Participant Information & Consent Form

Project title: Advanced osteoarthritis and joint replacement surgery – investigating associations of physical activity and sedentary behaviour with health status and postoperative outcomes**:** the AORA study

Principal Researcher: Dr. Stephen Gill

Associate Researchers: Dr. Henry Ring, Prof. Richard Page, A/Prof. Nicky Ridgers, Prof. Robin Daly, A/Prof. David Scott Dr. Simone Verswijveren

Protocol number: 21/224

You are invited to participate in the AORA study because you are undergoing hip, shoulder, or knee joint replacement surgery at Barwon Health or St John of God Hospital Geelong.

What is the purpose of this research?
This research is the first of its kind to use activity trackers, worn on the wrist and thigh, to measure your level of activity and sedentary behaviour during 4 stages in your operative journey. The research will help identify levels of activity and sedentary behaviour that produce the best outcomes following surgery for variables such as pain, physical function, quality of life, mental health and complications. This research project forms part of Dr. Henry Ring's Master of Surgical Research at Deakin University.

What does participation in the research involve?
Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

The study will take place at your place of residence as well as University Hospital Geelong and St John of God Hospital Geelong.

Activity trackers will be worn on your wrist and thigh for 7-8 consecutive days at five different times: 1) 2-4 weeks prior to your operation, 2) during and shortly after your hospital stay, 3) 3 months after surgery, 4) 12 months after surgery, and 5) 24 months after surgery. You will be shown how to wear the devices. The devices will measure the amount and intensity of physical activity. We don't want you to change your physical activity levels while you wear the devices, we simply want to measure what you normally do. It is important to note these devices do not allow access to your location nor do they detail what tasks you are doing. These devices should be worn at all times unless you are submerged in water (e.g., swimming).

A)  B) 

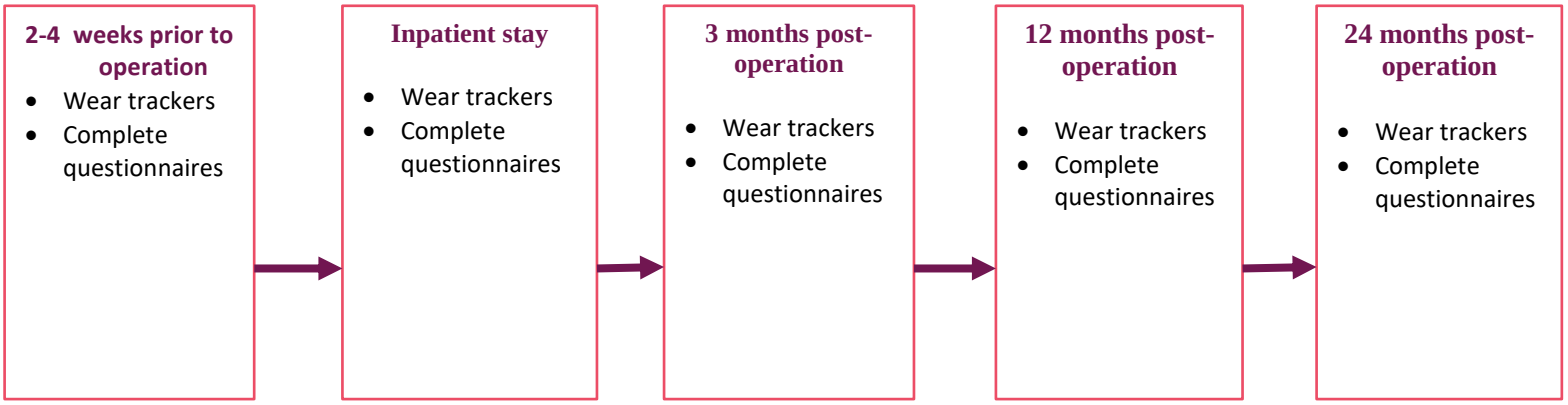
Activity trackers are worn on your wrist (A) and thigh (B).

In addition to wearing the activity trackers, you will complete questionnaires about your joint pain, ability to move about, quality of life, mental health, sleep quality, and whether you had any complications after surgery. These questionnaires will be completed at each stage of the project as outlined below. You will also complete physical tests such as walking and standing from a chair when you are in hospital. We will record demographic information about you such as your age, body weight and height. The devices will not only record activity, but monitor time spent at rest and sleep quality. It is therefore important to keep the trackers on at all times (this excludes water based tasks as the devices are NOT waterproof- the wrist worn device is water resistant so it can be used for activities such as dish washing, laundry).

If you do decide to take part, you will be given this consent form to sign as well as a copy to keep. You will be given time to consider your participation. Signed forms can be returned in person, via email, or post. Your decision to take part, or not, in this study will not affect your routine treatment, your relationship with those treating you, or your relationship with Barwon Health or St John of God Hospital Geelong. You will have an additional appointment prior to your operation to fit the device should you choose to participate. Following this (inpatient, 3 month, 12 month, and 24 month) are routine post-operative checks you are expected to attend regardless of participation.

On completion of each checkpoint participants are required to return the activity trackers to the research staff. Depending on patient preference and location, this will be completed via return post (envelopes provided) or delivered in person. A package containing this form, and all information regarding fitting of devices, questionnaires, contacts, and return envelopes will provided at the first fitting appointment.

Activities at each stage of the study:



What are the possible benefits of taking part?
The study will help us determine the optimum amount and type of physical activity to achieve the best possible outcomes following joint replacement surgery. Your participation will provide information that will benefit people who have surgery in the future and you might not experience any direct benefits yourself. You will not be paid to participate. You will be able to access a summary of your activity levels once the study is complete.

What are the possible risks and disadvantages of taking part?
We do not foresee any risks due to taking part in the study. The study simply measures what you are currently doing. You will need to wear the devices for up to eight days at a time, and although the devices are comfortable to wear, some people might find them annoying, or they might irritate the skin.

What do I do if I want to participate in this research project?
If you would like to be involved in this research, please complete the "Consent Form" at the end of this document and deliver it to the study coordinator at Barwon Health or St John of God Hospital. The study coordinator will then organise your participation in this study.

What if I want to withdraw from this research project?
If you commence the study and then wish to withdraw, please notify a member of the research team and complete the attached 'Withdrawal of Consent Form'.

What will happen to the information about me?
By signing the consent form you agree to relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Information about you may be obtained from your health records and the Barwon Joint Registry held at Barwon Health or St John of God Hospital. Electronic information will be kept on password protected computers at Barwon Health, St John of God and/or Deakin University. Information will be a kept for a minimum of seven years after the publication of the study, as required by Deakin University, following which it will be deleted or destroyed.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Only group-level de-identified data will be presented. You will be provided with a summary of the results via a written document and/or a presentation.

Ethical oversight and further information
All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC at Barwon Health and St John of God Healthcare.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project you can contact these researchers:

Dr. Henry Ring
Henry.ring@barwonhealth.org.au
0438248678

Dr. Stephen Gill
Stephen.gill2@deakin.edu.au
0434530285

Concerns or complaints
If you have any concerns or complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then for **Barwon Health patients** you may contact Barwon Health's Research Ethics, Governance and Integrity (REGI) Unit on 03 4215 3374 and tell them you are calling regarding project 21/224. If you are a **St John of God patient,** you may contact the SJGHC Ethics Office via email to ethics@sjog.org.au. Likewise, should you have any concerns regarding the devices (including irritation from tape, issues with function etc.) please contact the above parties.

Consent form

TO: Patients undergoing joint replacement at Barwon Health or St John of God Geelong

Project title: Advanced osteoarthritis and joint replacement surgery – investigating associations of physical activity and sedentary behaviour with health status and postoperative outcomes

Reference number: 21-224

Consent Agreement

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 described in the 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 research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior 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.

Name of Study Doctor/ Senior Researcher/Study coordinator† _____

Signature _____ Date _____

† A 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 consent form

TO: Patients undergoing joint replacement at Barwon Health or St John of God Geelong

Project title: Advanced osteoarthritis and joint replacement surgery – investigating associations of physical activity and sedentary behaviour with health status and postoperative outcomes

Reference number: 21-224

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 or my relationship with those treating me.

Name of Participant (please print) _____

Signature _____ Date _____

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/Study
coordinator† (please print) _____

Signature _____ Date _____

† A member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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