Official Title of the Study:
The Effect of Reflexology Applied to Patients with Stroke on Pain, Physiological Parameters, and Sleep Quality: A Randomized Controlled Trial

NCT Number:
Pending

Date of Document:
August 10, 2024

Institution:
Hakkari University, School of Health Services, First Aid Program

Study Location:
Physical Therapy and Rehabilitation Unit, Van Training and Research Hospital

Document Type:
Informed Consent Form and Study Protocol

INTERVENTION GROUP

VOLUNTEER INFORMATION AND CONSENT FORM

Dear participant;

This study will be conducted to examine the effect of reflexology applied to stroke patients on pain, physiological parameters, and sleep quality. The data obtained in the study will only be used for this study. You will not be charged for this study, nor will you be paid. Your information will be kept confidential, but it may be reviewed by officials supervising the quality of the study, ethics committees, or official authorities if deemed necessary. The following data collection tools will be used in the study: “Data Collection Form,” “Visual Analogue Scale (VAS),” “Richard-Campbell Sleep Scale (RCSS),” and “Physiological Parameters Recording Form.” It is very important for the outcome of the research that you fill out these forms completely and accurately. As part of this study, you will receive a 30-45 minute session of foot reflexology twice a week in a hospital setting for six weeks. At the end of the sixth week, the researcher will administer the forms mentioned above again. Individuals who wish to participate in this study will be included with their consent.

I kindly request your participation in this study and that you share this information with me. Thank you for your help and support.

I HAVE READ THE ABOVE INFORMATION AND HAVE BEEN PROVIDED WITH WRITTEN AND VERBAL EXPLANATIONS ABOUT IT. UNDER THESE CONDITIONS, I AGREE TO PARTICIPATE IN THE RESEARCH IN QUESTION OF MY OWN FREE WILL, WITHOUT ANY PRESSURE OR COERCION.

Participant Name, Surname / Signature: **Researcher Name, Surname / Signature:**

CONTROL GROUP

VOLUNTEER INFORMATION AND CONSENT FORM

Dear Participant;

This research aims to determine the effect of reflexology applied to stroke patients on pain, physiological parameters, and sleep quality. The research is based on voluntary participation. You may withdraw from the study at any stage. The following data collection tools will be used in the study: "Data Collection Form," "Visual Analog Scale (VAS)," "Richard-Campbell Sleep Scale (RCSS)," and "Physiological Parameters Recording Form." It is very important for the outcome of the research that you complete these forms fully and accurately. All your personal information will be kept confidential. You will not be asked to pay any fees for this study, nor will you be paid any fees. All this information will not be used anywhere other than for scientific research.

I kindly request your participation in this study and that you share this information with me. Thank you for your help and support.

I HAVE READ THE ABOVE INFORMATION AND HAVE BEEN PROVIDED WITH WRITTEN AND VERBAL EXPLANATIONS ABOUT IT. UNDER THESE CONDITIONS, I AGREE TO PARTICIPATE IN THE RESEARCH IN QUESTION OF MY OWN FREE WILL, WITHOUT ANY PRESSURE OR COERCION.

Participant Name, Surname / Signature: **Researcher Name, Surname / Signature:**

STUDY PROTOCOL

Purpose and Type of Research

The study was designed as a randomized controlled experimental research to determine the effects of reflexology applied to individuals who have suffered a stroke on pain levels, physiological parameters, and sleep quality. The study consists of an intervention group and a control group and aims to scientifically evaluate the place of reflexology within the holistic care approach.

Research Hypotheses

H0: Reflexology has no effect on pain in stroke patients.

H1: Reflexology has an effect on pain in stroke patients.

H0: Reflexology has no effect on arterial blood pressure in stroke patients.

H2: Reflexology has an effect on arterial blood pressure in stroke patients.

H0: Reflexology has no effect on pulse pressure in stroke patients.

H3: Reflexology has an effect on pulse pressure in stroke patients.

H0: Reflexology treatment has no effect on SPO2 in stroke patients.

H4: Reflexology treatment has an effect on SPO2 in stroke patients.

H0: Reflexology treatment has no effect on sleep quality in stroke patients.

H5: Reflexology treatment has an effect on sleep quality in stroke patients.

Location and Time of the Study

The study was conducted between October 15, 2024, and June 1, 2025, at the Physical Therapy and Rehabilitation Unit of Van Training and Research Hospital, Health Sciences University.

Research Population and Sample

The study sample consisted of stroke patients who met the inclusion and exclusion criteria. The sample selection was based on studies in the literature (Batvani et al., 2018; McFadden and Hernandez, 2010) and statistical consultation, the study power was calculated with the G* power analysis method at 80%, effect size 0.84, and 95% confidence interval. It was anticipated that a total of N=60 patients would be included, with n=30 patients in each group. Considering exclusion criteria and patient losses, the study was conducted with a total of N=70 patients, with n=35 patients in each group.

Inclusion Criteria

- Individuals over the age of 18,
- No diagnosis of any psychiatric illness or medication use,
- Hemiplegic stroke patients,
- Volunteering to participate in the study,
- According to the patient introduction form; patients describing hemiplegic shoulder pain and insomnia symptoms,
- No history of neurological or psychiatric disorders other than stroke,
- No irritation or ulceration in the skin area where reflexology will be performed,
- No history of deep vein thrombosis,
- Able to speak and understand Turkish and able to read and write,
- Patients who voluntarily agree to participate in the study will be included.

Exclusion Criteria

- Refusal to participate in the study,
- Tetraplegic and paraplegic patients,
- Patients with stroke due to malignant brain damage undergoing chemotherapy or radiotherapy
- Those with mental and psychiatric disorders,
- Those who have received professional massage therapy within the last month,
- Those with contraindications for foot massage and reflexology: those with generalized edema, pacemakers, heart attack, active gout, history of deep vein thrombosis, history of gallbladder and kidney stones, acute infection, fever, standing fracture, or wound will not be included in the study.

Randomization

The randomization process for the study was conducted using a computer-based random method. The randomization program available online at http://www.randomization.com was used to determine the groups. After defining the number of groups and participants in the study, this program randomly assigns participants to groups by generating a random number table.

Stroke patients who met the inclusion criteria and voluntarily agreed to participate in the study were assigned to the intervention (n=35) and control (n=35) groups according to the list generated by the program. The group distributions obtained as a result of randomization were kept confidential throughout the research process.

Form of Blinding in Research

Blinding is a control method that ensures participants do not know which group they belong to during the conduct and reporting of research. This method is applied to reduce the possibility of participants exhibiting biased attitudes and behaviors that could unknowingly influence the results. Blinding is one of the fundamental elements that increases the internal validity of randomized controlled trials (RCTs). As stated in the literature, only situations where participants' access to group information is restricted are defined as single blinding (Akın and Koçoğlu, 2017). In this study, the single blinding method was applied by keeping the information about which group the participants belonged to confidential.

Ethical Aspects of the Research

Prior to the research, ethical committee approvals were obtained from the “Hasan Kalyoncu University Health Sciences Non-Interventional Research Ethics Committee” (dated August 12, 2024, and numbered 2024/97). A work permit was obtained from the Van Provincial Health Directorate (dated October 3, 2024, and numbered E-50817530-770-255595908). During the study, the ethical principles outlined in the World Medical Association's Declaration of Helsinki were taken into consideration. Participants who voluntarily wished to participate in the study and who met the inclusion criteria were informed about the study and their informed consent

was obtained before they were assigned to the intervention and control groups. The necessary permissions were obtained from the authors of the scales used in the study.

Data Collection Tools

Data were collected using the Personal Information Form, Visual Analogue Scale (VAS), Richard-Campbell Sleep Scale (RCSS), and Physiological Parameters Recording Form.

Tools Used in Data Collection

The tools and equipment used in collecting research data and their purposes are detailed below:

• Digital blood pressure monitor: Used to measure participants' systolic and diastolic blood pressure.

• Pulse oximeter: Used to determine participants' oxygen saturation (SpO_2) and pulse rate levels.

Research Variables

Dependent Variables: Pain, Sleep Quality, and Physiological Parameters score averages are the dependent variables of the study.

Independent Variables: Reflexology application is the independent variable of the study.

Control Variables: Variables related to patients' socio-demographic and disease-related information are the control variables of the study.