Information Statement for the Research Project

Understanding and predicting recovery in patients undergoing total knee replacement

SuPeR Knee Support. Predict. Recover.

This research project is following the recovery of 1000 adults having total knee replacement surgery at Lake Macquarie, Kareena and Baringa Private Hospitals. It is being conducted by the Centre for Rehab Innovations (University of Newcastle).

Every person taking part in this study is helping to guide the development of precision-rehabilitation approaches tailored to meet people's individual needs for excellent recovery after knee replacement.

Why is the research being done?

Outcomes for people with arthritis who have knee replacements are usually very good, due to advances in surgical approaches, medical therapies and artificial knee joints. Still, some people don't recover as well or as quickly as expected. There is not enough scientific evidence to explain why there are marked differences in recovery between people, and there is also not enough information to guide the development of new rehabilitation therapies that meet people's individual needs.

This study will pull together data from a large group of people having knee replacements, to identify key factors linked to fast and full recovery. The research team will use the information collected to develop a computer-based tool for predicting recovery pathways for individual people. This tool can then assist hospitals to connect patients with the clinical services that best meet their individual needs.

The tool will become more accurate as more people contribute their information. It's especially important that a wide range of people take part – whether or not they feel their personal situation or knee joint replacement is straight-forward or complicated.

Why have you received this information?

You have been identified by your surgeon as being eligible to participate in this project. People who are having surgery because of a traumatic knee injury, who have had knee surgery in the past 6 months, are planning knee surgery for your other knee in the next 12 months or who are unable to complete the questionnaires won't be able to be included in this study.

This project has been funded by Ramsay Hospital Research Foundation.

What does taking part in this research involve?

You will be asked to take some time to provide researchers with some information, before, and then at three months after surgery. There are questionnaires and physical tests – explained below. This information will be used to determine which factors are the most important to predict individual long-term recovery outcomes for different people.

We will write to you and/or send an SMS between surgery and the 3-month follow-up timepoint with both our thanks for contributing to the study, and to give a friendly reminder that the follow-up is approaching.

1. Health-Related Questionnaires – about 45min each time

These questionnaires about your physical, social, and mental health will take about 45min altogether. If you prefer, you can complete the questions over several shorter sessions.

You can choose whether to do the questionnaires at home, or with our help. There's an online option or we can post you the questionnaires on paper. The questions come with instructions and contact details for the researchers who are available to help you.

Online option:

Look out for an email from email@optimalcare.com.au – click and complete questionnaires

We are using a secure online platform called 'VisionTree Optimal Care (VTOC)'. This platform has been used by hospitals all over the world to store confidential medical information. No one outside the research team will have access to your information on this platform.

The email will arrive 2-4 weeks before your surgery to give you time to complete this before your knee replacement. Because preparing for surgery can be busy, we may send you reminders by email if you have unfinished questions before surgery. Three months after surgery, we will send you a link to the follow-up questionnaires.

Paper option:

If you don't use email, we can post the questions to you on paper, with a reply-paid envelope

There will be a unique study ID number printed on your questionnaires. Your name and any other identifying information will not be written on any of the questionnaires.

We will send questions in the post 2-4 weeks before surgery, and then at 3 months after surgery.

2. Physical Performance Measures – about 20min each time, at home via videocall.

You can do these tests in your home while the research assistant talks to you and watches via a videocall.

Around 2-4 weeks before surgery, a research assistant will contact you and talk you through the videocall process and how to set up a safe space in your home for you to do the assessments.

During the appointment, the research assistant will take you through 3 simple physical tests of endurance and mobility.

These tests involve:

- Walking 10m at both your usual walk speed, and fastest safe speed
- A timed test of standing and sitting as many times as possible, in 30 seconds
- A timed test where you stand up, walk 3m, turn around, walk back 3m, then sit down again

You do not have to complete any tasks if you do not feel able. This won't influence your treatment or participation in the rest of the project.

We will schedule a follow-up video appointment for about 3 months after your surgery. The research assistant will organise a time with you.

3. Grip strength measure – about 5 minutes at one of your hospital appointments

At your pre-surgery clinic visit, or on the day of your surgery, a research assistant or one of the hospital staff will measure your grip strength. This will involve squeezing a handle with your hand as firmly as you can.

You don't have to complete this task if you do not feel able. This won't influence your treatment or participation in the rest of the project.

4. The research team will collect health and personal information from your medical record

In order to create a tool that understands and predicts how individuals recover from knee replacements, we need to collect some other information about you. So that you don't have to provide the information twice, our research team will retrieve it from your medical records relevant to this surgery.

This will include your height, weight, ethnicity, indigenous status, smoking history, employment status, length of your hospital stay, medications, your knee motion and arthritis, as well as, whether you leave the hospital to go home or go to a knee rehabilitation facility.

5. Participation Questionnaire

We value feedback about how you felt participating in this project. This will assist the research team in designing and performing meaningful research projects in the future.

When you exit or complete this research project, you will be invited to complete a 5 minute, confidential questionnaire about the study. It is completely voluntary.

We are using a secure platform for the questionnaire, which means it will be confidential.

Our research team will also collect some other information about your health and demographics from your medical file. This means that you don't have to give information again that you have already given the hospital. This is explained on the next page.

What are the benefits and risks of participating?

There are no direct benefits to you for participating in this research. Your participation will help us to understand the key factors linked to a great recovery after knee replacement and guide rehabilitation strategies for people in the future.

While we don't expect that you will be exposed to any risk or discomfort as a result of participating in this research, some questions in the health-related questionnaires ask about how you feel and respond to different situations. Thinking about this may raise concerns or cause distress for some people. Taking steps to cope with stressful situations is important. If you are experiencing high levels of distress, you may

- Talk to your GP or a counsellor;
- Call Lifeline on 13 11 14; or
- Visit one of the following support websites:
    - https://www.lifeline.org.au/
    - https://www.beyondblue.org.au/
    - https://www.blackdoginstitute.org.au/

The physical tasks will be explained and demonstrated to you so that you know what they involve, and you can choose not to do them. If you have any concerns, please discuss them with the research team.

How will your privacy be protected?

All information collected during this study will be stored securely on the University of Newcastle's own secure server and will only be accessible to authorised members of the research team, except as required by law.

To ensure confidentiality, your name is removed from your other personal and health information in the secure cloud-based VisionTree Optimal Care (VTOC) data system and replaced with a unique numerical study ID. Information you enter yourself online enters the VTOC system via a secure and encrypted connection. If you complete the questionnaires on paper, our research team will later enter the information into VTOC, and the physical forms will be stored in a locked filing cabinet in a secure location at the Hunter Medical Research Institute or at the University of Newcastle, Callaghan campus.

The information collected for this study will be retained for 15 years and then will be securely destroyed in line with University of Newcastle policy.

How will your information be used?

The de-identified data will be analysed and presented in a PhD thesis, publications in scientific journals and at international/national conferences. All data will be presented at a group level, which means that no individual person will be able to be identified in any reports arising from the project. A copy of the results will be available at the completion of this study on the Centre for Rehab Innovations website (www.centrerehabinnovations.com.au). No individual data will be available to participants.

How do I participate and how do I give consent?

Participation is voluntary. Your surgery and treatment will not be affected in any way whether you choose to participate or not.
Please read this Information Statement and be sure you understand its contents before you answer the questionnaires or attend an appointment for the physical performance. If there is anything you do not understand, or you have questions, please contact the research team.

Before you commence any questionnaires, you will be asked to re-review this Information Statement and then provide your consent to take part in the study.
In doing so, you are providing your consent:

- To participate in this research.
- For the research team to access your hospital records.
- Take part in the physical assessments.

.

We understand you may not want to participate in any or all of the activities. If you do not wish to participate, please contact our team via email at kneereplacement@newcastle.edu.au or telephone on (02) 02 4042 0779. If you do not contact our team, a Ramsay Health research assistant will call you to ensure you have received this information and that you have understood the contents. You can also let them know at this point if you do not wish to participate. If you start the study and decide you want to stop, you are free to stop at any point. If you do, your data can also be withdrawn.

Contact us for further information or help

Please feel free to get in touch if you have any questions about this study.

SuPeR Knee Support. Predict. Recover.

kneereplacement@newcastle.edu.au

02 4042 0779

The team at the Centre for Rehab Innovations is committed to developing scientifically-based precision-rehabilitation approaches for an excellent recovery after knee replacement, and we can only do this with your help. Thank you for generously taking the time to share your information for this study.

Professor Michael Nilsson
Director of Centre for Rehab Innovations (CRI)

Michael.Nilsson@newcastle.edu.au
(02) 4042 0570

Other Investigators for this project from Centre for Rehab Innovations, University of Newcastle

Professor Rohan Walker
Deputy Director, CRI
A/Prof Michael Pollack
Director of Rehabilitation, Clinical Co-Lead, CRI
Elizabeth Ditton
Senior Research Associate, CRI
Dr Nattai Borges
Lead of Outcome Evaluation Team, CRI
A/Prof Adrian Wills
Lead of Machine Learning Approaches, CRI
Professor Sarah Johnson
Head of Engineering, CRI
A/Prof Nicolette Hodyl
Research Development Officer, CRI
Gillian Mason
Clinical Research Assistant, CRI
Dr Xin Gu
Lead Application Developer, CRI
Ms Jodie Cochrane
PhD student, University of Newcastle. A/Prof Adrian Wills and Professor Sarah Johnson are Ms Cochrane's supervisors.

Complaints about this research

This project has been approved by the University's Human Research Ethics Committee, Approval No. H-2019-0109.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to the Human Research Ethics Officer, Research Services, NIER Precinct, The University of Newcastle, University Drive, Callaghan NSW 2308, Australia, telephone (02) 4921 6333, email Human-Ethics@newcastle.edu.au.