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**1. Project Title**

Chronic Obstructive Pulmonary Disease (COPD) management at home to reduce emergency department presentations: a randomised controlled, feasibility trial

**Short Title**: COPD at Home Service

**2. Research Personnel**

**Coordinating Principal Investigator**

Mrs Karen Royals

Clinical Practice Consultant, Respiratory Chronic Disease Nurse,
The Queen Elizabeth Hospital, South Australia

Business phone: 08 8133 4060 OR 0401678250

Email: karen.royals@sa.gov.au

**Principal Investigator**

1. Professor Brian Smith
Director, Respiratory Medicine Unit, Director Clinical Practice Unit,
The Queen Elizabeth Hospital, South Australia
Business phone: 08 8222 7966
Email: brian.smith@sa.gov.au
2. Mrs Mary Young
COPD Clinical Practice Consultant, Thoracic Medicine, Royal Adelaide Hospital,
South Australia
Business phone: 08 7074 2767
Email: mary.young@sa.gov.au

**Associate Investigators**

1. Mrs Kathryn Lawton
Clinical Practice Consultant, Respiratory Nursing Service, Respiratory Medicine Unit,

The Queen Elizabeth Hospital,

South Australia
Business phone: 08 8222 6906
Email: kathy.lawton@sa.gov.au

1. Dr Aeneas Yeo

Consultant Sleep & Respiratory Physician
Department of Thoracic Medicine

 Royal Adelaide Hospital, South Australia
 Business phone: 08 70742845
 Email: Aeneas.Yeo@sa.gov.au

1. Dr Zafar-Ahmad Usmani
Respiratory Physician,

Respiratory Medicine Unit,

The Queen Elizabeth Hospital, South Australia
Business phone: 08 8222 7966
Email: zafar-ahmad.usmani@sa.gov.au

1. Mr Joseph Van Agteren
Behavioural Change Researcher
South Australian Medical Health Research Institute (SAHMRI)

South Australia
Business phone: 0414 800 335
Email: joep.vanagteren@gmail.com

1. Ms Zoe Kopsaftis

PhD Student, The Clinical Practice Unit,
The Queen Elizabeth Hospital (Basil Hetzel Institute for Translational Health Research),
South Australia
Business phone: 08 8222 7886
Email: zoe.kopsaftis@sa.gov.au

1. Mr Mark Mastandanou

Extended Care Paramedic, Clinical Team leader

Specialist Services

SA Ambulance Services, South Australia

Business phone: 08 8274 0558

Email: mark.mastandanou@sa.gov.au

**3. Background**

In 2012 38 million deaths worldwide were attributed to non-communicable diseases, of these almost 11% were the result of chronic respiratory illnesses such as chronic obstructive pulmonary disease (COPD) (Mendis, Armstrong et al. 2014). COPD is a preventable chronic condition indicated by a progressive reduction of airflow through the lungs. The two mechanisms contributing to this airflow limitation are; an irreversible narrowing of the small airways of the lung caused by ongoing inflammation and fibrosis, and degeneration of structures which facilitate expansion and compression of the lung as well as oxygenation of the blood (Global Initiative for Chronic Obstructive Lung Disease 2015). People with COPD experience a number of symptoms and manifestations of the disease which negatively impact their quality of life. They may on any given day suffer one or multiple of the following: breathlessness, chronic cough, sputum production, wheezing, chest tightness, fatigue, anxiety, depression and weight loss (Abramson, Crockett et al. 2014, Global Initiative for Chronic Obstructive Lung Disease 2015).

COPD is responsible for 1.3% of all hospital admissions and 4% of deaths in patients aged 55 years or older (Australian Centre for Asthma Monitoring 2011). At a rate of 282.6 per 100,000 people, COPD is ranked second for avoidable hospital admissions in Australia with the median length of stay being five to six days for people 55 years and older (Page, Ambrose et al. 2007, Australian Institute of Health and Welfare 2014). The rate of hospitalisations increases with age and given Australia’s ageing population, with the number of older people projected to increase by approximately 10% by 2061 (Australian Centre for Asthma Monitoring 2011, Australian Bureau of Statistics 2013), the socioeconomic burden of COPD could be a long-term problem. The economic impact of this disease is significant, with estimated national expenditure for COPD in 2008/09 totalling $929 million, 57% of which was attributable to inpatient costs (Australian Institute of Health and Welfare 2014).

Central Adelaide Local Health Network (CALHN), consists of two tertiary hospitals; the Queen Elizabeth Hospital (TQEH) and the Royal Adelaide Hospital (RAH) both having an emergency department (ED). Combined data of years 2013-14 and 2014-15 resulted in a total of 966 COPD presentations at TQEH ED, and 1037 presentations at RAH ED. Data from both sites demonstrates commonality in timings of a COPD presentation between 0900 and 1200 hours and again 1400-1700 hours. For both RAH & TQEH ED 53.5% of all COPD presentations in 2013-14 occurred outside business hours, with similar results respectively in 2014-15 at 54.8% and 49.8%. Therefore 53% of all COPD presentations to a CALHN ED occur after-hours.

Both hospitals have access to Respiratory Nursing Services (RNS). At TQEH this service assists with long term management of patients whom are frequent users of tertiary hospitals providing an intermediary nursing service. This service offers chronic disease management support from 0800 -1630 Monday – Friday for COPD patients, with flexible home visiting or outpatient review. The service includes phone assessment and triage of exacerbation severity, facilitation of use of existing COPD action plan and emergency pack medications (prednisolone, antibiotic), other non-pharmacological strategies (airway clearance, energy conservation, breathing and relaxation techniques) and service coordination. Follow up is always provided with phone coaching and by linking the patient with their General Practitioner (GP) or Respiratory Specialist. At RAH, RNS offers an acute care coordination service only for people with COPD. The above listed chronic disease management strategies are utilised, however this service does not have capacity to offer rapid home and clinic nursing assessment options for unstable disease management.

In South Australia (SA), South Australian Ambulance Service (SAAS) is the sole provider for emergency ambulance services. The current method for any member of the public is to contact SAAS via 000. Calls are triaged through a defined medical triage process which is used globally. Any mention of shortness of breath or difficulty breathing (or chest pain etc.) will trigger a priority 2 SAAS response (lights/sirens) which means at least one emergency crew, and possibly an additional first responder will be deployed. The emergency ambulance will almost always transport a patient with COPD related shortness of breath with or without co-morbidities to an ED.

The Extended Care Paramedics (ECP) service commenced in 2008 providing a service that allows patients to be treated at home or in their home surrounds, and not be transported to a hospital ED if it is not necessary.

An ECP is a SAAS intensive care paramedic who has undergone intensive skills enhancement and training. ECPs can treat patients for a common range of medical issues and refer patients to other health providers such as General practitioners (GP) if needed. With this service, an ECP assesses the patient’s requirements through phone consultation and dispatches an ECP single responder in an ambulance response vehicle as opposed to a traditional stretcher carrying ambulance (Government of South Australia 2016).

Use of ECP with COPD exacerbation management is not standard practice for this service. Since October 2014, it has been trialled in Southern Adelaide Local Health Network (SALHN). SAAS ECP’s are enlisted to provide after-hours respiratory support to their known Respiratory Integrated Care Service (RICS) patients. As at December 2015, SAAS ECPs had seen 10 RICS clients with ED admission being avoided in approximately 50% of cases.

A large proportion of ED presentations and hospital admissions are preventable as they result from poor self-management skills and subsequently poor judgement of the severity of the manifesting symptoms. Furthermore, some admissions are due to other non-COPD related factors such as loneliness or misattribution of symptoms belonging to other diseases (e.g. anxiety or depression). A pre-triage conducted by trained health professionals who are experienced in detecting the severity of COPD exacerbations has the potential to reduce the number of unnecessary ED presentations.

Current best practice management of an exacerbation or flare-up of COPD symptoms is with the use of a written COPD Action Plan and Emergency Pack of medications for early recognition and treatment of symptoms, however evidence demonstrates a minimal reduction in healthcare utilisation or health-related quality of life (Walters, Turnock et al. 2010). An action plan with ongoing support by a case-manager may decrease the impact of exacerbations in health status (Trappenburg, Monninkhof et al. 2011).

Therefore the proposed intervention is for the addition of 24-hour exacerbation support using existing specialised RNS during business hours and after-hours with SAAS ECP’s. Trained health professionals will assess the patient’s disease status and determine if the patient could be managed at home or requires presentation to a hospital emergency department.

This study will be a randomised controlled trial and will be referred to as ‘COPD at Home Service’.

**4. Research Questions**

1. Can the randomised controlled trial (RCT) design of the COPD at home service compared to usual care be effectively implemented?
2. Is the COPD at home service intervention:
3. Acceptable,
4. Demanded,
5. Practical, and
6. Potentially effective?

**5. Study Aim**

To determine the implementation (RCT) feasibility as well as the acceptability, demand, practicality and efficacy of the COPD at Home Service.

**5.1 Primary Objective**

1. Evaluate the feasibility of the RCT design comparing the COPD at Home Service to usual care across two public hospitals (success or failure of execution, degree of execution, amount of resources needed to implement).

**5.2 Secondary Objectives**

1. Evaluate the COPD at Home Service intervention for:
	1. Acceptability (satisfaction, intent to continue use, perceived appropriateness and safety)
	2. Demand (actual use)
	3. Practicality (factors effecting implementation ease or difficulty, efficiency, speed and quality of implementation, positive/negative effects on target participants, ability of participants to carry out intervention activities)
	4. Efficacy
		1. Hospital utilisation (emergency department presentation, hospital admission, length of hospital stay, outpatient visits and general practitioner (GP) visits)
		2. Cost effectiveness
		3. Quality of life (SF-36)
		4. Dyspnoea (MMRC)
		5. Anxiety and depression (BAI and BDI)
		6. Self-management (PIH and C&R)
		7. Self-efficacy (COPD self-efficacy scale)
		8. COPD impact assessment (CAT)

**6. Method**

**6.1 Study Procedure**

Analysis and evaluation of the COPD at Home Service on ED presentations over a period of 6 months will be conducted, assessing if the intervention can be carried out within the existing resources of the hospital RNS and SAAS ECP services, to determine if the assessment, triage and review processes are feasible, if patients engage with the process and if the intervention is cost effective. The future intention is for this feasibility study to proceed to a larger randomised controlled trial.

**6.2 Inclusion and exclusion criteria**

|  |
| --- |
| **Inclusion Criteria** |
| * Confirmed diagnosis of COPD (Pulmonary function test (PFT)/spirometry performed within last 12 months as per GOLD 2015; post bronchodilator FEV1/FVC<0.7)
* Two emergency department presentations and/or hospital admissions within the last 12 months related to COPD
* Have SA Ambulance Cover
* 18 years or older
* Phone Access
* English literacy (speaking and reading)
 |
| **Exclusion Criteria** |
| * Unable to provide informed consent (cognitive impairment)
* COPD patients whom are active clients of a palliative care service
* Current case-managed patients of the Respiratory Nursing Service at TQEH
* Assessed patients who are at risk of significant undertreated co-morbidities ie high levels of anxiety or depression requiring referral to specialist services
* Resident of an Aged Care Facility
 |
| **Withdrawal Criteria** |
| * At the participant’s request
* Non-compliance
 |

Table 1 Inclusion, exclusion and withdrawal criteria for the study

**6.3 Screening and recruitment**

Patient eligibility to participate will be assessed using hospital electronic databases (OACIS,
Enterprise Patient Administration System (EPAS), and ED HASS) according to the criteria mentioned in Table 1.

Potential participants will be identified via:

* + Retrospective screening: CALHN ED admissions lists (including RAH and TQEH) for previous 12 months
	+ Prospective screening: OACIS and EPAS will be screened for current patients admitted with a primary diagnosis of COPD from RAH and TQEH

Existing patients of the RNS at TQEH who fulfil the inclusion criteria but already receive case-management determined by having received at minimum of 2 home visits and 4 phone calls for the previous 6 months will be excluded. These patients will continue to receive their normal management support through the RNS, but won’t have access to the SAAS out of hours service in the trial period.

Recruitment will continue until a sample size of minimum forty (40) is reached, which is estimated to take six months (see Figure 1).

For all participants retrospectively identified by a member of the research team (as listed in 2) will recruit for both hospitals via telephone (see attachment 1). All participants will receive verbal description of the study (attachment 1) and will be asked to indicate their interest in participation. Upon expression of interest a letter of invitation (see attachment 2), a participant information sheet (PIS) (see attachment 3) and a consent form (see attachment 3) will be provided to inpatients or mailed. The participant will then be given seven days to consider participation. After seven days a member of the research team will follow up to reaffirm interest and address any concerns or questions. If consenting to participation the researcher will schedule an appointment for baseline measurement at TQEH or at the participant’s home.

For participants identified prospectively at TQEH and RAH respiratory nursing consultants will approach during their hospital admission or outpatient encounter. The same recruitment process applies as listed above. If consenting to participation the researcher will schedule an appointment for baseline measurement at TQEH or at the participant’s home.

Patient Screening SSScreenScreeningPatient screening

Screening & Recruitment

Prospective

OACIS data

EPAS, HASS ED

Retrospective

OACIS, HOMER & HASS-ED data

Approval study

6M

-12M

*Figure 1. Visualisation of screening process ranging from 12 months prior to approval of the study (-12M) via retrospective audit and 6 months after approval (6M) via monitoring of hospitalisations for each subject recruited.*

**6.4 Initial participant appointment**

6.4.1 Randomisation

Following consent participants will be randomly assigned to the intervention or control group (Figure 2). Participant allocation will be performed using a pre-determined computer-generated block randomisation, with random variable block sizes ranging between 2 and 6 (Efird 2011). Randomisation will be performed by an independent researcher who is not involved in outcome assessment.

All study participants will be informed of which group they have been randomised, and of the actions to be undertaken relative to the allocated randomised group.

Participants randomised to the intervention group will be provided information about the COPD at Home Service triage process which includes daytime access to RNS and after-hours access to SAAS ECP’s. In the unlikely but possible event the participant cannot contact the COPD at Home Service, they will be instructed to utilise their GP, locum GP service, ED or SAAS emergency via 000. Participants in the intervention arm will be provided with the contact phone number to the COPD at home service on a laminated A4 poster to be put in their green folder (see attachment 5.1), or by the participant phone The participant will be given sufficient chance to ask questions and discuss the content of the provided information including the educational material (6.4.3).

If participants are randomised to the control group they will be advised to continue with normal management of their COPD as they have been advised by their health professionals.

Recruited population

Intervention Group:

COPD Action Plan, Emergency Pack & 24-hour health professional support

Control Group:

COPD Action Plan and Emergency Pack only

 Outcome

 Outcome

*Figure 2. Visualisation of randomised control trial groups: adapted from Kendall 2003*

6.4.2 Baseline measures

Signed consent will be obtained from the participant at the first visit. If the participant has forgotten to bring the form, or lost the form prior to the appointment, the researcher will provide the participant with a new copy.

For those participants where lung function testing has not been performed or is older than 12 months spirometry will be performed using an Easyone spirometer. This is to confirm presence and stage of COPD.

The participant will then complete baseline questionnaires; the researcher will be available to answer questions. Answers will be collected on the Case Report Form (CRF) according to the order they are presented below (see attachment 4). The requested information will be:

Both control and intervention participants:

* General demographics
	+ Recruitment information
	+ Information on GP
	+ Social situation
* Current medications
* Spirometry results
* Smoking history
* Depress Anxiety Stress Scales (DASS21)
* Patients with COPD may suffer from Stress, and/or Anxiety, and/or Depression which can influence their rate of ED presentation
* Modified Medical Research Council (MMRC) Dyspnoea Scale
* SF-36
* General HRQoL questionnaire allowing calculation of QALY’s
* Partners in Health (PIH) and Cue & Response (C&R) questionnaires: The Flinders Program for Chronic Condition Management
* To assess participant knowledge level in exacerbation self-management
* COPD Self-Efficacy Scale
* COPD Assessment Test (CAT)
* Immunisation status
* Malnutrition
* Access to COPD Action Plan and Emergency Pack
* Use of oxygen and/or non-invasive ventilation
* Vital signs

For Intervention Participants Only

RNS clinical assessment

* COPD action plan & emergency pack
* Respiratory inhalers technique assessment
* Respiratory assessment
* Checklist

6.4.3 Education for Intervention group participants only

All participants randomised to the intervention group will be provided with a COPD information pack (see attachment 6).

The RNS nurse will reinforce the principles of using the physician prescribed COPD Action Plan (see attachment 5.4) and Emergency Pack for intervention group participants, as recommended by current therapeutic guidelines ((Global Initiative for Chronic Obstructive Lung Disease 2015),(Abramson, Crockett et al. 2014)). Where the intervention group participant does not already have a COPD action plan or emergency pack both will be obtained from the Respiratory Registrar/Physician rostered to TQEH hospital consult service. The COPD Action Plan developed by Lung Foundation Australia (see attachment 5.4) will be used for intervention group participants that require one provided. All intervention group participants will receive education on the use of their inhalers in exacerbation management. Intervention group participants will also be educated on when to commence their emergency pack of prednisolone or antibiotics as per their COPD Action Plan. The medication and dosage in the emergency pack will comply with current therapeutic guidelines for exacerbation management in COPD (Therapeutic Gudelines Limited 2017).

All participants will be given an opportunity to ask questions; if no further questions exist from either the control or intervention participant, the RNS nurse will continue to explain the procedure for the remainder of the trial period (see figure 3). All intervention participants will be provided with the ‘green folder’ to keep relevant study information and to document information for communication (see 7.2).

Immediately after enrolment, the nominated local doctor of each participant will receive a letter advising of their participation in this research and a summary of the research project (see attachment 7).

**7. Project for COPD at Home Intervention**

**7.1 Planned contact**

The participants will be told that they will receive a total of two planned phone calls by the RNS nurse at one week and three months. With final assessment at six months being in-person contact (see Figure 3).

The main purpose of these phone calls is to ask about any changes in medical management, ambulance utilisation, presentation to any ED, after-hours clinic/locum service or GP and use of action plan if they have one. A respiratory phone assessment will be performed using the MMRC (see attachment 4.2) and the CAT (see attachment 4.9). If an issue is identified more specific questions relating to respiratory assessment can be performed (as per attachment 8). Participants in the intervention group can be reminded to call the specialised number at onset of worsening symptoms, If the respiratory nurse determines that a participant is not self-managing a current exacerbation at time of call from the control group they will remind them to seek medical review. If the respiratory nurse determines that an intervention participant is not self-managing a current exacerbation at time of call from the intervention group phone coaching will be provided in the first instance with other triage options of an outpatient or home nursing review available. Whilst recommending participants follow this protocol for changes in respiratory symptoms they can still utilise current ambulance emergency services if required.

Baseline assessment at TQEH or at home

M6 Final assessment at TQEH or at home

W1 check-up

M3 check-up

Figure 3. Planned contact with researchers. W1 = week 1, M3 = month three and M6 = month six the final assessment. Solid boxes represent in-person contact; dashed boxes represent contact via phone.

**7.2 Communication Protocol**

Communication between the RNS, SAAS and the patient will be using two methods:

1. a green folder (see attachment 5) to be kept with the participant at all times. The folder will contain
	* Laminated A4 poster with contact phone numbers for COPD at Home (for intervention group only)
	* Participants identification and demographics page
	* Advanced Care Directives (ACD) & ACD factsheet
	* A COPD Action Plan
	* Patient Medical Contact Log
	* List of current medications
	* Rapid Detection and Response (RDR) Adult Observation Chart (for Intervention group only)
2. EPAS

RNS: documentation of assessments, recommendations and actions occurring at every participant contact.

SAAS: have a read only capacity enabling the ability to review current participant’s status and management.

NB. EPAS is only presently available in its full form at TQEH, with SAAS having a ‘read only capacity’ and not yet implemented at RAH. As such a shadow patient record (green folder) will be utilised as a back-up and for SAAS to leave copies of documentation given they are currently unable to enter data into EPAS.

**7.3 Unplanned contact for intervention participants**

If a participant from the intervention group identifies a change in their baseline respiratory symptoms, they will be advised to contact the COPD at Home service available 24/7. They will contact the TQEH switchboard number (08 8222 6000) and ask for the COPD at Home Service. When participants call they will be transferred directly to:

* RNS between 08:00 hrs and 16:00 hrs weekdays
* SA Ambulance Service between 16:01 hrs and 07:59 hrs weekdays and 24 hours on weekends

The TQEH switchboard will be briefed prior to the start of this study to contact the appropriate service at the right time. TQEH switchboard diverts to RAH switchboard for 30 minutes every night between 3 and 4 am to accommodate meal breaks and any toilet breaks. RAH switchboard will also cover meal breaks for TQEH on weekends and public holidays throughout the day. For this reason, RAH switchboard will be briefed about the study and the instruction for both switchboards can be found in attachment 9.

Should the COPD at Home Service not respond within 15 minutes to the redirected call from switchboard, the participant is instructed to utilise their GP, locum GP service, ED or SAAS emergency ‘000’.

In the event of a participant calling the switchboard during office hours (0800 – 1600) the participant will be connected to the RNS service. RNS nurse will perform a respiratory symptom assessment with all participant phone calls using MMRC (see attachment 4.2), CAT (see attachment 4.9) and additional respiratory phone assessment questions (attachment 8). The RNS nurses will triage the participant over the phone and based on the assessment, one of two scenarios will occur.

7.3.1 RNS Triage options

7.3.1.1 Early change in symptoms: not requiring emergency services

RNS nurse assesses the participant as not experiencing a COPD exacerbation based on their symptoms the RNS nurse will advise the participant to seek GP review. RNS will provide a phone review after 1 week to document outcome in ‘reported exacerbations’). (see attachment 10)

RNS nurse assesses the participant as being in the early stages of an exacerbation based on their symptoms. The participant is advised to enact their action plan and/or emergency pack if they haven’t already done so. Other exacerbation management strategies that can be implemented at home e.g. sputum clearance options, breathing techniques, pacing of activities will be discussed. All participants whom are recommended to commence their emergency pack will also be instructed to see their GP within 24-48 hours. The RNS will contact the participant again in 3 days after initial contact to review management/outcome. Should the participant become concerned about their symptoms prior to the 3 day review the participant can contact the COPD at Home Service again. All reported exacerbations will be documented in ‘reported exacerbations’ (see attachment 10).

At the 3-day phone review, MMRC and CAT will be performed. If there is no improvement or deterioration of respiratory symptoms, and the participant does not require emergency services RNS will coordinate a rapid response assessment within 24 hours, if possible the same day (see 7.3.1.2), at participant’s home or as a hospital outpatient.

If the participant is assessed as acutely unwell, the RNS will facilitate specialist medical review or ED attendance following consent from the participant, family or significant other.

The RNS will notify the participant’s local doctor (by email, phone or facsimile) of the outcome for above scenarios.

7.3.1.2 Assessed as severe: not requiring emergency services

A rapid response assessment (see attachment 11) is conducted by the RNS nurse in their existing exacerbation clinic or in the participant’s home if they are unable to attend outpatients due to transport limitations within 24 hours and includes the following

* + Severity of shortness of breath, assessment via MMRC
	+ If symptoms were of sudden or gradual onset
	+ Cough: type- dry, moist, productive, non-productive and frequency
	+ Breathing pattern, use of accessory muscles
	+ Able to speak in full sentences
	+ Level of consciousness/alert
	+ Sputum production: colour and amount, presence of blood, or if difficulty clearing sputum
	+ Oxygen saturation level, respiratory rate, pulse rate, blood pressure, temperature
	+ Chest pain or other pain or discomfort
	+ Any peripheral oedema
	+ Current smoking status
	+ Difficulty sleeping
	+ Use of frequency of bronchodilator and other respiratory inhalers
	+ Perform lung auscultation
	+ Anxiety level
	+ Management of living at home activities
	+ Effort to treat: identify if participant has commenced their COPD Action Plan e.g. medications and other interventions used, pattern of use and effectiveness, and help to initiate COPD Action Plan if it is required
	+ If self-initiated increased use of oxygen therapy if already prescribed

Additional investigations include:

* Sputum specimen to determine causative organism and antibiotic sensitivities in participants who have not responded to first course of antibiotics
* Nasal viral swabs for suspected respiratory viral symptoms
* Blood samples for C-reactive protein (CRP) to confirm active inflammation; and complete blood exam to assess presence of anaemia and infection also draw blood.

The ordering of pathology will be prospectively managed on the day of collection from a Respiratory Consultant (associate investigator) or Advanced Respiratory Trainee using EPAS.

If RNS determines that the participant would benefit presenting to the ED they will either contact SAAS or send the participant to the ED via family members or friends. Alternatively, if RNS determines that the participant is safe to stay in own home the RNS will provide a follow up review between 1 & 3 days either by phone or home visit, and advise participant to see their GP or arrange appointment on participant behalf, and communicate findings and recommendations to the participants GP. If participant is brought to the Emergency Department the local doctor will receive separation summary of the presentation/admission as per standard practice.

RNS will seek respiratory medical opinion or review if participant assessed as having co-morbidities complicating exacerbation, to determine future patient management.

##### 7.3.1.3 Assessment: emergency

If the participant calls and the nurse assesses the situation as an emergency, the nurse will advise participant, family or significant other to contact SA Ambulance for presentation to ED. (See figure 4, for triage flow process for RNS service)

Figure 4: Triage flow process for RNS

7.3.2 SAAS Triage Options

SA Ambulance Service ECP’s will follow their ‘work instruction’ for participants (see attachment 12) for the proposed work instruction).

All participant phone calls will be triaged by the ECP Coordinator who will determine deployment of ECP or standard ambulance response (priority 2) based on severity of participant symptoms.

7.3.2.1 Assessment: not requiring emergency services

If the initial phone assessment indicates that the situation is *not an emergency*: An ECP will be sent to the home address of the participant for immediate review, assessment and management of their symptoms.

After the ECP assessment the ECP’s will notify the RNS by email (Health:TQEH Respiratory Nurses) and the participant’s local doctor (by email or facsimile) if they have visited and if participant was deemed safe to stay home to enable follow up of their condition by RNS and/or local doctor.

If ECP determines that the patient would benefit at this stage from presenting to the ED they will coordinate with SAAS. If participant is brought to the ED the ECP will notify the RNS (via email) only as local doctor will receive separation summary of the presentation/admission as per standard practice upon discharge. SAAS will use a specifically designed summary to communicate to RNS with the addition of chest pain and dyspnoea in the clinical summary and a comment on the recommendations which were given to the participant (attachment 13).

7.3.2.2 Assessed as emergency

If assessment indicates *emergency*, SAAS will send an emergency ambulance which will transport the participant to hospital for management of their condition. If participant is brought to the ED, the ECP will notify RNS (via email) only, as local doctor will receive separation summary of the presentation/admission as per standard practice.

After each ED presentation or hospital admission, RNS will contact the participant 1 week after discharge to assess recovery and identify any changes in their long term management plan (e.g. change in medication use, oxygen flow rates). Specific questions can be found in attachment 14. If RNS determines further ongoing instability they will either refer the patient to their GP or enact the COPD at home protocol. (Refer figure 4, for triage flow process for ECP service)

**8. Data collection and management**

### 8. 1 Externally captured data

### Feasibility of RCT design (primary outcome)

Feasibility outcomes will be collected via documentation from nursing and SAAS records following phone calls made by patients. The following data will be collected:

* Success or failure of execution: success determined by >80% of the population using the intervention as intended (calling the COPD at Home service as per instructions in times of exacerbation)
* Degree of execution: evaluated by the number of subjects that are eligible to participate actually agreeing to take part in the study
* Amount of resources needed to implement: number of phone calls made to the nursing service and ECP service

### Acceptability

Safety of the intervention will be determined by nursing and SAAS records identifying adverse events likely caused by the intervention.

### Demand

Actual use determined by the number of subjects using the intervention as intended and the number of occasions each subject utilised the intervention as intended based on nursing and SAAS records.

### Hospital utilisation

In South Australian hospitals casemix/DRG data is available to track patient admissions across public hospitals. Data will be collected for 5 years prior to enrolment and 6 months post enrolment for emergency department presentations, hospital admissions, and length of hospital stay and outpatient visits.

### Cost effectiveness

Costs will include the direct costs of the intervention (ambulance service use, nursing time and follow up) and the costs of associated health service use (inpatient frequency and duration, other health service use as captured by the casemix/DRG data sets).

### Patient delivered questionnaires

### Acceptability

Satisfaction, intent to continue use and perceived appropriateness of the intervention will be captured through qualitative semi-structured one-on-one interviews conducted during the final follow-up assessment at six months (see attachment 15). Subjects will also be asked if they believe any adverse events occurred due to the intervention (safety).

### Practicality

Factors effecting implementation ease or difficulty, efficiency, speed and quality of implementation, positive/negative effects on target participants and ability of participants to carry out intervention activities will be captured through qualitative semi-structured one-on-one interviews conducted during the final follow-up assessment at six months (see attachment 15)

### Efficacy

Data will be collected at baseline and 6 months post recruitment. All information will be collected into a standardised case report form that will be stored in a lockable filing cabinet. This data will then be entered electronically into a password protected database stored on the hospital server (Q drive).

### General Practitioner utilisation

Attendance with General Practitioners during the six month follow-up period will be captured by asking for date of appointment and reason for attendance. Participants will be advised to keep a medical log of all appointments related to their health including general practitioner (see medical log in attachment 6).

### Quality of life (SF-36)

Short-Form 36 is one of the most widely-used health related quality of life tool allowing for the calculation of QALY’s via converting scores using the SF-6D classification(Walters and Brazier 2003). Overall internal consistency is good (Cronbach’s α >0.85,)(Brazier, Harper et al. 1992) and internal consistency for subscales ranges from 0.76 to 0.98 (Jenkinson, Coulter et al. 1993). The minimally important difference ranges per sample, but was found to be 0.010 in a population of COPD (Harper, Brazier et al. 1997)

### Dyspnoea (MMRC)

The MMRC will be used to assess the level of disability due to dyspnoea (Bestall, Paul et al. 1999), (Hsu, Lin et al. 2013).

### Stress, Anxiety and Depression (DASS21)

The influence of anxiety and depression in patients with COPD is well-reported and can influence the number of ED presentations and hospital admissions (SIn, Anthonisen et al. 2006), (Light, Merrill et al. 1985), (Willgoss and Yohannes 2013). Measuring the extent of depression and anxiety in our two populations is therefore necessary. If any extreme responses are identified the researcher will notify the GP of the result and the participant will be advised to contact their GP to discuss management options.

DASS21: analysis confirms can successfully discriminate between the three emotional syndromes and are useful to the clinician in identifying emotional disturbances in assessment {Lovibond, 1994 #32}

### Self-management (PIH and C&R)

The ability of an individual to effectively self-manage their specific disease includes the monitoring and managing of daily symptoms and whilst exacerbating. Poor self-management has been attributed to high healthcare utilisation (Bodenheimer, Lorig et al. 2002). Performing of the Partners in Health (PIH) and Cue and Response (C&R) enables assessment of a person’s self-management knowledge, behaviours and barriers to perform self-management so health professionals can provide additional self-management education and support (Flinders Human Behaviour & Health Research Unit (FHBHRU) 2016).

### Self-efficacy (Confidence)

Confidence in managing breathing difficulties: the COPD Self-Efficacy Scale will be used (Wigal, Creer et al. 1991, Simpson and Jones 2013)

### COPD Assessment Test (CAT)

COPD Assessment Test (CAT): a tool to assess impact of current symptoms on health status (Jones, Harding et al. 2009), to evaluate exacerbation severity (Mackay, Donaldson et al. 2012), and is equitable in either a face to face or telephone interview questionnaire (da Silva, Morano et al. 2014).

Please refer to Table 2 for a summary of data collection tools and protocol timing for implementation

|  |
| --- |
| **Table 2 Data collection measures and timing** |
| **Measure** | **Group measured** | **When measure conducted** |
| **TQEH/Home** | **Phone** | **Phone** | **TQEH/Home** | **With exacerbation** | **Post GP, ED of HA presentation** |
|  | **Control** | **Intervention** | Baseline | Week 1 | Month 3 | Month 6 |
| RNS Clinical Assessment,  | ✓ | ✓ | ✓ |  |  | ✓ |  |  |
| Medication assessment | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Additional RNS assessment |  | ✓ |  |  |  |  | ✓ | ✓ |
| MMRC | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| COPD Assessment Test (CAT) | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Depress Anxiety Stress Scales (DASS21) | ✓ | ✓ | ✓ |  |  | ✓ |  |  |
| SF-36 | ✓ | ✓ | ✓ |  |  | ✓ |  |  |
| Partners in Health (PIH) | ✓ | ✓ | ✓ |  |  | ✓ |  |  |
| Cue and Response (C&R) | ✓ | ✓ | ✓ |  |  | ✓ |  |  |
| COPD Self Efficacy Scale | ✓ | ✓ | ✓ |  |  | ✓ |  |  |
| COPD Action Plan and ED utilisation assessment | ✓ | ✓ |  | ✓ | ✓ | ✓ | ✓ | ✓ |
| Semi Structured interview | ✓ | ✓ |  |  |  | ✓ |  |  |
| Medical Log (patient completion) | ✓ | ✓ |  | ✓ | ✓ | ✓ |  |  |
| Note: For control group participants, the 1 week and 3 month reviews is to collect exacerbation and health care utilisation data only |

**9. Sample size and data analysis**

**9.1 Sample size**

We have estimated that minimum 20 participants in each arm (minimum 40 in total) will be acceptable for recruitment, as per other similar published studies conducted in COPD cohorts (Mair, Wilkinson et al. 1999, Ernst, Welke et al. 2008, Farquhar, Higginson et al. 2009, Chau, Lee et al. 2012, Mazzoleni, Montagnani et al. 2014).

### 9.2 Data analysis plan

All statistical analysis will be done via IBM SPSS 20 or STATA14 unless otherwise indicated.

### Hospital utilisation and limited efficacy

The potential influence of the intervention on ED presentation and hospital admission rate will be explored using Poisson Regression. The potential effect of the intervention on continuous outcome data (e.g. MMRC, BAI & BDI scores) will be assessed via independent samples t-tests or their non-parametric counterparts (e.g. Mann-Whitney U) and categorical data by using χ² or Fishers Exact test.

### 9.2.2 Cost effectiveness

Costs and outcomes will be discounted at 5% per annum according to current PBAC guidelines (Commonwealth Department of Health and Ageing 2002). Analyses will report the discounted cost per life year gained ($/LY) and the discounted cost per quality adjusted life year gained ($/QALY) at trial end and extrapolated over a 15 year time horizon. One-way sensitivity analysis will be performed for key parameters and probabilistic sensitivity analyses will be conducted modelling (10,000 simulations) the distribution of individual parameters based on the patient level data leading to cost effectiveness acceptability curves, which report the probability that a particular intervention is cost-effective given a particular willingness to pay.

**Attachments**

|  |  |  |
| --- | --- | --- |
| **1** |  | **Recruitment Script** |
| **2** |  | **Letter of Invitation** |
| **3** |  | **Combined Participant Information and Consent** |
| **4** |  | **Case Report Forms (CRF)** |
|  | 4.1 | Participant Demographics  |
|  | 4.2 | MMRC |
|  | 4.3 | Depress Anxiety Stress Scales (DASS21) |
|  | 4.4 | Depress Anxiety Stress Scales (DASS21) Scoring |
|  | 4.5 | SF-36 |
|  | 4.6 | Partners In Health (PIH) |
|  | 4.7 | Cue & Response (C&R) |
|  | 4.8 | COPD Self Efficacy Scale |
|  | 4.9 | COPD Assessment Test (CAT) |
|  | 4.10 | RNS Clinical Assessment |
| **5** |  | **Green Folder** |
|  | 5.1 | Contact Instructions |
|  | 5.2 | RNS & ECP Participant Demographics |
|  | 5.3 | ACD Form |
|  | 5.4 | COPD Action Plan |
|  | 5.5 | Medical Log |
|  | 5.6 | Medications |
|  | 5.7 | RDR Chart |
| **6** |  | **Information Pack (Intervention Group Only)** |
|  | 6.1 | RNS Service Information |
|  | 6.2 | COPD Consumer Information |
|  | 6.3 | Advance Care Directive Kit |
|  | 6.4 | Breathing techniques |
|  | 6.5 | Depression, Stress, Anxiety |
|  | 6.6 | Pulmonary Rehabilitation |
|  | 6.7 | Falls Prevention – Fact Sheet 3 |
|  | 6.8 | Falls Prevention – Fact Sheet 8 |
|  | 6.9 | Eating Well with Lung Disease |
|  | 6.10 | Continence & Lung Disease |
|  | 6.11 | Infection Control |
|  | 6.12 | Quality of Life through Patient Support |
| **7** |  | **GP Correspondence** |
| **8** |  | **Additional Respiratory Assessment** |
| **9** |  | **Switchboard Instructions** |
| **10** |  | **Reported Exacerbations** |
| **11** |  | **Rapid Response Assessment (Home or Clinic)** |
| **12** |  | **SAAS ECP Work Instruction** |
| **13** |  | **ECP\_RNS Summary** |
| **14** |  | **Post ED of HA Assessment** |
| **15** |  | **Semi-Structured Interview** |
| **16** |  | **1 Week Review** |
| **17** |  | **3 Month Review** |
| **18** |  | **6 Month Final Review** |
| **19** |  | **6 Month RNS Review** |
| **20** |  | **Adverse Events** |
| **21** |  | **Study Violations** |
| **22** |  | **Participant Completion / Withdrawal** |

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