Participant Information Sheet/Consent Form – Person Responsible/Medical Treatment Decision Maker

Interventional Study - *Person responsible/Medical treatment decision maker consenting on behalf of participant*

Title	The HOME Rehab trial: comparing the effectiveness of occupational therapy homevisit discharge planning to in-hospital consultations to improve participation after stroke
Short Title	The HOME Rehab trial
Protocol Number	HREC/17/Alfred/236
Project Sponsor	La Trobe University/Alfred Health
Coordinating Principal Investigator/ Principal Investigator	A/Prof Natasha Lannin
Site Principal Investigator	Brynn Lewin
Location	Royal Talbot Hospital and Heidelberg Repatriation Hospital

Part 1 What does participation involve?

1 Introduction

The participant is invited to take part in this research project. This is because the participant has had a stroke. The research project aims to determine the effectiveness of a specialised intervention provided by occupational therapists during the participant's transition from hospital to home and returning to their daily life activities. These types of services are often referred to as 'discharge planning'.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want the participant 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 the participant can take part, you might want to talk about it with a relative, friend or the participant's local doctor.

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

If you decide you want the participant 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 the participant taking part in the research project
- Consent to the participant having the tests and treatments that are described
- Consent to the use of the participant's 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?

Both hospital-based and home-based discharge planning consultations are provided as part of getting a patient back home after stroke, and are believed to improve the transition from hospital to home. No-one has conducted a research study to see if there are differences in outcomes between hospital and home-based occupational therapy consultations for adults who are inpatients in rehabilitation after stroke. The purpose is to investigate whether one type of consultation, in-hospital or at home, is better than the other for improving participation in daily activities and reducing readmission rates for people who have suffered a stroke. We will use the findings to inform future stroke rehabilitation practice. We will recruit 360 adults from 13 rehabilitation hospitals in Australia. At Royal Talbot Hospital we expect to recruit 40 people.

The participant will be randomly assigned (like a toss of a coin) to receive either a hospital-based or home-based consultation involving an interview and assessment, education and training prior to discharge. There is equal chance that they will receive either intervention. This study is supported by national and international researchers' and has been funded by a National Health and Medical Research Council Project Grant.

3 What does participation in this research involve?

If you decide that the participant can take part in this research project, you will be asked to sign the consent form before any study assessments are performed. This study will be conducted over 12 months in total. Participants will be taking part in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is randomly put into a group (like the toss of a coin) to receive either a hospital-based or home-based consultation. For the hospital-based consultation, you will be asked questions about the participant's home environment as well as asked about what activities are important to them in the home and outside of hospital. You will also be asked to take photographs of the participant's home environment to help the rehabilitation team match the rehabilitation program to the needs of the participant. For the home-based consultation, an occupational therapist would also accompany you and the participant to the participant's home in a hospital car; there would be up to three such visits each taking about 75 minutes to complete. After these visits you and the participant will receive two follow up phone calls from the occupational therapist with the purpose to problem solve, provide feedback and encouragement. The home-based consultation offered in this study differs from standard practice. It is based on previous research about occupational therapy discharge planning. There is equal chance that the participant will receive either intervention.

All study participants will be asked to complete some questionnaires and functional tasks while in hospital and again 4 weeks and 6 months after discharge home. If the participant is not able to answer all questions, you will be asked to answer these on behalf of the participant. These will be completed in their own home by a researcher employed by the project and at no cost to you or the participant. For all assessments, questionnaires and the interview, the research team will come to the participant – they will not be required to travel back to the hospital.

There are no additional costs associated with participating in this research project. All medical care required as part of the research project will be provided to the participant free of charge. The participant will receive a gift card of $50 to acknowledge the time taken for each assessment.

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

4 What does the participant have to do?

In addition to the assessments conducted at 4 weeks and 6 months, you will be asked to record participant's health and community services on a calendar. Each month a research staff member will arrange for this information to be collected over the phone or returned to the study

investigator by either mail or email. Participants will otherwise be able to carry on with their normal lifestyle.

At the end of the study intervention we may also ask if the participant is willing to have a separate interview with one of the study researchers. The purpose of the interview is to seek feedback on the study interventions, satisfaction with the discharge planning process received and whether there are any suggestions for improvement. The interview will take about 30 mins. To ensure responses are correctly interpreted, responses to questions will be written down by the researcher and audio recorded. We will seek around 30 participants to be interviewed. It is your decision whether or not the participant will be interviewed.

Five weeks before the 12 month follow-up we will send both you and the participant a reminder of their final appointment and ask that you complete a diary to log their healthcare uitilisation for the following 4 weeks. At the final 12 month assessment this diary will be collected from a research staff member who will also administer two health questionnaires. This follow-up assessment will take about 10-15 minutes to complete and will be conducted over the phone. If the participant is not able to answer all questions, you will be asked to answer these on behalf of the participant.

5 Other relevant information about the research project

The project involves researchers from a number of healthcare organisations and universities across Australia and overseas, working in collaboration. The coordinating investigator, Associate Professor Natasha Lannin, is employed by Alfred Health (Melbourne) and La Trobe University.

6 Does the participant have to take part in this research project?

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

If you do decide that the participant can 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 the participant can take part or not take part, or take part and then be withdrawn, will not affect the participant's routine treatment, your or the participant's relationship with those treating them, or the participant's relationship with Austin Health.

7 What are the alternatives to participation?

The participant does not have to take part in this research project to receive treatment at this hospital. Other options are available; these include standard discharge preparations that may, or may not, include an occupational therapist assessment. You can discuss these options with the medical team before deciding whether or not to the participant can take part in this research project. You can also discuss the options with the participant's local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that the participant will receive any benefits from this research; however, possible benefits may include improved function and confidence with activities after discharge.

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

There are no known risks, other than those normally associated with rehabilitation, and no anticipated discomfort from taking part in this study. There may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any new or unusual symptoms that the participant develops.

10 What if I withdraw the participant from this research project?

If you decide to withdraw the participant from the project, please notify a member of the research team before you withdraw them. This notice will allow that person or the research supervisor to further discuss any health risks or special requirements linked to withdrawing.

If you do withdraw the participant during the research project, the researchers may ask you if you are willing to allow the participant to attend follow-up visits to allow collection of information regarding their health status. Alternatively, you may be asked permission for the research team to obtain access to the participant's medical records for the collection of follow-up information for the purpose of research and analysis. Personal health information already collected will be retained, unless you specifically request otherwise, to ensure that the results of the research project can be measured properly.

11 What happens when the research project ends?

You may, if requested on the consent page, receive a summary of the results of this research project at its completion. This summary will be shared by email. We anticipate this to be the end of 2021.

Part 2 How is the research project being conducted?

12 What will happen to information about the participant?

By signing the consent form you consent to the relevant research staff accessing the health records of the participant to collect personal and health information. Information about their participation in this research project will be recorded in their health records. The research staff will also collect information on the health services the participant has used for the 12 months before their stroke and 12 months following their discharge. Information about the participant will be obtained from their health records held at this and other health services. To collect this information, identifiable data (e.g. their name, age and address) will be submitted to the Australian Institute of Health and Welfare (AIHW) so that information about their health service usage can be obtained from a range of health datasets (such as Medicare) and linked to their study data. The health service data will be provided to the research team, by the AIHW, in a format where their identifiable data (e.g. their name and address) has been removed. This information will be used solely for the purposes of this project.

This trial involves transborder data flow within Australia, that is data collected from hospital sites outside of Victoria will be stored in Victoria. In these circumstances the participant's information will be dealt with in accordance with Victorian privacy laws, including the Victorian Health Privacy Principles. Any information obtained for the purpose of this research project that can identify the participant will be treated as confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

Data will be kept securely at the Alfred Hospital and LaTrobe in a locked filing cabinet and password protected research computer. Re-identifiable information will be kept to enable follow up assessments to be conducted at 4 weeks, 6 and 12 months post-discharge. Re-identifiable information will also be kept to follow up health service utilisation and outcomes via data linkage. Data will be stored for 7 years.

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 the participant cannot be identified, except with your permission. Any personal information that could identify the participant will be removed or changed before files are shared with other researchers.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to participant 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 the participant's information.

13 What happens if the participant is injured as a result of participating in this research project?

If the participant suffers any injuries during their participation in any occupational therapy sessions in this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment for the participant. If the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In the first instance the study occupational therapist and/or doctor will evaluate the participant's condition and then discuss treatment with both you and the participant's regular treating doctor. In the event of loss or injury, any question about compensation must initially be directed to the study doctor who should advise their insurer of the matter.

14 Who is organising and funding the research?

This research project is being conducted by A/Prof Natasha Lannin and a team of national and international researchers. It has been funded by a National Health and Medical Research Council Project Grant. No member of the research team will receive a personal financial benefit (other than their ordinary wages) from the participant's involvement in this research project.

15 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 Alfred Health.

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.

16 Further information and who to contact

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

For all enquiries concerning this project, you can contact the principal researcher, during business hours:

> Dr Natasha Lannin, Associate Professor in Occupational Therapy, Alfred Health. TEL: 03 9076 3230 or by email: n.lannin@latrobe.edu.au

If the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), then the number to call after hours is: 0417135153.

For complaints

For matters relating to research at the site at which the participant is taking part, the details of the local site complaints person are:

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

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 name	Alfred Hospital Ethics Committee
Complaints Contact	Complaints Officer, Office of Ethics & Research Governance
Telephone	(03) 9076 3619
Email	research@alfred.org.au

* You will need to tell the Complaints Officer the following project number 30/18.

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Consent Agreement

I am the Person Responsible/medical treatment decision maker for *[Participant's Name]* (the 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 believe that the participation of the participant in this study is not contrary to their best interests/their preferences and values and their social wellbeing.

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

I am aware of my responsibilities as the Person Responsible/medical treatment decision maker for the participant and I understand that I will be assisting the participant in meeting their responsibilities whilst they are participating in this study.

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Austin Health concerning the participant's disease and treatment for the purposes of this research project. I understand that such information will remain confidential.

I agree that data gathered for the study may be published provided the participant's name or other identifying information is not used.

□ I wish to receive results of this study □ I do not wish to receive results of this study

Declaration by Person Responsible/ medical treatment decision maker – for Person Responsible/medical treatment decision maker who has read the information

Name of Participant (please print)

Name of Person providing consent (please print)

Relationship of Person providing consent to Participant

Signature of Person providing consent Date

Declaration by the Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible/medical treatment decision maker has understood that explanation.

Name of Researcher† (please print)

Signature Date

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

Form for Withdrawal of Participation – Person Responsible/Medical treatment decision maker

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Declaration by Person Responsible/medical treatment decision maker

I wish to withdraw the participant from taking part in the above research project and understand that such withdrawal will not affect the participant's routine treatment, relationship with those treating them or their relationship with Austin Health.

Name of Participant (please print)

Name of Person providing consent (please print)

Relationship of Person providing consent to Participant

Signature of Person providing consent Date

Name of Researcher (please print)

Signature Date

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