Royal Perth Hospital

Participant Information Sheet - Caregiver

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 been identified as the primary care giver of an individual who has undergone major upper abdominal surgery (MUAS) recently 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.

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 and to better understand how being the primary caregiver of an individual who has undergone this surgery impacts the caregiver's quality of life and lived experiences. It is to establish what areas have become the responsibility of the primary care giver and if this is impacting the care giver's quality of life.

What participation in the project will involve

If you choose to participate the study will involve a 10–15-minute conversation in which a researcher will be asking you questions relating to the experiences you have had in caring for the individual who has undergone major upper abdominal surgery. The conversation will allow you to express feelings you have experienced during this time whether they are positive or negative.

Length of Study

This study is looking at medium term recovery after surgery, that is, approximately 3 months after the surgery of the person for whom you are providing care. The aspect of the study with which you are involved will involve a 10–15-minute phone call or on-line video call.

Possible side effects, risks and discomforts

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, however, your participation may help improve the recovery and quality of life of those adults awaiting to undergo major upper abdominal surgery in the future. By providing your experiences as a care giver it will allow the study to identify areas in which both the care giver, and the individual they are caring for, may be struggling. This will hopefully assist healthcare professionals to become more aware of these areas allowing for further education and strategies in how to improve the experiences of both the care giver and the individual receiving care.

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, on secure servers 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).

Royal Perth Hospital

Consent Form - Caregiver

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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 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 **[insert site name]**.

☐ 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.