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Protocol

Home-based prehabilitation before total knee arthroplasty: a randomized controlled trial protocol on feasibility and functional outcomes

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ABSTRACT

Background: Total knee arthroplasty is a common surgical intervention for patients with end-stage knee osteoarthritis. Prehabilitation programs have been shown to improve postoperative outcomes, however, access to in-person rehabilitation remains a barrier for many patients. Home-based exercise programs may offer a viable alternative to improve preoperative physical function and optimize recovery.
Methods: This study describes the protocol for a randomized controlled trial evaluating the feasibility and effects of a home-based prehabilitation intervention on physical function recovery for patients awaiting total knee arthroplasty. This is a prospective, two-arm, parallel-group, superiority randomized controlled trial, conducted at a national referral hospital. Patients scheduled for primary total knee arthroplasty will be randomized into either an experimental group receiving a structured home-based exercise program or a control group receiving standard hospital instructions. The intervention will be remotely monitored through digital communication tools. Feasibility outcomes include adherence rates and the occurrence of adverse events, while the study also assesses functional performance measures [Timed up and go test (TUG), sit-to-stand test], self-reported pain and function (WOMAC), postural balance, and knee extensor torque. Statistical analyses will be performed using a linear mixed-effects model (LMM) to assess intervention effects over time.
Conclusions: This trial will provide essential data on the implementation of home-based prehabilitation and its potential to improve access to rehabilitation for patients with limited healthcare resources. If feasible, this approach could be integrated into standard preoperative care, reducing barriers to rehabilitation and enhancing post-surgical recovery.
Trial registration: Approval from the local ethics committee (7.098.085) and was registered at clinicaltrials.gov (RBR-3m77djm).

Keywords: Exercise therapy, Knee function, Knee osteoarthritis, Tele-rehabilitation

INTRODUCTION

Projected to become one of the most prevalent diseases in developed countries over the coming decades, osteoarthritis is characterized as a progressive and degenerative condition that primarily affects load-bearing joints such as the knee and hip.[1,2] Treatment options include pharmacological therapy and physical exercise. However, in cases where conservative treatment fails to alleviate pain or functional impairment inherent to the disease, arthroplasty is recommended as the appropriate intervention.[3]

Due to the increasing prevalence of knee osteoarthritis, the arthroplasty of this joint has become one of the most performed orthopedic surgeries in recent years.[4,5] Although this procedure is an effective method for treating advanced-stage osteoarthritis, significantly reducing pain and improving functionality and quality of life, prolonged waiting times for surgery can further deteriorate patients' conditions, ultimately compromising postoperative recovery.[6] To address these challenges, preoperative exercise-based interventions have been implemented to enhance physical condition and optimize postoperative rehabilitation.[6] Indeed, a recent systematic review conducted by Gränicher et al found that prehabilitation can lead to significant improvements in functionality both prior to surgery and during the initial three months after total knee arthroplasty.[6] However, the authors highlight that the long-term benefits remain unclear.

Although the effectiveness of preoperative training is well established, barriers such as the lack of professional supervision, limited access to rehabilitation centers, transportation difficulties, and financial constraints may hinder patient adherence to preoperative exercise programs.[7,8] These challenges may be particularly relevant for patients treated at institutions which provide services through the public healthcare system. In this context, an unsupervised or home-based approach to delivering exercise programs could be a useful strategy. For example, a randomized trial found that a self-guided, web-based exercise program with behavior-change text messages improved knee pain and function in patients with osteoarthritis at 24 weeks, offering a scalable, low-cost solution.[9] For those undergoing total knee arthroplasty, evidence suggests that mixed rehabilitation strategies, including home exercises, may enhance pre-surgical outcomes and reduce hospital stays, though their postoperative impact remains unclear.[10] However, adherence to unsupervised exercise programs is poorly reported-only 40.9% of studies track it, limiting clinical interpretation.[11]

To address the low adherence rates of unsupervised exercise programs and the challenges of in-person rehabilitation, this study aims to evaluate the feasibility of a remotely semi-supervised home-based exercise protocol for patients awaiting total knee arthroplasty. Additionally, it will examine the program's effectiveness in improving physical function both before and after surgery. Study outcomes will be categorized into adherence and physical-functional measures. Adherence will be assessed based on the percentage of completed exercise sets relative to the prescribed regimen, as well as the occurrence of adverse events. Physical-functional outcomes will include self-reported pain and functionality as well as objective physical performance tests. Investigating these aspects is crucial, as assessing the feasibility and effectiveness of a home-based exercise training program may contribute to expanding preoperative interventions that enhance functional performance prior to surgery and facilitate postoperative recovery, ultimately improving patient satisfaction and quality of life.

METHODS

Ethical approval and protocol registration

All experimental procedures were designed in accordance with the ethical principles outlined in the declaration of Helsinki. The study protocol received formal approval from the local ethics committee (approval number: 7.098.085; approval date: September 24, 2024) and was prospectively registered with the Brazilian clinical trials registry (Registro Brasileiro de Ensaios Clínicos, ReBEC; RBR-3m77djm; approval date: February 28, 2025).

Study design

This prospective, superiority randomized controlled trial will be conducted at a single research center. The study employs a two-arm parallel-group interventional design and adheres to the SPIRIT guidelines.[12] Participants will be approached in person at five different time points. Visit 1: During the multidisciplinary consultation, patients who meet the study's inclusion criteria will be randomly allocated to either the experimental group or the control group. After signing the informed consent form, patients from both groups will complete the mini-mental state examination (MMSE) and the pain and knee functionality questionnaire (WOMAC). Following this, body mass, height, and waist circumference will be measured. The physical function assessments will include the timed up and go (TUG) test, 30-sit-to-stand test, postural balance, and peak knee extensor torque, conducted in this order. The experimental group will be instructed on the exercise program described below, while the control group will receive only the standard instructions provided by the hospital, with no additional intervention. Visit 2: One day before surgery, patients from both groups must visit the neuromuscular research laboratory at INTO for preoperative assessments, repeating the same evaluations from visit 1, except for the MMSE. Remaining visits: Visits three, four, and five will take place respectively three, six, and 12 months after primary total knee arthroplasty, during which the same tests conducted on the second visit will be repeated. To schedule these visits, participants will be contacted two weeks before each visit and again the day before to confirm attendance.

Recruitment

The recruitment manager will approach potential participants during the multidisciplinary consultation, a standard hospital procedure. Candidates who meet the eligibility criteria will be invited to participate in the study and will receive comprehensive information regarding the study protocol and objectives. Those who agree to participate will provide informed consent before

undergoing any procedures outlined in the study protocol. Following recruitment, participants will be randomly assigned to either the intervention or control group.

Randomization and allocation

Participants will be randomly assigned to one of two parallel groups: the experimental group (home-based exercise intervention) or the control group (standard hospital instructions with no additional intervention). Randomization will take place during the multidisciplinary consultation, after verifying eligibility criteria and obtaining informed consent. An independent researcher will conduct the allocation procedure using randomization software to ensure an equitable distribution of participants between groups. The method employed will be block randomization with a 1:1 allocation ratio.

Eligibility criteria

Participants will be eligible for inclusion if they are between 50 and 75 years old, are scheduled for primary total knee arthroplasty due to severe osteoarthritis and have not undergone a rehabilitative program within the past six months aimed at functional knee recovery. Additionally, they must have at least one cohabiting person without known cognitive or severe motor impairments, be familiar with WhatsApp usage, have internet access, and provide signed informed consent.

Exclusion criteria include experiencing unexpected adverse events that compromise the safety or continuity of the home-based exercise program, failure to attend scheduled telerehabilitation sessions or respond to communication attempts via WhatsApp, and failure to meet the minimum required score on the MMSE adjusted for educational level. Participants whose surgical procedure is canceled or rescheduled will also be excluded.

Standard prehabilitation

Patients in the control group will receive a booklet (supplementary material 1) with the standard instructions provided by the hospital.

Prehabilitation program

The training protocol described in Table 1 (supplementary material 2-demonstrative videos) was designed to enable patients to perform the exercises without the need for equipment, lasting eight weeks. The protocol is divided into three blocks: 1) warm-up; 2) balance exercises; and 3) muscle-strengthening exercises. The training protocol should be carried out for eight weeks, three times a week and with a 48-hour interval between sessions, totaling a maximum of 24 sessions.

Patients in the experimental group will undergo theoretical and practical training on the correct execution of the exercises at visit 1 and will receive instructional materials with demonstration videos to ensure proper execution of all exercises. Additionally, patients will be monitored weekly via WhatsApp through video calls (once per week), allowing real-time feedback on exercise techniques, and messages. WhatsApp was chosen for its accessibility (free of charge) and ease of communication, allowing the sending of messages, images, audio files, and making video calls.

Once a subject is officially enrolled in this trial, the research team will make every effort to minimize sample loss and maximize adherence. The primary strategy to ensure adherence will be the weekly live video call, which will also serve as a valuable tool for optimizing exercise technique. Additionally, on each training day, a reminder message will be sent via WhatsApp in the early morning to encourage patients to complete their exercises.

Table 1: Prehabilitation exercises.

Exercise	Sets	Repetitions	Rest
Knee extensions while sitting	3	10 movements on each leg	-
March on site	3	30 movements	30s
Single-leg support	3	15s on each side	30s
Tandem walk	3	10 steps in each direction	30s
Sit and stand	3	10	60s
Calf raises	3	10	60s

Measurements

Training adherence

To assess training adherence, patients will receive and be instructed to complete a training log (supplementary material 3) to record the exercises performed. At the end of the training period, patients will return their respective logs for adherence rate calculation. The adherence rate will be determined as the percentage of the total number of completed sets relative to the total number of prescribed sets. Additionally, the occurrence of adverse events will be documented, as these factors may influence adherence levels.

Cognitive function

The MMSE is a widely used neuropsychological test designed to assess cognitive function and detect deficits in areas such as orientation, memory, attention, calculation, language, and the ability to follow simple commands. The questionnaire consists of 30 items, with a maximum score of 30 points. Administration is brief, lasting approximately 10 to 15 minutes. Interpretation of

results accounts for the patient's educational level, as this factor may influence scoring. The suggested minimum scores for determining cognitive impairment are adjusted on the Portuguese version, with cutoff scores of ≤20 for illiterate individuals, ≤25 for primary school level, ≤26.5 for junior high school, ≤28 for high school, and ≤29 for higher education.[13]

Auto related knee function

The WOMAC is a validated patient-reported outcome measure designed to assess individuals with knee or hip osteoarthritis, including those who have undergone total knee arthroplasty.[14] It comprises three subscales: pain (five items), stiffness (two items), and physical function (17 items). Each item is scored on a 0 to 4 scale, where: 0=no difficulty; 1=mild difficulty; 2=moderate difficulty; 3=severe difficulty; and 4=extreme difficulty. Subscale scores range as follows: pain (0-20 points), stiffness (0-8 points), and physical function (0-68 points). The total score is calculated by summing the individual item scores. For ease of interpretation, the total score may be converted to a 0-100 scale, where 0 represents the best possible condition (no pain or functional limitations) and 100 indicates the worst condition (extreme pain and limitations).

Anthropometric measurements

Total body mass was measured using a Lider® model P150C digital scale (São Paulo, Brazil). Height was measured using a Ghrum Polar Manufacture Instruments® anthropometer (Geneva, Switzerland). Waist circumference was measured using a Sanny® anthropometric tape measure (São Paulo, Brazil).

Timed up and go

This test involves walking six meters as quickly as possible, starting from a seated position in a chair. The test is conducted on a flat, obstacle-free linear course in a private, covered space. The participant walks 3 meters, circles a cone, and returns to the starting position. The time required to complete the task is recorded.[15] The TUG will comprise test and retest, and the duration of the shortest task will be recorded.

Sit-to-stand

This test requires participants to sit and rise from an armless chair without assistance as many times as possible within 30 seconds. The number of successful repetitions is recorded as the test outcome. A chair with a seat height of approximately 43.2 cm and no armrests is used, positioned against a wall to prevent movement. The test begins with the participant seated in the middle of the chair, back straight, feet shoulder-width apart, and arms crossed over the chest. Participants are encouraged to complete as many repetitions as possible within the time limit. They are instructed to sit down fully between each repetition. Incorrectly performed repetitions-defined as incomplete movements or the use of hands for assistance-are not counted and are penalized.[15] As recommended by the osteoarthritis research society internation, the TUG and sit-to-and tests were used to assess physical function in participants with knee osteoarthritis.[15]

Postural balance

A smartphone will be positioned on the lower back and secured using an elastic belt.[16] Two tasks will be performed in a random order to assess static balance: semi-tandem with (1) eyes open and (2) eyes closed. The dominant leg (control group) or the affected leg (knee osteoarthritis group) will be positioned behind, with the hallux placed next to the contralateral heel.[17] For the task performed with eyes open, participants will be instructed to fix their gaze on a target at eye level, positioned two meters away. During all tasks, hands will be placed on the waist. Each task will be performed twice, with each trial lasting 30 seconds. If a participant is unable to maintain the position, an additional attempt will be made. A one-minute rest period will be provided between tasks. The reliability and sensitivity of this protocol have been previously established by our research group.[18]

Knee extensor torque

For strength measurements, an isokinetic dynamometer (HUMAC NORM II®, CSMi, USA) will be used. Participants will be seated in the equipment chair, with the knee joint axis aligned with the dynamometer axis. The hip will be maintained at 90°, while the knee will be fixed at 60°.[19] The right and left sides will be assessed in a random order. As a warm-up and familiarization procedure, participants will be asked to perform three submaximal contractions, each lasting 5 seconds, with a 30-second rest interval between them. Subsequently, maximal contractions will be performed, during which participants will be instructed to execute an isometric knee extension task with maximum force following the evaluator's command. Three repetitions will be performed, with force sustained for 5 seconds.

Statistics

All statistical analyzes will be conducted with the R programming language (version 4.2.0) and statistical significance will be set at $p<0.05$. Baseline demographic characteristics will be compared between the experimental and control groups using independent t-tests for normally distributed continuous variables, Mann-Whitney U tests for non-normally distributed variables, and chi-square or Fisher's exact tests for categorical variables.

To evaluate the effects of the intervention over time, a LMM will be used to analyze changes in primary and secondary outcomes. The model will include fixed effects for time (pre-intervention, pre-surgical, and 3, 6, and 12

months post-surgical), group (experimental vs. control), and the time×group interaction. Random intercepts will be included for participants to account for inter-individual variability, and random slopes will be tested and retained if they improve model fit. The model will be implemented using the package lmerTest with the Kenward-Roger method to approximate the degrees of freedom and estimate the p value.[20] Q-Q plot inspection will be used to assess the assumption of normality of residuals. The *emmeans* package will be used, when necessary, for multiple comparisons and to determine estimated marginal means with 95% confidence intervals.[21]

Effect sizes will be reported using Cohen's d for between-group comparisons. The minimal clinically important difference will be considered for the WOMAC score (≥10 points) and TUG test (≥0.8 seconds) to evaluate the clinical relevance of the findings.

Sample size

For a repeated measures with five time points (pre-intervention, pre-surgical, 3-month post-intervention, 6-month post-intervention, and 12-month post-intervention) and two groups (experimental and control), assuming a medium effect size of 0.25, an alpha error of 5%, and a statistical power of 80%, a sample size of 78 participants was determined (G*Power 3.1.9.2, University of Kiel, Germany). To account for a potential 10% attrition rate (e.g., due to dropout, loss to follow-up, or non-compliance), the final required sample size is 86 participants.

Blinding

This trial will be partially blinded due to the nature of the intervention. Participants will not be blinded, as those in the experimental group will receive explicit instructions on the home-based exercise program, while the control group will receive only institutional recommendations. Researchers responsible for data collection and evaluators will be aware of group allocation. However, statistical analyses will be conducted by an independent researcher who will remain blind to participant allocation, ensuring an impartial evaluation process. Therefore, this study is classified as single-blind, with blinding restricted to the data analyst.

DISCUSSION

This study is designed to assess the adherence of patients undergoing total knee arthroplasty to a semi-supervised, home-based exercise program and to determine whether it can improve physical-functional capacity both after the program and following surgery. Previous research highlights the effectiveness of prehabilitation programs in improving physical function, reducing pain, and enhancing patients' quality of life and postoperative mobility.[6,22] However, adherence to these programs is often hindered by financial costs, logistical barriers, and geographical constraints, as patients must commute to rehabilitation or training centers.[7,8] To address these limitations, home-based programs supervised via telerehabilitation have emerged as a viable alternative, offering greater accessibility than in person approaches.

A recent systematic review reported high adherence rates (~90%) to home-based prehabilitation programs, with significant improvements in pain management, quality of life, and a reduced hospital length of stay before surgery, although their impact on pre- and postoperative functional outcomes remains unclear.[10] Moreover, home-based programs have demonstrated enhancements in lower limb strength, mobility, and overall physical function, key factors in optimizing postoperative recovery.[23] Notably, home-based prehabilitation has demonstrated clinical effectiveness comparable to conventional in-person rehabilitation, yielding similar improvements in functional outcomes following total knee replacement.[24] Collectively, these findings highlight home-based exercise programs as a viable and accessible alternative to traditional rehabilitation.

In our study, telerehabilitation before total knee arthroplasty will be implemented through video calls and messaging for patient monitoring and support. This approach may be effective, as evidence shows that frequent contact-via phone, internet, or home visits-significantly improves adherence to rehabilitation programs among elderly patients.[25,26] A key challenge, however, is ensuring adherence, since the target age group (50 to 75 years) might encounter difficulties with technology and cognitive demands, potentially impacting program effectiveness. Nevertheless, visual interaction through video calls and messaging is expected to enhance participation by fostering motivation, accountability, and social support. While initial technical challenges are expected, these can be mitigated through clear instructions and ongoing support, with patients likely to overcome these barriers as they become more familiar with the process. Additionally, to further address this issue, only patients with at least one cohabiting person-without known cognitive or severe motor impairments and familiar with WhatsApp usage-will be included in the study.

CONCLUSION

This clinical trial protocol describes a structured home-based prehabilitation intervention designed to verify its feasibility and improve physical functional outcomes in patients awaiting total knee arthroplasty.

By assessing feasibility, patient-reported outcomes, and physical function, this study will generate essential data to support the integration of home-based prehabilitation into routine clinical practice, improving accessibility to rehabilitation and potentially enhancing postoperative recovery.

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Ethical approval: The study was approved by the Institutional Ethics Committee approval number 7.098.085. ReBEC; RBR-3m77djm

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