Original Paper

Effect of Green *Ocimum basilicum* Leaf Extract Capsule on the Quality of Life of Postmenopausal Women: A Randomized, Placebo-controlled, Clinical Trial

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Citation Zokaei F, Kamalinejad M, Farid M, Pirak A, Yazdkhasti M. Effect of Green *Ocimum basilicum* Leaf Extract Capsule on the Quality of Life of Postmenopausal Women: A Randomized, Placebo-controlled, Clinical Trial. J Holist Nurs Midwifery. 2026; 36(1):72-81. https://doi.org/10.32598/jhnm.36.1.2759

Running Title Effect of Green Basil Leaf Extract Capsule on the Quality of Life of Postmenopausal Women

https://doi.org/10.32598/jhnm.36.1.2759

Article info:
Received: 07/05/2025
Accepted: 23/11/2025
Available Online: 01/01/2026

Keywords:
Quality of life (QOL), Menopause, Complementary and alternative medicine

ABSTRACT

Introduction: Menopause can make women more vulnerable and has different vasomotor, psychosocial, physical, and sexual domains, which can reduce women's Quality of Life (QOL). The use of medicinal plants containing phytoestrogens can reduce the symptoms of menopause.

Objective: This study aimed to assess the effect of Green *Ocimum basilicum* Leaf Extract (GOBLE) capsule on the QOL of postmenopausal women.

Materials and Methods: This is a double-blind, randomized, controlled clinical trial conducted from November 2019 to May 2022 at a teaching hospital affiliated with Alborz University of Medical Sciences, Karaj, Iran. Eighty participants were allocated to the intervention (n=40) and control (n=40) groups using block randomization. The intervention group received 250 mg GOBLE capsules every 12 hours for eight weeks. In the control group, a placebo was used. Data were collected by the Menopause-Specific Quality of Life (MENQOL) questionnaire at three time points: Before the intervention, one month after the intervention, and two months after the intervention. Independent t-test, paired t-test, Wilcoxon test, Mann-Whitney U test, Friedman's test, and ANOVA were used for statistical analysis

Results: The majority of women were aged 47-51 years (51.4% in the intervention group and 43.6% in the control group), and had an age at menopause of 48-52 years (55% in the intervention group and 59% in the control group). The total MENQOL score ranged from 29 to 232. In the intervention group, the results one month after the intervention showed a significant reduction only in vasomotor (from 14.1±6.4 to 10.5±5.5, P=0.01) and sexual (from 15±6.7 to 11.5±7.2, P=0.03) domains. The trend of changes two months after intervention showed significant between-group differences in vasomotor (P=0.01, η_{p2}=0.35) and sexual (P=0.001, η^2=0.28) domains. There were no statistically significant differences in the control group.

Conclusion: The GOBLE capsule administration can reduce the effect of vasomotor and sexual symptoms of menopause on the QOL of postmenopausal women. Therefore, this product may help alleviate hot flashes, sweating, and night sweats (vasomotor symptoms) and improve sexual desire, vaginal dryness, and sexual activity in postmenopausal women.

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Highlights

- Based on the study literature, green basil can improve memory and reduce anxiety, depression, sleep disorders, and joint pain.

- The GOBLE capsule use in this study improved the quality of life of postmenopausal women by reducing vasomotor and sexual symptoms.

- The GOBLE capsule use had no significant effect on psychosocial or physical symptoms of menopause.

Plain Language Summary

Menopause is accompanied by decreased Quality of Life (QOL). The fear of side effects from hormone therapy, increased risk of breast cancer, potential negative impact on cardiovascular disease prevention, the indirect link between decreased ovarian hormones and menopausal symptoms, and the influence of sociocultural and psychological factors on menopausal symptoms and body image concerns may enhance women's willingness to use complementary and alternative medicine to alleviate the symptoms. In this study, green basil leaf extract capsules were administered to examine their effectiveness in improving the QOL of postmenopausal women. The findings revealed that the use of these capsules positively affected the QOL of these women by reducing vasomotor and sexual symptoms of menopause.

Introduction

Menopause causes various changes in women's physical, psychosocial, and sexual functioning that can significantly affect their Quality of Life (QOL) across different physical, psychosocial, and sexual aspects [1]. Symptoms of menopause and sociodemographic factors influence the QOL of postmenopausal women [1, 2]. Each year, half a million women is added to the middle-aged population of women. The average age of menopause is 51 years in the world, and 47.8 years in Iran. In 2022, about 5 million menopausal women were living in Iran [2, 3]. The most common symptoms of menopause include vasomotor symptoms. Most menopausal women complain of hot flashes, joint and bone pain, depression, and decreased sexual desire [3].

There is a wide range of therapeutic methods to control menopause symptoms, including Hormone Replacement Therapy (HRT), acupressure, various herbal compounds, acupuncture, massage therapy, and lifestyle changes, including exercise (yoga) and a healthy diet [4]. Decision-making regarding the treatment of menopausal symptoms is inherently complex and has increased over the past decade [5]. This complexity, in addition to the existing challenges in HRT and the uncertainty about the effects of other methods, such as Complementary and Alternative Medicine (CAM), may be due to the different nature of decision-making regarding the treatment of menopausal symptoms compared to other health fields. Since menopausal symptoms are common in all women, there is no single treatment for all symptoms, and even treating one symptom may aggravate other symptoms [6]. Reported hot flashes in postmenopausal women vary between different countries. In women from European and North American countries, the rate of hot flashes is 70-80%, while it is 14-25% in Japanese, Chinese, and Southeast Asian women. This difference is due to many factors. One possible factor is the presence of phytoestrogen-containing plants in the food [7, 8]. Phytoestrogens are plant compounds with estrogenic activity [9]. These plants have a special place in improving or treating menopause symptoms. Many plants, such as black cohosh, *Panax ginseng*, *Glycine max*, *Trifolium pratense*, *Vitex agnus-castus* [10], *Trigonella foenum-graecum* [11], *Passiflora incarnata* [12], and *Salvia officinalis* extract [13] are among this group. Their use has been shown to reduce menopausal symptoms [14].

One medicinal plant commonly used to alleviate menopausal symptoms is sweet basil (*Ocimum basilicum* L.), a member of the Lamiaceae family [15]. It is the only species of this family that is cultivated in Iran [8]. The green leaves of this plant are traditionally used for various medicinal purposes such as improving memory,

reducing anxiety and depression, relieving bone and joint pain, and promoting a sense of well-being. The Green *O. basilicum* Leaf Extract (GOBLE) capsules contain phytoestrogens, such as flavonoids and coumarins, which mimic estrogen and bind to estrogen receptors, making it beneficial for postmenopausal women experiencing hormonal decline. These compounds may help alleviate menopausal symptoms, including hot flashes and mood swings, by exerting weak estrogenic effects. Additionally, the antioxidants in green basil combat oxidative stress and inflammation, supporting overall hormonal health and reducing the risk of chronic conditions. The phytoestrogens in green basil may play a significant role in improving the QOL in postmenopausal women [15, 16]. Given the global trend and increasing interest in CAM and herbal medicines [17, 18], as well as the importance of QOL studies on menopausal women, this study aimed to evaluate the impact of GOBLE capsules on the QOL of menopausal women in Iran.

Materials and Methods

This is a double-blind, randomized clinical trial involving 80 women at a teaching hospital affiliated with Alborz University of Medical Sciences in Karaj, Iran, from November 2019 to May 2022. The sample size was estimated according to Taavoni et al.'s study on the effect of Lemon Balm supplementation on menopausal symptoms [19]. The sample size was calculated (n=80) using G*Power software, version 3.1, by considering α=0.05, Effect size (d)=0.72, test power (1-β) =0.90, and a 5% sample dropout rate. Inclusion criteria were a natural menopause (absence of menstruation in the last 12 months) and experiencing menopausal symptoms, being married, not having menopause due to chemotherapy or radiation therapy, not using HRT or herbal phytoestrogens, not consuming alcohol, tobacco, or drugs; no sensitivity to the plants from the Lamiaceae family or other phytoestrogen-contaning plants, and no history of unknown vaginal bleeding, diabetes, or hypertension. Exclusion criteria were unwillingness to continue participation in the research or failure to take medication regularly. For allocation concealment, the capsules and placebos were sequentially placed in sealed, opaque envelopes. The code for eligible participants to enter the study was the same as the code on the capsules' labels.

First, a list of menopausal women reporting menopausal symptoms was prepared from the patient files by referring to the gynecology department's medical records. Next, we contacted the women by phone, explained the study objectives, and invited them to attend the relevant center at the scheduled time (Figure 1). Then, their written consent was obtained. The participants were randomly assigned to two intervention (n=40) and control (n=40) groups using random sampling by quadruple random blocks. The first participant was randomly assigned to either the intervention or the control group via simple random sampling, using a lottery or a random number generator. Then, we defined a block size of 4 (each block consisting of 2 participants in the intervention group and 2 in the control group). Next, we created randomized sequences for each block of four. This method ensured that, at the end of each block, both groups had an equal number of participants, effectively preventing significant imbalances that could affect the study's outcomes. The process was repeated for subsequent blocks until all participants were assigned, with each new block following the same randomized order. Blinding was ensured by having an expert (the second author) prepare and label the capsules and manage group allocation. Neither the participants nor the first author who administered the intervention and collected outcome data were aware of the group assignments. This approach ensured a double-blind design, minimizing potential bias.

The sociodemographic form collected information on participants' characteristics, including age, Body Mass Index (BMI), occupation, educational level, age at menopause, and the number of living or deceased children. The Menopause-specific Quality of Life (MENQOL) questionnaire was used to measure the impact of menopausal symptoms on the QOL. It has 29 items covering vasomotor (3 items), psychosocial (7 items), physical (16 items), and sexual (3 items) domains of symptoms. The total scores for the four dimensions are 3-24, 7-56, 16-128, and 3-24, respectively. The total score for the overall scale ranges from 29 to 232, with higher scores indicating a lower QOL [20]. The Persian version of this questionnaire was validated in our other study [21]. The test re-test reliability, as measured by the intraclass correlation coefficient, was 0.84 for the overall MENQOL, 0.80 for the vasomotor domain, 0.79 for the psychosocial domain, 0.82 for the physical domain, and 0.83 for the sexual domain.

For the intervention group, 250 mg of GOBLE capsules (green basil leaf powder) was prescribed to be taken for 8 consecutive weeks, twice a day, every 12 hours, with breakfast and dinner. The capsules were prepared in Iran under the supervision of a professor of pharmacognosy (Mohammad Kamalinejad). The green basil leaves were collected from the Qasemabad Farm in Karaj, Iran. They were confirmed and registered in the Herbarium

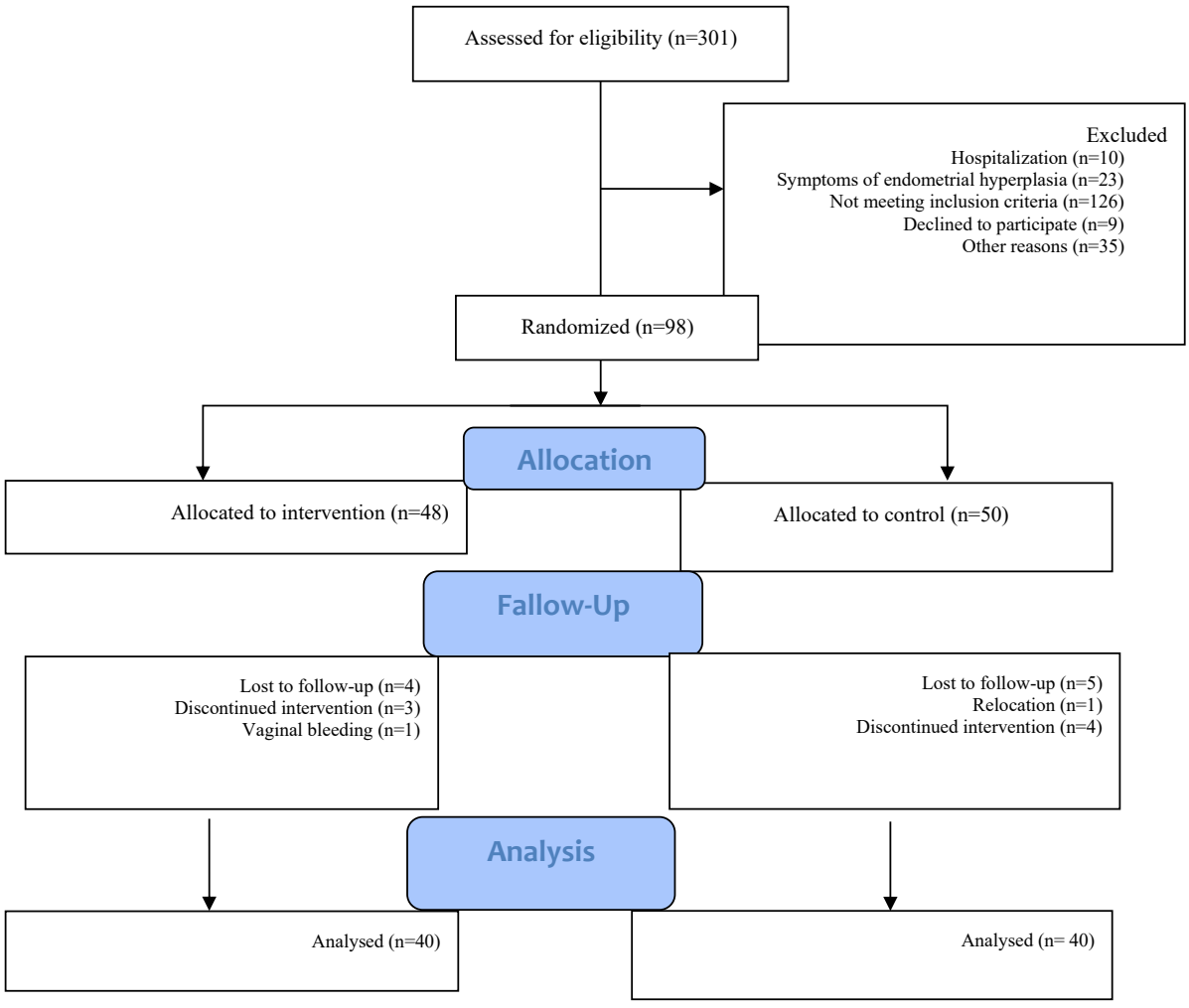

Figure 1. CONSORT diagram of the study

of the Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences (No.: SBMU-1084 A). To prepare the GOBLE capsules, the fresh green basil leaves were first dried in the laboratory at 25°C. Then, 100 g of dry leaves were added to 1000 cc of ethanol-water solvent (50% each) in a dish and macerated for 48 hours in the laboratory. Next, the extract was filtered, concentrated, dried in a bain-marie bath (freezing bath), ground in a mill, and placed in 250 mg capsules. For the control group, placebo capsules were used. The capsules were made of 250 mg corn starch, dipped in edible green color, and filled with green basil essential oil with the same color, smell, weight, and packaging as the original capsule used in the intervention group. The placebo was also prepared in the same pharmaceutical laboratory under the supervision of an expert in pharmacognosy (Mohammad Kamalinejad). The researcher monitored patients' adherence to medication usage by providing them with a checklist.

Data were collected via self-reporting before the intervention and one and two months after the intervention. Statistical analysis was conducted in SPSS software, version 23. Chi-square and Fisher's exact tests were used to analyze the qualitative variables. The quantitative data were presented as Mean±SD. The normality of the data was assessed based on the Skewness and Kurtosis values. Nonparametric tests such as the Mann-Whitney U test, the Wilcoxon test, and Friedman's test were used for variables with abnormal distributions, while parametric tests, including the independent t-test, the paired t-test, and the repeated measures ANOVA, were used for variables with normal distributions. The significance level was set at 0.05.

Results

In this study four participants in the intervention group and 5 participants in the control group were lost to follow-up and finally the participants included 80 women

(40 in each group). The majority of women were in the age range of 47-51 years (51.4% in the intervention group and 43.6% in the control group). The age at menopause for the majority of women in both groups was in the range of 48-52 years (55% in the intervention group and 59% in the control group). The intervention and control groups were homogeneous with respect to age, age at menopause, BMI, number of living or deceased children, education level, and occupation before the intervention (Table 1). Baseline MENQOL scores were not significantly different between the two groups before the intervention (Table 2). The results of the paired t-test for the intervention group showed that before and one month after the intervention, there was a statistically significant reduction in vasomotor (P=0.01) and sexual (P=0.03) dimensions, but not in psychosocial and physical dimensions and total score based on the results of the Wilcoxon test. In the control group, no statistically significant difference was found one month after the intervention in MENQOL total score or domain scores (Table 3).

Changes in the scores of the vasomotor and sexual dimensions two months after were measured using a repeated-measures ANOVA. In the vasomotor domain, the group effect (P=0.01), the time effect (P=0.02), and

Table 1. Sociodemographic characteristics of the participants

Variables		No. (%)		P
		Intervention Group (n=40)	Control Group (n=40)	
Age (y)	42-46	7(15.3)	6(12.8)	0.58*
	47-51	20(51.4)	17(43.6)	
	52-56	13(33.3)	17(43.6)	
Age at menopause (y)	38-42	5(10)	3(7.7)	0.72*
	43-47	13(30)	10(25.6)	
	48-52	19(55)	23(59)	
	53-57	3(5)	4(7.7)	
BMI (kg/m^2)	20-24	11(24.3)	8(17.9)	0.32*
	25-29	22(54.5)	20(51.3)	
	30-34	7(21.2)	12(30.8)	
Number of children (live)	0-2	35(89.7)	34(88.6)	0.1*
	3-5	5(10.3)	6(11.4)	
Number of children (deceased)	0	37(94.9)	40(100)	0.15*
	1	3(5.1)	0(0)	
Job	Employee	3(6.8)	2(4.6)	0.65*
	Housewife	34(86.4)	32(81.8)	
	Retired	3(6.8)	6(13.6)	
Level of education	Elementary	3(7.7)	5(12.8)	0.74**
	Middle school	3(7.7)	5(12.8)	
	High school	22(56.4)	24(54.4)	
	Academic	12(28.2)	6(20)	

*Chi-square test, **Fisher's exact test

Table 2. Pre-test scores of the MENQOL and its domains for the study groups

Domains	Mean±SD		P
	Intervention Group	Control Group	
Vasomotor	14.1±6.4	13.4±5.25	0.56*
Psychosocial	26.5±9.1	28.6±10.8	0.29**
Physical	78.3±23.4	76.8±25.7	0.78**
Sexual	15±6.7	16±7.1	0.34*
Total	133.9±6.9	134.89±40.3	0.18**

*Independent t-test, **Mann–Whitney U test.

the interaction effect of time and group (P=0.01) were significant with a partial eta-squared (η_p^2) value of 0.35. In the sexual domain, the group effect (P=0.001), the time effect (P=0.01), and the interaction effect of time and group (P=0.01) were also significant, with a η_p^2 score of 0.28 (Table 4). Changes in the scores of psychosocial and physical dimensions and total MENQOL score two months after were measured using Friedman's test, whose results showed no statistically significant difference in either the intervention group or the control group (Table 5).

Discussion

Some demographic/obstetric factors have been reported to affect the QOL of postmenopausal women [2]. Therefore, in this study, the effects of factors such as age, age at menopause, BMI, number of children (living or deceased), educational level, and occupation were measured in postmenopausal women. Also, the impact of vasomotor, psychosocial, physical, and sexual domains of menopausal symptoms on their QOL was assessed in two groups of intervention (received GOBLE capsules) and placebo. Based on the results, the intervention group showed a significant reduction only in the vasomotor and sexual domains after intervention.

Hot flash is the most common complaint in postmenopausal women. The hot flashes due to hypoestrogenism are related to the sudden deprivation of estrogen, which causes changes in brain mediators and instability of the thermoregulation center [22]. Studies on the effects of some plants containing phytoestrogens on menopausal symptoms have indicated that these plants can reduce menopausal symptoms [11, 23-25]. Green basil is rich in phytoestrogens, such as flavonoids and coumarins, which can bind to estrogen receptors and partially mimic estrogen. This activity may alleviate menopausal

Table 3. Comparison of the MENQOL scores before and one month after the intervention in each study group

Domains	Mean±SD		P	Mean±SD		P
	Intervention Group			Control Group		
	Before Intervention	One Month After Intervention		Before Intervention	One Month After Intervention	
Vasomotor	14.1±6.4	10.5±5.5	0.01*	13.4±5.25	13.2±5.9	0.9*
Psychosocial	26.5±9.1	25.5±9.8	0.9**	28.6±10.8	27.4±10.7	0.1**
Physical	78.3±23.4	68.3±27.1	0.08**	76.8±25.7	74.1±23.3	0.5**
Sexual	15±6.7	11.5±7.2	0.03*	16±7.1	15.8±6.7	0.6*
Total	133.9±6.9	115.8±42	0.09**	134.89±40.3	130.5±38.3	0.08**

*Paired t-test, **Wilcoxon test.

Table 4. Comparison of the scores of vasomotor and sexual domains between and within groups

Domains	Group	Mean±SD			P			η_p^2
					Repeated-measures ANOVA			
		Before	One Month After	Two Months After	Time Effect	Group Effect	Group×Time	
Vasomotor	Intervention	14.1±6.4	10.5±5.5	11±6.4	0.02	0.01	0.01	0.35
	Control	13.4±5.25	13.2±5.9	12.5±6.6				
Sexual	Intervention	15±6.7	11.5±7.2	10.2±6.3	0.01	0.001	0.01	0.28
	Control	16±7.1	15.8±6.7	14.5±7.2				

symptoms like hot flashes and mood swings. Its antioxidant properties further reduce oxidative stress and inflammation, supporting hormonal balance, metabolic health, and overall well-being in postmenopausal women [15, 16].

Hakimi et al. showed reduced hot flashes in the intervention group that received fenugreek seed [26]. Nahidi et al. showed reduced hot flashes in the intervention group that received Licorice root extract [27]. A comparison of the effects of *S. officinalis* (100 mg thrice a day) and black cohosh (6.5 mg once a day) on vasomotor symptoms revealed that black cohosh significantly reduced symptoms by the third week, while *S. officinalis* was effective from the second to the eighth week [28]. A study on the effects of standardized alcoholic extract of *T. pratense* (Kolubara) showed reduced hot flashes and improvement in other vasomotor symptoms [29]. A systematic review confirmed that various phytoestrogenic plants effectively reduce the severity and frequency of hot flashes in postmenopausal women [30]. However, one study reported no significant effect, suggesting that the type of herbal product, dosage, duration, and timing with meals influence efficacy [31]. Taking phytoestrogens with carbohydrates increases their absorption [29]. Sweat basil reduces vasomotor symptoms via binding to mineralocorticoid receptors and inhibiting beta-hydroxysteroid dehydrogenase [32]. Reduced vasomotor symptoms can enhance sexual function by improving sleep and reducing night sweats [33]. In our study, administration of GOBLE capsules also reduced the sexual symptoms of menopause. Other studies reported

Table 5. Comparison of the scores of psychological and physical domains and the total MENQOL score between and within groups

Domains		Mean±SD		P*		
		Intervention Group (n=40)	Control Group (n=40)	Time Effect	Group Effect	Group×Time
Psychosocial	Before	26.5±9.1	28.6±10.8	0.06	0.08	0.07
	One month after	25.5±9.8	27.4±10.7			
	Two months after	28.6±10.6	28.6±10.6			
Physical	Before	78.3±23.4	76.8±25.7	0.1	0.2	0.15
	One month after	68.3±27.1	74.1±23.3			
	Two months after	73.7±24.3	71.3±26.6			
Total	Before	133.9±6.9	134.89±40.3	0.09	0.1	0.08
	One month after	115.8±42	130.5±38.3			
	Two months after	120.9±37.6	126.9±44.5			

[a]Friedman's test.

benefits of *Ginkgo biloba*, while *G. max*, *T. pratense*, Korean red ginseng, and flaxseed did not affect sexual performance [34, 35]. In another study, *Dracocephalum* reduced vasomotor, psychosocial, physical, and sexual symptoms of menopause [19]. Menopause can cause depression and isolation. Sweat basil contains monoterpenes, flavonoids, rosmarinic acid, and phenolic compounds, which affect GABA receptors and may improve mood [36-38].

In our study, GOBLE capsule administration had no significant effect on psychosocial or physical symptoms of menopause. Similar Lamiaceae plants, such as *Dracocephalum*, have shown a positive impact on depression, sleep, anxiety, and stress in clinical studies [39]. Phytoestrogens may preserve bone health, but their efficacy and optimal doses remain uncertain [40]. They are mainly used to prevent osteoporosis [41]. Comparisons with hormonal drugs suggest that both can have beneficial or adverse effects, but further research and regulatory approval are needed for herbal therapies [42]. In our study, the GOBLE capsule administration had no positive effect on the physical symptoms of menopause. This result may be related to the fact that osteoporosis treatment requires a longer course. The use of phytoestrogens often affects the prevention of osteoporosis rather than having therapeutic effects [43]. One limitation of our study was that assessing participants' adherence to medication was challenging, which we addressed by using a checklist and conducting follow-up phone calls.

In conclusion, GOBLE capsule administration can reduce the effects of vasomotor and sexual symptoms of menopause on the QOL of Iranian postmenopausal women, but has no positive impact on psychosocial or physical symptoms or the overall symptoms. Therefore, this product may help alleviate hot flashes, sweating, and night sweats (vasomotor symptoms) and improve sexual desire, vaginal dryness, and sexual activity of postmenopausal women. Further research with a larger sample size and a longer duration is recommended to assess the effectiveness of GOBLE capsules on physical and psychological symptoms of menopause.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by the Research Ethics Committee of Alborz University of Medical Sciences, Karaj, Iran (Code: IR.ABZUMS.REC.1400.026) and was registered by the Iranian Registry of Clinical Trials (IRCT), Tehran, Iran (Code: IRCT20180110038302N7). Written informed consent was obtained from all the participants.

Funding

This study was funded by the Alborz University of Medical Sciences, Karaj, Iran.

Authors' contributions

Conceptualization and study design: Fateme Zokaei and Mansoureh Yazdkhasti; Preparation of GOBLE capsules and experiments: Mohammad Kamalinejad; Data analysis and interpretation: Malihe Farid; Sampling and writing the initial draft: Arezoo Pirak; Reagents preparation, resources, review and editnig: Mansoureh Yazdkhasti; Final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

Acknowledgments

The authors would like to thank the participants and the staff of Kamali Hospital in Alborz Province, Iran.

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