Participant Information/Consent Sheet

Interventional Study - *Adult providing own consent*

Title	An evaluation of a pilot, innovative interdisciplinary care clinic delivering targeted evidence-based care in bronchiectasis in a regional centre
Short Title	Outcomes of a bronchiectasis clinic
Protocol Number	1.0
Project Sponsor	Associate Professor Zoe McKeough The University of Sydney
Coordinating Principal Investigator/ Principal Investigator	Kirsty Watson
Associate Investigator(s)	Dr Annemarie Lee Dr Tiffany Dwyer
Location	Sub-acute and chronic care rehabilitation clinic (SACCR), Rockhampton

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in a research project that is testing the outcomes that can be achieved by a bronchiectasis outpatient clinic. The clinic has a respiratory nurse practitioner and a physiotherapist and follows the guidelines for bronchiectasis management in Australia and overseas.

This Participant Information/Consent Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described, including the review of your hospital medical record

You will be given a copy of this Participant Information/Consent Sheet to keep.

2 What is the purpose of this research?

There are guidelines in Australia and overseas on how to manage bronchiectasis. In regional and rural areas, access to this care can be limited. In bronchiectasis, we do not yet know if we can increase your quality of life and reduce how often you need to go to hospital or how often you are unwell by attending a targeted care clinic. We also do not know in regional areas if a targeted care bronchiectasis clinic will be well attended. We would like to see if we can achieve these outcomes.

The results of this research will be used by the study physiotherapist Kirsty Watson to obtain a Doctor of Philosophy degree.

This research has been initiated by the study physiotherapist, Kirsty Watson. Kirsty will be the researcher collecting data for this study, and also the physiotherapist who provides your care in the bronchiectasis clinic.

3 What does participation in this research involve?

If you decide to participate, you will have to sign the consent form before any study assessments take place.

Every person > 18 years of age who is referred to the SACCR bronchiectasis clinic will be invited to participate.

If you have been treated in another bronchiectasis clinic outside of Rockhampton with a doctor or a respiratory nurse practitioner and a physiotherapist in the last 12 months you will not be able to take part.

You will be participating in an unblinded study. In an unblinded study you know that you are part of a study looking at the outcomes from the bronchiectasis clinic you attend. Your physiotherapist will also know you are part of the study.

You will receive a phone call approximately one week after you have been invited to participate in this study. This is so you can ask any questions you have after reading the information in this sheet.

If you decide to participate, you will be scheduled a time to come to the SACCR clinic to complete the written consent form and to have some information collected.

You will receive a phone call the day before your scheduled appointment to confirm the time, and to check you are not unwell. If you are having an exacerbation, the appointment will be rescheduled for after you have recovered. This phone call will be repeated each time before you are due to come to the clinic for the study to make sure you are well when we collect your information.

You will be asked to answer some questions about yourself (e.g. age). This will take 15 minutes.

You will have your height, weight and lung function measured. This will take 15 minutes.

You will be asked to complete a questionnaire about your quality of life and a questionnaire about your cough. This will take 30 minutes.

You will also be asked about how many exacerbations of bronchiectasis you have had in the past 12 months. This will take 10 minutes.

You will be given a 12 month diary that you can record how many exacerbations you have had.

The study physiotherapist will review your hospital medical chart to see how often you have been in hospital in the last 12 months and to calculate the severity of your bronchiectasis.

You will have your first appointment scheduled at the clinic with a physiotherapist and respiratory nurse practitioner. You will receive the usual care of the bronchiectasis clinic if you are part of this study. This usual care involves an initial assessment, three and 12 month review appointments, as well as additional appointments if your nurse or physiotherapist decide it is needed to improve your health. The care of the clinic includes:

- a medication action plan
- a plan for clearing sputum/phlegm
- a referral to pulmonary rehabilitation or home exercise prescription
- general physical activity and sedentary behaviour advice according to the Australian guidelines
- education relating to smoking cessation, avoidance of environmental airborne pollutants, and hydration
- advice on the management of other problems such as sinusitis and musculoskeletal pain
- strategies to manage breathlessness
- education in infection control

You will come back to the clinic after three months for a review appointment. After this review, and at a separate scheduled day and time you will come back to the clinic to collect more information.

You will be asked to complete (for the second time) a questionnaire about your quality of life and a questionnaire about your cough. This will take 30 minutes.

You will be asked if you have attended pulmonary rehabilitation in the last three months. This will take 5 minutes.

You will have another review appointment at the bronchiectasis clinic at 12 months.

You will come back to the clinic after this 12 month appointment on a separate day. This will be the final time information is collected for the study.

You will be asked to complete a questionnaire about your quality of life and a questionnaire about your cough. This will take 30 minutes.

You will be asked to remember how many exacerbations of bronchiectasis you have had in the past 12 months. You can use the information from your diary. This will take 10 minutes.

In summary, you will come to the SACCR clinic three times during the study in addition to your usual clinic appointments. You will do the questionnaires three times. You will answer questions about how often you go to hospital or are unwell over a 12 month period. You will record this in a diary.

Total time required for answering questions/taking measurements: 2 hrs 25 minutes
Total time needed to record information in your dairy (maximum): 10 minutes/week

You will be involved in this study for 12-14 months from the time you start, depending on if you are unwell during the study.

The study physiotherapist will review your medical record to see how many days you have been in hospital, how many exacerbations you have had and if you have been to pulmonary rehabilitation. Information will also be collected on how many appointments you have scheduled at the bronchiectasis clinic and how many you attend.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids the study researchers or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid.

It is desirable that your local doctor be advised of your decision to participate in this research project.

4 What do I have to do?

Anyone referred to the SACCR bronchiectasis clinic can participate in this study. There are no restrictions on what you can do in your daily life.

5 Other relevant information about the research project

This project is a collaboration with the University of Sydney. We hope to have 72 people take part in the study over a two-year period.

Another study will be happening at the same time. You can choose to be part of one, or both studies. There is a separate information/consent sheet for each study.

If you take part in more than one study, we will only ask you the information about yourself once (e.g. age).

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with the Central Queensland Hospital and Health Service.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive care at the SACCR clinic. If you participate in this study, the outcomes we are measuring will be in addition to the clinic appointments you usually come to.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include increasing your quality of life, reducing the effect your cough has on your daily life, reducing the amount of time you spend in hospital and reducing the number of times you are unwell.

9 What are the possible risks and disadvantages of taking part?

There are no risks or disadvantages to taking part in this study.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the care that is being studied. If this happens, your study physiotherapist will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study physiotherapist will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study physiotherapist might consider it to be in your best interests to withdraw you from the research project. If this happens, she will explain the reasons and arrange for your regular health care to continue.

11 Can I have other treatments during this research project?

Whilst you are participating in this research project, you can continue with any other treatments you would like.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify the study physiotherapist before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.
If you do withdraw your consent during the research project, the study physiotherapist and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

13 What happens when the research project ends?

When the research project ends, you will continue to attend the SACCR bronchiectasis clinic.

You will receive a written summary of the results at your clinic appointment when the research project is completed. This will happen after all the results have been collected. It may be a maximum of three years after you have first started in the study. This is to allow time for results to be collected from 72 people.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form you consent to the study physiotherapist and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Only the study physiotherapist will have access to identifiable information. Other study researchers will have access to non-identifiable data only. Your data will be stored on a secure and encrypted data base supported by the University of Sydney. Your data will be kept for 5 years from the time of any publications resulting from this research in accordance with *The Australian Code for the Responsible Conduct of Research.* Your data will be securely deleted from the data base at the end of this period. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

In accordance with relevant Australian and Queensland privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.
Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

15 Complaints and compensation

If you wish to make a complaint about the study physiotherapist or any aspect of this study, you can contact:

Central Queensland Health Service District Human Research Ethics Committee
A/Administrator: Kristy Richardson
Chair: Dr Sunday Pam
Phone: 07 4920 5759
Email: CQHHShrec@health.qld.gov.au

16 Who is organising and funding the research?

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

There are no declarations of interest involved in this study.

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the CQHHS.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

18 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project, you can contact the principal study physiotherapist on 0416848214.

Clinical contact person

Name	Kirsty Watson
Position	Advanced Allied Health Practitioner
Telephone	0416848214
Email	Kirsty.watson@sydney.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	CQHHS
HREC Executive Officer	Dr Sunday Pam (Chair)
Telephone	0749205759
Email	CQHHShrec@health.qld.gov.au

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Kristy Richardson
Position	HREC Secretary
Telephone	0749205759
Email	CQHHShrec@health.qld.gov.au

Consent Form - *Adult providing own consent*

Title	An evaluation of a pilot, innovative interdisciplinary care clinic delivering targeted evidence-based care in bronchiectasis in a regional centre
Short Title	Outcomes of a bronchiectasis clinic
Protocol Number	1.0
Project Sponsor	Associate Professor Zoe McKeough The University of Sydney
Coordinating Principal Investigator/ Principal Investigator	Kirsty Watson
Associate Investigator(s)	Dr Annemarie Lee, Dr Tiffany Dwyer
Location	Sub-acute and chronic care rehabilitation clinic (SACCR), Rockhampton

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to The University of Sydney concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Physiotherapist/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Physiotherapist/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Name of Study Physiotherapist/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning the research project.

Note: All parties signing the consent section must date their own signature.