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ORIGINAL ARTICLE

Effect of a Program Based on a Family-Centered Empowerment Model on Total Knee Arthroplasty Patients and Their Caregivers: a Randomized Controlled Trial Protocol

Aile Merkezli Güçlendirme Modeline Dayalı Programın Total Diz Protezli Hasta ve Bakım Vericiler Üzerine Etkisi: Randomize Kontrollü Çalışma Protokolü

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ABSTRACT

Aim: This study aims to present the details of the program evaluating the effects of the Family-Centered Empowerment Model (FCEM) provided to individuals with Total Knee Arthroplasty (TKA) and their caregivers, on individuals' physically functioning and self-efficacy level, as well as the impact on caregivers' caregiving burden, caregiving competence, and coping skills with stress.
Methods: This study is designed as randomized controlled experimental research. A total of 62 patients, including both an intervention group and a control group, will be included in the study. Data will be collected between December 2023 and August 2024 using the Participant identification form, Barthel Index of Activities of Daily Living, General Self-Efficacy Scale, Zarit Caregiving Burden Scale, Caregiving Competence Scale, and Coping with Stress Scale. Patients in the intervention group will receive counseling eight times over a five-week period, along with a structured booklet based on the FCEM. Patients in the control group will receive standard care, and in the final follow-up (after the 30th day post-surgery), they will be provided with the section of the booklet detailing the actions to be taken after the 30th day post-surgery.
Results: In the statistical analysis of the data obtained from the research, descriptive statistics including frequency, percentage, mean, and standard deviation will be used. The chi-square test will be employed to compare the similarity/homogeneity of the groups in terms of their descriptive characteristics. The results will be evaluated at a significance level of $p<0.05$.
Conclusions: Our study protocol will guide subsequent research by providing details of the FCEM program.
Clinical Trial Number: NCT06402539

Keywords: Family-centered empowerment model, caregivers, patient outcomes, nursing, total knee replacement.

ÖZ

Amaç: Total Diz Protezli (TDP) bireylere ve bakım verenlerine verilen Aile Merkezli Güçlendirme Modeli (AMGM) programının bireylerin fiziksel fonksiyon düzeyi, öz yeterlilik düzeyi; bakım verenin bakım yükü, bakım verme yeterliliği ve stresle başa çıkma becerileri üzerindeki etkilerini değerlendiren çalışmanın içeriğinin ayrıntılarını sunmaktır
Gereç ve Yöntemler: Bu çalışma randomize kontrollü deneysel araştırma olarak tasarlanmıştır. Çalışmaya müdahale ve kontrol grubu olmak üzere toplamda 62 hasta dahil edilecektir. Veriler Aralık 2023-Ağustos 2024 tarihleri arasında Hasta Tanıtım Formu, Barthel Günlük Yaşam Aktiviteleri Indeksi, Genel Öz Yeterlilik Ölçeği, Zarit Bakım Verme Yükü, Bakım Verme Yeterliliği ve Stresle Baş Etme Ölçeği ile toplanacaktır. Müdahale grubundaki hastalara AMGM göre yapılandırılmış kitapçıkla beraber beş hafta boyunca sekiz kez danışmanlık verilecektir. Kontrol grubundaki hastalar ise standart bakımlarını alacak; son izlem de (ameliyat sonrası 30. günden sonra) kendilerine kitapçıktaki ameliyat sonrası 30. günden sonra yapılması gerekenler bölümü verilecektir
Bulgular: Araştırma sonucunda elde edilen verilerin istatistiksel analizinde tanımlayıcı istatistikler için sayı, yüzde, ortalama ve standart sapma, grupların tanımlayıcı özellikler yönünden benzerliğinin/homojenliğinin karşılaştırılmasında ki-kare analizi kullanılacaktır. Elde edilen sonuçlar $p<0,05$ anlamlılık düzeyinde değerlendirilecektir.
Sonuçlar: Çalışma protokolümüz AMGM programının detaylarını sunarak bir sonraki araştırmalara rehberlik edecektir.
Clinical Trials Numarası: NCT06402539

Anahtar Kelimeler: Aile merkezli güçlendirme modeli, bakım vericiler, hasta sonuçları, hemşirelik, total diz protezi.

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INTRODUCTION

The prevalence and impact of osteoarthritis increase significantly with age, causing a substantial burden. Total knee arthroplasty (TKA) is one of the most common orthopedic procedures that relieve pain and restore physical function. This procedure is considered the gold standard for treating end-stage knee arthritis, with long-term survival rates of 95% to 99% at 15 years (1, 2). However, complications associated with TKA include pain, joint infection, thromboembolism, lower extremity length difference, and restricted knee mobility (3). Given the mobility limitations imposed to enhance patient outcomes, effective nursing interventions play a crucial role in improving physical functionality, managing pain, facilitating necessary exercises, and ensuring patient satisfaction (4, 5).

Due to the reduced hospital stay after total knee arthroplasty, caregivers are given more responsibility in the early postoperative period. In the literature, caregivers are often referred to as 'secondary patients' because, similar to patients, they require education, however, they are expected to provide care without having received adequate training (6).

Through caregivers who are family members, the amount of postoperative care that would normally be provided by healthcare professionals is reduced, thus significantly decreasing the economic burden on the healthcare system. Caregivers can contribute to the reduction of complications, hospital readmissions, and associated medical costs (e.g., approximately $20,000 per revision surgery) following knee and hip replacement surgeries(7-9).

Family-Centered Empowerment Model (FCEM) helps plan, implement and evaluate health services through mutual partnerships between patients and families (10). The primary goal of is to empower the family in order to improve both the family's and the patient's health levels(10). It is expected that FCEM will simultaneously increase knowledge, skills, values, self-confidence, and self-control beliefs in both the patients and their families. Studies have shown that continuous education and empowerment of caregivers can significantly reduce hospital readmissions and mortality rates in patients(11, 12).

FCEM is expected to simultaneously increase knowledge, skills, values, self-confidence and self-control beliefs in patients and their families (13). The empowerment approach intervention can motivate the caregiver to take a proactive role in the caregiving context, to gain dynamic awareness to identify problems, to acquire information, to synthesize personal and social-contextual resources, and to make conscious and reasonable choices in coping with patients' demands and to meet their personal care needs (12, 14).

FCEM has been used primarily to improve the care and outcome of patients with chronic diseases (13). Liang (2024) , showed that the use of FCEM after TKA increases patient motivation and self-care effectiveness, promotes recovery of knee function in the short term after surgery, and reduces the likelihood of complications. (15). However, how FCEM-based nursing intervention affects the outcomes of TKA caregivers has not received attention in the literature.

Aim of the study:

This study aims to present a detailed analysis of the effects of the FCEM program,

administered to individuals who have undergone TKA and their caregivers. The study evaluates its impact on patients' physically function, self-efficacy, as well as on caregivers' care burden, caregiving competence, and stress-coping abilities.

MATERIALS and METHODS

Design

The protocol for this study was based on SPIRIT 2013 (Standard Protocol Items: Recommendations for Interventional Trials). This study was planned as a parallel group (1:1) randomized controlled clinical trial with repeated measurements. This study was registered with ClinicalTrials under the number NCT06402539.

Participants and Sampling

The study sample comprised patients admitted to the Orthopedics and Traumatology clinic at Selçuk University Hospital. for TKA and their caregivers. Power analysis was analyzed using the GPower v3.1.9.7 program. Considering the data of the study conducted by Durmaz et al. (2022) in which the effect of the coaching strategy applied to patients who had total knee arthroplasty was evaluated on the physically function (daily living activities/ Barthel) of the patients, it was determined that a minimum of 56 participants in total should be included in the study, with a minimum of 28 participants in each group, according to the results of repeated analysis of variance with 95% confidence (1-α), 95% test power (1-β) and f = 0.405 effect size. Since it is stated in the literature that it can be increased by 10%, it was decided to increase the study group by 10% (16, 17) and 31 people in the intervention group and 31 in the control group, for a total of 62 people.

The criteria for patients to be included in the study will be as follows:

•Volunteer to participate in the study,

•At least literate,18 years of age and older, If the patient is over 65 years of age, Mini-mental test scores of 25 points and above (can range from 0 to 30).

•Able to understand and speak Turkish,

•Being the first caregiver to a patient with TKA

•Not participating in any study during and after the hospital stay

•Undergoing elective primary unilateral TKA.

The criteria for caregivers to be included in the study will be as follows:

•Volunteer to participate in the study,

•Being a relative of the patient (spouse, daughter, son-in-law, grandchild, daughter-in-law, son, sibling, friend, etc.),

•At least literate,

•18 years of age and older,

•If the caregiver is over 65 years of age, Mini-mental test scores of 25 points and above (can range from 0 to 30).

•Being able to understand and speak Turkish,

•Being the primer caregiver to a patient with TKA.

Exclusion criteria for patients

•Having hearing or vision problems

•Having a communication problem such as vision or hearing that will prevent him/ her from understanding and expressing the information given correctly

•Having a diagnosed psychiatric disease.

Exclusion criteria for caregivers

•Having hearing or vision problems

•Having a communication problem such as vision or hearing that will prevent him/her from understanding and expressing the information given correctly

•Having a diagnosed psychiatric disease,

•Having TKA providing care to a patient for less than 6 weeks

•Providing care for a fee

Exclusion criteria for patients during the research process

•Developing complications (severe bleeding, arrest, staying intensive care unit, dislocation) before discharge

Exclusion criteria for caregivers during the research process

•Changing the family member providing care to the patient during the study period

•Not continuing to meet during the study period

Variables of the Study

Independent variable

Education and counseling provided through the family-centered empowerment model program

Dependent variables

•The demographic characteristics of patients and caregivers,

•Daily Living Activity Index score,

•General Self-Efficacy Scale score,

•Zarit Caregiver Burden Scale score,

•Caregiving Competence Scale score,

•Stress Coping Scale score.

Data Collection Tools

The primary outcome variables of this study are the physically functional levels of individuals who have undergone TKA (Total Knee Arthroplasty) and the caregiving competencies of caregivers. Data related to these variables will be collected using the Daily Living Activity Index score and the Caregiving Competence Scale. The secondary outcome variables include the patient's readmission to the hospital within 30 days after discharge, self-efficacy, and the caregiver's caregiving burden and coping skills with stress. Data for these variables will be collected through the question regarding whether the TKA patient was readmitted to the hospital and the reason for readmission, as well as using the General Self-Efficacy Scale, Zarit Caregiver Burden Scale, and the Stress Coping Scale.

Participant identification form: It has been created by the researcher through a literature review on the subject (18-20). The sociodemographic information includes twelve questions regarding employment status, chronic illnesses, previous surgeries, physical therapy history, certain characteristics of the caregiver.

Mini mental test: The Mini Mental Test (SMMT) was first published by Folstein and colleagues in 1975 (21). The Turkish validity and reliability study was conducted by Güngen et al. in 2002. It was determined that the Standardized Mini Mental Test showed 91% sensitivity, 95% specificity and 92% kappa value (22). In patients who underwent the Standardized Mini Mental Test, certain categories were determined regarding the patient's health. The patient's condition is clearly perceived with the answers given to these categories. It consists of recording memory, orientation, attention and calculation, recall and

language categories. In order for this test to be performed, the patients' senses of hearing and vision must be healthy. Each question is 1 point, and the total score is 30 points. The health of those who score 24-25 or more is considered normal, and scores of 23 and below are considered to be an indicator of cognitive disorder (22). This form also includes a question created by the researcher by reviewing the literature to determine complications that may develop after surgery(23-25).

Daily living activity index score: The Modified Barthel Index of Daily Living Activities, developed by Mahoney and Barthel (1965) , evaluates the individual's daily living activities. The Turkish validity and reliability of the scale was conducted by Küçükdeveci (2000) with 50 patients with neurological diagnoses. The scale consists of 10 subheadings: "eating, bathing, self-care, dressing, bladder control, bowel control, toilet use, chair/bed transfer, mobility, and stair use." The scale score is between 0 and 100, and the scoring is not distributed equally. For example, while a maximum of 5 points can be received for "personal care and bathing activity", the maximum score for "mobility status" is 15 points (27).

General self-efficacy scale: The General Self-Efficacy Scale, developed by Jerusalem and Schwarzer (1979) in Germany, was first prepared as 20 items. The scale, which was reduced to 10 items with corrections made in 1981, was finalized in 1995. It is known that the scale, which has been translated into 28 languages including English, is primarily used by many researchers. The scale tests the belief in the competence of different environments to cope with new and difficult tasks. The scale, which is completely positive and consists of 10 items, was prepared in a 4-point Likert type with limits of completely false and completely true. Getting high scores on the items indicates a high level of general self-efficacy. The Alpha internal consistency coefficients for the scale components were found to be .79 for the first component and .63 for the second component. The calculated Alpha coefficient in total was 0.83. It was adapted to Turkish culture by Aypay (2010) after carrying out validity and reliability studies (29).

Zarit caregiver burden scale: It was first developed by Zarit and colleagues to assess the care burden of individuals providing care to patients with dementia (30).The scale assesses the problems and care burden experienced by individuals providing care to individuals in need of care. The scale contains a total of 22 items and is a Likert-type scale where each item is scored between 0 and 4. The scale can be scored between 0 and 88. As the score obtained from the scale increases, the care burden experienced by the caregiver increases. The validity and reliability study of the Zarit Caregiver Burden Scale in Turkish was conducted by İnci and Erdem (2006). The internal consistency coefficient of the Turkish form of the scale is 0.95(31).

Caregiving competence scale: Caregiving Competence Scale (CCS), developed by Pearlin (1990) , was adapted to Turkish as part of the thesis. The four questions in the CCS measure the degree of self-efficacy of the caregiver regarding patient care. The Likert-type scale is organized as "1"=Not at all sufficient, "2"=Somewhat sufficient, "3"=Sufficient and "4"=Very sufficient. The lowest score from the scale is 4, the highest score is 16. As the score obtained

from the scale increases, the competence for caregiving increases (Pearlin et al., 1990). The internal consistency coefficient (Cronbach's alpha) of the original scale is 0.83. It was adapted to Turkish by Avcı and Gözüm (2022) .

Stress coping scale: The Turkish validity and reliability of the coping methods scale developed by Moos (1993) and specially prepared for adults was performed by Ballı and Kılıç (2016) . The original scale consists of two sections, avoidance and approach reactions, and a total of eight dimensions. In order to determine the reliability of the scale, it was found that the total internal consistency coefficient was 0.93; the problem solving dimension was 0.91; the positive evaluation dimension was 0.91; the logical analysis dimension was 0.91; the professional support seeking dimension was 0.80; and the environmental support seeking dimension was 0.73, and the scale had internal consistency.

Randomization and Blinding

Randomization

Patients who underwent TKA and met the inclusion criteria, along with their caregivers, were informed about the study and provided their consent prior to randomization. Those who met the study criteria and agreed to participate were assigned to the intervention and control groups using the block randomization method.

Randomization into the intervention and control groups was performed by a statistician using computer-generated random numbers and the block randomization method. In this study, 4-person permutation blocks were used.

In the first stage, blocks and calculations for the randomization process were prepared manually. In the second stage, random numbers were generated using a computer program, and participants from the predefined blocks were sequentially assigned to the intervention and control groups by the statistician.

Blinding

However, blinding the researcher was not possible because the researcher was also the implementer of the family-centered empowerment program. Nevertheless, just before the intervention, the researcher opened an envelope prepared by the statistician to learn which group the patient and caregiver were assigned to. The assignment of letters to the intervention or control group was determined at the beginning of the study by a draw. The letter "A" represented the intervention group, and the letter "B" represented the control group.

To prevent bias in data evaluation, the groups were coded as A and B, and data analysis will be conducted by an independent statistician. The codes for the intervention and control groups will only be revealed after the completion of data analysis and interpretation.

In the literature, it is recommended that each step of randomized controlled trials be conducted in accordance with the "Consolidated Standards of Reporting Trials (CONSORT)"(36-38). The flow diagram for the intervention and control groups was prepared following the guidelines specified in CONSORT, and the randomization process adhered to the CONSORT 2022 report(39) (Figure 1 and 2).

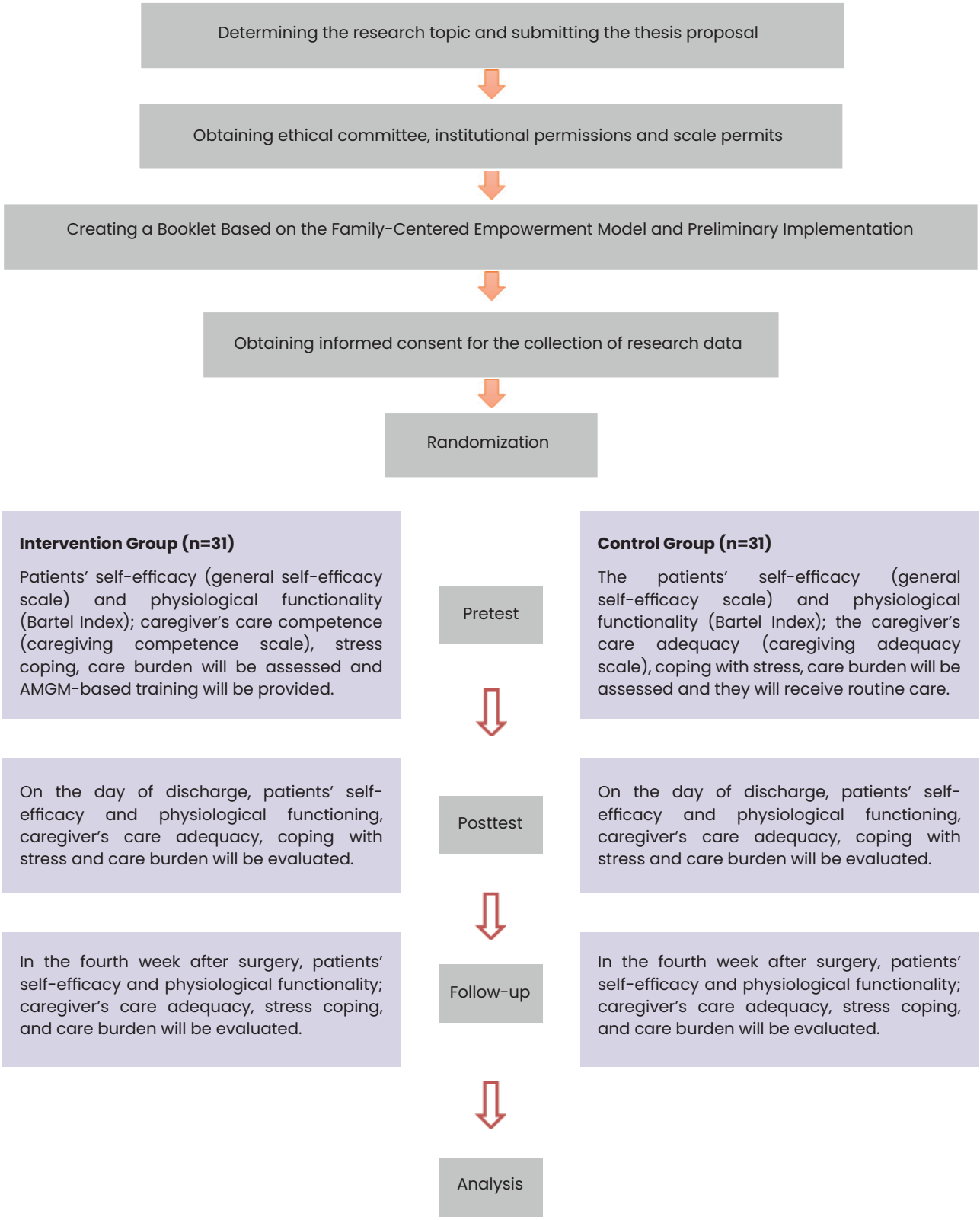

Figure 1: Work Flow Chart

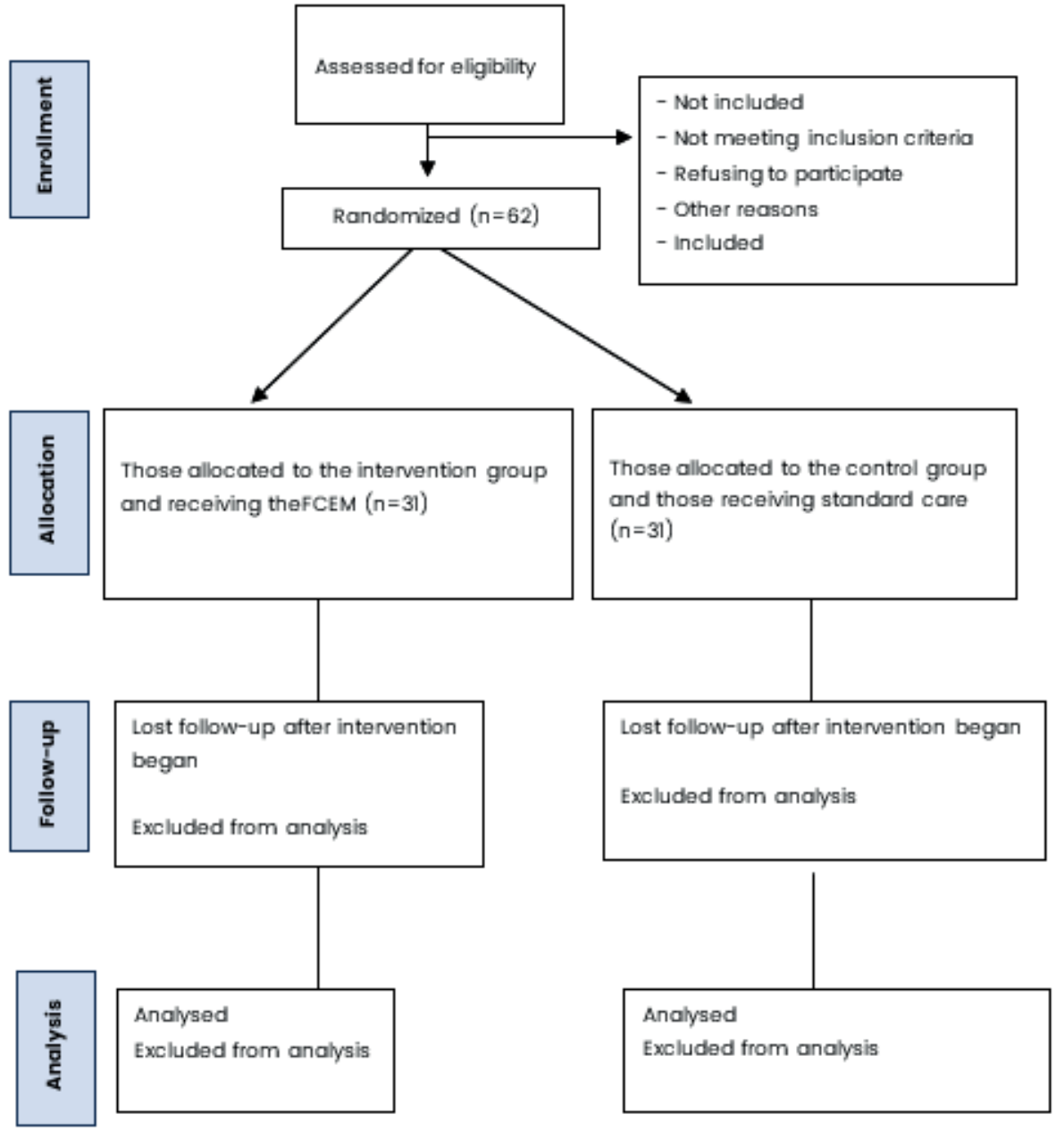

Figure 2: CONSORT Flow Diagram

Creation and Evaluation of a Booklet Prepared According to the Family-Centered Empowerment Model

While preparing the booklet, evidence-based current practices were combined with the practices carried out in the clinic. First, a detailed literature review was conducted, and the sections to be included in the booklet were divided into two main parts. Accordingly, the booklet consists of two main sections. The first section contains information about the TKA process (pre-operative, post-operative, and post-discharge care), and the second section is focused on stress management and healthy living for the caregiver.

In the first section, topics such as pre-operative care (deep breathing exercises, cough exercises), post-operative care (pain management, exercises, nutrition, bath time, medications, daily life considerations, home safety measures, follow-up appointments, return to work, sexual life, religious practices, and possible social activities) are included. The exercise photos in this section were taken in a studio with a professional camera, with the assistance of a faculty member from the Faculty of Fine Arts of the same university, in order to ensure that they are presented in a way that can be easily understood by the patients

For the second section of the booklet, the researcher who conducted the intervention attended a Stress Management and Motivational Interviewing course. This section includes topics such as Stress Management Techniques, Relaxation Exercises, Common Cognitive Distortions for Caregivers, and Healthy Living.

For the booklet, an easy-to-read Arial font was chosen, and the booklet was printed in A3 size.

The booklet "Assessment Form for the Appropriateness of Written Educational Materials" was sent to a total of 8 experts, including 1 specialist orthopedic nurse, 1 physiotherapist, and 6 academicians working in nursing faculties. It was updated according to the suggestions from the experts. In the analysis of the data obtained from the Assessment Form for the Appropriateness of Written Educational Materials, Kendall's Coefficient of Concordance test was performed. Accordingly, it was concluded that there was statistical agreement between the expert opinions.

Pilot Study

After the completion of the ethical approval and institutional permission, the pilot study was carried out with six patients and their caregivers who met the study criteria and agreed to participate.

As a result of the pilot study, additions were made to the sections related to household chores, religious practices, and nutrition in the booklet. In the second section of the booklet, additions were also made to the "Common Cognitive Distortions for Caregivers" section. The six patients who participated in the pilot study will not be included in the main study.

Data Collection

Data collection is planned between December 2023 and August 2024. Patients come to the anesthesia clinic before the surgery date. Patients will be interviewed here for the first time. Patients are admitted to the ward one day before the surgery date. Patients and caregivers who will have TKA and meet the inclusion criteria

will be informed about the study before randomization and their consent will be obtained. Individuals with TKA are usually elderly. Therefore, these individuals may have deterioration in cognitive functions such as memory, comprehension, and attention. The person may not know what year it is or where they are. Individuals who provide care to TKA patients may also be elderly.(40). Therefore, it uses standard methods to measure the extent to which brain functions are affected. The most well-known of these is the mini-mental test. This test, which was first prepared in 1975, provides a practical assessment of cognitive functions in about 10 minutes. In order for the training to be given within the scope of the research to be effective, participants must receive more than 25 points from this test (less than 10 points indicate serious impairment, 10-19 points indicate moderate dementia, and 19-24 points indicate early dementia). If the patient and caregiver have a mini-mental test score below 25 points, they will not be included in the study.

Patients and caregivers who meet the study criteria and agree to participate in the study will be assigned to the intervention and control groups using the block randomization method.

In the intervention group, the sessions will start with the family-centered assessment of the patient and caregiver in the anesthesia clinic/orthopedic clinic and the preliminary tests. The patients' self-efficacy (general self-efficacy scale) and physically functionality (Barthel Index); the caregiver's care competence (caregiving competence scale), stress coping, and care burden will be evaluated. It will be stated that they should consult the researcher about any questions they would like to ask about the booklet, and then the information booklet will be given to the families caring for the TKA patient and the information in the booklet will be explained.

The second interview will be held within the first eight ours after the patient is admitted to the ward. The purpose of this session is to reiterate the preparations that need to be made at home before being discharged after the surgery, to inform about pain management, medications to be used and their side effects, to teach the issues that need to be considered regarding the care of the operated knee, leg exercises, use of auxiliary equipment, getting out of bed, turning on the side, standing up, sitting, getting into the car, teaching the caregiver about their strengths and weaknesses, and to inform them about coping with stress. Progressive relaxation exercises will be taught to the caregiver.

The third interview will be held within 8 hours after the surgery. The purpose of this session is to teach the precautions that can be taken against the development of complications that may occur due to remaining inactive, the issues that need to be considered regarding using the toilet after the surgery, and the issues that need to be considered regarding bathing and dressing. In addition, the role of the caregiver (putting ice, accompanying the patient to the toilet, dressing them, using drains, catheters, correct anti-embolic socks, safety of catheters, etc.) will be reminded again. The importance of adequate and balanced nutrition and sleep after surgery will be emphasized.

The fourth meeting will be held on the day of discharge in the ward. The purpose of this

session is to conduct post-tests, manage the ups and downs in the caregiving process, teach the issues that need to be considered if returning to work after surgery and the issues that need to be considered in leisure activities, and remind the issues that need to be considered regarding wound care-dressing and housework. A general discussion will be held with the caregiver on the change in coping with stress. The caregiver will be taught where to get help according to their needs by facilitating the recognition and use of external social resources. It will be explained when to go to the emergency room. The patient and the caregiver will be taught how to use anticoagulant medication subcutaneously. It will be reminded how to use antiembolic stockings..

The fifth meeting will be held by phone with the patient and caregiver 1 week after surgery. The purpose of this meeting is to have a general discussion about the change, to share positive and negative experiences, to question coping behaviors and to guide exercises, and to answer questions.

The sixth interview will take place in the outpatient clinic 2 weeks after the surgery when the doctor comes for a check-up and stitch removal. The purpose of this interview is to evaluate the caregiver's general stress management. During this check-up, blood is drawn from the patients and x-rays are taken. The caregiver will be guided on where to have these done. They will be taught how to follow up on blood results. They will be motivated to develop health-enhancing behaviors during the caregiving process.

The seventh interview will be held by phone with the patient and caregiver 3 weeks after surgery. The purpose of this interview is to check whether the exercises are done and how often they are done, and to encourage health-enhancing behaviors during the caregiving process.

The eighth interview is planned to be held at the outpatient clinic where the patient comes for a doctor's check-up on the 4th week after the surgery. The purpose of this interview is to apply the follow-up test, to teach the patient and caregiver where to apply according to their needs, and to evaluate their education and interviews.

The details of the interview are given in Table 1 and Table 2.

Control Group

The control group will not receive any intervention other than the routine information given by the doctor and nurses and will be kept waiting. In the pre-operative period, the service nurse ensures that the patient is admitted to the clinic and also plays a role in introducing the service and the team, explaining the service order and rules, and providing necessary information. The nurse does not provide any information to the patient about the surgery. In the pre-operative period, she is responsible for treating the patient if any, putting on an operating room gown, and checking the necessary file preparations. Her duties after the surgery are to put on her clothes together with her relative, check her drains and catheters, assess her pain, administer the medications requested by the physician, and take vital signs. The patient is informed by the physician performing the surgery about the exercises that need to be done after the surgery. In the first stage, in-bed exercises are performed, then sitting on the edge of the bed, having a Continuous

Table 1. Planned data collection scales and measurement time points for patients with TKA and their caregivers

	Intervention group						Control group					
	Patients			Family Caregivers			Patients			Family Caregivers		
	Time Points											
Time Point	T_{-1}	T_0	T_1	T_{-1}	T_0	T_1	T_{-1}	T_0	T_1	T_{-1}	T_0	T_1
ENROLMENT:												
Eligibility screen, Mini Mental Test	*			*			*			*		
Informed consent	*			*			*			*		
List other procedures	*			*			*			*		
Allocation	*			*			*			*		
Participant Identification Form	*			*			*			*		
Daily Living Activity Index score	*	*	*				*					
General Self-efficacy scale	*	*	*				*					
Zarit Caregiver Burden Scale				*	*	*				*	*	*
Caregiving Competence Scale				*	*	*				*	*	*
Stress Coping Scale				*	*	*				*	*	*

T_{-1}: Pre test at the anesthesia clinic within 10 days before the surgery date ; T_0: Post test on the 3rd day after surgery.; T_1: The follow-up test was performed at the 30th day after surgery.

Table 2. Interview Content Plan of the Program Based on the Family-Centered Empowerment Model

Time- Place-Face to face/phone	Interview Content Plan of the Program Based on the Family-Centered Empowerment Model
1. session- Pre-operative – Polyclinic-face to face	Introduction, introduction of the patient and caregiver, role in the study, objectives of the study, time schedule and detailed questions -Providing information about FCEMP -Obtaining expectations from the program -Giving the booklet prepared according to FCEMP to the patient in the outpatient clinic -Explaining the purpose of the training program -Providing information about total knee arthroplasty -Providing information about daily living activities -Skill training
2. session- Within the first 8 hours of admission to the ward- face to face	-Summarizing the previous session -Teaching the necessary preparations to be made in the home environment before discharge -Teaching the necessary information about pain management in the post-surgical period -Teaching the medications to be used and their side effects -Teaching the key points regarding wound care after surgery -Teaching leg exercises, use of assistive devices, climbing and descending stairs, getting out of bed, turning over, standing up, sitting, and getting into the car -Teaching self-acceptance with both positive and negative aspects, recognizing strengths and weaknesses, identifying dilemmas, bringing out automatic thoughts, increasing awareness of behaviors, and developing a positive attitude toward oneself -Assessing the caregiver's risky health behaviors -How to understand stress? -Small exercises to reduce stress - Teaching Relaxation Exercise

Table 2 Cont. Interview Content Plan of the Program Based on the Family-Centered Empowerment Model

Time- Place-Face to face/phone	Interview Content Plan of the Program Based on the Family-Centered Empowerment Model
3. session- Within the first 8 hours after surgery- face to face	-Summarizing the previous session -Teaching the precautions to prevent complications related to movement -Teaching the important considerations regarding toilet use in the post-surgical period -Teaching the necessary precautions for bathing and dressing - Assigning tasks to the caregiver -Encouraging the caregiver to adopt help-seeking attitudes and behaviors -Teaching the importance of adequate and balanced nutrition in the post-surgical period and the considerations for proper nutrition -Teaching the important precautions regarding doing household chores after surgery -Teaching the importance of rest and sleep in the post-surgical period and the considerations to be made during sleep -Discussing change and providing encouragement - Asking the patient to repeat the learned skills
4. session- Discharge day- face to face	-Summarizing the previous session - Teaching the issues to be considered in working life after the surgical procedure - Teaching the issues to be considered in leisure activities after the surgical procedure - Making a general discussion on change -Emotion-focused coping strategies will be explained -Dealing with one's own emotions: anger, grief, loss and disappointment -Being able to manage the patient's subcutaneous anticoagulant medication - Facilitating the caregiver's recognition and use of external social resources - The caregiver will be taught where to seek help according to their needs -Explaining when it is necessary to go to the emergency room
5. session- Postoperative week 1- by phone	-Summarizing the previous session - Have a general discussion on change - Appreciate the change - Share positive and negative experiences -Coping Behaviors - Problem-focused coping strategies - Define the problem - Recognize external and internal resources - Intervention plan - Relaxation Exercise
6. session- Postoperative week 2- Polyclinic-face to face	-Stress Management -Giving a scenario and asking the caregiver to analyze -Self-Health Management -Meeting own health needs -Recognizing signs and symptoms -Healthy lifestyle -Developing health-promoting behaviors in the caregiving process - Recognizing which exercises are done and how often they are performed
7. session- Postoperative week 3- by phone	- Checking which exercises are done and how often they are performed. -Encourage health-promoting behaviors during the caregiving process.
8. session- Postoperative week 4- Polyclinic-face to face	Evaluation of the training and interviews

Passive Motion(CPM) device attached and doing exercises, and being taught how to stand up and walk with support. After being discharged, patients come to the outpatient clinic for their first check-up 15 days after the surgery. They come to the outpatient clinic for their second check-up 30 days after the surgery. The part of the booklet prepared for the intervention group that should be done starting from the 30th day after the operation will be given to the control group after the final follow-up.

Analyses

The data obtained in the research will be analyzed using IBM's SPSS Statistics 29 (IBM Corporation, New York, USA) software package. Descriptive statistical methods (number, percentage, mean, standard deviation) will be used to evaluate the data. Parametric tests will be used for normally distributed data while non-parametric tests will be utilized for non-normally distributed data. The significance level will be taken as $p<0.05$.

Ethical Considerations

This study was registered in the Clinical Trials database (NCT06402539).

The study's ethics committee approval was obtained from the Selçuk University Faculty of Nursing Non-Interventional Clinical Research Ethics Committee with the decision number 2023/43. Institutional permission was obtained from the hospital where the study would be conducted (583484/01.09.2023). Informed consent was obtained from the patients, both verbally and in writing. Scale usage permissions were obtained from scale owners. All stages of this study were carried out in accordance with the Declaration of Helsinki. This research was prepared, applied, and reported according to the Reporting Criteria for Randomized Parallel Group Studies (CONSORT 2022) (39).

DISCUSSION

This study highlights the important role played by family members in the caregiving process for individuals undergoing TKA and their caregivers using the FCEM.

In a randomized controlled trial examining the effect of the FCEM in the home care of older adult patients after THA, it was shown to improve patient motivation and self-care effectiveness, support recovery of knee function after surgery, and reduce the occurrence of complications.(15). In a multicenter study on strengthening the education of relatives of arthroplasty patients, it was determined that the information expectations of caregivers were not adequately addressed in any center.(40). Therefore, caregivers may have received less education than they expected regarding their patients' processes and may not be prepared to deal with any adverse situations during recovery.

In intervention studies based on the FCEM have demonstrated its ability to reduce caregivers' care burden, enhance self-efficacy and self-esteem, and improve stress management (12, 41). However, the majority of studies in the literature have focused on individuals with chronic diseases. A systematic review and meta-analysis indicated that future researchs are needed to explore the continuous intervention of nurse-led FCEM in diverse patient and caregiver populations. (42).

CONCLUSION

Our study protocol will guide subsequent research by providing details of the FCEM program. FCEM helps in planning, implementing and evaluating health services through the collaboration of patients and families. FCEM provides opportunities for family caregivers to gain knowledge and skills so that they can best manage family life and consequently improve the lifestyle and quality of life of all family members. As a result of the research, it is expected that caregivers will demonstrate improved knowledge and skills in providing TKA care, managing the behavioral problems of patients and caregivers after receiving FCEM, seeking relevant information from the provided booklet, the researcher, and healthcare professionals, discussing patient behavior with family members, and protecting their own mental health while performing these tasks.

Conflict of interest

There is no conflict of interest between the authors.

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Appendix

This study belongs to the study protocol of a doctoral thesis study with a randomized controlled design.

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ORIGINAL ARTICLE

Does an Increase in the Tibial Slope Angle Increase the Risk of Anterior Cruciate Ligament Re-rupture?

Tibial Eğim Açısındaki Artış, Ön Çapraz Bağ Rekonstrüksiyonunda Re-ruptür Riskini Artırır Mı?

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ABSTRACT

Aim: Despite the improvements in Anterior cruciate ligament recontruction (ACLR) surgery, results of revision surgeries are not satisfactory. One of the most current reasons that increases the risk of revision surgery after ACLR is the posterior tibial slope angle (PTSA). In this study, the relationship between posterior tibial slope angle and rupture after primary and revision surgery was investigated.
Methods: Patients over 18 years of age who underwent primary ACLR (primary group), patients with re-rupture (revision group) and individuals without any ligament injury (control group) were included in the study. Knee joint images of the participants were obtained by retrospective archive search. The posterior tibial slope angles in the included knee radiographs were measured using the anterior tibial cortex method.
Results: The study evaluated knee joint images of 124 patients in the primary group, 39 patients in the revision group and 100 participants in the control group. Intra-observer and inter-observer reliability of PTSA measurements was found to be appropriate. A statistically significant difference was observed between the mean tibial slope angle measurement of the control, primary and revision groups. (p=0,0001). It was found that the risk of primary anterior cruciate ligament (ACL) injury and ACL re-rupture for an individual with PTSA>11.4 was 7.6 times and 9.58 times higher, respectively, than for an individual with PTSA<11.4°.
Conclusions: Higher PTSA was observed to be an anatomical risk factor for primary and secondary ACL injuries. Patients with higher PTSA should be evaluated for additional risk factors and slope-reducing surgeries should be applied to these patients when necessary.

Keywords: Anterior cruciate ligament, graft failure, reconstruction, revision surgery, tibial slope angle.

ÖZ

Amaç: Ön çapraz bağ rekonstrüksiyonu (ÖÇBR) cerrahisindeki gelişmelere rağmen revizyon cerrahilerinin sonuçları tatmin edici değildir. ÖÇBR sonrası revizyon cerrahisi riskini artıran nedenlerden en güncel olanların başında posterior tibial eğim açısı (PTSA) gelmektedir.. Bu çalışmada, posterior tibial eğim açısı ile primer ve revizyon cerrahisi sonrası meydana gelen rüptür arasındaki ilişki incelenmiştir.
Gereç ve Yöntemler: Primer ÖÇBR geçiren 18 yaş üstü hastalar (primer grup), rerüptür olan hastalar (revizyon grubu) ve herhangi bir bağ yaralanması olmayan kişiler (kontrol grubu) çalışmaya dahil edilmiştir. Katılımcıların diz eklemi görüntüleri retrospektif arşiv aramasıyla elde edilmiştir. Dahil edilen diz radyografilerindeki posterior tibial eğim açıları anterior tibial korteks yöntemi kullanılarak ölçülmüştür.
Bulgular: Çalışmada primer gruptaki 124 hastanın, revizyon grubundaki 39 hastanın ve kontrol grubundaki 100 katılımcının diz eklemi görüntüleri değerlendirilmiştir. PTSA ölçümlerinin gözlemci içi ve gözlemciler arası güvenilirliğinin uygun olduğu bulunmuştur. Kontrol, primer ve revizyon gruplarının ortalama tibial eğim açısı ölçümü arasında istatistiksel olarak anlamlı bir fark gözlendi. (p=0,0001). PTSA>11,4 olan bir bireyde primer ön çapraz bağ (ÖÇB) yaralanması ve ÖÇB tekrar kopması riskinin sırasıyla PTSA<11,4° olan bir bireye göre 7,6 kat ve 9,58 kat daha yüksek olduğu bulundu.
Sonuçlar: Daha yüksek PTSA'nın primer ve sekonder ÖÇB yaralanmaları için anatomik bir risk faktörü olduğu gözlemlendi. Daha yüksek PTSA'ya sahip hastalar ek risk faktörleri açısından değerlendirilmeli ve gerektiğinde bu hastalara eğim azaltıcı cerrahiler uygulanmalıdır.

Anahtar Kelimeler: Ön çapraz bağ, greft yetmezliği, rekonstrüksiyon, revizyon cerrahisi, tibial eğim açısı.

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INTRODUCTION

An increase in the incidence of anterior cruciate ligament (ACL) rupture is being observed due to the increase in the number of individuals participating in sports (1). With advancements in surgical techniques, the widespread use of arthroscopy and an increase in the incidence of ACL injuries, there has been a similar increase in the number of ACL reconstruction (ACLR) surgeries. Despite the improvements in surgical techniques and graft options, the failure rate of ACLR still varies between 3-10% (1). Unfortunately, ACL revision surgery does not provide as impressive results as primary ACLR surgery (2).

It is known that the likelihood of re-injury after ACLR depends on various risk factors (2). These risk factors are classified as extrinsic (modifiable) and intrinsic (difficult to modify) factors (3). Although developments in reconstruction surgery are being aimed at limiting extrinsic factors that may cause graft failure, there is less data available on the improvement of intrinsic factors (4).

In recent studies, it has been found that posterior tibial slope angle (PTSA) is related to strain that occurs in ACL (5). In cadaver studies, it has been shown that increasing posterior tibial slope increases the shifting of the tibia to the front of the femur (5). Thus, it is thought that increased PTSA is related to primary ACL injury and graft failure after ACLR. In a prior study, it has been reported that the risk of ACL graft failure is 7 times higher in adults with PTSA>12º (6).

Reducing the rate of ACL re-rupture is important for improving the rates of return to sports and daily activities without pain after ACL revision surgery. (7,8). In this study, it was aimed to compare PTSA of knees with ACL injuries requiring revision surgery and knees that did not suffer re-injury after primary surgery. The hypothesis of the study is that PTSA will be higher in knees that need revision surgery.

MATERIALS and METHODS

Patients were evaluated after approval was obtained Ethics Committee (Decision No: 879-03.09.2021). The study was conducted under the principles of the Declaration of Helsinki. After the approval of the ethics committee was obtained, knees that had suffered an ACL injury and subsequently underwent surgery (primary group) and knees in need of revision surgery (revision group) were identified by a retrospective scan of the last 4 years. Images of patients over the age of 18 that were taken at least 9 months after surgery were included in the study. All of the selected primary ACLRs were performed with hamstring autografts. All primary surgeries were performed using the anatomical technique. Secondary interventions applied to the patients included in surgery notes were identified and noted. A total of 163 patients over the age of 18 who underwent ACLR or correction ACLR, were regularly followed up and followed the protocols. Patients with advanced osteoarthritis, those who had no follow-up and radiological imaging, those who underwent HTO in the same session, those with multiligament injuries, and those with ACL injuries from the other knee were excluded from the study. The control group included patients who had not undergone any orthopedic surgery, had magnetic resonance imaging (MRI), did not require additional surgery, did not have osteoarthritis, and were asked for an

MRI due to suspected meniscal injury but did not detect any pathology. From the available knee radiographs, images that allowed measuring the tibial slope angle (true lateral radiographs with femoral condyles overlapping) were selected for evaluation (Figure 1,2). In addition, PTSA of knee radiographs obtained from patients who did not have ligament and meniscus injuries were measured and included in the study as a control group. Measurements included in the study were performed blindly to each other by an orthopedics and traumatology specialist and a sports medicine specialist. To measure intraclass correlation, measurements were made twice, 4 weeks apart. PTSA measurements of images obtained from lateral knee radiographs were made via the built-in ruler in the Extreme Pacs v.3858 software system using the anterior tibial cortex method. First, a tangent line was drawn to the anterior cortex proximal to the tibia to represent the longitudinal axis of the tibia. A second line perpendicular to the longitudinal axis was drawn. Lastly a third line tangential to the tibia plateau was drawn. PTSA was accepted as the angle between 2nd and 3rd lines. (9).

Statistical Analysis

The statistical analyses of the data included in the study were performed using NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA) package program.

Figure 1: Figure of PTSA measurement in a patient undergoing ACLR

Figure 2: Figure of PTSA measurement in a patient undergoing revision ACLR

Table 1. Intra-rater reliability

	Rater 1	Rater 2
	Intraclass Correlation Coefficient (95% CI)	Intraclass Correlation Coefficient (95% CI)
Control Group	0,989 (0,983-0,992)	0,985 (0,977-0,990)
Primary Group	0,985 (0,979-0,990)	0,985 (0,978-0,989)
Revision Group	0,975 (0,953-0,987)	0,969 (0,940-0,984)
All Groups	0,991 (0,989-0,993)	0,990 (0,987-0,992)

Table 2. Inter-rater reliability

	Inter-Class Correlation Coefficient (95% CI)
Control Group	0,981 (0,975-0,986)
Primary Group	0,977 (0,970-0,982)
Revision Group	0,962 (0,940-0,976)
All Groups	0,987 (0,984-0,989)

Table 3. Evaluation of mean tibial slope angle measurements

	N	PTSA Measurement
Control Group	200	8,52±2,55
Primary Group	248	12,88±3,05
Revision Group	78	16,37±3,79
	p	0,0001

PTSA: Posterior tibial slope angle (Since the measurements were made twice, the total number in the two measurements is stated in the median value)

Table 4. Comparison of mean tibial slope angle measurements between groups using Tukey's multiple comparison test

Tukey's Multiple Comparison Test	p
Control Group / Primary Group	0,0001
Control Group / Revision Group	0,0001
Primary Group / Revision Group	0,0001

Table 5. Evaluation of the correlation between age and PTSA

	Group		PTSA Measurement
Age	**Control Group**	**r**	0,010
		p	0,889
	Primary Group	**r**	0,066
		p	0,301
	Revision Group	**r**	0,069
		p	0,546

PTSA: Posterior tibial slope angle

Table 6. Examining the distribution between groups when PTSA≥12°

		Control Group		Primary Group		Revision Group		p
Measurement	<12°	187	93,50%	87	35,08%	11	14,10%	0,0001
	≥12°	13	6,50%	161	64,92%	67	85,90%	

PTSA: Posterior tibial slope angle

Besides descriptive statistical methods (mean, standard deviation), the distribution of variables was examined with the Shapiro – Wilk test of normality as part of the evaluation of the data. One-way analysis of variance was used for comparing normally distributed variables. Tukey's multiple comparison test was used for comparing subgroups. Independent t test was used for comparing pairs of groups. Chi-square test was used for comparing qualitative data. Pearson correlation test was used to determine the relationships between variables. For differential diagnosis of primary surgery and revision surgery measurements, areas under the ROC Curve were calculated and sensitivity, specificity, positive predictive value, negative predictive value and LR (+) values and cut-off values of the variables were determined. A level of significance of $p<0.05$ was accepted as significant.

RESULTS

Measurements of 124 knee radiographs belonging to the primary group, 39 belonging to the revision group, and

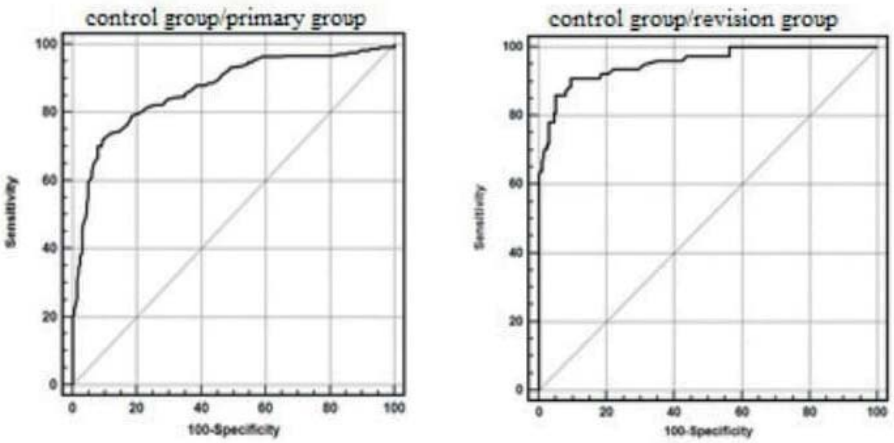

Figure 3: Figure of ROC curve of the tibial slope for the control group: primer group and control group:revision group (Vertical part sensitivity horizontal part specificity)

100 belonging to the control group were included in the study. The mean age of the primary group was 27.91±8.09, the mean age of the revision group was 29.18±7.25, and the mean age of the control group was 35.32±8.63. There was no statistically significant difference between the groups in terms of age (p>0.05). The average time elapsed after surgery in the primary group was found to be 24.15±8.51.

When the 1st and 2nd measurements of the evaluators were evaluated for reliability, all measurements were found to be above the accepted value of 0.700, meaning inter-rater reliability was high (Table 1-2).

A statistically significant difference between the mean tibial slope angle measurements of the control, primary and revision groups was observed (p=0,0001), (Table 3). When Tukey's multiple comparison test results were evaluated, the measurement averages of the control group were found to be statistically significantly lower than the measurement averages of the primary and revision groups (p=0.0001). The mean measurements of the primary group was observed to be statistically significantly lower than the mean measurements of the revision group (p=0,0001), (Table 4).

There was no statistically significant difference between the age and tibial slope angle measurements of all groups (Table 5).

When the distributions of the measurement results of the control, primary and revision groups were evaluated, a statistically significant difference was observed between measurement results (p=0,0001), (Table 6). The distribution of measurement results ≥12° in the control group was found to be lower than the primary and revision groups, and the distribution of measurement results ≥12° in the primary group was found to be lower than the revision group.

The area under the ROC curve of the measurement value of the primary group was found to be 0.870 (0.835-0.899). Sensitivity, specificity, positive predictive value, negative predictive value and LR(+) value for a predictive value of >11.4° were found to be 72.18, 90.50, 90.4, 72.4 and 7.60, respectively. The risk of primary ACL injury was found to be 7.6 times higher in individuals with PTSA>11.4° when compared to individuals with PTSA<11.4°.

The area under the ROC curve of the measurement value of the revision group was found to be 0,955 (0,920 -0,976). The risk of ACL re-rupture was found to be 9.58 times higher in individuals with PTSA>11.4° when compared to individuals with PTSA<11.4° (Figure 3).

DISCUSSION

It is known that increased tibial slope due to increased compressive axial load generates a greater anterior shear force in the tibiofemoral joint (3). An increase in PTSA increases the load on the ACL, the primary restraint against anterior tibial translation, increasing the risk of a potential ACL rupture (3). Studies on the extent of the effect increased PTSA has on ACLR re-ruptures are limited in number. In this study, the PTSA measurement of the control group was found to be lower than the primary group and revision group, and the PTSA measurement of the primary group was found to be lower than the revision group. No correlation between age and PTSA was found.

The relationship between PTSA and ACLR has been studied quite frequently in the literature in recent years. The studies conducted are mostly primary ACLR patients or revision ACLR studies, and we wanted to contribute to this area, which has less information in the literature, by comparing these two groups in our study.

To date, very few studies have addressed the relationship between tibial slope and re-injury. In a study by Dæhlin et al. examining PTSA in 728 patients, it has been shown that increased tibial slope is not associated with revision surgery, but knees that have suffered injuries have higher PTSA values than healthy knees (10). In their study which followed-up patients under the age of 21 after ACLR, Cooper et al. have found that the population requiring revision surgery had more patients with PTSA>12°. However, this finding was not statistically significant (11). The authors noted that further studies were needed to find out which angle distinguishes patients at the highest risk for revision surgery. However, it should be taken into account that obtaining data from a large database, in which the number of surgeons, their level of expertise and the volume of surgery were unknown, may have affected the results of the aforementioned study. In their study, Gwinner et al. have also reported that the risk of recurrent graft failure increased by 11.6 times in patients with PTSA>12° (7). In a review study by Liu et al., in which 20 studies were included, it has been reported that a relationship between increased PTSA and ACL graft failure has been found in 15 of the studies (12). Arguing that a higher PTSA is associated with risk of ACL graft failure, the authors have noted that although there are highly reliable methods for measuring PTSA, there is no consensus about which values are risky. In this study, PTSA values of the primary group and the revision group were also found to be higher than the PTSA values of the control group. These results are similar to previous studies and confirm that increased PTSA is a risk factor for primary injury and re-injury.

In another study conducted by Lee et al., PTSA of patients in need of revision surgery has been found to be significantly higher compared to patients without re-injury ($p<0.01$). Lee et al. have reported that the probability of ACL graft rupture increases 3.48 times in knees with PTSA≥11°, and the risk increases 4.52 times in knees

with PTSA≥12° (13). Salmon et al. have followed-up 200 ACLR patients (operated on by a single surgeon) for 20 years, and observed that graft rupture occurred in 37 of 179 patients whose follow-up was completed. During these 20 years, it has been found that ACL graft survival was 22% for adolescents with PTSA≥12°, and the risk of rupture was 11 times higher in adolescents with PTSA≥12° compared to adults with PTSA<12°. The authors have indicated that PTSA≥12° is a strong predictor of recurrent ACL injury (6). In a study by Webb et al., in which they included the results of 15 years of follow-ups, it has been found that the probability of suffering another ACL injury after reconstruction increased by 5 times in patients with a tibial slope ≥12° (14). In their study, Ahmed et al. have found that PTSA of patients who had more than 3 ACL injuries was significantly higher compared to patients who had less than 3 ACL injuries (p=0.002), (2). Napier et al. have also found that an increase in tibial slope angle poses a risk for a third injury. The authors have also associated increased PTSA with re-injury rates after ACL revision surgery (3). In this study, it was also found that increased PTSA was associated with re-injury and that re-rupture rate increased by 9.58 times in patients with PTSA>11.4. PTSA, despite having a strong correlation with risk of re-rupture, is rarely taken into account in surgical decision-making in revision ACLR surgery. Studies on which PTSA values should be considered as a risk factor are ongoing (2). In their current study, Luke V. Tollefson et al.(15) found patients with PTSA≥12° to be a risk factor for ACL injuries and reported that yto surgery should be added.

In the study of Lee et al., no significant correlation between PTSA and age has been found (p=0,241). In the same study, it has been found that PTSA did not have a correlation with body mass index either (p=0.613), (13). Through their measurements obtained from 1090 tibia belonging to cadavers, Weinberg et al. have also determined that PTSA was not affected by age (16). In this study, there was no significant correlation between PTSA and age in all 3 groups. Age-related correction is not a concern for the group of patients that are recommended slope-reducing surgery, for whom PTSA is considered a risk factor.

In their study conducted on cadavers, Bernhardson et al. have found that increased slope angle leads to an increase in the force applied on the ACL graft, and that low slope angles have a protective effect on the ACL graft (17). In their study, Sonnery-Cottet et al. followed-up combined ACL revision surgery and proximal tibia anterior closing wedge osteotomy performed on patients with PTSA>12°, and in a follow-up period of 31.5 months, the mean PTSA of patients has been found to be 9.2°, and no other injuries have been observed in the knee that underwent surgery (18). However, the authors noted that the functional results of these surgeries were less positive and the risk of potential morbidity was higher when compared to primary ACLR. In their study discussing the results of 2-year follow-up of 9 patients who underwent revision ACL reconstruction and tibial deflexion osteotomy, Dejour et al. have found that the PTSA value of patients decreased from 13.2° ± 2.6° to 4.4° ± 2.3° after surgery and have argued that tibial slope correction decreases the risk of ACL re-injury (19). The authors have emphasized the importance of careful analysis of risks of failure before ACL reconstruction and

recommended correction surgery if the tibial slope of the patient exceeds 12° in order to reduce the risk of graft failure. In a systematic review examining high tibial osteotomy (HTO) and ACLR surgery, it has been observed that re-rupture rate was 0% after the mentioned procedures (8). However, the authors have reported that there are limitations to these estimates due to limited number of patients, short follow-up periods and selective reporting. In their study retrospectively examining the results of 2-yer follow-up of 30 patients who underwent ACLR and medial opening wedge osteotomy, Arun et al. have shown that a correction surgery decreasing the tibial slope by >5° has a functionally positive effect on the restructured ACL graft (20). According to a review conducted by Nazzal et al., high tibial osteotomy reducing high PTSA can lower the risk of failure for ACLR (21). However, decision for surgery should be made by considering the risks, complications and technical difficulties, the long-term healing process of wedge osteotomy and its possibility of complicating future total knee replacement if necessary. In addition, combining HTO with the already technically demanding ACLR revision procedure can also lead to increased technical failures (8). Further studies are required in order to elucidate abnormal PTSA values and to determine the appropriate PTSA values that are indicative of an osteotomy surgery that reduces tibial slope for primary ACLR. How to utilize information on PTSA remains effectively unknown.

The population of the study being composed of only males, and, due to the retrospective nature of the study, information such as how much of the patients had contact injuries, the activity level of the individuals, the extent of compliance to pre/post-operative sports rehabilitation, the rate of return to sports activities and patient-reported outcome measures not being known were limitations of this study.

The strengths of this study were its inclusion of a control group composed of patients without ACL injuries and its retrospective period being as short as possible, taking into account the developing and changing surgical techniques and materials. Most of prior studies included in the literature have examined primary injuries, and a minority of these studies have studied multiple graft failures. According to our observations, this study is the only study on this subject that included a healthy control group for comparison.

CONCLUSION

High PTSA is significantly associated with possible graft failure. The causes of re-injury are multifactorial, but evaluations in this study support that there may be an anatomical predisposition to re-injury related to increased posterior tibial slope. It should be noted that predisposition to graft failure depends not only on anatomical conditions, but also on age, acquired injuries, graft tissue, graft position, treatment of secondary peripheral instabilities and postoperative rehabilitation. When the results related to risk of graft failure following primary and revision ACL surgery and the possible future consequences of tibial slope correction surgery are considered, it is seen that identifying patients who are at risk is important for the appropriate selection of patients for corrective surgery.

Conflict of Interest

The authors have no conflicts of interest to declare.

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