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The effects of reflexology on pain and sleep deprivation in patients with rheumatoid arthritis: A randomized controlled trial

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ABSTRACT

Objective: This study was intended to examine the effect of foot reflexology on RA patients' pain and sleep quality.
Methods: This is a randomized controlled trial and was held at the "Rheumatology Follow-up Polyclinic" in Turkey between January–July 2015. A total of 60 patients were included in the research. A socio-demographic data form, the Pittsburgh Sleep Quality Index (PSQI) and the Visual Analogue Scale (VAS) were used. Foot Reflexology was administered to the experimental group.
Results: The research found that the pain scores of the experimental group were statistically more significant than those of the control group ($p < .01$). The experimental group's average pain was reduced by the six weeks of foot reflexology. The total PSQI score of the experimental group was lowered.
Conclusions: Foot reflexology is a non-pharmacological nursing intervention that may reduce the pain and sleep deprivation symptoms of RA patients.

1. Introduction

Rheumatoid arthritis (RA) is a chronic, idiopathic, systemic, inflammatory, autoimmune disease characterized by pain in the joints and swelling, loss of function in the joints, morning stiffness and sleep deprivation as well as fatigue accompanying these states [1]. The loss of function due to the disease also leads to poor quality of life [2]. Depending on the prognosis, physical deformities and unbearable pain may become prominent over time [3]. Pain causes poor quality sleep; furthermore, patients complain about fatigue not only because of their disease but also because of sleep deprivation [4]. The incidence of sleep disorders in individuals with RA was reported to range between 54% and 70% Therefore, these individuals' productivity at work and skills for conducting daily practices decrease [3].

The dissatisfaction with medical treatment methods, invasive procedures and the necessity of using daily analgesics as well as the toxic and harmful effects of drugs push patients to different quests for symptom management. Non-pharmacological methods such as reflexology, massage, hydrotherapy, therapeutic touch, acupuncture, music therapy have been used for symptom control and functional improvement in these patients [5,6].

Reflexology is the stimulation of reflex points through massage on some body parts. Foot reflexology is the practice of applying pressure to specific areas of the feet. Reflexes in the feet match to organs, glands, and systems of the body. There are some theories on the mechanism of action of reflexology [7,8]. According to the haemodynamic theory, reflexology stimulation increases blood flow to the related organ or body part. The nerve impulse theory argues that reflexology stimulation enhances nervous connection to the corresponding body parts. According to the energy theory; organs and body parts are linked through electromagnetic fields and that these pathways are blocked in states of disease. Lactic acid theory defends that lactic acid accumulates on the soles of the feet in the form of crystals and reduces regular flow. Reflexology shows that the fusion of crystals promotes free circulation [7,8]. With these features, reflexology becomes an appropriate alternative method for RA patients.

Although the effect of foot reflexology on pain symptom has been evaluated in RA patients, no study has been conducted on sleep quality. The aim of this randomized controlled trial is to analyze the effects of foot reflexology on pain and sleep quality in RA patients. Two hypotheses were explored in this study. One of the hypotheses is that foot reflexology practice reduces pain and

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the other is that foot reflexology improves sleep quality in RA patients.

2. Material and methods

2.1. Ethics

The Institutional Ethics Committee of Gaziantep University Medical Faculty (No: 2014/344) approved this study before implementation. Informed consent was obtained from all the participants included in the study.

2.2. Design and sample

This study was planned as a randomized controlled trial to evaluate the effect of foot reflexology on pain and sleep quality in RA patients. The study was held at the "Rheumatology Follow-up Polyclinic" of a university hospital located in a big city in Turkey between January–July 2015. A total of 60 patients (30 for the intervention group and 30 for the control group) who agreed to participate in the research and met the criteria specified within the population were included in the research. All the patients were suffering from pain and sleep disturbances. The patients included in the research demonstrated the following characteristics: 18 years of age or older, diagnosed with RA for at least 1 year, VAS pain score of 4 or greater and voluntary participation in the study. The exclusion criteria were as follows: acute infection or fever, vascular disease in the lower extremities, impaired skin integrity, history of surgery, fractures, sprains or injuries in the lower extremity, pregnancy, diagnosis of diabetes, diagnosis of sleep apnea and using sleep medications, cigarette and alcohol consumption. Medical treatments of RA patients in both control and reflexology groups continued routinely. However, no change was allowed in medical treatment for RA during six reflexology applications and control. An a priori power analysis was performed to calculate the sample size (STATISTICA 2016 Quest Software Inc.). As a result of power analysis, the minimum sample size required for the study was found as the effect size = .50, alpha = .05 and the power of the test (1- beta) .80, while 30 patients were included in each group. Fig. 1 shows the progression of the study (Fig. 1). Patients with similar levels of VAS pain, gender and disease duration were selected for the experimental and control groups. They were then divided into two groups as foot reflexology and control group using a random number table.

2.3. Data collection

The interviews with RA patients were conducted face to face and individually at the Rheumatology Follow-up Polyclinic. At the interviews, the sociodemographic information and biochemical parameters of the patients as well as their Visual Analogue Scale for Pain (VAS-Pain) and Pittsburgh Sleep Quality Index (PSQI) scores were collected. The form questioning socio-demographic characteristics include the age, gender, marital status, educational status, health insurance, alcohol and smoking status of the patients as well as their duration of diagnosis and the medications they take [10,11]. The pain values of both the experimental and control groups were recorded weekly for 6 weeks. The sleep quality was assessed only at the first and sixth week follow-up because the scale used in the sleep quality assesment demonstrated the last month.

VAS- Pain – Visual Analogue Scale was used to assess pain symptoms. Using a 10 cm horizontal line, a plane starting at 0 and ending at 10 points was created even intervals of 1 cm "0" means no pain while "10" means the most severe, unbearable pain. The mean pain level during the last week was used to evaluate the baseline pain used in patient selection. Patients who had a baseline pain score of 4 or greater were admitted to the study. Current pain was assessed for weekly monitoring.

With the *Pittsburgh Sleep Quality Index,* the patients are asked 19 questions to assess their sleep quality within the past month. There are 7 components of PSQI. The assessment of each item is scored between 0 and 3 according to the frequency of symptoms. The total score is calculated including 0 and 21. Scores of six or above indicate that sleep quality is impaired [12]. The validity and reliability of the Turkish version of the scale was performed by Ağargün et al. (1996) and the Cronbach's alpha value was found to be 0.80 [13]. The Cronbach's alpha value for the current study was 0.78, indicating that the scale is highly reliable.

2.4. Interventions

Prior to any interventions and again at the completion of the interventions, all patients were asked to mark their pain level on the VAS plane. Interventions were undertaken by a certified researcher. In the experimental group, 30-min foot reflexology for a total of 6 times (once a week) was performed. After 6 weeks of reflexology, the patients in the experimental group were again subjected to VAS and PSQI assesment. All patients enrolled in the study were routinely given RA treatments. The patients, particularly in the experimental group, were reminded not to take analgesic medication during the days of intervention. As for the patients in the control group, they continued to undergo routine polyclinic monitoring which included intra-articular and extra-articular physical findings, laboratory tests, radiology examinations, and information on medication.

2.4.1. Foot reflexology protocol

The room temperature of the patients' follow-up polyclinics ranged between 71.60-75.20 ° F and the humidity ranged between 40 and 60%. For the application, colorless Vaseline with no additives was used. Beginning with the right foot, 5 min of foot warming movements were provided, 3-min massage for the brain part (application to the pituitary, pineal gland points at the big toe, from the big toe to the middle of the heel; the medulla spinalis point), 2-min pressure to the solar plexus point (the reflex point of the central nervous system on the sole), 3-min application to the lymph system, 3-min application to the diaphragm area, 3-min application to the thyroid point, 3-min application to the stomach point, 3-min application to the adrenal glands, and 5-min warming movements after the application was over which added up to a total of 30 min. Foot reflexology was performed with the same techniques on the left foot after the treatment to the right foot was completed. The entire procedure was completed with a 30 - min application for each foot which lasted for a total of 60 min. The treatment was repeated once a week for 6 weeks.

2.5. Data analysis

The data were evaluated with Statistical Package for Social Sciences 18.0 software (SPSSFW, SPSS Inc., Chicago, IL, USA SPSS). Kolmogrov Simirnov test was used to determine whether the data had a normal distribution or not, and nonparametric tests were conducted when the data did not demonstrate a normal distribution. Descriptive information on the patients was given in number, percentage and standard deviation. For the evaluation of data, Chi-Square and Significance of the Difference between Two