The Application of Wearable Device Guided Preoperative Exercise Programme for Patients Awaiting Total Knee Arthroplasty

NCT Number: N/A.

Revision dated 27 October 2026

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This study compares the effect of wearable exercise monitoring device on knee osteoarthritis patients undergoing structured home exercise intervention. Outcome assessment includes patient reported outcome measures, training adherence, and functional test performance.

Introduction

The global prevalence of knee osteoarthritis (KOA) requiring total knee arthroplasty (TKA) is projected to rise substantially in the coming decades [1-4]. This trend is also observed in Hong Kong, where more than 4,000 elective total joint replacement surgeries were performed in 2025, while over 30,000 patients remain on the waiting list, with some regions reporting a median waiting time exceeding 73 months [5].

Previous studies have suggested that pre-operative exercise programmes can significantly improve surgical outcomes following TKA, including increased knee range of motion (ROM), improved patient-reported outcome measures (PROMs), and enhanced lower limb function [6, 7]. Implementing structured exercise programmes during the pre-operative waiting period represents a pragmatic strategy to utilise this otherwise idle interval for optimising patient readiness and, consequently, post-operative recovery.

One of the major limitations of supervised exercise programmes is suboptimal adherence. Approximately 50% of participants fail to sustain engagement over the course of a programme [8]. While unsupervised home-based programmes have been proposed to improve the adherence by removing logistical barriers associated with clinic attendance, the effectiveness of such programmes in the absence of professional guidance remains a concern.

Smart wearable devices offer a potential solution by providing real-time, cost-effective guidance during unsupervised exercise, while simultaneously enabling the clinical team to monitor patient training adherence and progress remotely. In the context of the Hong Kong healthcare system, which faces significant resource constraints and prolonged surgical waiting times, wearable technology may serve as a valuable adjunct to pre-operative management. A brief period of supervised instruction, supplemented by an extended unsupervised programme supported by a wearable device, could help maximise the benefit of the lengthy waiting period.

In addition to enabling remote monitoring, wearable platforms can generate continuous objective functional data, which may serve as dataset for patient stratification and prediction of clinical outcomes. Such capabilities may support more efficient allocation of healthcare resources and inform clinical decision-making in this high-demand system.

To date, limited research has investigated the effectiveness of wearable device–assisted home-based exercise programmes for KOA patients. This study therefore seeks to address this evidence gap. To support effective implementation in an elderly pre-operative population, the study will incorporate internal workflow monitoring during the initial recruitment period to ensure consistency in onboarding, device setup, and exercise delivery.

Primary objective

To compare the training adherence of an unsupervised wearable-device guided home-based exercise programme versus an unsupervised home-based exercise programme without the wearable device, when used as an adjunct to the standard medical care, and assess the difference on knee-related quality of life, pain, other symptoms, function in daily living, function in sports and recreation using KOOS questionnaire among KOA patients from baseline to three months.

Secondary objectives

- Compare physical function, knee ROM, muscle strength, other PROMs and quality of life between groups using the secondary outcome measures and assessment schedule specified below.
- Compare between groups patient satisfaction with the programme, and assess in the wearable device group, device usability, clinician acceptability and feasibility of delivery.
- Evaluate the correlation between device-derived mobility metrics and scores with established gold-standard clinical assessments.

Hypothesis

Patients receiving the standard pre-operative exercise programme plus wearable device will have greater exercise adherence and a greater increment in KOOS score from baseline to three months than patients receiving the same exercise programme without wearable support.

Method

This will be a one-year longitudinal randomized controlled trial. Participants will be randomized in a 1:1 allocation ratio to either the intervention group, receiving the wearable device–guided home-based exercise programme in addition to standard care, or the control group, receiving standard care alone. Participants will be blinded of the presence of alternative group, and data collection will be conducted by a research assistant blinded to the participant allocation. Feedbacks from the first 10 intervention group participants will be used to identify wearable device application software workflow, setup, data capture or participant support that can be improved over the intervention period.

Participant recruitment

Potential participants referred to the Structured Nonsurgical Treatment Programme (SNTP) at Prince of Whales Hospital or Alice Ho Miu Ling Nethersole Hospital will be screened for suitability to participate based on the exclusion and inclusion criteria. Eligible individuals will be invited to participate in the study and provided with an informed consent form. They will be informed that anonymized data collected during the study may be used for academic publications. Participants will also be advised that declining to take part will not affect their status, access to other services, or position on any waitlist within the hospital system. No incentives will be offered for participation. This study protocol adheres to the principles of the Declaration of Helsinki.

Participants will be included if they meet all of the following inclusion criteria:

(a) aged 50 years or above;

(b) diagnosed with primary knee osteoarthritis (Kellgren–Lawrence grade II to IV) confirmed by radiographic imaging;

(c) enrolled to the SNTP program

(d) able to ambulate independently with or without a walking aid; and

(e) able to provide informed consent and willing to comply with the study procedures.

Participants will be excluded if any of the following apply:

(a) BMI < 28, not diagnosed for sarcopenia or osteoporosis.

(b) history of major lower limb surgery on the affected side within the preceding 12 months;

(c) presence of pain at knee due to lower limb injuries other than knee OA;

(d) severe cardiopulmonary disease or other medical conditions that preclude participation in an exercise programme;

(e) cognitive impairment that would limit the ability to follow exercise instructions or operate the wearable device;

(f) hip or spine problem affecting outcome measures.

(g) inability to operate a smartphone or the wearable device after training.

Sample size

The sample size was calculated based on the primary outcome, the Knee Injury and Osteoarthritis Outcome Score (KOOS). KOOS have five subscales, each scoring 0–100 on Likert scale. The mean score of KOOS Pain, Symptoms, Activities of Daily Living (ADL) and Quality of Life (QOL) is considered as the primary outcome, with Minimal Clinically Important Difference score of 10 considered [9]. Assuming a pooled standard deviation of 14 points, similar to prior RCTs of pre-operative exercise in TKA patients receiving non [9], and using a two-sided significance level of 0.05 with 90% statistical power [10], approximately 42 participants per group are required. To account for an anticipated dropout rate of 20%, a total of 106 participants (53 per group) will be recruited.

The first 10 recruited patients will participate in the internal usability testing but will remain part of the full RCT sample and will be included in the final analysis, unless excluded according to pre-specified withdrawal or exclusion criteria.

Study design

All participants from both groups will receive the SNTP training, includes weekly sessions of group exercise targeting the lower limb along with twice per week home based exercise prescription for the first six weeks of the program [11]. After 6 weeks, they will be required to conduct three times per week home based exercise prescription.

Intervention

Participants will receive the wearable device (KIMIA Recover, Kinexcs Pte Ltd, Singapore) at their first group training session, with further device familiarizations during follow up group training sessions They will then use the wearable on the affected lower limb for the supported parts of their home exercise programme. Device familiarization sessions will include training on the use of the wearable device and the accompanying smartphone application for approximately 30 minutes. A user manual and technical support contact will also be provided. Weekly review and training reminder will be sent via smartphone application.

Video instructions will be provided on all the training prescription, with a subset of the program having their movement kinematics recorded by the wearable device. Exercise data will include the knee movement, repetition and duration measures. Device model, software version, captured exercises and selected feedback functions will be documented before enrolment. Study data will be available to the research team.

Control

Control participants will follow the same SNTP exercise programme and follow-up schedule without additional supervision for following the initial six weeks period in accordance to the current SNTP practice [11].

Outcome measures

Primary outcome

The primary outcomes are exercise adherence based on the Exercise Adherence Scale (EXAS) [12], while improvement in pain, other symptoms, ADL, QOL, sports and recreation function would be measured using KOOS [13].

Secondary outcome

1. Adherence to the exercise program measured by device app activity log.

2. Knee Society Score (KSS), 5-level EQ-5D-5L quality of life questionnaire, Cybex-measured knee muscle strength, 30s sit-to-stand, active knee ROM and Timed-up and Go.

3. Usability questionnaires including device usability, patient's satisfaction and clinician's acceptability using System Usability Score (SUS), Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM) questionnaires [14, 15].

Measurement timeline

All outcome measures excluding usability questionnaires will be measured at baseline prior to intervention, six weeks, three months, six months and twelve months from the start of the intervention. The usability questionnaires will be given to the clinicians providing the training and the first ten intervention participants every week for the first six weeks of the training.

Statistical analysis

Descriptive statistics will be used to summaries baseline characteristics. Continuous variables will be presented as means and standard deviations, and categorical variables will be presented as frequencies and percentages. Between-group comparability at baseline will be assessed.

The primary analysis will compare the change in outcome measurement from baseline to third month between the two groups. Saphiro-Wilks test would first be done to test the normality of the data distribution. Independent-samples t-test would be used for parametric data while Mann–Whitney U test used for non-parametric data. Assuming parametric data distribution, a linear mixed-effects model with repeated measures will be used to examine between-group differences across all time points. Effect sizes (Cohen's d) will be reported. The significance level will be set at $p < 0.05$ (two-tailed). Multiple imputation or last observation carried forward will be used to handle missing data, with sensitivity analyses to assess the robustness of the findings. Secondary outcomes will be analysed using analogous methods. Subgroup analyses may be performed to explore whether the effect of the intervention varies by age, sex, or baseline disease severity. All statistical analyses will be performed using SPSS version 30.

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