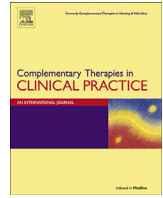




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Comparison of the effect of lavender and bitter orange on anxiety in postmenopausal women: A triple-blind, randomized, controlled clinical trial

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ABSTRACT

Introduction: This trial compared the effects of lavender and bitter orange on anxiety in postmenopausal women.

Methods: This trial was conducted in 2015. Eligible postmenopausal women were allocated into one of two intervention groups or a control group (n = 52 per group) in a 1:1:1 ratio using a randomized block design. Intervention groups received 500 mg capsules containing only bitter orange or lavender flower powder, and the control group received 500 mg capsules containing starch. The Spielberger's State-Trait Anxiety Inventory (STAI) was used before and eight weeks after starting the intervention. Data analyses were based on intention to treat.

Results: A one-way ANOVA showed no significant difference in mean state anxiety (P = 0.254) and trait anxiety (p = 0.972) score among the three groups before the intervention. The general linear model, adjusted for baseline state and trait anxiety scores and confounding factors, showed significant differences among the groups in the mean state anxiety (P = 0.010) and trait anxiety (p = 0.041) score after eight weeks of treatment. Bitter orange significantly reduced the mean state-anxiety scores compared with the control group [Adjusted Mean Difference (aMD): -1.99 (95% Confidence Interval, -3.64 to -0.34)]. Lavender significantly reduced the mean state-anxiety scores compared with the control group as well [aMD: -2.45 (95% CI -4.13 to -0.77)] and Bitter orange significantly reduced the mean trait-anxiety scores compared with the control group [aMD: -1.76 (95% CI -3.45 to -0.06)]. Lavender significantly reduced the mean trait-anxiety scores compared with the control group as well [aMD: -2.05 (95% CI -3.76 to -0.33)]. There was no significant difference between bitter orange and lavender groups after intervention in the mean trait-anxiety (p = 0.731) or state-anxiety (p = 0.578) scores.

Conclusion: The positive effect of bitter orange and lavender on anxiety in postmenopausal women suggests that they can be used to decrease anxiety in such women.

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1. Introduction

Menopause is an inevitable milestone and an important stage in every woman's life that generally occurs between 45 and 55 years of age with an average age at menopause of 50 years [1–3]. In developed countries, the average age at menopause is about 51 years [4]. The average age of menopause in Iran was reported as 48.2 years [5]. Estimates have indicated that the population of

postmenopausal women will increase from 742,150,000 in 2010 to 1.2 billion by 2030, with the greatest increase in developing countries [6].

Postmenopausal women report a high level of complaints related to the mental health and poor performance of ovarian function such as anxiety, stress, depression, etc. Studies have shown that main reasons of this mood change is due to changes in levels of estradiol and relation of level of serum estrogen with the monoamine oxidase levels of platelets (Platelet MAO) which is a marker of adrenergic and serotonergic function, also anxiety due to hormonal changes and other factors can cause signs such as

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migraine headaches, stomach problems, insomnia [7,8].

The prevalence of anxiety in US has been reported to be 23–30% among middle-aged women and 13% among middle-aged Australian women [9,10].

Anxiety is a state of unpleasant emotional feelings of worry, sadness, excitement, tension and fear. Restlessness, sadness, anorexia, hypertension, breath irregularities, palpitations, and impaired recall are among the signs and symptoms of anxiety and stress. Therefore, failure to control anxiety may have negative impacts on health [11]. On the other hand, high levels of anxiety may intensify the symptoms of menopause [12].

Various methods are used to overcome anxiety, the most important of which is anti-anxiety medications. At present, benzodiazepines, diazepam and oxazepam are the most common and applicable anti-anxiety oral medications [13]. However, the side effects of such medications (lightheadedness, imbalance and drowsiness on the one hand, and short duration of therapeutic effect on the other hand) have shifted the attentions towards non-chemical substances and medicinal plants [14].

Lavender, with the scientific name “*Lavandula angustifolia*”, is a kind of labiateae. Lavender flowers contain linalool, linalyl acetate, ocimene, camphor and flavonoid [15], which have antidepressant [16], sedative, local anesthetic, antioxidant, dose-dependent anti-seizure [17], hypnotic [16] antioxidant and anti-anxiety [18] effects. In oral use, linalool and linalyl acetate contents of lavender flowers have anti-anxiety effects [19].

This plant has been used in different studies without any reported side effects [20,21], although in some cases, nausea and vomiting [22] and dermatitis [23] have been observed with topical use. The World Health Organization confirmed that oral use of lavender is safe [24].

Bitter orange, with the scientific name of *Citrus Aurantium* belongs to the Rutaceae family and contains limonene, linalool, linalyl acetate and *p*-synephrine [25]. It has sedative, weight loss [26], hypnotic [27] and anti-anxiety [25] effects. The linalool and limonene in the Bitter orange flowers have sedative and hypnotic effect [27,28].

Bitter orange with a dose of 975 mg (54 mg *p*-synephrine 6%) for six weeks used for weight loss did not caused any particular side effects [29], while topical usage led to sensitivity to light [27]. The Food and Drug Administration confirmed that oral use of bitter orange is safe [25].

According to the WHO report, in the most countries, because of herbal medicine's effectiveness, low risk and accessibility, consumption of complementary medicine for therapeutic reasons has been increasing. In third world countries, the majority of people use herbal medicines due to the lower cost of herbal plants [30].

Due to the complications of anti-anxiety medications and the prevalence of complementary medicine, and given that no study of which we are aware has been conducted to compare the effects of oral lavender or bitter orange on anxiety in postmenopausal women to provide information to primary care providers who care for postmenopausal women.

2. Material and methods

2.1. Study design and participants

The recruitment of participants, data collection and follow-up were conducted from July 5, 2015 to November 21, 2015. This was a triple-blind, randomized, controlled trial that was conducted on 156 postmenopausal women. The inclusion criteria were: 45–60 years; last menstruation 1–6 years ago; cessation of menstruation occurred naturally; getting 20–53 from Spielberger's anxiety score in both state and trait anxiety separately (mild and moderate trait

and state anxiety); not taking anti-anxiety drugs or using tobacco or alcohol; having a telephone number for follow-up; no history of asthma or allergy to specific plants or citrus; no self-reported acute gastrointestinal problems; resident of Urmia; and agreed to participate in the study.

The exclusion criteria were: travelling or changing residence during the intervention; prior history of severe physical illness or disorder that caused anxiety; unpleasant occurrences, such as death of a family member during last three months; encountering events that caused anxiety; and use of other methods of traditional medicine. We investigated mild and moderate to high anxiety trait and state anxiety (20–53 score).

G*POWER (version 3.1.2) was used to determine the sample size. Based on the information in the study by Kalani and colleague [31] $m_1 = 49.45$ (mean anxiety score), $m_2 = 45.5$ (considering at least 5% improvement in anxiety in the intervention group), $sd_1 = sd_2 = 5.16$, two-sided, $\alpha = 0.05$, $\beta = 0.05$, the necessary sample size was determined to be 47 women per group. Considering a 10% sample loss, the necessary sample size was determined to be 52 participants for each group.

The Research Ethics Committee of Tabriz University of Medical Sciences approved the study protocol (code: 1394.98) which was also registered at the Iranian Registration Clinical Trial center (code: IRCT201504236582N11). The research setting was the Gynecology clinics in Imam Reza and Fatemiyeh hospitals in Urmia, Iran. All postmenopausal women were assessed for eight weeks ($n = 400$) in the selected clinics and the methodology, possible risks, potential benefits, and nature of voluntary participation in the study were explained to the women, and written informed consent was obtained from them. A total of 190 (47.5%) women did not meet the eligibility criteria, and 54 (25.7%) of those who were eligible were not willing to participate in the study (Fig. 1). Finally, 156 postmenopausal women participated in the study; 52 women were randomly assigned to each group.

2.2. Randomization and intervention

Participants were randomly allocated into one of three groups: bitter orange, lavender or placebo. The allocation sequence was determined by computer using a random numbers table with block size of 3 and 6 and a 1:1:1 allocation ratio. Capsules contained 500 mg of the powder of bitter orange or lavender flower, while placebo capsules contained 500 mg of starch. All capsules were similar in appearance, did not have volatile oils and thus had no odor. Most women (more than 50% in each of the three groups) could not guess correctly which intervention they received when asked at the end of the experiment for assessing the effectiveness of blinding ($p > 0.05$). Capsules were prepared by Yashil Sahand Drug Corporation in East Azerbaijan region, Iran. The capsules were first placed inside plastic containers then inserted into paper envelopes to prevent contamination of the herbs. Participants were instructed to close the containers and envelopes each time after taking their capsules. An opaque sealed envelope was given to each participant. Envelopes were numbered consecutively from 1 to 156 according to a random sequence, which prepared by a person not involved in group assignments, to determine each woman's assignment to lavender, bitter orange or placebo group for the eight weeks of the trial.

The drugs were taken twice daily (after breakfast and dinner). Because the dosage of the intervention drugs was 1 g, it was not adequate if only one capsule was taken at night. To ensure consumption of the capsules, participants were contacted by telephone at weeks two and six. Participants, data collectors and those who assessed outcomes were masked as to women's group assignments.

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