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# Evaluating the safety and efficacy of wormwood vaginal cream on sexual satisfaction and quality of sexual life of postmenopausal women: a randomized, triple-blinds, placebo-controlled clinical trial

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## Abstract

**Background** The physical and mental changes created during menopause cause sexual dysfunction, which affects the quality of life, self-esteem, and emotional relationships. Wormwood cream contains tannins, terpenoids, flavonoids, phytosterols, and alkaloids. The purpose of this study is to evaluate the safety and effectiveness of wormwood vaginal cream on the sexual satisfaction and quality of sexual life of postmenopausal women.

**Method** This study was a randomized, triple-blind, placebo-controlled clinical trial conducted on 112 postmenopausal women (45–65 years old) in 2021. The studied women were randomly assigned to two wormwood cream or placebo groups. Wormwood cream or placebo was used for 4 weeks and 3 times a week. The main data collection tools included the Larson Sexual Satisfaction Questionnaire (LSSQ) and the Sexual Quality of Life Questionnaire (SQOL-F). SPSS software version 26 and independent t, Mann–Whitney, paired t and Wilcoxon tests were used for statistical analysis.  $P < 0.05$  was considered significant.

**Results** Before the intervention, the mean and standard deviation of sexual satisfaction was  $73.57 \pm 3.84$  in the intervention group and  $73.16 \pm 4.52$  in the placebo group. After the intervention, the mean and standard deviation of sexual satisfaction in the intervention group was  $75.34 \pm 3.85$  and in the placebo group was  $72.82 \pm 4.32$ . The quality of women's sexual life before of the intervention in the intervention and placebo groups was  $59.16 \pm 14.10$  and  $57.18 \pm 12.38$ , and after the intervention, it was  $83.00 \pm 11.51$  and  $69.64 \pm 12.97$ , respectively. At the end of 4 weeks, participants in the wormwood cream group showed a significant improvement in sexual satisfaction and the quality of women's sexual life ( $P < 0.001$ ). It was meaningful.

**Conclusion** Based on the findings of this trial, wormwood vaginal cream can be used as an uncomplicated topical supplement to improve sexual satisfaction and quality of sexual life in postmenopausal women with low sexual satisfaction and quality of sexual life.

**Keywords** Wormwood, Sexual satisfaction, Quality of sexual life, Postmenopausal

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## Introduction

According to the World Health Organization (WHO), menopause is defined as the permanent cessation of menstruation due to the loss of ovarian follicular activity [1]. Menopause represents a psychosocial transition in a woman's life, marking the shift from fertility to infertility [2]. This stage is often accompanied by both physical and psychological changes that can negatively affect sexual function, potentially leading to sexual disorders and causing significant discomfort in this regard [3]. Between 88 and 43% of women report experiencing at least one sexual issue during their lifetime [4]. By 2030, the global population of postmenopausal women is expected to reach 1.2 billion [2]. In the United States, the prevalence of sexual problems increases with age, affecting 44.6% of women between the ages of 45 and 64 [5]. Among Iranian postmenopausal women, the prevalence of sexual dissatisfaction has been reported to be 40% in Shiraz and 36.9% in Amol [6, 7]. Sexuality plays a central role in initiating and maintaining relationships, and sexual satisfaction is fundamental to overall relationship satisfaction [8]. Sexual dysfunction affects self-esteem, mood, and quality of life, leading to the loss of interpersonal relationships and emotional stress [9]. Psychological factors such as anxiety and depression, which are commonly experienced during the climacteric period, negatively affect the sexual lives of postmenopausal women [10]. Age, relationship status, and overall health status are strongly associated with their influence on sexual activity [11]. Sexual satisfaction is consistently associated with relationship satisfaction, happiness, and quality of life [12]. Lawrence and Byers define sexual satisfaction as "an emotional response resulting from an individual's subjective evaluation of the positive and negative aspects related to their sexual relationship" [8].

There is a relationship between the quality of sexual life and overall life satisfaction, suggesting that the sexual quality of life for Bayin reflects their general life quality [13]. Given that women now spend a third or more of their lives post-menopause, attention must be given to addressing health and sexual problems and finding solutions for sexual dysfunction in women [10]. The decline in ovarian hormone function leads to significant changes in both the internal and external genitalia, the body as a whole, and mental health, with these hormonal changes contributing to menstrual disorders and vaginal bleeding, which may affect sexual response [2, 14]. Additionally, pelvic organ prolapse can impact sexual life, with significant concerns including vaginal appearance, embarrassment, partner satisfaction, reduced genital sensation, and fear of worsening the prolapse [15]. Hormone replacement therapy (HRT) is widely recommended to treat acute menopausal symptoms, including hot flashes,

vaginal dryness, night sweats, and mood swings [2]. However, due to the increased risk of breast cancer associated with HRT, many women seek alternative, non-pharmacological approaches, such as diet, exercise, and herbal products, to manage menopause [1]. Medicinal plants have been used for health care since ancient times. [16] and in recent years, their use has significantly increased in developing countries [17]. Wormwood possesses analgesic, anti-inflammatory, astringent, warming, and healing properties for treating irreparable injuries and wounds [18–21]. It contains various compounds, including carbohydrates, alkaloids, saponins, phytosterols, proteins, amino acids, tannins, phenolic compounds, and flavonoids. Phytosterols and increased nitric oxide levels enhance blood flow to the genital area, promoting more pleasurable orgasms [22]. Additionally, the flavonoids in wormwood exhibit antioxidant, antimicrobial, anti-inflammatory, and vasodilatory effects [23]. The antioxidant effects of wormwood help rejuvenate cells and restore vaginal elastin strength [24]. In a study by Kauser et al. (2023), wormwood extract was administered to rats at 50, 300, and 2000 mg/kg doses. The 50 mg/kg dose showed no side effects, while the 300 mg/kg dose exhibited mild toxicity [25]. Given the multiple benefits of wormwood extract—distinguishing it from other treatments—its lack of known side effects, its local availability in Khorasan, its affordability, and the limited research in this field, the researcher decided to conduct a study to evaluate the safety and effectiveness of wormwood vaginal cream on sexual satisfaction and the quality of sexual life in postmenopausal women.

## Methods

This study was approved by the ethics committee of Mashhad University (IR.MUMS.NURSE.REC.1400.077) and registered in the Iranian clinical trial system (IRCT20210223050471N2) on January 13, 2022.

## Trial design

This two-group, triple-blind clinical trial (intervention vs. placebo) was conducted in 2021–2022 with 112 postmenopausal women experiencing low sexual satisfaction and poor quality of sexual life. The participants were recruited from the women's clinic at Imam Reza Hospital in Mashhad. Participants were randomly assigned to either the intervention group, which received wormwood vaginal cream, or the placebo group, with a 1:1 ratio. Informed consent was obtained from all participants before the study commenced.

Participants were instructed to apply the vaginal cream three times per week before bedtime and half an hour before intercourse for four weeks. The placebo group received a cream identical in appearance, concentration,

and packaging but without the wormwood extract. This study adhered to the Helsinki protocol and followed CONSORT guidelines.

Random allocation was achieved using randomization software and permutation blocks of size two. A set of sealed, numbered envelopes containing the random sequence was prepared. Upon enrollment, each participant was assigned to a group by opening an envelope sequentially, revealing the assigned treatment (Gel A or Gel B). The creams were labeled by the pharmacist consultant, who was the only person aware of the contents of the creams, ensuring the trial's triple-blind nature. Neither the researcher nor the statistical analyst knew which cream was given to the participants.

Participants received both oral instructions and an educational pamphlet on using the cream. The pamphlet also provided the researcher's contact information for reporting side effects and asking questions. Additionally, participants were provided with a checklist to monitor usage and any side effects of the cream. Weekly telephone follow-ups were conducted to confirm adherence to the treatment, assess for side effects, ensure proper usage, and monitor for exclusion criteria throughout the trial.

### Participants

The inclusion criteria for this study required participants to be married women aged 45–65, with a follicle-stimulating hormone (FSH) level above 40, and to have been postmenopausal for at least one year, with a history of sexual activity at least twice during the intervention month. Participants were excluded if they were undergoing HRT, had liver, kidney, heart, thromboembolic, or mental health conditions, had a history of chemotherapy or radiotherapy to the pelvis or whole body, or were smokers, alcohol or drug users. Additional exclusion criteria included a depression score of 21 or higher, an anxiety score of 15 or higher, and a stress score of 26 or higher, as measured by the DASS-21 questionnaire. Furthermore, participants with a score below 75 on the Larson Sexual Satisfaction Questionnaire, those consuming phytoestrogens such as soy, flax seeds, clover sprouts, or alfalfa, and those with unexplained vaginal infections or bleeding were also excluded from the study.

### Assessment

The Larson Sexual Satisfaction Questionnaire, introduced by Larson et al. in 1998 [26] was used to assess sexual satisfaction. This questionnaire consists of 25 questions, using a 5-point Likert scale, with 13 negatively and 12 positively worded items. Scores range from 25 to 125, where a score below 50 indicates no sexual satisfaction, and scores between 51 and 75 indicate low sexual satisfaction. The reliability of the Larson Sexual

Satisfaction Questionnaire was established by Bahrami et al. (2012), with a Cronbach's alpha of 0.803 for positive questions, 0.778 for negative questions, and an overall internal correlation index of 0.801, confirming its reliability. The original version demonstrated an alpha coefficient of 0.91, and its test–retest reliability after one week was 0.93 [27]. In this study, the reliability of the Larson questionnaire was confirmed using Cronbach's alpha coefficient, yielding a value of 0.85.

The Female Sexual Quality of Life Questionnaire (SQOL-F) was also utilized, consisting of 18 questions scored on a Likert scale of 1 to 4, with four subscales: psychological-sexual feelings, interpersonal and sexual relations, self-worth, and sexual suppression. Total scores range from 18 to 108, with higher scores reflecting a higher quality of sexual life. The validity of the SQOL-F was established by Simmonds et al. (2005) [28] using criterion and construct validity methods, confirmed through known-group techniques, comparing groups with and without depression. In Iran, Pakpour's study confirmed the reliability of the questionnaire, with a Cronbach's alpha ranging from 0.84 to 0.98 [29]. In the present study, the reliability of the SQOL-F was determined using Cronbach's alpha coefficient, with a value of 0.79.

### The outcomes under consideration

After evaluating the participants based on the inclusion criteria, each participant who qualified for the study was asked to complete an informed consent form. Following this, participants filled out a demographic information questionnaire, the Larson Sexual Satisfaction Questionnaire, and the Female Sexual Quality of Life Questionnaire (SQOL-F) through a self-report method. Upon completion of the intervention, participants were again asked to complete the same questionnaires (Larson Sexual Satisfaction and SQOL-F) to assess changes in sexual satisfaction and sexual quality of life post-intervention.

### Statistical analysis

The sample size was calculated based on the study by Malakuti et al. [30] with a 5% error margin and an 80% test power. Using the average formula for two independent populations, the minimum sample size for each group was 51 participants. The final sample size was increased to 56 participants per group to account for potential attrition.

The research results are presented as mean  $\pm$  standard deviation (SD). For intragroup analysis, paired t-tests and Wilcoxon tests were employed to compare the stages before and after the intervention. A significance level of 5% was set for all statistical analyses. Data analysis

followed APA guidelines using IBM SPSS Statistics (Version 27).

## Results

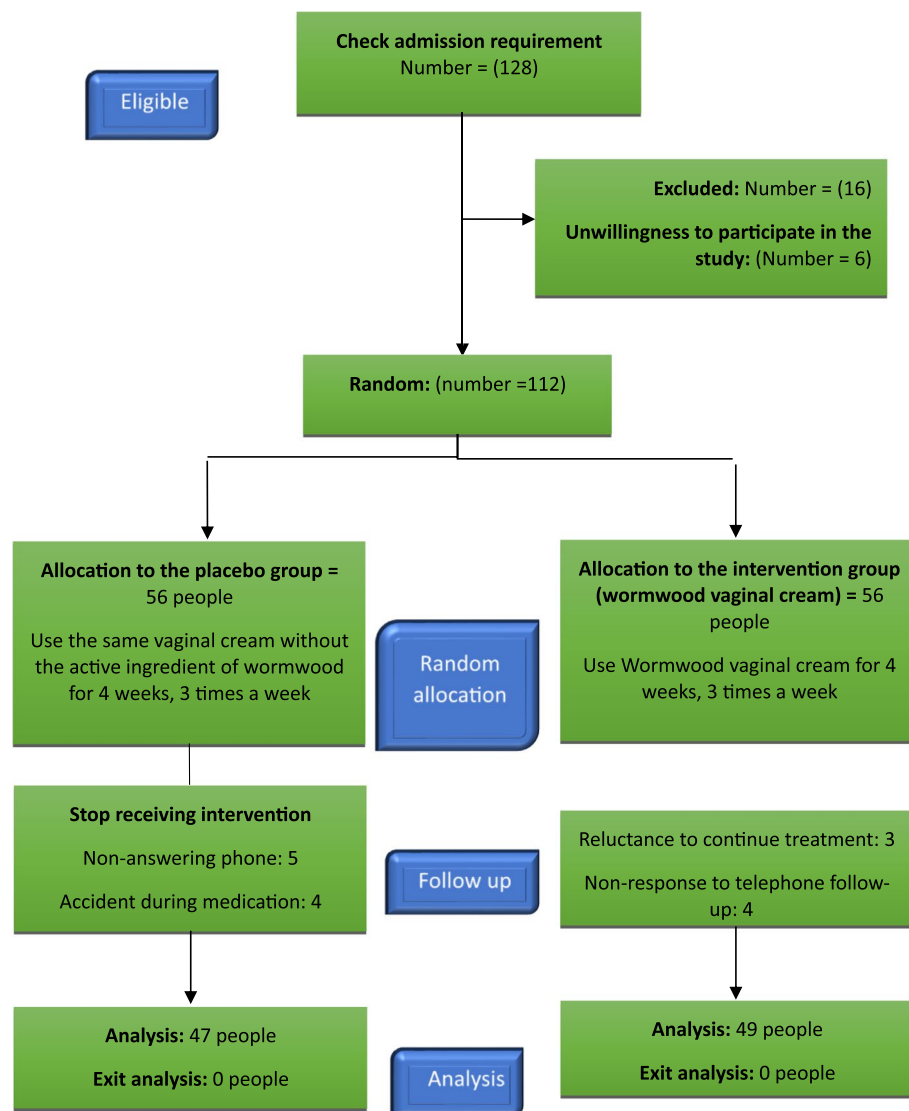
A total of 112 participants were initially included in the study, with 56 individuals in each group. However, during the study, 5 participants from the placebo group were excluded due to not responding to phone calls, and 4 others due to an unfortunate accident. In the intervention group receiving the wormwood cream, 4 participants were excluded for not answering phone calls, and 3 withdrew due to unwillingness to continue using the cream. Ultimately, 47 participants from the placebo group and

49 from the intervention group completed the study (see Fig. 1).

The average age of the women in the intervention and placebo groups was  $53.16 \pm 5.24$  and  $54.71 \pm 4.35$  years, respectively. Regarding literacy, 55.9% of the participants in the intervention group and 69.6% in the placebo group had minimal reading and writing skills (Table 1).

## Sexual satisfaction

The sexual satisfaction scores measured by the Larson questionnaire were  $73.57 \pm 3.84$  in the intervention group and  $73.16 \pm 4.52$  in the placebo group before the intervention. Four weeks after the completion of the wormwood cream treatment, the scores were



**Fig. 1** CONSORT flow of women participating in the study

**Table 1** Characteristics of the participants according to group (n = 112)

Variable	Group		Test result
	Placebo	Intervention	
	Mean ± Deviation Standard/ Percentage Number	Number	
Age (years)	54.71 ± 4.35	53.16 ± 5.24	<b>Z = -1.7</b> <b>P = .085</b> Mann–Whitney test
Spouse age (years)	60.71 ± 7.07	57.91 ± 8.00	<b>Z = -2.17</b> <b>P = 0.029</b> Mann–Whitney test
Housing situation			<b>P = 0.00</b> Chi-square
Rent	16 (28.6)	16 (28.6)	
Private	40 (71.4)	40 (71.4)	
Income			<b>P = 0.467</b> Chi-square
Less than sufficient	38 (67.9)	44 (78.6)	
Enough	17 (30.4)	11 (19.6)	
More than enough	1 (1.8)	1 (1.8)	
Occupation			<b>P = 0.430</b> Chi-square
Employed	7 (12.5)	10 (17.9)	
Homemaker	49 (87.5)	46 (82.1)	
Spouse occupation			<b>P = 0.160</b> Chi-square
Worker	21 (37.5)	23 (41.1)	
Jobholder	0 (0.0)	3 (5.4)	
Freelance Job	14 (25.0)	9 (16.1)	
Retired	9 (16.1)	14 (25.0)	
Unemployed	12 (21.4)	7 (12.5)	
Body Mass Index (kg / m <sup>2</sup> )	28.00 ± 23.78	26.06 ± 3.96	<b>Z = -2.3</b> <b>P = 0.18</b> Mann–Whitney test
Duration of marriage (years)	3.78 ± 5.97	35.38 ± 7.46	<b>Z = -1.40</b> <b>P = 0.160</b> Mann–Whitney test
The length of time since menopause	79.89 ± 87.85	75.59 ± 62.80	<b>Z = -.694</b> <b>P = 0.487</b> Mann–Whitney test
Education			<b>X<sup>2</sup> = 0.98</b> <b>P = 0.82</b> Chi-square
Minimum literacy	39 (69.6)	31 (55.4)	
Under diploma	9 (16.1)	15 (26.8)	
Diploma	5 (8.9)	3 (5.4)	
College education	3 (5.4)	7 (12.5)	
Type of delivery			<b>p = 0.481</b> Chi-square
Natural	55 (94.6)	48 (90.6)	
Cesarean section	3 (5.4)	5 (9.4)	
Number of children	5.04 ± 1.77	4.81 ± 1.85	<b>Z = -0.77</b> <b>P = 0.44</b> Mann–Whitney test

75.34 ± 3.85 in the intervention group and 72.82 ± 4.32 in the placebo group. The Mann–Whitney test revealed that this difference was statistically significant ( $P < 0.001$ ) (Table 2, Fig. 2).

### Sexual quality of life

The quality of sexual life, measured by the SQOL-F questionnaire, was 59.16 ± 14.10 in the intervention group and 57.18 ± 12.38 in the placebo group before

**Table 2** Results wormwood vaginal cream on the level of sexual satisfaction in the two study groups ( $n = 112$ )

	Placebo	Intervention	Inter-Group Comparison
Before Intervention	73.16 ± 4.52	73.57 ± 3.84	$z = 1.165$ $p = 0.244$ Mann–Whitney U
After Intervention	72.82 ± 4.32	75.34 ± 3.85	$t = 3.253$ $p = 0.002$ t test
Difference	-0.34 ± 3.06	1.77 ± 2.54	$z = 4.006$ $P < 0.001$ Mann–Whitney U
Intra-Group Comparison	$z = 0.907$ $p = 0.365$ Wilcoxon Signed Ranks Test	$z = 4.320$ $p < 0.001$ Wilcoxon Signed Ranks Test	-

the intervention. After the intervention, the scores were  $83.00 \pm 11.51$  in the intervention group and  $64.69 \pm 12.97$  in the placebo group. A t-test demonstrated that this difference was statistically significant ( $P < 0.001$ ) (Table 3, Fig. 3).

### Safety of treatment

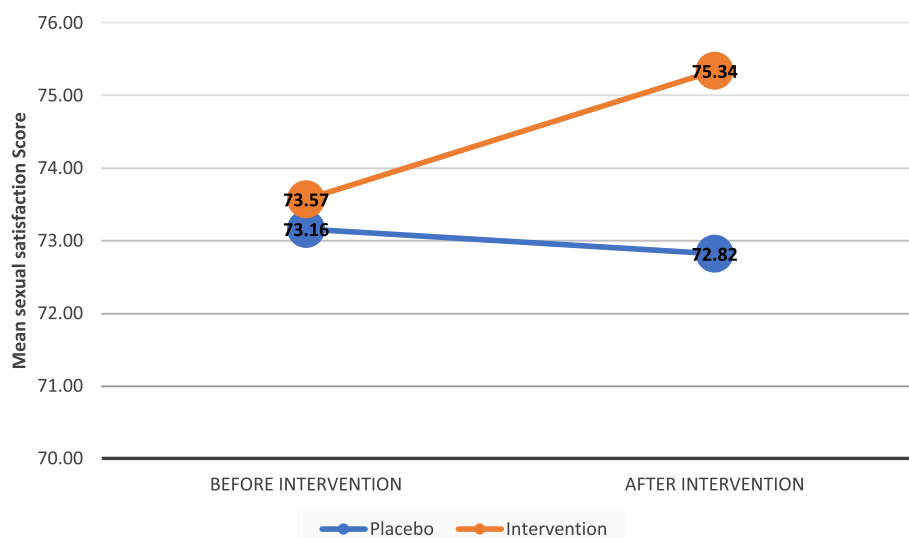
Participants in the intervention group reported no adverse effects such as burning, severe itching, or redness using the wormwood cream.

### Discussion

The present study demonstrated that four weeks of treatment with wormwood vaginal cream significantly improved both sexual satisfaction and the quality of sexual life among postmenopausal women. These findings support the use of wormwood as an effective treatment for sexual dysfunction in this population.

The results are consistent with previous studies that have explored the use of various treatments to improve sexual satisfaction in women. For example, a 2019 study showed that the use of pomegranate skin vaginal gel increased sexual satisfaction by enhancing orgasm quality [31]. Similarly, Eftikhar (2009) found that vaginal estrogen improved sexual satisfaction in postmenopausal women [32] while Mazalzadeh (2018) demonstrated that fenugreek vaginal cream, due to its phytoestrogen content, increased sexual satisfaction in this group [33]. Other studies, such as Malkuti (2017), reported that aromatherapy and ginkgo biloba tablets improved both sexual performance and satisfaction in postmenopausal women [30]. and Haiderpour (2023) found that the scent of sage had similar benefits [34]. These studies align with the findings of the current research.

However, some studies have yielded results that differ from the present findings. For instance, Yusufzadeh (2017) found that date pollen capsules had no significant effect on sexual satisfaction or orgasm in menopausal women [35]. The discrepancies may be attributed to factors influencing sexual satisfaction, such as fear, anxiety, environmental attitudes toward sexual relations, and individual roles within relationships. Similarly, Amiri (2014) found that ginkgo biloba capsules did not significantly improve sexual satisfaction [36] which could be



**Fig. 2** Intra-group and inter-group evaluation of wormwood vaginal cream on the level of sexual satisfaction



**Table 3** Results wormwood vaginal cream on the level of quality of sexual life in the two study groups ( $n = 112$ )

	Placebo	Intervention	Inter-Group Comparison
Before Intervention	57.18 ± 12.38	59.16 ± 14.1	$z = 0.553$ $p = 0.580$ Mann–Whitney U
After Intervention	69.64 ± 12.97	83.00 ± 11.51	$z = 5.477$ $p < 0.001$ Mann–Whitney U
Difference	12.46 ± 9.58	23.84 ± 11.48	$t = 5.692$ $p < 0.001$ $t$ test
Intra-Group Comparison	$t = 9.734$ $p < 0.001$ Paired $t$ Test	$t = 15.539$ $p < 0.001$ Paired $t$ Test	

due to the use of a different sexual performance measurement scale, such as the Saba Tesberg scale, rather than the tools used in this study.

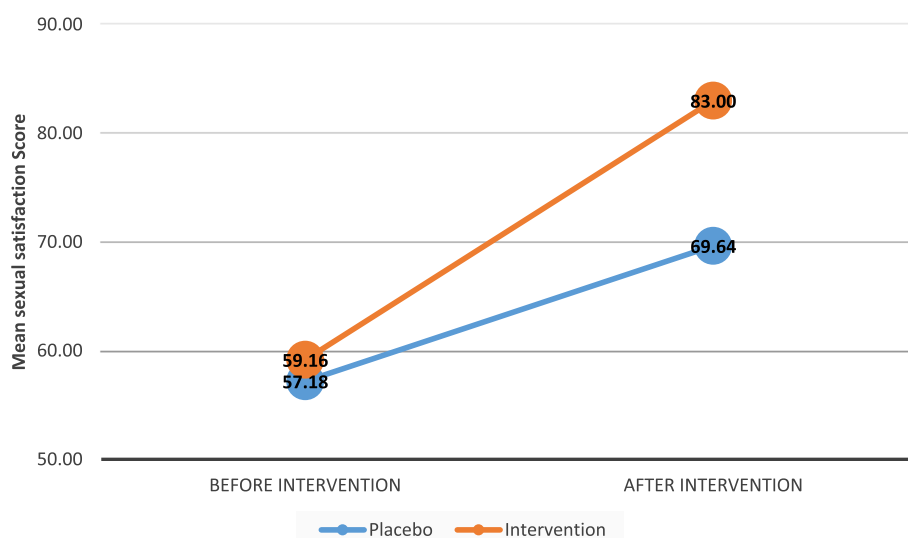
In Kim's 2009 study, ginseng improved women's quality of life, but the results were not significantly different from those of the placebo group [37]. Differences in the target populations may explain the inconsistency between these findings and the current study, as Kim's analysis focused on women aged 30–45, whereas the present study concentrated on postmenopausal women. The chemical differences between wormwood and ginseng may have contributed to the differing results.

Given the high prevalence of vaginal atrophy, dyspareunia, sexual dissatisfaction, and low treatment motivation in postmenopausal women, these individuals are at increased risk of poor sexual quality and

depression [38]. The results suggest that wormwood vaginal cream directly improves vaginal symptoms associated with menopause and sexual satisfaction and indirectly enhances the overall quality of sexual life in postmenopausal women. Sidi's (2016) study supports these findings, showing that Royal Gel Cream improved vaginal atrophy, urinary and reproductive issues, and overall quality of life in women [39]. However, in Mousavi's 2023 study, while Shilajet tablets improved sexual performance in reproductive-age women, they did not affect sexual life quality [40].

The results of specific studies are not consistent with the findings of our research, likely due to differences in target groups. It is important to note that sexual satisfaction and the quality of sexual life, particularly in menopausal women, are subjective concepts influenced by various confounding factors. These factors include psychological aspects, religious and cultural values, beliefs, lifestyle, and spousal-related variables such as sexual disorders in the spouse or a lack of knowledge about sexual health and menopause [41]. Additionally, economic and social factors [42], can also play a significant role, potentially affecting the outcomes of studies on sexual satisfaction.

Our study aimed to expand the understanding of treatment options for sexual satisfaction disorders in postmenopausal women by using an herbal remedy derived from wormwood. This research may open new therapeutic avenues for addressing sexual dysfunction in this population. One of the key strengths of our study is the triple-blind design, which ensures objective results. Furthermore, this study is the first to produce clinical evidence for the efficacy and safety of



**Fig. 3** Intra-group and inter-group evaluation of wormwood vaginal cream on the level of quality of sexual life

wormwood in improving both sexual satisfaction and the overall quality of sexual life in postmenopausal women.

However, the study is not without limitations. The relatively small sample size and reliance on self-reported data from menopausal women may introduce bias or affect the generalizability of the results. As such, further research involving larger sample sizes is recommended to confirm these findings and provide more robust evidence.

## Conclusion

Based on the results of this trial, wormwood vaginal cream can be considered a reliable natural and locally sourced supplement to enhance sexual satisfaction and, indirectly, improve the quality of sexual life in postmenopausal women. Its safety profile and effectiveness make it a promising option for addressing sexual dysfunction during menopause, providing a valuable alternative to conventional treatments. Further research is encouraged to validate these findings and explore their long-term benefits.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12905-024-03515-z>.

Supplementary Material 1.

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This article is extracted from an MSc thesis approved by the School of Nursing and Midwifery of Mashhad University of Medical Sciences and registered in the Iranian Registry of Clinical Trials (IRCT20210223050471N2). The authors would appreciate Mashhad University of Medical Sciences that supported the present study financially. We would like to thank all women who participated in this study.

## Authors' contributions

H. N.: Conception and design of the study, Provision of study material or patients, possession of raw data (doing experiments). B. R.: Conception and design of the study, Critical revision, Critical revision of the article for important intellectual content, Obtaining funding for the study, Guarantor of integrity of the entire study. S. R.: Provision of study material or patients J. J.: Analysis and interpretation of data, Statistical expertise, Statistical expertise. I.S.H.: Collection(data gathering) All authors reviewed the manuscript and approved.

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## Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

## Declarations

### Ethics approval and consent to participate

This study was approved by the Ethics Committee of Mashhad University of Medical Sciences (IR.MUMS.NURSE.REC.1400.077).

## Competing interests

The authors declare no competing interests.

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