The Effect of Pain Education Given to Patients Before Total Knee and Hip Replacement Surgery on Anxiety, Pain and Analgesic Use: A Randomized Controlled Study

23.09.2025

INFORMED CONSENT FORM (INTERVENTION GROUP)

You are invited to participate in a research study conducted under the responsibility of **Asst. Prof. Dr. ….**, a faculty member at Yeditepe University Faculty of Health Sciences, and carried out by **…**, a graduate student at Yeditepe University Institute of Health Sciences. The title of this scientific study is:
"The Effect of Pain Education Given to Patients Before Total Knee and Hip Replacement Surgery on Anxiety, Pain and Analgesic Use: A Randomized Controlled Study"

This research aims to evaluate the effects of preoperative and postoperative education provided through written and visual materials, along with nurse-supported pain counseling, on patients' preoperative anxiety levels, early postoperative pain severity, and frequency of analgesic use.

The study is planned to include adult patients scheduled for elective knee or hip joint surgery between **December 2024 and July 2025**, who meet the inclusion criteria defined within the study. The participation period for each volunteer will cover the **day before surgery, the day of surgery, and the first 48 hours postoperatively**.

The study will proceed with two groups — an **intervention group** and a **control group** — and at least 35 patients will be included in each group. Participants will be randomly assigned to one of the groups. This randomization will not affect your surgical procedure or the treatment and care you receive before or after surgery in any way.

As part of this study, you will receive a **booklet entitled "Pain in Surgical Patients"** before your surgery. You will be asked to read the information provided in the booklet, which is based on scientific evidence. Subsequently, the study coordinator will send you a **short educational video** on the same topic the day before your operation. Upon your admission to the clinic, the clinical nurse (who is also the study coordinator) will answer your questions regarding pain management and provide counseling throughout your surgical process.

During these procedures, the study coordinator will ask you several questions prepared for this study. Your responses are very important for the validity and reliability of the research. Other than answering these questions and reviewing the educational materials, you will have **no additional responsibilities** in this study.

The data will be collected through **face-to-face interviews** conducted by the study coordinator using two instruments: the **Patient Information Form** and the **Preoperative Anxiety Scale**. Answering all questions will take approximately **10–15 minutes**. The preoperative education session will be conducted **only once** and will not be repeated.

No risks or discomforts are anticipated for volunteers as a result of the procedures in this study. Participation is **entirely voluntary**. You have the right to **refuse participation or withdraw** from the study at any time without providing a reason and without facing any penalty, sanction, or change in your treatment or care plan.

All the information you provide will be kept **strictly confidential**, will **not be shared** with any third party, and will be used **only for scientific purposes** under conditions that ensure data privacy. The data obtained from your responses will be presented in scientific publications **without including any personal identifiers**. No personal information such as your name, surname, email address, postal address, or phone number will be collected.

There will be **no financial compensation or cost** associated with your participation. No medical intervention, treatment, or nursing care will be performed on you by the researchers as part of this study.

If you experience any adverse event or wish to obtain more information regarding your rights as a participant, you may contact the study coordinator **….** at **+90 ….** or the responsible investigator **Asst. Prof. Dr. …** at **+90 …..** at any time of the day.

Thank you for your consent and participation. Please indicate your voluntary participation below, confirming that you are joining this study of your own free will and without any coercion.

If your physician determines that postoperative intensive care is required, if a patient-controlled analgesia device is used, if a major complication occurs, or if you decide to withdraw from the study on your own accord, your participation in the study will be terminated.

Participant Statement

“I have read and understood all the information provided in this informed consent form. The purpose and details of the research titled above have been explained to me in both written and verbal form by the study coordinator named below. I voluntarily agree to participate in this study and understand that I may withdraw at any time, with or without providing a reason. I consent to the use of the study results in publications, reports, and other scientific documents without restriction. I have been assured that, in the event of any health problem directly or indirectly related to the research procedures, I will receive all necessary medical care. I hereby confirm that I am voluntarily participating in this study without any pressure or coercion.”

Participant Name–Surname:
Date:
Address:
Phone:
Signature:

Witness Name–Surname:
Date:
Address:

Phone:
Signature:

INFORMED CONSENT FORM (CONTROL GROUP)

You are invited to participate in a research study conducted under the responsibility of **Asst. Prof. Dr. ...**, a faculty member at Yeditepe University Faculty of Health Sciences, and carried out by **....**, a graduate student at the Institute of Health Sciences at Yeditepe University. The title of this scientific study is:
"The Effect of Pain Education Given to Patients Before Total Knee and Hip Replacement Surgery on Anxiety, Pain and Analgesic Use: A Randomized Controlled Study"

This research aims to evaluate the effects of preoperative and postoperative education provided through written and visual materials, along with nurse-supported pain counseling, on patients' preoperative anxiety levels, early postoperative pain severity, and frequency of analgesic use. The study is planned to include adult patients scheduled for elective knee or hip joint surgery between **December 2024 and July 2025**, who meet the inclusion criteria defined in the study protocol. The participation period for each volunteer in the control group will cover **the day of surgery and the first 48 postoperative hours**.

The research will proceed with **two groups** — an **intervention group** and a **control group** — with at least 35 patients in each. Participants will be **randomly assigned** to one of these groups. This randomization will not affect your surgical procedure or the treatment and care you receive before and after surgery in any way. As a participant in the control group, **no additional intervention** will be administered to you. All information and procedures related to your pain management before and after surgery will be carried out **in accordance with the clinic's routine practices**.

Throughout the study process, the study coordinator will ask you several questions that have been prepared for this research. Your responses are very important for ensuring the validity and reliability of the study. Apart from answering these questions, you will have **no additional responsibilities**. All data will be collected through **face-to-face interviews** conducted by the study coordinator. The data collection process will not interfere with or delay your ongoing hospital treatment or nursing care. Data will be collected using two instruments specifically developed for this research: the **Patient Information Form** and the **Preoperative Anxiety Scale**. Answering all questions will take approximately **10–15 minutes**, and no repeated applications will be performed. There are **no anticipated risks or discomforts** associated with participation in this study. Participation is **entirely voluntary**. You have the right to **refuse participation** or **withdraw from the study at any time**, without providing any reason and without facing any penalty, sanction, or change in your treatment or care plan.

All the information you provide will be kept **strictly confidential**, will **not be shared** with any third parties, and will be used **solely for the purposes of this research**, in compliance with data protection principles. The results obtained from your responses will be reported **only in**

aggregate form and published in scientific venues **without including any personal identifiers**. No personal data such as name, surname, email address, postal address, or phone number will be collected.

There will be **no financial compensation** for participation, and you will **not incur any costs**. The researchers will **not perform any medical intervention or nursing procedure** as part of this study. If you experience any adverse event or would like to obtain more information about your rights as a participant, you may contact the study coordinator **...** at **+90 ...**, or the principal investigator **Asst. Prof. Dr. ...** at **+90 ...**, available 24 hours a day. Thank you for your consent and participation. Please indicate your voluntary participation below, confirming that you are joining this study of your own free will and without any coercion. If your physician determines that postoperative intensive care is required, if a patient-controlled analgesia device is used, if a major complication occurs, or if you decide to withdraw from the study voluntarily, your participation will be terminated.

Participant Statement

"I have read and understood all the information provided in this informed consent form. The purpose and details of the research study described above have been explained to me in both written and verbal form by the study coordinator named below. I voluntarily agree to participate in this research and understand that I may withdraw at any time, with or without providing a reason. I consent to the use of the study results in publications, reports, and other scientific documents without restriction. I have been assured that, should any health problem arise directly or indirectly related to the research procedures, all necessary medical interventions will be provided. I hereby confirm that I am participating in this study voluntarily and without any pressure or coercion."

Participant Name–Surname:
Date:
Address:
Phone:
Signature:

Witness Name–Surname:
Date:
Address:
Phone:
Signature: