Participant Information Sheet

Interventional Study – *Adult providing own consent*

The Queen Elizabeth Hospital or The Royal Adelaide Hospital

Project Title	An Osteoarthritis Pain Science Education Intervention to Optimise Care for Total Knee Replacement Surgery (OPTIMISE) – Stage 2 Feasibility study
Short Title	Osteoarthritis Pain Science Education for Total Knee Replacement Surgery
HREC Reference	22160
Project Sponsor	Adelaide University
Principal Investigator	Prof Tasha Stanton (Adelaide University)
Location	The Queen Elizabeth Hospital and The Royal Adelaide Hospital

1 Introduction

You are invited to participate in the OPTIMISE study. This is because you are planning to have total knee replacement surgery for osteoarthritis at The Queen Elizabeth Hospital or The Royal Adelaide Hospital.

This Participant Information Sheet describes the research project and the processes involved in taking part. Please read this information and contact the researchers listed at the end of this sheet if you have any questions.

2 What is the purpose of this research

Osteoarthritis affects 1 in 2 older Australians. Knee osteoarthritis often causes pain, difficulty with activities and it can reduce quality of life in older adults. Many people decide to undergo total knee replacement surgery as a treatment for their knee pain. Receiving education about the surgery and what to expect afterwards as you recover is helpful.

In other health conditions, it is known that receiving more detailed information about pain and about strategies to keep moving and to manage pain, can result in better clinical outcomes (reduce pain and improve function). Further research is needed to determine whether education about pain can similarly improve outcomes for people with knee osteoarthritis who undergo total knee replacement surgery.

The goal of this research is to test the feasibility and acceptability of a pain education program for total knee replacement surgery (called OPTIMISE). OPTIMISE was co-designed with patients who have undergone (or are considering undergoing) total knee replacement surgery, health professionals (such as nurses, physiotherapists, orthopaedic surgeons) and other staff who provide support for the total knee replacement care pathway.

We want to understand if it is feasible in the future to undertake a large clinical trial that fully tests this new intervention. The best way to determine this is to 'trial-run' the intervention in a smaller study where you randomly allocate volunteers to two different treatment groups. That means; by participating in the study, you will have an equal chance of being in one of the two groups. You can't choose groups or change which group you're in along the way.

The two different treatment groups in this study are:

1. Website (information) group: Access to a website (or educational brochure) before and after your total knee replacement surgery. This education will cover information on total knee replacement surgery and recovery.
2. OPTIMISE Group: Access to an educational website before and after your total knee replacement surgery which you will review with a health coach. This intervention will provide specific education on pain.

We are interested in getting your opinion on how helpful these treatments are. We are also interested in whether you think that we can change certain parts of the treatments to make them better. Your opinion on these treatments is important to know before we test these treatments in a large clinical trial because we want to test the best option.

3 Who is undertaking this research?

This research is being undertaken by Professor Tasha Stanton who is the Co-Director of IIMPACT in Health at Adelaide University and Lead of Persistent Pain Research Group at the South Australian Health and Medical Research Institute (SAHMRI).

This research is funded by a grant from the Medical Research Future Fund from the Australian Government Department of Health, Disability, and Ageing.

This research will be conducted as a collaboration between Adelaide University, SAHMRI, CALHN, University of Melbourne, and the University of Bristol.

Findings from this study will contribute towards a PhD project being undertaken by Caroline Taylor at Adelaide University.

4 Do I have to take part in this research project?

This is a research project and you do not have to be involved. If you do not wish to participate, your medical care will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced and this will not affect your medical care.

5 What does participation in this research involve?

If you decide to participate, you will sign a consent form. You will be given a copy of your signed consent (and Participant Information sheet) for your records.

The research team will then collect some information about you and ask you to complete some questionnaires via an online survey (taking ~30 minutes to complete). After enrolling in the study and prior to surgery, you will be allocated to one of the two education interventions.

Participation will involve completing questionnaires before (as described below) and after (6- and 12-months post-) your total knee replacement surgery. These questionnaires will take ~30 minutes to complete.

All participants will follow the treating surgeon's rehabilitation plan as per normal. Participants in both groups will have contact with health professionals (nurses, physiotherapists etc) as per the usual health care pathway at each hospital.

The two treatment groups are:

Website (information) group: Before and after surgery, participants in this group will receive access to a website providing information (online or paper copy depending on the participant's preference) about total knee replacement surgery and recovery.

This information has been developed by health professionals who support people undergoing total knee replacement surgery. It has information and advice on things you can do to help your recovery. For example, it contains some ideas for exercises. Participants will be able to access the information at any time over the study and may keep a print-out of the information after the study has finished.

OPTIMISE group: Before and after surgery, participants in this group will receive access to a website (online or paper copy depending on the participant's preference) providing pain education related to total knee replacement surgery. Education will be reviewed with a health coach (trained in pain education). OPTIMISE sessions may be provided in person at home, in hospital, at the Adelaide University's Clinical Trial Facility or the South Australian Health and Medical Research Institute, via telehealth, or via a mix of in-person and telehealth sessions (depending on each participant's preference). Participants will be provided with up to 12 sessions (total) with the health coach. These sessions, will focus on individualising the education that has been provided, for example, creating individual exercise or activity goals. These sessions will be in addition to the usual care pathway provided by the hospital. Participants will be able to access the information at any time over the study and may keep a print-out of the information after the study has finished.

All participants will be offered the option of participating in one interview (up to one hour in duration) to describe your experiences of the project and the education and care you received. The interview will be conducted via phone and will be audio recorded.

To reimburse you for your time completing the questionnaires, you will be provided with a $50 honorarium for each questionnaire you complete (up to $150 for completion of all three questionnaires) and a $50 honorarium if you complete the interview. Gift vouchers will be used to provide honorariums.

6 What do I have to do?

Before you have your total knee replacement surgery, you will need to complete a questionnaire asking general information about you (age, sex, occupation), your health (weight, height, other medical conditions, current medications, other painful joints), your knee (what knee is affected, previous surgery, duration of knee pain, current knee pain, function / how easy or difficult different activities are for you, movement, quality of life, your thoughts about osteoarthritis), health care utilisation (what treatments and/or medications you use for your knee pain) and communication preferences. If your surgery is delayed, we may ask you to complete these questionnaires again (with extra $50 honorarium paid). Participants will then receive education about total knee replacement recovery before and after their surgery (as described above).

At 3-months, 6-months and 12-months after total knee replacement surgery, participants will be required to complete an online questionnaire again to re-assess the outcomes described above. These questionnaires will also ask about any other treatments you have received, any complications that you have experienced from your surgery (e.g., infection) and any hospital admissions that have occurred. The questionnaire will also contain a survey to rate how acceptable you thought the education you received was.

If you decide to complete the phone interview, we will ask you to talk about your experiences of the project. The interview will occur 4-6 weeks after your twelve month follow up questionnaire.

You will not be restricted in any way during the study. You will be able to participate in daily activities as you are instructed and able.

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

7 What are the possible benefits of taking part?

Participants in both groups may improve their understanding of the total knee replacement surgery process and experience. It is also possible that the information you receive improves the pain and physical function of your knee after surgery. Your contributions will also have wider benefit, by helping to improve the education and care of people who undergo total knee replacement surgery.

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

There are minimal risks of taking part in this project. Some people may find discussion of pain distressing. If so, please inform the clinician you are talking to and our researchers as soon as possible. They will help you to find the most appropriate care. We will have contact details available for the following organisations who may be able to assist:

- Lifeline – 13 11 14 or https://www.lifeline.org.au
- Beyond Blue - 1300 22 4636 or https://www.beyondblue.org.au
- Arthritis Australia - 1800 011 041 https://arthritisaustralia.com.au/get-support/infoline/

Some people may also experience increased discomfort or pain in their knee as they begin to return to normal activities after surgery. This is a normal part of recovery and typically increases in discomfort or pain do not last very long (1-2 days). If you experience bothersome discomfort or pain that lasts for longer than a few days, let a member of the research team know. We can help coordinate care with your general practitioner or a registered health professional.

9 Can I have other treatments during this research projects?

You are able to continue with all of your normal treatments or medications. You are expected to follow your surgeon's recommendations for treatment after surgery. Please tell the researchers about any treatments you are participating in or medications you are taking. This includes things like acupuncture, massage, vitamins, herbal remedies, over the counter medications and any other treatments. Please tell the researchers if you have any changes to these during the project.

10 What will happen to information about me?

When you sign the consent form, you consent to the research team collecting the information outlined in this information sheet and using it for the purposes of this project or future related research. Your information may only be disclosed with your permission, unless required by law.

Your information will be de-identified for the purposes of this project by assigning a unique identifier rather than your name as early as possible. A file linking your name to the unique identifier will be in a password protected drive and only accessible to the chief investigator. Additionally, all other digital data will be stored on a secure server at Adelaide University. Any physical data will be stored in locked filing cabinets at the South Australian Health and Medical Research Institute. Data will be stored for 15 years after publication of study findings in accordance with South Australian legislation and Adelaide University policy. After this time, all identifiable data will be deleted. Non-identifiable electronic data will be stored indefinitely. Non-identifiable data may be used for future purposes, for which ethics approval will be sought (for example, we may combine this data with other similar datasets to explore things that can better predict treatment outcome). Non-identifiable data will be supplied as a supplementary file when publishing the results so that other researchers can verify/check our analyses.

If a review of the project procedures and data is conducted, your information may be inspected. This may be done by institutions outlined in this participant information sheet, or, if required by law. When you sign the consent form, you agree to the release of or access to this information to such institutions.

The results of this project will be likely disseminated via presentations at scientific conferences, journal publications, and student theses. Results will describe group outcomes/findings (i.e., not data from a single individual). Any data reported will be de-identified and cannot be identified unless you provide permission.

The researcher cannot guarantee the confidentiality or anonymity of any material transferred by email or the internet.

Audio recordings may take place during the interview on a device only accessible to the researcher. However, this will only be available to the research team and will be transcribed. After transcription, audio files will be deleted. Audio files will not be used in research reporting without your permission.

In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your 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 your information.

11 What happens if I withdraw from this research project?

You are free to withdraw from this research at any time.

Please notify one of the researchers if you would like to withdraw from this study. We will ask you to complete a withdrawal consent form and return it to us.

If you withdraw, no further information will be collected from you. Data already collected from you will be de-identified and have already contributed to the research results. Therefore, this data will be reported on, but this will not be identifiable.

12 Complaints and Contacts

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023) 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 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 Chairperson, on 7117 2229.

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 approving this research, HREC Executive Officer details and Complaints Contact

HREC Name	Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC)
Contact	HREC Support Officer
Telephone	(08) 7117 2229
Email	Health.CALHNResearchEthics@sa.gov.au

Research contact person

If you have any questions or require any further information about this project, please contact the project coordinator.

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