STUDY PROTOCOL

including Statistical Analysis Plan

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)

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Administrative Information

- **Official Title:** A Randomised Comparison of Clinic- Versus Telehealth-Delivered Early-Stage Post-Operative Rehabilitation and Functional Assessment Following Total Knee Arthroplasty
- **ClinicalTrials.gov Identifier:** [NCT number to be assigned]
- **Sponsor:** University of Western Australia, 35 Stirling Highway, Crawley, WA 6009, Australia
- **Secondary Sponsor:** HFRC Rehabilitation Clinic, 117 Stirling Highway, Nedlands, WA 6009, Australia
- **Collaborator:** Coviu, SE 2/77 Hope Street, South Brisbane, QLD 4101, Australia (telehealth platform provider)
- **Funding Source:** Cooperative Research Centre Project (CRC-P) grant, "Transforming joint surgery rehabilitation with artificial intelligence in telehealth", Project number CRCPSIX000203. Department of Industry, Science, Energy and Resources, Australian Government.
- **Ethics Approval:** The University of Western Australia Human Research Ethics Committee, approval number RA/4/20/6103 (submitted 1 June 2020, approved 27 July 2020). Conducted in accordance with the Declaration of Helsinki.
- **Document Date:** 18 August 2026

Background and Rationale

Total knee arthroplasty (TKA) is an effective surgical intervention for people with end-stage knee osteoarthritis. Nonetheless, up to one in five patients report ongoing dissatisfaction following TKA, commonly due to persistent pain, stiffness, or slower-than-expected recovery of movement and function. Rehabilitation plays a crucial role in optimising post-operative outcomes, with structured exercise programs essential for restoring joint range of motion (ROM), muscle strength, and functional independence.

Post-operative rehabilitation following TKA has traditionally been delivered through supervised, in-person sessions within outpatient or clinic-based settings. This model of care can present barriers related to cost, travel, and accessibility, particularly for individuals living in rural or remote areas or those unable to drive in the early post-surgical period.

Telehealth, or telerehabilitation, has emerged as an alternative medium of service delivery for allied health interventions, extending the reach of assessment, education, and exercise programs to patients who lack convenient access to in-person services. Exercise-based telerehabilitation programs have demonstrated feasibility and efficacy across a range of musculoskeletal conditions, including knee osteoarthritis and chronic knee pain, achieving outcomes comparable to in-person care. However, at the time this study was

designed, there remained a shortage of studies comparing telerehabilitation with conventional in-person care that incorporated both objective and patient-reported outcome measures over a longer-term follow-up period beyond the early post-operative window.

Study Objectives and Hypotheses

This study was designed to investigate outcomes after TKA in patients undergoing early-stage post-operative rehabilitation delivered via a telehealth model of care, compared with a traditional in-person clinic-based model.

It was hypothesised that outcomes achieved via telehealth-delivered rehabilitation would be non-inferior to those obtained through in-person, supervised clinic-based rehabilitation, with no clinically meaningful differences between groups in: (1) the Quality of Life (QOL) subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS); (2) other patient-reported outcome measures (PROMs); (3) active knee flexion and extension range of motion; and (4) objective measures of lower-limb function.

Study Design

This was a randomised controlled, single-blinded, non-inferiority trial, was conducted at a single private rehabilitation clinic (HFRC Rehabilitation Clinic) in Western Australia, in conjunction with the surgical caseloads of six orthopaedic surgeons.

Study Arms

The Clinic Group served as the active comparator arm, receiving in-person, clinic-based rehabilitation delivered face-to-face at a single private rehabilitation clinic. The Telerehabilitation Group served as the experimental arm, receiving rehabilitation sessions of identical content and frequency delivered remotely via a telehealth videoconferencing platform (Coviu, Sydney, Australia).

Eligibility Criteria

Patients meeting the following criteria were eligible for inclusion in the study:

- Age ≥18 years
- Undergoing primary elective TKA for the treatment of end-stage knee osteoarthritis
- Able to independently provide informed consent
- Willing to attend all rehabilitation sessions and assessment time points, irrespective of the mode of delivery to which they were allocated

Patients were excluded from the study if they:

- Had comorbidities preventing participation in rehabilitation (e.g., severe obstructive pulmonary disease, hemiplegia following stroke)
- Undergoing revision TKA
- Intra-operative complications precluding participation in rehabilitation
- Likely difficulties with follow-up (e.g., no fixed address, planned relocation, or inadequate support network)
- Inability to read or speak English
- Unable to attend in-person clinic visits due to travel distance, or unwilling to comply with the rehabilitation protocol

Recruitment, Informed Consent and Randomisation

Patients scheduled for primary elective TKA under the care of participating orthopaedic surgeons were identified and their potential involvement in the study made known. Interested patients were contacted by the study coordinator, who discussed study details and participant requirements. Consenting patients were scheduled for a pre-surgery clinic visit at which written informed consent was obtained and baseline (pre-operative) outcome measures collected prior to randomisation.

Participants were randomised to either the Telerehabilitation or Clinic group using a simple, computer-generated randomisation sequence. Allocation was concealed using opaque sealed envelopes and maintained by an independent researcher not involved in outcome assessment.

The primary outcome assessor remained blinded to group allocation throughout the study, as did personnel undertaking statistical analysis of the data. Participants were instructed not to disclose their group allocation to the assessor or to ask the assessor clinical questions relating to their treatment group; assessors likewise did not seek this information from participants.

Interventions

Regardless of group allocation, all participants were allocated nine supervised rehabilitation sessions over a 6-week post-operative period: twice weekly for the first three weeks, followed by once weekly for a further three weeks. The first session was scheduled approximately one week following surgery (4–7 days post-operatively). Each session lasted approximately 30 minutes and was led by an Accredited Exercise Physiologist (AEP), with sessions focused on patient education (pain and swelling control, safe and progressive ambulation, activities of daily living), review and progression of the Home Exercise Program (HEP), and measurement of knee ROM.

A standardised, progressive HEP was prescribed to all participants irrespective of group allocation, comprising ROM exercises and strengthening exercises for the quadriceps, hamstrings, calves, and gluteals. The HEP was developed based on clinical experience of the treating therapists and research team, together with published rehabilitation protocols[1, 2]. The HEP was delivered and monitored through an

online exercise platform (Physitrack, Physitrack Ltd., London, UK), which provided video-based exercise demonstrations, adherence and pain/difficulty monitoring (via participant-reported VAS and RPE scores after each session), and secure patient–provider messaging. Expected HEP duration was approximately 40 minutes per day, varying with individual progress; exercise frequency and intensity were progressively adjusted by the treating AEP according to individual pain tolerance, ROM progression, and clinical judgement.

Participants allocated to the Clinic group attended their nine supervised rehabilitation sessions in person at a single private rehabilitation clinic. Knee ROM was measured during these sessions using a standard hand-held goniometer.

Participants allocated to the Telerehabilitation group received a familiarisation session with the telehealth platform (Coviu, Sydney, Australia) and subsequently received all nine supervised sessions remotely via videoconference.

At the 7-week assessment, participants judged by the blinded assessor to require further rehabilitation, based on collected outcome measures, were booked for an additional in-person rehabilitation session.

Outcome Measures

The primary outcome measure was Quality of Life (QOL) subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS)[3] non-inferiority analysis and sample size calculation.

Secondary outcome measures comprised the following:

- Remaining KOOS subscales (Pain, Symptoms, Activities of Daily Living, Sport and Recreation)
- Visual Analogue Scale (VAS) pain (0–10)
- University of California, Los Angeles (UCLA) activity scale
- Active knee flexion and active knee extension range of motion (ROM)
- 40-metre Fast-Paced Walk Test (FPWt)
- 30-Second Sit-to-Stand Test (STS)
- 9-Step Stair Climb Test (SCT)
- Timed Up and Go (TUG) test
- Global Rating of Change (GRoC) scale
- Self-Administered Patient Satisfaction Scale (SAPS) following knee surgery

Outcome measures were collected via in-person assessment pre-operatively (baseline, within two weeks prior to surgery), at 7 weeks post-surgery (primary post-intervention time point, following completion of the 6-week rehabilitation program), and at 12 months post-surgery. Online PROMs only were

administered at 6 months post-surgery. All in-person assessments were conducted by a single therapist, blinded to group allocation, in a standardised order.

Sample Size Calculation

Sample size was calculated to detect non-inferiority of the Telerehabilitation group relative to the Clinic group at the 7-week post-surgery time point, based on the primary outcome measure (KOOS-QOL subscale). The non-inferiority margin was set at 10 points, consistent with the minimal clinically important difference (MCID) reported for the KOOS-QOL subscale in early post-operative TKA populations. Assuming a standard deviation of 12.5 points[4] and using a one-sided alpha of 0.05 and 90% power, the required sample size was estimated at 42 participants per group. Allowing for an anticipated 25% loss to follow-up, while preserving statistical power for the primary analysis, a total target sample size of 108 participants (54 per group) was determined necessary.

Statistical Analysis Plan

Continuous outcome data, including baseline measures, were analysed using linear mixed models to assess between- and within-group differences at each follow-up time point. Models were adjusted for baseline values of each outcome variable, together with age, sex, and body mass index (BMI). Group, time, and group-by-time interaction terms were included as fixed effects for all outcome variables, with a random intercept for participant included in all models.

Adjusted mean differences with 95% confidence intervals were derived from estimated marginal means with pairwise contrasts, used to assess adjusted between-group differences at each time point and to examine significant main and interaction effects. Effect sizes were calculated as standardised mean differences (SMD), derived from model-estimated differences and the pooled baseline standard deviation.

Non-inferiority of the Telerehabilitation group relative to the Clinic group was assessed for the primary outcome (KOOS-QOL) at each time point, using the pre-specified non-inferiority margin of 10 points[5]. Non-inferiority was concluded if the lower bound of the 95% confidence interval for the between-group difference in change from baseline did not exceed the non-inferiority margin in the direction unfavourable to the Telerehabilitation group.

The proportion of participants achieving the MCID (10 points) for the KOOS-QOL subscale was calculated at each follow-up time point and compared between groups using chi-square analysis.

Between-group differences in patient satisfaction outcomes (SAPS and GRoC) were assessed using the Mann–Whitney U test.

Both intention-to-treat and as-treated analyses were performed in accordance with CONSORT guidelines for non-inferiority trials. Analyses were conducted using JASP (JASP Team, version 0.95.4), with statistical significance set at $p<0.05$ (two-sided, unless otherwise specified).

References

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