**Participant Information Sheet**

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| **Title** | *A pre-post feasibility and acceptability study investigating the effects of a goal-setting coaching intervention using accelerometer guided objective feedback on sedentary behaviour and physical activity in hip fracture patients: The HIP MOVE Study* |
| **Short Title** | The HIP MOVE Study |
| **Protocol Number** | HREC/ / TQEH |
| **Principal Investigator** | Professor Renuka Visvanathan |
| **Student researcher** | Mr Unyime Jasper |
| **Associate Investigator(s)** | Dr Joanne Dollard, Dr Agathe Daria Jadczak, A/Professor Solomon Yu, Dr Mellick Chehade, Dr Olga Theou, Mr Adam Govier, Mr Scott Main, Mr David Dewick |
| **Location** | The Queen Elizabeth Hospital (TQEH) |

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

**1 Introduction**

You are invited to take part in this research project called “A pre-post feasibility and acceptability study investigating the effects of a goal-setting coaching intervention using accelerometer guided objective feedback on sedentary behaviour and physical activity in hip fracture patients: The HIP MOVE Study”, as you are a patient on this ward. We would like you to participate in this study, which aims to measure the level of sedentary behaviour and physical activity in older patients following surgery for hip fracture. We value your cooperation and participation in this research study.

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

Sedentary behaviour and physical inactivity is very common in older people, especially when in hospital, and this can be harmful to patients’ health. The aim of this research is to explore the prevalence of sedentary behaviour and physical activity among older people following surgery for hip fracture. We hope that the information gathered will help us to guide an intervention to reduce sedentary behaviour and increase physical activity in hospitalised older people who have undergone surgery for hip fracture.

**3 Who is undertaking this research project?**

This research is being conducted by Mr Unyime Jasper, a PhD candidate at the University of Adelaide, as part of his PhD studies, under the supervision of Professor Renuka Visvanathan (Director, Aged & Extended Care Servicers, The Queen Elizabeth Hospital (TQEH). All the researchers are from The University of Adelaide and the Central Adelaide Local Health Network (CALHN).

1. **What does participation in this research involve?**

If you decide to take part in the study, we will ask you to sign a consent form. During the study you will be required to wear an ActivPAL on the unaffected thigh until discharge. If you are hairy, we may need to shave the area where ActivPAL will be placed and the removal of the opsite may pull out some hair. The ActivPAL will only be removed if you are going for X-rays or MRI. There are no costs or reimbursements associated with participating in this research project.

**5 Do I have to take part in this research project?**

This is a research project and you do not have to be involved. In addition, you may withdraw from the project at any time after you have commenced. Your decision whether to take part or not, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with TQEH.

**6 What are the possible benefits of taking part?**

Taking part in this research will provide rich information on the extent of sedentary behaviour and physical inactivity among older patients following surgery for hip fracture. This information will be used to guide an intervention to reduce sedentary behaviour and increasing physical activity among older patients who have undergone surgery for hip fracture. In addition, this study will help us to identify the times when patients are the most sedentary and we will be able to target those times in future trials. Our aim is to discharge patients after hip fracture surgery to their homes rather than to rehabilitation/nursing homes, regain their pre-fracture level of function and mobility, reduce their number of days spent on admission and reduce sedentary behaviour and physical inactivity over time.

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

We don’t expect any foreseeable risk or disadvantage.

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

**8 What will happen to the information about me?**

By signing the consent form, you consent to the research team collecting and using information you provided for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. There will be no identifying information in the data collected from you. The signed consent form will be stored in a paper format in the Basil Hetzel Institute for Translational Health Research. This will be saved in hard copy and securely archived in the University of Adelaide/TQEH for 15 years after publication, before being shredded. Your information will only be used for the purpose of this research project. Participant data will be coded with a research ID to protect privacy and confidentiality. Only the researcher involved with data collection will have access to participant data. All paper documents will be stored in locked compactus storage available at Basil Hetzel Institute.

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

**9 What happens if I withdraw from this research project?**

You may withdraw at any time, with no implications. If you decide to withdraw from the project, please notify a member of the research team and they will not collect additional information from you. The data collected up to the time you withdraw will form part of the project results. If you do not want your data to be included, you must tell the researchers when you withdraw.

Your decision whether to take part or not, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with TQEH.

**10 What happens if I am injured from taking part in the study?**

Your participation in this study shall not affect any other right you may have to compensation under common law.

**11 Who has reviewed the research project?**

An independent group of people called Central Adelaide Local Health Network (CALHN) Human Research Ethics Committee reviews all research in Australia involving humans. The ethical aspects of this research project have been approved by the Human Research Ethics Committee (TQEH/LMH/MH). 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.

**12. Complaints and contacts (Investigators and Ethics Committee)**

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

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee.

If you want any further information or if you have any problems, you can contact the chief investigator Professor Renuka Visvanathan on 8222 6000 or Mr Unyime Jasper on 82227676.

If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chair, Mr Ian Tindall, on 7117 2229 or 8222 6841

**Consent Form**

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| --- | --- |
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| **Location** | The Queen Elizabeth Hospital (TQEH) |

**Declaration by Participant**

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

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

The nature, purposes, procedures and risks of the research have been explained to me. I freely understand them and agree to take part.\*

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future 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 | |  |  |
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*Under certain circumstances (see* Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness\* to informed consent is required*

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|  | Name of witness\* to Participant’s signature (please print) | |  | |  |  |  |
|  | | | | | | | |
|  | Signature |  | | Date | |  |  |
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\* 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 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 Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† An appropriately qualified 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.

**Withdrawal of Participation**

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**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my relationships with the clinical staff and researchers.

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|  | Name of Participant (please print) | |  | |  | |  | |
|  | | | | | | | | | |
|  | Signature |  | | Date | |  | |  | |
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In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by 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 Researcher (please print) | |  |  | | |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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