

The Efficacy of Squill Oil on Sexual Satisfaction among Women of Reproductive Age: A Double-blind Randomized Placebo-Controlled Trial

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ARTICLE INFO	ABSTRACT
Article type: Original article	Background & aim: Sexual satisfaction is an important component of women's health and quality of life, influenced by biological and psychosocial factors. Although Squill oil is traditionally believed to enhance sexual arousal, evidence for its effectiveness is limited; therefore, this study examined the effect of Squill oil on sexual satisfaction among women of reproductive age. Methods: This double-blind randomized placebo-controlled trial was conducted on 60 women aged 15–45 years who were referred to the Women's Clinic of Mashhad University of Medical Sciences, Mashhad, Iran. Participants were randomly assigned to either the Squill oil group, in which participants applied 2–3 drops of Squill oil topically to the clitoral area five minutes before intercourse, 1–3 times weekly for four weeks, or the placebo group. Sexual satisfaction was assessed using the Larson Sexual Satisfaction Questionnaire before and four weeks after the intervention. Data were analyzed using SPSS software (version 21) using the chi-square, independent t-test, Mann–Whitney U, and Wilcoxon tests. Results: The mean preintervention sexual satisfaction score was 40.0 ± 0.4 in the intervention group and 41.9 ± 4.1 in the control group, with no statistically significant difference between groups. Four weeks after the intervention, the mean score increased by 37.4 ± 10.4 points in the intervention group and 7.1 ± 10.3 in the control group. A statistically significant difference was seen between the two groups after the intervention ($P < 0.001$). Conclusion: Squill oil may improve sexual satisfaction among women of reproductive age. Further robust clinical trials are recommended.
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Introduction

One of the most important philosophies of marriage is that husband and wife find peace together. This peace depends on the factors, one of the most important of which is healthy sexual intercourse and sexual satisfaction (1–3). Sexual satisfaction is a very important aspect of the

relationship between couples and plays an important role in the psychological health of couples (4). Women with complete physical, mental, sexual, and emotional health are the strong foundations of a healthy and happy family. The suppression of women's sexual needs will

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harm the intimacy and vitality of family members (5-6). Sexual satisfaction is a personal experience in marriage that can only be evaluated by the individual in response to the level of pleasure in the marital relationship, and this feeling plays an important role in the level of normal family functions (7-8). It is one of the important indicators of couples' satisfaction with each other (9). Sexual satisfaction refers to a person's pleasant feeling about their sexual relations (10). It is one of the important factors of marital life satisfaction, one of the important and effective factors on the health and quality of couples' life, and is especially important in the fields of family and marital issues and causes the stability of the family center (11). Lack of sexual satisfaction is associated with feelings of failure, frustration, and depression and can endanger the psychological health of spouses (12-13). Studies have shown that the number of sexual activities in a person, as well as the number of times which reaches orgasm in each sexual relationship, is also related to satisfaction with sexual relationships (14-16).

Evidence suggests that higher levels of sexual satisfaction are associated with better relationship functioning, increased emotional intimacy, and improved overall life satisfaction. Conversely, reduced sexual satisfaction may contribute to decreased relationship quality and lower psychological well-being within couples. A recent meta-analysis has emphasized that sexual satisfaction is influenced by a complex interaction of individual, relational, and psychosocial factors, highlighting its central role in marital adjustment and relationship outcomes (17).

Various biological and psychosocial factors influence sexual satisfaction. In recent years, there has been increasing interest in using herbal medicine as complementary or alternative therapies for various health conditions, including sexual dysfunction. This trend is partly due to cultural preferences, accessibility, and the perception of natural products as being safer; however, evidence shows that herbal medicines are not free of adverse effects and may also have contraindications, drug interactions, and potential toxicities, including hepatic and renal complications. A systematic review reported that several herbal and nutritional products have

been marketed for improving female sexual function; however, evidence regarding their effectiveness remains inconsistent. According to this systematic review, some herbal interventions may show potential benefits in improving sexual function, but the overall quality of evidence is limited and heterogeneous, and placebo effects have also been reported in several clinical trials (18). A study by Pamenari et al. (2015) reported that both Femora and placebo gel improved sexual performance to a similar extent (19). The study by Taavoni et al. (2016) showed that Aphrodite improved the sexual performance of postmenopausal women (20).

Considering these few studies, there is an increasing need for the development and evaluation of effective, accessible, and evidence-based interventions for the management of sexual dysfunction. Among medicinal plants, Squill (*Drimys maritima*) has been traditionally used in herbal medicine and has attracted research interest due to its bioactive compounds and potential physiological effects, including possible influences on sexual function. Nevertheless, clinical evidence regarding its effectiveness in women's sexual health remained limited, warranting further well-designed trials (21-22). Squill, also known as sea onion, is a pear-shaped medicinal plant native to southern and western regions of Iran. It contains bioactive compounds such as flavonoids, particularly quercetin, which are suggested to have phytoestrogenic and antioxidant properties. These compounds may potentially influence sexual function by improving sexual desire, arousal, lubrication, and orgasm through hormonal and blood flow-related mechanisms. The plant also contains various minerals and vitamins (A, B, C, and E) that are associated with antioxidant, anti-inflammatory, and energy-enhancing effects (23-24). Squill oil has been described in traditional medical texts as a warming agent with potential effects on circulation. Warming oils are suggested to promote peripheral blood flow and vasodilation, which may theoretically influence sexual arousal; however, these effects are mainly based on traditional claims and limited pharmacological hypotheses rather than robust clinical evidence (23-25).

Given the limited relevant scientific evidence in this area, it was not possible to provide a comprehensive review of similar previous studies, and this issue itself indicates a significant gap in the existing knowledge. In fact, this research is considered one of the few studies investigated the effect of Squill oil using a randomized, double-blind clinical trial design. Therefore, the aim of the present study was to fill this knowledge gap and to investigate the effect of Squill oil on sexual satisfaction in women of reproductive age.

Materials and Methods

This double-blind, randomized, placebo-controlled clinical trial was conducted among women referred to the gynecology outpatient clinics of two teaching hospitals affiliated with Mashhad University of Medical Sciences, Mashhad, Iran, for the evaluation and management of gynecological complaints. Participants were randomly assigned to two groups: an intervention group and a control group. The trial was registered with the Iranian Registry of Clinical Trials (IRCT) under registration code of IRCT2017051033897N1.

The inclusion criteria were being aged 15–45 years, being literate, being married for at least six months, living with one's spouse, not being pregnant, having no genital scars in either partner, having sexual intercourse one to three times per week, having no specific underlying disease in either the woman or her husband, having no addiction in either partner, and having a sexual satisfaction score of less than 28 based on the Larson questionnaire.

The exclusion criteria were failure to use the prescribed oil correctly and regularly, withdrawal from the study, failure to respond appropriately to follow-up, and the death of the spouse. Information regarding contraceptive methods was not included in the eligibility criteria and was not controlled during the study.

To estimate sample size, a pilot study was conducted. In this way, 20 subjects in the intervention group (Squill oil) and 20 in the control group (placebo) were studied, and the statistical indicators of the sexual satisfaction score were considered to calculate the sample size. According to the detection of a statistically significant difference in the sexual satisfaction score between the two groups after the

intervention at a significance level of 0.05, power of 80%, a common standard deviation of 12 ($s_1 = s_2$), and a score difference (d) of 9 units, a sample size of at least 28 subjects was determined for each group. Considering the possibility of dropout of 10%, the minimum sample size was calculated to be 32 subjects in each group.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (s_1^2 + s_2^2)}{(d)^2} \\ = \frac{(1/96 + 0/84)^2 (12^2 + 12^2)}{(9)^2} \\ \approx 28$$

In this research, the participants were selected from the women of reproductive age who referred to the hospital at the time of the study period and met the sampling criteria. Convenience sampling was primarily used to select the participants. Then the participants were randomly assigned to two groups of A (Squill oil) and B (placebo) using permuted block randomization with a block size of six (using the table related to random permutations). The randomization list was prepared by a statistician. The intervention was assigned according to the randomized list by an individual who was not involved in the study and was unaware of the research objectives and according to the corresponding codes in the sealed envelopes.

The tools used in this study included demographic characteristics and Larson Sexual Satisfaction Questionnaire. The demographic characteristics questionnaire included questions about current age, age at the time of marriage, level of education, employment status, spouse's age, number of children, and number of sexual intercourses per week. Larson Sexual Satisfaction Questionnaire consisted of 25 items, including 13 negative questions (4, 5, 6, 7, 8, 9, 11, 14, 15, 18, 20, 24, 25) and 12 positive questions (1, 2, 3, 10, 12, 13, 16, 17, 19, 21, 22, 23). The questionnaire assessed different dimensions of sexual satisfaction, including sexual desire, sexual attitude, quality of sexual life, and sexual adjustment. Each item was rated on a five-point Likert scale (never, rarely, sometimes, most of the time, and always), with scores ranging from 1 to 5. Total scores range was from 25 to 125. A score below 50 indicated no sexual satisfaction, 51–75 low satisfaction,

76–100 moderate satisfaction, and a score above 100 indicated high sexual satisfaction (20).

The demographic questionnaire was developed based on the relevant scientific literature. Its face and content validity were evaluated under the supervision of the supervisors and co-supervisors. Subsequently, the questionnaire was reviewed by 10 faculty members from the Departments of Midwifery at Mashhad University of Medical Sciences, and their comments were considered. The content validity index (CVI) and content validity ratio (CVR) were calculated, with values above 0.90. The validity of the Larson Sexual Satisfaction Questionnaire was confirmed by 10 academic staff members in the study by Bahrami et al. (2016). The reliability of the questionnaire was also evaluated using Cronbach's alpha coefficient, which was 0.93 (26). In the present study, its reliability was confirmed with a Cronbach's alpha coefficient of 0.86.

The oils used in the study had the same appearance and smell, and were placed in completely similar boxes by the pharmacist. The participants and the researcher were not aware of the type of oil given (double-blind). Before intervention, Larson satisfaction questionnaire was completed by the participants at the same place and in case of need for further explanations, necessary instructions were given by the researcher. At the same time as receiving the oils, both groups of the participants were given an educational pamphlet which explained how to use the oil and the anatomy of reproductive system and the clitoral area in simple language and photos. Then for 4 weeks, 1 to 3 times a week and each time 5 minutes before intercourse, the participants rubbed 2 to 3 drops (equivalent to 0.5 cc) of oil in a completely gentle manner on the clitoral area (the sensitive prominent part above the urethra) and its surroundings in a circular manner. Then, based on the prepared checklist, the number of intercourses per week, the number of times the oil was used, the amount used and its side effects were recorded through

phone follow-up. At the end of 4 weeks, in a phone call, the date of visiting the clinic for the post-test was reminded. When referring to the clinic, Larson satisfaction questionnaire was measured again in two groups, and the side effects and satisfaction with the treatment were also asked by the researcher in the form of questions from the subjects.

To analyse data, quantitative variables were reported as mean and standard deviation, and qualitative variables were reported as number (percentage). The normality of quantitative variables was checked using the Kolmogorov-Smirnov test. Moreover, Chi-square test (or Fisher exact test) was used to investigate the relationship between qualitative variables, and independent t-test or its non-parametric equivalent (Mann-Whitney test) was used to compare quantitative variables between two independent groups. Intragroup comparisons were performed using the Wilcoxon test. The data analysis was done using SPSS software (version 21). $P < 0.05$ was considered statistically significant.

Results

In this research, out of 32 participants which allocated to each intervention and placebo group, two participants were excluded from the intervention group due to traveling abroad and their spouse's death, and two participants were excluded from the control group due to pregnancy and addiction, and the final analysis was performed on 60 subjects (30 in each group). The flow of participants through the study is presented in Figure 1.

The demographic characteristics of women in the two groups are presented in Table 1. The results of the independent t-test and Mann-Whitney test showed that before the intervention, there was no statistically significant difference between the Squill oil and placebo groups in terms of demographic variables ($P > 0.05$).

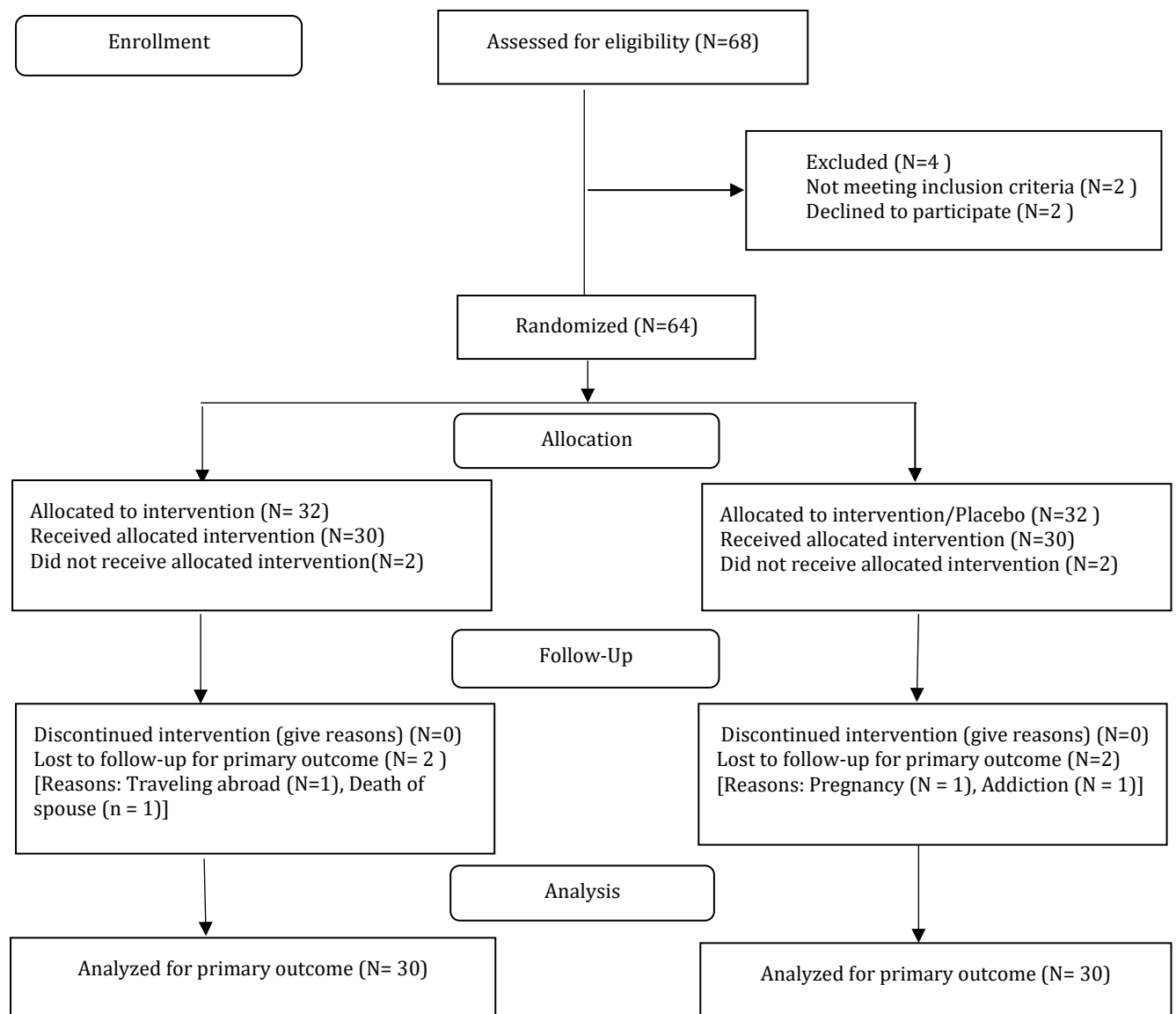


Figure 1. CONSORT Flowchart of the study

The mean sexual satisfaction score before the intervention was 40.0 ± 0.4 in the intervention group and 41.9 ± 4.1 in the control group. The two groups were homogeneous regarding sexual satisfaction scores before the intervention ($P=0.074$). Four weeks after the intervention, the mean sexual satisfaction scores were 77.4 ± 9.6 in the intervention group and 49.0 ± 11.3 in the control group. The Mann–Whitney test

demonstrated a statistically significant difference between the two groups after the intervention ($P<0.001$). The increase in sexual satisfaction scores after the intervention compared with baseline was 37.4 ± 10.4 in the intervention group and 7.1 ± 10.3 in the control group. The Wilcoxon test showed that the changes in sexual satisfaction scores were statistically significant in both the intervention

($P < 0.001$) and the control group ($P = 0.001$) (Table 2). No side effects were observed during the study.

Table 1. Comparison of demographic characteristics of women of reproductive age in two groups of Squill oil and placebo before intervention

Variable	Placebo group N=30	Intervention group N=30	P-Value
Age	30.0±6.5	30.0 ± 6.1	£ 0.575
Husband's age	8.2±23.9	34/9 ± 5/8	0£.984
Age at marriage	4.8±22.3	21/2 ± 4/9	0£.346
Number of children N (%)			€ > 0.99
One	9 (42.9)	8 (34.8)	
Two	7 (33.3)	12 (52.2)	
Three and more	5 (23.8)	3 (13.0)	
Employment status N (%)			* 0.754
Household	23 (76.7)	24 (80.0)	
Employed	7 (23.3)	6 (20.0)	
Level of education N (%)			0£.257
Reading and writing	6 (20.0)	6 (20.0)	
Secondary school	7 (23.3)	12 (40.0)	
High school	9 (30.0)	8 (26.7)	
College	8 (26.7)	4 (13.3)	
Frequency of intercourse per week N (%)			0£.992
Once	5 (16.7)	4 (13.3)	
Twice	21 (70.0)	23 (76.7)	
Three times	4 (13.3)	3 (10.0)	

£ Two-sample t test, € Mann-Whitney test, * Chi-square test

Table 2. Comparison of the sexual satisfaction score of women of reproductive age before and after the intervention in two groups of Squill oil and placebo

Variable	Placebo group N=30	Intervention group N=30	Variable	P-Value
Sexual satisfaction score			Sexual satisfaction score	
Pre-intervention	41.9±4.1	40.0±4.0	Before intervention	0£.074
Post-intervention	49.0±11.3	77.4±9.6	After intervention	€ < 0.001
P-Value	¶ 0.001	¶ < 0.001	P-value	-
Changes of pre and post-intervention	7.1±10.3	37.4±10.4	Changes of before and after intervention	€ < 0.001

€ Mann-Whitney test, ¶ Wilcoxon signed-rank test

Discussion

The findings showed that sexual satisfaction scores increased significantly after the intervention in both groups. However, the magnitude of improvement was substantially greater in the intervention group than in the placebo group, suggesting that Squill oil may have a more pronounced effect on improving women's sexual satisfaction. Although a slight improvement was also observed in the placebo

group, the greater change in the intervention group highlights the potential effectiveness of the intervention. The findings of the present study showed that a four-week intervention improved sexual satisfaction among women of reproductive age. In line with this finding, Taavoni et al. in a clinical trial showed that the use of Aphrodite could improve desire and orgasm after 4 weeks (20). Karimi et al. (27) investigated the effect of Squill oil on dyspareunia in postmenopausal women and

concluded that Squill oil improved dyspareunia in these women (27). In another study conducted by Abbasi Piroz et al. in 2016 on the effect of Squill oil on the sexual performance of women at reproductive age, Squill oil improved women's sexual performance and sexual satisfaction (28). In another study conducted in 2014 by Akhtari and colleagues to investigate the effect of tribulus on women's sexual performance, it was found that this plant can improve sexual performance and its dimensions in women (29). Pamenari et al. (2017) conducted a study on 76 women aged 19-58 years and reported that topical L-arginine (femora gel) and placebo gel both improved the sexual performance of women to the same extent (19). Mohammadzadeh et al. (2018) investigated the effect of pomegranate peel gel on orgasm and satisfaction of women of childbearing age. Pomegranate peel gel increased women's satisfaction by improving orgasm (30). Yosufzadeh et al. (2017) investigated the effect of date pollen capsule on orgasm and satisfaction of menopausal women. Date pollen capsule improved the orgasm of menopausal women, but did not affect their sexual satisfaction (31). It is noteworthy that relatively few studies have specifically investigated women's sexual satisfaction. To our knowledge, few studies have specifically investigated the effect of Squill oil on sexual satisfaction among women of reproductive age.

One limitation of the current study was that the oil was self-administered by participants at home, which may have resulted in incorrect use. To minimize this limitation, an educational pamphlet was provided and telephone follow-up was conducted to help participants use the oil correctly. This study has been specifically focused on the satisfaction of women at reproductive age for the first time in Iran; for this reason, few articles were available for further discussion. It should be acknowledged that sexual response in women depends on many factors, such as pleasant sexual experience, woman's sexual skill, as well as the quality of interpersonal and emotional relationships of couples. It is not possible to have a completely biological view of sexual issues, but due to the variety of treatments and methods to improve sexual problems, which are mostly non-native and expensive, no adverse effects were reported

during the four-week intervention period; however, the absence of rare or long-term adverse effects cannot be established based on this study. It is noteworthy that given the limited sample size of the study, the absence of rare or long-term side effects cannot be definitively ruled out, and therefore conclusions regarding safety should be interpreted with caution. Therefore, further clinical studies are needed to evaluate the safety of this product particularly during pregnancy and its possible effects on the fetus. However, in the present study, no side effects were reported or observed during the intervention period, which may, to some extent, indicate its short-term safety. Further clinical studies are needed to establish the safety and efficacy of Squill oil before it can be recommended as a routine complementary intervention.

Conclusion

Squill oil may improve sexual satisfaction. Although further clinical trials are needed to assess the efficacy and safety of this product, given the prevalence of sexual problems during the reproductive years and their potential effect on marital quality of life, Squill oil may be considered as a complementary approach for improving sexual satisfaction.

Declarations

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Conflicts of interest

The authors declared no conflicts of interest.

Ethical approval

Written informed consent was obtained from all participants after explaining the objectives and methods of the study. They were ensured of the anonymity and confidentiality of the data and the possibility of withdrawing from the study at any time during the study without any

consequences. All data were kept confidential and used solely for research purposes.

Code of Ethics

This study was approved by the Ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran (Ethical code: IR.MUMS.REC.1396.64).

Use of Artificial Intelligence

No artificial intelligence tools were used in the design, data collection and analysis of this study.

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Authors' contributions

MAP contributed to data collection, study implementation, and manuscript preparation. AZ contributed to the study design, supervision, and scientific revision of the manuscript. MTS performed statistical analysis and interpretation of data. KMN contributed to the methodology development and critical review of the manuscript. All authors read and approved the final version of the manuscript.

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