

# ORIGINAL ARTICLE

## The Effect of Palm Pollen Extract on Sexual Disorders in Postmenopausal Women: A Randomized Clinical Trial

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### ABSTRACT

**Background:** Considering the numerous nutritional and estrogenic compounds of palm pollen and their effect on sexual function, this study was performed to investigate the effect of palm pollen extract on sexual disorders in postmenopausal women.

**Methods:** In this three-blind clinical trial, 110 postmenopausal women from December 2019 to December 2020 from Rafsanjan comprehensive health service centers were randomly assigned to two groups, using a lottery method. The intervention group received 300 mg capsule of palm pollen extract, and the control group received placebo for 4 weeks. Sexual disorders were assessed with a 6-item female sexual function index before, at the end of the intervention, and 4 weeks after the end of the intervention. Independent t-test, Chi-square and repeated measures ANOVA were used to analyze the data through SPSS software version 21. The statistically significant level was considered P value less than 0.05.

**Results:** The mean scores of sexual disorders before the intervention in the intervention and control groups were  $15.36 \pm 5.01$  and  $14.13 \pm 4.67$  ( $P=0.68$ ); at the end of the intervention, they were  $15.18 \pm 4.50$  and  $14.22 \pm 3.91$  ( $P=0.43$ ) and 4 weeks after the end of the intervention we obtained  $15.7 \pm 4.77$  and  $14.44 \pm 3.78$ , respectively ( $P=0.90$ ).

**Conclusions:** According to the results, daily consumption of 300 mg of date pollen extract had no effect on improving sexual disorders in postmenopausal women. Further studies in this field are suggested.

**Trial Registration Number:** IRCT20160308026971N10

**Keywords:** Postmenopausal women, Palm pollen, Sexual disorders

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## INTRODUCTION

Expectancy has considerably increased since 1970, and now more than 50% of women are expected to break the 90-year barrier by 2030.<sup>1</sup> The average age of menopause in Iran is estimated at 48.26 years, with a range of 46.5 to 49.67 years.<sup>2</sup> Most women can expect to spend about 40% of their lives after menopause.<sup>4</sup> Although the main health challenge in the 20<sup>th</sup> century was just “survival”, the main concern in the 21<sup>st</sup> century is “living with a superior quality”.<sup>5</sup>

Sexual intercourse meets the biological and social needs of human beings and increases the quality of life.<sup>6</sup> Sexual function can seriously affect a person’s quality of life, which is an essential part of life quality.<sup>7</sup> The status of menopausal hypoestrogenism has a severe negative effect on the health of the genitourinary system.<sup>8</sup> The prevalence of sexual dysfunction in postmenopausal women is high (85.2%). The most influential sexual domains are: dissatisfaction (89%), arousal (67%), and desire (62.40%).<sup>9</sup> A study in Iran showed that more than 80% of women studied in their middle life had sexual dysfunction.<sup>10</sup> Ignorance about the importance of sexual problems in marital relationships has caused a lot of damage to marital relations. Sexual disorders may significantly reduce self-esteem and impair the quality of life and social activities.<sup>11</sup> Many aggressions, controversies, and couples’ monitoring and control over each other’s activities can be linked to sexual problems.<sup>12, 13</sup>

Considering that the symptoms of menopause, including sexual disorders, are related to the severe drop in estrogen at this time, one of the primary treatments for these symptoms is hormone therapy.<sup>14</sup> However, due to the health risks associated with hormone therapy, many women cannot or prefer not to use it.<sup>15-17</sup> Approximately 51% of women use complementary and alternative medicine, and more than 60% find it effective for menopausal symptoms.<sup>15</sup> One of the plants the fruit and different parts of which are used is the date

palm.<sup>18</sup> Since ancient times, date palm has been used in Greece, China and Egypt to treat infertility and increase sexual desire and fertility in females.<sup>19</sup>

The effect of date palm pollen may be due to the presence of alkaloids, saponins and flavonoids. This pollen contains cholesterol, retinol and carotenoids, which trigger the activity of gonadotropins in rats.<sup>20</sup> It has estrogenic substances, i.e., estriol, estradiol, and estrogen, which were recognized to alleviate infertility problems.<sup>21</sup> In a study, palm pollen was effective on several ovarian parameters, including ovarian diameter, number of primary and secondary follicles, results of increased estrogen and progesterone in female mice.<sup>22</sup> Administration of palm pollen extract to mice with thyroid disorders in another study increased the sperm count and motility, serum levels of Luteinizing Hormone as well as testicular antioxidant status.<sup>23</sup> Also, 35-day consumption of palm pollen improved sexual desire and arousal and was effective in improving orgasm in postmenopausal women, but it had no effect on sexual satisfaction.<sup>24</sup> A review of these studies showed the effect of palm pollen on the reproductive system; given the high prevalence of sexual disorders after menopause, the adverse effects of these disorders on the quality of life, women’s willingness to use alternative therapies and complementary medicine, and a limited number of studies, the present study was conducted with the aim of investigating the effect of date pollen extract on sexual disorders of postmenopausal women.

## MATERIALS AND METHODS

This three-blind randomized controlled clinical trial was conducted from December 2019 to December 2020 on 110 postmenopausal women covered by comprehensive health service centers in Rafsanjan. In this study, 200 postmenopausal women were examined to enter the study; 110 subjects were enrolled, and 89 of them completed the study (Figure 1).

According to a similar study,<sup>25</sup> the

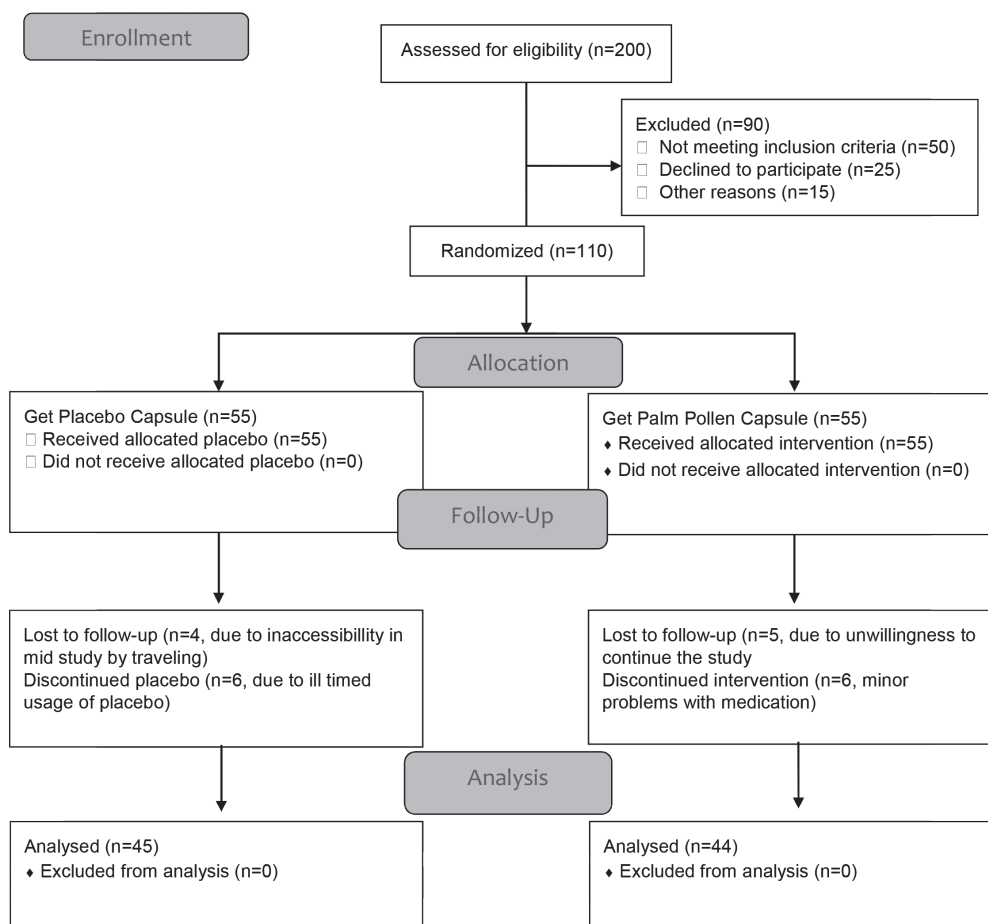


Figure 1: CONSORT flowchart of the participants of the study.

approximate mean values of the physical effects in the studied groups and considering  $X_1=4.15$ ,  $X_2=2.42$ ,  $S_1=3.02$ , and  $S_2=3.28$ ,  $z_{1-\beta}=0.84$ ,  $z_{1-\alpha/2}=1.95$ , the error of 5% ( $\alpha=0.05$ ), and power of 80% ( $\beta=0.20$ ), 52 subjects were estimated by using the following formula. Considering the possibility of 5% attrition, 55 individuals were considered in each group.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 (S_1^2 + S_2^2)}{(\bar{x}_1 - \bar{x}_2)^2}$$

$$52 = \frac{(3.02^2 + 3.28^2)(1.96 + 0.84)^2}{(4.15 - 2.42)^2}$$

The inclusion criteria were married women aged 50 to 65; at least 12 months or more after the last menstrual period; sexually active women; no history of diseases such as breast and uterine cancer, abnormal vaginal bleeding, known depression or mental disorders, liver, kidney and thyroid disease; no history of

taking hormonal drugs such as progesterone, estrogen, gonadotropin-releasing hormone agonists and antagonists; lack of a history of regular use of herbal medicines; and a score of less than 19 obtained from the questionnaire female sexual function index (FSFI). Participants were excluded from the study under the following conditions: having allergic reactions to palm pollen, experiencing any accident during the study, forgetting to take the drug for two or more days in a row, starting other herbal remedies for any cause, and suffering abnormal vaginal bleeding during the study.

Sampling was done purposefully, based on the inclusion criteria, and with written consent. The subjects were assigned into the intervention and control groups randomly by using lottery. An equal number of sheets with codes 1 and 2 were placed in packages where the codes could not be seen, and the participants were asked to remove one of the

sheets from the container. The capsules of palm pollen extract and placebo with code 1 and 2, respectively, and without name were received from Chemistry Laboratory of Shahid Bahonar University of Kerman (Drug Manufacturing Department). Each person was given one capsule daily for 4 weeks, according to the assigned code. To prevent forgetfulness, it was recommended to take the drug at a certain time each day. By forming a group in WhatsApp, daily consumption was reminded and possible questions were answered. The daily medication intake registration form was also provided to the participants, so that they could mark each intake of medication and hand it in at the end of the intervention. After data analysis, the date palm extract code and placebo were determined by the manufacturer. Thus, postmenopausal women who participated in the project, researchers, data collection partners, and data analysts were unaware of the type of drug.

The construction of this capsule was performed in the chemistry laboratory of Shahid Bahonar University of Kerman. First, pollen powder was placed in distilled water for 24 hours at laboratory temperature, and the extraction steps were performed for 24-48 hours using a Soxhlet apparatus. Then, to dry the extract, we placed the resulting solution at a temperature of 50 degrees, and then the resulting powder was poured into 300 mg capsules and ready to use. Completely similar capsules containing 300 mg of starch were also prepared as placebo.

The data collection tool included a demographic information checklist and a standard FSFI-6 questionnaire. Demographic information included age, weight, height, body mass index, age of menarche (first menstruation), age of menopause (last menstruation), duration of menopause, gravida and parity, education, use of non-hormonal drugs, and occupation.

Sexual function was evaluated with the 6-question version of the FSFI before the intervention, at the end of the intervention, and 4 weeks after it. This questionnaire was

designed in 2010 by Andrea M. Isidori and colleagues to summarize the original version of 19 questions.<sup>26</sup> The items are divided into six domains (desire, arousal, lubrication, orgasm, satisfaction, and pain), addressing different aspects of female sexual function. Items related to sexual desire and satisfaction are scored based on a five-point Likert scale from 1 to 5. The items related to lubrication, arousal, orgasm and pain are scored based on a six-point Likert scale from 0 to 5. By adding the scores of six sub-scales, the score of the whole scale is obtained. The total score varies between 2 and 30, and higher scores indicate better sexual performance. A score of zero indicates that the person has not had sexual activity during the last 4 weeks. According to the results of various studies, the appropriate cut-off point for diagnosing functional impairment in women's sexuality was determined as 19, and women with a score less than 19 were considered to have sexual disorders.<sup>26</sup> The receiver operating characteristic analysis showed that the FSFI-6 had excellent accuracy with sensitivity and specificity greater than 94% ( $P < 0.001$ ), internal consistency ( $\alpha \geq 0.78$ ), test-retest reliability ( $R = 0.95$ ), and high positive and negative predictive values in discriminating women with and without female sexual dysfunction (FSD).<sup>26</sup>

Construct validity of the 6-FSFI structure in Iran was investigated by Ghassami and colleagues in 2014 using exploratory factor analysis, and its validity by examining convergence and divergence with related tools. The results of exploratory factor analysis led to the extraction of 1 factor with an eigenvalue greater than 1. This factor explained 57.05 percent of the variance in women's sexual performance scores. The calculated Cronbach's alpha coefficient was equal to 0.83, Retest coefficient was  $R = 0.77$ , and examination of diagnostic validity was  $P = 0.0001$ . The evaluation of convergent validity by calculating the correlation coefficient obtained with positive affects subscale and Locke & Wallace-Marital

adjustment test indicated the convergent validity of the scale. Calculating the correlation between the depression anxiety stress scales, Female sexual distress scale- revised (FSDS-R) and negative affects subscale showed that FSFI-6 had divergent validity.<sup>27</sup>

The data were analyzed using SPSS statistical software, version 21. Descriptive statistics including frequency, mean and standard deviation were used to describe the characteristics of the research units. To assess the homogeneity of the groups for demographic characteristics, we used Independent T-Test and Chi-square tests. Repeated measure analysis was used to assess the impact of the intervention on sexual disorders in three times of completing the questionnaires. P value<0.05 was considered statistically significant. Also, the Kolmogorov-Smirnov test was used to check the normality of the data.

The current study was approved by the ethics committee of Rafsanjan University of Medical Sciences (Approval ID: IR.RUMS.REC.1399.097). The subjects participating in the study were assured that their names

would not be mentioned in the study and that they could leave the study at any time without affecting their routine care.

## RESULTS

Demographic findings of the study indicated that both groups were homogeneous in terms of age, body mass index, age of first menstruation, age of last menstruation, occupation, level of education, number of deliveries, and drug use before the intervention (P>0.05). (Table 1).

Based on the results of the repeated measurement test, by examining the effect of group, time and time group interaction, the average score of sexual function disorders of the two groups before the intervention (P=0.68), at the end of the intervention (P=0.43) and 4 weeks after it (P=0.90), it was found that there was no statistically significant difference (Table 2).

## DISCUSSION

The results of this study showed that daily consumption of palm pollen extract did not

**Table 1:** Demographic characteristics of the participants in intervention and control groups

Variable	Group	Control	Intervention	P value
		Mean±SD	Mean±SD	
Age (year)		55.58±4.77	56.6±4.40	0.50*
Age of first menstruation (year)		12.87±1.80	12.87±1.97	0.80 *
Age of last menstruation (year)		48.6±4.96	48.13±5.62	0.97 *
BMI <sup>a</sup> (kg/m <sup>2</sup> )		N (%)	N (%)	0.47**
	Thin	0 (0)	1 (1.80)	
	Normal	11 (20)	9 (16.40)	
	Overweight	20 (36.40)	30 (54.50)	
	Grade 1 obesity	20 (36.40)	11 (20)	
	Grade 2 obesity	3 (5.50)	2 (3.60)	
Education				0.65**
	Illiterate	20 (36.40)	25 (45.50)	
	Middle School degree	24 (43.60)	20 (36.40)	
	Diploma	9 (16.40)	7 (12.70)	
Job				0.76**
	Housewife	49 (89.10)	48 (87.30)	
Number of deliveries				>0.99 **
	Employed	6 (10.90)	7 (12.70)	
	Nullipar	4 (7.30)	4 (7.30)	
Use of chemical drugs				0.23**
	Primpar	1 (1.80)	0 (0)	
	Multipar	50 (90.90)	51 (92.70)	
Use of chemical drugs				0.23**
	Yes	31 (56.40)	37 (67.30)	
	No	24 (43.60)	18 (32.70)	

\*Independent t-test; \*\*Chi-square test; <sup>a</sup>Body Mass Index

**Table 2:** Comparison of mean and standard deviation of the total score of sexual disorders in the intervention and control groups at different times

Variable	Intervention	Control	P value*		
	(N=44)	(N=45)	Group effect	Time effect	Group Time effect
Before the intervention	15.36±5.01	14.13±4.67	0.91	0.21	0.55
After the intervention	15.18±4.50	14.22±3.91			
4 weeks after the ending intervention	15.07±4.77	14.44±3.78			
P value*	0.94	0.86			

\*Repeated measures ANOVA

significantly reduce the score of sexual disorders in postmenopausal women. In the present study, which aimed to investigate the effect of palm pollen extract on sexual disorders in postmenopausal women, after the intervention and one month after, the difference in the score of sexual disorders between the two groups was not significant. Due to the fact that only few studies were found on the effect of palm pollen on female sexual function, the results were discussed and interpreted with the most relevant and closest articles to the research topic.

In a clinical trial on postmenopausal women, it was shown that consumption of capsules of palm pollen improved orgasm in postmenopausal women, but it had no effect on sexual satisfaction.<sup>24</sup> In another study on dyspareunia and vaginal lubrication in postmenopausal women, a daily dose of palm pollen reduced dyspareunia in postmenopausal women and increased the vaginal lubrication.<sup>28</sup> In these studies, the menopausal women who participated did not have sexual disorders, the palm pollen used was grown in the groves of Hormozgan province, the prescribed capsules contained date pollen without any changes and the 19-question FSFI questionnaire was used. However, in the present study, postmenopausal women with sexual disorders were included in the study, the palm pollen used was grown in the groves of Larestan region in the south of Fars province, and the prescribed capsules contained date pollen extract; also, to evaluate the sexual function, we used the 6-question FSFI questionnaire. These differences can be the reason for the difference in the obtained results.

The use of date pollen extract for the first time instead of whole pollen, while it is the strength of this study, can have an impact on the difference between the results of this study and similar articles; it is suggested that other extraction methods should be used or the current method should be revised in future studies.

As an explanation of the differentness of the groves, it should be added that amino acids including aspartic, threonine, glutamine, proline, glycine, alanine, valine, methionine, isoleucine, leucine, tyrosine, phenylalanine, histidine, lysine, arginine, and serine in different dates with different percentages can be found.<sup>29</sup> Therefore, due to the great diversity of palms in Iran and also the difference in the type of palm and type of date in different geographical areas, the composition or percentage of pollen composition of different palms can be different.

In another study, daily consumption of palm pollen capsules in infertile couples improved their sexual function.<sup>30</sup> In this study, the difference of the research community, in addition to the previous reasons, could have caused the difference in the results.

A study showed that consumption of palm pollen per kg of body weight leads to a significant increase in the serum levels of estrogen and progesterone in female mice.<sup>31</sup> Another study showed that higher doses of palm pollen ethanolic extract increased the antioxidants and gonadotropin hormones in female rats.<sup>32</sup> From this study, it can be concluded that the effects of palm pollen on sexual function are probably dose-dependent,

and probably if a higher dose was used in this study, the result would be different.

On the other hand this important point should be kept in mind that sexual dysfunction in menopausal women is rooted in a wide range of predisposing, precipitating, and maintaining factors, which may be of biological, psychological and socio-cultural origin.<sup>33</sup> It follows that a multidimensional approach to the management of sexual dysfunction is of particular importance in menopause. It is likely that the reason for the lack of effect of palm pollen extract in this study was the influence of other factors and their lack of precise control.

One of the most important strengths of this study, as stated, is that the prescribed date pollen was scientifically extracted in a chemical laboratory, and this is the first study in this way. Being three-blind is another strength of the study. Among the limitations of the study, we can point out the lack of control of all factors affecting sexual function in postmenopausal women, including psychological factors and individual characteristics, for which we tried to reduce this limitation through including a control group.

## CONCLUSION

Daily consumption of 300 mg of palm pollen extract does not significantly improve the sexual function of postmenopausal women with sexual disorders. Due to the Phytoestrogenic and antioxidant compounds of palm pollen, the need for further study with different doses and periods of consumption and palms of different regions is suggested.

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**Conflict of Interest:** None declared.

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