Participant Information Sheet/Consent Form

Adult providing own consent

Title	*Allied Health Assistant Care for Patients with Acute Hip Fracture: a feasibility randomised controlled trial*
Short Title	*Allied Health Assistant Care for Patients with Acute Hip Fracture*
Protocol Number	*Protocol version number 2 28/04/2020*
Project Sponsor	*David Snowdon*
HREC ID	HREC63005PH-2020
Coordinating Principal Investigator/ Principal Investigators	*David Snowdon, Peggy Vincent, Michele Calisaya, Taya Collyer, Nicholas Taylor*
Location	*Peninsula Health*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have broken your hip and are currently receiving management for your fracture at Peninsula Health. This research project is investigating whether it is feasible for allied health (physiotherapy) assistants to provide rehabilitation (e.g. walking after surgery) after your surgery.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the 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 health care team.

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 treatments that are described
• Consent to complete the questionnaire described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

After hip fracture many people have very low levels of physical activity during their hospital stay. There is evidence that increasing walking and physical activity has many health benefits, but is challenging for people after hip fracture. This randomised controlled trial will find out if receiving your physiotherapy rehabilitation from an allied health assistant is a feasible intervention for increasing your activity after surgery and improving health outcomes for you.

Researchers from Peninsula Health and Eastern Health are conducting this research.

3 What does participation in this research involve?

Following your surgery it is standard physiotherapy practice that you be provided with the following physiotherapy care:

- walking aid to assist with walking
- standing or seated exercise to improve your strength and hip movements
- practice walking, transferring on/off bed, on/off chair and up/down stairs
- education regarding your fracture, surgery and physical function

Either a physiotherapist or an allied health (physiotherapy) assistant may provide these activities to you. Both a physiotherapist and allied health (physiotherapy) assistant are qualified to provide this therapy. To try and make sure the groups are the same at the beginning of the study, each participant is put into a group by chance. Therefore, there will be one chance in two that you will end up in either of the two groups with a physiotherapist or an allied health assistant providing your physiotherapy care.

If you are allocated to the allied health assistant group, an allied health assistant will provide your physiotherapy care during your stay at Frankston Hospital. This care will be supervised by your treating physiotherapist.

If you are allocated to the physiotherapy group, a physiotherapist will provide your physiotherapy care during your stay at Frankston Hospital.

The goals and activities of care you receive will be similar, as listed above, regardless of the group you are allocated to. However, the time you spend receiving care may differ between groups.

You will also be asked to complete one questionnaire about your satisfaction with the physiotherapy care you receive at Frankston Hospital as part of this study. You would also be agreeing to the researchers of this study accessing the data that is routinely collected as part of usual hospital care. This includes information on the number of days that you walk in Frankston Hospital, the level of assistance you require to walk, the distance that you walk, the number of days you are in hospital, where you discharge to from hospital and any adverse events (for

example falls) that you experience during your hospital stay. We will collect all information from your medical file.

We will also collect information from your medical file in regard to your age, pre-existing medical conditions and details of your hospital admission.

Reimbursement
There are no costs associated with participating in this research project, nor will you be paid. All interventions provided as part of the research project will be free of charge.

4 What do I have to do?

By choosing to participate in this study you are committing to receiving care from either the allied health assistant or a physiotherapist, dependent on what group you are allocated to. You will also be asked to complete one questionnaire about your satisfaction with the physiotherapy care you receive at Frankston Hospital.

5 Other relevant information about the research project

This project will recruit 50 participants recovering from a hip fracture at Frankston Hospital, Peninsula Health.

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 Peninsula Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital.

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 the associated benefits of walking and physical activity following hip fracture.

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

Both groups will receive care that is standard physiotherapy for patients following surgery for hip fracture. However, there are some possible risks in taking part:

For all people recovering after hip fracture there is an increased risk of falling. Whichever group you are allocated to, you will receive falls prevention education as part of your standard care at Peninsula Health. This may include prescription of an appropriate walking aid, exercises to assist with balance and advice regarding footwear.

Peninsula Health

You may experience exacerbation of symptoms such as pain that may be mild, moderate or severe when completing the physiotherapy program. There is also a very small risk that you may experience symptoms such as fatigue, dizziness, nausea or shortness of breath. If you have any of these symptoms, or are worried about them, talk with your treating physiotherapist or allied health assistant.

There may be symptoms that the researchers do not expect or do not know about and that may be serious. Tell your treating physiotherapist or allied health assistant about any new or unusual symptoms that you get.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the principal researcher will tell you about it and discuss with you whether you want to continue in the research project.

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

11 Can I have other treatments during this research project?

While you are participating in this research project, you will continue to receive standard care, such as usual consultations with your doctor(s) and other members of your treatment team.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; the project coordinator will provide this to you.

If you do withdraw your consent during the research project, the research team 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.

13 What happens when the research project ends?

At the conclusion of the study, the research team will send a written report summarising the findings of the research study to all participants who request it.

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 research team collecting and using personal information about you for the research project. Your information will only be used for the purpose of this research project or in future research projects that are extensions of or closely related to this project and it will only be disclosed with your permission, except as required by law. Further, your consent is only specific to participation in this and closely related research projects and does not involve the establishment of a databank.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored.

Peninsula Health

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

We have put in measures to maintain your confidentiality throughout this research process. These include the following:

- Each participant will be assigned a unique subject code. Only researchers involved in the research project can identify the participant from this subject code.
- A paper copy of the data (which identifies participants and their subject code) will be stored in a locked cabinet in the researcher's office. Only the researchers involved in the research project will have access to this cabinet.
- An electronic copy of the data, (which only identifies participants, under their subject code) will be stored in a secure computer folder. This folder will require a unique username and password to access information, which is only known to the researchers involved in the research project.

Information about your participation in this research project may be recorded in your health records.

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

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for 5 years. Following this time period hard copies of the questionnaires and all electronic information will be permanently destroyed. Access to information about you after this point will not be possible as the information will have been disposed of securely.

15 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the research team as soon as possible and you will be assisted with arranging appropriate medical treatment.

16 Who is organising and funding the research?

This research project is being conducted by David Snowdon (Peninsula Health). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

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 Peninsula Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Peninsula Health

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 or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher (clinical contact person) or any of the following people:

Clinical contact person

Name	David Snowdon
Position	Principal Researcher
Telephone	[redacted]
Email	[redacted]

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person and reviewing Human Research Ethics Committee

Name	Peninsula Health Human Research Ethics Committee
Position	Manager
Telephone	[redacted]

Peninsula Health

Consent Form – *Adult providing own consent*

Title	*Allied Health Assistant Care for Patients with Acute Hip Fracture: a feasibility randomised controlled trial*
Short Title	*Allied Health Assistant Care for Patients with Acute Hip Fracture*
Protocol Number	*Protocol version number 2 28/04/2020*
Project Sponsor	*David Snowdon*
Coordinating Principal Investigator/s	*David Snowdon, Peggy Vincent, Michele Calisaya, Taya Collyer, Nicholas Taylor*
Location	*Peninsula Health*

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 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 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 Senior Researcher† (please print) _____

Signature _____ Date _____

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

Peninsula Health

Form for Withdrawal of Participation - *Adult providing own consent*

Title	*Allied Health Assistant Care for Patients with Acute Hip Fracture: a feasibility randomised controlled trial*
Short Title	*Allied Health Assistant Care for Patients with Acute Hip Fracture*
Protocol Number	*Protocol version number 2 28/04/2020*
Project Sponsor	*David Snowdon*
Coordinating Principal Investigators	*David Snowdon, Peggy Vincent, Michele Calisaya, Taya Collyer, Nicholas Taylor*
Location	*Peninsula Health*

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Peninsula Health.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Senior Researcher† (please print) _____

Signature _____ Date _____

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

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