Questionnaire research Informed Consent

Protocol Number		**IRB Number**	ECKIRB1100504	**NCT Number**	NCT05030662
Protocol Title	The effect of “Walking stick exercise ” following total knee arthroplasty on lower limb strength, knee range of motion, and quality of life of patients				
Study Period	2 year 0 month				
Sponsor/Pharmaceutical Company for this study	No	**Study Institution**		En Chu Kong hospital	
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1 Background

The prevalence of knee osteoarthritis (OA) is 15~20% in people 60 years old or older in Taiwan, according to 2019 Taiwan health and welfare report. According to the data from Taiwan's Health Insurance Bureau, about 20,000 people undergo total knee replacement (TKR) every year between 2009 and 2011. Previous studies found that rehabilitation program following TKR could reduce postoperative pain and increased muscle power and the range of motion of the knee extension. “Walking stick exercises” can improve walking ability and knee range of motion.

2 Purpose of this study

The purpose of this study is to examine whether “walking stick exercises” can improve lower limb strength, knee range of motion, and quality of life compared with conventional care 12 weeks after total knee arthroplasty.

3 Materials and Methods

The study will be undertaken in the Department Orthopaedics of a regional teaching hospital. All patients who meet the inclusion criteria are admitted for primary total knee arthroplasty and the informed consent were obtained.

3.1 Inclusion criteria

(1) Patients with symptomatic knee osteoarthritis

(2) Receipt of elective unilateral primary knee arthroplasty surgery

(3) Age between 60 and 85 years

(4) Informed consent

3.2 Exclusion criteria

(1) Non-degenerative arthritis, including rhematoid arthritis, or traumativ arthritis

(2) Patients receiving rehabilitation simultaneously

(3) Patients with other musculoskeletal or neurological problem, including fractures, Parkinsonism, cerebrovascular events, or patients with multiple comorbidity

(4) Cancer patients receive chemotherapy

(5) Patients with peri-operative complication that has adverse effect on outcomes, for example: intra-operative fractures, thromboembolism, peri-operative infections, or phlebitis.

4 Methods and related procedures of this study

The appropriate sample size is calculated by G-power (effect size, f = 0.25, alpha error = 0.05, power = 0.80, number of groups = 3). If the rate of lost to follow up is 7%, a minimum sample size of 44 for each group is necessary.

This is a longitudinal-experimental study. The data collection and analysis are in a single-blind manner. The study will be undertaken in the Department Orthopaedics of a regional teaching hospital. All patients who meet the inclusion criteria are admitted for primary total knee arthroplasty and assigned to control group or intervention group randomly. The 44 patients in the control group received routine guidance of " Rehabilitation and precautions for artificial knee replacement ". In addition to the routine guidance, the 44 patients in the intervention group received two educations of " Walking stick exercise " on the day before surgery and before discharge, as well as a follow-up call at least once a week after discharge. The outcome measurements include 30-second chair stand test, knee range of motion (ROM), and Knee injury and Osteoarthritis Outcome Score (KOOS). The 30-second chair stand test, knee ROM were recorded at baseline (preoperative period after patient admission), 1 weeks and 6 weeks and 12 weeks after operation. The 30-second chair stand test, knee ROM were recorded and KOOS was scored. Descriptive statistics, chi-square test, independent sample ***t***-test, paired-sample ***t*** -test, and generalized estimating equation (GEE) were used for statistical data analysis. Statistical methods use descriptive statistics, chi-square test, independent sample ***t*** -test, paired-sample ***t*** -test, and GEE for data analysis.

5 Possible risks and and countermeasures

The questionnaire itself might be disturbing to the patients during their hospital stay.

6 Anticipated study benefits

Participating in this trial does not guarantee improvement of your disease or bring you any other direct benefits. However, the trial research results may be helpful to the

Sponsor and/or Principal Investigator and may also benefit other patients with the same disease in the future.

7 Contraindications, restrictions and rules that must be abided by during the trial

1.Complete the questionnaire. 2.Perform the rehabilitation program according to the protocol.

8 Confidentiality of subject's personal information

En Chu Kong Hospital will abide by the law to keep the confidentiality of any record containing your identification and your personal private information, and will not disclose it. The research staff will assign you with a research code, and this code will not show any identifiable information such as your name, identification number or address. In the event that trial results are published, your identification will continue to be kept confidential. You also understand that by signing this consent form, you are approving direct use of your original medical records by the monitors, auditors, (the name of the hospital IRB) and the competent authorities, in order to ensure that the clinical trial is conducted and data are collected in accordance with applicable laws and regulations. The aforementioned personnel guarantee the confidentiality of your identity will not be violated. Except the aforementioned authority's inspection as required by law, we will carefully protect your privacy.

9 Compensation and insurance

The hospital will provide professional medical care and consultations for adverse events or damages resulting from following the protocol designed for this clinical trial. You will not be responsible for the necessary medical expenses with respect to the treatment for the adverse events or damages.

Reimbursement for participating in the trial research is NT$150 Convenience Store Gift Voucher.

10 Rights and interests of the subject

10.1 During the trial, if you have any questions about the nature of the trial or any concerns about your rights as a patient, please contact the 周玉華 to request for consultation. The telephone number is 0927-977-137.

10.2 During the trial, if you have any questions about the nature of the trial or any

concerns about your rights as a patient, or suspect that you have suffered injury as a result of participating in this research, please contact the ECK IRB to request for consultation. The telephone number is 02-26723456 ext. 6835. E-mail: eckirb@km.eck.org.tw

10.3 This trial was approved by the ECK IRB. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

10.4 The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

10.5 All clinical trials have risks. Please make your decision after careful consideration.

11 Withdrawal and termination of the trial

11.1 You are free to decide whether to take part in this trial. During the trial, you can withdraw your consent and leave the trial at any time, without giving any reason, and no unpleasantness will be caused, nor will your medical care from your physician be affected.

12 Signature

12.1 The Principal Investigator/Sub-investigator or his/her authorized personnel has explained in detail the nature and objectives of the above research method in this protocol, as well as the possible risks and benefits.

Signature of Principal Investigator/Sub-investigator:_____

Date: _____(Month) _____(Day), _____(Year)

12.2 I fully understand the research method mentioned above and the possible risks and benefits after the explanation, and my questions about the clinical trial have been answered in full detail. I agree to participate in this research voluntarily and will

hold a duplicate of the Informed Consent Form.

Signature of the Subject:_____

Date: _____(Month) _____(Day), _____(Year)

This consent form is in duplicate, with each party holding one copy after being signed.