**FULL STUDY TITLE**

Evaluating the effectiveness of a brief self-efficacy intervention to improve outcomes in patients recovering from a Total Knee Replacement (TKR)

**SHORT STUDY TITLE**

Self-efficacy after Total Knee Replacement (TKR)

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# STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Table of Contents

[STATEMENT OF COMPLIANCE 1](#_Toc165123590)

[GLOSSARY OF ABBREVIATIONS 5](#_Toc165123591)

[1. Study Management 5](#_Toc165123592)

[2. INTRODUCTION AND BACKGROUND 5](#_Toc165123593)

[2.2 Research Question 7](#_Toc165123594)

[2.3 Rationale for Current Study 7](#_Toc165123595)

[3 STUDY OBJECTIVES 7](#_Toc165123596)

[4 STUDY DESIGN 7](#_Toc165123597)

[4.1 Type of Study 7](#_Toc165123598)

[4.2 Study Design 7](#_Toc165123599)

[4.3 Number of Participants 8](#_Toc165123600)

[4.4 Expected Duration of Study 8](#_Toc165123601)

[4.5 Primary and Secondary Outcome Measures 8](#_Toc165123602)

[5 STUDY INTERVENTION 9](#_Toc165123603)

[5.1 Description of the Intervention 9](#_Toc165123604)

[5.2 Study Arms 9](#_Toc165123605)

[6 PARTICIPANT ENROLLMENT AND RANDOMISATION 9](#_Toc165123606)

[6.1 Recruitment 9](#_Toc165123607)

[6.2 Eligibility Criteria 10](#_Toc165123608)

[6.3 Informed Consent Process 10](#_Toc165123609)

[6.4 Enrolment and Randomisation Procedures 10](#_Toc165123610)

[6.5 Blinding Arrangements 11](#_Toc165123611)

[6.6 Breaking of the Study Blind 11](#_Toc165123612)

[6.7 Participant Withdrawal 11](#_Toc165123613)

[6.8 Trial Closure 12](#_Toc165123614)

[7 STUDY VISITS AND PROCEDURES SCHEDULE 12](#_Toc165123615)

[Study Flow Chart 12](#_Toc165123616)

[8 SAFETY REPORTING: 13](#_Toc165123617)

[8.1 MANAGEMENT and REPORTING 13](#_Toc165123618)

[9 STATISTICAL METHODS 13](#_Toc165123619)

[9.1 Sample Size Estimation 13](#_Toc165123620)

[9.2 Population to be analysed 14](#_Toc165123621)

[9.3 Statistical Analysis Plan 14](#_Toc165123622)

[10 DATA MANAGEMENT 14](#_Toc165123623)

[10.1 Data Collection 14](#_Toc165123624)

[10.2 Data Storage 14](#_Toc165123625)

[10.3 Data Confidentiality 14](#_Toc165123626)

[10.4 Study Record Retention 15](#_Toc165123627)

[11 ADMINISTRATIVE ASPECTS 15](#_Toc165123628)

[11.1 Independent HREC approval 15](#_Toc165123629)

[11.2 Amendments to the protocol 15](#_Toc165123630)

[11.3 Serious Breach Reporting 15](#_Toc165123631)

[11.4 Financial disclosure and conflicts of interest 15](#_Toc165123632)

[12 USE OF DATA AND PUBLICATIONS POLICY 16](#_Toc165123633)

[13 REFERENCES 16](#_Toc165123634)

[14 APPENDICES 17](#_Toc165123635)

**PROTOCOL SYNOPSIS**

|  |  |
| --- | --- |
| Title | Evaluating the effectiveness of a brief self-efficacy reminiscence intervention to improve outcomes for patients recovering from a Total Knee Replacement (TKR) |
| Objectives | **Primary**: To evaluate the short-term effectiveness of a brief reminiscence (mastery experience) intervention on self-efficacy to do prescribed exercises despite pain and adherence to prescribed exercises.**Secondary:** To explore whether the intervention is associated with improvements in pain, range of motion and confidence to engage with activities of daily living. |
| Study Design | Randomised controlled trial (two-arms: intervention vs waitlist control) with masked group allocation. |
| Planned Sample Size | 72 (29 per group, accounting for 20% dropout) |
| Selection Criteria | * Undergone total knee replacement in the past two weeks
* Attending Epworth outpatient physiotherapy clinic for post-surgery rehabilitation
* Able to read and understand the consent form autonomously
 |
| Study Procedures | Patients attending Epworth outpatient clinic during the first two weeks after their surgery will be provided with a QR code by their clinicians to learn more about the study if they are interested. Patients will express interest in participating by inputting their contact details and consenting to be contacted by the researchers. Researchers will contact participants with the information sheet and consent form.Researchers will contact participants by phone to conduct a short conversational reminiscence intervention which asks them to recall a time in their life they have overcome a challenge, and think about this time before and whilst doing their exercises. Outcome measures will be measured by physiotherapists during appointments as part of usual care, with some additional measures recorded on a take-home exercise diary and a follow-up survey.  |
| Statistical ProceduresSample Size Calculation:Analysis Plan: | With an $α $level of 0.05, and a study power of 80%, expecting a 1.5 point difference out of 10 between the two groups at the end of Week 3 in perceived self-efficacy to complete exercises despite pain (controlling for baseline self-efficacy), and a standard deviation of 2, we require a sample of 29 participants per group (total 58). If we assume a 20% drop out, that means we will require 72 participants.A one-way between-subjects analysis of variance (ANOVA) * IV: group (intervention or waitlist control)
* DV: change scores (week 3) on perceived self-efficacy to complete exercises despite pain, perceived self-efficacy to participate in daily living activities, pain intensity and range of motion as the dependent variables.

Between-subjects analysis of covariance (ANCOVA)* IV: group (intervention or waitlist control)
* DV: adherence to exercise
* Covariate: opioid medication use
 |
| Duration of the study | June-December 2024  |

# GLOSSARY OF ABBREVIATIONS

|  |  |
| --- | --- |
| **ABBREVIATION** | **TERM** |
| TKR | Total Knee Replacement |

# Study Management

* 1. **Statistician**

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* 1. **Sponsor**

The University of Sydney

* 1. **Funding and resources**

This study is being funded from the research account of Claire Ashton-James at the University of Sydney. Funding will be used to pay for the cost of the ethics application. No other funding is required for the study. Neither investigators nor participants are being paid as part of this study, and there are no material costs of implementing this study.

# INTRODUCTION AND BACKGROUND

* 1. **Background Information**

In 2023, 64,846 Total Knee Replacements (TKRs) were performed in Australia (Australian Orthopaedic Association National Joint Replacement Registry, 2023), and this number is expected to increase to over 160,000 per year by 2030 (Ackerman et al., 2019). As part of physiotherapy recovery, regular exercises are prescribed to improve pain levels and functional outcomes for TKR patients (Bakaa et al., 2022; Rosal et al., 2011). However, most patients discontinue their prescribed exercise at home (Duong et al., 2022), which is associated with long-term complications including increased pain, stiffness, and muscle weakness (Bakaa et al., 2022).

Perceived self-efficacy, defined as an individual’s belief that they can produce certain attainments (Bandura, 1977) is a strong predictor of adherence to home-based physical therapies for a wide range of patient populations (Essery et al., 2017). Self-efficacy provides individuals with the confidence that they can initiate coping behaviour and sustain effort in the face of obstacles (Bandura, 1977) such as the pain or discomfort experienced when completing physiotherapy exercises after surgery (Bakaa et al., 2022; Essery et al., 2017).

Psychological interventions implemented in a physiotherapist setting often aim to increase self-efficacy through the CBT strategies of pain education, goal setting and development of coping skills (Chen et al., 2013; Guerrero et al., 2018; Losina et al., 2016; Meng et al., 2022; Söderlund & Lindberg, 2001; Whale et al., 2019). Despite potential benefits of these programs for exercise adherence and some aspects of functioning (Chen et al., 2013; Meng et al., 2022), physiotherapists feel they lack the training, confidence and time required to implement these interventions (Alexanders et al., 2015; Driver et al., 2017, 2021) and, more broadly, to address psychological, cognitive and social factors with patients (Synnott et al., 2015). As a result, interventions based on psychological principles are often underutilised in physiotherapy practice (Alexanders et al., 2015; Driver et al., 2017, 2021).

Additionally, research suggests that these CBT-based interventions demonstrate no benefits to disability levels or functioning (Guerrero et al., 2018; Losina et al., 2016) and only long-term, not short term benefits for self-efficacy (Guerrero et al., 2018) for those with knee osteoarthritis or undergoing TKR. A possible reason is that these strategies require patients to challenge their thoughts through cognitive restructuring, which is cognitively demanding for patients who are dealing with pain and feelings of vulnerability post-surgery, so time and practice may be required to yield benefits.

An alternative approach is designing interventions which elicit experiences of mastery; the most effective way of building a strong sense of self-efficacy (Bandura, 2008). Mastery experiences refer to past experiences where one is able to overcome obstacles through perseverant effort (Bandura, 2008). Although self-efficacy is considered domain-specific, the skills gained through mastery experiences can generalise to activities which require similar self-discipline and perseverance, and therefore greatly improve self-efficacy across diverse realms of functioning (Bandura, 2006; Bandura et al., 1980). This is important as individuals may not have had past mastery experiences directly relevant to the challenge they are currently facing, like post-surgery recovery.

Recent research has examined the use of reminiscence-based interventions, which encourage participants to recall a memory of accomplishment and persistence in the face of challenges, to remind participants of mastery experiences and thus increase their self-efficacy (Hallford et al., 2022; Paersch et al., 2022; Pinquart & Forstmeier, 2012). These reminiscence interventions have not been previously studied in a TKR population, but demonstrate promising benefits in non-clinical samples.

A meta-analysis of 128 randomised-controlled trials on reminiscence interventions found significant improvements for a range of outcomes including depression, purpose in life, mental health, positive wellbeing and mastery compared to the control group (Pinquart & Forstmeier, 2012). Only six of the nine main outcome variables remained significant at follow-up, but this was likely due to the smaller number of studies that provided follow-up data rather than absence of an effect (Pinquart & Forstmeier, 2012).

In research by Hallford et al. (2022), young adults completed 3 sessions of cognitive-reminiscence therapy (CRT) delivered via an online teleconference platform, where they focused on past experiences of pride, success and meaning. CRT participants reported significantly higher self-esteem, general self-efficacy, meaning in life and optimism post-intervention and at a 2-week follow-up than the waitlist control group, and effect sizes for self-efficacy were large at both timepoints.

Paersch et al. (2022) also showed that participants who recalled times they had demonstrated strength and self-efficacy to manage a situation successfully despite barriers subsequently appraised a personal negative memory as less distressing compared to participants who recalled a positive memory.

* 1. **Research Question**

Can a brief self-efficacy intervention, which involves reminiscence of a mastery experience, improve self-efficacy to complete prescribed physiotherapy exercises and adherence to these exercises for patients in week 3 after Total Knee Replacement (TKR) surgery?

* 1. **Rationale for Current Study**

Existing CBT-based and reminiscence interventions are resource and time-intensive, often requiring extensive clinician training to implement (Guerrero et al., 2018; Hallford et al., 2022; Pinquart & Forstmeier, 2012), which limits the feasibility of including these interventions as part of usual TKR recovery (Alexanders et al., 2015; Driver et al., 2017, 2021). The current study addresses these issues by evaluating a short, reminiscence-based intervention conducted over the phone that consists of only one autobiographical memory prompt, and would require minimal additional training or resources for clinicians to implement. Further, the intervention does not require patients to challenge their thoughts, as is often required in CBT, but simply asks them to reflect upon a past mastery experience, so may result in more short-term benefits to self-efficacy and functioning.

 Interventions involving autobiographical memory recall have not yet been studied in a TKR population. Existing research on reminiscence in non-clinical samples only uses general measures of self-efficacy (Hallford et al., 2022; Paersch et al., 2022), rather than self-efficacy for a specific domain, which likely obscures significant effects (Bandura, 2006; Paersch et al., 2022). The current study examines the effectiveness of the intervention for improving self-efficacy to complete exercises despite pain, as exercise adherence is an important predictor of clinical outcomes during TKR recovery (Bakaa et al., 2022; Rosal et al., 2011).

# STUDY OBJECTIVES

* 1. **Primary Objective**

The primary objective of this study is to test the hypothesis that a brief reminiscence (mastery experience) intervention improves self-efficacy to do prescribed exercises despite pain and adherence to prescribed exercises for patients recovering from TKR.

* 1. **Secondary Objectives**

The secondary objective of this study is to explore whether the intervention is associated with changes in pain, range of motion and confidence to engage with activities of daily living.

1. **STUDY DESIGN**

## Type of Study

Two-arm randomised controlled trial with waitlist control

* 1. **Study Design**

The proposed study involves a randomised controlled trial with masked group allocation. Baseline data will be measured for all participants in week 3 post-surgery. Participants will be randomised to either Group A: who will receive the intervention in week 3 post-surgery, or Group B: who will receive the intervention the week after, in week 4 post-surgery. In this way, Group B will serve as a waitlist control condition of usual care in week 3.

* 1. **Number of Participants**

We will recruit 72 patients, 36 in each study arm (see section 9. Statistical methods).

* 1. **Expected Duration of Study**

June 1st – December 31st 2024

* 1. **Primary and Secondary Outcome Measures**

The following outcome measures will be recorded by clinicians in four appointments for all participants: the first and second appointment of week 3 post-surgery, and the first and second appointment of week 4 post-surgery.

**Primary outcome:**

***Perceived self-efficacy to complete exercises despite pain***

At the end of each appointment, clinicians will ask participants “At the moment, how confident do you feel that you can complete your exercises at home despite pain? Please indicate your level of confidence from 0-100%”.

**Secondary outcomes:**

***Exercise adherence***

Participants will complete a daily exercise diary (see Appendix 2) given by the clinician after each appointment to measure exercise adherence.

***Perceived self-efficacy to participate in daily living activities despite pain***

 At the end of each appointment, clinicians will ask participants “At the moment, how confident do you feel that you can participate in social roles and activities of daily living despite the pain? Please indicate your level of confidence from 0-100%”

***Pain intensity***

Pain intensity will be measured using the Numerical Rating Scale (NRS), where participants are asked to rate their pain on a scale from 0-10, with 0 representing ‘no pain at all’ and 10 representing ‘the worst pain ever possible’ (Haefeli & Elfering, 2006). Pain intensity will be measured three times in each appointment. At the beginning of the appointment, clinicians will ask participants to rate the overall pain they have experienced over the past 24 hours, and the pain they experienced while doing their exercises at home in the past 24 hours. After doing a session of exercises with the physiotherapist in the appointment, participants will rate the pain they experienced while doing these exercises. Participants will also rate the pain they experienced whilst doing their exercises daily in the exercise diary.

***Range of motion***

Active and passive knee range of motion (ROM) will be measured by physiotherapists as part of usual care, using a goniometer to record an angle in degrees of range of motion.

***Medication use***

Clinicians will ask participants if they are currently taking opioid pain medication or not. Clinicians will follow up by asking if they are taking any other medication, and if so, what medication and how often.

***Patient feedback***

The evening after their second physio appointment in week 4, researchers will contact participants with another link to a (qualitative) survey, which will ask participants 1) *“Did you think about the hard experience you overcame before or during your exercises?”* 2) *“If yes, how often? If no, why not?* 3) “*Did you find thinking about this time helpful? If so, how? If not, why not?” 4) “How did thinking about this time make you feel whilst doing your exercises?”* 5) “*Any other feedback about the contents or delivery of the intervention?”.*

***Demographic information***

Demographic information including participants’ age, gender and date of surgery will be obtained from the hospital clinic notes.

# STUDY INTERVENTION

* 1. **Description of the Intervention**

To minimise bias and to ensure there are no changes to usual care as conducted by clinicians, the intervention will be conducted by the researchers via phone call. Researchers will contact participants to conduct the intervention between the first and second appointment of either week 3 or week 4 post-surgery, depending on group allocation.

The intervention is a guided reminiscence intervention conducted over the phone, which will involve the researcher prompting participants to recall a positive memory of a time that they have overcome something difficult that made them feel proud, and encouraging participants to think about the strength they demonstrated during this time before and whilst completing their exercises at home (see Appendix 3) The participant will not share their challenging experience with the researcher, they will simply personally recall it. Whilst they are recalling this memory, the researcher will ask how thinking about this memory made the participants feel, as a manipulation check to ensure the intervention is evoking positive feelings of pride, strength and resilience. If the participant indicates that the memory does not evoke positive feelings, the researcher will ask if they can think of an example that makes them feel proud of themselves.

* 1. **Study Arms**

Participants will receive the intervention between their first and second physiotherapy appointment of the week. In week 3 post-surgery, Group A will receive usual care as well as the intervention, whilst Group B will serve as a waitlist control, and receive usual care only. In week 4 post-surgery, Group A who have already received the intervention will receive usual care, whilst Group B will receive usual care and the intervention.

Group A will receive the intervention in week 3 after surgery because this is the earliest possible time that we can be assured that the majority of patients will be scheduled for an appointment at the outpatient rehabilitation clinic. Some patients are receiving care at the outpatient clinic 2 weeks after surgery, but many don’t have their appointments at the clinic scheduled until week 3. These estimates are based on the advice of our co-investigators (clinicians) at Epworth Hospital.

Group B will also receive the intervention, but in week 4 after surgery. Therefore, all participants will receive the intervention. This is because recruiting patients for research studies can be difficult, and retaining patients in studies is particularly difficult when they are in the control group (not receiving any additional services, which may be perceived as a benefit of participating). Patients are often more willing to participate in studies if they know they will receive the intervention at some point in time. Hence, we are offering the intervention to Group B as well. In addition, we are offering the intervention to all participants (Week 3 or 4) to control for the potential effect of knowing that an intervention will be received on participants’ treatment expectations (optimism) and outcomes.

# PARTICIPANT ENROLLMENT AND RANDOMISATION

* 1. **Recruitment**

The study will include patients in week 3 and 4 of recovery from a Total Knee Replacement (TKR) who are attending the physiotherapy clinic at a private hospital in Melbourne, Australia (Epworth Hospital). Inpatient and outpatient TKR patients attending physiotherapy sessions in week 2 after surgery will be shown a flyer by their clinician during their appointment with brief information about the study, and asked to scan the QR code on their mobile phone if they are interested in learning more. The QR code will send patients to a form that will ask if they give consent for their contact details to be passed on to the researchers for the purposes of providing further information about participating in the study, and if so, to input their contact details and preferred contact method (phone or SMS). Researchers will then contact the patients to begin the consent process (see 6.3 – Informed Consent Process).

* 1. **Eligibility Criteria**
		1. **Inclusion Criteria**
* Able to read and understand the consent form autonomously
* Undergone total knee replacement in the past two weeks
* Attending Epworth outpatient physiotherapy clinic for post-surgery rehabilitation
	+ 1. **Exclusion Criteria**
* Patients who cannot read and understand English autonomously

## Informed Consent Process

Patients will indicate interest in the study by scanning the QR code presented by clinicians during their appointment, inputting their contact details and consenting to be contacted by the research team. It will be made clear in the form that this initial expression of interest via the QR code is not consent to participate, and that patients will have the chance to learn more about the study and ask questions before consenting to participate.

After expressing interest, the research team will send patients a link to the consent form on an online platform (Qualtrics) via SMS. This consent form will include all information about the study and the process for providing consent and withdrawal (see Appendix 4). In the same message, patients will additionally be sent a separate document containing the study information so they can refer to this information whenever needed, take time to consider their decision to participate in the study and ask any questions they may have before providing consent through the form.

Patients who indicate they prefer to discuss the study over the phone will be called by the researchers to give them opportunity to ask questions and the option to be guided through the consent process, and all patients would be provided with a contact number if patients have any concerns or questions. Older populations generally appreciate hearing about study information verbally, so this option will be offered to participants should they require it. However all patients will receive the written information about the study which they can refer back to any time, and will still be required to complete the formal written consent form.

Patients will be assured that their decision that their decision about participating in the study will not have any impact on the care they receive from clinicians. By nature of this consent process, clinicians will not be aware of which patients consent to participate or not, although they are aware of who expresses an interest or not.

* 1. **Enrolment and Randomisation Procedures**

The participant will be enrolled into the study after the informed consent process has been completed and the participant has met all inclusion criteria and none of the exclusion criteria. The participant will be allocated a unique participant identifier which will be documented on all study documents. After providing consent, participants will be randomised using the Qualtrics software to Group A (receiving intervention in week 3) or Group B (receiving intervention in week 4)

* 1. **Blinding Arrangements**

Clinicians will be blinded, such that they will not be aware of the patient’s decision to enrol in the study or not beyond their initial consent to be contacted by the researchers, and the research team will not inform clinical teams of participating patients’ group allocation. Participants will be aware that they will receive the intervention sometime across the two weeks, but their group allocation will be masked. The researcher responsible for conducting the intervention will be aware of participants’ randomly allocated condition, but have no involvement in the data collection process and remain blinded to participants scores on the outcome measures until study completion.

* 1. **Breaking of the Study Blind**
		1. **On Study**

Clinicians remain blind to participant involvement and participant allocation and are not unmasked at any time. The statistician will remain blind to group allocation until data analysis is complete, at which point the researcher conducting the intervention will identify group allocation in the data.

* + 1. **Following Completion of the Study**
	1. **Participant Withdrawal**

After participants consent, they will be sent a link by their preferred contact method (text or email) through which they can withdraw from the study at any time.

* + 1. **Reasons for withdrawal**

Participants can withdraw for any reason. When they complete the withdrawal survey they are invited to provide a reason for their withdrawal but it is optional.

The possible circumstances that may lead to participant withdrawal include:

1. Health and Safety
2. Non-compliance
3. Lost to follow-up
4. Consent withdrawn
	* 1. **Handling of withdrawals and losses to follow-up**

 Participants retain the right to withdraw from the study at any time and can choose whether the study will delete or retain the information it has collected up to the point that the de-identified data has been analysed and published. This can be done by through an online link that will be sent to participants when they consent to participate in the study. Participants can also withdraw by sending an email to hmil4014@uni.sydney.edu.au at any time. The reason for withdrawal (not mandatory to report), along with the time point at which they withdrew, will be recorded in the withdrawal form.

* + 1. **Replacements**

 We have estimated a 20% drop-out rate in the calculated sample size for recruitment. We will not be replacing participants who drop out of the study.

* 1. **Trial Closure**

There is no follow-up with participants beyond the study as this intervention is provided in addition to usual care. Therapeutic follow-up remains with the clinician.

# STUDY VISITS AND PROCEDURES SCHEDULE

## Study Flow Chart

Enrolment

Randomisation

Week 3 post-surgery

Group A Group B

Intervention + Usual care Usual care only

 Week 4 post-surgery

Group A Group B

Usual care only Intervention + Usual care

Participants will receive a phone call from the researcher to conduct the intervention in the evening after participants’ first appointment in week 3 (Group A) or week 4 (Group B) after surgery.

The following outcome measures will be recorded over the two-week period for each participant. Clinicians will measure most of the outcomes as part of business as usual in four appointments: the first and second appointment of week 3 post-surgery, and the first and second appointment of week 4 post-surgery.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **List of Outcomes** | **Week 3 appointment 1** | **Week 3 appointment 2** | **Week 4 appointment 1** | **Week 4 appointment 2** | **Daily exercise diary** | **Follow-up** |
| Perceived self-efficacy to complete exercises despite pain | ✓ | ✓ | ✓ | ✓ | ✓ |  |
| Exercise adherence |  |  |  |  | ✓ |  |
| Perceived self-efficacy to participate in daily living activities despite pain | ✓ | ✓ | ✓ | ✓ |  |  |
| Pain intensity | ✓ | ✓ | ✓ | ✓ | ✓ |  |
| Range of motion (ROM) – Active and Passive | ✓ | ✓ | ✓ | ✓ |  |  |
| Medication use | ✓ | ✓ | ✓ | ✓ |  |  |
| Patient feedback |  |  |  |  |  | ✓ |

# SAFETY REPORTING:

# MANAGEMENT and REPORTING

 We do not anticipate any adverse events associated with the intervention, however, if a participant expresses distress/concern for any reason, related or unrelated to the intervention, it is escalated to the clinicians involved in the study, who are responsible for patient care. Any adverse events will be reported in the results of the study. Participants in both arms will continue to work with their physiotherapists and other health practitioners on “usual care”. Participants are advised if they experience a flare-up of pain or any other pain-related problem, they should contact their treating doctor/clinician as part of their usual care component.

# STATISTICAL METHODS

* 1. **Sample Size Estimation**

With an $α $level of 0.05, and a study power of 80%, expecting a 1.5 point difference out of 10 between the two groups at the end of Week 3 in perceived self-efficacy to complete exercises despite pain (controlling for baseline self-efficacy), and a standard deviation of 2, we require a sample of 29 participants per group (total 58). If we assume a 20% drop out, that means we will require 72 participants.

* 1. **Population to be analysed**

The target population is patients in week 3 and 4 after TKR surgery. The participants in the two treatment arms will be compared.

* 1. **Statistical Analysis Plan**

A one-way between-subjects analysis of variance (ANOVA) will be conducted with the group (intervention or waitlist control) as the independent variable and the change scores from the first appointment to the second appointment in week 3 post-surgery on perceived self-efficacy to complete exercises despite pain, perceived self-efficacy to participate in daily living activities, pain intensity and range of motion as the dependent variables. Only participants who have received the intervention in week 3 post-surgery (*Group A)* will be included as the ‘intervention group’.

A between-subjects analysis of covariance (ANCOVA) will be conducted with intervention/waitlist control as the independent variable, adherence to exercise as the dependent variable and opioid medication use as the covariate.

If we do not meet our sample size requirements, a one-sided t-test with an 80% confidence interval will be used to determine the effect of the intervention on these outcomes, as a traditional significance test is not expected to reveal significance.

Analyses will be conducted using SPSS software (version 29). Additionally, patient feedback will be transcribed verbatim and analysed descriptively by two independent coders.

# DATA MANAGEMENT

* 1. **Data Collection**

Physiotherapists at the outpatient rehabilitation clinic of Epworth Hospital will collect all outcome measures as part of usual care for patients in week 3 and 4 of recovery from TKR (see Appendix 5). Self-efficacy measures that were developed with consumer input for this study have been adopted by the clinic as usual care for all patients in week 3 and 4 of recovery from TKR, ensuring that clinicians cannot distinguish between patients who are participating and those who are not, and so that clinicians can use these self-efficacy measures as additional information to enhance their care of patients. Participant feedback on their experience of the intervention will be obtained by researchers, who will send participants a link to a feedback survey upon completion of the study.

Upon completion of the study, an independent member of the research team will input the data from the paper documents into a password-protected spreadsheet, and transfer this via secure share drive (eg. Onedrive) to researchers at the University of Sydney.

* 1. **Data Storage**

Paper documents (eg. clinician data sheet, participant exercise diary) will be stored in locked cupboards at Epworth. Any electronically-stored data will be in password-protected spreadsheets stored on secure online servers (eg. Onedrive) to ensure data security.

* 1. **Data Confidentiality**

Patients’ privacy will be protected for archiving, storage, and publication. We are recording their name, mobile phone number, and email address but no other identifying data such as the exact dates of birth, addresses, country of birth, Aboriginality or sexual orientation.

The data will be re-identifiable, but individual patient data will be de-identified: patient outcome data will not be stored together with patient name and phone number. Here are the steps for maintaining data confidentiality:

* The University of Sydney-based research team will have a data sheet ~~with~~ with participants’ name, mobile phone number, participant ID and group allocation.
* That document will be shared with a researcher at Epworth, who will input the patient outcome data gathered by the Epworth clinic into the spreadsheet with the patient name.
* Importantly, before saving and sending the document back to the University of Sydney Researchers, the researcher at Epworth will de-identify that data by removing the participant name and phone number.
* The file containing the patient’s name and participant ID number will remain password-protected, and will be stored separately to the patient outcome data.

 Electronic data (feedback survey) will be deleted after 15 years from the publication of the project’s final report. Physical data (papers) will be securely destroyed after 15 years from the publication of the project’s final report.

* 1. **Study Record Retention**

 The data will be maintained for a minimum of 15 years from the publication for the final report.

#  ADMINISTRATIVE ASPECTS

After HREC approval and prior to enrolment of the first participant, the trial will be registered with the Australia New Zealand Clinical Trials registry. The registration number will be mentioned in the subsequent protocol versions (if amended), communications with committees, and in reports and publications.

* 1. **Independent HREC approval**

This study will be submitted to the NSLHD HREC.

* 1. **Amendments to the protocol**

Any amendments will be submitted to the HREC for review prior to implementation as per HREC guidelines.

* 1. **Serious Breach Reporting**

Serious Breaches will be submitted to the HREC for review by the CPI within 7 calendar days of the breach.

* 1. **Financial disclosure and conflicts of interest**

There are no conflicts of interest and no funding to disclose.

# USE OF DATA AND PUBLICATIONS POLICY

The results of this study will be presented at scientific meetings and submitted to peer-reviewed scientific journals for publication. There will also be dissemination of results back to the participants (if they request), in the media, and to the policy makers where relevant. All investigators on the protocol will be acknowledged in publications

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1. **APPENDICES**

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| 1 | QR Code Brochure for Participant v1.0 29 04 24 |
| 2 | Participant Exercise Diary v1.0 29 04 24 |
| 3  | Intervention Script v1.0 29 04 24 |
| 4  | Participant Information Sheet and Consent Form v1.0 29 04 24 |
| 5 | Clinician Data Collection Sheet v1.0 29 04 24 |