**Study Protocol**
**Official Title:** The Effect of Tele-Nursing Service on Patients' Pain and Activity Level in Patients Diagnosed With Fibromyalgia
**Brief Title:** The Effect of Tele-Nursing Service in Patients Diagnosed With Fibromyalgia
**Unique Protocol ID:** NTK
**NCT Number:** [NCTXXXXXXXX]
**Document Date:** August 18, 2025
**Sponsor:** Çankırı Karatekin University
**Principal Investigator:** Assist. Prof. Nedret Tekin Kaya
**IRB Approval:** Çankırı Karatekin University Scientific Research Ethics Committee, Approval No: 2023/09
**Facility Location:** Çankırı Karatekin University, Kırkevler Mahallesi, Kastamonu Caddesi, No:244 Uluyazı Kampüsü 18200 Merkez Çankırı, Turkey

Brief Summary:

The aim of the study was to determine the effect of tele-nursing service provided to patients diagnosed with fibromyalgia on the pain and activity level of patients. The study was designed as a randomised controlled experimental study in a pretest-posttest design. The research was conducted in a State Hospital between April 2024 and June 2024 with patients diagnosed with fibromyalgia who applied to the physical therapy outpatient clinic and met the inclusion criteria. The sample was divided into two groups as intervention and control groups of 22 participants by simple randomisation. Descriptive Information Form, Fibromyalgia Impact Questionnaire Revised (FIQR), Mcgill Pain Scale were used as data collection tools in the study. The second researcher was given the contact information of all patients and the data collection forms were applied as a pre-test. The second researcher did not know which group the patients were in. Thus, the researcher collecting the data was blinded. Data collection forms were administered by the researcher by interviewing the patient in approximately 15-20 minutes. Patients in the intervention group were called three times by phone and were trained in accordance with the prepared training booklet by first researcher.

Detailed Description:

Fibromyalgia is a chronic condition of unknown etiology, characterized by widespread musculoskeletal pain, sleep disturbances, fatigue, anxiety, and impaired cognitive functions.Fibromyalgia-related pain often increases during or after physical activity and may interfere with patients' ability to perform daily living activities. Despite extensive research, the exact cause of the disease remains unknown.

This study aimed to evaluate the effectiveness of nurse-led telephone counseling on pain severity and physical activity levels in patients who met the inclusion criteria. A total of 44 participants were enrolled: 22 in the intervention group (who received telephone-based counseling and education from a nurse) and 22 in the control group (who received no intervention).

All participants were informed about the study, and written informed consent was obtained. At baseline, all patients completed pre-test questionnaires. The intervention group received additional follow-up through two telephone calls during the intervention period.

The nurse provided education and counseling on various topics, including pain management strategies, ways to increase physical activity, appropriate exercise, and stress coping techniques. Non-pharmacological treatment options for pain relief were also discussed. The educational intervention lasted approximately 4 weeks.

Following the completion of the intervention, post-tests were administered to all participants. Two months after the intervention, the FIQR (Fibromyalgia Impact Questionnaire-Revised),and the McGill Pain Questionnaire were completed by all patients to assess outcomes.

Ethical Considerations Prior to the initiation of the study, ethical approval was obtained from the Institutional Scientific Research Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki. Participants were informed that their involvement was voluntary and that they could withdraw from the study at any time without any consequences.

Statistical analysis The data were analyzed using IBM SPSS Statistics version 26.0. Group comparisons were performed using independent-samples t-tests and ANOVA. Statistical significance was set at $p<0.05$. The data were analyzed using IBM SPSS Statistics version 26.0. Group comparisons were performed using independent-samples t-tests and ANOVA. Statistical significance was set at $p<0.05$. Descriptive data were shown with mean, standard deviation, median, number and percentage. Socio-demographic differences between the intervention and control groups were analyzed using Chi-squared tests for nominal variables and independent samples t-tests for continuous variables. Paired t test was used to determine the difference between two normally distributed groups and independent t test was used for nonnormally distributed variables.

Edit Conditions

Conditions: Pain

Tele-nursing

Fibromyalgia Syndrome

Keywords: Fibromyalgia (FM)

Tele-nursing

Pain

Telehealth

Edit Study Design

Study Type: Interventional [Change...]

Primary Purpose: Prevention

Study Phase: N/A

Interventional Study Model: Parallel Assignment

The study involved two parallel groups: an intervention group receiving nurse-led telephone counseling and education, and a control group receiving no intervention. Participants were randomly assigned to each group.

Number of Arms: 2

Masking: Triple (Participant, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 44 [Actual]

Open Arms and Interventions

Arms Assigned Interventions

Experimental: Intervention-telenursing

The second researcher did not know which group the patients were in. Thus, both the patient and the researcher who collected the data were blinded. the data collection forms were applied as a pre-test by second researcher. The first researcher sent an educational booklet prepared on the educational topics or the topics the patient needed to the patients in the experimental group as a message. The patient was then called by phone and informed about the educational booklet. After the main interview, the patients were called 2 more times for follow-up. The intervention group was given education on topics such as reducing pain complaints, increasing activity level, exercise, and coping with stress. The education of the intervention group lasted approximately 4 weeks. After the completion of the training of the intervention group, the second researcher applied the post-tests to all patients. The FIQR, VAS, and Mcgill pain scale were filled out as the post-tests.

Behavioral: Intervention-telenursing

The first researcher sent an educational booklet prepared on the educational topics or the topics the patient needed to the patients in the experimental group as a message. The patient was then called by phone and informed about the educational booklet. After the main interview, the patients were called 2 more times for follow-up. The intervention group was given education on topics such as reducing pain complaints, increasing activity level, exercise, and coping with stress. The education of the intervention group lasted approximately 4 weeks.

No Intervention: Controll

The second researcher did not know which group the patients were in. Thus, both the patient and the researcher who collected the data were blinded. The second researcher was given the contact information of all patients and the data collection forms were applied as a pre-test.After the completion of the training of the intervention group, the second researcher applied the post-tests to all patients. The FIQR, VAS, and Mcgill pain scale were filled out as the post-tests. Participants in this group did not receive any counseling or educational intervention. They completed pre- and post-tests during the same period as the intervention group but received standard care only.

Edit Outcome Measures

Primary Outcome Measure:

1.Change in pain severity as measured by the Short Form McGill Pain Questionnaire (SF-MPQ) sensory subscale at 2 months

The Short Form McGill Pain Questionnaire (SF-MPQ) is a widely used tool for assessing the qualitative and quantitative aspects of pain.The SF-MPQ consists of three main components:

1-Pain Rating Index (PRI) — Divided into: Sensory subscale: 11 descriptors (e.g., throbbing, shooting, stabbing) Affective subscale: 4 descriptors (e.g., tiring, fearful, punishing) Each descriptor is rated on a 4-point scale:0 = None,1 = Mild,2 = Moderate,3 = Severe.

A 6-point ordinal scale where the participant selects one of the following to describe their current pain:

0 = No pain

= Mild

= Discomforting

= Distressing

= Horrible

= Excruciating Higher scores indicate more severe pain.SF-MPQ was administered at baseline and at 2 months post-intervention.

[Time Frame: At the beginning and at week 8]

Secondary Outcome Measures:

Change in health status as measured by Revised Fibromyalgia Impact Questionnaire (FIQR) at 2 months

The Revised Fibromyalgia Impact Questionnaire (FIQR) is a patient-reported outcome measure designed to assess the health status and impact of fibromyalgia on daily life. The FIQR is a revised version of the original FIQ, providing better psychometric properties and more comprehensive coverage of functional domains.The FIQR is a 21-item questionnaire measuring the impact of fibromyalgia across function, overall impact, and symptom domains. Each item is scored from 0 (no impact) to 10 (maximum impact). The total score ranges from 0 to 100, with higher scores indicating worse fibromyalgia-related health status. FIQR was administered at baseline and at 2 months post-intervention.

The FIQR consists of 21 items divided into 3 domains:

Function domain (9 items) — assesses physical functioning

Overall impact domain (2 items) — measures overall impact of fibromyalgia

Symptom domain (10 items) — evaluates common fibromyalgia symptoms (e.g., pain, fatigue, sleep quality).

[Time Frame: At the beginning and at week 8]

Other Pre-specified Outcome Measures:

Change in pain severity as measured by Visual Analog Scale (VAS) at 2 months

The Visual Analog Scale measures pain severity on a scale from 0 to 10, where 0 indicates no pain and 10 indicates the worst imaginable pain. Higher scores indicate worse pain.VAS was administered at baseline and at 2 months post-intervention.

[Time Frame: At the beginning and at week 8]

Edit Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria:

Inclusion Criteria:

Individuals diagnosed with fibromyalgia

Aged 18 years or older

No communication impairments that would hinder participation in the study or the ability to receive education (e.g., hearing loss, visual impairment, or difficulty understanding/speaking Turkish)

Reachable by phone

Literate

Willing to participate voluntarily.

Exclusion Criteria:

People with communication problems

People with hearing and/or speech problems

Can't speak Turkish,

Open Contacts/Locations

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Contact: Nedret Tekin Kaya

Edit IPD Sharing Statement

Plan to Share IPD: Yes

Study protocol, Informed Concent Form (ICF)

Supporting Information: Study Protocol

Informed Consent Form (ICF)

Time Frame:

for 3 years

Access Criteria:

https://ebap.karatekin.edu.tr/?act=guest&act2=projeler&durum=tamam

URL: https://ebap.karatekin.edu.tr/?act=guest&act2=projeler&durum=tamam