 

**Participant Information Sheet / Consent Form**

**Interventional Study** -*Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | *A new model of physiotherapy rehabilitation**to improve outcomes after hip fracture* |
|  |  |
| **Coordinating Principal Investigator/ Principal Investigator** | *Ms Catherine Senserrick, Prof Nicholas Taylor* |
| **Associate Investigator(s)** | *Dr Genevieve Kennedy, Mr Grant Scroggie, Ms Kim Williams, Ms Kate Lawler* |
| **Location**  | *Peter James Centre* |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have had surgery for a hip fracture. The research project is testing a new way of providing physiotherapy after hip fracture surgery.

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 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. An interpreter can also be organised to assist you.

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.

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

**2 What is the purpose of this research?**

Currently physiotherapy for people receiving rehabilitation after surgery for a broken hip is prescribed at an average of 45 minutes/ 5 sessions per week. However, we know from previous research that the maximum dosage of walking tolerated by patients recovering from hip fracture in rehabilitation is 6 minutes for each bout of exercise. Research has also shown that patients in rehabilitation wards often spend the rest of the day alone and inactive. This project aims to determine if 3 shorter sessions of physiotherapy each therapy day helps patients recover faster than 1 longer session, where much of the time may be spent resting. We aim to test whether this model helps the patient do more walking each day, improves their mobility faster, and gives them a greater chance of returning to their own home.

The study investigator, Cathy Senserrick, a physiotherapist at Peter James Centre, has initiated this research. Professor Nicholas Taylor, Dr Genevieve Kennedy, Mr Grant Scroggie, Ms Kim Williams and Ms Kate Lawler are supervising her.

This research has been funded by both the rehabilitation unit at Eastern Health and the physiotherapy department at Eastern Health. Professor Taylor works for La Trobe University as well as at Eastern Health.

**3 What does participation in this research involve?**

If you agree to participate, you will be randomly allocated to go in either the new model of physiotherapy (3 x 15 minute sessions 5 days/ week) or the usual model (1x 45 minute session 5 days/week). This means that you have an equal chance of being in either group.

This is called 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. To do this 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 2 groups of people are the same, each participant is put into a group by chance (random) - this means you cannot choose which group you think will be better or suit you best.

Participants in both groups will first undergo a mobility test. This takes about 10 minutes and involves watching you get in and out of bed and a chair, balance in standing, walk with assistance and pick an object off the floor if you can.This test will be repeated after you have been in the rehabilitation unit for about 2 weeks, and again at discharge, depending on how long you need to stay in rehabilitation.

There are only two “different” things you will do by being part of this project. First, you will wear an activity monitor continuously, for up to 7 days from the second week of your admission (depending on how long you need to stay). Consistent with the manufacturer’s recommendations, this small device called the ActivPAL is taped to your thigh. This tells a computer how much walking you do each day, both in physiotherapy and the rest of the day. The activity monitor does not interfere with medications, and does not restrict activities, for example you can wear it in the shower. Low allergy tape will be used to attach the monitor to your thigh to help protect your skin; we have used these in similar research projects without any problems. The activity monitor should not be worn in the pool if you are having hydrotherapy; in this case we will take it off before you get into the pool and then reattach it afterwards. Second, you will be asked to complete a very short survey at the end of your stay in rehabilitation, telling us how you coped with the physiotherapy, whether you thought it was too much or too little. This should take less than 5 minutes to complete and will be completely anonymous- surveys can be “posted” into a box at the centre without your name attached.

We will monitor your safety at all times, and check that you have not been readmitted to hospital Eastern Health in the first 30 days after you are discharged from Peter James Centre. To do this we will check your medical record.

We will also collect other data about your condition and your progress from your medical record. This will include routine measures that your physiotherapists record such as your functional independence plus details of your injury, such as the date and type of surgery you had.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way, and avoids study investigators or participants jumping to conclusions. This is why the health professional who tests you, will not know which group you are in, and you must not tell them.

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

**4 What do I have to do?**

If you decide to participate, the project officer will organise for your mobility test to be completed. Next you will be randomly allocated to your treatment group and then physiotherapy will be booked in for you according to your group. The shorter physiotherapy sessions will take place in your room/ walking in the corridor, whereas the longer sessions may take place in your room, or you may be taken to the gymnasium in a wheelchair, which is usual care.

The project officer will organise your activity monitor to be attached to your thigh in the second week of your admission to Peter James Centre. You will wear this for up to 7 days, depending on when you are discharged.

As usual for all patients at Eastern Health, interpreters can be provided to assist you in your recovery. We can order an interpreter a day in advance, to attend a treatment session, or use a telephone interpreter. You also have the right to refuse treatment at any time, and we will note which sessions you have missed and the reasons why, as is usual practice.

Below is a table summarising the timeline for participants in each group.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***First working Day of Admission*** | ***Therapy Day1*** | ***Day 1*** | ***Day2-6*** | ***Day 7*** | ***Day8-13 (or day of discharge)*** | ***Day 13- discharge if still admitted*** | ***Day14 or discharge day if earlier than this*** | ***Discharge Day*** |
| ConsentUsual physio assessment and treatment plan/goals made | **Mobility Test** | **Assigned to control group**Physio 1x 45 minutes | Physio 1x 45 mins | **Activity monitor attached**Physio 1x 45 mins | Usual physio | Physio 1x 45 minsFinal assessment and referrals/ equipment organised | **Activity monitor removed and repeat Mobility Test** | **Repeat Mobility Test** |
| ConsentUsual physio assessment and treatment plan/goals made | **Mobility Test** | **Assigned to new model of physio group****Physio 3x 15 mins** | **Physio 3 x 15 mins** | ***Activity monitor attached******Mobility Test******Physio 3 x15mins*** | **Physio 3x 15 mins** | **Physio 3 x 15 mins**Final assessment/ referrals and equipment organised | **Activity monitor removed and repeat Mobility Test** | **Repeat Mobility Test** |

**5 Other relevant information about the research project**

72 patients will be recruited for this study, 36 in each group, over the course of approximately 10 months.

This is being trialled at Peter James Rehabilitation Centre only.

**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 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 Eastern Health/ Peter James Centre.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Physiotherapy will still be provided as usual (1x 45 minute session 5 days/week), including follow up physiotherapy should this be required.

**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 more physiotherapy/walking, a faster return of mobility, reduced time in hospital and a greater chance of returning to your home.

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

There are risks associated with having a hip fracture and subsequent surgery, as well as hospital stay, for example infection, blood clots and further falls. We think that the risk will be

equal in both groups but will monitor this carefully and inform the relevant ethics committees should any incidents occur. All patients will be assessed and managed by the health care team as part of usual care. In the event of any adverse events, participants will be assisted to seek treatment of these immediately.

Some patients may experience fatigue from having frequent physiotherapy, but longer sessions and being taken to the gym can also be very tiring. It is also our experience that many patients feel sleepy when they are left unoccupied. It is also usual for there to be pain after this surgery. Physiotherapists timetable their sessions in advance to allow nursing staff to administer appropriate pain medications beforehand. This will apply to both groups.

There is a small chance you may have an allergic reaction to the tape attaching the activity monitor to your thigh. You may get an itchy red rash. In the event of this occurring, the device should be removed immediately and medical attention will be provided.

**10 What if I withdraw from this research project?**

If you decide to withdraw from this 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 co-ordinator Cathy Senserrick will provide this to you.

If you do withdraw your consent during the research project, the study team will not collect further personal information from you, although personal information already collected will be retained to ensure the results of the research project can be measured properly and to comply with the law. You should be aware that data collected by the team 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.

**11 What happens when the research project ends?**

After the project ends and the information is analysed, a report will be written up. This will be finished in the early stages of 2018. This report summarises the results of the whole study. A copy of this report can be mailed to or emailed to you if you are interested. Following this, the project team will seek to publish this as an article in rehabilitation journals, and also to reports the findings at relevant conferences. Only group data will be reported and you will not be individually identified in any reports.

**Part 2 How is the research project being conducted?**

**12 What will happen to information about me?**

By signing the consent form you consent to the study investigator and research team collecting and using personal information about you for the research project. This includes your age, sex, whether you were using a gait aid before you were admitted, if you lived in a house/unit/residential facility, whether you have a carer, whether there are steps at home, and whether you speak English. This is routine information we collect on every patient from the medical record. Your information will only be used for the purpose of 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 research project.

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

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 project can identify the participant from this subject code.
* A paper copy of the subject codes will be kept in a locked cabinet in the researcher’s office, which only she will have access to.
* An electronic copy of the data (which only identifies participants by 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 research team.
* All surveys will be anonymous

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

The results of this project may be used as the basis for further research in this area, however information will be provided in such a way that you cannot be identified. It is anticipated that the results may be published in journals or presented in a variety of forums. All information provided for these purposes will be presented in such a way that you cannot be identified.

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 Cathy Senserrick if you would like access to your information.

In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 15 years. Access to information about you after this point will not be possible as the information will have been disposed of securely.

**13 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

If you have any complaints about any aspect of the project then you may contact Cathy Senserrick on 988111845; email Catherine.senserrick@easternhealth.org.au or the Chair of the Eastern Heath Human Research Ethics Committee 98953398, email: ethics@easternhealth.org.au

**14 Who is organising and funding the research?**

The Peter James Centre Rehabilitation Unit together with the Eastern Health Physiotherapy Department are funding this research project.

No member of the team will receive a personal financial benefit from your involvement in this research project other than his or her ordinary wages.

**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 Eastern Health and La Trobe University.

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 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 | Cathy Senserrick |
| Position | Project coordinator, Principal researcher |
| Telephone | 9881 1145 |
| Email | Catherine.senserrick@easternhealth.org.au |

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 HREC**

|  |  |
| --- | --- |
| Name | Eastern Health Human Research Ethics Committee  |
| Position | Chairperson |
| Telephone | 9895 3398 |
| Email | ethics@easternhealth.org.au |

**La Trobe University Human Ethics Committee contact person**

|  |  |
| --- | --- |
| Name | Sara Paradowski |
| Position | Senior Human Ethics Officer |
| Telephone | Ph: (03) 9479 1443 |
| Email | humanethics@latrobe.edu.au  |

 

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | *A new model of physiotherapy rehabilitation to**Improve outcomes after hip fracture* |
| **Coordinating Principal Investigator/****Principal Investigator** | *Ms Catherine Senserrick, Prof Nicholas Taylor* |
| **Associate Investigator(s)** | *Dr Genevieve Kennedy, Mr Grant Scroggie, Ms Kim Williams, Ms Kate Lawler* |
| **Location**  | *Peter James Centre* |

**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 Eastern Healthconcerning 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.

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|  |
|  | 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.

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|  |
|  | 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.

 

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

|  |  |
| --- | --- |
| **Title** | *A new model of physiotherapy rehabilitation to**Improve outcomes after hip fracture* |
|  |  |
|  |  |
| **Coordinating Principal Investigator/****Principal Investigator** | *Ms Catherine Senserrick, Prof Nicholas Taylor* |
| **Associate Investigator(s)** | *Dr Genevieve Kennedy, Mr Grant Scroggie, Ms Kim Williams, Ms Kate Lawler* |
| **Location**  | *Peter James Centre* |

**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 Eastern Health.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Study Doctor/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.

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|  | 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.