐	☐	☐	☐
2. சென்ற 3 மாதங்களில் எனக்கு இருந்த சளியை நான் இருமி துப்பினேன்:	☐	☐	☐	☐	☐
3. சென்ற 3 மாதங்களில் எனக்கு மூச்சுத்திணறல் இருந்து வந்தது:	☐	☐	☐	☐	☐
4. சென்ற 3 மாதங்களில் எனக்கு மூச்சிரைப்பு தாக்குதல் இருந்து வந்தது:	☐	☐	☐	☐	☐

5. சென்ற 3 மாதங்களில் உங்களுக்கு எத்தனை கடுமையான அல்லது மிகவும் அசவுகரியமான மார்புப் பிரச்சனைத் தாக்குதல் இருந்து வந்தது?

தயவு செய்து *ஒன்றை* குறியிடவும்(✓):

- 3 தாக்குதலுக்கு மேல் ☐
- 3 தாக்குதல் ☐
- 2 தாக்குதல் ☐
- 1 தாக்குதல் ☐
- 0 தாக்குதல் ☐

6. மிக மோசமான மார்புப் பிரச்சனை தாக்குதல் எவ்வளவு நேரம் நீடித்தது?
(உங்களுக்கு மிக கடுமையான தாக்குதல் இல்லை என்றால் கேள்வி எண் 7க்கு செல்லவும்)

தயவு செய்து *ஒன்றை* குறியிடவும்(✓):

- ஒரு வாரம் அல்லது அதற்கு மேல் ☐
- 3 அல்லது அதிக நாட்கள் ☐
- 1 அல்லது 2 நாட்கள் ☐
- ஒரு நாளைக்கும் குறைவாக ☐

7. சென்ற 3 மாதங்களில் ஒரு சராசரியான வாரத்தில் (மிகக் குறைந்த மார்புப் பிரச்சனையோடு) எத்தனை நல்ல நாட்கள் உங்களுக்கு இருந்து வந்தது?

தயவு செய்து *ஒன்றை* குறியிடவும்(✓):

- நல்ல நாட்கள் இல்லை ☐
- 1 அல்லது 2 நல்ல நாட்கள் ☐
- 3 அல்லது 4 நல்ல நாட்கள் ☐
- ஏறத்தாழ தினமும் நல்ல நாளே ☐
- தினமும் நல்ல நாளே ☐

8. உங்களுக்கு மூச்சிரைப்பு இருந்தால் அது காலையில் நீங்கள் எழுந்திருக்கும் பொழுது மிக மோசமாக உள்ளதா?

தயவு செய்து *ஒன்றை* குறியிடவும்(✓):

- இல்லை ☐
- ஆமாம் ☐

தொடரும்...

செயின்ட் ஜார்ஜின் சுவாசிப்புப் பிரச்சனைகளின் வினாப்பட்டியல்
பகுதி 2

பிரிவு 1

உங்கள் மார்புப் பிரச்சனை நிலைமையை நீங்கள் எப்படி விவரிப்பீர்கள்?

தயவு செய்து ஒன்றை குறியிடவும்(✓):

- எனக்கிருக்கும் மிக முக்கியமான பிரச்சனை ☐
- மிக அதிகமான பிரச்சனைகளை எனக்கு ஏற்படுத்துகின்றது ☐
- சில பிரச்சனைகளை எனக்கு ஏற்படுத்துகின்றது ☐
- பிரச்சனை எதுவும் ஏற்படுத்தவில்லை ☐

நீங்கள் எப்போதாவது ஊதிய உத்தியோகத்தில் இருந்திருந்தால்

தயவு செய்து *ஒன்றை* குறியிடவும்(✓):

- ஆகமொத்ததில் என் மார்புப் பிரச்சனை என்னை வேலை செய்ய விடாமல் நிறுத்திவிட்டது ☐
- என் மார்புப் பிரச்சனை என் வேலையில் குறுக்கீடு செய்கிறது அல்லது வேறு வேலைக்கு மாறச் செய்தது ☐
- என் மார்புப் பிரச்சனை என் வேலையைப் பாதிக்கவில்லை ☐

பிரிவு 2

<u>தற்போது</u> என்ன நடவடிக்கைகள் சாதாரணமாக உங்களுக்கு மூச்சுத்திணறலை உணர வைக்கின்றன என்பதைக் குறிப்பிடும் கேள்விகள்.

தயவு செய்து ***ஒவ்வொரு கட்டத்திலும் தற்போது*** உங்களுக்குப் பொருந்துவதில் குறியிடுக(✓):

	சரி	தவறு
அசையாமல் உட்காருதல் அல்லது அசையாமல் படுத்திருத்தல்	☐	☐
உடற் பகுதிகளைக் கழுவுதல் அல்லது ஆடை அணிந்துகொள்வது	☐	☐
வீட்டைச் சுற்றி நடந்து வருதல்	☐	☐
வெளியே சம தரையில் நடத்தல்	☐	☐
படிக்கட்டுக்களில் ஒரு மாடி நடத்தல்	☐	☐
குன்றுகளின் மேல் நடத்தல்	☐	☐
விளையாடுதல் அல்லது உடற்பயிற்சி நடவடிக்கை மேற்கொள்ளுதல்	☐	☐

தொடரும்...

செயின்ட் ஜார்ஜின் சுவாசிப்புப் பிரச்சனைகளின் வினாப்பட்டியல்
பகுதி 2

பிரிவு 3

<u>தற்போது</u> உங்கள் இருமல் மற்றும் மூச்சுத்திணறல் பற்றிய சில கூடுதலான கேள்விகள்.

தயவு செய்து ***ஒவ்வொரு கட்டத்திலும் தற்போது*** உங்களுக்குப் பொருந்துவதில் குறியிடுக(✓):

	சரி	தவறு
என் இருமல் என்னை வருத்துகிறது	☐	☐
என் இருமல் என்னைச் சோர்வடைய செய்கிறது	☐	☐
நான் பேசும்போது மூச்சுத் திணறுகின்றேன்	☐	☐
நான் குனியும்போது மூச்சுத் திணறுகின்றேன்	☐	☐
என் இருமல் அல்லது மூச்சுத் திணறல் என் தூக்கத்தை தொந்தரவு செய்கின்றது	☐	☐
நான் எளிதில் சக்தியிழந்து போய்விடுகின்றேன்	☐	☐

பிரிவு 4

<u>தற்போது</u> உங்கள் மார்புப் பிரச்சனையால் உங்களுக்கு ஏற்படும் பிற விளைவுகள் பற்றிய வினாக்கள்.

தயவு செய்து ***ஒவ்வொரு கட்டத்திலும் தற்போது*** உங்களுக்குப் பொருந்துவதில் குறியிடுக(✓):

	சரி	தவறு
என் இருமல் அல்லது சுவாசம் பொது இடத்தில் நெருக்கடிக்கு உள்ளாக்குகின்றது	☐	☐
என் மார்புப் பிரச்சனை என் குடும்பத்தினருக்கும், நண்பர்களுக்கும் அல்லது அண்டை வீட்டாருக்கும், ஒரு தொந்தரவாக இருக்கின்றது	☐	☐
எனக்கு மூச்சு வராதபோது நான் பயப்படுகின்றேன் அல்லது கிலி அடைகிறேன்	☐	☐
நான் என் மார்புப் பிரச்சனை என் கட்டுப்பாட்டுக்குள் இல்லாததுபோல் உணர்கின்றேன்	☐	☐
என் மார்புப் பிரச்சனை மேலும் நலமாகும் என்று நான் எதிர்பார்க்கவில்லை	☐	☐
என் மார்புப் பிரச்சனையால் நான் பிறரைச் சார்ந்திருப்பவராக அல்லது பயனற்றவராக ஆனேன்	☐	☐
உடற்பயிற்சி எனக்குப் பாதுகாப்பானதாக இல்லை	☐	☐
அனைத்துச் செயல்களை செய்வது மிக அதிகப்படியான முயற்சியாகத் தோன்றுகின்றது	☐	☐

பிரிவு 5

உங்கள் மருத்துவ சிகிச்சை பற்றிய வினாக்கள், நீங்கள் மருத்துவ சிகிச்சை ஏதும் பெறவில்லை என்றால் நேராக பிரிவு 6 க்கு செல்லவும்.

தயவு செய்து ***ஒவ்வொரு கட்டத்திலும் தற்போது*** உங்களுக்குப் பொருந்துவதில் குறியிடுக(✓):

	சரி	தவறு
என் மருத்துவ சிகிச்சை எனக்கு பெரிய அளவில் உதவியாக இல்லை	☐	☐
என் மருத்துவ சிகிச்சையை பொதுஇடத்தில் பயன்படுத்தும்போது நான் நெருக்கடிக்கு உள்ளாகின்றேன்	☐	☐
என் மருத்துவ சிகிச்சையால் நான் விரும்பத்தகாத பக்க விளைவுகளை பெற்றேன்	☐	☐
என் மருத்துவ சிகிச்சை வாழ்க்கையில் மிக அதிகம் குறுக்கிடுகின்றது	☐	☐

தொடரும்...

செயின்ட் ஜார்ஜின் சுவாசிப்புப் பிரச்சனைகளின் வினாப்பட்டியல்

பகுதி 2

பிரிவு 6

இந்த கேள்விகள், உங்கள் நடவடிக்கைகளை உங்களது மூச்சுத்திணறல் எப்படி பாதிக்கின்றது என்பதைப் பற்றியவை.

	தயவு செய்து *ஒவ்வொரு கட்டத்திலும் உங்களது மூச்சுத்திணறல் காரணமாக* உங்களுக்குப் பொருந்துவதில் குறியிடுக(✓): சரி	தவறு
நான் உடற்பகுதிகளைக் கழுவுவதற்கு அல்லது ஆடை அணிந்து கொள்வதற்கு நீண்ட நேரம் எடுத்துக்கொள்கின்றேன்	☐	☐
என்னால் குளிக்கவோ அல்லது தலை முழுகவோ முடியவில்லை அல்லது நான் நீண்ட நேரம் எடுத்துக்கொள்கின்றேன்	☐	☐
நான் பிறரைவிட மெதுவாக நடக்கின்றேன் அல்லது இளைப்பாற நின்றுவிடுகின்றேன்	☐	☐
வீட்டுவேலைகள் போன்ற பணிகளைச் செய்ய அதிக நேரம் எடுக்கிறது அல்லது இளைப்பாறுவதற்காக நான் நிற்க வேண்டியுள்ளது	☐	☐
நான் படிக்கட்டுக்களில் ஒரு மாடி ஏற வேண்டுமானால், மெதுவாகச் செல்ல வேண்டியுள்ளது அல்லது நின்றுவிடவேண்டியுள்ளது	☐	☐
நான் அவசரப்பட்டாலோ அல்லது வேகமாக நடந்தாலோ, நின்றுவிடவேண்டியுள்ளது அல்லது மெதுவாகச் செல்லவேண்டியுள்ளது	☐	☐
குன்றுகளின் மேல் நடத்தல் அல்லது மேடான பகுதிகளில் நடத்தல், பொருள்களை சுமந்து மாடிப்படிகளில் ஏறுதல், களைபிடுங்குதல் போன்ற லேசான தோட்ட வேலை, உல்லாச நடை, கபடி அல்லது கிரிக்கெட் விளையாடுதல் போன்ற வேலைகளை செய்வது என் சுவாசத்தால் கடினமாகிறது	☐	☐
பெரும் சுமைகளைச் சுமத்தல், தோட்டத்தில் மண் அகழ்தல் விரைந்து நடத்தல் (8 கி.மீ. /மணி) டென்னிஸ் விளையாடுதல் அல்லது நீந்துதல் ஆகியவற்றைச் செய்வது என் மூச்சுத்திணறலால் கடினமாகின்றது	☐	☐
மிகக் கடுமையான உடலுழைப்பு, ஓட்டம், மிதிவண்டி ஓட்டுதல், வேகமான நீச்சல் அல்லது கடுமையான போட்டிமிகுந்த விளையாட்டுகளில் பங்கு எடுத்தல் போன்றவற்றை செய்வது என் மூச்சுத்திணறலால் கடினமாகின்றது	☐	☐

பிரிவு 7

உங்கள் மார்புப் பிரச்சனை உங்கள் அன்றாட வேலைகளை <u>சாதாரணமாக</u> எப்படி பாதிக்கின்றது என்பதை நாங்கள் தெரிந்துகொள்ள விரும்புகின்றோம்.

	தயவு செய்து *ஒவ்வொரு கட்டத்திலும் உங்களது மார்புப் பிரச்சனை காரணமாக* உங்களுக்குப் பொருந்துவதில் குறியிடுக(✓): சரி	தவறு
விளையாடுவதை அல்லது உடற்பயிற்சி மேற்கொள்ளுவதை என்னால் செய்ய முடியவில்லை	☐	☐
பொழுதுபோக்கிற்கும் அல்லது கேளிக்கைகளுக்கும் என்னால் வெளியே செல்ல முடியவில்லை	☐	☐
வீட்டைவிட்டு வெளியே கடைக்கு என்னால் செல்ல இயலவில்லை	☐	☐
வீட்டு வேலை செய்ய என்னால் இயலவில்லை	☐	☐
என் படுக்கையைவிட்டோ அல்லது நாற்காலியைவிட்டோ என்னால் வெகு தூரம் நகர இயலவில்லை	☐	☐

தொடரும்...

செயின்ட் ஜார்ஜின் சுவாசிப்புப் பிரச்சனைகளின் வினாப்பட்டியல்

இங்கே, உங்கள் மார்புப் பிரச்சனை உங்களை செய்யவிடாமல் தடுக்கக்கூடிய மற்ற நடவடிக்கைகளின் பட்டியல் உள்ளது. (இவற்றை நீங்கள் () குறியிடக்கூடாது. அவை, உங்கள் மூச்சுத்திணறல் உங்களை பல வழிகளில் எப்படி பாதிக்கலாம் என்பதை உங்களுக்கு நினைவுபடுத்தவே கொடுக்கப்பட்டுள்ளன):

உலாவச் செல்லுதல் அல்லது நாயுடன் உலாவச் செல்லுதல்

வீட்டில் அல்லது தோட்டத்தில் வேலைகள் செய்தல்

உடலுறவு கொள்ளுதல்

வழிபாட்டு இடங்களுக்கு செல்வது, மனமகிழ் மன்றங்கள், விளையாட்டுச் சங்கங்கள், கேளிக்கை விடுதிகள் போன்ற பொழுது போக்கு இடங்களுக்கு செல்வது

மோசமான வானிலையில் வெளியே அல்லது புகை நிறைந்த அறைகளின் உள்ளே செல்வது

குடும்பத்தினர் அல்லது நண்பர்களை பார்த்து வருவது அல்லது குழந்தைகளுடன் விளையாடுவது

தயவு செய்து, உங்களது மார்புப் பிரச்சனை உங்களை செய்ய விடாமல் தடுக்ககூடிய வேறு ஏதேனும் முக்கியமான நடவடிக்கைகள் இருந்தால் இங்கே எழுதவும்:

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உங்கள் மார்புப் பிரச்சனை உங்களைப் பாதிப்பதை எது சிறப்பாக விளக்குகின்றது என்று நீங்கள் நினைக்கின்றீர்களோ அதை இப்பொழுது கட்டத்தில் (ஒரு கட்டத்தில் மட்டும்) குறியிடுகின்றீர்களா:

நான் செய்வதற்கு விரும்புகின்ற எந்த செயல்களை செய்வதிலிருந்து என்னை அது தடுக்கவில்லை ☐

நான் செய்வதற்கு விரும்புகின்ற ஒன்று அல்லது இரண்டு செயல்களை செய்வதிலிருந்து என்னை அது தடுக்கின்றது ☐

நான் செய்வதற்கு விரும்புகின்ற அதிகமான செயல்களை செய்வதிலிருந்து என்னை அது தடுக்கின்றது ☐

நான் செய்வதற்கு விரும்புகின்ற அனைத்து செயல்களையும் செய்வதிலிருந்து என்னை அது தடுக்கின்றது ☐

இந்த வினாப்பட்டியலை பூர்த்தி செய்ததற்கு நன்றி. தயவு செய்து, நீங்கள் முடிக்கும் முன்னர், நீங்கள் எல்லா கேள்விகளுக்கும் பதில் அளித்துவிட்டீர்களா என்று சரி பார்க்கவும்.

1.கடந்த 7 நாட்களில் எப்போது எல்லாம் உங்கள் இன்ஹாலெர்/ உருஞ்சி மருந்தை எடுக்க மறந்திர்கள்?

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

2. உங்கள் இன்ஹாலெர் எடுக்க மறந்துள்ளீர்களா

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

3. நன்றாக உணரும் போது இன்ஹாலெர் எடுப்பதை நிருத்திவிட்டிர்களா

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

4. விடுமுறை நாட்கள் அல்லது வார இருதியில் இன்ஹாலெர் பயன்படுத்துவதை நீருத்திவிட்டிர்களா?

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

5. நீங்கள் சோகமாக அல்லது கவலையாக இருக்கும் இருக்கும்போது இன்ஹாலெர் உபயோக படுத்துவதை நிறுத்தினீர்களா

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

6. நீங்கள் பயத்தினாலோ அல்லது பக்கவிளைவிற்காக இன்ஹாலெர் உபயோகிப்பதை நிறத்துனீர்களா

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

7. உங்கள் உடல் நிலை சரியாக வில்லை என்று என்னதில் இன்ஹாலெர் பயன்படுத்துவதை நீருத்திவிட்டிர்களா?

◯எப்போதும் ◯பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

8. மருத்துவர் சொன்னதை விட குறைந்த அளவு இன்ஹாலெர் பயன்படுத்துகிறீர்களா?

◯ எப்போதும் ◯ பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯ பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

9. உங்கள் அன்றாட வாழ்வில் இன்ஹாலெர் பயன்பாடு தடையாக இருப்பதால் நீங்கள் நீருத்திவிட்டிர்களா?

◯ எப்போதும் ◯ பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯ பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

10. இன்ஹாலெர் வாங்க பிரச்சனை இருப்பதால் நீருத்திவிட்டிர்களா?

◯ எப்போதும் ◯ பாதி வாரத்துக்குமேல் ◯ பாதி நாட்கள்
◯ பாதி நாட்களுக்கு குறைவாக ◯ எப்போதும் இல்லை

11. சிகிச்சை பெருபவர் அவர்களுக்கு பரிந்துரைக்கப்பட்ட மருந்தின் அளவு ஞாபகம் வைத்துள்ளனரா?

◯ இல்லை ◯ ஆம்

12. மருந்தை உள்ளிழுக்கும் முறை

◯ இல்லை ◯ ஆம்

Clinical Assessment and Review Form

RUHSA Hospital

Christian Medical College, Vellore

RESPIRATORY HEALTH RECORD

Name: _____ **Age:** _____ **Gender** ☐

Medical Record #: ☐☐☐☐☐☐☐ **FI NO.** ☐☐☐☐☐☐☐☐

Study ID No. ☐☐☐☐☐☐☐☐

Address:

House No. ……

Street……..

Village……

PSU……..

Date: / /

Diagnosis:

Primary: ……

Severity/complication: ……

History:

☐ Cough → Duration _____

☐ Morning ☐ Night ☐ Intermittent ☐ Constant

☐ Breathing difficulty → Duration _____

☐ Wheezing → Duration _____

☐ Increased Sputum production

☐ Haemoptysis

☐ Exacerbations (No.on an average)

Yearly Monthly ☐ Weekly ☐ Nil ☐

Hospital admissions due to exacerbations during the last 3 months ☐

☐ Other _____

Past History:

☐ Childhood asthma
☐ Recurrent resp. infections
☐ TB → year _____ Treatment 1. Completed 2. Defaulted
☐ Cardiac disease _____
☐ Other _____

Family History:

☐ TB
☐ Asthma
☐ Other allergy _____
☐ Other _____

Social History:

☐ Smoking → years ___ No. / Day _____

Beedi / Cigarette / Other ……(Circle all that apply)

☐ Smoking by household members
☐ Occupation……
☐ Exposures to allergens
  ☐ Household → fuel type _____
  ☐ Environmental _____

☐ Other……..

Treatment History: (Check all that apply)

☐ Oral Bronchodilator
  ☐ Salbutamol ☐ Theophylline ☐ Combo

☐ Inhaled bronchodilator (short-acting)

  ☐ Salbutamol ☐ Ipratropium ☐ Terbutaline ☐ Combo

☐ Inhaled bronchodilator (long-acting)

  ☐ Seroflo ☐ Formanide ☐ …….. ☐ ……..

☐ Inhaled corticosteroids
☐ Oral corticosteroids
☐ Acute ☐ Chronic
☐ O2 Therapy
☐ Hospitalizations
☐ RUHSA ☐ Pvt.
☐ CMC / GVMC ☐ GH

INVESTIGATIONS

Chest X-ray: Date: / /

REPORT

……

……..

……..

Spirometry Date: / /

	Pre best	Post best	% change (Reversibility)
FEV1 / FVC ratio			
FEV1 (L) %			
FVC (L) %			
FET 25-75 (L/S) %			

Other PFTs:

……
……
……
……

Treatment Date:

COPD

Assessment of severity of COPD

Symptom assessment [mMRC Questionnaire (Please tick in the box that applies (One box only)]

Grade 0. I only get breathless with strenuous exercise ☐

Grade 1. I get short of breath when hurrying on the level or walking up a slight hill ☐

Grade 2. I walk slower than people of the same age on the level because of breathlessness, or I have to stop for breath when walking on my own pace on the level ☐

Grade 3. I stop for breath after walking about 100 meters or after a few minutes on the level ☐

Grade 4. I am too breathless to leave the house or I am breathless when dressing or Undressing ☐

ABCD groups COPD assessment

EXACERBATION HISTORY

≥ 2 or ≥ 1 leading to hospital admission	**C**	**D**
0 or 1 (not leading to hospital admission)	**A**	**B**
	mMRC 0-1	mMRC ≥ 2

SYMPTOMS

Spirometric Classification of COPD (Post Bronchodilator FEV1/FVC <0.70)

Stage	Spirometry Findings
Gold I: Mild	FEV1 ≥ 80% predicted
Gold II: Moderate	FEV1 ≥ 50% - < 80% predicted
Gold III: Severe	FEV1 ≥ 30% - < 50% predicted
Gold IV: Very severe	FEV1 < 30% predicted or < 50% predicted plus chronic respiratory failure

Treatment Recommendation:

ASTHMA

GINA assessment of asthma control

A. Asthma symptom control

In the past 4 weeks, has the patient had

- Daytime asthma symptoms more than twice / week? ☐ Yes ☐ No
- Any night waking due to asthma? ☐ Yes ☐ No
- Reliever needed more than twice/week? ☐ Yes ☐ No
- Any activity limitation due to asthma? ☐ Yes ☐ No

Asthma symptom Control		**Level of asthma symptom control**		
In the past 4 weeks, has the patient had:		**Well controlled**	**Partly controlled**	**Uncontrolled**
Daytime asthma symptoms more than twice/week?	☐ Yes ☐ No			
Any night waking due to asthma?	☐ Yes ☐ No	None of these	1-2 of these	3-4 of these
Reliever needed more than twice/week?	☐ Yes ☐ No			
Any activity limitation due to asthma?	☐ Yes ☐ No			

B. Risk factors for poor asthma outcomes

- ☐ High SABA use (>1x200-dose canister/month)
- ☐ Inadequate ICS: ☐ not prescribed ICS; ☐ poor adherence, ☐ incorrect inhaler technique
- ☐ Low FEV1 especially if <60% predicted
- ☐ Higher bronchodilator reversibility
- ☐ Major psychological and socio-economic problems
- ☐ Exposures smoking allergen exposure if sensitized
- ☐ Comorbidities: ☐ obesity ☐ chronic rhinosinusitis ☐ confirmed food allergy
- ☐ Blood eosinophilia (AEC > 500 cells)
- ☐ Pregnancy
- ☐ Ever intubated or in intensive care unit for asthma
- ☐ ≥1 severe exacerbation in last 12 months

ASSESSING SEVERITY OF ASTHMA

Symptoms	☐ ≤2 days/week	☐ >2 days/eek but not daily	☐ Daily	☐ Throughout the day
Night time awakenings	☐ ≤2x/month	☐ 3-4x/month	☐ >1x/week but not nightly	☐ Often 7x/week
Short acting beta, agonist use for symptom control (not prevention of EIB)	☐ ≤2 days/week	☐ >2 days/week but not daily, and not more than 1x on any day	☐ Daily	☐ Several times per day
Interference with normal activity	☐ None	☐ Minor limitation	☐ Some limitation	☐ Extremely limited
Spirometry	☐ FEV1 >80% Predicted	☐ FEV1 >80% Predicted	☐ FEV1 >60% but <80% Predicted	☐ FEV1 <60% Predicted
	☐ FEV1/FVC normal	☐ FEV1/FVC normal	☐ FEV1/FVC reduced 5%	☐ FEV1/FVC reduced >5%
Recommended Rx Step	☐ Step 1	☐ Step 2	☐ Step 3	☐ Step 4 or 5

Treatment Recommendations:

Review No. …… Date:_____

History of the following symptoms during last 3 months:

☐ Cough
☐ Morning ☐ Night ☐ Intermittent ☐ Constant
☐ Breathing difficulty
☐ Wheezing
☐ Increased sputum production
☐ Hemoptysis
☐ Exacerbations (No. on an average) ☐

☐ No. of visits to Emergency Department / Private clinic / Medical shop due to exacerbation

☐ Hospitalization

No. of Hospital Admissions due to RD last 3 months

S.No	Date/Month	Duration	Complications

INVESTIGATIONS

Spirometry Date _____

	Pre best	**Post best**	**% change (Reversibility)**
FEV1 / FVC ratio			
FEV1 (L) %			
FVC (L) %			
FET 25-75 (L/S) %			

PFTs: Other results _____

……

……

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	☐ FEV1/FVC normal	☐ FEV1/FVC normal	☐ FEV1/FVC reduced 5%	☐ FEV1/FVC reduced >5%
Recommended Rx Step	☐ Step 1	☐ Step 2	☐ Step 3	☐ Step 4 or 5

Treatment Recommendations:

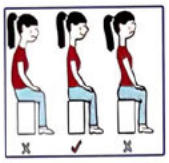
Follow-up date:

Calendar of steps of inhaler use and respiratory exercises

Technique for Using a Metered Dose Inhaler (STEPS)
Checklist for Using Metered Dose Inhaler With Spacer

RESPIRE

1 Stand or sit upright when using your inhaler and spacer



2 Firmly assemble the spacer if needed

3 Uncap mouthpiece and the spacer and check for loose objects in the device.

4 Hold the inhaler upright and shake four or five times.

5 Hold the MDI upright with your index finger on the top of the medication canister and your thumb supporting the bottom of the inhaler and insert into the spacer. You may need to use the other hand to hold the spacer.

6 Breathe out normally through your mouth.

7 Put the mouthpiece between your teeth and close your lips tightly around mouthpiece of spacer to make a tight seal Make sure your tongue does not block the opening of the mouthpiece of the spacer.

8 Press down the top of the canister with your index finger to release the medicine.

9 At the same time, breathe in deeply and slowly through your mouth until your lungs are completely filled; this should take three to five seconds.

10 Hold the medicine in your lungs for about 10 seconds. If you didn't get a full breath or can't hold your breath long enough, you can inhale a second time to fully empty the chamber and hold your breath again for about five seconds.

11 If you need more than one puff, wait about 30 seconds between puffs. Shake canister again before the next puff. Do not load both puffs into the chamber and then empty the chamber with a single inhalation.

12 Remove inhaler from spacer and replace the cap straight away to keep out dust.

Note: 1. If your inhaler contains a steroid medicine (sometimes called glucocorticoid or corticosteroid), rinse your mouth and gargle with water after you use it. Then spit out the water. Do not swallow it.
2. You can use your spacer for more than one medication. Just remove the first MDI and insert the other one.
3. Clean your spacer with warm running water once a week and let it dry completely overnight
4. Clean the inhaler once per week with warm running water and let it dry completely overnight
5. **Prime your inhaler before first time use**

Prime your inhaler if this is the first time you are using it, if you have not used it for several days, or if you have dropped it. Priming a metered dose inhaler usually involves shaking it and spraying it into the air (away from your face) up to 4 times. See the information that came with your inhaler for exact instruction.

Ways to control your breathing
RUHSA Chrisitian Medical College, Vellore

Take a few minutes to feel your breath, put one hand on your stomach and the other hand on your chest and feel. When you have COPD, airway obstruction and loss of lung elasticity traps air inside your lungs. Due to air trapping, breathing muscle is not able to function effectively and you start using other muscles such as neck, ribs and stomach for breathing. This results in developing shortness of breath. Later shortness of breath makes you feel frightened, exhausted, and anxious finally leads to disability. So the important thing is to control your shortness of breath by reducing air trapping. This can be done by medication, breathing exercise and body positions.

We have a simple breathing exercisewith 6 steps to control your shortness of breath:

1) Relax your neck and shoulder muscles

2) Place one hand on your belly just below the ribs and the other hand on the upper part of your chest

3) Breathe in slowly through your nose like you are going to, "smell the roses."

4) "Purse" your lips like you are going to whistle.

5) Breathe out slowly through your pursed lips like you are gently, "blowing out a candle."

6) As you breathe out, you should feel your belly move in.

Rest for 20 seconds before you repeat the next breathing exercise.

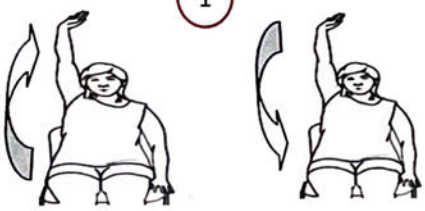
First 10 days	Inhale for 2 counts	Exhale for 4 counts
11 – 20 days	Inhale for 4 counts	Exhale for 8 counts
21 – 30 days	Inhale for 6 counts	Exhale for 12 counts
After 31 days	Inhale for 8 counts	Exhale for 16 counts

With regular practice, this technique will get easier and become part of your everyday breathing.
BUT DO NOT FORCE YOUR LUNGS TO EMPTY

If you find it difficult in doing it in sitting down in a chair then lie down on your back.
These exercises can slow your breathing and help you breathe better. It will:

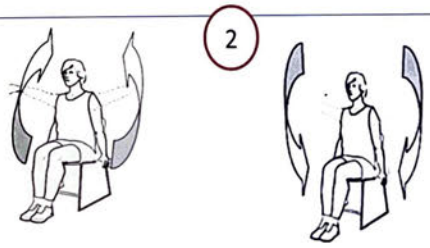
★ Keep your airway open longer. ★ Help you regain control if you have trouble catching your breath.
★ Make it easier to breathe. ★ Move old air out of your lungs and let new air in. ★ Make you feel more relaxed.

1



Sit with your arms relaxed by your side.
Breathe in through your nose.
Breathe out and lift one arm up, reaching to the sky.
Breathe in.
Breathe out and return the arm to the start position.
Repeat with the other arm.
Repeat cycle 3 to 5 times.

2



Sit with arms relaxed by your side.
Breathe in through your nose.
Breathe out through your pursed lips and bring your arms up over your head and try to touch your palms together.
Breathe in.
Breathe out and bring your arms back to the start position.
Repeat 3 to 5 times.

3

Sit with your shoulder relaxed and your arms by your side.
Breathe in through your nose.
Breathe out through your mouth and lift your shoulders up as if trying to touch your ears.
Breathe in.
Breathe out through your pursed lips and relax your shoulders to the start position.
Repeat 3 to 5 times.

4

Sit with your shoulders relaxed and your arms by your side.
Breathe in through your nose and out through your pursed lips in a slow, controlled manner.
Roll your shoulders backwards for 3 to 5 breath cycles.
Repeat rolling your shoulders in a forward direction for 3 to 5 breath cycles.

5

Sit in a relaxed position with both feet flat on the floor.
Breathe in through your nose.
Breathe out through your pursed lips and kick your foot up off the floor.
Breathe in.
Breathe out and lower it back to the start position.
Repeat with the other leg.
Repeat cycle 3 to 5 times.

6

Walk slowly on flat ground with no waving of hands.
Breathe in through your nose and out through your pursed lips in a slow, controlled manner.
Walk for 10 - 15 min