Integrated Care for COPD

**GP and Chronic Disease Community Rehabilitation Service (CDCRS) Partnership Model**

**CONFIDENTIAL**

This document is confidential and the property of the Chronic Disease Community Rehabilitation Service (CDCRS) Northern Sydney Local Health District, the University of Sydney and the University of Wollongong.

No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the Institution.

**STATEMENT OF COMPLIANCE**

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)

**PROTOCOL SYNOPSIS**

|  |  |
| --- | --- |
| Title | Integrated Care for COPD  GP and Chronic Disease Community Rehabilitation Service (CDCRS) Partnership Model of Care |
| Objectives | To assess the acceptability and feasibility of a novel physiotherapy outreach service from the Chronic Disease Community Rehabilitation Service (CDCRS) within Primary and Community Health (PACH) in Northern Sydney Local Health District (NSLHD) to provide an integrated model of GP – CDCRS partnership for the effective identification and management of people with COPD. |
| Study Design | Before and after feasibility study |
| Planned Sample Size | We will recruit four general practices in Northern Sydney to the study.  Based on a physiotherapist available 4 days per week to work in general practice, the maximum number of baseline assessments possible over a six-month period is 192. Therefore it is anticipated that between 150 and 200 people will be assessed. |
| Selection Criteria | Two groups of patients will be identified:   1. Adults aged 40 or over, and have a documented history of smoking (current or former smoker) but not a diagnosis of COPD or receiving treatment for COPD, and they have visited the GP in the last 12 months. 2. Adults aged 40 or over, have a diagnosis of COPD recorded or are taking medications prescribed for COPD, and they have visited the GP in the last 12 months.   Patients will be excluded if they have terminal cancer, cognitive impairment or require home oxygen, do not speak sufficient English or are pregnant. |
| Study Procedures | All participants will undergo a baseline assessment including pre and post bronchodilator spirometry with the physiotherapist. A small sample of patients will be invited to undergo an incremental step test.  ***Existing COPD patients***   * Physical activity (PA) advice using the 5 A’s approach (Ask, advise, assess, assist and arrange follow-up), exercise prescription and pedometer to monitor PA goals. * Referral to exercise rehabilitation if meets requirement. * Patient education and booklet from the Lung Foundation Australia (if required) * A written Lung Foundation Australia COPD action plan. * Smoking cessation advice and referral if necessary.   ***Newly diagnosed COPD***   * Referral to GP for review and medications. * Physical activity advice using the 5 A’s approach, exercise prescription and pedometer to monitor PA goals. * Referral to exercise rehabilitation if meets requirement. * Patient education and booklet from Lung Foundation Australia. * Smoking cessation advice and referral if necessary.   ***Those without COPD on spirometry***   * Physical activity advice using the 5 A’s approach, exercise prescription. * Smoking cessation advice and referral to the GP if necessary   All participants with COPD will attend two follow-up visits with the physiotherapists at 1 and 3 months. |
| Statistical Procedures | Descriptive analyses will be used to evaluate the process outcomes. Paired t-test for significance will be performed to compare patient responses in the baseline and 3 month follow up questionnaires. Data will be analysed using SPSS statistical software with a two-sided significance level set to 0.05.  The interviews with the participating GPs, physiotherapists and patients will be digitally recorded, transcribed verbatim and analysed thematically. The researchers will use NVivo for the qualitative analysis. |
| Duration of the study | 24 months |

# Study Management

* 1. **Principal Investigator**

Dr Sally Wootton, Chronic Disease Community Rehabilitation Service (CDCRS), Northern Sydney Local Health District

* 1. **Associate Investigators**

Associate Professor Sarah Dennis, Discipline of Physiotherapy, University of Sydney

Dr Zoe McKeough, Discipline of Physiotherapy, University of Sydney

Professor Nick Zwar, Faculty of Medicine, University of Wollongong

Dr Andrew Chan, Department of Respiratory Medicine, Royal North Shore Hospital

Dr Sri Mahadev, Department of Respiratory Medicine, Royal North Shore Hospital

* 1. **Funding and resources**

Chronic and Complex Care, Primary and Community Health, Northern Sydney Local Health District.

# INTRODUCTION AND BACKGROUND

* 1. **Background Information**

Chronic obstructive pulmonary disease (COPD) has a significant impact in terms of mortality, hospitalisations and health care costs. In Australia, COPD is a leading cause of death, representing 4.2% of all deaths in males and 3.3% of all deaths in females (1). In 2007-2008, 59,427 Australian hospitalisations were attributed to COPD, with an average length of stay of 7 days, which is over twice the average of all hospital stays (1).

COPD is commonly managed in primary care but the quality of care is mixed

COPD is the 11th most commonly managed chronic condition in general practice with 1 in 100 general practice encounters for COPD management(2). The recently published *COPD-X Concise Guide for Primary Care*, which incorporates best available evidence-based recommendations on the diagnosis and management of COPD, positions general practice as an ideal setting for: (1) case finding and diagnosis confirmation with spirometry; (2) optimising function using a stepwise approach with referral to pulmonary rehabilitation programmes as required; (3) preventing deterioration through smoking cessation and immunisation; (4) chronic care planning including work with clinical support teams to enhance patient quality of life; and (5) managing exacerbations (3).

However, despite best available evidence-based recommendations, COPD remains under-diagnosed and under-treated. Based on the Australian *Burden of Obstructive Lung Disease Study*, a large population-based prevalence study of 1620 men and 1737 women aged ≥40 years, 7.5% met the GOLD Stage II spirometric criteria for COPD, but in the same population only 5.3% were ever diagnosed with COPD by their doctors(4). Among people diagnosed with COPD, management has been suboptimal with:

1. poor adherence to COPD medications, poor inhaler technique;
2. low referral rates to pulmonary rehabilitation programmes;
3. ongoing tobacco smoking and low immunisation rates; and
4. poor management of exacerbations(5).

***Awareness of COPD-X guidelines in primary care is low***

Awareness among GPs of the *COPD-X Guidelines* is low. Surveys conducted for Lung Foundation Australia found only 8.3% of GPs were aware of the guidelines and our surveys of GPs taking part in the *Primary Care Early Intervention for COPD Management* (PELICAN) study (6) found only 27% of the GPs taking part had a copy of the guidelines at baseline (unpublished data). Additionally a recent qualitative study of doctors (seven GPs and nine hospital-based medical practitioners) found that they lacked confidence managing COPD and were unclear about their role particularly surrounding discussions about pulmonary rehabilitation and complex behaviour change (7).

***Spirometry use is suboptimal and interpretation inaccurate***

The *COPD-X Guidelines* recommend spirometry to confirm the diagnosis of COPD (3) but the use of spirometry in general practice is low (8-10). Even when patients do undergo spirometry the diagnosis is frequently incorrect (9, 10). In an Australian study only 58% of patients with a doctor diagnosis of COPD were found to meet the GOLD Stage II spirometric criteria for COPD (11). Initial results from our PELCIAN study have shown that GPs and practice nurses misinterpreted the spirometry in 30% of cases (unpublished data). A recent Australian study explored the use of the COPD Diagnostic Questionnaire (CDQ) as a screening tool for spirometry to improve the diagnostic accuracy. A cut-off of 14.5 on the CDQ had a 96% negative predictive value for confirmation of COPD on spirometry (12). This suggests that the CDQ could be used as a first screen to identify those patients who require spirometry to confirm the diagnosis of COPD.

***Referral to pulmonary rehabilitation is suboptimal***

The *COPD-X Guidelines* recommend pulmonary rehabilitation as a cost-effective way of improving exercise capacity and quality of life for people with COPD (3), yet repeated surveys have shown that referrals to pulmonary rehabilitation from both hospitals (13) and primary care (14, 15) are low. The low referral rates may be due to a lack of capacity in the health system to adequately provide pulmonary rehabilitation, especially in rural and remote areas (16), however, some may be because of poor understanding of the potential benefits. A qualitative study exploring reasons for low rates of pulmonary rehabilitation referral in Australian general practice (14) found many of the GPs interviewed were unfamiliar with the evidence for pulmonary rehabilitation and its effectiveness in the management of COPD. They were unaware of programs in the local area and how to refer to them. Once referred to pulmonary rehabilitation many patients did not attend.(17) Some of the reasons given for non-attendance were related to access (travel and parking) but three studies described the influence of the GP (18-20), with the patient less likely to attend pulmonary rehabilitation when the doctor seemed unsure.

A recent narrative review exploring strategies for improving the management of COPD in primary care found little evidence for the effectiveness of both GPs with a special interest in respiratory medicine or practice nurse COPD clinics at improving outcomes for people with COPD; and recommend further primary-care based trials to explore alternate strategies (21). A randomised controlled trial published since this review found no difference between GP and nurse partnership approach to management of newly diagnosed COPD compared to usual care (22) and that some of the nurses lacked confidence in the management of COPD in spite of additional training (23).

***Physiotherapists are well trained in cardiorespiratory management and increasingly contribute to chronic care management but are underused in primary care***

Physiotherapy students in Australia undertake extensive training in cardiopulmonary physiotherapy at an undergraduate level. This training includes the use and interpretation of spirometry, conducting exercise testing for people with respiratory disease, and exercise prescription within a pulmonary rehabilitation program. It is an expectation that these skills are met as minimum criteria for graduation. As an example, *University of Sydney* graduates experience over 10 hours of academic content in cardiorespiratory management and gain further hands-on experience in their clinical placements. Many physiotherapists who work in the community continue to use their cardiopulmonary skill set to manage people with respiratory diseases in their homes. Physiotherapists are therefore well positioned to work in partnership with GPs to better manage patients with chronic lung disease but are currently underused in this role in primary care. To our knowledge there is no published literature on this GP-physiotherapist partnership model in primary care

* 1. **Research Questions**

What is the acceptability and feasibility of a novel physiotherapy outreach service from the Chronic Disease Community Rehabilitation Service (CDCRS) within Primary and Community Health (PACH) in the Northern Sydney Local Health District (NSLHD) to provide an integrated model of GP–CDCRS partnership?

Research question that the novel physiotherapy outreach service has been designed to address:

Can a novel physiotherapy outreach service from the Chronic Disease Community Rehabilitation Service (CDCRS) within Primary and Community Health (PACH) in the Northern Sydney Local Health District (NSLHD) to provide an integrated model of GP–CDCRS partnership:

* produce high quality spirometry with accurate interpretation to both identify new cases of COPD and determine stage of severity for known cases of COPD?
* increase physical activity levels in people with exiting or newly diagnosed COPD?
* increase general practice referrals to pulmonary rehabilitation for people that meet the *COPD-X Guidelines* criteria for referral?
  1. **Hypothesis**

Our hypothesis is that an integrated model of a GP and CDCRS physiotherapist working in partnership will be feasible and acceptable to physiotherapists, GPs and patients.

The hypothesis that the integrated model of a GP and CDCRS physiotherapist working in partnership result in the following (when tested in a subsequent cluster randomised controlled trial):

* Spirometry meeting the European Respiratory Society (ERS)/American Thoracic Society (ATS) quality criteria with accurate interpretation to both identify new cases of COPD and determine stage of severity for known cases of COPD.
* Improvements in patient self-reported physical activity following completion of a brief assessment of physical activity and provision of information, advice and goal setting for physical activity.
* Referral to pulmonary rehabilitation and increased uptake for those patients that meet the *COPD-X Guidelines* criteria for referral.
* Use of the COPD Diagnostic Questionnaire (CDQ) will reduce the number (%) of negative spirometry results for COPD.
* Use of the incremental step test to assess exercise capacity is feasible.
* Increased smoking cessation in those who are current smokers at baseline.
* Improvements in COPD symptoms using COPD Assessment Test (CAT).
* Improvements in COPD self-management skills using Patient Activation Measure (PAM).
* Reduction in self-reported exacerbations of COPD.
* Reduction in self-reported hospital or emergency department admissions.

# STUDY OBJECTIVES

* 1. **Primary Objectives**
* To determine the acceptability and feasibility of a novel physiotherapy outreach service from the Chronic Disease Community Rehabilitation Service (CDCRS) within Primary and Community Health (PACH) in the Northern Sydney Local Health District (NSLHD) to provide an integrated model of GP–CDCRS partnership.
  1. **Secondary Objectives**
* To produce high quality spirometry with accurate interpretation to both identify new cases of COPD and determine stage of severity for known cases of COPD.
* To increase physical activity levels in people with existing COPD or newly diagnosed COPD.
* To increase general practice referrals to pulmonary rehabilitation for people that meet the *COPD-X Guidelines* criteria for referral.
* To determine if the use of the COPD Diagnostic Questionnaire (CDQ) will reduce the number (%) of negative spirometry results for COPD.
* To increase smoking cessation at three months in those who are current smokers at baseline.
* To improve COPD symptoms at three months as assessed by the COPD Assessment Test (CAT).
* To improve COPD self-management skills at three months as assessed by the Patient Activation Measure (PAM).
* To reduce self-reported exacerbations of COPD at three months.
* To reduce in self-reported hospital or emergency department admissions at three months.
* To determine if it is feasible to perform an incremental step test for exercise capacity in primary care.

# STUDY DESIGN

* 1. **Type of Study**

Before and after feasibility study.

* 1. **Number of Participants**

Four general practices in Northern Sydney will be recruited to the study. Four physiotherapists from CDCRS will spend one day per week each at a general practice. It is anticipated that between 150 and 200 patients will be assessed by the CDCRS physiotherapists during the study.

* 1. **Study sites**

Four general practices in the Sydney North *Primary Health Network* (SNPHN) will be invited to take part in this project.

* 1. **Expected Duration of Study**

The feasibility study will start in April 2017 (once ethics and site specific approvals in place) and end after 24-months in March 2019.

Patient recruitment will take place from May 2017 for approximately six months.

It is anticipated that the three-month follow-up will be complete by the end of January 2018.

* 1. **Primary and Secondary Outcome Measures**

Both process outcomes and patient outcomes will be reviewed to determine the feasibility and acceptability of the intervention. The effectiveness of the integrated model for the GP-CDCRS Physiotherapist partnership for COPD will be determined from process and patient outcomes. It is anticipated that the effectiveness of the integrated model for GP-CDCRS physiotherapy partnership for COPD will be further assessed in a cluster randomised controlled trial, once feasibility has been deteremined.

**Process outcomes**

The process outcomes are listed in the table below. Data will be collected throughout the project period with summaries determined on a three monthly basis with data complete at three months following entry of the final patient.

|  |  |
| --- | --- |
| Existing COPD | New cases of COPD |
| Number (%) with spirometry completed (FEV1 and FVC data) meeting ERS / ATS quality criteria | Number (%) with spirometry completed (FEV1 and FVC data) meeting ERS / ATS quality criteria |
| Number of known COPD patients over 40 years in the general practice | Number of smokers/ex-smokers over 40 years in the general practice |
| Number (%) invited to attend | Number (%) invited to attend |
| Number (%) completed the CDQ | Number (%) completed the CDQ |
| Number (%) attended appointment with physiotherapist | Number (%) attended appointment with physiotherapist |
| Number (%) confirmed diagnosis and severity | Number (%) confirmed diagnosis and severity |
| Number (%) provided physical activity advice | Number (%) provided physical activity advice |
| Number (%) eligible for pulm rehab | Number (%) eligible for pulm rehab |
| Number (%) referred to pulm rehab | Number (%) referred to pulm rehab |
| Number (%) attended pulm rehab | Number (%) attended pulm rehab |
| Number (%) with result of incremental step test | Number (%) with result of incremental step test |

**Patient outcomes**

The patient outcomes are listed in the table below. The data will be collected at baseline and at the three-month follow-up visit with the physiotherapist so level of change in the outcomes following the intervention can be determined. If patients are unable to attend the appointment at three months with the physiotherapist, the research assistant will complete the assessment by telephone.

|  |  |
| --- | --- |
| Existing COPD | New cases of COPD |
| Physical activity score | Physical activity score |
| Meeting physical activity guidelines (Y/N) | Meeting physical activity guidelines (Y/N) |
| Symptom score (CAT) | Symptom score (CAT) |
| COPD Diagnostic Questionnaire (CDQ) score | COPD Diagnostic Questionnaire (CDQ) score |
| Patient activation measure (PAM) | Patient activation measure (PAM) |
| Smoking status | Smoking status |
| Self-reported exacerbations | Self-reported exacerbations |
| Self-reported hospital admission | Self-reported hospital admission |
| Self-reported emergency attendance | Self-reported emergency attendance |
| Result of incremental step test in a sub-sample of patients | Result of incremental step test in a sub-sample of patients |

**Acceptability of the partnership approach**

All the participating GPs and CDCRS physiotherapists will be asked to take part in one semi-structured interview to explore their experiences of providing an integrated model of care for COPD working in partnership primary care. There will be at least four GPs (some practices may have >1 GP involved in the study) and a maximum of four physiotherapists (a CDCRS physiotherapist may work in >1 GP practice) interviewed.

A sample of patients (n = 20) will also be asked to take part in semi-structured interviews to explore their experience of the integrated GP-physiotherapist partnership model of care. All interviews will be digitally recorded and transcribed verbatim in preparation for thematic analysis.

These interviews will inform the revision of the integrated model for COPD in preparation for a larger funding application for a cluster randomised controlled trial. This feasibility process is an essential step in the Medical Research Council guidelines for the development of complex interventions (24, 25).

1. **PARTICIPANT ENROLLMENT**
   1. **Recruitment**

**General practice identification**

Four general practices in the Sydney North *Primary Health Network* (SNPHN) will be identified invited to take part in this project. General practices will be eligible if they use computerised clinical software, have a room available for use by the physiotherapist and are interested in an integrated GP-CDCRS partnership model for COPD management. The practices will be identified that meet the SNPHN strategic directions for integrated care and are close to one of the CDCRS community pulmonary rehabilitation programs. One member of the project team and the research assistant will visit the GPs to discuss the project. A detailed agreement / contract will be prepared between NSLHD and the general practices taking part in the study.

**Physiotherapists**

The CDCRS in Northern Sydney Local Health District will identify four physiotherapists to partner with the four local general practices.

**Patients**

The research assistant will visit the GP practice to assist the practice staff to conduct the search of the electronic records to identify eligible patients. The list will be reviewed by the practice and patients known to be ineligible will be excluded. Letters and a participant information sheet with reply slip will be sent to all potentially eligible patients inviting them to attend for assessment with the CDCRS physiotherapist. Patients without a diagnosis of COPD will also be sent the CDQ with the participant information sheet and reply slip. The research assistant or the practice reception staff will make an appointment with the CDCRS physiotherapist for those patients who express an interest in the study by returning the reply slip or by directly contacting (in person or via telephone) the GP practice. Patients will be excluded if they are unable to understand English sufficiently to complete study questionnaires or procedures, or have cognitive impairment (as assessed by the nurse or GP).

The GP-CDCRS physiotherapist integrated model of care will target two groups of patients:

***New cases of COPD:*** Patients will be identified if they have attended the practice at least twice, with at least one visit in the preceding 12 months, are aged 40 or over, and have a documented history of smoking (current or former smoker) in their medical notes. A history of current smoking or past smoking will identify those patients who are at high risk of developing COPD. This inclusion criteria has been used in a previous primary care COPD case finding study (22, 26). Patients will be asked to complete the CDQ. They will be eligible for assessment if they have a score of 14.5 or more on the CDQ (6, 12).

Existing COPD: Patients will be eligible if they are aged 40 or over, have a diagnosis of COPD recorded or are taking medications prescribed for COPD (such as inhaled β2 agonists, inhaled corticosteroids, ipratropium bromide, tiotropium, oral theophylline and oral corticosteroids), and they have visited the GP in the last 12 months. Potentially eligible patients will be identified from a search of the practice electronic records of all participating general practices. Patients will be excluded if they have terminal cancer, cognitive impairment or require home oxygen. This method of patient identification has been used in a previous study (11).

Incremental step test: Patients will be eligible if they are aged 40 and over with a diagnosis of COPD.

No history of infection or exacerbation of COPD in the last 3 months and able to walk without an assistive device. The step test is being conducted by a University of Sydney Physiotherapy Honours student under the supervision of the physiotherapist working in ***one*** of the general practices. Only those patients attending that particular practice will be invited to take part.

**Eligibility Criteria**

* + 1. **Inclusion Criteria**

New cases of COPD

Patients will be eligible for inclusion if they:

* have attended the practice at least twice, with at least one visit in the preceding 12 months,
* are aged 40 or over,
* have a documented history in their medical notes of smoking (current or former smoker), and
* have a score of 14.5 or more on the CDQ.

Existing COPD

Patients will be eligible for inclusion if they:

* are aged 40 or over,
* have a diagnosis of COPD recorded or are taking medications prescribed for COPD (such as inhaled β2 agonists, inhaled corticosteroids, ipratropium bromide, tiotropium, oral theophylline and oral corticosteroids),
* have visited the GP in the last 12 months.

Participants for the incremental step test

Patients will be eligible to take part in the incremental step test if they:

* are aged 40 and over with a diagnosis of COPD,
* have no history of infection or exacerbation of COPD in the last 3 months,
* able to walk without an assistive device.
  + 1. **Exclusion Criteria**

Patients will be excluded if they have terminal cancer, cognitive impairment or require home oxygen, do not speak sufficient English or are pregnant.

# Informed Consent Process

All participants will be required to provide written informed consent to participate in the project evaluation and to take part in an interview about their experience in the study. All GPs and physiotherapists that have taken part in the study will give their written informed consent to take part in the semi-structured interview about their experience in the study.

* 1. **Participant Withdrawal**

All GPs, CDCRS physiotherapists and participants will be able to withdraw from the study at any time.

# STUDY VISITS AND PROCEDURES SCHEDULE

* 1. **Baseline assessment**

The participant will attend for a baseline assessment with the CDCRS physiotherapist. This assessment will include the following:

Self-report (demographic and health status) questionnaire: this questionnaire will collect data on demographic characteristics, co-morbidities, medication use and smoking status. Participants will also be asked, if in the last six months, whether they recall having spirometry, being referred / attending exercise rehabilitation, receiving advice about physical activity, smoking cessation, flu vaccination, having their inhaler technique checked, having a COPD action plan and whether they were admitted to hospital or an emergency department for their breathing.

Spirometry: The physiotherapist will perform a baseline pre- and post- bronchodilator spirometry, funded using the GP Medicare item for spirometry (Item number 11506).

Symptoms: This will be assessed using the COPD Assessment Test (CAT).

Participant self-management: This will be assessed using the Participant Activation Measure (PAM).

Physical activity: This will be assessed using the Active Australia questionnaire and assessment of stage of change for physical activity.

Inhaler technique will be reviewed.

Exercise capacity A sub-sample of participants will undergo an Incremental Step Test (IST), which will involve subjects stepping up and down on a wooden bench, 20 cm in height, 40 cm in width, and 60 cm in depth. The stepping rate is dictated by an audio signal, with the initial rate starting at 10 steps/min, increasing by one-step every 30 seconds until the subject is unable to tolerate the workload. Subjects will be attached to an O2 Saturation monitor in order to monitor their O2 desaturation.

* 1. **Intervention of an action plan**

The physiotherapist will initiate a new COPD-specific GP Management Plan (GPMP) and Team Care Arrangement (TCA) for the participant, using the template developed for the PELICAN study (22) or review an existing GPMP. The GPMP and TCA will detail problems identified in the assessment and the plan for action including details of specific management such as:

Existing COPD

* + Physical activity advice using the 5 A’s approach (Ask, advise, asses, assist and arrange follow-up), exercise prescription and pedometer to monitor PA goals.
  + Referral to exercise rehabilitation if meets requirement.
  + Participant education and booklet from Australian Lung Foundation (if required)
  + A written COPD action plan.
  + Smoking cessation advice and referral if necessary.

Newly cases of COPD

* + Referral to GP for review and medications.
  + Physical activity advice using the 5 A’s approach, exercise prescription and pedometer to monitor PA goals.
  + Referral to exercise rehabilitation if meets requirement.
  + Participant education and booklet from Australian Lung Foundation.
  + Smoking cessation advice and referral if necessary.

Those without COPD on spirometry

* + Physical activity advice using the 5 A’s approach, exercise prescription.
  + Smoking cessation advice and referral to the GP if necessary.

It is anticipated that the number of people at risk of COPD subsequently identified to not have COPD will be minimized by using the CDQ to identify those with a score of 14.5 or more before attending for assessment with the physiotherapist. This has been demonstrated to have 96% negative predictive value for a diagnosis of COPD confirmed with spirometry (12). This will better target the use of spirometry in these participants and make more effective use of the physiotherapists’ time.

The CDCRS physiotherapist will forward the GPMP and TCA to the participant’s GP, and discuss the assessments and the management plans from the respiratory clinic that day. The discussion will highlight the problems identified and the roles of the members of the team to ensure a GPMP is complete and comprehensive. The GP will update the GPMP and TCA, and provide the participant with a written COPD action plan.

* 1. **Follow up assessment**

Participants with existing or newly diagnosed COPD will return for a follow-up visit with the physiotherapist at 1 month to monitor progress towards physical activity goals and at 3 months to complete a final assessment. The GP will be provided with the updated GPMP and TCA. If additional physiotherapy interventions are required they can be negotiated as part of the TCA.

At the three month assessment the following will be completed:

Self-report (demographic and health status) questionnaire: this questionnaire will collect data on medication use and smoking status. Participants will also be asked, if in the last three months, whether they were admitted to hospital or an emergency department for their breathing.

Symptoms: This will be assessed using the COPD Assessment Test (CAT).

Participant self-management: This will be assessed using the Participant Activation Measure (PAM).

Physical activity: This will be assessed using the Active Australia questionnaire and assessment of stage of change for physical activity.

Inhaler technique will be reviewed.

# ADVERSE EVENT REPORTING

It is unlikely that participants will experience adverse events. There is a chance that they might feel light headed after performing spirometry. This will be explained to the participants and the physiotherapist will observe the participant carefully. There is a chance that participants might feel short of breath or light headed during the exercise capacity test (incremental step test). Participants will be monitored with an oxygen saturation monitor. The physiotherapists are very experienced senior cardiorespiratory physiotherapists and monitor participants careful and record if adverse events occur.

# STATISTICAL METHODS

Descriptive analyses will be used to evaluate the process outcomes. Paired t-test for significance will be performed to compare participant responses in the baseline and 3 month follow up questionnaires. Data will be analysed using SPSS statistical software with a two sided significance level set to 0.05. The interviews with the participating GPs, PNs and physiotherapists will be digitally recorded, transcribed verbatim and analysed thematically.

The researchers will use NVivo for the qualitative analysis. The interview transcripts will be coded using the Theoretical Domains Framework (27, 28). This is a framework that is used in implementation research and contains 14 domains relating to clinician behaviour and attitudes. The investigators have previously used this framework to understand the clinician experiences in implementing complex interventions for COPD in primary care (23).

* 1. **Sample Size Estimation**

We will recruit four general practices to the study. Based on data from our previous COPD study we anticipate the practices will identify 150 potentially eligible participants with a diagnosis of COPD 11, 50% participation (75 participants are likely to consent to take part in the study) and 85% repeat participation (64 participants are likely to complete the follow up questionnaire).

Based on Pelican data, 612 participants will be identified who are at risk of COPD but without a current diagnosis. Of these, 104 (17%) will attend for spirometry and assessment and 18 (17.5%) of these participants will receive a new diagnosis of COPD (22).

Therefore it is anticipated that 250 people will be assessed during the course of this feasibility study.

# DATA MANAGEMENT

* 1. **Data Collection**

The data will collected by the physiotherapists at baseline and three month assessment using the prepared data collection questionnaires.

* 1. **Data Storage**

Data will be entered on the University of Sydney RedCap site by the research assistant. Only the project team will have access to this password protected secure database. Interviews with GPs, physiotherapists and participants will be digitally recorded and transcribed by professional transcription service. The transcripts will be de-identified and stored on a University of Sydney password protected computer. The digital recordings will be deleted once the transcriptions have been checked.

* 1. **Data confidentiality**

All data entered will be de-identified, no records will be identifiable in the RedCap database. The de-identified data will be coded with a participant number. The master file of coded participant numbers will be kept in a locked filing cabinet in the general practice to which they belong. Results will be presented in the final report publication in a way that none of the participants can be identified.

* 1. **Study Record Retention**

Data collected as part of this feasibility will be retained for a minimum of 5 years post study completion as required (29).

# ADMINISTRATIVE ASPECTS

* 1. **Independent HREC approval**

This study has been approved by the Northern Sydney Local Health District HREC, reference number: HREC/16/HAWKE/434.

* 1. **Amendments to the protocol**

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

* 1. **Participant reimbursement**

Participants will not be reimbursed for their time in the study.

* 1. **Financial disclosure and conflicts of interest**

There are no conflicts of interest.

# USE OF DATA AND PUBLICATIONS POLICY

The results of this project will be submitted for presentation at the RACGP Annual conference, the Primary Health Care conference organised by PHCRIS, the Australian Physiotherapy Association conference and the Thoracic Society of Australia and New Zealand. The results will also be submitted for publication in an appropriate peer reviewed journal. The results of this project will be essential in the development of a larger research proposal for an NHMRC Partnership or Project grant. All participants will be provided with a plain language summary of the findings.

# REFERENCES

1. Australian Institute of Health and Welfare. Australia’s health 2010. Canberra: AIHW; 2010. AUS 122.

2. Britt H, Miller GC, Henderson J, Bayram C, Valenti L, Harrison C, et al. A decade of Australian general practice activity 2004–05 to 2013–14. Sydney: Sydney University Press; 2014.

3. Michael Abramson, Alan J Crockett, Eli Dabscheck, Peter A Frith, Johnson George, Nicholas Glasgow, et al. The COPD-X Plan: Australian and New Zealand Guidelines for the management of Chronic Obstructive Pulmonary Disease 2014;V2.38.

4. Brett G Toelle, Wei Xuan, Tessa E Bird, Michael J Abramson, David N Atkinson, Deborah L Burton, et al. Respiratory symptoms and illness in older Australians: the Burden of Obstructive Lung Disease (BOLD) study. Med J Aust. 2013;198(3):144-8.

5. Ta M, George J. Management of chronic obstructive pulmonary disease in Australia after the publication of national guidelines. Internal Medicine Journal. 2011;41(3):263-70.

6. Bunker J, Reddel H, Dennis S, Middleton S, Van Schayck CP, Crockett A, et al. A pragmatic cluster randomized controlled trial of early intervention for chronic obstructive pulmonary disease by practice nurse-general practitioner teams: Study Protocol %U <http://www.implementationscience.com/content/7/1/83>. Implementation Science. 2012;7 %@ 1748-5908(1 %M doi:10.1186/1748-5908-7-83):83.

7. Johnston KN, Young M, Grimmer-Somers KA, Antic R, Frith PA. Why are some evidence-based care recommendations in chronic obstructive pulmonary disease better implemented than others? Perspectives of medical practitioners. International Journal of Chronic Obstructive Pulmonary Disease. 2011;6:659-67.

8. Walters JA, Hansen EC, Johns DP, Blizzard EL, Walters EH, Wood-Baker R. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of COPD. Thorax. 2008;63(5):408-14.

9. Miravitlles M, de la Roza C, Naberan K, Lamban M, Gobartt E, Martin A. Use of spirometry and patterns of prescribing in COPD in primary care. Respiratory Medicine.101(8):1753-60.

10. Joo MJ, Au DH, Fitzgibbon ML, McKell J, Lee TA. Determinants of Spirometry Use and Accuracy of COPD Diagnosis in Primary Care. Journal of General Internal Medicine. 2011;26(11):1272-7.

11. Nicholas A Zwar, Oshana Hermiz, Elizabeth Comino, Sandy Middleton, Sanjyot Vagholkar, Wei Xuan, et al. Care of patients with a diagnosis of chronic obstructive pulmonary disease: a cluster randomised controlled trial. MJA. 2012;197(7):394-8.

12. Stanley AJ, Hasan I, Crockett AJ, van Schayck OCP, Zwar NA. COPD Diagnostic Questionnaire (CDQ) for selecting at-risk patients for spirometry: a cross-sectional study in Australian general practice. Npj Primary Care Respiratory Medicine. 2014;24.

13. Jones SE, Green SA, Clark AL, Dickson MJ, Nolan A-M, Moloney C, et al. Pulmonary rehabilitation following hospitalisation for acute exacerbation of COPD: referrals, uptake and adherence. Thorax. 2014;69(2):181-2.

14. Johnston KN, Young M, Grimmer KA, Antic R, Frith PA. Barriers to, and facilitators for, referral to pulmonary rehabilitation in COPD patients from the perspective of Australian general practitioners: a qualitative study. Primary Care Respiratory Journal. 2013;22(3):319-24.

15. Xavier Perez , Juan P. Wisnivesky, Linda Lurslurchachai, Lawrence C. Kleinman, Ian M. Kronish. Barriers to adherence to COPD guidelines among primary care providers. Respiratory Medicine. 2012;106:374e81.

16. The Australian Lung Foundation. Improving access to proven self-management therapies for effective chronic disease management. Pulmonary rehabilitation: an Illustration.; 2008.

17. Keating A, Lee A, Holland AE. What prevents people with chronic obstructive pulmonary disease from attending pulmonary rehabilitation? A systematic review. Chronic Respiratory Disease. 2011;8(2):89-99.

18. Fischer M, Scharloo M, Abbink J, Thijs-Van A, Rudolphus A, Snoei L, et al. Participation and drop- out in pulmonary rehabilitation: a qualitative analysis of the patient’s perspective. . Clin Rehabil. 2007;21:212-21.

19. Arnold E, Bruton A, Ellis-Hill C. Adherence to pulmonary rehabilitation: a qualitative study. Respir Med 2006. 2006;100:1716-23.

20. Harris D, Hayter M, Allender S. Improving the uptake of pulmonary rehabilitation in patients with COPD: qualitative study of experiences and attitudes. . Br J Gen Pract 2008. 2008;58:703-10.

21. Josephine M Cranston, Alan J Crockett, John R Moss, Robert W Pegram, Nigel P Stocks. Models of chronic disease management in primary care for patients with mild-to-moderate asthma or COPD: a narrative review. MJA. 2008;188(8 Suppl):S50-S2.

22. Zwar N, Bunker J, Reddel H, Dennis S, Middleton S, van Schayck O, et al. Early intervention for chronic obstructive pulmonary disease by practice nurse and GP teams: a cluster randomised trial. Family Practice. 2016.

23. Sarah Dennis, Helen Reddel, Sandy Middleton, Iqbal Hasan, Oshana Hermiz, Rosemary Phillips, et al. Barriers and outcomes of an evidence based approach to diagnosis and management of chronic obstructive pulmonary disease (COPD) in Australia: a qualitative study. Family Practice. 2016.

24. Peter Craig, Paul Dieppe, Sally Macintyre, Susan Mitchie, Irwin Nazareth, Mark Petticrew. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.

25. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. BMJ. 2007;334(7591):455-9.

26. Bunker J, Reddel H, Dennis S, Middleton S, Van Schayck C, Crockett A, et al. A pragmatic cluster randomized controlled trial of early intervention for chronic obstructive pulmonary disease by practice nurse-general practitioner teams: Study Protocol. Implementation Science. 2012;7(1):83.

27. French S, Green S, O'Connor D, McKenzie J, Francis J, Michie S, et al. Developing theory-informed behaviour change interventions to implement evidence into practice: a systematic approach using the Theoretical Domains Framework. Implementation Science. 2012;7(1):38.

28. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Science. 2012;7(1):37.

29. National Health and Medical Research Council. National Statement on Ethical Conduct in Human Research (updated May 2015) 2007 [Available from: <https://www.nhmrc.gov.au/book/national-statement-ethical-conduct-human-research>.