Participant Information and Consent Form

Study Title:

Telerehabilitation Versus Clinic-Based Rehabilitation for Functional Recovery Following Primary Total Knee Arthroplasty

ClinicalTrials.gov Identifier (NCT Number): [NCT number to be assigned]

Sponsor: The University of Western Australia

Principal Investigator: Ray Seaby

Human Research Ethics Approval: RA/4/20/6103 (UWA Human Research Ethics Committee)

Mr Ray Seaby
School of Human Sciences, M408
The University of Western Australia
35 Stirling Highway, Crawley WA 6009
Tel: 6488 2668
Email: ray.seaby@uwa.edu.au
https://www.uwa.edu.au/science

Participant Information Form

Telerehabilitation Versus Clinic-Based Rehabilitation for Functional Recovery Following Primary Total Knee Arthroplasty

Names of Researchers: Mr Ray Seaby, Dr Jay Ebert, Prof Timothy Ackland, Dr Brendan Joss, Dr Peter Edwards, Dr Silvia Pfeiffer

Surgeon Partners: Orthopaedic surgeons from the Perth Orthopaedic and Sports Medicine Centre (POSM).

Invitation:
We invite you to participate in a project that seeks to determine the efficacy of post-operative rehabilitation delivered via telehealth compared to that delivered via 'usual care' (face-to-face delivery either within a clinic facility or at your home). You have been asked to take part in this study because you have been scheduled by your orthopaedic surgeon for a total knee arthroplasty (TKA) operation in the near future.

Aim of the Study (What is the project about?)
This study will determine if short-term and medium-term TKA patient outcomes are similar following a 6-week rehabilitation program delivered either via telehealth or face-to-face.

What does participation involve?
Patients who reside within a 30 km radius of Nedlands, and who meet certain inclusion/exclusion requirements, will be invited to join the study to receive a 6-week post-surgery exercise rehabilitation program. This program will be tailored to your specific needs and is supported by your surgeon.

Participants will be randomly allocated to one of two groups for the rehabilitation program – a Telehealth group or Clinic group (usual care). Apart from the cost of transport to the clinic, where necessary, there will be no cost to you for participating in this rehabilitation program.

The Telehealth Group – participants in this group will undertake the rehabilitation exercises at home under the guidance of an experienced Exercise Physiologist (EP) using a video link from your preferred device (smart phone, iPad or laptop computer). If you don't have a device, we can provide you with one for the duration of your rehabilitation program. Devices will be loaded with the *Coviu* app which allows you and your EP to communicate (sound and vision) during the therapy session, and *Physitrack* so that your therapist can provide the specific exercises to you. These sessions are encrypted for your security and privacy.

The Clinic Group – participants in this group will undertake the rehabilitation exercises at HFRC's exercise rehabilitation clinic under the guidance of an experienced EP. All necessary precautions due to the COVID-19 pandemic, as determined by the W.A. Government, will be followed during this period.

Both groups of participants will participate in a goal-oriented exercise rehabilitation program that is tailored to your individual needs. The exercises will be specific for patients recovering from knee surgery and you will

be guided through nine sessions – twice per week for the first 3 weeks, then once per week for the next 3 weeks. Total time for these rehabilitation sessions is 4.5 hours over 6 weeks.

Participants will be assessed for clinical outcomes at a number of stages throughout the program, as follows.

Time-point	Location / Time	Test	Description
Pre-surgery Assessment and Familiarization Session	Clinic ~ 1 hour	• PROMs • ROM • Function	• Patient-reported outcome measures (see below) • Knee range of motion • Physical function tests (see below)
Post-surgery exercise rehabilitation sessions for 6 weeks	Clinic or Online 30 min	• ROM	• Knee flexion range of motion • Individually-tailored rehabilitation sessions - Twice/week for weeks 1-3 - Once/week for weeks 4-6
End of rehab program (at +7 weeks)	Clinic 40 min	• PROMs • ROM • Function	• Patient-reported outcome measures (see below) • Knee range of motion • Physical function tests (see below)
+6 months post-surgery	Via email	• PROMs	• Patient-reported outcome measures (see below)
+12 months post-surgery	Clinic 40 min	• PROMs • ROM • Function	• Patient-reported outcome measures (see below) • Knee range of motion • Physical function tests (see below)

PROMs – These are questionnaires about your current feelings of pain, swelling and knee function and should take about 15 minutes to complete. These questionnaires will be in the form of an online survey which simply requires you to click your response (on screen) and the data are then securely transferred via the internet to the study coordinator.

- Knee Injury and Osteoarthritis Outcome Score (KOOS)
- Visual-Analogue Scale for Pain (VAS)
- University of California, Los Angeles (UCLA) activity scale
- Self-Administered Patient Satisfaction Scale (SAPS)
- Patient Satisfaction questionnaire
- Global Rating of Change(GRoC) scale

Physical function tests – You will be asked to perform these tests to the best of your ability and within the limits of your pain and stiffness on the day. These tests will take about 15 min to complete.

- The 40 metre Walk Test – Elapsed time for you to walk 40 m (4 x 10 m repeats) will be recorded.
- 30 second Sit-to-Stand Test – Number of times you can rise to the standing position from seated.
- Stair climb Test – Elapsed time to ascend and descend a flight of stairs (9 steps).
- Timed Up-and-Go Test – Elapsed time to rise from a seat, walk 3 m, turn and walk back to the seat, then sit down again.

Voluntary Participation and Withdrawal from the Study

Your decision to participate in this study is voluntary; that is, you may decide whether to be in this study or not. If you do decide to participate initially, you are able to change your mind and withdraw at any time without any explanation needed. If you decide to withdraw, we will destroy any research assessment-related data unless you agree in writing that it can be retained and used for our research. Your treatment notes, however, will be kept on file at HFRC for 7 years as required by law.

Please note that if you decide not to participate in this study, or subsequently withdraw from the study, there will be no consequences for you, and this will not affect your ongoing treatment with your orthopaedic surgeon.

Your safety

All the patient outcome tests we plan to implement have been thoroughly trialled in research and applied ubiquitously in clinical practice. None of the tests is physically invasive.

Your privacy

We wish to emphasize that you and your data will remain private and secure throughout the study and beyond. Your participation in this study and any information you provide will be treated in a confidential manner. Information from this project may be published but your name and identifying details will not be used in any publication arising out of the research without your consent.

The research assessment data will be kept in a password protected computer or a secure server for minimum of 25 years. Treatment notes will be kept by your therapist separately to the study information and will be name-identified as required by law. These treatment notes will not be used for any other purpose than your ongoing treatment or referral.

Possible Benefits

Participants will benefit from this study by undertaking a post-surgery exercise rehabilitation program at no financial cost. This program will be administered by an accredited EP who will guide you through this phase with individually-tailored exercises that are designed to help you meet expected goals following TKA surgery. Your therapist will monitor your progress over the course of the study and liaise with both you and your surgeon; this is usual in best-practice patient care.

The benefits to patients more broadly are to add to the existing evidence regarding the efficacy of telehealth/telerehabilitation services and help promote access to rebates for these services through Medicare and private health funds. In turn, this will allow a larger portion of Australia's population to access rehabilitation services – especially those in rural and remote areas.

Possible Risks and Risk Management Plan

You have been recommended by your orthopaedic surgeon as being suitable for this study. Our EPs have many years' experience in providing post-surgery rehabilitation for knee replacement patients, so we are aware of the myriad factors that impact on a patient's progress after TKA surgery. We have strict guidelines in place to assist patients who may be struggling with the post-surgery phase and we will be in contact with your surgeon at all times.

Therefore, we can be confident that there are few foreseeable risks associated with the research, provided you follow the advice and exercise instructions provided by your therapist.

However, to ensure optimal outcomes for participants who have been allocated to the telehealth group, a safety net, known as a *delayed recovery intervention protocol,* will be implemented. This means if any participant does not meet minimum standards for recovery within 3 weeks of commencement, then they will be referred for a (face-to-face) clinic follow-up.

Potential Conflict of Interest Statement

This research is funded via a Cooperative Research Centre grant, with Coviu one of the main financial partners. There are financial implications for Coviu (and co-investigator Dr Silvia Pfeiffer) if the outcome of this trial is successful. Similarly, as a provider of telehealth services, the research partner organisation HFRC (and co-investigators Dr Brendan Joss and Prof. Timothy Ackland) may derive financial benefits if the outcome of this trial is successful. However, the other investigators (Dr Peter Edwards and trial coordinator Mr Ray Seaby) are not associated with either of the abovementioned research partners.

Contacts

If you would like to participate or discuss any aspect of this study, please feel free to contact the project coordinator, Mr Ray Seaby by email (ray.seaby@curtin.edu.au) or phone (0420 222 513).

Yours sincerely,
Ray Seaby



Approval to conduct this research has been provided by the University of Western Australia, in accordance with its ethics review and approval procedures. Any person considering participation in this research project, or agreeing to participate, may raise any questions or issues with the researchers at any time. In addition, any person not satisfied with the response of researchers may raise ethics issues or concerns, and may make any complaints about this research project by contacting the Human Ethics office at UWA on (08) 6488 4703 or by emailing to humanethics@uwa.edu.au. All research participants are entitled to retain a copy of any Participant Information Form and/or Participant Consent Form relating to this research project.

Participant Consent Form

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I, _____ have read the information provided and any questions I have asked have been answered to my satisfaction. I agree to participate in this research project, realizing that I may withdraw at any time without reason and without prejudice.

I understand that all identifiable information that I provide is treated as confidential and will not be released by the investigator in any form that may identify me unless I have consented to this. The only exception to this principle of confidentiality is if this information is required by law to be released.

_____ _____

Participant signature Date

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