Study Title: An evaluation of a Pilot, Innovative Interdisciplinary Care Clinic delivering targeted evidence-based care in bronchiectasis in a regional centre (PIICC)

Chief Researcher

Associate Professor Zoe Mc Keough

The University of Sydney
Rm No 203, O Block, Cumberland Campus
The University of Sydney NSW 2141
+61 2 9351 9269
Zoe.mckeough@sydney.edu.au
https://orcid.org/0000-0002-3657-7229

Principal Investigator

Kirsty Watson

Advanced Allied Health Practitioner (Acute)
Level 3 Intensive Care Unit Rockhampton Hospital
Canning St Rockhampton 4700
+61 7 49206175
Kirsty.watson@health.qld.gov.au
https://orcid.org/0000-0002-4381-8940

Co-investigators

Dr Annemarie Lee

Senior Lecturer
Department of Physiotherapy
School of Primary and Allied Health Care
Monash University Building B,
McMahons Road
Frankston Victoria 3199
Annemarie.lee@monash.edu
https://orcid.org/0000-0002-8631-0135

Dr Tiffany Dwyer

Senior Lecturer
The University of Sydney
Discipline of Physiotherapy, Sydney School of Health Sciences, Faculty of Medicine and Health
Rm O156, O Block Cumberland Campus
The University of Sydney NSW 2141
Tiffany.dwyer@sydney.edu.au
https://orcid.org/0000-0001-6403-28

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Abstract

Background

Bronchiectasis is a chronic respiratory disease of increasing prevalence. Access to interdisciplinary outpatient clinics which meet the national and international guidelines in the management of bronchiectasis outside of metropolitan centres is limited. An innovative interdisciplinary bronchiectasis clinic which delivers targeted evidence-based interventions based on national and international guidelines has the potential to improve quality of life and healthcare utilization, reduce exacerbation frequency, and deliver high levels of clinic acceptability, uptake and attendance.

Methods

This is two prospective pilot studies. Study one will test the hypothesis that the delivery of targeted evidence-based interventions by an interdisciplinary bronchiectasis outpatient clinic will improve quality of life and healthcare utilization, reduce exacerbation frequency and result in high levels of clinic uptake and attendance. Study two will test the hypothesis that targeted evidence-based interventions delivered by an interdisciplinary bronchiectasis outpatient clinic will be acceptable to patients according to the components of the theoretical framework of acceptability.

Adult patients who have been referred to the interdisciplinary bronchiectasis clinic at the Sub Acute and Chronic Care Rehabilitation (SACCR) service in the Central Queensland Hospital and Health Service (CQHHS) will be invited to participate. All patients are referred to the clinic by a respiratory physician and have clinically significant bronchiectasis (i.e. bronchiectasis confirmed on computed tomography scan and persistent symptoms of bronchiectasis). The clinic includes a respiratory nurse practitioner and a physiotherapist, with referral to other services as required (e.g. pulmonary rehabilitation). Patients will be offered an initial assessment, three and 12 month reviews, followed by ongoing six monthly or annual review according to interdisciplinary team clinical decision making, with additional appointments as clinically indicated. Patients will have the option of participating in both study one and two. The targeted evidence-based interventions will depend on patient need and will include any of the following: a medication action plan, an airway clearance therapy plan, referral to pulmonary rehabilitation or home exercise prescription, physical activity (PA) and sedentary behaviour (SB) advice according to PA guidelines, and education relating to smoking cessation, avoidance of environmental airborne pollutants, hydration, the management of co-morbidities such as sinusitis, and musculoskeletal pain, strategies for breathlessness and infection control. The airway clearance therapy plan will be developed by a physiotherapist with expertise in respiratory disease and will involve the use of a range of possible techniques including the active cycle of breathing technique (ACBT), positive expiratory pressure (PEP) devices, patient positioning, forced expiration technique (FET), percussion/vibrations and inhalation therapies. The medication action plan will be developed by a respiratory nurse practitioner following the respiratory physician assessment and will be combined with the airway clearance therapy plan to form an individualized bronchiectasis action plan that has strategies suggested for when the patient is well and unwell.

Participants in study one will have quality of life (Quality of Life-Bronchiectasis (QOL-B) and Leicester Cough Questionnaires), health care utilization (days in hospital), exacerbation frequency, clinic uptake and attendance and pulmonary rehabilitation attendance as outcome measures.

Participants in study two will undertake semi structured interviews to measure clinic acceptability against the components of the theoretical framework of acceptability.

Discussion/significance

If the pilot innovative interdisciplinary care clinic (PIICC), delivering targeted evidence-based care in bronchiectasis, is effective at improving patient centred outcomes (quality of life, healthcare utilization and exacerbation frequency), and is acceptable to patients, this model may be used to improve the delivery of care in bronchiectasis outside of larger centres.

Keywords bronchiectasis, acceptability, outpatient clinic, interdisciplinary care, physiotherapy, respiratory nurse practitioner, quality of life, health care utilization, self-management

Contributions to the literature

- Interdisciplinary outpatient clinics for the management of bronchiectasis are limited outside of metropolitan areas.
- These studies describe the impact of an innovative interdisciplinary care clinic- delivering targeted evidence-based care on quality of life, health care utilization, exacerbation frequency, uptake, attendance, and clinic acceptability.
- If successful, these studies could provide a template for the provision of targeted evidence-based interdisciplinary bronchiectasis outpatient care.

1. Background

Bronchiectasis is a chronic respiratory disease involving permanent dilation of the airways. It is characterised by recurrent infection, persistent cough and sputum production. The misdiagnosis, and coexistence of bronchiectasis with other respiratory diseases such as chronic obstructive pulmonary disease (COPD), is leading to an increasing health burden in non-indigenous and indigenous populations in Australia (1), New Zealand (2) and worldwide (3-5).

Both national (6) and international guidelines (7, 8) support the importance of a multidisciplinary approach to bronchiectasis management. Audit data has demonstrated a low level of adherence to the recommendation for multidisciplinary care, with the involvement of a respiratory nurse or physiotherapist occurring less than 40% of the time (9). The addition of specialized respiratory physiotherapy to outpatient bronchiectasis management has demonstrated improvements in quality of life (9), and patients managed in a specialized clinic were more likely to have an individualized management plan and to receive care according to the bronchiectasis guidelines (10). In COPD, integrated disease management (two or more disease management strategies provided by two or more professions with a duration of at least three months) has been shown to improve quality of life, exercise capacity, days in hospital and hospital admissions (11).

Interdisciplinary care *implies mutually respectful engagement between health professionals in planning and implementing care together* (12) and is now recognized as an important feature in improving health care outcomes in chronic disease (13). It has been demonstrated that interdisciplinary care can increase adherence to evidence-based guidelines in chronic disease (14).

In regional and rural areas of Australia, interdisciplinary outpatient clinics offering interventions recommended by the national (6) and international guidelines (7, 8) in bronchiectasis management are often not available. Targeted evidence-based interventions in bronchiectasis can include any of the following: a medication action plan, an airway clearance therapy plan, referral to pulmonary rehabilitation or home exercise prescription, PA and SB advice, and education relating to smoking cessation, avoidance of environmental airborne pollutants, hydration, the management of co-morbidities such as sinusitis and musculoskeletal pain and strategies for breathlessness and infection control. The airway clearance therapy plan is developed by a physiotherapist with expertise in respiratory disease and involves the use of a range of possible techniques including the ACBT, PEP devices (oscillating and non-oscillating), positioning, FET, percussion/vibrations and inhalation therapies. Referral to pulmonary rehabilitation is supported by the Australian and New Zealand Pulmonary Rehabilitation Clinical Practice Guidelines (15). Supervised exercise training has also been found to reduce the frequency of exacerbations in bronchiectasis (16). The goal of bronchiectasis care is to improve quality of life, reduce exacerbations, maintain lung function and improve symptom management (17).

Adults with bronchiectasis have demonstrated the potential to self-manage using strategies such as airway clearance therapy, exercise and medication (18). Focus groups have highlighted the importance of healthcare professionals in providing information and guidance, and in reviewing self-management strategies (18). A Cochrane review of disease self-management in bronchiectasis determined there was currently insufficient evidence to evaluate if self-management strategies are of benefit in bronchiectasis (19).

The role of targeted interdisciplinary bronchiectasis care which promotes disease specific strategies and supports self-management is unknown. There is an opportunity to improve quality of life, health care utilization and exacerbation frequency in adults with bronchiectasis through targeting evidence-based interventions in an interdisciplinary care clinic. It is also important to evaluate the acceptability, uptake and attendance of an interdisciplinary care clinic to adults with bronchiectasis in a regional area.

2. Study one aim

2.1 Primary aim

To evaluate whether a pilot, innovative, interdisciplinary bronchiectasis clinic in a regional setting delivering targeted evidence-based interventions to adults with bronchiectasis will lead to improvements in quality of life.

2.2 Secondary aim

The secondary aims of this study are:

1. To evaluate whether there is a reduction in health care utilization in adults with bronchiectasis as a result of delivering an innovative, interdisciplinary bronchiectasis clinic in a regional setting with targeted evidence-based interventions.
2. To evaluate whether there is a reduction in the frequency of bronchiectasis exacerbations as a result of delivering an innovative, interdisciplinary bronchiectasis clinic in a regional setting with targeted evidence-based interventions.
3. To evaluate the impact of a pilot innovative interdisciplinary clinic in a regional setting for adults with bronchiectasis on implementation outcomes such as uptake and attendance.
4. To evaluate if patients attending the interdisciplinary bronchiectasis clinic do attend pulmonary rehabilitation if referred.

3. Study One Outcomes

3.1 Primary Outcomes

Primary outcomes of the study are:

1. Quality of life outcomes:
a. Quality of life- Bronchiectasis (QOL-B) questionnaire (20)
b. Leicester Cough Questionnaire (21)

3.2 Secondary outcomes

Secondary outcomes of the study are:

1. Number of days in hospital for a primary admission of bronchiectasis in the 12 months prior to the study and 12 months after enrolment (health care utilization).
2. Number of exacerbations of bronchiectasis in the 12 months prior to enrolment in the study and the 12 months after enrolment.

An exacerbation will be defined as a deterioration in three or more of the following key symptoms for at least 48 h: cough; sputum volume and/or consistency; sputum purulence; breathlessness and/or exercise tolerance; fatigue and/or malaise; haemoptysis AND a clinician determines that a change in bronchiectasis treatment is required (22).

3. Implementation outcomes
a. Number of adults with bronchiectasis referred to the clinic who attended an initial appointment with either the respiratory nurse practitioner or the physiotherapist (uptake).
b. Number of appointments for the interdisciplinary bronchiectasis clinic that were attended out of the appointments that were offered (attendance).

4. Attendance at pulmonary rehabilitation of at least six weeks if referred (measured at three and 12 months).

3. Study two aim

3.1 Primary aim

To evaluate whether a pilot, innovative, interdisciplinary bronchiectasis clinic in a regional setting delivering targeted evidence-based interventions to adults with bronchiectasis will be acceptable to patients.

4. Study two outcomes

4.1 Primary outcome

The primary outcome will be the measurement of clinic acceptability through semi structured interviews describing the components of the theoretical framework of acceptability including: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy (23).

5. Methods

The PIICC project involves health services research and is comprised of two prospective pilot studies. Study one and two are uncontrolled clinical trials evaluating the effects of an interdisciplinary care clinic on quantitative outcomes (study one) and qualitative outcomes (study two).

The study is being conducted at the Sub-acute and Chronic Care Rehabilitation (SACCR) service in Rockhampton, which is provided by the Central Queensland Hospital and Health Service (CQHHS).

5.1 Inclusion criteria

All patients > 18 years of age with clinically significant bronchiectasis (22) who have been referred to the interdisciplinary bronchiectasis outpatient clinic at the SACCR service (CQHHS) will be invited to participate.

5.2 Exclusion criteria

Patients will be excluded if they have attended a bronchiectasis outpatient clinic with the inclusion of a respiratory physician or respiratory nurse practitioner and a physiotherapist outside of the CQHHS in the 12 months prior to the study.

5.3 Recruitment

After obtaining ethical approval, patients who have been referred to the interdisciplinary bronchiectasis clinic will be invited to participate in study one and two. Patients will be invited to participate by the respiratory physician during a clinic appointment. Patients will be given

separate participant information sheets for study one and two. They will be informed that the study principal investigator (PI) will call in the following week to answer any questions about participation. This time is for potential participants to consider the information provided and to discuss it with family or support networks. If patients are not invited during a respiratory physician clinic appointment for any reason, they will be called by the study PI to be informed of study one and two. In this event, the participant information sheet will be posted to patients, followed by a second phone call one week after the participant information sheet has been received to answer any questions regarding participation. Patients will be able to participate in one, or both of the studies. Study recruitment will not affect the care delivered in the clinic which is based on national and international guidelines in bronchiectasis.

Patients who provide verbal consent on the telephone for participation in study one and/or two will return to the clinic at a scheduled time to complete a written consent form and baseline assessment measures. Baseline assessment measures will be conducted prior to the initial appointment at the interdisciplinary bronchiectasis clinic. The day prior to baseline assessment, participants will receive a telephone call to confirm the appointment, and to screen for a current exacerbation. An exacerbation will be defined as a deterioration in three or more of the following key symptoms for at least 48 h: cough; sputum volume and/or consistency; sputum purulence; breathlessness and/or exercise tolerance; fatigue and/or malaise; haemoptysis AND a clinician determines that a change in bronchiectasis treatment is required (22). Participants will only undergo baseline assessment measures after the completion of any antibiotic therapy prescribed for treatment of the exacerbation, and when respiratory symptoms are back to the patient's self-reported baseline.

6. Study Processes

6.1 Baseline assessment- study one/two

Baseline assessments will occur on the same day to reduce the inconvenience to participants. The baseline characteristics in bold text will be collected as part of the QOL-B questionnaire.

Baseline characteristics

1. **Age**
2. **Sex**
3. **Employment**
4. **Ethnicity**
5. **Education**
6. Height
7. Weight
8. BMI
9. Co morbidities (COPD, other chronic respiratory disease, heart disease, cancer, sinusitis, gastroesophageal reflux disease (GORD), other chronic disease)
10. Modified Medical Research Council (MMRC) Dyspnoea scale (24)
11. Participation in PR of at least six weeks duration in the last 12 months

Participants will have measured:

1. FEV1 (to allow the collection of the Bronchiectasis Severity Index (BSI)

The PI will calculate through audit of the medical record:

1. Bronchiectasis Severity Index (BSI) (25)

6.2 Baseline assessment- study one

Participants will complete the following questionnaires via the Redcap database with the PI present to assist with computer use and the understanding of questions:

1. QOL-B questionnaire (20)
2. Leicester Cough Questionnaire (21)

Healthcare utilization and exacerbation frequency will be audited from the hospital medical record:

1. Number of days in hospital for a primary admission of bronchiectasis in the 12 months prior to the study
2. Number of exacerbations of bronchiectasis in the 12 months prior to the study (self-reported and audited from information in the medical record)

6.3 Clinic intervention- study one/two

All participants will continue to receive care from the interdisciplinary bronchiectasis outpatient clinic throughout study one and two. The clinic offers appointments for initial assessment (new clinic patients), three and 12 month reviews in the first year, followed by six and 12 month ongoing review. This is supported by the British Thoracic Society (BTS) guidelines on bronchiectasis management (7). Additional appointments will be scheduled if clinically indicated after interdisciplinary team decision making (patients with recurrent infection and/or hospital admission or requiring additional education in self-management techniques). Patients will receive a follow up telephone call two weeks after the initial assessment from the physiotherapist to answer any questions from the bronchiectasis action plan developed. Patients will also be encouraged to contact the work telephone number of the physiotherapist if they have further questions prior to the scheduled three month review appointment.

The targeted evidence-based interventions of the clinic will depend on patient need and will include any of the following (6, 7): a medication action plan, an airway clearance plan, referral to pulmonary rehabilitation or home exercise prescription, PA and SB advice according to PA guidelines (26), and education relating to smoking cessation including Quitline referral, avoidance of environmental airborne pollutants, hydration, the management of co morbidities such as sinusitis, and musculoskeletal pain and strategies for breathlessness and infection control.

The medication action plan will be commenced by the respiratory physician prior to referral to the clinic, and then completed by the respiratory nurse practitioner at the clinic, along with education on medication timing and technique. The airway clearance therapy plan will be developed by a physiotherapist with expertise in respiratory disease and will involve the use of a range of possible techniques including the ACBT, PEP devices (oscillating and non-oscillating), patient positioning, FET, percussion/vibrations and inhalation therapies. Education on hydration will involve targeting the colour of urine to achieve optimal hydration of secretions to improve airway clearance. Sinusitis management will assess the need for sinus wash out and/or ongoing medications to minimize the effect of sinus discharge into the respiratory tract. Musculoskeletal pain will be evaluated for its role in affecting cough and airway clearance therapy effectiveness. Pain profiles will influence the components/techniques used in the airway clearance therapy plan, with strategies to minimize pain prescribed. If breathlessness at rest or during activity is a feature of the presentation, specific advice on activity pacing, positioning, relaxed breathing

techniques and fan therapy will be tailored to the individual. All patients will be given infection control advice relating to general respiratory hygiene and the cleaning of any airway clearance equipment or nebulisers used to minimize the potential for recurrent infection.

6.4 Outcome measures- study one

Participants will return to the SACCR clinic for review appointments at three and 12 months. The following outcome measures will be collected at a separate study appointment after the clinic appointments. If participants are experiencing an exacerbation, this data will be collected following the completion of antibiotics and the return to baseline symptoms.

Primary outcome measures

Patient outcomes at three and 12 months:

1. Quality of life- Bronchiectasis questionnaire
2. Leicester Cough Questionnaire

Secondary outcome measures

Healthcare utilization, exacerbation frequency and PR attendance will be audited from hospital medical records:

a. Number of days in hospital for a primary admission of bronchiectasis (12 months)
b. Number of exacerbations of bronchiectasis (12 months)
c. Attendance at pulmonary rehabilitation of at least six weeks if referred (measured at three and 12 months)

Participants will also self-report exacerbations using a 12 month diary kept during the study.

Implementation outcomes will be collected by the physiotherapist and respiratory nurse practitioner for the 12 months from study enrolment including:

a. Number of adults with bronchiectasis offered an initial clinic appointment who attended the clinic (uptake).
b. Number of appointments for the interdisciplinary bronchiectasis clinic that were attended out of the appointments that were offered (attendance).

6.5 Outcome measures- study two

The semi-structured interview will be scheduled following the three month review appointment and the collection of three month outcomes for study one (if participating in study one and two). If participants are experiencing an exacerbation, the interview will be conducted following the completion of antibiotics and the return to baseline symptoms.

Interviews will be conducted by a person with skills in qualitative research methods and semi-structured interviewing who is not the PI. An interview guide (appendix 1) will be used to assess the components of the theoretical framework of acceptability (23). Interviews will be approximately one hour- 90 minutes in length and will occur in a room at the SACCR clinic.

Interviews will be audio recorded by the interviewer and transcribed verbatim by the PI. The first two interviews will be coded by two researchers independently (the PI and chief researcher) to

establish consistency in coding approach. The remaining interviews will be coded by the PI, with emerging themes discussed and reviewed by the chief researcher (CR) and co-investigators (CI). Quotations will be selected from the transcripts which demonstrate the identified themes.

7. Safety Considerations

A risk assessment will be conducted by The University of Sydney Clinical Trials Support Office in accordance with Clinical Trials Policy (2016). This assessment will be finalised once ethics approval has been received.

7.1 The PI

The PI is enrolled as a Higher Degree Research (HDR) student of the University of Sydney in addition to being employed by the CQHHS. The research activities will be covered by the University of Sydney insurance for HDR students (appendix 2).

7.2 The participant

There are no safety considerations identified for participants. Participants will be receiving the standard care of the interdisciplinary bronchiectasis clinic throughout study one and two.

8. Data Management and Statistical Considerations

8.1 Sample size

The bronchiectasis outpatient clinic is held monthly. There are 60 new patient appointments per year. For study one a convenience sample of 72 patients over a period of 2 years is predicted for each study, based on 80% participation of included patients and a 25% drop out rate. For study two, patients will be recruited, and interviews conducted until no additional themes are emerging from the analysis (minimum 10 participants).

8.2 Data analysis

Baseline characteristics will be analysed using frequencies and descriptive statistics. Mean, median and 95% confidence intervals (95% CI) will be estimated for continuous variables.

Study one

Data analysis will be performed using SPSS (Version 25 for Windows IBM, USA).

Quality of life, at baseline, three and 12 months will be compared using one-way repeated measures ANOVA. Mean and standard deviation will be calculated. Quality of life outcomes will be reported against published minimally clinically important differences (MCID).

Health care utilization and exacerbation frequency will be compared for the 12 months prior to and the 12 months after the study using paired sample t tests.

Clinic uptake and attendance, and pulmonary rehabilitation attendance will be presented as percentages.

Study two

Data from the semi structured interviews will be analysed according to the phases of thematic analysis (27) including: familiarizing yourself with the data; generating initial codes; searching for themes; reviewing themes; defining and naming themes and producing the report. The first and second transcript will be coded by the PI and CR independently to generate initial codes and compare for consistency of coding. Coding will occur in categories which correspond to the seven components of the theoretical framework of acceptability (affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy) (23). The PI will then code the remaining transcripts, discussing themes that emerge with the CR and CIs. As themes emerge, purposive sampling will occur to gain further information in developing categories. NVivo 12 software will be used for the coding and analysis of the interviews. Participant consent will be gained to use quotations from the interviews that demonstrate the themes that emerge from the data.

8.3 Data security

Quantitative data will be stored on the REDCap database administered by the University of Sydney. REDCap provides for data de identification, secure storage, and encryption. Only the PI will have access to participants names and linking unique study identification number that is generated by REDCap. The CR and CIs who are external to Queensland Health will have access to de-identified data only. The University of Sydney research data store (RDS) will be used to store audio files and transcripts of the semi structured interviews. Only the study PI will have access to identifying data for participants in study 2 who will be allocated a unique study identification number in REDCap. E notebooks will be used to store finalised protocols, research notes, and interview guides. Data once analysed will be stored in a de-identified format on the RDS.

Data will be retained for 5 years and then disposed of in accordance with the data storage and disposal requirements of Queensland Health and the Research Data Management Policy (2014) of the University of Sydney.

9. Expected outcomes of the study

Targeted interdisciplinary outpatient clinics for the management of bronchiectasis are limited outside of metropolitan areas in Australia. This study will describe the impact of an innovative interdisciplinary care clinic delivering targeted evidence-based care on quality of life, health care utilization, clinic uptake, attendance, and acceptability. If successful, this study could provide a template for the provision of targeted evidence-based interdisciplinary bronchiectasis outpatient care.

10. Dissemination of results and publication

The results of this study will provide the basis for a Doctor of Philosophy thesis at the University of Sydney where the PI is enrolled as a current higher degree research (HDR) student. The aim is to publish the results in a series of journal articles:

a. Characteristics and health care utilization of adults with bronchiectasis who have not previously received targeted specialized bronchiectasis care.

b. Quality of life, health care utilization, exacerbation frequency, clinic uptake and attendance and pulmonary rehabilitation attendance of an innovative interdisciplinary bronchiectasis clinic delivering targeted evidence-based interventions in adults with bronchiectasis.

c. The acceptability to regional patients of an innovative interdisciplinary bronchiectasis outpatient clinic with targeted evidence based interventions.

In the CQHHS the results of this study will be disseminated via the Research and Innovation Showcase, and a summary of published results circulated via CQHHS daily news, weekly newsletters and social media platforms.

Community engagement with the results will occur through presentations to local radio, newspaper and television.

National and international dissemination of results will occur through presentations at national and international conferences such as the Australian Physiotherapy Association Conference, Thoracic Society of Australia and New Zealand conference, and the European Respiratory Society conference.

11. Duration of project

	2020		2021		2022		2023	
	Apr-Aug	**Sep-Dec**	**Jan-Jun**	**Jul-Dec**	**Jan-Jun**	**Jul-Dec**	**Jan-Jun**	**Jul-Dec**
Recruitment								
Data collection								
Data Analysis								

	2024		2025		2026		
	Jan-Jun	**Jul-Dec**	**Jan-Jun**	**Jul-Dec**	**Jan-Jun**	**Jul-Oct**	
Data analysis							
Writing and publication							

12. Project management- roles of each investigator

Chief researcher: to provide expert advice in all research processes (protocol, data collection, data analysis) and the critique of data and publication writing.

Principal investigator: to develop the protocol for the study. To collect the study data, de-identify, analyze and report on the data. To write for publication of results and disseminate this information nationally and internationally.

Co- investigators: to assist in the development of the protocol for the study. To guide the data analysis, interpretation of study findings and results and provide input into the final manuscript.

13. Ethics

The PI could be perceived as having a conflict of interest between being the physiotherapist who manages adults with bronchiectasis at the SACCR clinic and also the PI on a study looking at the outcomes from the clinic.

This perceived conflict of interest will be managed by potential participants being informed of the dual roles of the PI (clinician and researcher) in the participant information sheet and during the follow up phone call. At the time of participation consent, the PI will not be known to participants as they have not yet attended the interdisciplinary clinic. Participation will not influence the care delivered by the interdisciplinary clinic, as this is designed to meet the national and international guidelines in bronchiectasis. Potential participants will be given a participant information sheet, which will include details of how to contact the CQHHS Human Research Ethics Committee (HREC) if participants want to report a complaint. The participant can withdraw consent at any time.

A second ethical consideration is the time involved for participants in the collection of data at baseline, three and 12 months. The estimated time involved will be discussed at the initial phone call to gain verbal consent for participation. It will also be outlined on the participant information sheet. Participants can withdraw from the study at any time.

14. Consent- process for obtaining and forms used

The process for obtaining consent is outlined in section 4.3 Recruitment. Participant information and consent forms will be uploaded to Ethical Review Manager (ERM).

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Appendix 1: Interview Guide- Acceptability of an innovative interdisciplinary bronchiectasis clinic

You have been invited to participate in this interview because you have bronchiectasis, and you have attended the bronchiectasis clinic at the Sub Acute and Chronic Care Rehabilitation (SACCR) service. I am going to ask you some questions about your experience of the clinic. I am going to record what you say. It will take roughly an hour. The information you give is confidential and cannot be identified as coming from you. The answers you give will not influence the care you receive from the bronchiectasis clinic. Do you have any questions before I start?

Affective attitude- how an individual feels about the intervention

A clinic is one way of providing strategies to help you manage your bronchiectasis.

Q1. Do you think the bronchiectasis clinic you have been to has helped a lot, somewhat, a little or not at all to give you ideas for managing your bronchiectasis?

Q2. What has helped the most from the clinic? Why?

Q3. What have you not liked (or what has been the least helpful thing) about the clinic? Why?

Burden- the perceived amount of effort that is required to participate in the intervention

Q4. Has coming to the bronchiectasis clinic been a good use of your time?

Q5. Please describe a reason for your answer

Q6. Do you think coming to the clinic has taken a lot of effort, some effort, hardly any effort or no effort at all? This effort might be time, physical effort, time lost at work, travel costs etc.

Q7. Can you give a reason for your answer?

Ethicality- the extent to which the intervention has a good fit with an individual's value system

Q8. Do you think the clinic gave you good or useful ideas for managing your bronchiectasis?

Q9. Can you give a reason for your answer?

Q10. Do you feel the ideas were tailored to you as an individual and were practical?

Q11. Can you describe reasons for your answer?

Intervention coherence- the extent to which the participant understands the intervention and how it works

Q12. The clinic has been designed to provide you with an 'action plan' to manage your bronchiectasis when you are well and unwell. Do you think the action plan has helped you a lot, somewhat, a little or not at all to manage your bronchiectasis?

Q13. Can you give a reason for your answer?

Q14. Can you describe how you know you are well?

Q15. Can you describe how you know you are unwell?

Q16. What things do you change if you are unwell?

Q17. Do you think you will always have to come to the clinic? Please explain your answer

Q18. Have you been referred to or attended pulmonary rehab?

Q19. Why do you think you were referred?

Q20. If you have started pulmonary rehab, have there been any benefits to going?

Q21. Have there been any negative impacts from attending pulmonary rehab? Please describe your answer

Q22. Have you been given advice on doing exercise at home?

Q23. Can you describe what role exercise has played in helping you with your day to day life (if any).

Q24. Have you been given advice on staying active and reducing the amount of time you rest during the day?

Q25. Can you describe the role changing your activity and rest has played in helping you with your day to day life (if any).

Q26. Were you given advice about smoking?

Q27. Can you describe any changes you have made as a result of the advice you were given.

Q28. If you were unable to make changes, can you describe why.

Q29. Were you given advice on avoiding dust, mould or other potential environmental pollutants?

Q30. Have you made any changes after this advice? Please describe.

Q31. Can you describe any changes you made regarding hydration after coming to the clinic.

Q32. If you made changes, why? If you didn't make changes, why?

Questions 33-35 will be asked if the participant has sinusitis:

Q33. Were you given strategies to manage sinusitis?

Q34. Have you tried these strategies?

Q35. If so, have you noticed any changes as a result? If you haven't, can you describe why not.

Questions 36-37 will be asked if the patient has pain which affects their bronchiectasis

Q36. Were you given strategies to manage pain in your body which affects your ability to cough or manage your bronchiectasis?

Q37. Can you describe if these strategies helped? If not, can you describe why they didn't help

Q38. Did you discuss what to do if you are out of breath, either during exercise or daily life?

Q39. Please describe if and how these strategies have helped

Q40. Were you given advice on how to reduce the risk of getting more infections?

Q41. Can you describe the advice you were given and if it has been useful? If it hasn't been useful, please explain why.

Opportunity costs- the extent to which benefits, profits or values must be given up to engage in the intervention

Q42. Have you had to give up anything or make any changes in your daily life to follow your action plan?

Q43. Please describe the things you have given up or had to change

Q44. Do you think it has been worth it?

Q45. Can you give a reason for your answer?

Perceived effectiveness- the extent to which the intervention is perceived as likely to achieve its purpose

Q46. If you think back to before you first came to the clinic, do you think you have achieved what you were hoping to achieve (e.g cough less, feel better, have more energy) by coming to the clinic?

Q47. Please describe reasons for your answer

Q48. Do you think you are likely to achieve these things in the future if you continue to come to the clinic?

Q49. Please describe reasons for your answer

Q50. Have you changed what you are hoping for by coming to the clinic?

Q51. Please explain your answer

Self- efficacy- the participant's confidence that they can perform the behaviour(s) required to participate in the intervention

Q52. In the time between your clinic visits, do you feel confident carrying out your action plan?

Q53. Please describe the things you feel confident doing. Can you say why you feel confident doing these things?

Q54. Please describe the things you find difficult to do between clinic visits. Can you describe why they are difficult to do?

This is the end of the interview. Do you have any other suggestions or anything else you would like to say about the bronchiectasis clinic?

Thank you for your time.

This information is going to be used to improve the bronchiectasis clinic.

Appendix 2

Certificate of Currency

Date of Issue: 19 November 2019

AON
Empower Results®

The University of Sydney

Sydney 2006
New South
Wales Australia

We hereby certify that the under mentioned insurance policy is current as at the date of this certificate, please refer to the important notices below.

Policy Type No Fault Compensation Insurance for Clinical Trials and/Human Volunteers Studies

Insured The University of Sydney and others as per policy

Interest All sums in excess of the deductible that the Insured shall become liable to pay as damages or compensation and claimants costs and expenses in respect of any Claim made by Research subjects for Bodily Injury caused by an Occurrence happening after the Retroactive Date within the Policy Territory and arising out of the Business of the Insured.

Business The undertaking of any Trial by or on behalf of the Insured in connection w ith the Insured's business as University.

Insurer Certain Underwriters at Lloyds of London (New line syndicate)

Policy Number(s) WIBCLT17522

Period of Insurance From: 4.00 pm 31st October 2019 Local Standard Time
To: 4.00 pm 31st October 2020 Local Standard Time

Limits of Liability $20,000,000 in the aggregate for any one Period of Insurance

Geographical Limit Within Australia

Further Information
Should you have any queries, please contact us on the details set out at the top of the page.

Important notes

- Aon does not guarantee that the insurance outlined in this Certificate will continue to remain in force for the period referred to as the Policy may be cancelled or altered by either party to the contract, at any time, in accordance with the terms of the Policy and the Insurance Contracts Act 1984 (Clth).
- Aon accepts no responsibility or liability to advise any party who may be relying on this Certificate of such alteration to or cancellation of the Policy.
- Subject to full payment of premium
- This certificate does not:

- represent an insurance contract or confer rights to the recipient;
  or Amend, extend or alter the Policy
- Contain the full policy terms and conditions