



THE EFFICACY OF SALVIA OFFICINALIS IN ON PROMOTION OF SEXUAL FUNCTION IN POSTMENOPAUSAL WOMEN: A DOUBLE-BLIND RANDOMIZED CONTROLLED CLINICAL TRIAL

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Menopause is a stage in women's life usually associated with sexual dysfunction. Estrogen plays a significant role in women's sexual well-being. This study aimed to evaluate the effect of Salvia Officinalis extract on the sexual function of postmenopausal women. This was a double-blind randomized clinical trial on 66 eligible postmenopausal women referring to the Bone Density Measurement Center of Namazi Hospital in Shiraz, Iran in 2015. Subjects in the intervention and control groups daily received three tablets of Salvia Officinalis extract and a placebo, respectively. A sexual function questionnaire with domains of sexual arousal, lubrication, orgasm, and sexual satisfaction was completed for them at the baseline and 3 months after the intervention. Data were analyzed with SPSS-21 software using paired t-test at a significance level of 0.05. The mean score of sexual function, sexual desire, orgasm, sexual satisfaction, and pain relief in the Salvia Officinalis group increased after the intervention by 4.6, 1.1, 0.9, 1.1, and 0.5 units, respectively, which were significantly different from those of the control group. However, the mean score of sexual arousal did not show a statistically significant difference ($P= 0.082$). Due to the positive effect of Salvia Officinalis on sexual performance scores, it is recommended to be used as a supplement during menopause. Although no significant side effects were observed, further studies are recommended.

Keywords: Salvia Officinalis, Non-pharmacological, Sexual Function, Postmenopausal

INTRODUCTION

Menopause is a common and natural physiological phenomenon that has become more important in recent years due to the global population aging and the increasing number of postmenopausal women¹. This stage of women's life is associated with significant physical and hormonal changes such as vasomotor changes or hot flashes, mood disorders such as anxiety and depression, as well as sexual dysfunction as a result of decreased sexual satisfaction².

Studies have shown that depression and anxiety were the strongest predictors of female sexual dysfunction. Stress, anxiety, and depression affect marital life and relationships between people. They can also affect people's sexual function³. Therefore, sexual relationships, as part of marital relationships, have been studied extensively. These relationships have several extensively studied aspects that pave the way for further research to strengthen the family bonds⁴. Hellmiss believes that knowledge of the natural sexual function and its disorders have a large impact on the

quality of life. Natural sexual response is divided into 4 stages of (i) desire, (ii) arousal, (iii) orgasm, and (iv) resolution. Sexual dysfunction may occur at any of these stages⁵. The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) classifies sexual dysfunction as one of the Axis I disorders. Sexual dysfunctions listed in DSM-5 are related to the above-mentioned four stages of sexual response. Sexual dysfunction is the inhibition of one or more of those stages⁶. Sexual dysfunction includes a group of heterogeneous disorders and is generally a significant clinical disorder characterized by an inability to have a sexual response or experience sexual pleasure⁷. Studies suggest that sexual dysfunction is around 55% in the age of 40-45 years and increases to 82% in the age of 52-55 years⁸. The prevalence of the disorder among women during pre-menopause varies from 20.6% to 28.2%⁹. As the average age of menopause is 50 years, desire and arousal disorders are the main sexual dysfunctions in postmenopausal women compared to premenopausal women. These disorders are due to several genetic, biological, emotional, hormonal, and social factors. Sexual problems increase with age, decreased estrogen levels, and natural menopause, and they have significant negative impacts on sexual relationships, especially sexual desire, arousal, orgasm, and activity¹⁰. Menopause seems to be the time when the vulnerability to depression increases and may impair sexual function³. Meanwhile, estrogen plays a significant role in women's sexual well-being, so that a deficiency of this hormone leads to thinning, drying and loss of elasticity and flexibility of the vaginal epithelium, known as the main cause of atrophy of the vulva and vagina, which subsequently affects the sexual function of postmenopausal women¹¹. Among the therapeutic solutions for these people is the use of topical and oral estrogens in cases with severe and moderate symptoms, which in turn increase the risk of breast and uterine cancer and significant thromboembolic and cardiovascular complications¹². Due to the complications of chemical estrogens, a new generation of plant estrogens called phytoestrogens have received more attention because of their lower side effects. Phytoestrogens are a large family of molecules derived from plants that have varying degrees of estrogen-like activities and can bind to

estrogen alpha and beta receptors and act as both estrogen agonists and antagonists¹³. Among the plants that have this effective substance and help postmenopausal women is *Salvia officinalis*, from the Lamiaceae family, a phytoestrogen used as a medicinal plant in Iranian traditional medicine. It is native to Mediterranean Europe and is cultivated in East Azerbaijan and the gardens of some other regions in Iran. Recent research on some of the properties of *Salvia officinalis*, including antibiotics, antispasmodic, anti-anxiety, anti-fungal, anti-toxic, hypoglycemic, estrogenic, and menopause pain reduction properties has emphasized that it has the mechanism of binding to the complex GABA benzodiazepines in the brain and participates in the treatment of hot flashes and sweating due to its estrogenic effects. It is also effective in improving memory and relaxation due to its positive effect on the nervous system^{14&15}. The WHO has also identified complementary medicine as a method of preventing diseases that may improve the symptoms of menopause and enhance a long-term sense of well-being in postmenopausal women¹⁶. Considering that treating the menopausal symptoms is important; *Salvia officinalis* has phytoestrogenic properties; there are no studies in Iran on this plant; and previous research has usually examined the prevalence and types of sexual dysfunction and rarely various treatment aspects such as education, counseling and medication; the present study was conducted to determine the effect of *Salvia officinalis* on sexual function of postmenopausal women to help improve their quality of life and introduce this herbal medicine as a suitable and safe method to control menopausal symptoms if the treatment was effective.

MATERIALS AND METHODS

This double-blind randomized clinical trial (RCT) (IRCT: IRCT2015111713940N2) was performed on 60 eligible postmenopausal women who have referred to the Bone Density Assessment Center of Shiraz Namazi Hospital in 2015. Since there was no similar study comparing the above drugs in the community of postmenopausal women, based on the consultation with a statistician, we examined all eligible women who have referred to the desired center in Namazi Hospital for bone density measurement during 3 months for

inclusion in the study by the census method. According to the statistics of the center that the researcher has received from this center, it was predicted that at least 66 people will enter the study in these 3 months, who were divided into two groups of 33 people. The inclusion criteria were postmenopausal women, women who were willing to cooperate, not taking any hormonal drugs, and lack of sensitivity to herbal medicines. The exclusion criteria were allergic reaction to the drug, and unwillingness to continue cooperation. During the study, 2 participants in the interventional group and 5 in the placebo group were excluded from the study due to incomplete use of the pills, and finally, 59 subjects completed the study. Overall, 66 individuals were selected through the purposive sampling technique and were divided into two groups using the block permutation method. The questionnaires (demographic information and sexual function) were completed after obtaining informed consent from postmenopausal women.

Research tools

Personal Information Questionnaire

The questionnaire consisted of 11 questions that were used to assess and obtain information such as age, duration of menopause, body mass index, number of deliveries, number of pregnancies, number of children, number of abortions, level of education, occupational status, residential status, and marital status.

Female Sexual Function Index (FSFI) (FSFI): A questionnaire on female sexual function included 19 items assessing women's sexual function in six domains of sexual desire, psychological stimulation, lubrication, orgasm, satisfaction, and sexual pain. Women answer questions based on their sexual performance and feelings over the past 4 weeks.

Items are score from 0 to 5 and a score ≤ 28 is considered sexual dysfunction^{17&18}. This scale is standardized in Iran by Mohammadi Kh.*, Heydari Masoumeh, & Faghihzadeh S. and they reported that Cronbach's alpha coefficient was 70% for the entire scale and 80% for the subscales¹⁹. In another study, Sepehrian reported Cronbach's alpha of 0.95 for the total score of female sexual function²⁰ which was considered as the basis of the present study.

Intervention

Salvia officinalis extract pills and placebo pills were given to women in the intervention and control groups to take three every day for 3 months. Then, women were contacted and again sexual function questionnaires in the areas of sexual arousal, lubrication, orgasm, and sexual satisfaction were completed by women after the intervention. The intervention group received *S. officinalis* tablets (containing 100 mg *S. officinalis* extract produced by Gol Daroo company in Isfahan), which were prescribed three tablets a day for three months, while the control group received placebo tablets (containing 100 mg starch produced by the Shiraz Pharmacy University of Medical Science). Placebo and *Salvia officinalis* tablets were similar in size and shape but very little in color. Therefore, the tablets were placed in black envelopes with the help of the researcher and were coded. The researcher did not know the code number until the end of the sampling and the patients did not see each other.

Statistical analysis

Codes were assigned to the groups and statistical analysis was performed by a statistical consultant blind to the types of groups. In the end, the codes were determined by a specialized drug consultant. Assuming that the data are normal, paired t-test was used for in-group comparison (before and after in each group). An independent t-test was used to for intra-group comparison in SPSS-21 software.

Ethical Consideration

The study is approved by the ethics committee of Shiraz University of Medical Sciences (IR.SUMS.REC.1394.185).

RESULTS AND DISCUSSION

Results

In this study, 60 postmenopausal women were divided into two groups of *Salvia Officinalis* and a placebo. The paired t-test showed that the mean score of sexual function increased by 4.6 units in the *Salvia Officinalis* group after the intervention, which was statistically significantly different from the baseline ($P < 0.05$). The mean score of sexual function in the control group before and after the intervention was the same and there was no statistically significant difference ($P = 0.234$).

(Table 1). The paired t-test showed that the mean score of sexual desire increased by 1.1 units in the *Salvia Officinalis* group after the intervention, which was not statistically significantly different from the baseline ($P > 0.05$). The mean score of sexual desire was statistically significantly different between the intervention and control groups after the intervention ($P = 0.047$) (Table 2).

The mean score of sexual arousal increased by 1.1 units in the *Salvia Officinalis* group after the intervention, which was statistically significantly different from the baseline ($P < 0.05$). However, the mean score of sexual arousal after the intervention, although higher in the *Salvia Officinalis*, was not statistically significantly different from the control group ($P = 0.082$) (Table 3).

The t-test showed that the mean score of lubrication was similar before and after the intervention in the *Salvia Officinalis* and control groups ($P > 0.05$) (Table 3). The mean score of orgasms increased by 0.9 units in the

Salvia Officinalis group after the intervention, which was statistically significantly different from the baseline ($P < 0.05$). The mean score of orgasm was statistically significantly different between the intervention and control groups after the intervention ($P = 0.013$) (Table 3).

The mean score of sexual satisfaction increased by 1.1 units in the *Salvia Officinalis* group after the intervention, which was statistically significantly different from the baseline ($P < 0.05$). The mean score of sexual desire was statistically significantly different between the intervention and control groups after the intervention ($P = 0.01$) (Table 3). The mean score of pain relief increased by 0.5 units in the *Salvia Officinalis* group after the intervention, which was statistically significantly different from the baseline ($P < 0.05$). However, the score of pain relief was not statistically significantly different between the intervention and control groups after the intervention ($P = 0.055$) (Table 3).

Table 1: Comparison of sexual function score before and after intervention in the intervention and control groups.

Sexual Function	Sage Group, mean \pm SD	Control Group, mean \pm SD	P-Value*
Before Intervention	21.5 \pm 8	21.5 \pm 10.7	0.645
After Intervention	26.1 \pm 7.4	21.5 \pm 10.7	0.1
Variables	4.6 \pm 2.7	0.2 \pm 0.05	< 0.001
P-Value**	< 0.001	0.234	

*independent t-test ** paired sample t-test.

Table 2: Comparison of mean sexual function score (field of sexual desire) before and after intervention in the intervention and control groups.

Sexual Desire	Sage Group, mean \pm SD	Control Group, mean \pm SD	P-Value*
Before Intervention	3 \pm 1.6	3.3 \pm 1.8	0.56
After Intervention	4.1 \pm 1.4	3.3 \pm 1.8	0.047
P-Value**	< 0.001	1	

* independent t-test ** paired sample t-test.

Table 3: Comparison of the mean score of sexual function in the field of sexual arousal, lubrication, orgasm and sexual satisfaction before and after the intervention in the intervention and control groups.

Field of Sexual function		Sage Group, mean \pm SD	Control Group, mean \pm SD	P-Value*
Sexual Arousal	Before intervention	3 \pm 1.7	3.3 \pm 1.9	0.533
	After intervention	4.2 \pm 1.4	3.3 \pm 1.9	0.082
	Variable	1.1 \pm 0.8	0	<0.001
	p-value**	< 0.001	1	
Lubrication	Before intervention	3.5 \pm 1.7	3.3 \pm 2.2	0.655
	After intervention	3.7 \pm 1.7	3.3 \pm 2.1	0.662
	Variable	0.4 \pm 0.2	0.02 \pm 0.1	0.165
	p-value**	0.033	0.425	
Orgasm	Before intervention	3.7 \pm 1.4	3.5 \pm 1.9	0.784
	After intervention	4.6 \pm 1.1	3.6 \pm 1.9	0.013
	Variable	0.9 \pm 0.7	0.07 \pm 0.01	<0.001
	p-value**	<0.001	0.327	
Sexual Satisfaction	Before intervention	3.7 \pm 1.6	3.6 \pm 1.9	0.518
	After intervention	4.8 \pm 1.3	3.6 \pm 1.9	0.01
	Variable	1.1 \pm 1	0.07 \pm 0.01	<0.001
	p-value**	< 0.001	0.327	
Pain	Before intervention	4.4 \pm 1.8	3.9 \pm 2.2	0.369
	After intervention	4.9 \pm 1.5	3.9 \pm 2.2	0.055
	Variable	0.8 \pm 0.5	0	<0.001
	p-value**	0.002	1	

*independent t-test ** paired sample t-test.

Discussion

This study examined the effect of *Salvia Officinalis* on sexual functions (sexual desire, sexual arousal, orgasm, sexual satisfaction) of postmenopausal women. Similar studies have been conducted on the effect of *Salvia Officinalis* on other menopausal symptoms, but not specifically on sexual function. The present study showed that *Salvia Officinalis* extract improved overall sexual function in women compared to placebo. As sexual dysfunction in postmenopausal women is caused by estrogen reduction, the use of plants such as *Salvia Officinalis* that have a lot of phytoestrogens improves overall sexual function¹¹. It is safe to say that today's medicine owes to the valuable treasure of cultural and spiritual heritage and the unwritten knowledge of traditional medicine. Women's sexual disorder is an umbrella term including several worrying factors related to women's sexual health, in which aging plays a major role by causing hormonal changes. Using herbal medicines such as *Tribulus terrestris*, *Hop*, *Rosa damascena*, *Cannabis*, and *Ginseng* to establish hormonal balance has been studied²¹⁻²⁵. A

similar study by Bommer *et al.*, on the effectiveness and safety of *Salvia Officinalis* extract on hot flashes in postmenopausal women and other climacteric symptoms for 8 weeks concluded that daily consumption of one *Salvia Officinalis* extract tablet significantly reduced and cured the severity and frequency of hot flashes in postmenopausal women. In addition to the above, other criteria mentioned in the tool for measuring menopausal symptoms such as sleep disorders, psychological symptoms and Genitourinary syndrome of menopause (GSM) have also improved. Also, no side effects or laboratory disorders were observed during the study¹⁵. The findings of the present study are consistent with those of Bommer *et al.* Chen *et al.* also emphasized the effect of plants with strong sources of phytoestrogens, especially isoflavones, on improving hot flashes in postmenopausal women²⁵. Besides, in another study Hot flashes can be controlled with *Salvia officinalis*, which has EA. A study investigating an aqueous-ethanolic extract of this plant discovered EA in the ERLUX assay with an EC50 =64mg/ml. As a result of fractionation,

the estrogenic compound in the extract was luteolin-7-O-glucuronide (EC50 = 159 mg/ml). Researchers concluded that the effects of *Salvia officinalis* on hot flashes are caused by the presence of estrogenic flavonoids²⁷.

It is estimated that about 25 percent of all currently prescribed medications in the world are derived from plants that have first been used traditionally²⁸. Ito *et al.*, examined the effect of ArginMax as a nutrition supplement and phytoestrogenic agent to improve women's sexual function in 2001 in the US. In their double-blind randomized clinical trial, 77 women aged 22-71 years participated who suffered from sexual dysfunction. They randomly assigned 34 subjects to the ArginMax group and 43 subjects to the placebo group. After 4 weeks, the ArginMax group reported a significant improvement in satisfaction with sexual life in general (73.5%) compared to the placebo group (37.2%) (P<0.01). The intervention group also reported increased sexual desire (70.6%) compared to the placebo group (41.9%)^{29&30}. An intervention study was conducted by Fereshteh Dadfar and Kourosh Bamdad on 30 women aged 46-58 years in 2019 in Iran to examine the effect of *Salvia Officinalis* on menopausal symptoms. In their study, patients were given 100 mg capsules of *Salvia Officinalis* extract daily for 4 weeks and the severity of menopausal symptoms was assessed before and after the intervention. They highlighted the effect of *Salvia Officinalis* extract on night sweats, hot flashes, fatigue, and increased concentration³¹. With the increasing advancement of pharmaceutical science, the high amount of using medicinal plants in the world shows their undeniable importance. About 85% of traditional treatments depend on medicinal plants and 10-18% of the world's plant species have medicinal use³². Abdnezhad *et al.*,³³ examined the effect of *Salvia officinalis* on the severity of premenstrual syndrome (PMS). After two months of treatment with 500mg *Salvia officinalis* capsules or placebo once a day on 90 college students, They found that *Salvia officinalis* was an effective alternative therapy to reduce the severity of PMS psycho-physical symptoms. Researchers suggest that *Salvia officinalis* contains anti-inflammatory, anti-anxiety, antioxidant, and diterpene compounds, such as rosmarinic and carnosic acids, flavonoids, diterpenes, and phenolic acids. There is a possibility that its phytoestrogenic compounds

could act as a relaxant through neurochemical receptors in the central nervous system (CNS). Other studies have reported on the phytoestrogenic properties of *Salvia officinalis*^{34&35}. A study by De Leo *et al.* on the effect of phytoestrogenic herbal products on menopausal symptoms also used the combined extract of *Salvia Officinalis* leaves and Alfalfa and reported reduced symptoms after three months of continuous use. They concluded that the phytoestrogens in these plants may reduce menopausal symptoms due to their mild antidopaminergic effect on the central nervous system and their effect on neurotransmitters³⁵. Qnais *et al.*, also suggested that *Salvia Officinalis* has analgesic properties due to flavonoids such as quercetin 3,7-O-dimethylether via the Cyclic guanosine monophosphate (cGMP) pathway, which is consistent with the present study³⁶.

Conclusion

Salvia Officinalis extract improves sexual function. It has a positive effect on sexual desire, sexual arousal, orgasm, sexual satisfaction, and pain relief. Since sexual dysfunction increases during menopause, *Salvia Officinalis* extract is recommended to be used as a supplement during menopause. Although no important complications were observed in using *Salvia Officinalis* extract in this study, more accurate studies with a larger sample size are recommended to evaluate its effects and safety.

Conflict of interest

Authors declared no conflict of interest.

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نشرة العلوم الصيدلانية جامعة أسيوط



فعالية سالفيا أوفيسيناليس في تعزيز الوظيفة الجنسية عند النساء بعد سن اليأس: تجربة سريرية عشوائية مزدوجة التعمية

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إيران

انقطاع الطمث هو مرحلة في حياة المرأة ترتبط عادة بالضعف الجنسي. يلعب الإستروجين دورًا مهمًا في الصحة الجنسية للمرأة. هدفت هذه الدراسة إلى تقييم تأثير مستخلص سالفيا أوفيسيناليس على الوظيفة الجنسية للنساء بعد سن اليأس. كانت هذه تجربة سريرية عشوائية مزدوجة التعمية على ٦٦ امرأة مؤهلة بعد سن اليأس تشير إلى مركز قياس كثافة العظام في مستشفى نامازي في شيراز ، إيران في عام ٢٠١٥ . تلقى الأشخاص في مجموعات التدخل والمراقبة يوميًا ثلاثة أقراص من مستخلص سالفيا أوفيسيناليس و ثلاثة أقراص وهمية على التوالي. تم الانتهاء من استبيان الوظيفة الجنسية مع مجالات الإثارة الجنسية والتشحييم والنشوة والرضا الجنسي بالنسبة لهم وبعد ٣ أشهر من التدخل. تم تحليل البيانات باستخدام برنامج SPSS-21 باستخدام اختبار t المقترن عند مستوى أهمية ٠.٠٥. زاد متوسط درجة الوظيفة الجنسية ، والرغبة الجنسية ، والنشوة الجنسية ، والرضا الجنسي ، وتسكين الآلام في مجموعة سالفيا أوفيسيناليس بعد التدخل بمقدار ٤.٦ ، ١.١ ، ٠.٩ ، ١.١ ، و ٠.٥ وحدة على التوالي ، والتي كانت مختلفة بشكل كبير عن تلك الخاصة بمجموعة المراقبة. ومع ذلك ، فإن متوسط درجة الإثارة الجنسية لم يظهر فرقًا معتد به إحصائيا (P= ٠.٠٨٢) نظرًا للتأثير الإيجابي لـ سالفيا أوفيسيناليس على درجات الأداء الجنسي ، يوصى باستخدامه كمكمل غذائي أثناء انقطاع الطمث. على الرغم من عدم ملاحظة أي آثار جانبية كبيرة ، يوصى بإجراء مزيد من الدراسات.