Unique Protocol ID:
2025/284
Brief Title:
Effect of Foot Bath on Pain, Sleep, and Comfort Levels After Abdominal Surgery

Official Title:
Effect of Foot Bath on Pain, Sleep, and Comfort Levels After Abdominal Surgery: A Randomized Controlled Trial
25/08/2025

Dear participant

You are invited to participate in a research project with the following information.

This research was approved by the Trakya University Faculty of Medicine Scientific Research Ethics Committee with decision number … …… . . dated …… .

Before deciding to participate in the research, it is crucial to understand why and how the research will be conducted.

Participation in this research is entirely voluntary, and refusing to participate will not result in any penalty or loss of any benefits.

Similarly, once you have agreed to participate in the research, you can withdraw from it at any point without giving any reason, without causing any harm or loss of expected benefit.

The financial expenses for the procedures carried out as part of the research will be covered by the researchers, and will not impose any financial burden on you or your social security institution.

Please read the following information carefully and give it some time to decide whether or not you would like to participate in the research.

- **The scientific title of the study is:** The Effect of Foot Baths After Abdominal Surgery on Pain, Sleep, and Comfort Levels: A Randomized Controlled Trial.
- **The study's simple and understandable title is:** The effect of foot bath application on postoperative sleep, comfort, and pain levels in patients undergoing abdominal surgery: a randomized study.
- **Responsible Researcher's name and affiliation:** BLINDED, Trakya University, Faculty of Health Sciences, Department of Nursing.
- **Study objective:** The aim of this study was to determine the effect of foot bath application on postoperative sleep, comfort, and pain levels in patients undergoing abdominal surgery.
- **Nature of the research (clinical, laboratory, epidemiological, thesis study, etc.):** Thesis study
- **Research start date and projected duration:** 2025-2026
- **Expected number of volunteers to participate in the study:** 96
- **All methods, interventions, and treatments to be applied to the volunteer during the study:** You will be asked the questions in the questionnaire by nurses before and after the surgery. You will be able to ask questions about any parts you do not understand. If you are in the experimental group, a foot bath will be applied the evening after the surgery.
- **Reason for the participant's inclusion in the study:**
- who are hospitalized in the General Surgery Clinic,
- are on day 0 of surgery ,
- volunteer to participate in the study ,
- have no neuropsychiatric diagnosis and are not taking antipsychotic medications
- are over 18 years of age
- accept random selection ,

- and undergo abdominal surgery.
- For the experimental group , all patients with no infectious diseases (shingles , fungal) infections , eczema , warts , calluses), localinfections (abscesses , etc.), open lesions / wounds , scar tissue , edema , hematomas , thrombophlebitis , deep vein thrombosis,lymphangitis , coagulation disorders , varicose veins , osteoporosis , osteomyelitis , hepatitis , degenerative joint diseases, neuropathy due to diabetes , toe deformities , recent fractures , dislocations , or ruptures of muscle fibers , tendons , or ligaments willbe included in the sample .

- **The expected direct benefit for volunteers from the study** is to determine postoperative sleep, comfort, and pain levels in patients.
- **Volunteer's responsibilities:** To answer the questions in the questionnaire after the surgery.
- **Risks or discomfort to the volunteer (and, if the research is to be conducted on pregnant or postpartum women, on the embryo, fetus or infant):** The study carries no risks.
- **Measures taken against risks :** -
- **Situations or reasons requiring the termination of a volunteer's participation in the study:** Volunteers may withdraw from the study if patients wish to leave during the post-operative period.
- **Will the volunteers be informed at the end of the study?** No.
- **The person volunteers can contact to obtain more information about the research, themselves, or any unexpected events related to the research, and who can be reached 24 hours a day at the following phone number:** Responsible researcher Zeynep Kızılcık Özkan, Trakya University Faculty of Health Sciences, Contact number : 0 505 6010101
- **The purposes for which biological materials obtained from volunteers will be used:** No biological materials will be collected from you.

The purpose of the study, which is clearly described above, and who will carry it out and how it will be carried out, were explained to me in a way that I could understand.

I was informed about the benefits this research would provide to me and others.

The potential risks and discomforts that could occur during the research were explained to me in language I could understand.

I was informed about the procedures to be followed in case of any damage that may occur during the research.

During the course of the study, I was given the name and phone number of an authorized person I could contact 24 hours a day regarding possible side effects, risks, and harms, and my rights.

I was informed that no fees would be charged to me or my social security institution for any examinations, tests, and medical care services included in the research.

I am participating in this research voluntarily, without any pressure or coercion.

I was informed that I have the right to refuse to participate in the study.

I understand that I can withdraw from this study at any time without giving any reason, provided I inform the responsible investigator/physician.

I understand that if I refuse to participate in this study or withdraw later, I incur no liability and that this will not affect my access to medical care now or in the future.

I understand that the researcher/physician leading the study or the supporting organization may remove me from the study without my consent due to my negligence in fulfilling the requirements of the study program.

I understand that the Trakya University Faculty of Medicine Non-Interventional Scientific Research Ethics Committee may, if deemed necessary, have direct access to my original medical records related to the research topic, in accordance with the principle of protecting my confidentiality.

I have been informed that, in accordance with relevant legal regulations, records that could reveal my identity will be kept confidential.

I have read the Informed Consent Form, which outlines the information that should be given to volunteers before the research. I was given the opportunity to ask all the questions that came to mind and received satisfactory answers. Written and oral explanations regarding the research mentioned above were given by the researcher named below.

Under these conditions, I agree to participate in the research in question voluntarily and without any pressure or coercion.

the Informed Consent Form .

- ***The volunteer's (handwritten)***

Name-Surname:

Signature:

Address (and telephone and/or fax number, if available):

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History:

- ***For those under guardianship or custody; (Handwritten)***

Parent's or Guardian's Name and Surname:

Signature:

History:

Address (and telephone and/or fax number, if available):

- ***The researcher who made the statements***

Title, Name-Surname: (Handwritten)

Department where he/she works:

Signature:

History: