A research protocol is a complete written description of, and scientific rationale for, a research activity. In keeping with best practice, all research activity undertaken at Barwon Health should be documented in an up-to date study protocol. The Principal Investigator (PI) is responsible and accountable for designing, conducting, and monitoring the research protocol.

All research activities conducted at Barwon Health that involve human participants, their tissue or data, require ethics oversight.

The full protocol and associated documents must be submitted to REGI for ratification or approval by Barwon Health’s Human Research Ethics Committee (HREC).

# The protocol should provide sufficient detail to enable:

# Understanding of the background, rationale, objectives, study population, interventions, methods, statistical analyses;

# Ethical considerations, dissemination plans, and administration of the project;

# Replication of key aspects of project methods and conduct; and

# Appraisal of the project’s scientific and ethical rigor from ethics approval to dissemination of results.

Protocol amendments should be reported to the REGI by submitting an HREC amendment form as they occur. Information on the application process, amendments and reports can be found at <http://www.barwonhealth.org.au/research/column-1/regi>.

**PROTOCOL**

|  |
| --- |
| **Advanced osteoarthritis and joint replacement surgery – investigating associations of physical activity and sedentary behaviour with health status and postoperative outcomes - the AORA study** |
| Barwon Health Reference #21/224  Version #1.4  Date: 21/12/2021 |
|  |
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| **CONFIDENTIAL**  This document is confidential and the property of Barwon Health, St John of God, and Deakin University. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.  **STATEMENT OF COMPLIANCE**  This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007) and the ICH Guidelines for Good Clinical Practice (ICH-GCP). |

**Study summary**

This multicentre study will investigate physical activity and sedentary behaviour in people before and after hip or knee replacement surgery. At present, the physical activity profile of this large group of Australians is largely unknown. One hundred participants will wear small cutting-edge devices 24 hours/day that monitor physical activity and sedentary behaviour. Participants’ health and well-being will be assessed before and after surgery; the assessments include pain, function, quality-of-life, mental health and complications from surgery. Using advanced analytical techniques, this study will be the first to determine the optimum levels of physical activity and sedentary behaviour associated with better post-operative outcomes.

**1.0 Introduction and Background Information**

Being physically active improves health and quality of life, whereas sedentary behaviour increases the risk of non-communicable disease and mortality.1, 2 Our team has been at the forefront of this research in musculoskeletal health and demonstrated that higher levels of physical activity are associated with better bone density, muscle mass, strength and function,3 whereas increased sedentary behaviour was associated with an increased risk of muscle loss and sarcopenia.4 Despite this, the majority of adults do not achieve the recommended amount of physical activity and a large proportion of the day is spent sedentary.5 Increasing physical activity and reducing sedentary behaviour (PA and SB) is a major public health priority throughout the world.6, 7

Joint replacement surgery is one of the most common and successful elective surgical procedures worldwide. In Australia, more than 120,000 joint replacements are conducted each year, and this number is increasing rapidly.8 Hips and knees are the most commonly replaced joints and advanced osteoarthritis is the most common indication for surgery.8 By 2030, the incidence of hip and knee replacements for osteoarthritis is expected to rise by 208% and 276% respectively,9 with a total direct cost to the healthcare system of $AUD5.32 billion.9 The number of shoulder replacements completed in Australia is growing rapidly and is outpacing the growth of hip and knee replacements.8

People with advanced osteoarthritis are often sedentary and complete only small amounts of PA each day. For instance, a small number of high-quality studies indicate that less than one in five people with advanced hip or knee osteoarthritis achieve the recommended amount of PA for older adults according to published guidelines.10 Given that joint replacement surgery successfully improves pain and physical function, it is expected that PA and SB would improve following surgery. However, most evidence to date suggests that PA and SB does not change postoperatively, which is influenced by patient uncertainty regarding the optimum amount and type (including intensity) of PA and SB following joint replacement.11-13 Evidence is limited to a small number of studies and a recent systematic review concluded that the evidence is insufficient for determining the effects of joint replacement on PA.11 Only two Australian studies, with a combined total of 133 participants were identified in the review. No studies have examined how the composition of a person’s day (that is, how much time they spend engaged in PA and SB as well as sleep) effect post-operative outcomes such as pain, function, quality of life, mental health and complications.

Rehabilitation following joint replacement surgery focuses on improving pain and function with specific joint mobility and strengthening exercises, rather than broader efforts to increase habitual PA and reduce SB in daily life.9 No studies have investigated PA and SB during the early post-operative period when the patient is in hospital or inpatient rehabilitation, nor how this relates to post-operative outcomes. No evidence or guidelines currently exist to inform patients or health care providers regarding the optimum levels of preoperative and postoperative PA and SB that are associated with the best postoperative outcomes.14

Given the increasing number of people with advanced joint disease undergoing hip, knee or shoulder replacement surgery and the importance of PA and SB for health and well-being, it is imperative that we develop a detailed understanding of the relationship between these factors. Modern wearable devices enable the objective assessment of daily PA and SB including the intensity of PA and time spent sitting, standing and sleeping. Hence, the aim of the proposed study is to compare PA and SB in people before and after joint replacement surgery of the hip, knee or shoulder using state-of-the-art wearable technology and to determine associations of PA and SB with preoperative health status and how PA and SB might impact post-operative outcomes.

**2.0 Study Objectives**

**Aim/s, hypothesis and /or research question**

This is primarily a feasibility study to ascertain the achievability of larger scale studies involving the use of activity trackers in joint replacement (and potentially other operations) patients.

**Primary aim:**

To investigate the association between PA and SB and postoperative outcomes (pain, function, quality of life, complications) and determine the composition of PA and SB (including the intensity of PA and time spent sitting, standing and sleeping) associated with better postoperative outcomes.

**Secondary aim:**

1. Investigate the association between preoperative PA and SB and preoperative health status (pain, function, quality of life)
2. Characterise and compare PA and SB (including the intensity of PA and time spent sitting, standing, stepping, sleeping, number of sit-to-stand transitions per day, number of bouts of prolonged sitting >30 min) in patients undergoing hip or knee replacement in the preoperative, immediate-postoperative and 3-month postoperative stages

Evidence gathered from the proposed study will be used to initiate a program of research to inform the design and implementation of larger multicentre *observational* and *interventional* studies with larger numbers of the participants and extended follow up periods.

**Primary hypothesis:** Post-operative outcomes will be associated with PA and SB and will be influenced by the intensity of PA performed and the amount of sedentary time. Those with higher levels of pre-operative activity will be less likely to have post-operative complications, and the inverse relating to sedentary time.

# Significance and innovation

The study seizes upon a unique opportunity to investigate an important yet under-researched topic- levels of pre and post-operative physical activity and sedentary behaviour and how they might impact post-operative outcomes. Study findings will be immediately relevant for increasingly large numbers of people undergoing hip, knee or shoulder replacement surgery in Australia (>120,000) and worldwide each year (>4million), which will have a direct impact on waiting lists. The study will not only enhance our understanding of people’s PA and SB before and after joint replacement surgery and the barriers and facilitators to physical activity, but importantly by describing the relationship between PA and SB and post-operative outcomes, the study will provide a basis for developing evidence-based guidelines to prescribe the optimum amount and combination of PA and SB (as well as sleep and rest) to achieve the best possible post-operative outcomes. The study will also consider complications following surgery which are known to be affected by comorbidities such as obesity and cardiovascular disease. National-level data indicates that 49% of people undergoing joint replacement surgery are obese and 40% have one or more moderate to severe systemic diseases. PA and SB affects these health conditions, which highlights the importance of understanding and optimizing PA and SB in this group to reduce the risk of postoperative complications and overall health status.

The study will be the first to determine the optimum levels of PA and SB associated with better post-operative outcomes. The study will subsequently inform ongoing research that will extend to a larger and externally funded observational study and then interventional studies. Once the feasibility of the current study protocol is established, a larger prospective multicentre trial will be undertaken to generate the largest and highest quality of evidence to date of PA and SB in people undergoing joint replacement surgery. Subsequently, this epidemiological data will be used to create evidence-based interventions to optimise PA and SB to achieve the best post-operative outcomes and health possible.

**3.0 Study Design and Methods**

**Study setting**

The study will take place at St John of God Hospital Geelong and University Hospital Geelong.

St John of God Hospital Geelong and University Hospital Geelong are the region’s largest private and public health providers respectively. Approximately 1400 hip and knee joint replacements occur each year across both sites (700 per site). Fourteen orthopaedic surgeons work across both sites, with 80% of these surgeons working at both sites.

The study will be nested within the *Barwon Joint Registry.* The Registry is a clinical quality register that routinely assesses all consenting patients undergoing joint replacement surgery at St John of God Hospital Geelong or University Hospital Geelong. The registry has been collecting data for more than 30 years at University Hospital Geelong and for the last three years at St John of God Hospital Geelong (ethics approved project, HREC ref: 12-95). Data are collected preoperatively, intraoperatively and postoperatively and include patient reported outcome measures such as pain, function, quality of life, complications and operation details.

**Table 1. Study timelines 2022-23**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | June-July | Aug- Sep | Sep- Nov | Nov- Dec | Dec- Jan | Jan- Feb | 2023 | 2024 |
| Participant recruitment | X | X |  |  |  |  |  |  |
| Assessments |  |  |  |  |  |  |  |  |
| Preoperative | X | X | X |  |  |  |  |  |
| Inpatient |  | X | X |  |  |  |  |  |
| 3 months |  | X | X | X | X |  |  |  |
| 12 months |  |  |  |  |  |  | X |  |
| 24 months |  |  |  |  |  |  |  | X |
| Analysis and write up |  |  |  |  | X | X |  |  |

**Participants and recruitment procedure**

All adult patients undergoing primary hip, knee or shoulder replacement surgery at the study sites, who are willing, able and mentally competent to provide informed consent will be eligible to participate. Patients undergoing revision surgery are excluded.

Consecutive patients will be invited to participate by study personnel and clinical staff (doctor, physiotherapists) as part of the current preoperative assessment process that routinely occurs for participation in the Barwon Joint Registry. This will primarily occur in the outpatient clinic setting. Participation in the study is voluntary. All participants will provide informed consent. No financial incentives will be offered.

**Inclusion criteria**

All adult patients undergoing primary hip, knee or shoulder replacement who voluntarily participate in the study.

**Exclusion criteria**

Any patient who is not undergoing primary total hip, knee, or shoulder replacement (includes unicompartmental knee replacements, hemiarthroplasty, and revision joint replacements). Individuals deemed cognitively incapable of providing consent to participating in this study, based on the ability to consent for the operation itself, will not be included in this study. Individuals not willing to participate will be excluded from the study.

**Consent**

Informed consent will be obtained from all participants. Potential participants will be provided with the Participant Information and Consent Form (PICF) and provided with opportunity to discuss the study with study personnel and clinical staff.

* 1. **Data Collection**

**Assessment time points:** Data will be collected on four occasions: 1) 2 weeks before surgery, 2) during the inpatient stay, 3) three months after surgery, and 4) 12 months after surgery (see Table 2 for the assessment schedule).

**Table 2. Assessment Schedule 2022/23**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Assessments** | **Preoperative**  **period** | **Post-operative period** | | | |
| **Inpatient** | **3 months** | **12 months** | **24 months** |
| Physical activity/sedentary behaviour |  |  |  |  |  |
| Trackers | X | X | X | X | X |
| IPAQ-short Questionnaire | X | X | X | X | X |
| Sleep quality tracker data | X |  | X |  |  |
| Sleep quality questionnaire (Pittsburg sleep quality assessment) | X |  | X | X | X |
| Participant characteristics | X |  |  |  |  |
| Joint pain |  |  |  |  |  |
| Numerical rating scale (0-100) | X | X | X | X | X |
| Oxford Score (hip, knee or shoulder) | X |  | X | X | X |
| Physical function |  |  |  |  |  |
| Oxford Score (hip, knee or shoulder) | X |  | X | X | X |
| 10 metre walk test |  | X |  |  |  |
| 30-second chair stand test |  | X |  |  |  |
| Timed up and go test (TUG) |  | X |  |  |  |
| Quality of life |  |  |  |  |  |
| EQ-5D-5L | X |  | X | X | X |
| Mental health |  |  |  |  |  |
| Hospital Anxiety & Depression Scale | X |  | X | X | X |
| Fear of Movement |  |  |  |  |  |
| Brief Fear of Movement Scale | X | X | X | X | X |
| Length of stay |  | X |  |  |  |
| Discharge destination (home, rehabilitation) |  | X |  |  |  |
| Global change |  |  | X | X | X |
| Analgesia | X | X | X | X | X |

**Physical activity and sedentary behaviour** will be measured using two wearable devices that capture a diverse range of activities including sleep and activity intensity.

The thigh-mounted activPAL micro inclinometer (PAL Technologies Ltd, Glasgow, UK) will measure time spent lying, sitting, standing and stepping and will be worn for eight consecutive days at each assessment time point. The activPAL is a small, lightweight monitor worn on thigh that detects limb position using an inclinometer. The activPAL is attached using waterproof Tegaderm dressing. Raw data will be downloaded using activPAL proprietary software into event files and then processed using the ProcessingPAL software (University of Leicester, Leicester, UK) using algorithms developed for adults to determine daily sitting, standing, stepping and sleep (min/day).15

The wrist-mounted tri-axial GT9X ActiGraph accelerometer (Pensacola FL, USA) will also measure body position and movement, and will capture physical activity intensity and time spent sleeping. Participants will wear both monitors for eight consecutive days at each assessment time point. The device is removed for water-based activities (e.g. bathing) as it is not waterproof. Accelerometer data will be analysed in RStudio using package GGIR.16 Published prediction equations will be used to determine time spent in sedentary, light, moderate and vigorous physical activity (min/day) at each assessment time point.16 Sleep parameters will also be obtained. Patients do not get notified of activity level through these devices.

A log book will be provided for participants to record any ActiGraph and/or activPAL removal times, as well as to document time of going to bed and time of waking. Trackers will be returned via mail.

**Clinical outcomes** will be assessed according to the assessment schedule (table 2) and includes:

1. Joint pain
   1. Numerical rating scale (0-100)
   2. Oxford Score (hip, knee or shoulder)
2. Self-reported physical function
   1. Oxford Score (hip, knee or shoulder)
3. Performance based measures
   1. Timed 10m walk test, 30 second chair stand test, Timed up and Go Test (TUG)
4. Quality of life
   1. EQ-5D-5L
5. Mental Health
   1. Hospital Anxiety and Depression Scale (HADS)
6. Fear of Movement
   1. Brief Fear of Movement Scale
7. Sleep quality
   1. Tracker data
   2. Questionnaire
8. Complications
   1. Revision surgery, infection, falls, readmission to hospital
9. Global change
   1. 7 point Likert scale
10. Discharge destination
    1. Usual residence or inpatient rehabilitation
11. Hospital and inpatient rehabilitation length of stay
12. Analgesia requirements

**Participant characteristics:** Preoperative participant characteristics will be collected and include age, gender, BMI, ethnicity, employment status, comorbidities including musculoskeletal pain in other body parts, social support/marital status, educational level achieved and perceived barriers to physical activity.

**Sample size:** A convenience sample of 100 participants will be recruited to the pilot study, with approximately 50 participants recruited from each site. Given that 120 hip, knee and shoulder joint replacements occur per month across both sites (60/site), if just 25% of eligible patients agreed to participate, we would reach our sample size targets within 3-4 months, which would allow the study to be completed within 24-months (allowing for 12-month follow up).

In addition to study investigators, key stakeholders have been invited to review the study protocol and provide feedback regarding the acceptability and feasibility of the proposed study. Stakeholders included two consumer advocates (patients undergoing knee or hip replacement), an orthopaedic surgeon who specialises in hip and knee replacement, the Director of Allied Health, two orthopaedic physiotherapists and the manager of the Barwon Joint Registry. The final protocol has been endorsed as constituting important research and as feasible within the proposed timelines. Together with study investigators, key stakeholders will form a steering committee to provide oversight of the study.

**5.0 Data Management**

Hard copy records will be stored physically under lock and key in the University Hospital Geelong and St John of God Hospital Geelong. Online data will be stored in the REDCap database and using password protected computers. Only authorized personnel will be allowed access to these records. Data that is routinely recorded as part of the Barwon Joint Registry will be kept indefinitely as part of the clinical quality register. Data that is unique to the study will be kept for 7 years, after which time they will be destroyed or further application for their use will be submitted.

**6.0 Data Analysis**

**Analysis of quantitative data**

As this is a feasibility study it is not necessary to have a fully powered study. A convenience sample of 100 participants will be recruited to the study, with approximately 50 participants recruited from each hospital. Given that 120 hip and knee joint replacements occur per month across both sites (60/site), and assuming that approximately 25% of eligible patients agree to participate, we would reach our sample size targets within 3-4 months.

Compositional analyses will be used to account for the co-dependency of the 24-hour behaviour Each 24-hour period will be divided into four behaviours (ActiGraph: sleep, sedentary, light, and moderate-to-vigorous physical activity; activPAL: sleep, sitting, standing, and stepping). The proportion of the total day spent in these behaviours will be normalized for each participant so that their sum equals one. Descriptive statistics for the components in this composition will be reported using standard statistics (i.e., range, interquartile range, and median) as well as the compositional mean (i.e., centre of the composition). The change in the composition of behaviours between time-points will be measured using by Aitchison’s perturbation method.10 Mixed models will then be used to test associations between the observed changes in the composition of movement behaviours and postoperative health outcomes (e.g. quality of life), adjusting for covariates such as age, sex and type of replacement (e.g., knee, hip). Analyses will be conducted using RStudio.

The primary outcome measure is the amount of physical activity and sedentary behaviour of participants and how this affects patients post-operatively. Clinical outcomes will be assessed with questionnaires and performance-based tasks. Validated questionnaires, such as the Oxford Score, EQ-5D-5L and HADS, will assess joint pain, physical function, quality of life, mental health, and complications from surgery. Performance-based tasks will assess walking ability with a timed walking test.

**7.0 Results, Outcomes and Future Plans**

Results will be shared with participants once the project is complete to avoid confounding the data. The plan for this project is go on and publish this in an orthopaedic journal and present at conferences. This data will be used to guide further studies in the area.

**8.0 Budget and Funding**

The study requires funding for:

1. Study Coordinator
2. Activity monitors
3. Waterproof dressings
4. Postage of activity monitors

The **Study Coordinator** will oversee the successful execution of the study protocol. The Study Coordinator will report directly to the study investigators. The Study Coordinator will be responsible for the operational management of this study. The coordinator will oversee:

1. Recruitment - ensuring that eligible participants are invited to be involved in the study
2. Consenting – ensuring that all participants have provided informed consent
3. Study promotion – ensuring that all key stakeholders such as orthopaedic surgeon’s and clinical staff are adequately informed and updated regarding the study during its 12 month Life cycle.
4. Data collection
   1. PA and SB monitoring - ensuring that all participants are correctly fitted with a monitoring device according to the study schedule. At the three-month preoperative and postoperative time-point this will involve mailing devices to participants and a home visit/telehealth appointment to support participants to correctly affix the inclinometer and accelerometer. This will be supported by PA and SB questionnaires.
   2. Clinical outcome assessments - ensuring that all participants complete all assessments in a timely manner
5. Data cleaning and collation – ensuring that the dataset is error-free, complete and compiled ready for analysis
6. Data analysis – under the direction of study investigators
7. Ethical requirements – reporting to relevant HREC committees regarding study progress

To successfully execute the study protocol, a Study Coordinator will be required at 0.4FTE. The Study Coordinator will need pre-existing research skills to efficiently and independently oversee the study, and will cost $43,166 (Deakin University, Level A, Step 6 research assistant, including 27.32% oncosts).

The activPAL micro costs $460/device and will be provided in-kind by study investigators from existing stores. **Waterproof dressings** to adhere the activPAL micro will cost $960.

The **GT9X ActiGraph accelerometer** costs $476/device. Most of the devices will be provided in-kind by study investigators from existing stores. An additional 4 devices will be required for the study to ensure timely data collection, equivalent to $1904.

**Postage** is required to send accelerometers to each participant’s home for the preoperative and 3 month assessment, together with a reply-paid envelope. Postage costs are $3,960.

In-kind contributions: Study investigators will provide in-kind contributions to supervise the Study Coordinator, ensure study fidelity, complete data analysis, and collate and disseminate study results. All activPAL micro devices and a portion of GT9X Actigraphs will be provided without cost.

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