Royal Perth Hospital

Participant Information Sheet

Exploring outcomes in adults following major abdominal surgery

Principal Investigator: Dr Megan Harrold, Physiotherapist, RPH

You are being invited to participate in this research project because you have recently undergone, or are about to undergo, major upper abdominal surgery (MUAS) at Royal Perth Hospital This information sheet explains what will be involved should you decide to participate. Please read the information carefully and ask any questions you might have. You may also wish to discuss the project with a relative or friend or your GP.

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

Should you have questions about the study you may contact the study investigator listed below. Furthermore, if you wish to be kept up to date with this study, please email the below contact.

- Dr Meg Harrold
- Email: M.Harrold@curtin.edu.au
- Phone: (08) 9266 9228

Background and aim

The purpose of this study is to understand what factors influence the recovery of adults three months after having major upper abdominal surgery. Little is known about how a person's lifestyle is affected after major upper abdominal surgery. Information gathered during this study hopes to establish what factors separate adults who recover well following major upper abdominal surgery from those who do not. In doing so this will give adults awaiting major upper abdominal surgery reliable information on their likely recovery following the surgery as well as help optimise their recovery through healthcare interventions.

What participation in the project will involve

If you choose to participate you will be asked to provide a residential address along with a suitable phone/mobile number. This is to ensure we can contact you at the appropriate times following your surgery.

This study consists of two parts, Part A and Part B.

Part A of the study will involve you filling out a questionnaire at Royal Perth Hospital prior to or just after your surgery. A physiotherapist will then document your surgery details and grade you on a scale called the clinical frailty scale. Two-and-a-half-months after your surgery at Royal Perth Hospital, you will receive a phone call from a student researcher

who will arrange with you a suitable time for your follow-up interview in approximately two weeks-time (three months after your surgery). During this appointment you will be graded using the clinical frailty scale, and will then be given the option of filling out three more questionnaires during the interview or have them posted to your residential address for you to fill in in your own time. If posted, these questionnaires will need to be posted back to us, and this can be done using the attached reply-paid self-addressed envelope. During the phone call at two and a half months, there will also be a discussion regarding your primary caregiver (the person that has been taking care of you since your surgery). We will ask if they would like to participate in a short (10-15 minute) interview which will discuss how they were impacted by your recovery. If they agree, a consent form will be mailed out to them to sign and return in a reply-paid self-addressed envelope.

Part B involves having a conversation with a researcher in which you will be able to openly express and tell your experiences of how the surgery has impacted your life over the last three months. Agreeing to the study means you are not required to participate in both parts as you are allowed to select which parts you wish to partake in. All information gathered from the questionnaires you have filled out and the interviews will be stored securely and confidentially, please see 'Will my taking part in this study be kept confidential?'.

Length of Study

This study is looking at medium term recovery after surgery, that is approximately 3 months after you have had the operation. Participation involves filling out a questionnaire (5-10 mins) and/or having a conversation (online video call or face to face interview) (30 mins) both of which occur at 3 months post-surgery.

Possible side effects, risks, and discomforts

Because there are no additional medical procedures involved in this project, there are no foreseeable major risks or side-effects associated with participation. The only foreseeable risks for this study are the inconvenience of this study's participation time, and the possibility of emotional distress. There is also the risk of a breach of confidentiality of your medical information, however there are strong data management and security measures in place to manage this risk.

Possible benefits

Participation in this project may have no direct benefit for you, but may improve the recovery and quality of life of those adults awaiting to undergo major upper abdominal surgery in the future. Your lived experiences following your surgery will help health professionals understand the trajectory of recovery experienced following a procedure such as this, and in particular help identify challenges experienced during your recovery. These challenges can then be addressed in the future in order to improve patient-centred care and optimise recovery.

Protection of your privacy and confidentiality

The information gathered about you by the investigator or obtained during this project will be held by the investigator in strict confidence as far as the law allows. All the people who handle your information will comply with the Privacy Act 1988. Your study data will be held securely at **Royal Perth Hospital** in locked filing cabinets and, where electronic, it

will be stored on a secure WA Health W:\ Drive and accessed via a password protected computer. It will be held in "re-identifiable" format. This means the research data is "coded" with your data held against a unique study code, not your name. Once the data for the whole study is complete, the code link that matches your name and study code will be deleted meaning it will be impossible from that point forward to match you to your data (i.e., the research data will be "non-identifiable").

If the results of the trial are published in a medical journal, as is intended, no reader will be able to identify individual patients. If you wish to know the results of the study, please contact Dr Meg Harrold.

Protection of your rights
Because this is an "observational study" that will access your medical information and will not alter or affect your treatment, it is considered "negligible risk" and so there are no expected side effects or other significant consequences associated with your participation. However, should any consequences arise related to your participation in this project, this does not alter any right to compensation that you may have under statute or common law.

Cost of participation
There is no cost to you to participate in this study.

You will not be paid for participation.

Sponsorship of Study
The School of Allied Health at Curtin University is sponsoring the study. Funding received has been used to cover the posting costs. No researcher has a financial interest in this study or will receive payment for this research.

Voluntary participation and withdrawal
Participation in any research project is entirely voluntary. You do not have to participate if you do not want to and your decision to participate or not will in no way affect your current or future care at **Royal Perth Hospital.**

You are also free to withdraw from the project at any time without reason or justification by contacting the Investigators.

Contacts for further information
- If you have questions about this project, please contact Dr Meg Harrold on 08) 9266 9228

This project has been granted ethical approval by the *Royal Perth Hospital (RPH) Human Research Ethics Committee (HREC)*. If you have any concerns about the conduct of the project or your rights as a research participant, phone (08) 9224 2292 or email: EMHS.REG@health.wa.gov.au and quote the ethics approval number (RGS0000004684).

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Consent Form

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I have read the Participant Information Sheet.

I understand the purposes, procedures and risks of the research 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 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 Study Doctor/
Senior Researcher[†]
(please print) _____

Signature _____ Date _____

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

Royal Perth Hospital

Form for 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 routine treatment, my relationship with those treating me or my relationship with **Royal Perth Hospital**.

☐ I consent to the information obtained so far being used for research purposes (all information is de-identified)

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher must describe the circumstances:

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.

Name of Study Doctor/ 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.