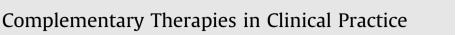
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# Effect of aromatherapy massage with lavender essential oil on pain in patients with osteoarthritis of the knee: A randomized controlled clinical trial





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### ABSTRACT

*Background:* Osteoarthritis of the knee is the most common chronic joint disease that involves middle aged and elderly people. The purpose of this study was to investigate the effect of aromatherapy massage with lavender essential oil on pain in patients with osteoarthritis of the knee.

*Methods:* In this single-blinded, randomized clinical trial, 90 patients with osteoarthritis of the knee who referred to the outpatient rheumatology clinics affiliated with Birjand University of Medical Sciences were selected through convenience sampling method. They were randomly assigned to three groups: intervention (aromatherapy massage with lavender essential oil), placebo (massage with almond oil) and control (without massage). The patients were evaluated at baseline, immediately after the intervention, 1 week, and 4 weeks after the intervention in terms of pain via visual analogue scale. The data were analyzed in SPSS (version 16) using the repeated measure ANOVA, one-way ANOVA, and chi-squared test.

*Results:* Pain severity of the patients in the intervention group was significantly different immediately and 1 week after the intervention compared with their initial status (p < 0.001) and that of the control group (p < 0.001 and p = 0.009 respectively). However, at the third phase of follow-up (i.e., 4 weeks after the intervention), there was no significant difference between the groups according to the visual analogue scale (p = 0.67).

Conclusion: Aromatherapy massage with lavender essential oil was found effective in relieving pain in patients with knee osteoarthritis. However, further studies are needed to confirm findings of this study. © 2016 Elsevier Ltd. All rights reserved.

#### 1. Introduction

Osteoarthritis (OA), also known as degenerative arthritis or osteoarthrosis is a type of joint disease which affects joint cartilage and underlying bone [1]. OA can affect any joint, but it occurs most often in knees [2]. OA of the knee is one of the five main causes of disability in the elderly [3]. Pain in the affected joints is the most important symptom of OA [4]. Common risk factors for developing OA include obesity, increasing age, previous joint injury, race, overuse of the joint, hormonal problems and the job. The most important risk factor reported is age such that the prevalence of OA

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increases considerably from 4% in the 18-24 years age group to 85% among 75–79 years age group [5,6]. Approximately 3.6% of the population on the global scale has OA of the knee [7]. OA affects nearly 27 million people in the United States and approximately 8 million people in the United Kingdom [8]. According to WHO-ILAR COPCORD study, the prevalence of knee OA is about 19.3% in rural communities in Iran. According to the same study, Iranians are the community most involved with knee OA among the nationalities included in the study [9]. Treatment strategies for OA focus on reducing symptoms especially pain and include pharmacological and non-pharmacological treatments as well as surgical interventions as a last resort [10]. Since pharmacological treatments and surgical interventions have many side-effects and are expensive [11,12], the use of complementary therapies to reduce complications and costs can be helpful in the management of these patients. Aromatherapy is a form of complementary therapy using essential oil extracted from plants, which can be absorbed into the body through the skin or the olfactory system [13]. Different procedures are used to deliver aromatherapy such as inhalation, massage, baths and compresses.

Aromatherapy massage is the most widely used complementary therapy [14]. Several studies have been conducted to investigate the effects of aromatherapy massage as a way to manage OA symptoms [15–17]. One of the essential oils used in aromatherapy is lavender. Lavandula angustifolia Mill (Lavender) is well known as a powerful aromatic and medicinal herb. Lavender is used in complementary therapy in different parts of the world for its analgesic and anti-inflammatory effects [18]. Numerous studies have reported that aromatherapy massage with lavender is effective in reducing pain in patients with many types of pain conditions, including infantile colic, dysmenorrhoea, and terminal cancer [19–21]. Therefore, because of the high prevalence of knee OA, especially in older people, and complications of surgical and pharmacological treatments in these patients, as well as safety, convenience, and cost-effectiveness of complementary therapies, this study investigated the effectiveness of aromatherapy massage with lavender essential oil on pain in patients with knee OA.

## 2. Materials and methods

## 2.1. Study design

This single-blinded, randomized clinical trial was conducted to determine the effect of aromatherapy massage on the pain of patients with knee OA, who referred to the outpatient rheumatology clinics of hospitals affiliated to Birjand University of Medical Sciences, Iran, in 2015. The sample size was calculated by considering a confidence interval of 95% and a power of 90%. According to Yip's study [22], it was determined to be 22 participants in each group. To compensate probable 25% dropouts, we recruited 30 patients in each group.

#### 2.2. Participants

Ninety patients who had OA of the knee were selected by convenience sampling on the basis of predetermined inclusion criteria. Inclusion criteria were as follows: knee OA as confirmed by a rheumatologist, knee pain level>4 on a visual analogue scale, age between 18 and 65 years, willingness to participate in the research, no history of allergy or sensitivity to herbal ingredients, no olfactory impairment, no symptoms of acute infection in the knee joint, no history of knee surgery, no history of asthma, and ability to communicate and answer questions. Exclusion criteria were intraarticular steroid injections, physiotherapy prescribed for knee pain, knee surgery, allergic reaction to lavender, admittance to hospital, and unwillingness to continue participation. Participants were allocated into one of three groups of aromatherapy massage (N = 30), placebo (N = 30), or control (N = 30). Random sampling method was used to allocate the participants into study groups. To do this, as many cards were prepared as were the participants. The names of treatment methods were written on the cards and were put in a bag. At the referral of participants, they were requested to take one card from the bag, and thus, the treatment type for each participant was specified.

#### 2.3. Ethics considerations

The study protocol was approved by the Ethics and Research Committee of Birjand University of Medical Sciences (Code, 2015-03-22). The study was also registered in the Iranian Registry of Clinical Trials with the registration number: IRCT2015041921839N1. First, one of the researchers explained the objectives of and procedure to perform the study to the participants. Then, written informed consent was signed by them. All of them were informed that they would be free to withdraw from the study at any time.

#### 2.4. Intervention

First, the researcher studied aromatherapy massage theoretically based on a technique from a basic aromatherapy textbook [23], completed a training course in massage protocols, and received practical training from a specialist in traditional medicine. Then, effleurage massage (a gliding or sliding movement over the skin) [24,25] was taught privately to each and any of the participants at the time the sampling by the researcher. The training was considered accomplished when the participants could apply effleurage massage correctly. Therefore, they were already familiar with the effleurage massage technique and had reviewed it several times using written paper instructions before the intervention started. Afterwards, the researcher gave a bottle containing 50 cc of Lavender oil 3% accompanied by an illustrated pamphlet and a weekly massage timetable to each participant in the aromatherapy massage group. The placebo group received a bottle containing 50 cc of only sweet almond oil along with the same pamphlet and timetable. The participants of the aromatherapy massage group massaged their knees for 20 min with 5 mL of lavender essential oil that was diluted in sweet almond oil at a final concentration of 3% using of the same type of syringe at each session. Concentration of essential oil used in this study was determined on the basis of a review of the literature [26–28] and in consultation with the herbal medicine specialist. The self-massage was performed in a quiet room and at a fixed-time of day while the patient was sitting in a chair. While the control group received no massage during the study, the placebo group used the same intervention as that of the aromatherapy massage group except that they used sweet almond oil only; it is because there is no proved respiratory effect and its frequent application in other studies as a placebo [21,26,29]. Both aromatherapy massage and placebo groups performed selfmassage nine times within 3 weeks on the affected knee using the oils provided by the researcher. In addition, the researcher reminded timely interventions to the participants through phone calls. As follow-up, he also made phone calls on a weekly basis to review the application of the oils by the participants. All participants received similar conventional drugs, including NSAIDs, acetaminophen, etc. which were administered by the rheumatologist. The lavender essence and sweet almond oil had been produced by Barij Essence Pharmaceutical Company (producer of herbal medicines in Iran), Kashan, Iran.

#### 2.5. Data collection

The severity of pain was measured by the visual analogue scale (VAS) because it is an easy, reliable and valid tool for self-report of pain [30,31]. It is a simple assessment tool consisting of a 10 cm horizontal line in which 0 on the left indicates no pain, and 10 on the right shows the worst pain the patient could imagine. Complementary information was obtained using a demographic characteristics form. The form included items on participants' age, height, weight, BMI, education, residence, occupation, and gender. In this study, the data collector was blinded to the group allocation. Data were collected at four time points. The first point of time was before the intervention when the demographic characteristics form and VAS were administered to the participants in the rheumatology clinic. The next points of time for data collection included immediately after the three-week intervention, 1 week, and 4 weeks after

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