Research Protocol

Official Title: The effectiveness of a patient-navigation-based preoperative rehabilitation exercise program in patients undergoing total knee arthroplasty: a randomised controlled trial

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1. Study design

This study is a prospective, single-centre, superiority randomised controlled trial (RCT) involving two parallel groups. Participants were recruited from among patients newly admitted to the orthopaedic ward who met the selection criteria.

2. Participants

A total of 84 participants were consecutively recruited from among patients newly admitted to the orthopaedic ward who met the selection criteria.

2.1. Participant selection criteria

Inclusion Criteria: (ⅰ) patients diagnosed with knee osteoarthritis who are undergoing primary unilateral total knee arthroplasty; (ⅱ) aged between 45 and 90 years; (ⅲ) assessed by the attending physician as having sufficient physical capacity to tolerate preoperative rehabilitation exercises and adequate communication skills to cooperate with all examinations and assessments; and (ⅳ) informed consent was obtained from the patient, and the signed informed consent form was duly completed.

Exclusion Criteria: (ⅰ) patients who are uncooperative due to impaired consciousness, cognitive dysfunction, or other factors; (ⅱ) presence of severe concurrent comorbidities, including liver cirrhosis, respiratory failure, renal failure, malignancy, or trauma; (ⅲ) a history of significant neuromuscular disorders or other joint diseases, as determined by the attending physician, that impair knee joint function; (ⅳ) a time interval of greater than 7 days or less than 3 days between the admission day date and the scheduled surgery date; and (ⅴ) patients who have undergone systematic lower limb functional training within the past four weeks.

2.2. Sample size

This study used knee osteoarthritis severity as the primary outcome measure. Given the lack of prior research on the effect of patient navigation mode on patients' knee osteoarthritis severity. Therefore, the sample size calculation for the present study was based on the results of the pre-experiment, which showed an effect size of 0.8 on knee osteoarthritis severity. To achieve a statistical power of 0.80 and an alpha level of 0.05, a sample size of 33 participants per group is required. Considering a 20% attrition rate, the total estimated sample size is 84 participants, with 42 participants per group.

3. Randomization and blinding

A non-research team member randomly selected an initial starting point from a pre-generated computerised random number table. From this point, the corresponding random numbers were sequentially identified, ranging from 1 to 84. After sorting the random numbers, participants were randomly assigned in a 1:1 ratio to either Group 1 (the experimental group) or Group 2 (the control group). Group assignments were concealed within 84 consecutively numbered, identical, opaque, and sealed envelopes, which the non-research team member securely kept. On the day of participant enrolment, after completing demographic and clinical data collection, as well as baseline assessments, the principal researcher (recruiter) retrieved the envelope corresponding to the participant’s sequential number from the custodian. The envelope was opened, and the participant was assigned to the designated group.

Due to the nature of the intervention, the experimental group received exercise guidance from navigator, while the control group did not. Consequently, blinding of participants, recruiters, or research intervention staff was not feasible. However, outcome assessors and data entry analysts will be blinded. The outcome assessor is an independent research assistant who remained unaware of the allocation status throughout the study. Before the

study, the principal researcher (recruiter) trained the outcome assessor. The outcome assessor independently assessed outcomes and collected data for both groups from T0 to T4. Moreover, the principal researcher (recruiter) instructed all participants not to disclose their group assignment to the outcome assessor. Furthermore, two research assistants, who were not involved in the study process, served as data entry analysts. The group assignment was concealed from these analysts by using coded group identifiers (Group 1 and Group 2) to ensure blinding.

4. Intervention

4.1.Control Group

4.1.1. Summary: Received an autonomous preoperative rehabilitation exercise programme.

4.1.2. Method: On the day of admission, a research assistant provided a verbal explanation of the preoperative rehabilitation exercise regimen and distributed a guidance manual. Participants are advised to perform autonomous exercises 2–3 times daily according to the manual from admission day to surgery day (preoperative). They were also advised to promptly inform ward medical staff of any unusual conditions or concerns.

4.1.3. Preoperative rehabilitation exercise regimen

A. Exercises for pulmonary function:

a) Abdominal breathing: 10 sets per time, 2-3 times per day.

b) Effective coughing: Practice repeatedly until mastered.

B. Exercises for quadriceps Strength:

a) Straight leg raise: Alternate legs, 10 sets per time, 2-3 times per day.

b) Lateral leg raise: Alternate legs, 10 sets per time, 2-3 times per day.

C. Exercises for the knee range of motion:

a) Knee flexion: Alternate legs, 10 sets per time, 2-3 times per day.

b) Knee extension: Alternate legs, 10 sets per time, 2-3 times per day.

D. Exercises for preventing lower limb thrombosis:

a) Ankle pump exercise: Both feet simultaneously, 10 sets per time, 2-3 times per day.

4.2. Experimental Group

4.2.1. Summary: Received a patient-navigation-based preoperative rehabilitation exercise programme

4.2.2. Method: From admission day to surgery day (preoperative), navigator provided full-period preoperative rehabilitation exercise guidance and navigation services aimed at promoting rehabilitation exercise.

A. The navigator provided full-period preoperative rehabilitation exercise guidance, which displayed as follows: (The preoperative rehabilitation exercise regimen guided by the navigator was the same as that of the control group.)

a) On the day of admission, in addition to explaining the preoperative exercise regimen and distributing a guidance manual as done for the control group, the navigator demonstrated the exercise movements and required participants to perform return demonstrations to ensure mastery of the exercises.

b) During the preoperative period, navigators conducted daily ward visits to provide face-to-face exercise guidance, including two 20-minute supervised sessions per day, and sent exercise reminder text messages every night from 7:00 PM to 8:00 PM.

B. The navigation services aimed at promoting rehabilitation exercise encompassed the following seven themes: On the day of admission, (ⅰ) establish contact with participants or their carers, and (ⅱ) provide disease-related education. During the preoperative exercise period, (ⅲ) assess participant needs and facilitate access to resources; (ⅳ) offer social and emotional support; (ⅴ) provide verbal interpretation services

available upon request; (vi) identify and address barriers to exercise implementation; and (vii) support participants' self-management.

(ⅰ) Establish contact with participants or their carers: On the day of admission, the navigator will add the participant's or their carer's contact details and inform them that they may consult the navigator via these contact details should they have any queries or requirements during the preoperative rehabilitation exercise period.

(ii) Provide disease-related education：

① Knee Osteoarthritis Information: Including the definition of osteoarthritis, the development of knee osteoarthritis, and the grading of knee osteoarthritis.

② Total Knee Arthroplasty Surgery Information: Surgical method and benefits of the surgery.

③ Perioperative care guidance: Including preoperative daily life precautions, management of perioperative pain, respiratory care, postoperative lower limb thrombosis prevention, and preparation of surgical supplies.

(iii) Assess participant needs and facilitate access to resources:

① Needs assessment: Navigators will understand participants' illness conditions, prior treatment histories, and current physical states and will discuss expectations regarding the surgery with participants, which includes pain management, functional recovery, and quality-of-life improvements, alongside anticipated post-operative rehabilitation requirements such as physiotherapy, independence in activities of daily living, and care support.

② Resource linkage: Based on the needs assessment, the navigator

will introduce available hospital resources to participants, such as rehabilitation and pain management teams, the hospital's psychological counseling centre, and continuing care services.

③ Information provision and assistance: The navigator will explain the surgical procedure, post-operative precautions, and expected recovery timeline in detail according to the participant's needs, ensuring they understand each step. Information on hospital companion services will be provided, including details of companions, contact information, service content, and fees. Offer medical insurance reimbursement details, with navigators explaining coverage scope, claim procedures, and consultation channels for different insurance schemes. Additionally,navigators will assist with scheduling appointments for specialised examinations or treatments.

④ Reminder services: Navigators will provide reminders for scheduled preoperative examinations, including advance notification of any special requirements (e.g., fasting, holding urine). Navigators will also offer weather-related reminders and guidance as appropriate.

(ⅳ) Offer social and emotional support：

① Provide encouragement and support: During preoperative rehabilitation exercises, navigators offer positive feedback and encouragement to help participants build confidence and overcome psychological barriers. Sharing video testimonials of successful recovery cases inspires participants' motivation to exercise; using quantifiable metrics (such as scales) to document progress enables participants to perceive the effects of rehabilitation.

② Provide psychological counseling: Should participants exhibit negative emotions such as anxiety or depression, navigators

promptly offer psychological support, providing effective coping strategies and encouraging participants to express their feelings to aid emotional regulation.

③ Encourage family or carer involvement: Encourage family members or carers to actively join in the participant's rehabilitation exercises and active communication with participants, and jointly provide support and reassurance to participants.

(v) Provide verbal interpretation services available upon reques: navigators can provide participants with verbal interpretation services in Cantonese, Mandarin, and Teochew.

(vi) Identify and address barriers to exercise implementation:

① Lack of interest or motivation in exercise: Explain the purpose and benefits of preoperative rehabilitation exercises; actively share success stories of preoperative rehabilitation exercises; provide positive feedback and encouragement.

② Negative emotional impact: Offer timely psychological counseling, encourage participants to express their feelings, and assist in emotional regulation; teach participants relaxation techniques (such as meditation and deep breathing) to alleviate stress; and encourage mutual support and communication among participants.

③ Failure to perceive anticipated outcomes: Utilise quantifiable knee metrics (e.g., knee function scales, pain scales, etc.) to document participant progress; conduct daily exercise progress reviews with participants and adjust preoperative rehabilitation programmes based on feedback.

④ Fear of pain: Inform participants about normal pain thresholds during rehabilitation exercises and provide pain relief strategies; guide participants to perform preoperative rehabilitation exercises at an intensity tolerable to them; Inform participants that a rehabilitation navigator will provide ongoing guidance in the ward.

⑤ Limitations due to comorbidities: Measures as per (vii)② below.

⑥ Insufficient family and carer support: Measures as per (iv)③ above.

⑦ Weather impediments: Provide participants with considerate reminders and rehabilitation exercise guidance based on weather conditions.

(vii) Support participants' self-management:

① Perioperative safety guidance: Inform participants of safety precautions when using walking aids, fall prevention measures, and safety considerations for using medical facilities and equipment.

② Guidance for participants with underlying conditions: Upon admission, navigators conduct detailed assessments of participants' underlying conditions, collaborating with the medical team to develop personalised management plans. Participants receive instruction on monitoring relevant indicators and operating associated devices, adhering to medication schedules as prescribed, managing daily lifestyle factors (diet, exercise, weight control), and recognising and handling emergencies or abnormal symptoms.

③ Postoperative self-management guidance for TKA:

- Wound care: Explain dressing change schedules, precautions during dressing changes, and wound dressing observation.
- Complication prevention: Instruct on preventing postoperative wound infections, deep vein thrombosis, and constipation.
- Postoperative life precautions: Inform on prohibited movements, allowed actions, and mobility techniques.

5. Data collection

Data collection will be conducted at five time points: on admission day (baseline, T0), surgery day (preoperative) (T1), one week post-surgery (T2),

two weeks post-surgery (T3), and four weeks post-surgery (T4). The collected study data will include demographic and clinical information collected by the principal investigator (recruiter), as well as outcome measures collected by assessors from T0 through T4. These outcome indicators encompass knee osteoarthritis severity, exercise adherence, self-efficacy, knee joint function, knee range of motion, and pain intensity.

6. Outcome assessment

6.1. Primary outcome

The primary outcome is the change in knee osteoarthritis severity from admission day (baseline, T0) to surgery day (preoperative) (T1). As the intervention in this study aims to enhance patient adherence to preoperative rehabilitation exercises, the ultimate objective is to improve their rehabilitation outcomes. Therefore, the change in knee osteoarthritis severity from T0 to T1 in both groups of participants will be used to evaluate the effectiveness of the intervention.

Knee osteoarthritis severity will be measured using the Chinese version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Scale, which is a self-administered instrument specifically developed to assess the severity of knee osteoarthritis and the efficacy of related treatments (Bellamy et al., 1988). The scale consists of 24 items divided into three subscales: pain (5 items), stiffness (2 items), and physical function (17 items). Several scoring methods have been developed for the Western Ontario and McMaster Universities Osteoarthritis Index Scale items (Noyes, 2016). In this study, a 5-point Likert scale is employed, where 0 represents “no difficulty” and 4 represents “extreme difficulty”. The total score ranges from 0 to 96, with higher scores reflecting more severe knee osteoarthritis.

6.2. Secondary outcomes

The secondary outcomes are changes from baseline in exercise adherence, self-efficacy, knee joint function, knee range of motion, and pain intensity at T1, T2, T3, and T4, as well as changes from baseline in knee osteoarthritis severity at T2, T3, and T4.

Exercise adherence will be measured using the Orthopaedic Patient Functional Exercise Compliance Scale developed by Chinese scholars (Tan et al., 2019). This instrument effectively assesses rehabilitation adherence among orthopaedic patients. It consists of 15 items covering three dimensions—physical exercise adherence, psychological exercise adherence, and active learning exercise adherence—with patients rating their ability to perform each activity. Each item is rated on a five-point Likert scale ranging from 1 (“Not at all possible”) to 5 (“Completely possible”). Total scores range from 15 to 75, with higher scores reflecting greater adherence to rehabilitation exercises.

Self-efficacy will be measured using the Chinese version of the Self-Efficacy for Rehabilitation Scale (SER) (Wang et al., 2014). This scale has demonstrated strong reliability and validity in assessing rehabilitation self-efficacy among patients undergoing knee replacement. The Chinese version of the Self-Efficacy for Rehabilitation Scale includes two dimensions—Rehabilitation Self-Efficacy (five items) and Coping Self-Efficacy (seven items)—for a total of 12 items. Each item is rated on an 11-point Likert scale ranging from 0 (“Not at all”) to 10 (“No difficulty whatsoever”), yielding a maximum total score of 120. Higher scores denote greater rehabilitation self-efficacy.

Knee joint function will be measured using the Hospital for Special Surgery (HSS) Knee Scoring System (Weitzel et al., 2002). This 100-point scoring system includes pain (30 points), function (22 points), range of motion (18 points, one point per eight degrees), muscle strength (10 points), flexion

deformity (10 points), and stability (10 points). Points are deducted if patients use walking aids or present with flexion contracture or varus/valgus deformities. Total scores range from 0 to 100, with higher values reflecting superior knee joint function.

Knee range of motion (ROM) will be measured with a goniometer. ROM measurement assesses knee movement amplitude, serving as a critical indicator of knee joint function and a key indicator for evaluating rehabilitation outcomes following total knee arthroplasty. Normal knee range of motion values are as follows: flexion, 0°–135°; extension, 0° (some individuals may exhibit hyperextension of 0°–10°); active range, 0°–135°; and passive range, up to 150°.

Pain intensity will be measured using the Visual Analogue Scale (VAS). The VAS consists of a 10-centimetre horizontal line divided into 10 equal intervals, where higher scores represent greater pain intensity. A score of 0 denotes no pain, whereas a score of 10 denotes the most severe pain imaginable. Patients are instructed to mark the point on the line corresponding to their perceived pain intensity.

7. Statistical analysis

IBM® SPSS Statistics 27.0 will be used to analyse the data from all randomised participants. Statistical significance was set at $p \leq 0.05$. Categorical variables (e.g., gender, marital status, payment type) appeared as frequencies and percentages. Continuous variables (e.g., age, height, weight) appeared as mean ± standard deviation (SD). Continuous data meeting the assumptions of normality and homogeneity of variance were analysed using independent-sample t-tests; otherwise, the Wilcoxon signed-rank test appeared. Categorical data were analysed using the chi-square test or Fisher's exact test for intergroup comparisons. Generalised Estimating

Equations (GEE) were employed to compare longitudinal changes in outcome variables between groups, with statistical significance set at $p < 0.05$ (two-tailed). The GEE was chosen as it accounts for within-subject correlations inherent in repeated measures, thereby improving the efficiency of parameter estimation in longitudinal analyses. Moreover, the GEE approach flexibly accommodates missing data. When the proportion of missing data was below 5%, the GEE inherently accommodated the missing values; otherwise, multiple imputation procedures were applied.

8. Trial monitoring

The Clinical Research Management Department and the Ethics Committee of the study-conducting hospital will oversee trial implementation and ensure compliance with ethical standards. The principal researcher is required to submit regular progress reports and interim results to the Clinical Research Management Department and the Ethics Committee of the study-conducting hospital. They will review the completeness, accuracy, and timeliness of data collection, as well as procedures related to participant enrolment, informed consent, eligibility assessment, and protocol adherence. Based on the findings of interim reports and a comprehensive evaluation of the study's efficacy, safety, and feasibility, they will make the final determination regarding whether the trial should be terminated.

9. Ethical

9.1. Research ethical approval and informed consent

This study adheres to the ethical principles outlined in the Declaration of Helsinki and has received approval from the Ethics Committee of the research implementation hospital (No. KY-2025-105). All participants will receive written information detailing the study objectives, procedures, potential risks, and benefits. Participation in the study is entirely voluntary, and participants may

withdraw at any time without providing a reason or facing any consequences. Each participant must sign a written informed consent form before enrolment. Participants will withdraw from the study under the following circumstances: withdrawal of consent, loss to follow-up, receipt of unapproved rehabilitation or treatment during the study period, or a clinician’s determination that the participant is unsuitable to continue, such as in cases of serious adverse events or serious complications.

9.2. Confidentiality

The results of this study may be published in medical journals. However, all members of the research team will maintain participants' confidentiality in accordance with legal requirements. Personal information will not be disclosed unless required by pertinent legal or regulatory mandates. All case report forms were securely stored in a locked cabinet located in the principal researcher’s office, and the principal researcher retained sole custody of the key. Participant identities were anonymised using a sequential number to protect confidentiality. The trial data collected will only be accessible to authorised members of the research team during the study.