SAKARYA UNIVERSITY FACULTY OF MEDICINE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE APPLICATION FORM

Date: 17.11.2025

1- NAME OF THE STUDY: Investigating the Effects of Face-to-Face and Telenursing-Based Education Based on Pender's Health Promotion Model on Fatigue, Pain, Sleep, and Urinary Tract Infections in Patients with Multiple Sclerosis: A Randomized Controlled Study

2- GENERAL NATURE OF THE RESEARCH (Epidemiological, Clinical Research, Survey, etc.)

Educational and Survey Study

3- SPECIFIC NATURE OF THE RESEARCH

Randomized Controlled Study

4- PARTICIPATING CENTERS

o Single center

o Multiple centers

5- IN MULTICENTREPRENEURIAL STUDIES, CENTERS OUTSIDE THE INSTITUTION:

Name:

Address:

6- RESPONSIBLE RESEARCHER

NAME: Ayşe ÇEVİRME **POSITION:** Head of Department of Public Health Nursing, Faculty of Health Sciences, Sakarya University **TITLE:** Prof. Dr. **SIGNATURE:**

7-ASSISTANT RESEARCHERS

NAME: Elif Seda UĞURLU **POSITION:** Sakarya Training and Research Hospital (Nurse) - Sakarya University Institute of Health Sciences Nursing Program Doctoral Student **TITLE:** Specialist Nurse

SIGNATURE:

8- CLINIC / DEPARTMENT WHERE THE RESEARCH WILL BE CONDUCTED

NAME AND ADDRESS: Sakarya Training and Research Hospital - Neurology Polyclinic / Şirinevler Neighborhood, Adnan Menderes Street No: 195 Adapazarı / SAKARYA **Phone:**0 264 888 40 00 FAX: 0 264 275 91 92

A- BIOCHEMICAL TESTS TO BE PERFORMED AND THE LABORATORY WHERE THEY WILL BE CONDUCTED:

TESTS:

NAME ADDRESS: TEL: FAX:

B- ANALYTICAL TESTS TO BE PERFORMED AND THE LABORATORY WHERE THEY WILL BE CONDUCTED:

TESTS:

NAME ADDRESS: TEL: FAX:

C- OTHER EXAMINATIONS TO BE PERFORMED

(e.g., MICROBIOLOGICAL, RADIOLOGICAL, etc.)

REVIEWS:

NAME ADDRESS: TEL: FAX:

9- SUPPORTING ORGANIZATION (IF ANY)

NAME: ADDRESS: AUTHORIZED PERSONS:

10- IN MULTI-CENTER STUDIES, THE RESEARCH COORDINATOR'S

NAME: ORGANIZATION: ROLE: TITLE:

11- PERSON TO CONTACT REGARDING THE RESEARCH:

NAME: TEL: FAX:

12- RATIONALE / PURPOSE OF THE STUDY: (detailed)

Education is a crucial aspect of disease management in MS patients. As a strategy to improve patients' health and wellness behaviors, education benefits patients by enhancing their quality of life, self-efficacy, and trust in ongoing care; reducing anxiety and stress; decreasing the incidence of disease symptoms; increasing patient participation in care plans; and enhancing their autonomy and self-management. Selecting an appropriate educational model is the first step in planning this, and one of the most comprehensive and widely used models offered by nurses for patient education is Pender's health promotion model (Bijani et al., 2022; Habibzadeh et al., 2021).

Introduced by Pender in 1982, the "Health-Promoting Lifestyle" (HPLP) model focuses on empowering people to achieve higher levels of well-being (Masoudi et al., 2020; Jalili et al., 2020). The model encompasses six areas of health promotion and development, including nutrition, physical activity (exercise), health responsibility, stress management, interpersonal relationships, and self-actualization, as well as factors influencing dimensions within these areas (Habibzadeh et al., 2021; Dehghani et al., 2023; Chu Ko et al., 2021; Masoudi et al., 2020).

One method that enables nurses to receive training to improve nursing services and enhance patient well-being is telenursing. Telenursing is considered a part of telemedicine, and according to the definition, nurses meet patients' health needs through information and communication technologies. Telenursing offers a tool for providing continuous care to patients with chronic illnesses. Thus, patients can receive the care information they need without the need for long journeys, at a high quality and low cost, which can have positive effects on their recovery process (Ghoulami-Shilsari and Bandboni, 2019; Dehghani et al., 2023).

In this context, the aim of our study is to evaluate the effects of face-to-face and telenursing-based education based on Pender's Health Promotion Model on fatigue, pain, sleep, and urinary tract infections in patients diagnosed with Multiple Sclerosis (MS) who apply to the Multiple Sclerosis outpatient clinics of Sakarya Training and Research Hospital. Thus, the goal is to reduce MS symptoms and severity, prevent secondary problems, and improve quality of life for these patients.

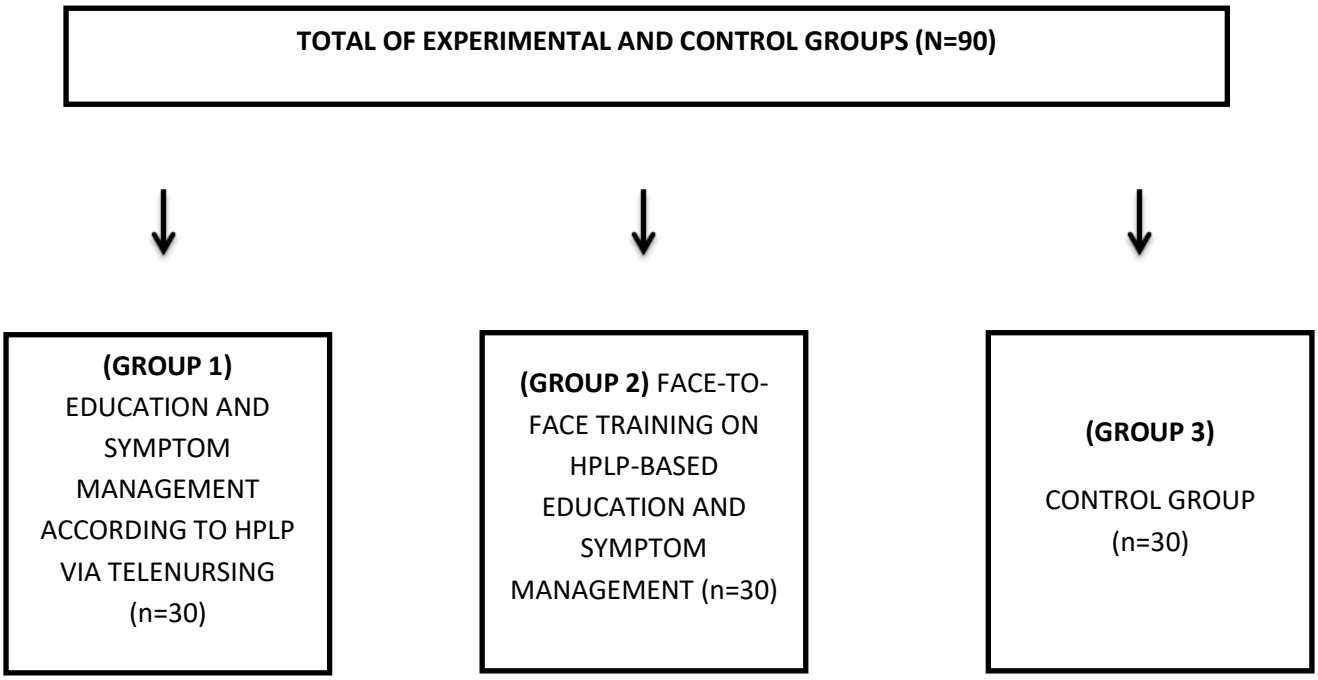
13- APPROACHES AND METHODS TO BE APPLIED: (detailed)

The Population and Sample of the Study

The study population will consist of patients diagnosed with MS who applied to the Multiple Sclerosis outpatient clinics of the Neurology Department at Sakarya Training and Research Hospital. The total number of patients who applied to the Multiple Sclerosis Outpatient Clinics in the last year was determined to be 3552.

The power analysis performed using the G-Power 3.1.9.7 program determined a sample size of 22 people in each group and 66 people in total, based on type 1 error of 0.05, type 2 error of 0.80, and effect size of 0.40, to detect differences in measurements between groups. Participants will be assigned to the intervention and control groups according to their order of presentation to the clinic, using computer-assisted block randomization to ensure an equal and homogeneous number of participants in each group.

Our study includes 2 intervention groups and 1 control group.



Taking into account that participants who do not meet the criteria may withdraw from the study, 90 participants randomly selected from the population will be assigned to experimental and control groups (Group 1, Group 2, and Group 3), with 30 patients diagnosed with MS in each group.

Each participant considering joining the research will be given general information about the study by the researcher, the inclusion criteria will be evaluated, and the consent of the participants who meet the eligibility criteria will be obtained. The study will then be conducted by applying pre-tests and interventions.

Data Collection Tools and Their Characteristics to be Used in the Study

1. Demographic Characteristics Data Form,

2. Visual Analog Scale (VAS),

3. S-LANSS Scale (Self-Leeds Assessment of Neuropathic Symptoms and Signs),

4. Fatigue Severity Scale (FSS),

5. Epworth Sleepiness Scale (ESS),

6. Healthy Lifestyle Behaviors Scale II (HLBS),

7. Urinary Tract Infection Assessment form, accessible from patient files and created by the researcher, will be used.

1. Descriptive Characteristics Data Form:

Developed by the researcher through a literature review, this form, consisting of 20 questions, includes sociodemographic characteristics of MS patients (age, marital status, family type, education level, economic level of the family, place of residence, having children, presence of other individuals with MS in the family, date of diagnosis, complaints, attendance at health check-ups, presence of an additional disease) (Karaağaç et al., 2021; Özdemir and Ayaz, 2020; Karnak, 2020; Altun and Özer, 2020; Seferoğlu and Koca, 2020; Uludağ et al., 2015; Temiz et al., 2022; Cin et al., 2023; Kesik and Özdemir, 2021).

2. Visual Analog Scale (VAS):

Developed by Freyd, the visual analog scale (VAS) is a well-known pain measurement tool consisting of a single 100 mm line (Yaray et al., 2011). Pain is determined using the visual analog scale by the patient marking a value on a 10 cm ruler according to the intensity of the pain felt (0 = no pain, 10 = unbearable pain) (Güven et al., 2016).

Based on the scores given by the patient on the ruler for pain intensity; 3 points and below out of 10 are indicated as mild pain, 3-6 points as moderate pain, and 6 points and above as severe pain (Arslan et al., 2016).

3. S-LANSS Scale (Self-Leeds Assessment of Neuropathic Symptoms and Signs):

S-LANSS, Leeds Assessment of Neuropathic Symptoms and Signs, is a modified form of the LANSS pain scale. Unlike the LANSS scale, it allows patients to easily self-assess neuropathic pain without requiring a physician's examination (Koç, 2008; Bıçakçı, 2017).

The Turkish validity and reliability study of the S-LANSS scale, developed by Bennett et al. for the detection and identification of neuropathic pain, was conducted by Koç and Erdemoğlu in 2010 (Bennett et al, 2005; Koç and Erdemoğlu, 2010).

The scale consists of a total of 7 questions; the first 5 questions inquire about pain symptoms, while the last 2 questions involve clinical self-examination by the patient. The questions are answered with yes or no, and each question has a different score. The total score on the scale is 24, with a score of 12 or higher indicating the presence of neuropathic pain, and a score below 12 supporting the presence of nociceptive pain (Ertem and İrdesel, 2021; Koç, 2008; Koç and Erdemoğlu, 2010; Bıçakçı, 2017).

4. Fatigue Severity Scale (FSS):

The FSS is a nine-item scale developed by Krupp in 1989 to measure the severity of fatigue and is widely used in patients with multiple sclerosis (Armutlu et al., 2007). The Turkish validity and reliability studies of the scale were conducted by Armutlu et al. in 2007, and the Turkish version was found to be valid and reliable (Küçüktepe et al., 2018; Armutlu et al., 2007).

In the scale, for each question, the patient is asked to rate each statement from 1 to 7, indicating how much they agree with each statement; (1) indicates strong disagreement (strongly disagree), while (7) indicates strong agreement (strongly agree) (Armutlu et al., 2007; Kaya et al., 2009). As the total score obtained from the scale decreases, fatigue decreases, while a high average score indicates increased fatigue severity (Pekçetin et al., 2019; Kaya et al., 2009).

5. Epworth Sleepiness Scale (ESS):

The Epworth Sleepiness Scale (ESS) was first developed by M.W. Johns in 1991 to assess general sleepiness levels in adults. Its Turkish validity and reliability were established by İzci et al. in 2008 (Johns, 1992; Demir and Kesgin, 2020; İzci et al., 2008; Kocamaz et al., 2020).

The scale is a four-point Likert-type scale designed to evaluate the likelihood of individuals falling asleep or taking short naps in eight different life situations (while reading a book, watching television, sitting in a public place, traveling by car, resting in the afternoon, talking to someone, sitting quietly after a non-alcoholic lunch, and waiting for a few minutes in a car in traffic) (Güneş and Şensoy, 2022; Rujnan et al., 2018).

The scale uses a scoring system of 0, 1, 2, and 3, with higher scores indicating increased daytime sleepiness (Rujnan et al., 2018; Kocamaz et al., 2020). A total score between 0 and 24 can be obtained from the scale; a score of 0-5 indicates normal, 6-10 indicates normal but increased daytime sleepiness, 11-12 indicates increased but moderate daytime sleepiness, 13-15 indicates increased, moderate daytime sleepiness, and 16-24 indicates increased, severe daytime sleepiness (Demir and Kesgin, 2020; Rujnan et al., 2018; Kocamaz et al., 2020).

6. Healthy Lifestyle Behaviors Scale II (HLBS):

The first version of the Healthy Lifestyle Behaviors Scale, consisting of 48 items and 6 factors, was developed by Walker et al. in 1987 to measure individuals' health-promoting behaviors, based on Pender's health promotion model (Gömleksiz et al., 2020; Akgün et al., 2021). Later, in 1996, Walker et al. revised the scale by adding 4 more items, resulting in HLBS II, which now consists of 52 items (Gömleksiz et al., 2020; Akgün et al., 2021).

The Turkish translation and validity/reliability study of the scale was conducted by Bahar et al. in 2008, and the Alpha reliability coefficient of the scale was found to be 0.92 (Gömleksiz et al., 2020; Bahar et al., 2008). The scale consists of six sub-dimensions, and their reliability coefficients were reported as follows: health responsibility 0.77, physical activity and exercise

0.79, nutrition 0.68, spiritual development 0.79, interpersonal support 0.80, and stress management 0.64 (Gömleksiz et al., 2020; Bahar et al., 2008).

The Turkish version of the scale consists of 52 items, all positive, on a four-point Likert scale [1 (never), 2 (sometimes), 3 (frequently), and 4 (regularly)], with the lowest possible score for participants being 52 and the highest being 208 (Gömleksiz et al., 2020; Bahar et al., 2008; Akgün et al., 2021).

7. Urinary Tract Infection Assessment:

By accessing the patient's physician diagnoses and laboratory findings available in their files, a comparison will be made between the patient's data regarding urinary tract infections before and after the training.

Research Implementation Stages:

Participants will be assigned to experimental and control groups using block randomization based on their order of clinical visit. Prior to the interventions, each participant in each group will be administered the following scales: Demographic Characteristics Data Form, FSS, VAS, S-LANSS Scale, EUÖ, and Healthy Lifestyle Behaviors Scale II (HLBS). Additionally, physician diagnoses and laboratory findings related to urinary tract infections will be recorded from the patient's file.

1. **TELENURSING-BASED EDUCATION AND SYMPTOM MANAGEMENT ACCORDING TO HPLP (GROUP 1):** The researcher nurse will prepare training modules for MS symptoms (pain, fatigue, sleep, and urinary tract infections), taking into account expert opinions. These training modules will be delivered via an online application (WhatsApp software or creating an internet access address, etc.) with the approval and support of training and IT specialists. Within this scope, volunteer patients meeting the study criteria will receive training via telenursing for six weeks, three days a week. Furthermore, as part of the telenursing application, patients will be able to call the researcher for 10-15 minutes between 8 AM and 8 PM on weekdays if they need consultation (Dehghani net al., 2023).

2. **FACE-TO-FACE TRAINING ON HPLP-BASED EDUCATION AND SYMPTOM MANAGEMENT (GROUP 2):** A training program will be planned for patients who meet the study criteria and who visit the Sakarya Training and Research Hospital MS Polyclinic during the days of the clinic (THURSDAY 09:00-16:00). The training will be conducted by a research nurse using HPLP-based methods. Literature suggests that the ideal number of participants for focus groups is 4-10, and that the number of participants in each group should not exceed 10 for group dynamics and interaction. Our study plans to complete the training with a total of 3-5 focus group sessions (Öner and Karabudak, 2021; Çokluk et al., 2011).

3. **CONTROL GROUP (GROUP 3):** In the control group, no intervention will be performed; patients will continue to receive their routine treatments. At the end of the study, individuals in the control group who volunteered to participate will receive an educational program prepared according to HPLP, either in person or via telenursing, from the research nurse, upon their request.

14-ANTICIPATED STUDY DURATION (cannot begin before the ethics committee approval date):

Start date: Will begin after ethics committee approval is received. 01.04.2024

End date: 02.01.2026 (Pre-test and intervention period)

15-A-STUDY DESIGN (Leave irrelevant sections blank depending on the nature of the study)

□ PARALLEL REVIEW

□ CROSS-REVIEW

□ **RANDOMIZED**

□ UNCONTROLLED

□ **SINGLE-BLIND**

□ DOUBLE-BLIND

B- LOCATION

□ **HOSPITAL**

□ POLYCLINIC

□ HEALTH CENTER

□ FIELD

□ OTHERS (Please specify:.....)

C- QUALIFICATIONS OF VOLUNTEERS

□ HEALTHY

□ **SICK** (**NAME OF DISEASE:** Multiple Sclerosis (MS)

□ CHILD

D-OTHER INFORMATION REGARDING VOLUNTEERS

Minimum number of volunteers to be included in the study	Total	Male	Female	Age Range
Patient (Diagnosed with MS)	90			18-55
Healthy				
Specific criteria				

16-CRITERIA FOR INCLUSION AND EXCLUSION FROM THE RESEARCH

Inclusion Criteria for the Study

- Willingness to participate in the study,
- Being between 18-55 years of age,
- Being literate,
- Having been diagnosed at least 1 year prior,
- Having been diagnosed with Relapsing-Remitting type MS (the most common, RRMS - characterized by attacks and remissions),
- Having been determined by a specialist (psychologist or psychiatrist) to have a suitable cognitive level for participation in the study,
- Scoring 4 or higher on the Visual Analog Scale (VAS) for pain,
- Scoring 4 or higher on the Fatigue Severity Scale (FSS),
- Scoring 10 or higher on the Epworth Sleepiness Scale (ESS),
- Not having used other complementary and alternative treatments in the last 6 months,
- Patients who own or have a family member who owns a smartphone, tablet, or computer will be included (Eren, 2018).

Exclusion Criteria for the Study

- Those who are unwilling to participate in the study for any reason,
- Those with communication barriers,
- Those with hearing or visual impairments,
- Those who fail to attend three consecutive treatment sessions except for medical indications,
- Those who do not complete 70% of the training program (or 17 out of 24 sessions) (Alonso Martínez et al., 2023),
- Those who develop serious physical or mental illnesses during the study,
- Those whose cognitive level is determined to be unsuitable for participation in the study (assessed by a psychologist or psychiatrist),
- Those who use other complementary therapies such as acupuncture, yoga, meditation, etc. during the study,

- Patients who experience an exacerbation of their illness or require hospitalization during the intervention will not be included in the study.

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