The Informed Consent Form

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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The Informed Consent Form for the Research Project: The effectiveness of a patient-navigation-based preoperative rehabilitation exercise programme in patients undergoing total knee arthroplasty: A randomised controlled trial

Informed Page

Research Institution: The First Affiliated Hospital of Jinan University

Department: Orthopaedic and Sports Medicine Department

Dear Participant:

We cordially invite you to participate in the research titled 'The effectiveness of a patient-navigation-based preoperative rehabilitation exercise programme in patients undergoing total knee arthroplasty: a randomised controlled trial', which was approved by the First Affiliated Hospital of Jinan University. This research is expected to be conducted at the First Affiliated Hospital of Jinan University, with an anticipated enrolment of 84 volunteers. This research has been reviewed and approved by the Ethics Review Committee for Human Participant Research at the First Affiliated Hospital of Jinan University. Your participation in this research is entirely voluntary, and you may choose not to take part. Should you decide not to participate, this will not affect your relationship with your doctor. To help you decide whether to participate, it is essential to understand the details of this research. Please read the following information carefully and feel free to discuss it with your family, friends, or doctor. Should you have any questions or require further clarification regarding this research, do not hesitate to ask your doctor.

1. Research background and objectives

Preoperative rehabilitation exercises refer to a series of targeted exercises

performed before surgery. Their purpose is to enhance muscle strength around the affected limb's joints and improve joint range of motion. This builds better physical reserves to cope with the stress of surgery, thereby promoting faster postoperative recovery. Due to the unique domestic healthcare environment, specialised rehabilitation institutions are unavailable to implement these preoperative exercise programmes. Patients undergoing preoperative rehabilitation exercises within orthopaedic wards often exhibit poor exercise adherence. This stems from an insufficient understanding of rehabilitation exercises and various practical obstacles encountered during the exercise process. In light of the above background, this research adds the role of a navigator to provide patients with comprehensive and personalised rehabilitation exercise guidance prior to surgery, alongside disease knowledge education and links to hospital resources and information tailored to individual needs. The aim is to facilitate better adherence to preoperative rehabilitation exercises among participants, thereby potentially improving participants' rehabilitation outcomes.

2. Who will be invited to participate in the research?

They all conform to (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. And without (ⅰ) patients who are uncooperative due to impaired consciousness, cognitive dysfunction, or other factors; (ⅱ) patients with the presence of severe concurrent comorbidities, including liver cirrhosis, respiratory failure, renal failure, malignancy, or trauma; (ⅲ) patients with a history of significant neuromuscular disorders or other joint diseases, as determined by the

attending physician, that impair knee joint function; (ⅳ) patients with a time interval of greater than 7 days or less than 3 days between the admission day date and the scheduled surgery date; (ⅴ) patients who have undergone systematic lower limb functional training within the past four weeks. Individuals who do not meet the above criteria or who are unwilling to participate in this research will not be included in the research. Participants will withdraw from the research under the following circumstances: withdrawal of consent, loss to follow-up, receipt of unapproved rehabilitation or treatment during the research period, or a clinician's determination that the participant is unsuitable to continue, such as in cases of serious adverse events or serious complications.

3. Research process and methods

3.1. Randomisation Method

Participants who meet the selection criteria and sign an informed consent form will be assigned a sequential number by the recruiter, based on the order of their enrollment. Each participant will receive a sealed, opaque envelope bearing their assigned sequential number. The envelopes contain pre-assigned group numbers. These group numbers were generated by a non-research team member randomly selecting an initial starting point from a pre-generated computerised random number table, and from this point, the corresponding random numbers were sequentially identified, ranging from 1 to 84, and then after sorting the random numbers, which were randomly assigned in a 1:1 ratio to either group 1 (the experimental group) or group 2 (the control group). All envelopes were kept in the custody of this non-team member. Recruiters will assist participants in opening the envelope and assigning them to groups according to the group numbers contained within. Since research team members are unaware of the allocation details in advance and cannot predict the order of participant enrolment, each participant has an equal

chance of being assigned to either the control group or the experimental group.

3.2. Intervention methods for different groups

(1) Control group: 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 self-directed 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.

(2) Experimental group: 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, as well as establishing contact with participants or their carer and providing disease-related education. 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. As well, the navigator will assess participant needs and facilitate access to resources, offer social and emotional support, provide translation services when necessary, identify and address barriers to exercise implementation, and support participants' self-management.

4. Tasks requiring participant cooperation

During the research, participants must complete the prescribed rehabilitation exercises within the specified timeframe and prioritise self-safety during exercise sessions. Researchers will collect data at five specific time points: admission day, surgery day (preoperative), one week post-surgery, two weeks

post-surgery, and four weeks post-surgery, which will be collected through questionnaires, interviews, or observations, with each collection lasting no longer than 20 minutes. During this period, participants need to cooperate with researchers in data collection. Additionally, participants were not allowed to disclose their situation of grouping to anyone during the research.

5. Potential benefits

This research may prompt participants to better adhere to preoperative rehabilitation exercises, thereby potentially facilitating earlier restoration of lower limb function following surgery.

6. Potential risks and discomfort

The preoperative rehabilitation exercises and patient navigation model employed in this research are both non-invasive, non-pharmacological intervention methods. Based on the nature of these interventions, the overall risk profile of this research is low. Furthermore, the preoperative rehabilitation exercise regimen has undergone systematic evaluation by a specialised orthopaedic rehabilitation team. During the revision process, exercises posing a fall risk were excluded, and rehabilitation therapists provided standardised movement guidance. These established a multi-layered safeguard mechanism to ensure the safety of participants during exercise.

7. Treatment and compensation for injuries resulting from research

The overall risk profile of this research is low. If any harm occurs to participants during the research period as a result of the intervention, they will receive active treatment at first and receive compensation or indemnification in accordance with relevant domestic laws and regulations.

8. Alternative treatment options available to participants

If participants do not wish to participate in this research, they can decline participation outright or withdraw at any stage of the trial. Withdrawal will not affect any subsequent treatment or care provided to participants.

9. Research-related expenses

Participants will not be required to pay any fees for this research and will receive complimentary rehabilitation exercise guidance or navigation services provided by this research. But participants will not obtain any financial compensation or insurance coverage.

10. Privacy and confidentiality

The results of this research may be published in medical journals. However, all members of the research team will maintain patient confidentiality in accordance with legal requirements. Personal information will not be disclosed unless mandated by relevant laws. All paper-based case report forms will be stored in a locked cabinet designated for this purpose in the principal researcher's office. Participant identities were anonymised using a sequential number to protect confidentiality. Data collected for this research will be accessible only to authorised members of the research team.

11. Contact information

If you have any concerns or questions about the research, or any emergency, please contact your doctor promptly. Please keep this information.

Physician's name (Printed):_____

Contact phone (Landline):_____

Contact phone (Mobile):_____

If you have any questions regarding your rights, you may contact the Institutional Ethics Review Committee during regular business hours on national statutory workdays at: 020-38688217

12. Additional information

Your participation in this research is voluntary. You may decline to participate or withdraw at any stage of the trial without facing discrimination or retaliation, and your medical care and rights will not be affected. Should any significant new information arise during the research that may influence your willingness to continue participating, your doctor will promptly notify you.

Consent Signature Page

Participant declaration:

I have read the above information and understand the nature, purpose, risks, and benefits of this research. I have had the opportunity to discuss this research with the physician and ask questions. All the questions I raised have been satisfactorily answered.

I will comply with the requirements outlined in the participant information sheet and fully cooperate with the research team. I will truthfully and objectively provide the research team with information regarding my health status and relevant circumstances before participating in this research, during the research, and at each follow-up visit.

I understand that participation in this research is voluntary. I confirm that I have had sufficient time to consider this decision and understand that I may withdraw from the research at any time without any adverse effect on my future treatment. I understand that the physician has the right to terminate my participation in the research at any time based on my condition.

I hereby express my consent to participate in this clinical research. This informed consent form is in duplicate. I will receive one copy of the signed and dated informed consent form.

Participant signature: _____

Contact number: _____

Date:_____year_____month_____day_____hour _____minute.

(If applicable) Legal representative/guardian signature: _____
Relationship to participant: _____

Contact number: _____

Note: For participants unable to express consent, the above introduction and explanation shall be provided to their legal representative/guardian.

(If applicable) Impartial witness signature:_____

Phone number: _____

Date:_____year_____month_____day_____hour _____minute.

Note: When the participant or their guardian is unable to read, the impartial witness shall read the informed consent form and other written materials aloud and witness the informed consent.

Researcher's Statement:

I have explained the relevant details of this research to the above-mentioned participant and obtained a signed informed consent form.

Researcher's signature: _____

Contact number: _____

Date:_____year_____month_____day_____hour _____minute.