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Effects of chicory and fumitory on hot flashes in postmenopausal women; a prospective non-randomized single arm clinical trial

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Abstract

Introduction: Hot flashes are the most common annoying symptom in menopause and impair the quality of life in postmenopausal women.
Objectives: The present study aimed to assess the effects of a product prepared from chicory and fumitory on hot flashes in postmenopausal women.
Patients and Methods: This prospective non-randomized single arm clinical trial study was performed on 43 postmenopausal women with hot flashes. After recording the number and severity of hot flash episodes on a daily basis for one week, an herbal product made of chicory and fumitory was administered for four weeks (5 cc in the morning and 5 cc at night), and they completed the form designed for the daily record of hot flashes.
Results: In the week before the intervention, most episodes were severe, and there was only one day without hot flashes among patients. The number and severity of hot flash episodes decreased significantly within 1 to 4 weeks after the intervention, compared to the period before the treatment. Moreover, the mean number of severe and very severe episodes decreased significantly, while the mean number of mild episodes increased during the study period. Furthermore, with the progress of the study, the number of days without hot flashes in patients increased significantly.
Conclusion: Based on the results of our study, the use of chicory and fumitory was effective in the improvement of the number and severity of hot flash episodes, and the effect was observed one week after administration.
Trial Registration: This trial protocol was approved by the Iranian Registry of Clinical Trial (identifier: IRCT20160722029027N13; ethical code; IR.SBMU.MSP.REC.1398.460).

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Introduction

Hot flashes are the most common complication around menopause, affecting 40% of women (1). Hot flashes commonly occur at night, disrupt sleep patterns, and cause episodes of waking up at night. These in turn lead to fatigue, irritability, anxiety, decreased concentration, and memory performance, and even depression which result in decreased quality of life in postmenopausal women (2). Each hot flash episode typically lasts from 30 seconds to 5 minutes (typically 4 minutes) (3) and varies from 1-2 times per hour to 1-2 times per week.

Although the exact mechanism of hot flashes is unknown, there are generally two treatments for hot flashes which include hormone replacement therapy and non-hormonal therapies. An estrogen alone or in combination with progesterone treatment regime is often recommended to be administered periodically or sequentially; however, these regimes have multiple short-term or long-term side effects, such as thromboembolism, vaginal bleeding, stroke, and breast tenderness. In addition, these regimes could not prescribed in some cases, such as a history of stroke, breast cancer, venous thromboembolic event and coronary artery disease (4). For these reasons, the use of this type of treatment in postmenopausal women has decreased from 26.9% in 1999-2000 to about 4.7% in 2017-2020 (5).

On the other hand, several non-hormonal therapies for hot flashes include treatment with gabapentin, clonidine, and selective serotonin reuptake inhibitors, or serotonin and norepinephrine reuptake inhibitors.

Key point

Hot flashes are the most common symptom in menopause, which may be associated with a decrease in quality of life of postmenopausal women. In this prospective non-randomized single arm clinical trial study, we investigated the effect of an herbal product of chicory and fumitory on 43 postmenopausal women with hot flashes for 4 weeks. The results showed that the number and severity of hot flashes episodes decreased significantly, and gradually with the progress of the study, the number of days without hot flashes increased significantly. As a result, the use of chicory and fumitory is effective in improving the number and intensity of hot flashes.

Each of these medications has different mechanisms of effect that reduce the severity and duration of menopausal vasomotor symptoms. Nonetheless, the side effects of these medications have prompted researchers and scientists to find more available and less expensive medications with fewer or at least more controlled side effects in an attempt to bring about a relative improvement in other menopausal complications other than hot flashes (6).

Today, due to the growing popularity of herbal remedies in many societies, researchers have turned their attention to the effects of herbal remedies, such as *Glycine max, Cimicifuga racemosa, Vitex agnus-castus*, and *Glycyrrhiza glabra* (Licorice) on hot flashes in postmenopausal women. Chicory (*Cichorium intybus hsj*) and fumitory (*Fumaria officinalis*) are native medicinal plants in Iran that have long been used for the treatment of various diseases, and current studies have pointed to their antioxidant and anti-inflammatory properties (7,8).

According to Iranian traditional medicine, chicory has a cold and wet temperament and fumitory has a warm and dry temperament which could suppress the heat of blood and bile. Therefore, they can be possibly effective in the treatment of hot flash episodes caused by menopause; however, no scientific study has been performed in this regard.

Objectives

The present study aimed to investigate the effect of a product prepared from chicory and fumitory on hot flash episodes in postmenopausal women.

Patients and Methods

Study design and participants

These sections are written based on the consort guidelines. This prospective non-randomized single arm clinical trial study was performed on postmenopausal women with hot flashes who were referred to the clinic and gynecology ward of Shohada Tajrish hospital, Tehran, Iran, in 2021.

Inclusion and exclusion criteria

The inclusion criteria included the manopausal women at age of 45-60 years; with complaints of hot flashes; with no menstruation in the last 12 months and follicle-stimulating hormone (FSH)> 40 IU/L. The exclusion criteria at the beginning of the study were use of anticoagulants drugs; no history of diseases (e.g., cardiovascular diseases, diabetes, hypertension, neurological diseases, cancer of breast, ovary, and uterus, or hormone-sensitive diseases, such as endometriosis or uterine fibroids); use of cupping and acupuncture; use of medication, especially hormonal drugs; and use of antidepressants in the last four weeks (e.g., venlafaxine, bupropion, fluoxetine, paroxetine, citalopram and sertraline).

The exclusion criteria during the intervention included unwillingness to continue participating in the study at any time and for any reason, use of acupuncture and complementary medicine, use of a variety of medications affecting hot flashes (e.g., anti-anxiety medications, gabapentin, pregabalin, clonidine, aspirin, vitamin E, omega-3, phytoestrogen supplements, and high phytoestrogen diets), self-medication, the consumption of herbal medicine or special diets to treat hot flashes, and allergy to chicory and fumitory products.

Randomization

Non-randomization.

Sampling

The sample size in this pilot study included 45 patients who were selected from 100 women referred to the clinic and gynecology ward of Shohada Tajrish Hospital, Tehran, Iran. Written informed consent was obtained from the participants after the objectives of the study were explained to them. During the study, two patients were ruled out from the study (one from the first week due to nausea and the other from the second week due to coronary heart disease). Eventually, 43 patients completed the study (Figure 1).

Blinding

No blinding.

Preparation of traditional chicory and fumitory products

The traditional product used in this study was chicory and fennel syrup, for which a similar sample was not found in the pharmaceutical market. Initially, the dried limbs of chicory and fumitory plants were purchased in the amount required for all patients from a reputable perfumery in Tehran. They were then approved and registered by medicinal plants experts in the Faculty of Pharmacy of Shahid Beheshti University of Medical Sciences, Tehran, Iran. Subsequently, quality control tests, including microbial contamination tests, were performed according to the valid guidelines (United States Pharmacopeia guidelines [USP, 2006]). Subsequently, dried chicory and fumitory plants were cleaned and washed out of dust and possible wastes. The mill was masfumitoryd with alcohol 70% after drying.

The prepared extract was first concentrated by rotary rotation and then dried using a freezer. Afterward, 36 g of

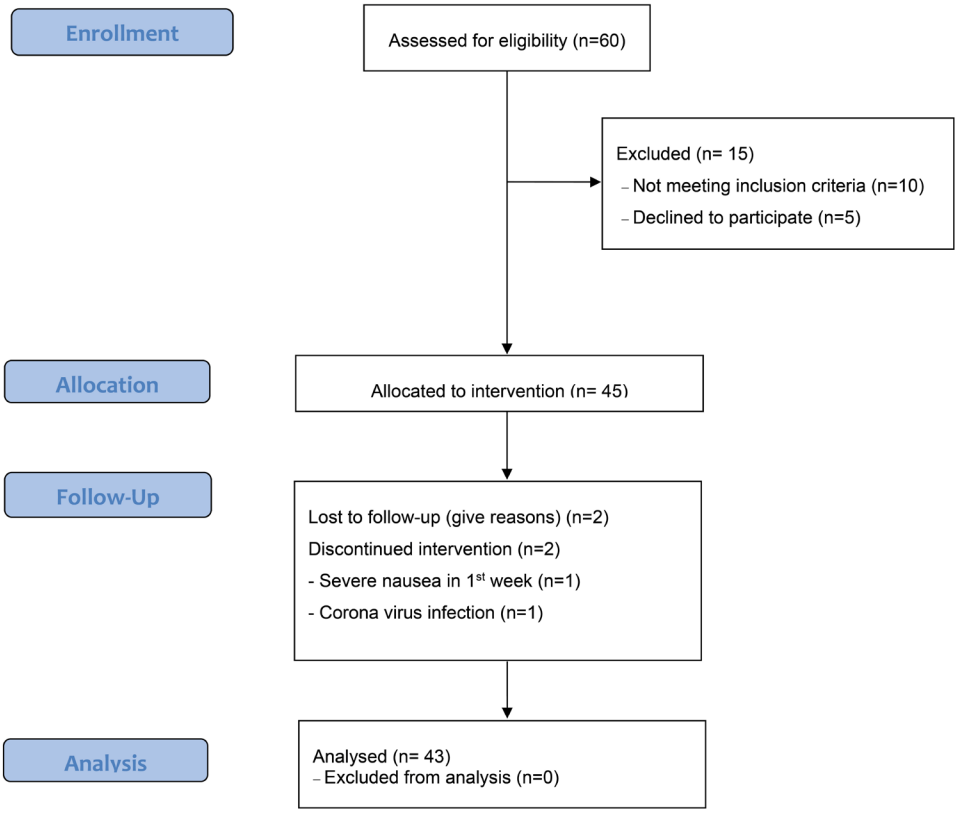

Figure 1. CONSORT flow diagram of the study.

dried extract of chicory and 18 g of dry extract of fumitory were dissolved in 120 cc of syrup containing distilled water and 70% sugar and mixed afterward. Special bottles were delivered to the patient at a daily dose of 10 cc (5 cc in the morning and 5 cc in the evening). Dose of chicory and fumitory used in this product was within the recommended range mentioned in traditional Iranian medicine texts and according to the studies conducted by Nishmura et al (9) on chicory and the studies performed by Brinkhaaus et al (10) on *Fumaria officinalis*.

The standardization of the prepared herbal products in this study was determined according to the Folin Cicalto method, spectrophotometry, and the measurement of the total phenol. Furthermore, quality control and microbial contamination tests were performed on the components of herbal products during the preparation stages, and plant analysis was performed according to the relevant monograph in pharmacopeias.

Intervention

Patients were treated with herbal products made of chicory and fumitory for four weeks. The prepared herbal products (5 cc) were administered to patients in the morning of fasting and at night.

Data collection

Patients' information (age, weight, height, disease history and type, smoking status, history of substance use, menarche and menopausal age, history of oral conceptive pill (OCP) use), as well as its duration and clinical symptoms was recorded. Patients then completed the Green Climacteric Scale on a daily basis for one week. In this form, the severity of hot flash episodes is divided into four categories of mild, moderate, severe, and very severe. The items are rated from 1-4, respectively, and the patient records the number of episodes in each severity category on a daily basis. At the end of the week, the total number of hot flash episodes, the number of episodes in each severity category, the total score of hot flashes (based on the sum of the numbers of episodes in each severity category multiplied by the severity score) and the number of days without hot flashes were considered as baseline values.

During the follow-up period, patients completed a form in which they registered the details of their hot flash episodes on a daily basis. in addition, they were contacted weekly by telephone for information about the consumption of herbal product and recording hot flashes. Other symptoms of patients were measured and recorded at the end of the second and fourth weeks. In case the complaints were annoying, the patient could receive other standard treatments after she was excluded from the study.

Outcomes

The effect of the herbal products on the number and severity of flash episodes were analyzed after four weeks.

Statistical analysis

The obtained data in this study were analyzed in SPSS

statistical software (version 25). Qualitative variables were described using frequency and percentage, while quantitative variables were presented as mean and standard deviation. Repeated measure analysis of variance (ANOVA) and Friedman's test were conducted to analyze the data. A *P* value less than 0.05 was considered statistically significant.

Results

A total of 43 patients with a mean±SD age of 53.16±3.66 years and a mean menopause duration of 2.80±1.62 years completed this study. Table 1 displays the demographic characteristics of patients. A history of some diseases, such as gastritis, hypothyroidism, and osteoporosis was reported in 13 (30%) patients. Twenty one (49%) patients reported using OCP for a duration of 3-13 years and the mean ± SD of 7.48±2.70 years.

The most common clinical symptoms before intervention included sweating, fatigue, depression, insomnia, and constipation, respectively. The mean number of patients' clinical symptoms was 5±1 before the intervention, which decreased significantly with the progress of the study (2±1 in second week; 1±1 in forth week; $P<0.001$, Related-samples Friedman's two-way ANOVA). Many of the symptoms improved significantly after the intervention (Table 2). Moreover, sweating, which was the most common pre-intervention symptom, was not reported in the second and fourth weeks after intervention.

Table 3 displays the number of hot flash episodes, the severity of the episodes, and the total score of hot flashes obtained in the week before intervention. In terms of severity, most hot flash episodes were severe. Moreover, there were no hot flash episodes days in only one patient for one day.

As illustrated in Table 4, and Figures 2 and 3, the number of episodes and the hot flash score were significantly reduced over time after intervention ($P<0.001$).

Furthermore, gradually and with the progress of the study, the number of severe and very severe episodes per week reduced significantly, while, the number of mild episodes increased ($P<0.001$; Table 5). In addition, the number of days without hot flashes increased significantly with the progress of the study ($P<0.001$; Table 6, Figure 4).

Discussion

Although there are numerous hormonal and non-hormonal treatments for hot flashes, various herbs have been used to treat menopausal hot flashes. Some studies have reported to the properties of chicory and fumitory mentioned in traditional Iranian medicine.

The results of the current study demonstrated that the mean (SD) of the total number of hot flash episodes and its total score was obtained at 28±8 and 81±26 in the week before the intervention, respectively. Most episodes were severe, and there was only one day without hot flashes among patients. Nevertheless, the number and score of hot flash episodes, as well their severity reduced significantly after the consumption of chicory and fumitory products. Moreover, by the progress of the study, the number of

Table 1. Demographic characteristics of patients (n=43)

	Range	Mean (SD)
Age, year	47-60	53.16 ± 3.66
Weight, kg	53-85	69.93 ± 8.22
Height, centimeters	148-173	161.40 ± 6.28
BMI, kg /m²	20.8-36.5	26.87 ± 3.13
Menarche age, year	9-13	11.56 ± 0.96
Menopausal age, year	45-55	50.37 ± 2.77
Duration of menopause, years	1-7	2.80 ± 1.62

Table 2. Clinical symptoms before the intervention and in the second and fourth weeks after the intervention

	Before the intervention	Second week	Fourth week
Anorexia	14 (33%)	7 (16%)	3 (7%)
Nausea	13 (30%)	1 (2%)	1 (2%)
Constipation	18 (42%)	3 (7%)	0 (0%)
Diarrhea	5 (12%)	1 (2%)	1 (2%)
Dry mouth	13 (30%)	4 (9%)	2 (5%)
Insomnia	19 (44%)	8 (19%)	5 (12%)
Drowsiness	15 (35%)	9 (21%)	5 (12%)
Fatigue	26 (60%)	13 (30%)	6 (14%)
Headache	7 (16%)	0 (0%)	0 (0%)
Being nervous	13 (30%)	4 (9%)	1 (2%)
Anxiety	15 (35%)	9 (21%)	6 (14%)
Depression	20 (47%)	7 (16%)	7 (16%)
Sweating	41 (95%)	0 (0%)	0 (0%)

Table 3. Number and score of hot flash episodes in the week before the intervention

	Range	Mean (SD)
Total number	11-43	27.65 ± 7.68
Total score	27-136	80.56 ± 26.39
Mild	0-11	1.19 ± 2.17
Moderate	0-16	7.51 ± 4.14
Severe	3-20	11.47 ± 3.84
Very severe	0-17	7.49 ± 5.04

Table 4. Comparison of the number of episodes and hot flash score before the intervention and in the first to fourth weeks after the intervention

	Number of episodes		Hot flash score	
	Mean (SD)	*P* value*	Mean (SD)	*P* value*
Before the intervention	27.65 ± 7.68	<0.001	80.56 ± 26.39	<0.001
First week	13.05 ± 5.95		26.65 ± 14.84	
Second week	10.47 ± 5.41		18.67 ± 11.40	
Third week	8.7 ± 4.70		14.07 ± 9.323	
Fourth week	7.02 ± 5.28		10.95 ± 9.12	

* Repeated measure ANOVA.

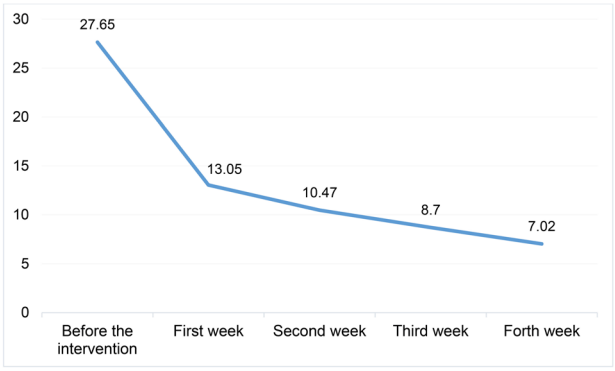

Figure 2. Average number of hot flash episodes before the intervention and in the first to fourth weeks after the intervention

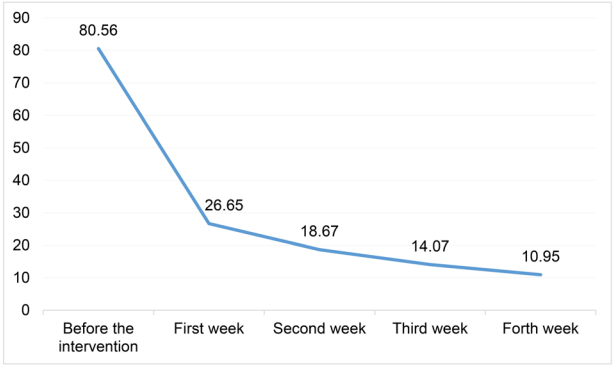

Figure 3. Mean hot flash score before the intervention and in the first to fourth weeks after the intervention.

days in which women did not experience hot flashes increased significantly. In addition, the mean number of patients' clinical symptoms decreased significantly with the progress of the study, and many of their symptoms improved significantly. Moreover, sweating, which was the most common symptom before the intervention was not reported in the second and fourth weeks.

Although the mechanism of hot flashes is still unclear, it seems that the hypothalamic thermoneutral zone, as well as the related mechanisms and relationships, are disturbed (11,12). These disorders begin before the onset of menopause and continue for some time after that, suggesting that some symptoms, such as hot flashes, gradually adjust to one's body condition, and even though hormone replacement therapy is used, symptoms may return by the abrupt disruption of hormone replacement therapy. However, it seems that, the effects of herbal medicines may be caused and influenced by multiple mechanisms due to the fact that a range of hormonal and non-hormonal drugs with different mechanisms of action are used in the usual treatment of hot flashes, and considering a wide range of herbal medicines that affect hot flashes.

Some herbal medicines, such as soybeans, contain isoflavones antioxidant properties (13). It is already known that free radicals are effective in the development of numerous diseases and malignancies (14). Moreover, inflammatory mediators can be another important factor in the onset of disease symptoms (15). As a result, chicory (especially its roots) contains sesquiterpene lactone compounds, which are potent inhibitors of prostaglandin production by the inhibition of the enzyme cyclooxygenase 2 (16). Consequently, chicory as a plant with special anti-inflammatory properties can be useful in many inflammatory diseases (17).

The extract used in the present study was obtained from the dried chicory plant (except its root). Fumitory also has anti-inflammatory properties and is effective in the management of pain (18,19). The results of the present study confirmed the positive effect of the combined use of these two plants on menopausal hot flashes. Therefore, this combination can be used in the treatment of patients with hot flashes.

Regarding the strengths of the present study, one can refer to the fact that since chicory and fumitory extract is

Table 5. Comparison of severity of hot flash episodes before the intervention with the first to fourth weeks

	Before the intervention	First week	Second week	Third week	Fourth week	*P* value*
Mild episodes	1.19 ± 2.17	3.07 ± 2.23	3.77 ± 2.68	4.07 ± 2.44	3.51 ± 2.76	<0.001
Moderate episodes	7.51 ± 4.14	6.88 ± 3.1	5.37 ± 2.69	3.93 ± 2.67	3.05 ± 2.45	<0.001
Severe episodes	11.47 ± 3.84	2.56 ± 2.18	1.14 ± 1.7	0.65 ± 1.38	0.42 ± 0.96	<0.001
Very sever episodes	7.49 ± 5.04	0.53 ± 1.32	0.19 ± 0.7	0.05 ± 0.31	0.02 ± 0.15	<0.001

* Related-Samples Friedman›s two-way ANOVA.

Table 6. Comparison of the number of days without hot flashes before the intervention and in the first to fourth weeks after the intervention

	None	1-2 days	3-4 days	5-7 days	*P* value*
Before the intervention	42 (98%)	1 (2%)	0 (0%)	0 (0%)	<0.001
First week	32 (75%)	7 (16%)	4 (9%)	0 (7%)	
Second week	22 (51%)	15 (35%)	5 (12%)	1 (2%)	
Third week	18 (42%)	13 (30%)	9 (21%)	3 (7%)	
Fourth week	6 (14%)	17 (40%)	12 (28%)	8 (19%)	

* Related-Samples Friedman›s two-way ANOVA.

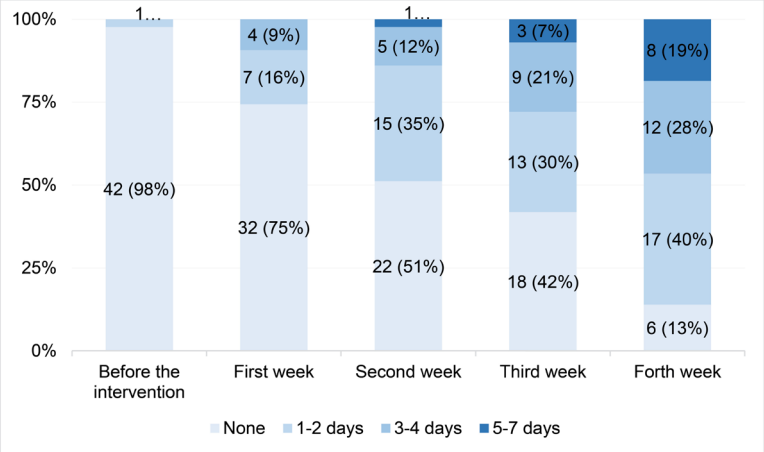

Figure 4. Number of days without hot flashes before the intervention and in the first to fourth weeks after the intervention.

not phytoestrogen or hormonal treatment, it can be used in the treatment of hot flashes in cases with hormonal contraindications, such as women with a history of breast cancer or active masses (i.e., fibroids or endometriosis). The findings of the current study indicated that the combination of chicory and fumitory is effective in the treatment of menopausal hot flashes.

Conclusion

According to the results of the present study, the use of chicory and fumitory products is effective in the improvement of the number and severity of hot flash episodes and other clinical symptoms in menopausal women one week after administration. Therefore, the use of this combination is recommended in postmenopausal patients with hot flashes.

Limitations of the study

As a pilot study, the small sample size and lack of placebo or control group are the notable limitations of this study. Accordingly, studies with a larger sample size that include a control group (or placebo) are required to evaluate the effect of this combination in comparison with the conventional treatments for hot flashes.

Authors' contribution

Conceptualization: Ladan Ajori, Mojgan Tansaz, Leila Nazari, Roya Gharedaghi
Data curation: Mojgan Tansaz, Leila Nazari, Mozhgan Mehri, Roya Gharedaghi
Formal analysis: Ladan Ajori, Mojgan Tansaz, Roya Gharedaghi
Funding acquisition: Ladan Ajori, Mojgan Tansaz, Roya Gharedaghi
Investigation: Ladan Ajori, Mojgan Tansaz, Roya Gharedaghi
Methodology: Ladan Ajori, Mojgan Tansaz, Leila Nazari, Mozhgan Mehri, Roya Gharedaghi
Project administration: Ladan Ajori, Mojgan Tansaz
Resources: Mojgan Tansaz, Roya Gharedaghi
Software: Roya Gharedaghi
Supervision: Ladan Ajori, Mojgan Tansaz
Validation: All authors.
Visualization: All authors.
Writing–original draft: All authors.
Writing–review & editing: All authors.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

The research conducted in accordance with the principles of the Declaration of Helsinki. The Ethics Committee of Shahid Beheshti University of Medical Sciences approved this study (Ethical code#IR.SBMU.MSP.REC.1398.460). Accordingly, written informed consent was taken from all participants before any intervention. The trial protocol was approved in the Iranian registry of clinical trial (identifier: IRCT20160722029027N13). Additionally, ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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