RANDOMIZED, DOUBLE-BLIND, CONTROL TRIAL STUDY TO COMPARE THE EFFICACY OF CLINICAL OUTCOMES OF USING AND NON-USING WALKING SUPPORT MACHINE TRAINING AFTER TOTAL KNEE REPLACEMENT

SIRIPEN RATTANASOMBOONCHAI

A Thesis Submitted in Partial Fulfillment of the Requirements for the
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การศึกษาเชิงทดลองแบบสุ่มและปกปิดข้อมูลทั้งสองทางเพื่อเปรียบเทียบประสิทธิภาพของผลลัพธ์ทางคลินิกของการฝึกด้วยเครื่องช่วยพยุงเดินและไม่ใช้เครื่องช่วยพยุงเดินหลังการผ่าตัดเปลี่ยนข้อเข่า

นางสาวศิริเพ็ญ รัตนสมบูรณ์ชัย

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิศวกรรมศาสตรมหาบัณฑิต
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Suranaree University of Technology has approved this thesis submitted in partial fulfillment of the requirements for a Master's Degree.

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ศิริเพ็ญ รัตนสมบูรณ์ชัย : การศึกษาเชิงทดลองแบบสุ่มและปกปิดข้อมูลทั้งสองทางเพื่อเปรียบเทียบประสิทธิภาพของผลลัพธ์ทางคลินิกของการฝึกด้วยเครื่องช่วยพยุงเดินและไม่ใช้เครื่องช่วยพยุงเดินหลังการผ่าตัดเปลี่ยนข้อเข่า (RANDOMIZED, DOUBLE-BLIND, CONTROL TRIAL STUDY TO COMPARE THE EFFICACY OF CLINICAL OUTCOMES OF USING AND NON-USING WALKING SUPPORT MACHINE TRAINING AFTER TOTAL KNEE REPLACEMENT) อาจารย์ที่ปรึกษา : ผู้ช่วยศาสตราจารย์ ดร.สุขเกษม วัชรมัยสกุล, 90 หน้า.

คำสำคัญ: เครื่องช่วยพยุงเดิน, ผ่าตัดเปลี่ยนข้อเข่า, การกายภาพ

การกายภาพบำบัดเพื่อฟื้นฟูสมรรถภาพของผู้ป่วยหลังผ่าตัดเปลี่ยนข้อเข่าเทียม เป็นขั้นตอนที่สำคัญที่ทำให้ผู้ป่วยสามารถกลับมาใช้ชีวิตประจำวันได้ปกติ การศึกษานี้มีวัตถุประสงค์เพื่อประเมินประสิทธิผลของการใช้เครื่องพยุงเดินต้านแรงโน้มถ่วง (Co-walk) เพื่อเพิ่มประสิทธิภาพของผลลัพธ์ทางคลินิกในผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียม (TKR) ในการทดลองนี้ ทำการสุ่มผู้ป่วย 62 คน โดยแบ่งผู้ป่วยออกเป็น 2 กลุ่ม ได้แก่ กลุ่มควบคุม (Non Co-Walk) และกลุ่มทดลอง (Co-walk) โดยทั้งสองกลุ่มปฏิบัติตามโปรแกรมการกายภาพบำบัดและฟื้นฟูสมรรถภาพ เป็นเวลา 45 นาทีตามปกติ และในกลุ่มทดลองจะเพิ่มขั้นตอนการกายภาพบำบัดโดยใช้เครื่องพยุงเดินต้านแรงโน้มถ่วง เป็นเวลา 15 นาที สัปดาห์ละ 1 ครั้ง เป็นเวลา 6 สัปดาห์ ทำการวัดผลลัพธ์ที่ระยะเวลา 2 สัปดาห์ 6 สัปดาห์ 3 เดือน และ 6 เดือน ตัวชี้วัดได้แก่พิสัยของข้อ (Range of Motion ; ROM), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), การทดสอบ Timed up-and-go (TUG), Weight-Bearing Balance, Postural control และ Length of stay (LOS) ถูกบันทึกทั้งก่อนและหลังการผ่าตัด ใช้การทดสอบ t-test และการทดสอบ Mann Whitney เพื่อเปรียบเทียบตัวแปรต่อเนื่องระหว่างผู้ป่วย 2 กลุ่ม ในขณะที่การทดสอบแบบ Chi-square นั้นดำเนินการสำหรับตัวแปรตามหมวดหมู่ ANOVA ที่วัดซ้ำหรือแบบทดสอบของ Friedman ได้รับการวิเคราะห์เพื่อเปลี่ยนค่าเฉลี่ยหรือคะแนนมัธยฐานในช่วงเวลา 4 จุดขึ้นไปภายในกลุ่มการเดินร่วมและกลุ่มเดินร่วม ค่า p-value แบบสองด้าน <0.05 ถือว่ามีนัยสำคัญทางสถิติสำหรับการทดสอบทั้งหมดที่ดำเนินการ

ผลการศึกษาพบว่า พารามิเตอร์ที่สำคัญ ($p<0.001$) คือ TUG และ WOMAC โดย Co-walk group ที่ 2 สัปดาห์ 6 สัปดาห์ และ 3 เดือน การเคลื่อนไหว WOMAC มีนัยสำคัญทางสถิติในกลุ่ม Co-walk ที่ 2 สัปดาห์ 6 สัปดาห์ 3 เดือน และ 6 เดือน ($p<0.001$) ความแข็งของ WOMAC มีนัยสำคัญทางสถิติในกลุ่ม Co-walk ที่ 2 สัปดาห์ ($p<0.001$) ROM ของกลุ่ม Co-walk แตกต่างกันอย่างมีนัยสำคัญที่ 6 สัปดาห์ เมื่อเทียบกับกลุ่ม Non-Co walk ($p=0.024$) การควบคุมท่าทางของกลุ่มที่เดิน

ร่วมแสดงท่าที่ดีขึ้นอย่างมีนัยสำคัญเมื่อเทียบกับกลุ่มที่เดินไม่ได้ไปทางซ้าย (p=0.024) และขวา (p=0.019) ตามลำดับที่ 2 สัปดาห์ 6 สัปดาห์ 3 เดือน และ 6 เดือน อย่างไรก็ตามตำแหน่งด้านหน้าและด้านหลังไม่แตกต่างกันอย่างมีนัยสำคัญ ข้อจำกัดที่สำคัญคือการศึกษาระยะยาว LOS ของกลุ่มทดลองไม่มีความแตกต่างอย่างมีนัยสำคัญในจำนวนวันเมื่อเทียบกับกลุ่มควบคุม (p=0.379) สรุปได้ว่า Co-walk ช่วยปรับปรุงผลลัพธ์อย่างมีประสิทธิภาพในช่วงฟื้นฟูระยะแรก อาจดีกว่าโปรแกรมการฟื้นฟูสมรรถภาพทางกายภาพบำบัดแบบแยกส่วน การศึกษานี้ได้รับการจดทะเบียนกับ Thai Clinical Trials Registry (เลขที่ TCTR20210123002) (www.clinicaltrials.in.th)

สาขาวิชา นวัตกรรม วิศวชีวการแพทย์ ลายมือชื่อนักศึกษา .....

ปีการศึกษา 2566 ลายมือชื่ออาจารย์ที่ปรึกษา .....

SIRIPEN RATTANASOMBOONCHAI : RANDOMIZED, DOUBLE-BLIND, CONTROL TRIAL STUDY TO COMPARE THE EFFICACY OF CLINICAL OUTCOMES OF USING AND NON-USING WALKING SUPPORT MACHINE TRAINING AFTER TOTAL KNEE REPLACEMENT THESIS ADVISOR: ASST. PROF. SUKASEM WATCHARAMAISAKUL, Ph.D. 90 PP.

Keyword: Walking support machine, Total Knee Replacement (TKR), Rehabilitation

Rehabilitation is one of the key successes in Total Knee Replacement (TKR). Many methods reduce knee forces during weight-bearing exercises. This study aims to assess the effectiveness of using a walking support machine (Co-walk) to improve clinical outcomes in TKR patients. The experiment was randomly 62 patients dividing the patients into 2 groups, the control group, and the experimental group (Co-walk). Both groups were followed the normal for 45 minutes rehabilitation program. The experimental group had an additional 15 minutes Co-walk session once a week and continuously for 6 weeks. Outcomes were measured at the admission period, 2 weeks, 6 weeks, 3 months, and 6 months in TKR patients. Primary outcome measure: Range of Motion (ROM), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcome measure: Timed up-and-go test (TUG), Weight-Bearing Balance, Postural control, and Length of stay (LOS) were recorded for both pre and post-operation. The student t-test and Mann Whitney test were used to compare continuous variables between Co-walk and Non-Co walk, whereas Chi-square tests were performed for categorical variables. A repeated-measures ANOVA or Friedman's test was analyzed to change the mean or median score over 4 or more time points within Co-walk and Non-Co walk groups. A two-tailed p-value<0.05 was considered statistically significant for all tests performed.

The study results are follows, the significant parameters ($p<0.001$) were TUG and WOMAC pain by Co-walk group at 2 weeks, 6 weeks, and 3 months. WOMAC movement was statistically significant in the Co-walk group at 2 weeks, 6 weeks, 3 months, and 6 months ($p<0.001$). WOMAC stiffness was statistically significant in the

Co-walk group at 2 weeks ($p<0.001$). ROM of the Co-walk group was significantly different at 6 weeks compared with the Non-Co walk group ($p=0.024$). Co-walk group postural control showed significant improvement in position compared with the Non-Co walk group left ($p=0.024$) and right ($p=0.019$), respectively, at 2 weeks, 6 weeks, 3 months, and 6 months. However, the anterior and posterior positions were not significantly different. The main limitation is the long-term study. The experimental group LOS showed no significant difference in days compared with the control group ($p=0.379$). It can be concluded that Co-walk does effectively improve outcomes during the early rehabilitation period. It may be better than isolated physical therapy rehabilitation programs. The study was registered with the Thai Clinical Trials Registry (No. TCTR20210123002) (www.clinicaltrials.in.th)

School of Biomedical Innovation Engineering Student's Signature Piriyen Rattanasomboonchai

Academic Year 2023 Advisor's Signature .....

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LIST OF ABBREVIATIONS

ROM	=	Range of Motion
WOMAC	=	Western Ontario and McMaster Universities Osteoarthritis Index
TUG	=	Time up and go
LBPP	=	Lower body positive pressure
TKR	=	Total Knee Replacement
TKA	=	Total Knee Arthroplasty
Co-walk	=	Walking Support Machine
LOS	=	Length of stay
OA	=	Osteoarthritis
MRF	=	Medical Research Foundation of Thailand
POD	=	Post-operation day
BMI	=	body mass index

CHAPTER I
INTRODUCTION

1.1 Background of rational

Rehabilitation remains crucial for achieving good clinical outcomes, such as short-term function, range of motion, patient quality of life, and prevention of postoperative complications, in total knee replacement (TKR). Decreased pain with a greater range of motion and independence are important goals for physiotherapy, while early rehabilitation is considered necessary for increasing the range of motion and muscle strength. The trend toward early hospital discharge to reduce the length of stay has gained popularity in the last decade. Postoperative knee range of motion (ROM) is one of the most crucial factors influencing patient satisfaction after TKR. The mean 1-year Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score is lowest in the first three months. It is essential to avoid bad experiences during the early postoperative period, including pain, knee stiffness, and hospital readmission due to complications such as falling. Weight-bearing activities such as walking are often considered highly effective in rehabilitation and promoting a return to function. High knee forces (3 times body weight), non-weight-bearing, or partial weight-bearing are usually recommended. Full weight-bearing may delay a return to full function. Many methods can be used to reduce the forces on the knee during weight-bearing exercises, such as hydrotherapy (walking in water), the use of harness systems that physically lift the patient, the use of lower body positive pressure (LBPP) chambers, and LBPP treadmills. These methods produce a significant reduction in the weight the patient bears with minimal alteration to gait kinematics.

An increase in knee forces may affect postoperative rehabilitation, for example, through pain, leading to the restriction of motion and increased joint stiffness. The degeneration of immobilized muscle groups and early joint stiffness remain essential factors influencing whether there is a prolonged course of healing. A study

demonstrated improvements in pain intensity, gait velocity, cadence, and stride length as the result of a six-week gait physical therapy program after TKR. Our study aimed to improve clinical outcomes for patients following TKR by using a walking support machine (Co-walk) and compare the results over a 6-month period to those obtained with a standard rehabilitation protocol. Some research shows that accelerated device rehabilitation can improve recovery outcomes after patient injuries. However, no research has investigated clinical outcomes in patients who underwent TKR. Our study aimed to improve the clinical outcomes of TKR patients by using a walking support machine (Co-walk) in addition to standard rehabilitation compared to a standard rehabilitation protocol alone. We assessed the results over a 6-month period and focused on improving ROM, timed up-and-go test (TUG) scores, Western Ontario and McMaster University (WOMAC) scores, weight-bearing balance, postural control, and Length of stay (LOS).

1.2 Research Objectives

The main aim of this research is to improve clinical outcomes for patients following TKR by using a walking support machine (Co-walk) and compare the results over a 6-month period to those obtained with a standard rehabilitation protocol, and there are more objectives are:

1.2.1 To study the effect of Range of Motion (ROM), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Time Up and Go (TUG), Weight-bearing balance, Postural control, and Length of stay (LOS)

1.2.2 To study the effect results compare in Total Knee Replacement (TKR) patients using and non-using Co-walk.

1.3 Scope and limitation of the study

1.3.1 Scope of population

This research studied only osteoarthritis patients who received medical service at the Orthopedic Department and underwent total knee replacement surgery at Suranaree University of Technology Hospital. To reduce the

confounding factors such as surgical techniques and surgical skills of the surgeon, we collected cases that were operated on by one experienced surgeon. We used the same medial parapatella technique and the same type fix posterior sacrificed total knee prosthesis for all the patients. The duration of the follow-up was 2 weeks, 1 month, 3 months, 6 months after surgery. All patients were under the approval of the medical ethics commission, with the consent of the Medical Institute of Suranaree University of Technology, and the patients signed a patient consent form

1.3.2 Scope of content

This research studied in

1.3.2.1. Personal general demographic data

1.3.2.2. The severity of osteoarthritis by using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

1.3.2.3. Range of Motion of the knee (ROM)

1.3.2.4. Time up and go (TUG)

1.3.2.5. Balance of the patients

1.3.2.6. Length of stay (LOS)

1.3.3 Scope of research site

This research was conducted at the Orthopedic Department Suranaree University of Technology University Hospital, Muang District, Nakhon Ratchasima Province. This research used data from 1st August 2020 to 31st July 2021.

1.4 Limitation of the study

1.4.1 The average number of patients who did total knee replacement surgery is 73 people per year at Suranaree University of Technology Hospital. The study will take time more than 1 year if patients did not have enough or lose follow up.

1.4.2 The assessment tool that was the WOMAC Score and Pain Score is the Self-Assessment in which each person is different. Objective was to determine Range of Motion (ROM), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Time Up and Go (TUG), Weight-bearing balance, Postural control, and Length of stay (LOS) compared in Total Knee Replacement (TKR) patients using and non-using Co-walk.

1.5 Conceptual Framework

The care process after knee replacement surgery involves in many areas, including

1.5.1 Physiological means the ability to return to normal, including free body movement, various organs work normally, with reduced pain, and fatigue without complications.

1.5.2 Psychological means to return to the normal mental and emotional state with happiness without depression, anger, anxiety. Including having a good experience.

1.5.3 Social means returning to duty in society, independent of others, including proper interaction with other people.

There are a variety of tools for evaluating postoperative knee replacement surgery, including ROM, WOMAC Score, TUG, and other tools that help assess the risk of falls in patients after surgery. If the patient does not use Gait aids and can maintain normal balance Meaning that the patient can live independently in normal life.

Post-surgical rehabilitation is considered an important step in the recovery of patients after surgery. If the patients do physiotherapy training regularly and balance training, it will help them return to normal life faster. Therefore, the idea of using Co-

walk device to help in restoring the body after surgery by giving the patients free to move the lower part of the body with reduce pressure by reducing weight acting on the lower part of the body. It makes the patients painless, early ROM, and balancing body. And also including a patient's confidence in walking. The experiment was divided into 2 groups: using Co-walk device and non-using Co-walk devices in postoperative physiotherapy. The participants received gait training using CO-Walk for 15 minutes also with the normal rehabilitation program total 45 minutes for each session, twice a week in the experimental group for 6 weeks. A control group used the normal rehabilitation program as 45 minutes for each session, twice a week for 6 weeks. After 6 weeks both follow up program for 3 months and 6 months. We evaluate by tools for patients 4 times during admission, 2 weeks, 6 weeks, 3 months, and 6 months.

CHAPTER II

LITERATURE REVIEWS

Relevant topics and previous research results were reviewed to improve understanding of efficacy of clinical outcomes of using and non-using walking support machine training after total knee replacement. This chapter describes the Range of Motion (ROM), Western Ontario and McMaster Universities Arthritis Index (WOMAC), Time Up and Go (TUG), Weight-bearing balance, Postural control, and Length of stay (LOS) showing the important roles of tools. The sources of information obtained from journals, researches, dissertation and books. The results of the review are summarized as follows.

2.1 Recovery of knee replacement surgery

Osteoarthritis treatment with knee replacement surgery is a treatment to reduce pain, restore function, and improve the quality of life in the elderly. The recovery process after knee replacement surgery may take different times for each person. Depending on different physical and environmental factors. Recovery is a process of adaptation of the patient, both physically and mentally, which occurs after surgery. Return to normal work or as good as before surgery and able to return to perform duties and activities as usual without having to rely on others or without walking equipment. (Myles, Weitkamp, Jones, Melick and Hensen, 2000)

Recovery after surgery means the process in which the body returns to normal, both physically, mentally, socially, and can return to function normally or at an equivalent level before surgery. Which consists of 4 aspects as follows

1. Physiological means to return to normal, including bodywork. Movement freely various organs work normally, with reduced pain, fatigue. No or few complications

2. Psychological means to return to the normal mental and emotional state with happiness without depression, anger, anxiety. Including having a good experience

3. Social means returning to duty in society, not dependent on others, including proper interaction with other people.

4. Habitual function means the ability to live a normal life. Daily activities Eating, working, etc. (Allvin, Berg, Idvall and Nilsson, 2007)

Therefore, recovery after knee replacement surgery means the adjustment process of patients after surgery. Physical, mental, occurring after surgery to be able to return to normal activities without relying on gait aids and caregivers.

2.2 Assessment model for assessing recovery after knee replacement surgery.

2.2.1 Range of Motion

The range of motion refers to the full movement of your joint (in this case knee). Your knee ROM will include flexion (bending), extension (straightening), adduction (movement towards middle of the body), abduction (movement away from the middle of the body), and rotations (inward and outward) must be worked towards. Your knee ROM is measured with a "goniometer". The knee is a hinge joint and primarily only moves in one plane of movement, flexion, and extension.

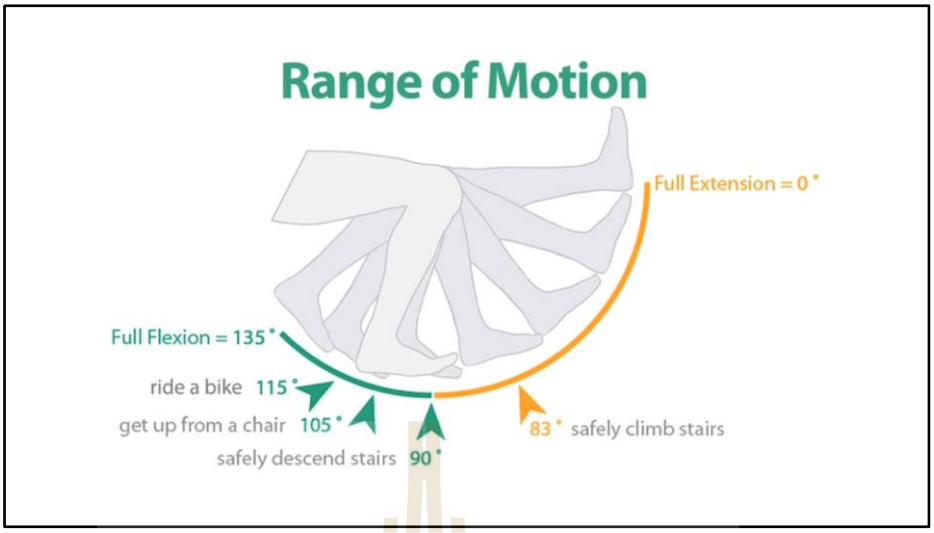

Figure 2.1 Range of Motion

A completely straight knee joint will measure at 0° and a fully bent knee will have the flexion at 135° degrees. These are the benchmark "normal" ROM measures.

2.2.2 Western Ontario and MacMaster University (WOMAC)

The evaluation form was created to assess the condition of osteoarthritis of the knee and hip. which consists of 3 parts: pain dimension, Stiffness dimension, and function dimension. Commonly are used as a tool to measure recovery after knee replacement surgery.

2.2.3 Time Up and Go test

TUG test was to assess general mobility and fall risk in total knee replacement patients with limited mobility. The American Geriatric Society recommends that TUG be utilized as a routine screening test for falls. For the testing, individuals are asked to rise from a seated position, walk 3 m., turn, walk back to the chair, and return to a seated position, and moving as quickly as they are safely able.

2.2.4 Balance

The balance is important in the controlling of the body to its center of gravity. In the support base while the body is still or having various activities to avoid falling. Control of body balance is a complex system including the eye-to-ear recognition system and the perception of joints which has mechanical sensory neurons (Mechanoreceptor) pressure tension that found in muscles, tendons, and joints from sensory neurons send information to interpret the brain. To control the contraction of the muscles in the balance while moving in which the knee joint has a sensory and many mechanical sensory cells. The cruciate ligaments, collateral ligaments, and menisci. In people with knee joints, changes in bone structure, tendons, muscles, membranes, joints, and the surrounding tissue results in a reduction of mechanical exposure cells. From the study of balance in people with osteoarthritis found that, those with moderate to severe knee joint have more balance defects than those with early knee osteoarthritis which affects posture may cause it to fall balance control or balance of the body can assess both balances while standing still and balance while in motion or moving, balancing tests in motion, such as walking, standing, and balancing tests while standing still, such as standing posture while having various activities, closing eyes, standing still have external forces, both conscious and unconscious.

Poor balance control, especially during standing or movement, is one risk factor for falls that could be addressed in the knee OA population. The balance consists of maintaining, achieving, or restoring the center of mass within the base of support. the control of which is multidimensional. It is dependent on the task characteristics as well as the environment in which these tasks are performed. In those with knee OA, balance is also affected by variables such as muscle strength, radiographic severity, knee alignment, pain, and proprioceptive acuity. Better standing balance has been associated with increased quadriceps muscle strength, more advanced radiographic disease severity, less varus alignment, less pain, and better proprioception. (Schwartz et al., 2012)

2.2.5 Length of stay (LOS)

Length of stay (LOS) is a clinical metric that measures the length of time elapsed between a patient's hospital admittance and discharge. LOS can be calculated on a hospital-wide basis or by therapy area, including the Total Knee Replacement Patients.

CHAPTER III

RESERCH METHODOLOGY

In this work was performed an experimental clinical trial. The study was registered with the Thai Clinical Trials Registry (No. TCTR20210123002) (www.clinicaltrials.in.th), which legally conducts trials in Thailand under the Medical Research Foundation of Thailand (MRF), and received ethical approval from the university's ethics committee (EC 63-74). The patients were enrolled patients and randomized them to the experimental and control groups, as shown in the flow diagram in Figure 3.1.

The patients were randomly divided into two groups using the block method. The samples in both groups were included knee osteoarthritis patients who underwent TKR and referred to physiotherapy for TKR rehabilitation. The sample size was calculated using data from a previous study by Mutsuzaki H et al. (H. Mutsuzaki, Ryoko Takeuchi, Yuki Mataki, et al., 2017), mean ROM change from preoperative before surgery to 6 months after TKA. Using an unpaired t-test with a 2-sided significance level of 0.05, the study would have 90% power to detect a difference of 3.0 between the Co-walk and Non-Co-walk groups. The percentage of missing data was settled at 7%. The number of participants needed were, 31 in each group. Therefore, the minimum number of subjects to be recruited was 62 for the study. The control group 31 issues (Non-Co-walk) received the standard protocol for rehabilitation. The experimental group 31 subjects (Co-walk) used the walking support machine (Co-walk) in addition to undergoing the standard protocol for rehabilitation.

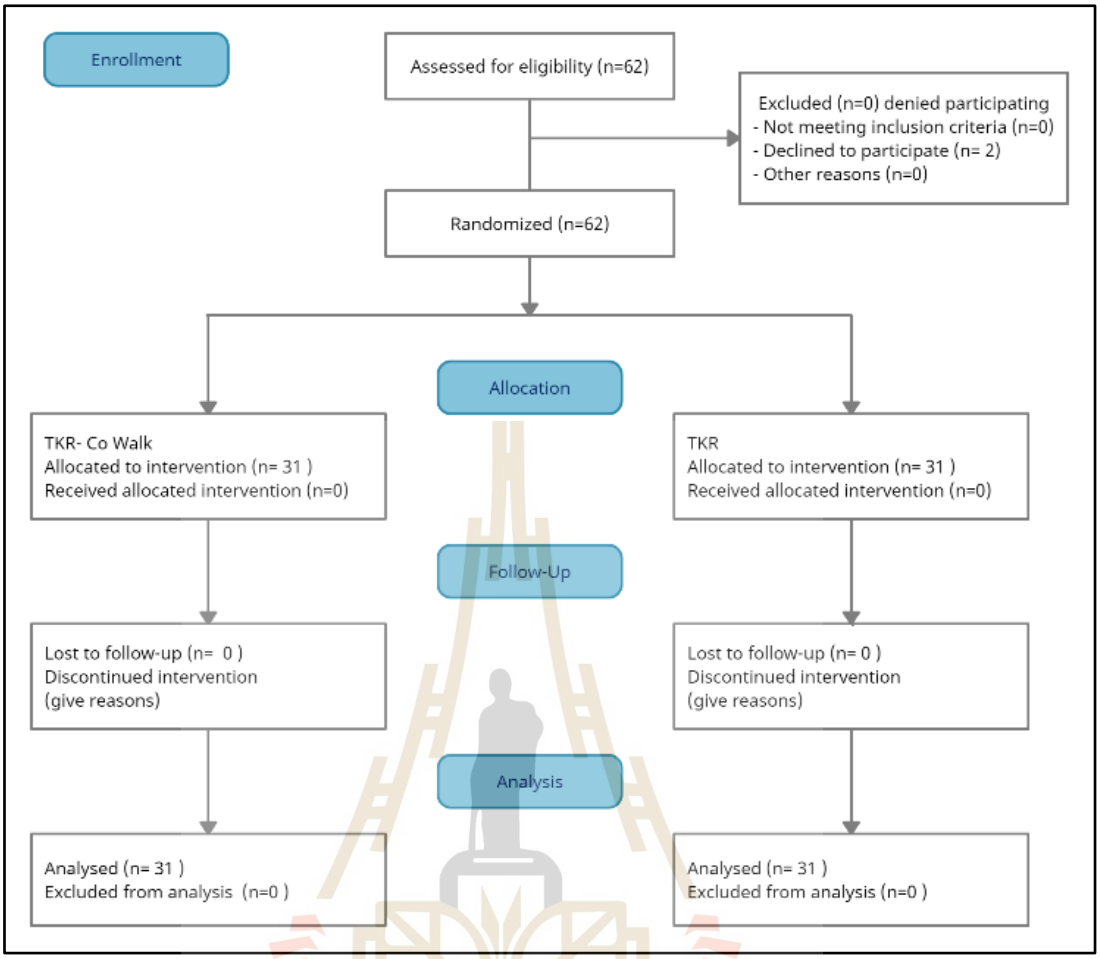

Figure 3.1 CONSORT 2010 Flow Diagram

Table 3.1 Rehabilitation protocol for TKR based on the Insall Scott Kelly® Institute for Orthopaedics and sports medicine.

Week	Program
2 to 4 Pre-operation	**Pre-op** 1. Review of the TKR 2. Restore normal range of motion (ROM) exercise, 3. Stair training 4. Bed mobility training and education on the importance of cold compression 5. Ambulation training with crutches 6. Assessment using a range of Motion (ROM), timed up-and-go (TUG) score, and the WOMAC score

Table 3.1 Rehabilitation protocol for TKR based on the Insall Scott Kelly® Institute for Orthopaedics and sports medicine. (Continued)

Week	Program
0 to 2 Post-operation	1. Post-operation day (POD) #1 • cold compression of the knee for 20 minutes for a minimum of 2 times per day (more if necessary). • Review and perform all bedside exercises, including ankle pumps, quadriceps sets, gluteal sets, and heel slides. • Sit at the edge of the bed with necessary assistance. • Ambulate with a standard walker 15' with moderate assistance. • Sit in a chair for 15 minutes. • Actively move knee 0-70°. 2. POD #2 • Continue as above with emphasis on improving ROM, performing proper gait patterns with an assistive device, decreasing pain and swelling, and promoting independence with functional activities. • Perform bed exercises independently 5 times per day. • Perform bed mobility and transfers with minimum assistance. • Ambulate with a standard walker 75-100' with contact guarding. • Ambulate to the bathroom and review toilet transfers. • Sit in a chair for 30 minutes twice per day, in addition to at all meals. • Actively move knee 0-80°. 3. POD #3 • Continue as above. • Perform bed mobility and transfers with contact guarding. • Ambulate with a standard walker 150' with supervision. • Negotiate 4 steps with necessary assistance. • Begin standing hip flexion and knee flexion exercises. • Sit in a chair for most of the day, including during all meals. Limit sitting to 45 minutes in a single session. • Use the bathroom with assistance for all toileting needs. • Actively move knee 0-90°. 4. Continue physiotherapy in the same way as in the hospital when patients are discharged
2 to 5 Post-operation	1. Weeks 2-3 • Monitor incision site and swelling. • Progress ambulation distance (increase 1/2 block to 1 block each day) with WBQC. • Begin stationary bicycle with supervision for 5-10 minutes. • Begin standing wall slides. DO NOT ALLOW THE KNEES TO MOVE FORWARD OF THE TOES. • Incorporate static and dynamic balance exercises. • AROM 0-115°. 2. Weeks 3-4 • Continue as above. • Practice with straight crutches indoors. • Increase stationary bicycle endurance to 10-12 minutes twice per day. • Attempt unilateral stance on the involved leg and side stepping. • Incorporate gentle semi-squats (BODY WEIGHT ONLY) concentrating on eccentric control of the quadriceps. • Attain AROM 0-120°. 3. Weeks 4-5 • Continue as above. • Ambulate with a straight cane only. • Increase stationary bicycling to 15 minutes twice per day. • Progress with gentle lateral exercises, i.e., lateral stepping and carioca. • Attain AROM 0-125°.

Table 3.1 Rehabilitation protocol for TKR based on the Insall Scott Kelly® Institute for Orthopaedics and sports medicine. (Continued)

Week	Program
6 to 12 Post-operation	1. Weeks 6-9 • Continue as above. • Ambulate indoors WITHOUT device. • Focus exercises on strength and eccentric control of muscles. DO NOT USE CUFF WEIGHTS UNTIL CLEARANCE FROM THE SURGEON. • Focus on unilateral balance activities. • Continue aggressive AROM exercise to promote knee range of motion 0-135° 2 Weeks 10-12 • Continue as above. • Develop and instruct the patient on an advanced exercise program for continued strength and endurance training. • Ambulate without a straight cane

3.1 Subject selection and allocation

3.1.1 Inclusion criteria

The inclusion criteria are patients who were willing to enroll in the program, were over 50 years old, with knee osteoarthritis, and had a severe stage of osteoarthritis that required TKR.

3.1.2 Exclusion criteria

The exclusion criteria are patients with a history of cerebrovascular events such as ischemic stroke, hemorrhagic stroke, undetermined stroke, transient ischemic attack, and patients lost to follow-up.

3.1.3 Withdrawal or termination criteria

The withdrawal or termination criteria were judged from greater pain intensity than before enrollment and discomfort with continuing the program. Both groups were received the same postoperative pain control and rehabilitation protocol as shown in Table 3.2. To reduce confounding factors, such as surgical techniques, the surgical skills of the surgeon, and the type of implants, all operations were performed by one experienced surgeon who used the same operation, same implant type, and same surgery method

3.2 Data collection

The datas were collected from 19 January 2021 until 30 July 2021 at Suranaree University Hospital. The evaluator and the physical therapist were used different

people. Patients were assessed for general demographics such as sex, age, and body mass index (BMI). The evaluation of the primary outcome were used the WOMAC, which consists of two domains— pain, stiffness, and function. Range of motion (ROM) was assessed by using a goniometer. The secondary outcomes were used LOS, time up and go (TUG) score, weight-bearing balance, and postural control, as assessed by EP40 System Biometrics Ltd. The re-evaluation of both groups were used the same parameters before and after the operation. For the Co-walk group, were used Co-walk once a week for 6 weeks based on the Insall Scott Kelly® Institute for Orthopaedics and Sports Medicine protocol. The walking duration was 15 minutes. For the Non-Co-walk group, we used a 45 minutes rehabilitation program once a week for 6 weeks. Outcomes data were measured on admission and at the 2nd, 6th, 12th, and 24th weeks.

Table 3.2 Data collection procedure

	VS	V0[a]	V1	V2	V3	V4	V5
Day	-7 to -1	D0[a]	D2+3	14 ± 7	42 ± 7	84±10	168±15
Week				2	6	12	24
Month					1.5	3	6
1. Consent process	x						
2. Collect demographic data (date of birth, sex, weight, height)	x				x[b]	x[b]	x[b]
3. Osteoarthritis Diagnosis	x						
4. Assessment of disease severity with the KL system (Kellgren-Lawrence radiographic grading scale) [f.]	x						
5. Knee Physical Examination: Visual Examination, Range of Motion, Anterior Drawer, Valgus Test, Varus Test, Posterior Drawer, McMurray's Test, Balance Test, Quadriceps	x		x	x	x	x	x

Table 3.2 Data collection procedure (Continued)

	VS	V0[a]	V1	V2	V3	V4	V5
Day	-7 to -1	D0[a]	D2+3	14 ± 7	42 ± 7	84±10	168±15
Week				2	6	12	24
Month					1.5	3	6
6. Check the inclusion/exclusion criteria.	x	x f.					
7. Randomization			x				
8. Recovery status			x	x	x	x	x
9. Pain score	x		x	x	x	x	x
10. Time on the timed up-and-go test			x	x	x	x	x
11. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Assessment	x		x	x	x	x	x
12. Collect data on the use of analgesics or muscle relaxants	x[c]		x[d]	x	x	x	x
13. Use Co-Walk [e] in rehabilitee session			x[g]				

Notes:

a. V0 or D0 is the time the patient underwent knee surgery.

b. Weight and height only.

c. Collect all analgesic or muscle relaxant use within 1 month prior to D0.

d. Analgesic or muscle relaxant use was collected from the time the surgery was completed until the day of hospital discharge.

e. Only the experimental group was used throughout physical therapy until recovery or until the end of the study. It depends on what happened first.

f. Double check before randomizing.

g. Use the aid for 15-20 minutes.

3.2.1 Consent process

The protocol of accessment those who will be invited to participate in the research in detail, who, where, how, and how to contact, for example, requesting letters for requesting data collection from volunteers, for example, requesting letters for hospitals, schools, agencies. that the researcher will collect data Including the use

of various media such as documents / posters to promote to prevent the bias from the research project leader, who may be the patient's physician. Participants will be responsible for inviting volunteers, i.e. patients who plan to undergo total knee replacement (TKR), to participate in the trial.

After the patient was informed of the study program, the study participants were provided information about it both verbally and in writing. And are willing to participate in research projects. Participants may refer subjects to the investigating physician to allow subjects to ask any additional information they may obtained before signing the consent form. Nevertheless, if subjects have any additional questions that participants may not be able to answer satisfactorily. And the patient wants the research lead the doctor to answer the patient's questions. Research assistant nurses may refer volunteers to research physicians who may be responsible for patient care. If the patient's suspicions are disturbing, the subject will not be included in the study without affecting the patient's normal treatment at all.

Participation in this research project is voluntary. If you do not voluntarily participate in the program, you can opt out and if you do, you can withdraw at any time. Withdrawing from the research program will not affect your medical care in any way.

3.2.2 Collect demographic data (date of birth, sex, weight, height)

Date of birth and sex are obtained from the patient's medical record, weights are collected in kilograms and height was collected in centimeters.

3.2.3 Osteoarthritis Diagnosis

Osteoarthritis diagnosis data will be collected, including the date onset of symptoms and the date of diagnosis. These data are collected from the information in the patient's medical record. and if not inadequately information recorded, data were obtained from volunteer interviews. Including the planned date of surgery. This data will be collected at the screening appointment interview.

3.2.4 Assessment of disease severity with the KL system (Kellgren-Lawrence radiographic grading scale)

Assessment of disease severity with the KL stage of the pre-screening system will be assessed only in patients with osteoarthritis at the screening stage prior to total knee replacement. This was obtained from volunteer interviews and recorded directly into the questionnaire.

3.2.5 Knee Physical Examination

The knee will be examined at the appointments listed in the Schedule and Clinical Examination Plan in the study above. The information collected during the screening period will be defined as basic information.

The knee examination is a routine medical procedure that is routinely performed in patients with osteoarthritis before or after having already undergone surgical treatment protocol as follows:

3.2.5.1 Visual Examination

1. Characteristics of walking, including
    1) Ability to walk (yes/no).
    2) Having a short stance phase, known as antalgic gait (yes/no).
    3) Seeing the patient tilt (yes/no).
2. Problems with shortening of the legs not included (yes/no)
3. Abnormal redness and swelling of the knee joint (yes/no)
4. Deformity of the knee joint such as bending out or twisting in (yes/no)

3.2.5.2 Tests of movement or function of the knee joint.

The knee mobility test was performed in this study. It is a standard medical examination that is already done on a regular basis. As follows:

1. Range of motion of joints It examines the ability to fully straighten the knee joint according to medical standard method.

2. Anterior Drawer Test is an examination of the function of the anterior cruciate ligament, performed according to medical standards.

3. Posterior Drawer Test is a function check of the posterior cruciate ligament which is performed according to standard medical procedures. Assessment results and the following information will be collected.

4. Valgus Test to assess the overall stability of the knee joint while applying weight in a straight knee position at 30 degrees, which will be performed according to standard medical procedures.

5. Varus Test to assess the overall stability of the knee joint while applying weight in straight knee position at 0-degree angle.

6. McMurray's Test to find traces of abnormal intervertebral discs.

7. Balance Test as information for assessing the risk of falling patients.

8. Quadriceps muscle strength to consider muscle force to reduce the risk of accidents for patients.

3.2.5.3 Randomization

Patients will be randomly assigned to the experimental group or the control group. On the day the patient is discharged from the hospital (before discharge from the hospital)

The investigator's doctor or investigator's nurse will randomly randomize subjects to the experimental group or control group in a 1:1 ratio by opening the envelopes, respectively.

Physicians, investigators or nurses, research assistants, or physiotherapists cannot predict in advance whether a subject will be allocated to a group before the random code envelope is opened. Including using the Random Block technique of Block size 6 randomizations. To create a random code therefore the researcher does not guess which group the next subject will be in the study. Envelopes used are sealed in Opaque Envelopes and do not allow more than the number of patients to be randomized.

3.2.5.4 Recovery status

Recovery status will be assessed by the investigating physician. It will assess how the patient condition after surgery at various times. As outlined in the table and the clinical assessment plan in the study are:

1. Recovered/resolved – The patient has recovered and able to walk in normal condition. While taking the time up to go test, the volunteer must:

a. stand on their own without having to support or assistive devices.

b. Walking normally, defined as being able to walk back and forth on his own.

c. No unbearable knee pain. while Time Up and Go testing.

2. Recovering/resolving – The condition is improving, and the patient is expected to return to normal.

3. Not recovered/not resolved – The patient's condition has not improved. Time up to go test cannot be performed.

4. Fatal – This term is used when a patient has died, although it is not related to the instrument used in the study.

5. Unknown – This term will only be used if the patient is missing from tracing.

3.2.5.5 Pain score

The researcher's physician or nurse will have the volunteer's assessment with the pain level of the knee that was operated on. By asking the patient to look and tell how the pain feels as shown in the picture and will record the pain score 0, 2, 4, 6, 8, 10, respectively. in the Figure 3.2.

Figure 3.2 Pain score chart

3.2.5.6 Time Up and Go test.

The patient wears the shoes that the patient normally wears in daily life for testing. The test begins with the patient sitting in an armchair. After that, have the patient stand up. and walk straight for 3 meters and walk back to sit on the chair.

The time taken by the patient starts from being instructed to get up from the chair - walk back and forth, for a total of 6 meters - back into the chair. are recorded in minutes.

Patients will be observed while testing:

a. Patients can get out of the chair on their own. If not, can someone help the patient?

b. The distance that the patient able to walk is recorded in meters, with the closest distance to 0.5 meters being used (0.5,1.0, 1.5, 2.0, 2.5, 3.0).

3.2.5.7 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Assessment

The research nurses or physicians will ask volunteers questions on the Western Ontario and MacMaster University (WOMAC) questionnaire. Answers from the volunteers are recorded directly on the study's case record form.

3.2.5.8 Collect data on the use of analgesics or muscle relaxants.

Data on the use of analgesia used within 30 days prior to total knee replacement (TKR) until the last day of study subjects were collected.

3.2.5.9 Use Co-Walk e in rehabilitation session.

Data on the duration of use of the Co-Walk antigravity support during each physical therapy session were collected in minutes.

3.3 Intervention

The innovative walking support machine (Co-walk) was invented by our staff and is shown in Figure 3.3. Co-Walk helps reduce pressure by reducing the weight on the lower part of the body (such as the knees and ankles). The mechanism of the Co-

walk is the air pump piston support system that includes 4 pillars that maintain a specific vertical direction only to move up or down. The pillars connect to the patients via special canvas pants. The canvas elevates the patient using compressed air (propulsion mechanism) delivered from the pillars. When the air is compressed into the propulsion mechanism, a large amount of pressure produces the lifting force. The result is that the patient is placed in a virtually weightless state that reduces pressure and the risk of shocks to the lower limbs during physiotherapy. The physiotherapist or the caregiver can enter the desired elevation percentage on the panel to enable the device to send suitable air pressure. Instructing the device to start working causes the motor to rotate and the compressed air pump to drive when the air delivered to the driving mechanism meets the specified limits. Afterward, the patient can begin physical therapy by walking or running on a medical treadmill. In case of an accident or emergency, a circuit breaker stops the electrical circuit, causing the motor and a compressed air pump to stop. Before exercise, each patient enters the machine, and the canvas connected with the waist seal is secured to isolate the pelvis and lower extremities in the machine. With the patient standing on a standard spring scale (placed on the treadmill), the pressure is increased by an air pump to determine the height needed to achieve 20% of baseline body weight. Next, the scale is removed. In random order, each patient walked for the first minute to 15 minutes at a comfortable walking speed of 0.67 m/second (1.5 mph). The Co-walk group participants performed gait training using the Co-walk and the total 45 minutes rehabilitation program. The walking duration was 15 minutes, taking place once a week for 6 weeks. The control group participants performed the usual 45 minutes rehabilitation program once a week for 6 weeks, as shown in Table 1. Outcomes were measured on admission and at the 2nd, 6th, 12th, and 24th weeks.

Figure 3.3 Co-walk with the treadmill.

3.4 Statistical analysis

Data are described using the mean (±standard deviation) or median (percentile 25-percentile 75) for continuous data and frequency (percentage) for categorical data. Student's t-test and the Mann Whitney test were used to compare continuous variables between the Co-walk and Non-Co-walk groups, whereas chi-square tests were performed for categorical variables. Repeated-measures ANOVA or Friedman's test was used to analyze changes in mean or median scores over 4 or more time points within the Co-walk and Non-Co-walk group. A two-tailed p-value<0.05 was considered statistically significant for all tests performed. PASW Statistic (SPSS) 18.0 (SPSS, Inc., Chicago, IL, USA) was used to perform all statistical analyses.

CHAPTER IV
RESULTS AND DISCUSSION

This research we randomly divided the patients into two groups using the block method. The samples in both groups included knee osteoarthritis patients who underwent TKR and were referred to physiotherapy for TKR rehabilitation. Using an unpaired t-test with a 2-tailed significant level of 0.05, the study would have 90% power to detect a difference between the Co-walk and Non-Co-walk groups. The percentage of missing data was set at 7%. The number of participants needed was, therefore, 31 in each group. Thus, the minimum number of subjects to be recruited was 62 for the study. The control group (31 issues) (non-Co-walk) received the standard protocol for rehabilitation. The experimental group (31 subjects) (Co-walk) used the walking support machine (Co-walk) in addition to undergoing the standard protocol for rehabilitation.

Research Hypothesis

The use of Co-Walk in physiotherapy procedures affects clinical outcomes for TKR patients.

Statistic Hypothesis

Null Hypothesis

H_0: The use of the Co-Walk in physical therapy procedures did not affect clinical outcomes for TKR patients.

Alternative Hypothesis

H_1: The use of Co-Walk in physiotherapy procedures affects clinical outcomes for TKR patients.

Level of Significance

$\alpha = 0.05$

4.1 Results

4.1.1 Personal general demographic data.

Sixty-two patients with severe OA underwent TKR surgery in this clinical trial. This study randomized patients into two groups: the control group, which used the standard TKR rehabilitation protocol, as shown in Table 4.1, and the experimental group, which used gait training with the Co-walk in addition to 15 minutes of the usual 45 minutes rehabilitation protocol.

The cohort included 11 males (17.74%) and 51 females (82.26%). The participants' average age was 67.77 years old, the average height was 154.61 cm, and the average BMI was 26.44 kg/m2. The analysis of demographic characteristics revealed no significant difference between the two groups of patients, as shown in Table 4.2

The results of the clinical trial established a normal distribution of the balance score data in both groups. No patients in either group experienced an injury during the rehabilitation process, and no surgery failed in either group.

Table 4.1 Baseline data

Characteristic		Total	Co-Walk	Non-Co-Walk	p-value
Knee	Left	28 (45.16%)	11 (35.48%)	17 (54.84%)	0.126
	Right	34(54.84%)	20 (64.52%)	14 (45.16%)	
Sex	Male	11 (17.74%)	8 (25.81%)	3 (9.68%)	0.096
	Female	51 (82.26%)	23 (74.19%)	28 (90.32%)	
Length of stay (days)		6.08 ± 2.14	5.84 ± 1.66	6.32 ± 2.55	0.379

Table 4.2 Demographic data

	group	N	Mean	Std. Deviation	p-value
Age	Non Co-Walk	31	67.4839	6.95639	0.747
	Co-Walk	31	68.0645	7.16443	
Weight	Non Co-Walk	31	62.8161	11.99389	0.805
	Co-Walk	31	63.5516	11.38973	
Height	Non Co-Walk	31	154.0323	7.79523	0.559
	Co-Walk	31	155.1935	7.77783	
BMI	Non Co-Walk	31	26.5218	4.99551	0.894
	Co-Walk	31	26.3669	4.10330	

4.1.2 Range of Motion (ROM)

The control group (Non-Co-Walk) and the experimental group (Co-Walk) of TKR patients were compared in terms of preoperative and postoperative ROM. The ROM of the experimental group (119.84±8.99) was significantly different from that of the control group (112.42±15.32) (p=0.024) at 6 weeks, as shown in Figure 4.1.

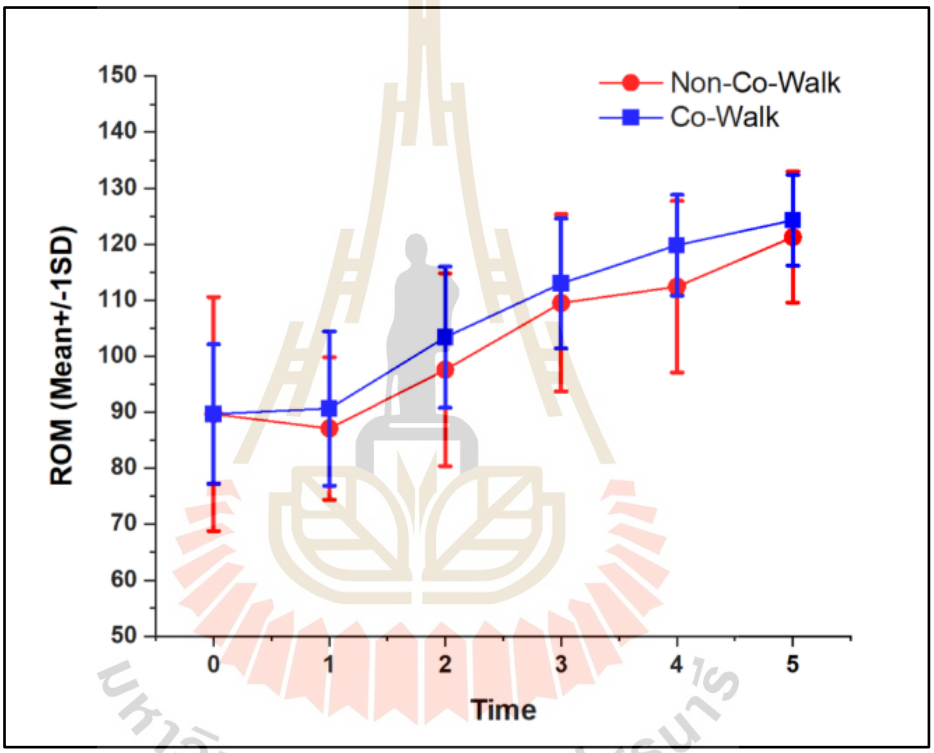

Figure 4.1 Rang of Motion (ROM) between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

Table 4.3 Range of Motion data

	group	N	Mean	Std. Deviation	p-value
ROM_VS	Non Co-Walk	31	89.6774	20.89400	1.000
	Co-Walk	31	89.6774	12.44558	
ROM_V1	Non Co-Walk	31	87.0968	12.70001	0.296
	Co-Walk	31	90.6452	13.76844	
ROM_V2	Non Co-Walk	31	97.5806	17.21777	0.135
	Co-Walk	31	103.3871	12.60867	
ROM_V3	Non Co-Walk	31	109.5161	15.83008	0.327
	Co-Walk	31	113.0000	11.57584	
ROM_V4	Non Co-Walk	31	112.4194	15.32269	0.024*
	Co-Walk	31	119.8387	8.98924	
ROM_V5	Non Co-Walk	31	121.2903	11.68815	0.245
	Co-Walk	31	124.2903	8.10018	

* p-value in the table is obtain significantly different.

4.1.3 The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire

The WOMAC scores for the pain of the experimental group (13.29±5.49) and 7 control group (22.52±5.47) were significantly different ($p<0.005$) at 2 weeks, 6 weeks, and 3 months. The WOMAC movement scores of the experimental group (36.10±13.78) and control group (63.52±12.71) were significantly different ($p<0.001$) at 2 weeks, 6 weeks, 3 months, and 6 months. The WOMAC scores for stiffness of the experimental group (6.03±3.62) and control group (10.16±3.42) were significantly different ($p<0.001$) at 2 weeks. as shown in Figure 4.2.

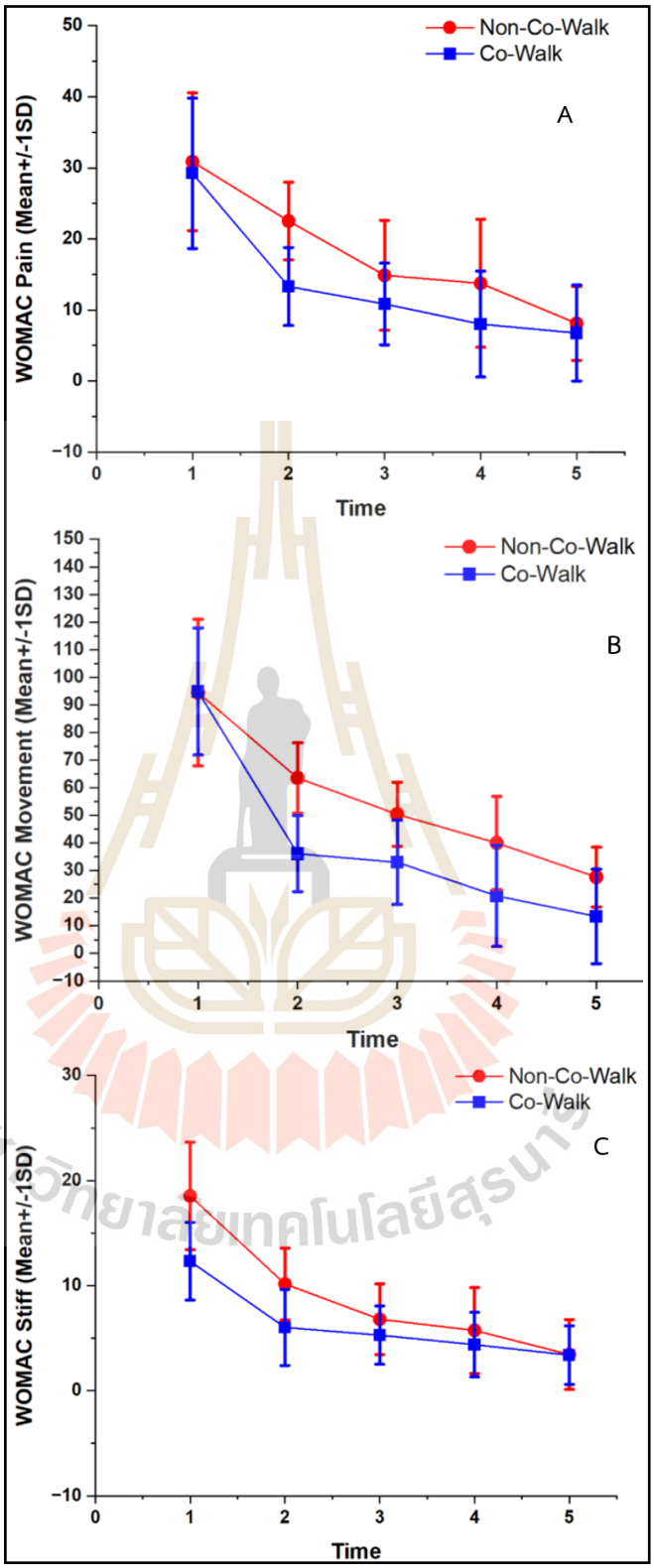

Figure 4.2 Western Ontario and McMaster University index (WOMAC) pain (A), movement (B), and stiffness (C) between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

Table 4.4 The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) data

	group	N	Mean	Std. Deviation	p-value
WOMAC_pain_vs	Non Co-Walk	31	30.8710	9.70822	0.526
	Co-Walk	31	29.2258	10.57894	
WOMAC_pain_v2	Non Co-Walk	31	22.5161	5.47035	0.000*
	Co-Walk	31	13.2903	5.49056	
WOMAC_pain_v3	Non Co-Walk	31	14.8710	7.73193	0.023*
	Co-Walk	31	10.8387	5.74512	
WOMAC_pain_v4	Non Co-Walk	31	13.7419	9.01838	0.008*
	Co-Walk	31	8.0000	7.45654	
WOMAC_pain_v5	Non Co-Walk	31	8.0968	5.20484	0.380
	Co-Walk	31	6.7419	6.74768	
WOMAC_move_vs	Non Co-Walk	31	94.4516	26.95779	0.948
	Co-Walk	31	94.8710	23.04162	
WOMAC_move_v2	Non Co-Walk	31	63.5161	12.71186	0.000*
	Co-Walk	31	36.0968	13.77765	
WOMAC_move_v3	Non Co-Walk	31	50.3871	11.57779	0.000*
	Co-Walk	31	33.0000	15.25560	
WOMAC_move_v4	Non Co-Walk	31	39.9677	16.86907	0.000*
	Co-Walk	31	20.8387	18.29043	
WOMAC_move_v5	Non Co-Walk	31	27.6452	10.79675	0.000*
	Co-Walk	31	13.3871	17.09128	
WOMAC_stiff_vs	Non Co-Walk	31	12.5484	5.09797	0.843
	Co-Walk	31	12.3226	3.70033	
WOMAC_stiff_v2	Non Co-Walk	31	10.1613	3.41659	0.000*
	Co-Walk	31	6.0323	3.61924	
WOMAC_stiff_v3	Non Co-Walk	31	6.8065	3.36075	0.057*
	Co-Walk	31	5.2903	2.77120	
WOMAC_stiff_v4	Non Co-Walk	31	5.7419	4.08222	0.145
	Co-Walk	31	4.3871	3.07330	
WOMAC_stiff_v5	Non Co-Walk	31	3.4516	3.32504	0.934
	Co-Walk	31	3.3871	2.77702	

* p-value in the table is obtain significantly different.

4.1.4 Time up and go (TUG)

The TUG scores of the experimental group (18.10±6.45) and those of the control group (41.92±15.62) were significantly different ($p<0.001$) at 2 weeks, 6 weeks, and 3 months, as shown in Figure 4.3.

Table 4.5 Time up and go data

	group	N	Mean	Std. Deviation	p-value
TUG_v1	Non Co-Walk	31	68.0306	18.06929	0.394
	Co-Walk	31	71.8232	16.64641	
TUG_v2	Non Co-Walk	31	41.9194	15.62058	0.000*
	Co-Walk	31	18.1006	6.45097	
TUG_v3	Non Co-Walk	31	22.9448	12.66623	0.000*
	Co-Walk	31	13.2294	3.32085	
TUG_v4	Non Co-Walk	31	16.4703	9.10267	0.008*
	Co-Walk	31	11.6903	2.52385	
TUG_v5	Non Co-Walk	31	12.7645	6.29226	0.153
	Co-Walk	31	11.0416	1.87417	

* p-value in the table is obtain significantly different.

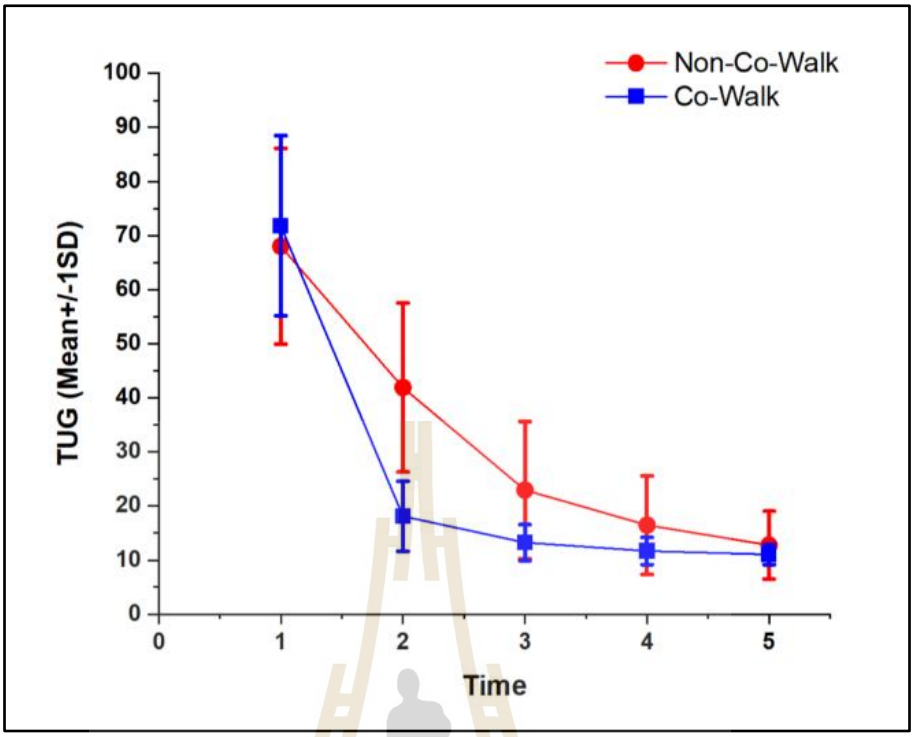

Figure 4.3 Time Up and Go (TUG) between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

4.1.5 Balance of the patients

Weight-Bearing on the left and right was not significantly different in the experimental group. The experimental group showed significant improvement in postural control in position (Left 16 [8.5(6.5-14.0)] and Right 11[10.0(3.0-24.0)]) when compared with that of the control group (Left 6[14.0(14.0-17.0)] and Right 22[24.0(13.0-30.0)] (p=0.024), (p=0.019)) at 2 weeks, 6 weeks, 3 months, and 6 months. However, the anterior and posterior positions were not significantly different, as shown in Figure 4.4.

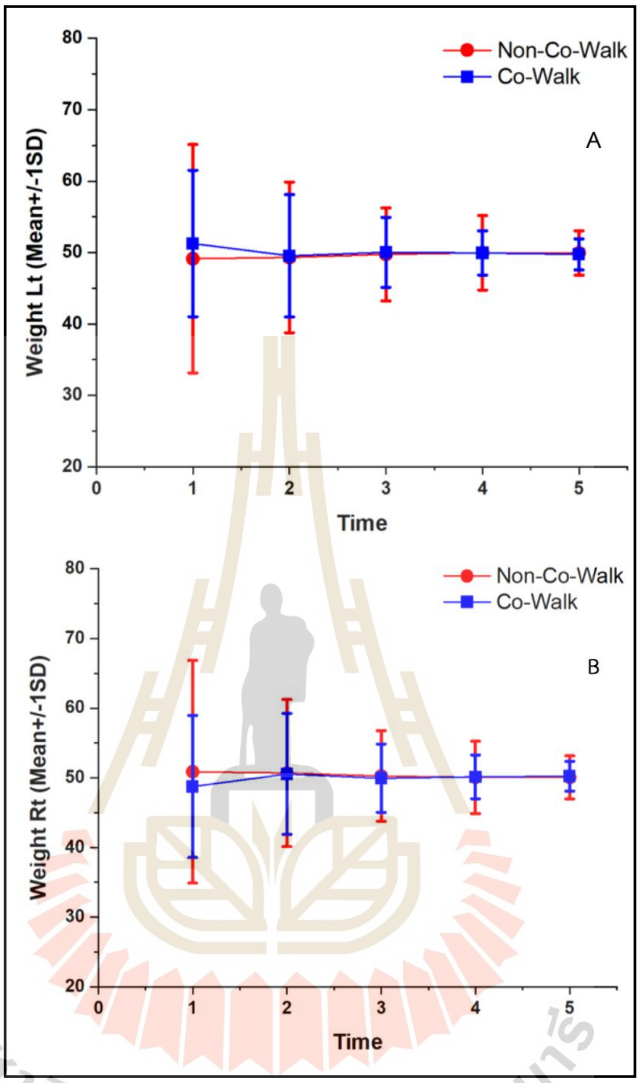

Figure 4.4 Weight-Bearing Left (A) and Right (B) between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

Table 4.6 Weight bearing Balance data

	group	N	Mean	Std. Deviation	p-value
Weight_Rt_V1	**Non Co-Walk**	31	50.8710	15.99113	0.535
	Co-Walk	31	48.7419	10.19793	
Weight_Lt_V1	**Non Co-Walk**	31	49.1290	15.99113	0.535
	Co-Walk	31	51.2581	10.25985	
Weight_Rt_V2	**Non Co-Walk**	31	50.6774	10.55584	0.958
	Co-Walk	31	50.5484	8.68654	
Weight_Lt_V2	**Non Co-Walk**	31	49.3226	10.55584	0.927
	Co-Walk	31	49.5484	8.59395	
Weight_Rt_V3	**Non Co-Walk**	31	50.2581	6.51136	0.827
	Co-Walk	31	49.9355	4.91213	
Weight_Lt_V3	**Non Co-Walk**	31	49.7419	6.51136	0.843
	Co-Walk	31	50.0323	4.89547	
Weight_Rt_V4	**Non Co-Walk**	31	50.0323	5.21206	0.930
	Co-Walk	31	50.1290	3.13839	
Weight_Lt_V4	**Non Co-Walk**	31	49.9677	5.21206	0.976
	Co-Walk	31	49.9355	3.09769	
Weight_Rt_V5	**Non Co-Walk**	31	50.0645	3.09769	0.812
	Co-Walk	31	50.2258	2.14024	
Weight_Lt_V5	**Non Co-Walk**	31	49.9355	3.09769	0.776
	Co-Walk	31	49.7419	2.15975	

* p-value in the table is obtain significantly different.

4.2 Discussion

In this study, was investigated the postoperative clinical outcomes of TKR patients using Co-walk. Variables measured during the study included ROM, the TUG, the WOMAC, weight-bearing balance, postural control, and LOS. it found no significant differences on a postoperative day 1 or postoperative day 2; but 2 weeks after surgery, found that the experimental group demonstrated significantly decreased time on the

TUG test. 2 weeks after the operation; we compared preoperative and postoperative WOMAC scores. Scores decreased in all 3 domains (pain, movement, and stiffness) and were significantly different at 2 weeks, 6 weeks, and 12 weeks. Moreover, subjects who used Co-walk after surgery showed improved knee function and improved walking performance at admission and 2 weeks compared with those who used the standard rehabilitation protocol. In addition, no adverse events occurred during the research. The results of this study were consistent with Wiliam D. et al. (William, Shantanu Patil, Nikolai Steklov,. Bugbee, 2013), who used the AlterG Anti-Gravity Treadmill in male and female subjects with mean ages of 66.5 years and 66.9 years, respectively, after posttraumatic, postmenopausal total knee arthroplasty (TKA). The study found that pain was reduced and knee function improved after surgery. Ahmed AR et al. (AR Ahmed, Abd-Elkader SM and Al-Obathani KS., 2010) studied a 6-week postoperative exercise program for patients following TKA; however, the study period was not long enough to restore walking abilities to their pre-surgery values. A longer period of rehabilitation is needed to improve the quality of the patient gait. Heike A. Bischoff and colleagues (A Heike. Bischoff, Hannes B. Stähelin, Andreas U. Monsch, Maura D. Iversen, Antje Weyh, Margot von Dechend, Regula Akos, Martin Conzelmann, Walter Dick, Robert Theiler, 2003) studied the cut-off time of the TUG test in community-dwelling and elderly women. They found that community-dwelling elderly women between 65 and 85 should be able to perform the timed up-and-go test in 12 seconds or less. We found that using Co-Walk after surgery can improve gait ability. Patients who used Co-Walk could walk faster, as measured by the TUG test (11.69 seconds), than patients who underwent normal rehabilitation after 6 weeks. Further study over a long-term period should be conducted.

CHAPTER V
CONCLUSION AND RECOMMENDATION

5.1 Conclusion

The results of this study demonstrate that the inclusion of the Co-walk device in the rehabilitation process following total knee replacement (TKR) surgery can lead to significant improvements in patients' clinical outcomes. Notably, the patients who underwent Co-walk training experienced reduced pain levels, improved range of motion in the knee joint, and increased balance and confidence while walking. These positive effects were observed consistently over multiple follow-up intervals, spanning from 2 weeks to 6 months after the surgery. Additionally, utilizing the Co-walk device resulted in a decreased length of hospital stay for the patients.

These findings present strong evidence in favor of incorporating the Co-walk into the standard rehabilitation protocols for TKR patients. By augmenting the recovery process and enhancing clinical outcomes, the Co-walk can be a valuable addition to the existing treatment methods for individuals who have undergone TKR surgery. This research underscores the potential of the Co-walk as an effective aid in accelerating patients' recuperation and overall improvement in their post-surgery condition.

In conclusion, the study supports the efficacy of using the Co-walk walking support machine as a complementary approach to traditional rehabilitation methods for TKR patients. It highlights the device's ability to bring about positive changes in pain levels, knee joint mobility, balance, and walking confidence. The Co-walk's inclusion in the rehabilitation process may offer significant benefits in terms of improved patient recovery and reduced hospital stay. Further research and implementation of the Co-walk in clinical settings could enhance post-TKR rehabilitation outcomes and ultimately enhance the quality of life for patients.

5.2 Recommendation

Based on the findings of this study, the following recommendations are made:

The use of Co-walk should be considered as an adjunct to standard rehabilitation protocols for patients who have undergone TKR. Incorporating Co-walk training into post-TKR rehabilitation may lead to improved clinical outcomes and faster recovery.

More extensive research is needed to confirm the long-term benefits of using Co-walk in patients who have undergone TKR. Longitudinal studies with larger sample sizes are essential to establish the sustained effectiveness of Co-walk over an extended period.

Further research is required to investigate the effects of Co-walk on other important clinical outcomes, such as pain management, functional capacity, and overall quality of life. Understanding the broader impact of Co-walk on these aspects will provide a more comprehensive assessment of its potential benefits.

5.3 future directions

The findings of this study underscore the importance of exploring Co-walk further through future research efforts:

Long-term follow-up: Longitudinal studies with extended follow-up periods are needed to ascertain the sustained benefits of Co-walk over time.

Comparative studies: Comparative studies with larger and more diverse patient populations can offer additional insights into the effectiveness of Co-walk compared to other rehabilitation approaches.

Quality of life assessments: Future research should include comprehensive assessments of patients' quality of life, including aspects beyond clinical measures, to understand the holistic impact of Co-walk on post-TKR patients.

By addressing these recommendations and future research directions, healthcare professionals can better understand the potential benefits and limitations of integrating Co-walk into post-TKR rehabilitation practices, leading to improved patient care and outcomes.

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APPENDIX A

CASE RECORD FORM (CRF)

Page 1 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

**CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)*

CASE RECORD FORM (CRF)

RANDOMIZED, DOUBLE-BLIND, CONTROL TRIAL STUDY TO COMPARE THE EFFICACY OF CLINICAL OUTCOMES OF USING AND NON-USING WALKING SUPPORT MACHINE TRAINING AFTER TOTAL KNEE REPLACEMENT (.....)

☐ CASE ☐ CONTROL

ID#__ __ __

**CONTROL ID TO BE MATCHED WITH CASE ID **

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****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

ตารางกิจกรรม

	VS	V0[a]	V1	V2	V3	V4	V5
Day	-7 to -1	D0[a]	D2+3	14 ± 7	42 ± 7	84±10	168±15
Week				2	6	12	24
Month					1.5	3	6
1. กระบวนการขอความยินยอม	x						
2. เก็บข้อมูลลักษณะประชากร (วันเกิด, เพศกำเนิด, น้ำหนัก, ส่วนสูง)	x				x[b]	x[b]	x[b]
3. การวินิจฉัยโรคข้อเสื่อม (Osteoarthritis))	x						
4. การประเมินความรุนแรงของโรคด้วยระบบขั้นเคแอล (Kellgren-Lawrence radiographic grading scale) [f.]	x						
5. ตรวจข้อเข่า (Knee Physical Examination) ได้แก่ การตรวจด้วยสายตา, การทดสอบ Range of Motion, Anterior Drawer, Valgus Test, Varus Test, Posterior Drawer, McMurray's Test, Balance Test, แรงในกล้ามเนื้อQuadriceps	x		x	x	x	x	x
6. ตรวจสอบเกณฑ์การคัดเข้า/คัดออก	x		x [f.]				
7. การสุ่ม (Randomization)			x				
8. สถานะการฟื้นตัวจากการผ่าตัดรักษา (Recovery status)			x	x	x	x	x
9. ประเมินระดับความเจ็บปวดของเข่า (Pain score)	x		x	x	x	x	x
10. ทดสอบ (Time on the timed up-and-go test)			x	x	x	x	x
11. **การประเมิน** Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)	x		x	x	x	x	x
12. **การประเมิน** Knee Society Score (ประกอบด้วย Function score และ Knee score)	x		x	x	x	x	x
13. เก็บข้อมูลการใช้ยาระงับปวดหรือคลายกล้ามเนื้อ	x[c]		x[d]	x	x	x	x
14. ใช้เครื่องพยุงต้านแรงโน้มถ่วง CoWalk [e]					x[g]		
15. **ความพึงพอใจ (Satisfaction)**						x	x
16. ข้อร้องเรียนทางเทคนิค (Technical complaints)					x		

หมายเหตุ: a. V0 หรือ D0 จะเป็นเวลาที่ผู้ป่วยได้รับการผ่าตัดข้อเข่า b. เฉพาะน้ำหนักและส่วนสูง c. เก็บรวบรวมการใช้ยาระงับปวดหรือคลายกล้ามเนื้อใช้มาภายใน 1 เดือนก่อน D0 d. เก็บรวบรวมการใช้ยาระงับปวดหรือคลายกล้ามเนื้อใช้นับจากเวลาที่การผ่าตัดเสร็จสิ้นจนถึงวันที่ออกจากโรงพยาบาล e. เฉพาะกลุ่มทดลอง โดยใช้ตลอดการทำกายภาพบำบัดจนกระทั่งกลับมาหายเป็นปกติหรือจนกว่าจะสิ้นสุดการศึกษา ขึ้นกับว่าสิ่งใดเกิดขึ้นก่อน. f. ตรวจสอบอีกครั้งก่อนทำการสุ่ม **g. ใช้เครื่องช่วยพยุงเป็นเวลา 15-20 นาที**

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****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

VS

Day -7 to -1

	Variable	Data	code
1	กระบวนการขอความยินยอม		
1.1	ICF date (dd/mmm/yyyy)	__ __ / __ __ __ / __ __ __ __ Investigator who obtained consent signature/date _____date_____	ICF
2	เก็บข้อมูลลักษณะประชากร		
2.1	Biological sex	☐ 1. Male ☐ 2. Female	sex
2.2	Date of birth (dd/mmm/yyyy)	__ __ / __ __ __ / __ __ __ __	DOB
2.3	RACE	☐ 1. Thai ☐ 2. Other	Race
2.4	Occupation	☐ 1. Farmer / Agriculture (ทำนา ทำเกษตรกรรม) ☐ 2. Officer (พนง. ออฟฟิต ธนาคาร) ☐ 3. Worker (ใช้แรงงาน) ☐ 4. Nurse (พยาบาล) ☐ 5. Other (อื่นๆ) โปรดระบุ.....	OCC
2.5	Operative date	__ __ / __ __ __ / __ __ __ __	date_OP
2.6	Weight (Kg)	__ __ __ kg.	wt
2.7	Height (cm)	__ __ __ cm.	ht
3	Inclusion criteria		
3.1	Inclusion	☐ CASE 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_case01 Inc_case02

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****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ CONTROL 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยไม่ใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_con01 Inc_con02
4	Knee Physical Examination		
4.1	ROM	...../.....	ROM
4.2	Pain score		Pain score
4.3	Gait aids	ขณะอยู่ที่บ้านผู้ป่วยได้ใช้อุปกรณ์ช่วยเดินหรือไม่ ☐ ใช้ ☐ ไม่ใช้ O Walker O 1-point cane O 3-point cane O 4-point cane O Crutches เวลาทิ้งไม้ ..... สัปดาห์	Gait aids
4.4	Balance	**Weight bearing** Left..... Right..... **Postural control** .....% to Lt / Rt .....% to Ant. / Post. Std. dev.	Weight bearing Postural control
4.5	Quadriceps Force	..... mV	Q. Force
5	Knee Society Score		
5.1	Knee score	**1. Pain อาการเจ็บ ใน 4 สัปดาห์ที่ผ่านมา** ☐ None (ไม่เจ็บเลย) ☐ Mild / Occasional (มีอาการเจ็บเล็กน้อย เป็นบางครั้งคราว) ☐ Mild (Stairs only) (เจ็บเล็กน้อยเวลาขึ้นบันไดเท่านั้น) ☐ Mild (Walking and Stairs) (เจ็บเล็กน้อยเวลาเดินและขึ้นบันได)	

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****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ Moderate – Occasional (มีอาการเจ็บ บ่อยๆ) ☐ Moderate – Continual (มีอาการเจ็บตลอดเวลา) ☐ Severe (มีอาการเจ็บอย่างมาก) **2. Flexion Contracture If present** ☐ 5°-10° ☐ 10°-15° ☐ 15°-20° ☐ $>20^{\circ}$ **3. Extension lag** ☐ $<10^{\circ}$ ☐ 10°-20° ☐ $>20^{\circ}$ **4. Total Range of Flexion** ☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐ 51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 86-90 ☐ 91-95 ☐ 96-100 ☐ 101-105 ☐ 106-110 ☐ 111-115 ☐ 116-120 ☐ 121-125 **5. Anteroposterior** ☐ <5 mm ☐ 5-10 mm ☐ 10+ mm **6. Alignment (Varus & Valgus)** ☐ 0° ☐ 1° ☐ 2° ☐ 3° ☐ 4° ☐ 5-10° ☐ 11° ☐ 12° ☐ 13° ☐ 14° ☐ 15° ☐ Over 15° **7. Mediolateral** ☐ $<5^{\circ}$ ☐ 6°-9° ☐ 10-14° Final Knee Score is _____	
5.2	Function Score	**1. Walking** ☐ Unlimited ☐ >10 blocks (มากกว่า 800 เมตร) ☐ 5-10 blocks (มากกว่า 400 แต่น้อยกว่า 800 เมตร) ☐ <5 blocks (น้อยกว่า 400 เมตร) ☐ Housebound (เฉพาะในบ้าน) ☐ Unable (ไม่สามารถเดินได้) **2. Stairs (การขึ้นลงบันได)** ☐ Normal Up and Down (ขึ้นลงได้ปกติ) ☐ Normal Up and Down with rail (ขึ้นลงได้ปกติด้วยการจับราวบันได) ☐ Up and Down with rail (ขึ้นลงได้ด้วยการจับราวบันได) ☐ Up with rail, down unable (ขึ้นได้ด้วยการจับราวบันได แต่ลงไม่ได้)	

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****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

<table>
<tr><th></th><th>Variable</th><th>Data</th><th>code</th></tr>
<tr><td></td><td></td><td>☐ Unable (ขึ้นและลงไม่ได้)
3. Walking aids used (การใช้เครื่องช่วยเดิน)
☐ None used (ไม่ต้องใช้)
☐ Use of Cane/Walking stick deduct (ใช้ไม้เท้า/ไม้ค้ำยันเพียงข้างเดียว)
☐ Two Canes/sticks (ใช้ไม้เท้า/ไม้ค้ำยัน ทั้งสองข้าง)
☐ Crutches or frame (ใช้เครื่องช่วยเดิน 4 ขา)
Functional Score (Knee Society score) is _____</td><td></td></tr>
<tr><td>6</td><td colspan="3">The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)</td></tr>
<tr><td></td><td colspan="3">ให้ผู้ป่วยประเมิน แล้วบันทึกระดับความเจ็บปวดตามที่ผู้ป่วยบอก (วงกลมเลือก)
โดย 0 = ไม่, 1 = เล็กน้อย, 2 = ปานกลาง, 3 = มาก, 4= มากที่สุด</td></tr>
</table>

อาการปวด	1. เดินบนพื้นราบ	0	1	2	3	4
	2. เดินขึ้นบันได	0	1	2	3	4
	3. ขณะนอนบนเตียงตอนกลางคืน	0	1	2	3	4
	4. ขณะลุกนั่ง	0	1	2	3	4
	5. ขณะยืนลงน้ำหนัก	0	1	2	3	4
อาการฝืดข้อ ข้อตึง	6. เมื่อตื่นนอนตอนเช้า	0	1	2	3	4
	7. ขณะเปลี่ยนอิริยาบถระหว่างวัน	0	1	2	3	4
การใช้งานข้อในการทำกิจวัตรประจำวัน	8. เดินลงบันได	0	1	2	3	4
	9. เดินขึ้นบันได	0	1	2	3	4
	10. ลุกยืนจากท่านั่ง	0	1	2	3	4
	11. ขณะยืน	0	1	2	3	4
	12. ก้มตัว	0	1	2	3	4
	13. เดินบนพื้นราบ	0	1	2	3	4
	14. ขึ้น ลง รถ	0	1	2	3	4
	15. ไปซื้อของที่ตลาด ร้านค้า	0	1	2	3	4
	16. ใส่ถุงเท้า	0	1	2	3	4
	17. นอนบนเตียง	0	1	2	3	4
	18. ถอดถุงเท้า	0	1	2	3	4
	19. ลุกจากเตียง	0	1	2	3	4
	20. เข้า-ออกจากห้องน้ำ	0	1	2	3	4

Page 7 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data						code
		21. Sitting	0	1	2	3	4	
		22. ลุกเข้า-ออกจากส้วม	0	1	2	3	4	
		23. ทำงานบ้านหนัก	0	1	2	3	4	
		24. ทำงานบ้านเบา	0	1	2	3	4	

Recorder/interviewer Signed/date _____

Page 8 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

V0

Day 0

	Variable	Data	code
1	Inclusion criteria		
1.1	Inclusion	☐ CASE 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_case01 Inc_case02
		☐ CONTROL 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยไม่ใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_con01 Inc_con02

Recorder/interviewer Signed/date _____

Page 9 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

V1

Day 2+3

	Variable	Data	code
1	Knee Physical Examination		
1.1	ROM	...../.....	ROM
1.2	Pain score		Pain score
1.3	Gait aids	ขณะอยู่ที่บ้านผู้ป่วยได้ใช้อุปกรณ์ช่วยเดินหรือไม่ ☐ ใช้ ☐ ไม่ใช้ O Walker O 1-point cane O 3-point cane O 4-point cane O Crutches เวลาทิ้งไม้ ..... สัปดาห์	Gait aids
1.4	Balance	**Weight bearing** Left..... Right..... **Postural control** .....% to Lt / Rt .....% to Ant. / Post. Std. dev.	Weight bearing Postural control
1.5	Quadriceps Force	..... mV	Q. Force
2	Knee Society Score		
2.1	Knee score	**1. Pain อาการเจ็บ ใน 4 สัปดาห์ที่ผ่านมา** ☐ None (ไม่เจ็บเลย) ☐ Mild / Occasional (มีอาการเจ็บเล็กน้อย เป็นบางครั้งคราว) ☐ Mild (Stairs only) (เจ็บเล็กน้อยเวลาขึ้นบันไดเท่านั้น) ☐ Mild (Walking and Stairs) (เจ็บเล็กน้อยเวลาเดินและขึ้นบันได) ☐ Moderate – Occasional (มีอาการเจ็บ บ่อยๆ)	

Page 10 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ Moderate – Continual (มีอาการเจ็บตลอดเวลา) ☐ Severe (มีอาการเจ็บอย่างมาก) **2. Flexion Contracture If present** ☐ 5°-10° ☐ 10°-15° ☐ 15°-20° ☐ >20° **3. Extension lag** ☐ <10° ☐ 10°-20° ☐ >20° **4. Total Range of Flexion** ☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐ 51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 86-90 ☐ 91-95 ☐ 96-100 ☐ 101-105 ☐ 106-110 ☐ 111-115 ☐ 116-120 ☐ 121-125 **5. Anteroposterior** ☐ <5 mm ☐ 5-10 mm ☐ 10+ mm **6. Alignment (Varus & Valgus)** ☐ 0° ☐ 1° ☐ 2° ☐ 3° ☐ 4° ☐ 5-10° ☐ 11° ☐ 12° ☐ 13° ☐ 14° ☐ 15° ☐ Over 15° **7. Mediolateral** ☐ <5° ☐ 6°-9° ☐ 10-14° **Final Knee Score is** _____	
2.2	Function Score	1. **Walking** ☐ Unlimited ☐ >10 blocks (มากกว่า 800 เมตร) ☐ 5-10 blocks (มากกว่า 400 แต่น้อยกว่า 800 เมตร) ☐ <5 blocks (น้อยกว่า 400 เมตร) ☐ Housebound (เฉพาะในบ้าน) ☐ Unable (ไม่สามารถเดินได้) 2. **Stairs (การขึ้นลงบันได)** ☐ Normal Up and Down (ขึ้นลงได้ปกติ) ☐ Normal Up and Down with rail (ขึ้นลงได้ปกติด้วยการจับราวบันได) ☐ Up and Down with rail (ขึ้นลงได้ด้วยการจับราวบันได) ☐ Up with rail, down unable (ขึ้นได้ด้วยการจับราวบันได แต่ลงไม่ได้) ☐ Unable (ขึ้นและลงไม่ได้)	

Page 11 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		3. Walking aids used (การใช้เครื่องช่วยเดิน) ☐ None used (ไม่ต้องใช้) ☐ Use of Cane/Walking stick deduct (ใช้ไม้เท้า/ไม้ค้ำยันเพียงข้างเดียว) ☐ Two Canes/sticks (ใช้ไม้เท้า/ไม้ค้ำยัน ทั้งสองข้าง) ☐ Crutches or frame (ใช้เครื่องช่วยเดิน 4 ขา) **Functional Score (Knee Society score) is _____**	
3	**The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)**		

ให้ผู้ป่วยประเมิน แล้วบันทึกระดับความเจ็บปวดตามที่ผู้ป่วยบอก (วงกลมเลือก)

โดย 0 = ไม่, 1 = เล็กน้อย, 2 = ปานกลาง, 3 = มาก, 4= มากที่สุด

อาการปวด	1. เดินบนพื้นราบ	0	1	2	3	4
	2. เดินขึ้นบันได	0	1	2	3	4
	3. ขณะนอนบนเตียงตอนกลางคืน	0	1	2	3	4
	4. ขณะลุกนั่ง	0	1	2	3	4
	5. ขณะยืนลงน้ำหนัก	0	1	2	3	4
อาการฝืดข้อ ข้อตึง	6. เมื่อตื่นนอนตอนเช้า	0	1	2	3	4
	7. ขณะเปลี่ยนอิริยาบถระหว่างวัน	0	1	2	3	4
การใช้งานข้อในการทำกิจวัตรประจำวัน	8. เดินลงบันได	0	1	2	3	4
	9. เดินขึ้นบันได	0	1	2	3	4
	10. ลุกยืนจากท่านั่ง	0	1	2	3	4
	11. ขณะยืน	0	1	2	3	4
	12. ก้มตัว	0	1	2	3	4
	13. เดินบนพื้นราบ	0	1	2	3	4
	14. ขึ้น ลง รถ	0	1	2	3	4
	15. ไปซื้อของที่ตลาด ร้านค้า	0	1	2	3	4
	16. ใส่ถุงเท้า	0	1	2	3	4
	17. นอนบนเตียง	0	1	2	3	4
	18. ถอดถุงเท้า	0	1	2	3	4
	19. ลุกจากเตียง	0	1	2	3	4
	20. เข้า-ออกจากห้องน้ำ	0	1	2	3	4
	21. Sitting	0	1	2	3	4

Page 12 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data						code
		22. ลุกเข้า-ออกจากส้วม	0	1	2	3	4	
		23. ทำงานบ้านหนัก	0	1	2	3	4	
		24. ทำงานบ้านเบา	0	1	2	3	4	

Recorder/interviewer Signed/date _____

Page 13 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

V2

Day 14 + 7

	Variable	Data	code
1	Knee Physical Examination		
1.1	ROM	...../.....	ROM
1.2	Pain score		Pain score
1.3	Gait aids	ขณะอยู่ที่บ้านผู้ป่วยได้ใช้อุปกรณ์ช่วยเดินหรือไม่ ☐ ใช้ ☐ ไม่ใช้ O Walker O 1-point cane O 3-point cane O 4-point cane O Crutches เวลาทิ้งไม้ ..... สัปดาห์	Gait aids
1.4	Balance	**Weight bearing** Left..... Right..... **Postural control** .....% to Lt / Rt .....% to Ant. / Post. Std. dev.	Weight bearing Postural control
1.5	Quadriceps Force	..... mV	Q. Force
2	Knee Society Score		
2.1	Knee score	1. **Pain อาการเจ็บ ใน 4 สัปดาห์ที่ผ่านมา** ☐ None (ไม่เจ็บเลย) ☐ Mild / Occasional (มีอาการเจ็บเล็กน้อย เป็นบางครั้งคราว) ☐ Mild (Stairs only) (เจ็บเล็กน้อยเวลาขึ้นบันไดเท่านั้น) ☐ Mild (Walking and Stairs) (เจ็บเล็กน้อยเวลาเดินและขึ้นบันได) ☐ Moderate – Occasional (มีอาการเจ็บ บ่อยๆ)	

Page 14 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ Moderate – Continual (มีอาการเจ็บตลอดเวลา) ☐ Severe (มีอาการเจ็บอย่างมาก) 2. Flexion Contracture If present ☐ 5°-10° ☐ 10°-15° ☐ 15°-20° ☐ >20° 3. Extension lag ☐ <10° ☐ 10°-20° ☐ >20° 4. Total Range of Flexion ☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐ 51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 86-90 ☐ 91-95 ☐ 96-100 ☐ 101-105 ☐ 106-110 ☐ 111-115 ☐ 116-120 ☐ 121-125 5. Anteroposterior ☐ <5 mm ☐ 5-10 mm ☐ 10+ mm 6. Alignment (Varus & Valgus) ☐ 0° ☐ 1° ☐ 2° ☐ 3° ☐ 4° ☐ 5-10° ☐ 11° ☐ 12° ☐ 13° ☐ 14° ☐ 15° ☐ Over 15° 7. Mediolateral ☐ <5° ☐ 6°-9° ☐ 10-14° Final Knee Score is _____	
2.2	Function Score	1. Walking ☐ Unlimited ☐ >10 blocks (มากกว่า 800 เมตร) ☐ 5-10 blocks (มากกว่า 400 แต่น้อยกว่า 800 เมตร) ☐ <5 blocks (น้อยกว่า 400 เมตร) ☐ Housebound (เฉพาะในบ้าน) ☐ Unable (ไม่สามารถเดินได้) 2. Stairs (การขึ้นลงบันได) ☐ Normal Up and Down (ขึ้นลงได้ปกติ) ☐ Normal Up and Down with rail (ขึ้นลงได้ปกติด้วยการจับราวบันได) ☐ Up and Down with rail (ขึ้นลงได้ด้วยการจับราวบันได) ☐ Up with rail, down unable (ขึ้นได้ด้วยการจับราวบันได แต่ลงไม่ได้) ☐ Unable (ขึ้นและลงไม่ได้)	

Page 15 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		3. Walking aids used (การใช้เครื่องช่วยเดิน) ☐ None used (ไม่ต้องใช้) ☐ Use of Cane/Walking stick deduct (ใช้ไม้เท้า/ไม้ค้ายันเพียงข้างเดียว) ☐ Two Canes/sticks (ใช้ไม้เท้า/ไม้ค้ายัน ทั้งสองข้าง) ☐ Crutches or frame (ใช้เครื่องช่วยเดิน 4 ขา) **Functional Score (Knee Society score) is _____**	
3	**The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)**		

ให้ผู้ป่วยประเมิน แล้วบันทึกระดับความเจ็บปวดตามที่ผู้ป่วยบอก (วงกลมเลือก)

โดย 0 = ไม่, 1 = เล็กน้อย, 2 = ปานกลาง, 3 = มาก, 4= มากที่สุด

อาการปวด	1. เดินบนพื้นราบ	0	1	2	3	4
	2. เดินขึ้นบันได	0	1	2	3	4
	3. ขณะนอนบนเตียงตอนกลางคืน	0	1	2	3	4
	4. ขณะลุกนั่ง	0	1	2	3	4
	5. ขณะยืนลงน้ำหนัก	0	1	2	3	4
อาการฝืดข้อ ข้อตึง	6. เมื่อตื่นนอนตอนเช้า	0	1	2	3	4
	7. ขณะเปลี่ยนอิริยาบถระหว่างวัน	0	1	2	3	4
การใช้งานข้อในการทำกิจวัตรประจำวัน	8. เดินลงบันได	0	1	2	3	4
	9. เดินขึ้นบันได	0	1	2	3	4
	10. ลุกยืนจากท่านั่ง	0	1	2	3	4
	11. ขณะยืน	0	1	2	3	4
	12. ก้มตัว	0	1	2	3	4
	13. เดินบนพื้นราบ	0	1	2	3	4
	14. ขึ้น ลง รถ	0	1	2	3	4
	15. ไปซื้อของที่ตลาด ร้านค้า	0	1	2	3	4
	16. ใส่ถุงเท้า	0	1	2	3	4
	17. นอนบนเตียง	0	1	2	3	4
	18. ถอดถุงเท้า	0	1	2	3	4
	19. ลุกจากเตียง	0	1	2	3	4
	20. เข้า-ออกจากห้องน้ำ	0	1	2	3	4
	21. Sitting	0	1	2	3	4

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****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data						code
		22. ลุกเข้า-ออกจากส้วม	0	1	2	3	4	
		23. ทำงานบ้านหนัก	0	1	2	3	4	
		24. ทำงานบ้านเบา	0	1	2	3	4	

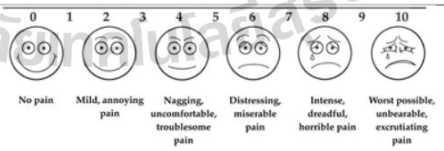
Recorder/interviewer Signed/date _____

Page 17 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

V3

Day 42 + 7

	Variable	Data	code
1	เก็บข้อมูลลักษณะประชากร		
1.1	Weight (Kg)	__ __ __ kg.	wt
1.2	Height (cm)	__ __ __ cm.	ht
2	Inclusion criteria		
2.1	Inclusion	☐ CASE 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_case01 Inc_case02
		☐ CONTROL 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยไม่ใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_con01 Inc_con02
3	Knee Physical Examination		
3.1	ROM	...../.....	ROM
3.2	Pain score		Pain score
3.3	Gait aids	ขณะอยู่ที่บ้านผู้ป่วยได้ใช้อุปกรณ์ช่วยเดินหรือไม่ ☐ ใช้ ☐ ไม่ใช้ O Walker O 1-point cane O 3-point cane	Gait aids

Page 18 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		O 4-point cane O Crutches เวลาทิ้งไม้ ..... สัปดาห์	
3.4	Balance	**Weight bearing** Left..... Right..... **Postural control** .....% to Lt / Rt .....% to Ant. / Post. Std. dev.	Weight bearing Postural control
3.5	Quadriceps Force	..... mV	Q. Force
4	Knee Society Score		
4.1	Knee score	**1. Pain อาการเจ็บ ใน 4 สัปดาห์ที่ผ่านมา** ☐ None (ไม่เจ็บเลย) ☐ Mild / Occasional (มีอาการเจ็บเล็กน้อย เป็นบางครั้งคราว) ☐ Mild (Stairs only) (เจ็บเล็กน้อยเวลาขึ้นบันไดเท่านั้น) ☐ Mild (Walking and Stairs) (เจ็บเล็กน้อยเวลาเดินและขึ้นบันได) ☐ Moderate – Occasional (มีอาการเจ็บ บ่อยๆ) ☐ Moderate – Continual (มีอาการเจ็บตลอดเวลา) ☐ Severe (มีอาการเจ็บอย่างมาก) **2. Flexion Contracture If present** ☐ 5°-10° ☐ 10°-15° ☐ 15°-20° ☐ >20° **3. Extension lag** ☐ <10° ☐ 10°-20° ☐ >20° **4. Total Range of Flexion** ☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐ 51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 86-90 ☐ 91-95 ☐ 96-100 ☐ 101-105 ☐ 106-110 ☐ 111-115 ☐ 116-120 ☐ 121-125 **5. Anteroposterior** ☐ <5 mm ☐ 5-10 mm ☐ 10+ mm **6. Alignment (Varus & Valgus)** ☐ 0° ☐ 1° ☐ 2° ☐ 3° ☐ 4° ☐ 5-10° ☐ 11° ☐ 12° ☐ 13° ☐ 14° ☐ 15° ☐ Over 15° **7. Mediolateral**	

Page 19 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ <5° ☐ 6°-9° ☐ 10-14° **Final Knee Score is** _____	
4.2	Function Score	1. **Walking** ☐ Unlimited ☐ >10 blocks (มากกว่า 800 เมตร) ☐ 5-10 blocks (มากกว่า 400 แต่น้อยกว่า 800 เมตร) ☐ <5 blocks (น้อยกว่า 400 เมตร) ☐ Housebound (เฉพาะในบ้าน) ☐ Unable (ไม่สามารถเดินได้) 2. **Stairs (การขึ้นลงบันได)** ☐ Normal Up and Down (ขึ้นลงได้ปกติ) ☐ Normal Up and Down with rail (ขึ้นลงได้ปกติด้วยการจับราวบันได) ☐ Up and Down with rail (ขึ้นลงได้ด้วยการจับราวบันได) ☐ Up with rail, down unable (ขึ้นได้ด้วยการจับราวบันได แต่ลงไม่ได้) ☐ Unable (ขึ้นและลงไม่ได้) 3. **Walking aids used (การใช้เครื่องช่วยเดิน)** ☐ None used (ไม่ต้องใช้) ☐ Use of Cane/Walking stick deduct (ใช้ไม้เท้า/ไม้ค้ำยันเพียงข้างเดียว) ☐ Two Canes/sticks (ใช้ไม้เท้า/ไม้ค้ำยัน ทั้งสองข้าง) ☐ Crutches or frame (ใช้เครื่องช่วยเดิน 4 ขา) **Functional Score (Knee Society score) is** ____	
5	The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)		

ให้ผู้ป่วยประเมิน แล้วบันทึกระดับความเจ็บปวดตามที่ผู้ป่วยบอก (วงกลมเลือก)

โดย 0 = ไม่, 1 = เล็กน้อย, 2 = ปานกลาง, 3 = มาก, 4= มากที่สุด

อาการปวด	1. เดินบนพื้นราบ	0	1	2	3	4
	2. เดินขึ้นบันได	0	1	2	3	4
	3. ขณะนอนบนเตียงตอนกลางคืน	0	1	2	3	4
	4. ขณะลุกนั่ง	0	1	2	3	4
	5. ขณะยืนลงน้ำหนัก	0	1	2	3	4

Page 20 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data						code
	อาการฝืดข้อ ข้อตึง	6. เมื่อตื่นนอนตอนเช้า	0	1	2	3	4	
		7. ขณะเปลี่ยนอิริยาบถระหว่างวัน	0	1	2	3	4	
	การใช้งานข้อในการทำกิจวัตรประจำวัน	8. เดินลงบันได	0	1	2	3	4	
		9. เดินขึ้นบันได	0	1	2	3	4	
		10. ลุกยืนจากท่านั่ง	0	1	2	3	4	
		11. ขณะยืน	0	1	2	3	4	
		12. ก้มตัว	0	1	2	3	4	
		13. เดินบนพื้นราบ	0	1	2	3	4	
		14. ขึ้น ลง รถ	0	1	2	3	4	
		15. ไปซื้อของที่ตลาด ร้านค้า	0	1	2	3	4	
		16. ใส่ถุงเท้า	0	1	2	3	4	
		17. นอนบนเตียง	0	1	2	3	4	
		18. ถอดถุงเท้า	0	1	2	3	4	
		19. ลุกจากเตียง	0	1	2	3	4	
		20. เข้า-ออกจากห้องน้ำ	0	1	2	3	4	
		21. Sitting	0	1	2	3	4	
		22. ลุกเข้า-ออกจากส้วม	0	1	2	3	4	
		23. ทำงานบ้านหนัก	0	1	2	3	4	
		24. ทำงานบ้านเบา	0	1	2	3	4	

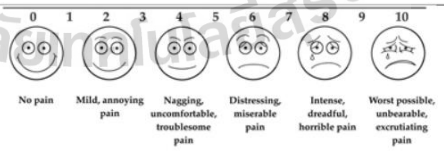
Recorder/interviewer Signed/date _____

Page 21 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

V4

Day 84+10

	Variable	Data	code
1	เก็บข้อมูลลักษณะประชากร		
1.1	Weight (Kg)	__ __ __ kg.	wt
1.2	Height (cm)	__ __ __ cm.	ht
2	Inclusion criteria		
2.1	Inclusion	☐ CASE 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_case01 Inc_case02
		☐ CONTROL 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยไม่ใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_con01 Inc_con02
3	Knee Physical Examination		
3.1	ROM	...../.....	ROM
3.2	Pain score		Pain score
3.3	Gait aids	ขณะอยู่ที่บ้านผู้ป่วยได้ใช้อุปกรณ์ช่วยเดินหรือไม่ ☐ ใช้ ☐ ไม่ใช้ O Walker O 1-point cane O 3-point cane	Gait aids

Page 22 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		O 4-point cane O Crutches เวลาทิ้งไม้ ..... สัปดาห์	
3.4	Balance	**Weight bearing** Left..... Right..... **Postural control** .....% to Lt / Rt .....% to Ant. / Post. Std. dev.	Weight bearing Postural control
3.5	Quadriceps Force	..... mV	Q. Force
4	Knee Society Score		
4.1	Knee score	**1. Pain อาการเจ็บ ใน 4 สัปดาห์ที่ผ่านมา** ☐ None (ไม่เจ็บเลย) ☐ Mild / Occasional (มีอาการเจ็บเล็กน้อย เป็นบางครั้งคราว) ☐ Mild (Stairs only) (เจ็บเล็กน้อยเวลาขึ้นบันไดเท่านั้น) ☐ Mild (Walking and Stairs) (เจ็บเล็กน้อยเวลาเดินและขึ้นบันได) ☐ Moderate – Occasional (มีอาการเจ็บ บ่อยๆ) ☐ Moderate – Continual (มีอาการเจ็บตลอดเวลา) ☐ Severe (มีอาการเจ็บอย่างมาก) **2. Flexion Contracture If present** ☐ 5°-10° ☐ 10°-15° ☐ 15°-20° ☐ $>20^{\circ}$ **3. Extension lag** ☐ $<10^{\circ}$ ☐ 10°-20° ☐ $>20^{\circ}$ **4. Total Range of Flexion** ☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐ 51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 86-90 ☐ 91-95 ☐ 96-100 ☐ 101-105 ☐ 106-110 ☐ 111-115 ☐ 116-120 ☐ 121-125 **5. Anteroposterior** ☐ <5 mm ☐ 5-10 mm ☐ 10+ mm **6. Alignment (Varus & Valgus)** ☐ 0° ☐ 1° ☐ 2° ☐ 3° ☐ 4° ☐ 5-10° ☐ 11° ☐ 12° ☐ 13° ☐ 14° ☐ 15° ☐ Over 15° **7. Mediolateral**	

Page 23 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ <5° ☐ 6°-9° ☐ 10-14° **Final Knee Score is** _____	
4.2	Function Score	1. **Walking** ☐ Unlimited ☐ >10 blocks (มากกว่า 800 เมตร) ☐ 5-10 blocks (มากกว่า 400 แต่น้อยกว่า 800 เมตร) ☐ <5 blocks (น้อยกว่า 400 เมตร) ☐ Housebound (เฉพาะในบ้าน) ☐ Unable (ไม่สามารถเดินได้) 2. **Stairs (การขึ้นลงบันได)** ☐ Normal Up and Down (ขึ้นลงได้ปกติ) ☐ Normal Up and Down with rail (ขึ้นลงได้ปกติด้วยการจับราวบันได) ☐ Up and Down with rail (ขึ้นลงได้ด้วยการจับราวบันได) ☐ Up with rail, down unable (ขึ้นได้ด้วยการจับราวบันได แต่ลงไม่ได้) ☐ Unable (ขึ้นและลงไม่ได้) 3. **Walking aids used (การใช้เครื่องช่วยเดิน)** ☐ None used (ไม่ต้องใช้) ☐ Use of Cane/Walking stick deduct (ใช้ไม้เท้า/ไม้ค้ำยันเพียงข้างเดียว) ☐ Two Canes/sticks (ใช้ไม้เท้า/ไม้ค้ำยัน ทั้งสองข้าง) ☐ Crutches or frame (ใช้เครื่องช่วยเดิน 4 ขา) **Functional Score (Knee Society score) is** _____	
5	The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)		

ให้ผู้ป่วยประเมิน แล้วบันทึกระดับความเจ็บปวดตามที่ผู้ป่วยบอก (วงกลมเลือก)

โดย 0 = ไม่, 1 = เล็กน้อย, 2 = ปานกลาง, 3 = มาก, 4= มากที่สุด

อาการปวด	1. เดินบนพื้นราบ	0	1	2	3	4
	2. เดินขึ้นบันได	0	1	2	3	4
	3. ขณะนอนบนเตียงตอนกลางคืน	0	1	2	3	4
	4. ขณะลุกนั่ง	0	1	2	3	4
	5. ขณะยืนลงน้ำหนัก	0	1	2	3	4

Page 24 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data						code
	อาการฝืดข้อ ข้อตึง	6. เมื่อตื่นนอนตอนเช้า	0	1	2	3	4	
		7. ขณะเปลี่ยนอิริยาบถระหว่างวัน	0	1	2	3	4	
	การใช้งานข้อในการทำกิจวัตรประจำวัน	8. เดินลงบันได	0	1	2	3	4	
		9. เดินขึ้นบันได	0	1	2	3	4	
		10. ลุกยืนจากท่านั่ง	0	1	2	3	4	
		11. ขณะยืน	0	1	2	3	4	
		12. ก้มตัว	0	1	2	3	4	
		13. เดินบนพื้นราบ	0	1	2	3	4	
		14. ขึ้น ลง รถ	0	1	2	3	4	
		15. ไปซื้อของที่ตลาด ร้านค้า	0	1	2	3	4	
		16. ใส่ถุงเท้า	0	1	2	3	4	
		17. นอนบนเตียง	0	1	2	3	4	
		18. ถอดถุงเท้า	0	1	2	3	4	
		19. ลุกจากเตียง	0	1	2	3	4	
		20. เข้า-ออกจากห้องน้ำ	0	1	2	3	4	
		21. Sitting	0	1	2	3	4	
		22. ลุกเข้า-ออกจากส้วม	0	1	2	3	4	
		23. ทำงานบ้านหนัก	0	1	2	3	4	
		24. ทำงานบ้านเบา	0	1	2	3	4	

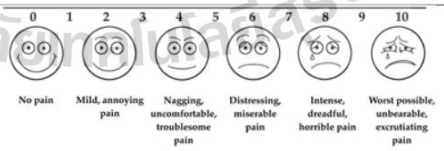
Recorder/interviewer Signed/date _____

Page 25 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

V5

Day 84+10

	Variable	Data	code
1	เก็บข้อมูลลักษณะประชากร		
1.1	Weight (Kg)	__ __ __ kg.	wt
1.2	Height (cm)	__ __ __ cm.	ht
2	Inclusion criteria		
2.1	Inclusion	☐ CASE 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_case01 Inc_case02
		☐ CONTROL 1. ผู้ป่วยผ่าตัดเปลี่ยนข้อเข่าเทียมที่ได้รับฟื้นฟูร่างกายโดยไม่ใช้เครื่องช่วยพยุง CoWalk ☐ 1.Yes ☐ 2. No 2. ลงนามยินยอมเข้าร่วมการวิจัย ได้ด้วยตนเอง ☐ 1.Yes ☐ 2. No	Inc_con01 Inc_con02
3	Knee Physical Examination		
3.1	ROM	...../.....	ROM
3.2	Pain score		Pain score
3.3	Gait aids	ขณะอยู่ที่บ้านผู้ป่วยได้ใช้อุปกรณ์ช่วยเดินหรือไม่ ☐ ใช้ ☐ ไม่ใช้ O Walker O 1-point cane O 3-point cane	Gait aids

Page 26 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		O 4-point cane O Crutches เวลาทิ้งไม้ ..... สัปดาห์	
3.4	Balance	**Weight bearing** Left..... Right..... **Postural control** .....% to Lt / Rt .....% to Ant. / Post. Std. dev.	Weight bearing Postural control
3.5	Quadriceps Force	..... mV	Q. Force
4	Knee Society Score		
4.1	Knee score	**1. Pain อาการเจ็บ ใน 4 สัปดาห์ที่ผ่านมา** ☐ None (ไม่เจ็บเลย) ☐ Mild / Occasional (มีอาการเจ็บเล็กน้อย เป็นบางครั้งคราว) ☐ Mild (Stairs only) (เจ็บเล็กน้อยเวลาขึ้นบันไดเท่านั้น) ☐ Mild (Walking and Stairs) (เจ็บเล็กน้อยเวลาเดินและขึ้นบันได) ☐ Moderate – Occasional (มีอาการเจ็บ บ่อยๆ) ☐ Moderate – Continual (มีอาการเจ็บตลอดเวลา) ☐ Severe (มีอาการเจ็บอย่างมาก) **2. Flexion Contracture If present** ☐ 5°-10° ☐ 10°-15° ☐ 15°-20° ☐ $>20^{\circ}$ **3. Extension lag** ☐ $<10^{\circ}$ ☐ 10°-20° ☐ $>20^{\circ}$ **4. Total Range of Flexion** ☐ 0-5 ☐ 6-10 ☐ 11-15 ☐ 16-20 ☐ 21-25 ☐ 26-30 ☐ 31-35 ☐ 36-40 ☐ 41-45 ☐ 46-50 ☐ 51-55 ☐ 56-60 ☐ 61-65 ☐ 66-70 ☐ 71-75 ☐ 76-80 ☐ 81-85 ☐ 86-90 ☐ 91-95 ☐ 96-100 ☐ 101-105 ☐ 106-110 ☐ 111-115 ☐ 116-120 ☐ 121-125 **5. Anteroposterior** ☐ <5 mm ☐ 5-10 mm ☐ 10+ mm **6. Alignment (Varus & Valgus)** ☐ 0° ☐ 1° ☐ 2° ☐ 3° ☐ 4° ☐ 5-10° ☐ 11° ☐ 12° ☐ 13° ☐ 14° ☐ 15° ☐ Over 15° **7. Mediolateral**	

Page 27 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data	code
		☐ <5° ☐ 6°-9° ☐ 10-14° **Final Knee Score is** _____	
4.2	Function Score	1. **Walking** ☐ Unlimited ☐ >10 blocks (มากกว่า 800 เมตร) ☐ 5-10 blocks (มากกว่า 400 แต่น้อยกว่า 800 เมตร) ☐ <5 blocks (น้อยกว่า 400 เมตร) ☐ Housebound (เฉพาะในบ้าน) ☐ Unable (ไม่สามารถเดินได้) 2. **Stairs (การขึ้นลงบันได)** ☐ Normal Up and Down (ขึ้นลงได้ปกติ) ☐ Normal Up and Down with rail (ขึ้นลงได้ปกติด้วยการจับราวบันได) ☐ Up and Down with rail (ขึ้นลงได้ด้วยการจับราวบันได) ☐ Up with rail, down unable (ขึ้นได้ด้วยการจับราวบันได แต่ลงไม่ได้) ☐ Unable (ขึ้นและลงไม่ได้) 3. **Walking aids used (การใช้เครื่องช่วยเดิน)** ☐ None used (ไม่ต้องใช้) ☐ Use of Cane/Walking stick deduct (ใช้ไม้เท้า/ไม้ค้ำยันเพียงข้างเดียว) ☐ Two Canes/sticks (ใช้ไม้เท้า/ไม้ค้ำยัน ทั้งสองข้าง) ☐ Crutches or frame (ใช้เครื่องช่วยเดิน 4 ขา) **Functional Score (Knee Society score) is** ____	
5	The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)		

ให้ผู้ป่วยประเมิน แล้วบันทึกระดับความเจ็บปวดตามที่ผู้ป่วยบอก (วงกลมเลือก)

โดย 0 = ไม่, 1 = เล็กน้อย, 2 = ปานกลาง, 3 = มาก, 4= มากที่สุด

อาการปวด	1. เดินบนพื้นราบ	0	1	2	3	4
	2. เดินขึ้นบันได	0	1	2	3	4
	3. ขณะนอนบนเตียงตอนกลางคืน	0	1	2	3	4
	4. ขณะลุกนั่ง	0	1	2	3	4
	5. ขณะยืนลงน้ำหนัก	0	1	2	3	4

Page 28 of 28 ☐ **CASE** ☐ **CONTROL** **ID** ☐☐☐

****CONTROL ID TO BE MATCHED WITH CASE ID (Matched age)***

	Variable	Data						code
	อาการฝืดข้อ ข้อตึง	6. เมื่อตื่นนอนตอนเช้า	0	1	2	3	4	
		7. ขณะเปลี่ยนอิริยาบถระหว่างวัน	0	1	2	3	4	
	การใช้งานข้อในการทำกิจวัตรประจำวัน	8. เดินลงบันได	0	1	2	3	4	
		9. เดินขึ้นบันได	0	1	2	3	4	
		10. ลุกยืนจากท่านั่ง	0	1	2	3	4	
		11. ขณะยืน	0	1	2	3	4	
		12. ก้มตัว	0	1	2	3	4	
		13. เดินบนพื้นราบ	0	1	2	3	4	
		14. ขึ้น ลง รถ	0	1	2	3	4	
		15. ไปซื้อของที่ตลาด ร้านค้า	0	1	2	3	4	
		16. ใส่ถุงเท้า	0	1	2	3	4	
		17. นอนบนเตียง	0	1	2	3	4	
		18. ถอดถุงเท้า	0	1	2	3	4	
		19. ลุกจากเตียง	0	1	2	3	4	
		20. เข้า-ออกจากห้องน้ำ	0	1	2	3	4	
		21. Sitting	0	1	2	3	4	
		22. ลุกเข้า-ออกจากส้วม	0	1	2	3	4	
		23. ทำงานบ้านหนัก	0	1	2	3	4	
		24. ทำงานบ้านเบา	0	1	2	3	4	

Recorder/interviewer Signed/date _____

APPENDIX B

THAI CLINICAL TRIALS REGISTRY

Thai Clinical Trials Registry
www.thaiclinicaltrials.org

TCTR ID : TCTR20210123002

OTHER ID :

Overall Recruitment Status : Recruiting

Retrospective registration
This protocol was registered after enrollment of the first participant.

Tracking Information

First Submitted Date :	23 January 2021
First Posted Date :	23 January 2021
Last Update Posted Date :	23 January 2021

Title

Public Title :	RANDOMIZED, DOUBLE-BLIND, CONTROL TRIAL STUDY TO COMPARE THE EFFICACY OF CLINICAL OUTCOMES OF USING AND NON-USING WALKING SUPPORT MACHINE TRAINING AFTER TOTAL KNEE REPLACEMENT
Acronym :	Cowalk TKR
Scientific Title :	RANDOMIZED, DOUBLE-BLIND, CONTROL TRIAL STUDY TO COMPARE THE EFFICACY OF CLINICAL OUTCOMES OF USING AND NON-USING WALKING SUPPORT MACHINE TRAINING AFTER TOTAL KNEE REPLACEMENT
Sponsor ID/ IRB ID/ EC ID :	63-74
Registration Site :	Thai Clinical Trials Registry
URL :	https://www.thaiclinicaltrials.org/show/TCTR20210123002
Secondary ID :	Other Identifier; Issuing Organization : EC63-74 cowalk - TKR

Ethics Review

1. Board Approval :	Submitted, approved
Approval Number :	63-74
Date of Approval :	18 January 2021
Board Name :	Human Researches Ethics Committee
Board Affiliation :	Suranaree University of Technology
Board Contact :	Business Phone : 044223000 Ext. No Data Business Email : ECSUT@g.sut.ac.th Business Address : 111 university ave Meung Nakornratchasema

Sponsor

Source(s) of Monetary or Material Supports :	suranaree university of technology hospital
Study Primary Sponsor :	no
Responsible Party :	Name/Official Title : Human Researches Ethics Committee Organization : suranaree university of technology Phone : 0805886686 Ext. No Data Email : bura@sut.ac.th
Study Secondary Sponsor :	No Study Secondary Sponsor

Protocol Synopsis

Protocol Synopsis :	1.Principle investigator: Miss Siripen Rattanasomboonchai principle director : Asst. Prof. Leu.Col. Bura sindhupakorn M.D. 2. Rationale and Background: Rehabilitation is one of the keys to success after Total Knee Replacement (TKR). Many methods reduced the forces on the knee taking place during weight-bearing exercise. The purpose of this study assessed the use of a walking support machine (Co-walk) to improve clinical outcomes. 3. Material and Methods The control group (30 patients) and experimental group (30 patients) were randomly divided. Both groups did the same rehabilitation program for 45 minutes. The experimental group had an additional 15-minute Co-walk once a week for 6 weeks. Range of Motion (ROM), timed up-and-go test (TUG), Western Ontario and MacMaster University (WOMAC), Weight-Bearing Balance, Postural control, and Length of stay (LOS) were recorded for pre and post-operation at admission period, 6th, 3 months, and 6 months.
URL (Link to project website / Link to protocol website) :	https://www.researchgate.net/publication/348694124_baebsenxkhorngkarwicaypheuxkhxkarrabrxng_EC-Peem_Ver_2_11_Jan_2021

Date : 2021-01-18
Version : 1

Health Conditions

Health Condition(s) or Problem(s) Studied : Total Knee Replacement (TKR)
Keywords : Walking support machine, TKR, Rehabilitation

Eligibility

Inclusion Criteria : 1. all patients that need TKR
2. sign inform and consent
Gender : Both
Age Limit : Minimum : 50 Years Maximum : 90 Years
Exclusion Criteria : 1. patients who had Cerebrovascular events such as Ischemic stroke, Hemorrhagic stroke, Undetermined stroke, Transient Ischemic stroke
2.patients who lose follow up
Accept Healthy Volunteers : No

Status

Overall Recruitment Status : Recruiting

Key Trial Dates	Study Start Date (First enrollment) : 19 January 2021	Indicate Type : Actual
	Completion Date (Last subject, Last visit) : 14 February 2021	Indicate Type : Anticipated
	Study Completion Date : 28 February 2021	Indicate Type : Anticipated

Design

Study Type : Interventional
Primary Purpose : Device Feasibility
Study Phase : Phase 2/Phase 3
Intervention Model : Parallel
Number of Arms : 2
Masking : Masked Masked Role : Allocation concealment, Subject, Caregiver, Investigator, Outcome Assessor,
Allocation : Randomized
Control : No treatment / Standard of care
Study Endpoint Classification : Efficacy Study
Sample size

Planned sample size : 62

Intervantion Arm 1

Intervention name : control group
Intervention Type : No Intervention
Intervention Classification : No treatment
Intervention Description : a rehabilitation program for 45 minutes

Intervantion Arm 2

Intervention name : experimental group
Intervention Type : Experimental
Intervention Classification : Device
Intervention Description : had an additional 15-minute Co-walk once a week for 6 weeks. Co-walk is is a walking support machine that helps to reduce pressure by reducing weight acting on the lower part of the body (such as the knees and ankles). The mechanism of Co-Walk is the supporting system by air pump piston in 4 pillars that having a specific vertical direction or move up and down only in which the driving mechanism moves from the air pressure control unit. Pillars connect to the patients by canvas with special pants. The canvas will elevate the patient by the compressed air delivered from the pillars. Then compressed air into the propulsion mechanism. When the air is compressed into the drive mechanism a large amount will cause the lifting force. When instructing the device to start working will cause the motor to rotate and drive the compressed air pump to work and when the air delivered to the driving mechanism has a high pressure at the specified limits. After that, the patient can begin physical therapy by walking or running on a medical

treadmill. There is a circuit breaker to stop the electrical circuit causing the motor to stop and the compressed air pump to stop working in case of an accident or emergency. Before exercise, each patient entered the machine and the canvas connected with waist seal was secured to isolate the pelvis and lower extremities in the machine. With the patient standing on a standard spring scale (placed on the treadmill), pressure was increased by an air pump to determine the height needed to achieve 20% of baseline body weight. Then the scale was removed. In random order, each patient walked for the first minute to 15 minutes at a comfortable walking speed of 0.67 m/second (1.5 mph).

Outcome

Primary Outcome

1. Outcome Name : Range of motion(ROM), Western Ontario and MacMaster University (WOMAC)
Metric / Method of measurement : questionaire and range of motion goniometry
Time point : admission period, 2th, 6th, 12th, and 24th week.

Secondary Outcome

1. Outcome Name : Length of stay (LOS), time up and go (TUG), Weight-Bearing Balance, and Postural control
Metric / Method of measurement : date and balance machine
Time point : admission period

Location

Section A : Central Contact

Central Contact: First Name : Bura | Middle Name : | Last Name : Sindhupakorn
Degree : | Phone : 0805886686 Ext. : No Data | Email : bura@sut.ac.th

Central Contact Backup: First Name : darawan | Middle Name : | Lastname : jomkoh
Degree : | Phone : 0935080066 Ext. : No Data | Email : darawan.3556@gmail.com

Section B Facility Information and Contact

1. Site Name : Human Researches Ethics Committee
City : meung | State/Province : nakornratchasema | Postal Code : 30000
Country : Thailand | Recruitment Status : Recruiting

Facility Contact: First Name : Bura | Middle Name : | Last Name : Sindhupakorn
Degree : | Phone : 0805886686 Ext. : No Data | Email : bura@sut.ac.th

Facility Contact Backup: First Name : darawan | Middle Name : | Last Name : jomkoh
Degree : | Phone : 0935080066 Ext. : No Data | Email : darawan.3556@gmail.com

Investigator Name: First Name : siripen | Middle Name : | Last Name : Rattanasomboonchai
Degree : | Role : Principal Investigator

Section C : Contact for Public Queries (Responsible Person)

First Name : Bura | Middle Name : | Last Name : Sindhupakorn
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Postal Address : 111 university ave Meung
State/Province : TH | Postal Code : 30000
Country : Thailand | Official Role : Study Director
Organization Affiliation : suranaree university of technology

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Bura | Middle Name : | Last Name : Sindhupakorn
Degree : No Data | Phone : 0805886686 Ext. : No Data | Email : bura@sut.ac.th
Postal Address : 111 university ave Meung
State/Province : TH | Postal Code : 30000
Country : Thailand | Official Role : Study Director
Organization Affiliation : suranaree university of technology

Deidentified Individual Participant-level Data Sharing

Plan to share IPD : Yes
Plan description : principle director

Publication from this study

MEDLINE Identifier : No Data

URL link to full text publication : No Data

APPENDIX C

LIST OF PUBLICATION

A Randomized, double-blind, control trial study to compare the Efficacy of clinical outcomes between using and non-using walking support machine after total knee replacement surgery.

Rehabilitation is one of the key successes in Total Knee Replacement (TKR). Many methods reduce knee forces during weight-bearing exercises.

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Additional Keywords and Phrases: Walking support machine, TKR, Rehabilitation

1 ABSTRACT

Rehabilitation is one of the key successes in Total Knee Replacement (TKR). Many methods reduce knee forces during weight-bearing exercises. This study aims to assess the effectiveness of using a walking support machine (Co-walk) to improve clinical outcomes in TKR patients. The experiment was randomly 62 patients dividing the patients into 2 groups, the Control group and the experimental group (Co-walk). Both groups followed the usual 45-minute rehabilitation program. The experimental group had an additional 15-minute Co-walk session once a week for 6 weeks. Outcomes were measured at the admission period, 2 weeks, 6 weeks, 3 months, and 6 months in TKR patients. Primary outcome measure: Range of Motion (ROM), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcome measure: Timed up-and-go test (TUG), Weight-Bearing Balance, Postural control, and Length of stay (LOS) were recorded for both pre and post-operation. The student t-test and Mann Whitney test were used to compare continuous variables between Co-walk and Non-Co walk, whereas Chi-square tests were performed for categorical

* Corresponding

variables. A repeated-measures ANOVA or Friedman's test was analyzed to change the mean or median score over 4 or more time points within Co-walk and Non-Co walk groups. A two-tailed p-value<0.05 was considered statistically significant for all tests performed.

The study results are as follows, The significant parameters (p<0.001) were TUG and WOMAC pain by Co-walk group at 2 weeks, 6 weeks, and 3 months. WOMAC movement was statistically significant in the Co-walk group at 2 weeks, 6 weeks, 3 months, and 6 months (p<0.001). WOMAC stiffness was statistically significant in the Co-walk group at 2 weeks (p<0.001). ROM of the Co-walk group was significantly different at 6 weeks compared with the Non-Co walk group (p=0.024). Co-walk group postural control showed significant improvement in position compared with the Non-Co walk group left (p=0.024) and right (p=0.019), respectively, at 2 weeks, 6 weeks, 3 months, and 6 months. However, the anterior and posterior positions were not significantly different. The main limitation is the long-term study. The experimental group LOS showed no significant difference in days compared with the control group (p=0.379). It can be concluded that Co-walk does effectively improve outcomes during the early rehabilitation period. It may be better than isolated physical therapy rehabilitation programs. The study was registered with the Thai Clinical Trials Registry (No. TCTR20210123002) (www.clinicaltrials.in.th)

2 INTRODUCTION

Rehabilitation remains crucial for achieving good clinical outcomes, such as short-term function, range of motion, patient quality of life, and prevention of postoperative complications, in total knee replacement (TKR) [1,2]. Decreased pain with a greater range of motion and independence are important goals for physiotherapy [3,4], while early rehabilitation is considered necessary for increasing the range of motion and muscle strength [5,6]. The trend toward early hospital discharge to reduce the length of stay has gained popularity in the last decade [7-10]. Postoperative knee range of motion (ROM) is one of the most crucial factors influencing patient satisfaction after TKR [11]. The mean 1-year Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score is lowest in the first three months [12]. It is essential to avoid bad experiences during the early postoperative period, including pain, knee stiffness, and hospital readmission due to complications such as falling. Weight-bearing activities such as walking are often considered highly effective in rehabilitation and promoting a return to function. High knee forces (3 times body weight), non-weight-bearing, or partial weight-bearing are usually recommended. Full weight-bearing may delay a return to full function. Many methods can be used to reduce the forces on the knee during weight-bearing exercises, such as hydrotherapy (walking in water) [13], the use of harness systems [14] that physically lift the patient, the use of lower body positive pressure (LBPP) chambers [15], and LBPP treadmills [16]. These methods produce a significant reduction in the weight the patient bears with minimal alteration to gait kinematics.

An increase in knee forces may affect postoperative rehabilitation, for example, through pain, leading to the restriction of motion and increased joint stiffness. The degeneration of immobilized muscle groups and early joint stiffness remain essential factors influencing whether there is a prolonged course of healing [17-20]. A study demonstrated improvements in pain intensity, gait velocity, cadence, and stride length as the result of a six-week gait physical therapy program after TKA [21]. Our study aimed to improve clinical outcomes for patients following TKR by using a walking support machine (Co-walk) and compare the results over a 6-month period to those obtained with a standard rehabilitation protocol. Some research shows that accelerated device rehabilitation can improve recovery outcomes after patient injuries. However, no research has investigated clinical outcomes in patients who underwent

TKR. Our study aimed to improve the clinical outcomes of TKR patients by using a walking support machine (Co-walk) in addition to standard rehabilitation compared to a standard rehabilitation protocol alone. We assessed the results over a 6-month period and focused on improving ROM, timed up-and-go test (TUG) scores, Western Ontario and McMaster University (WOMAC) scores, weight-bearing balance, postural control, and Length of stay (LOS).

3 MATERIALS AND METHODS

We performed an experimental clinical trial. The study was registered with the Thai Clinical Trials Registry (No. TCTR20210123002) (www.clinicaltrials.in.th), which legally conducts trials in Thailand under the Medical Research Foundation of Thailand (MRF), and we received ethical approval from the university's ethics committee (EC 63-74). We enrolled patients and randomized them to the experimental and control groups, as shown in the flow diagram in Figure 1.

We randomly divided the patients into two groups using the block method. The samples in both groups included knee osteoarthritis patients who underwent TKR and were referred to physiotherapy for TKR rehabilitation. The sample size was calculated using data from a previous study by Mutsuzaki H et al. [11], mean ROM change from preoperative before surgery to 6 months after TKA. Using an unpaired t-test with a 2-sided significance level of 0.05, the study would have 90% power to detect a difference of 3.0 between the Co-walk and Non-Co-walk groups. The percentage of missing data was set at 7%. The number of participants needed was, therefore 31 in each group. Thus the minimum number of subjects to be recruited was 62 for the study. The control group (31 issues) (Non-Co-walk) received the standard protocol for rehabilitation. The experimental group (31 subjects) (Co-walk) used the walking support machine (Co-walk) in addition to undergoing the standard protocol for rehabilitation. The inclusion criteria were patients who were willing to enroll in the program, were over 50 years old, had knee osteoarthritis, and had a severe stage of osteoarthritis that required TKR. The exclusion criteria were patients with a history of cerebrovascular events such as ischemic stroke, hemorrhagic stroke, undetermined stroke, transient ischemic attack, and patients lost to follow-up.

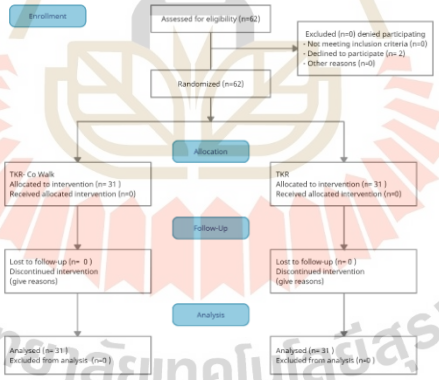

Figure 1: CONSORT 2010 Flow Diagram

The withdrawal or termination criteria were greater pain intensity than before enrollment and discomfort with continuing the program. Both groups received the same postoperative pain control and rehabilitation protocol as shown in Table 1. To reduce confounding factors, such as surgical techniques, the surgical skills of the surgeon, and the type of implants, all operations were performed by one experienced surgeon who used the same process, same implant type, and same surgery method

Table 1: Rehabilitation protocol for TKR was based on the Insall Scott Kelly® Institute for Orthopaedics and sports medicine.

Week	Program
-2 to -4	**Pre-op** 1. Review of the TKR 2. Restore normal range of motion (ROM) exercise, 3. Stair training 4. Bed mobility training and education on the importance of cold compression 5. Ambulation training with crutches 6. Assessment using a range of Motion (ROM), timed up-and-go (TUG) score, and the WOMAC score.
0 to 2	1. Post-operation day (POD) #1 • cold compression of the knee for 20 minutes for a minimum of 2 times per day (more if necessary). • Review and perform all bedside exercises, including ankle pumps, quadriceps sets, gluteal sets, and heel slides. • Sit at the edge of the bed with necessary assistance. • Ambulate with a standard walker 15' with moderate assistance. • Sit in a chair for 15 minutes. • Actively move knee 0-70°. 2. POD #2 • Continue as above with emphasis on improving ROM, performing proper gait patterns with an assistive device, decreasing pain and swelling, and promoting independence with functional activities. • Perform bed exercises independently 5 times per day. • Perform bed mobility and transfers with minimum assistance. • Ambulate with a standard walker 75-100' with contact guarding. • Ambulate to the bathroom and review toilet transfers. • Sit in a chair for 30 minutes twice per day, in addition to at all meals. • Actively move knee 0-80°. 3. POD #3 • Continue as above. • Perform bed mobility and transfers with contact guarding. • Ambulate with a standard walker 150' with supervision. • Negotiate 4 steps with necessary assistance. • Begin standing hip flexion and knee flexion exercises. • Sit in a chair for most of the day, including during all meals. Limit sitting to 45 minutes in a single session. • Use the bathroom with assistance for all toileting needs. • Actively move knee 0-90°. 4. Continue physiotherapy in the same way as in the hospital when patients are discharged
2 to 5	1. Weeks 2-3 • Monitor incision site and swelling. • Progress ambulation distance (increase 1/2 block to 1 block each day) with WBQC. • Begin stationary bicycle with supervision for 5-10 minutes. • Begin standing wall slides. DO NOT ALLOW THE KNEES TO MOVE FORWARD OF THE TOES. • Incorporate static and dynamic balance exercises. • AROM 0-115°. 2. WEEKS 3-4 • Continue as above. • Practice with straight crutches indoors. • Increase stationary bicycle endurance to 10-12 minutes twice per day. • Attempt unilateral stance on the involved leg and side stepping. • Incorporate gentle semi-squats (BODY WEIGHT ONLY) concentrating on eccentric control of the quadriceps. • Attain AROM 0-120°. 3. WEEKS 4-5 • Continue as above. • Ambulate with a straight cane only. • Increase stationary bicycling to 15 minutes twice per day. • Progress with gentle lateral exercises, i.e., lateral stepping and carioca. • Attain AROM 0-125°.
6 to 12	1. WEEKS 6-9 • Continue as above. • Ambulate indoors WITHOUT device. • Focus exercises on strength and eccentric control of muscles. DO NOT USE CUFF WEIGHTS UNTIL CLEARANCE FROM THE SURGEON. • Focus on unilateral balance activities. • Continue aggressive AROM exercise to promote knee range of motion 0-135° 2. WEEKS 10-12 • Continue as above. • Develop and instruct the patient on an advanced exercise program for continued strength and endurance training. • Ambulate without a straight cane

3.1 Data collection

The data were collected from 19 January 2021 until 30 July 2021 at Suranaree University Hospital. The evaluator and the physical therapist were different people. Patients were assessed for general demographics such as sex, age, and body mass index (BMI). We evaluated the primary outcome using the WOMAC, which consists of two domains— pain, stiffness, and function. Range of motion (ROM) was assessed by using a goniometer. The secondary outcomes were LOS, time up and go (TUG) score, weight-bearing balance, and postural control, as assessed by EP40 System Biometrics Ltd.

We reevaluated both groups using the same parameters before and after the operation. For the Co-walk group, we used Co-walk once a week for 6 weeks based on the Insall Scott Kelly® Institute for Orthopaedics and Sports Medicine protocol. The walking duration was 15 minutes. For the Non-Co-walk group, we used a 45-min rehabilitation program once a week for 6 weeks. Outcomes were measured on admission and at the 2nd, 6th, 12th, and 24th weeks.

3.2 Intervention

The innovative walking support machine (Co-walk) was invented by our staff and is shown in Figure 2. Co-walk helps reduce pressure by reducing the weight on the lower part of the body (such as the knees and ankles). The mechanism of the Co-walk is the air pump piston support system that includes 4 pillars that maintain a specific vertical direction only to move up or down. The pillars connect to the patients via special canvas pants. The canvas elevates the patient using compressed air (propulsion mechanism) delivered from the pillars. When the air is compressed into the propulsion mechanism, a large amount of pressure produces the lifting force. The result is that the patient is placed in a virtually weightless state that reduces pressure and the risk of shocks to the lower limbs during physiotherapy. The physiotherapist or the caregiver can enter the desired elevation percentage on the panel to enable the device to send suitable air pressure. Instructing the device to start working causes the motor to rotate and the compressed air pump to drive when the air delivered to the driving mechanism meets the specified limits. Afterward, the patient can begin physical therapy by walking or running on a medical treadmill. In case of an accident or emergency, a circuit breaker stops the electrical circuit, causing the motor and a compressed air pump to stop. Before exercise, each patient enters the machine, and the canvas connected with the waist seal is secured to isolate the pelvis and lower extremities in the machine. With the patient standing on a standard spring scale (placed on the treadmill), the pressure is increased by an air pump to determine the height needed to achieve 20% of baseline body weight. Next, the scale is removed. In random order, each patient walked for the first minute to 15 minutes at a comfortable walking speed of 0.67 m/second (1.5 mph). The Co-walk group participants performed gait training using the Co-walk and the total 45-min rehabilitation program. The walking duration was 15 minutes which took place once a week for 6 weeks. The control group participants performed the usual 45-min rehabilitation program once a week for 6 weeks, as shown in Table 1. Outcomes were measured on admission and at the 2nd, 6th, 12th, and 24th weeks.

Figure 2: Showed Co-walk with the treadmill

3.3 Statistical analysis

Data are described using the mean (±standard deviation) or median (percentile 25-percentile 75) for continuous data and frequency (percentage) for categorical data. Student's t-test and the Mann Whitney test were used to compare continuous variables between the Co-walk and Non-Co-walk groups, whereas chi-square tests were performed for categorical variables. Repeated-measures ANOVA or Friedman's test was used to analyze changes in mean or median scores over 4 or more time points within the Co-walk and Non-Co-walk group. A two-tailed p-value<0.05 was considered statistically significant for all tests performed. PASW Statistic (SPSS) 18.0 (SPSS, Inc., Chicago, IL, USA) was used to perform all statistical analyses.

4 RESULTS

Sixty-two patients with severe OA underwent TKR surgery in this clinical trial. This study randomized patients into two groups: the control group, which used the standard TKR rehabilitation protocol, as shown in Table 1, and the experimental group, which used gait training with the Co-walk in addition to 15 minutes of the usual 45-minute rehabilitation protocol. The cohort included 11 males (17.74%) and 51 females (82.26%). The participants' average age was 67.77 years old, the average height was 154.61 cm, and the average BMI was 26.44 kg/m2. The analysis of demographic characteristics revealed no significant difference between the two groups of patients, as shown in Table 2.

Table 2: Baseline data

Characteristic	total	Co-walk	Non-Co-walk	p
Knee				
Left	28(45.16)	11(35.48)	17(54.84)	0.126
Right	34(54.84)	20(64.52)	14(45.16)	
Sex				
Male	11(17.74)	8(25.81)	3(9.68)	0.096
Female	51(82.26)	23(74.19)	28(90.32)	
Age (years)	67.77±7.01	68.06±7.16	67.48±6.96	0.747
Weight (kg)	63.18±11.61	63.55±11.39	62.82±11.99	0.805
Height (cm)	154.61±7.74	155.19±7.78	154.03±7.80	0.559
BMI	26.44±4.53	26.37±4.10	26.52±5.00	0.894
Length of stay (days)	6.08±2.14	5.84±1.66	6.32±2.55	0.379
The range of Motion (ROM)	89.68±17.06	89.68±12.45	89.68±20.89	1.00
WOMAC Pain	30.05±10.10	29.23±10.58	30.87±9.71	0.526
WOMAC Movement	94.66±24.87	94.87±23.04	94.45±26.96	0.948
WOMAC Stiff	12.44±4.42	12.32±3.70	12.55±5.10	0.843

Table 3: ROM, Weight left or right between co-walk and Non-co-walk.

	total	Co-walk	P a.	Non-Co-walk	P a.	P b.
ROM						
Before surgery	89.68 ±17.06	89.68 ±12.45	<0.001	89.68 ±20.89	<0.001	1.00
1-2 days after surgery	88.87 ±13.26	90.65 ±13.77		87.10 ±12.70		0.296
2wk after surgery	100.48 ±15.25	103.39 ±12.61		97.58 ±17.22		0.135
6wk after surgery	111.26 ±13.86	113.00 ±11.58		109.52 ±15.83		0.327

	total	Co-walk	P a.	Non-Co-walk	P a.	P b.
3mo after surgery	116.13 ±13.01	119.84 ±8.99		112.42 ±15.32		0.024
6mo after surgery	122.79 ±10.09	124.29 ±8.10		121.29 ±11.69		0.245
Average day 1- 6mo	104.87 ±10.98	106.81 ±8.98		102.93 ±12.51		0.167
TUG						
1-2 days after surgery	69.93 ±17.34	71.82 ±16.65	<0.001	68.03 ±18.07	<0.001	0.394
2wk after surgery	30.01 ±16.87	18.10 ±6.45		41.92 ±15.62		<0.001
6wk after surgery	18.09 ±10.41	13.23 ±3.32		22.94 ±12.67		<0.001
3mo after surgery	14.08 ±7.05	11.69 ±2.52		16.47 ±9.10		0.008
6mo after surgery	11.90 ±4.69	11.04 ±1.87		12.76 ±6.29		0.153
Average day 1- 6mo	28.80 ±8.33	25.18 ±3.81		32.43 ±9.98		0.769
Weight Left						
1-2 days after surgery	50.19 ±13.37	51.26 ±10.26	0.603	49.13 ±15.99	0.777	0.535
2wk after surgery	49.44 ±9.55	49.55 ±8.59		49.32 ±10.56		0.927
6wk after surgery	49.89 ±5.71	50.03 ±4.90		49.74 ±6.51		0.843
3mo after surgery	49.95 ±4.25	49.94 ±3.10		49.97 ±5.21		0.976
6mo after surgery	49.84 ±2.65	49.74 ±2.16		49.94 ±3.10		0.776
Average day 1- 6mo	49.86 ±6.39	50.10 ±4.57		49.62 ±7.88		0.769
Weight Right						
1-2 days after surgery	49.81 ±13.34	48.74 ±10.20	0.586	50.87 ±15.99	0.777	0.535
2wk after surgery	50.61 ±9.59	50.55 ±8.69		50.68 ±10.56		0.958
6wk after surgery	50.10 ±5.72	49.94 ±4.91		50.26 ±6.51		0.827
3mo after surgery	50.08 ±4.27	50.13 ±3.14		50.03 ±5.21		0.930
6mo after surgery	50.15 ±2.64	50.23 ±2.14		50.06 ±3.10		0.812
Average day 1- 6mo	50.15 ±6.40	49.92 ±4.58		50.38 ±7.88		0.778
Diff Weight Left to Right						
1-2 days after surgery	-0.39 ±26.71	-2.52 ±20.45	0.594	1.74 ±31.98	0.777	0.535
2wk after surgery	1.18 ±19.12	1.00 ±17.26		1.35 ±21.11		0.942
6wk after surgery	0.21 ±11.44	-0.10 ±9.81		0.52 ±13.02		0.835
3mo after surgery	0.13 ±8.52	0.19 ±6.23		0.06 ±10.42		0.953
6mo after surgery	0.31 ±5.29	0.48 ±4.30		0.13 ±6.20		0.794
Average day 1- 6mo	0.29 ±12.79	-0.19 ±9.15		0.76 ±15.76		0.773

a.* p-value within group related mean before surgery to 6 months after surgery by repeated measure ANOVA.

b.p-value for comparison of mean between groups by Independent t-test.

The TUG scores of the experimental group (18.10±6.45) and those of the control group (41.92±15.62) were significantly different (p<0.001) at 2 weeks, 6 weeks, and 3 months, as shown in Figure 3.

The WOMAC scores for the pain of the experimental group (13.29±5.49) and control group (22.52±5.47) were significantly different (p<0.005) at 2 weeks, 6 weeks, and 3 months. The WOMAC movement scores of the experimental group (36.10±13.78) and control group (63.52±12.71) were significantly different (p<0.001) at 2 weeks, 6 weeks, 3 months, and 6 months. The WOMAC scores for stiffness of the experimental group (6.03±3.62) and control group (10.16±3.42) were significantly different (p<0.001) at 2 weeks. (Figure 4).

Weight-Bearing on the left and right was not significantly different in the experimental group. The experimental group showed significant improvement in postural control in position (Left 16 [8.5(6.5-14.0)] and Right 11[10.0(3.0-24.0)]) when compared with that of the control group (Left 6[14.0(14.0-17.0)] and Right 22[24.0(13.0-30.0)] (p=0.024), (p=0.019)) at 2 weeks, 6 weeks, 3 months and 6 months. However, the anterior and posterior positions were not significantly different, as shown in Figure 5.

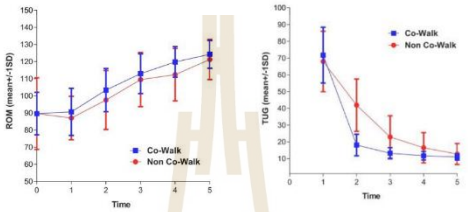

Figure 3: Range of Motion (ROM) and Timed Up and Go test (TUG) between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

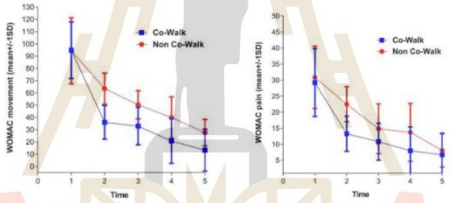

Figure 4: Western Ontario and McMaster University index (WOMAC) movement, stiffness, and pain between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

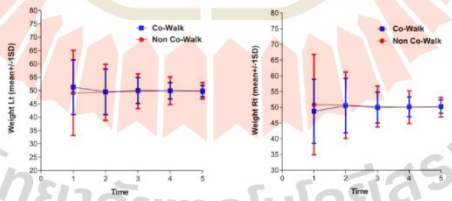

Figure 5: Weight-Bearing Left (A) and Right (B) between the Control group (Non-Co-Walk) and Experimental group (Co-Walk).

5 DISCUSSION

In this study, we investigated the postoperative clinical outcomes of TKR patients using Co-walk. Variables measured during the study included ROM, the TUG, the WOMAC, weight-bearing balance, postural control, and LOS. We found no significant differences on a postoperative day 1 or postoperative day 2; but 2 weeks after surgery, we found that the experimental group demonstrated significantly decreased time on the TUG test. 2 weeks after the operation; we compared preoperative and postoperative WOMAC scores. Scores decreased in all 3 domains (pain, movement, and stiffness) and were significantly different at 2 weeks, 6 weeks, and 12 weeks. Moreover, subjects who used Co-walk after surgery showed improved knee function and improved walking performance at admission and 2 weeks compared with those who used the standard rehabilitation protocol. In addition, no adverse events occurred during the research. The results of this study were consistent with Wiliam D. et al. [21], who used the AlterG Anti-Gravity Treadmill in male and female subjects with mean ages of 66.5 years and 66.9 years, respectively, after posttraumatic, postmenopausal total knee arthroplasty (TKA). The study found that pain was reduced and knee function improved after surgery. Ahmed AR et al. [22] studied a 6-week postoperative exercise program for patients following TKA; however, the study period was not long enough to restore walking abilities to their pre-surgery values. A longer period of rehabilitation is needed to improve the quality of the patient gait. Heike A. Bischoff and colleagues [23] studied the cut-off time of the TUG test in community-dwelling and elderly women. They found that community-dwelling elderly women between 65 and 85 should be able to perform the timed up-and-go test in 12 seconds or less. We found that using Co-Walk after surgery can improve gait ability. Patients who used Co-Walk could walk faster, as measured by the TUG test (11.69 seconds), than patients who underwent normal rehabilitation after 6 weeks. Further study over a long-term period should be conducted.

6 CONCLUSION

The findings in this study indicate that routine rehabilitation programs are important in improving gait capability. Co-Walk may help improve gait ability and reduce pain after surgery. Rehabilitation that includes Co-Walk in the rehabilitation protocol for 6 weeks after TKR surgery positively enhances knee joint function and decreases pain after surgery.

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