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## Original Article

## Effect of date palm pollen supplementation on female sexual function in non-menopausal women: A double blind randomized clinical trial

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## ABSTRACT

**Objective:** Despite numerous experimental studies in the literature, there are few clinical trials regarding the effect of date palm pollen (DPP) supplementation on sexual function improvement. In the present study, we sought to evaluate the impact of DPP on female sexual function in Iranian non-menopausal women.

**Methods:** Between October 2019 and December 2019, health centers in the city of Khalkhal, volunteers meeting the inclusion criteria were recruited in randomized clinical trials. Sixty-eight women were randomly stratified and assigned to one of the two study groups: placebo group ( $n = 35$ ) and palm pollen group ( $n = 35$ ), and received a starch or palm pollen capsule (300 mg per day), respectively, for 35 d. The Female Sexual Function Index (FSFI) instrument was used to assess female sexual function.

**Results:** After DPP supplementation, the increase in desire, lubrication, and the overall score, was statistically significant compared to the placebo group ( $P = 0.002$ ,  $P = 0.000$ , and  $P = 0.042$ ; respectively); Whilst there was no significant differences in the remaining domains (arousal:  $P = 0.763$ ; orgasm:  $P = 0.370$ ; satisfaction:  $P = 0.474$ ; pain:  $P = 0.259$ ). There was a statistically significant positive correlation between the coitus and preintervention levels of desire ( $r = 0.298$ ,  $P = 0.038$ ), arousal ( $r = 0.328$ ,  $P = 0.021$ ), lubrication ( $r = 0.361$ ,  $P = 0.011$ ), orgasm ( $r = 0.320$ ,  $P = 0.025$ ), satisfaction ( $r = 0.327$ ,  $P = 0.022$ ), and overall scores ( $r = 0.338$ ,  $P = 0.018$ ).

**Conclusion:** This study suggests that DPP (300 mg supplementation for 35 d), given to non-menopausal women, could improve the lubrication and desire domains of FSFI.

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## 1. Introduction

Female sexual dysfunction (FSD) is a multidimensional medical issue that can have a significant effect on the quality of life and social health in women (Mayer et al., 2007). According to the *Diagnostic and Statistical Manual of Mental Disorders*, fourth edition (DSM-IV), sexual dysfunction is defined as a clinically significant disturbance in a person's ability to respond sexually or to experience sexual pleasure (Mitchell et al., 2016). Healthy female sexual function is characterized by vascular smooth muscle relaxation

caused by the neurotransmitter such as vasoactive intestinal polypeptide (VIP) and nitric oxide (NO), augmented vaginal lubrication, increase in vaginal luminal diameter, and clitoral length and diameter expansion (Berman, 2005). Sexual dysfunction, as a medical problem is reported to be more prevalent among women (43%) than men (31%) (Addis et al., 2006), whilst the estimated prevalence of sexual dysfunction in the Iranian community is 31.5% for women and 18.8% for men (Bakoyi, Sh, & Nasiri, 2006). Indeed, this prevalence varies widely in different communities due to medical, psychological, socio-economic, cultural, and racial factors (Omani-Samani et al., 2019; Tabaghdehi, Keramat, & Khosravi, 2017). Moreover, FSD may be a contributory factor to familial discord and divorce, and infertility (Jaafarpour, Khani, Khajavikhan, & Suhrabi, 2013; Oindi, Murage, Lema, & Mukaindo,

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2019). Several strategies, such as pharmacologic therapy and alternative medicine, have been used to treat or reduce FSD (Raina et al., 2007). As reported by World Health Organization (WHO), 70%–80% of the global population trust traditional medicine for primary health care (Organization, 2002).

Date Palm Pollen (DPP), pollen from *Phoenix dactylifera* L., was historically used by ancient Egypt and Chinese people to treat infertility in women (Moshfegh et al., 2016). Further, the results of a study showed DPP could treat male infertility by bettering the quality of sperm parameters (Bahmanpour et al., 2006). Data from Jiheel and Arrak (Jiheel & Arrak, 2015) highlighted an elevation in serum levels of follicle-stimulating hormone (FSH) and luteinizing hormone (LH) in female rats that received 100 mg/kg of DPP extract; Additionally, the ethanolic extract of DPP grains yielded an improvement in total glutathione and gonadotropin hormones. Sex hormones affect sexual response and sexual function; For instance, the estrogen hormone has an impact on genital anatomy, improving vascular function and peripheral blood flow, and enhancing vaginal lubrication and pelvic connective tissue resilience for pleasant intercourse (Porst & Buvat, 2008; Santoro, Worsley, Miller, Parish, & Davis, 2016). Abedi et al. (Abedi, Parviz, Karimian, & Rodsari, 2013) evaluated the aphrodisiac activity of aqueous extract of *P. dactylifera* pollen in male rats and found that, in a dose-dependent manner, this extract could enhance appetitive sexual behavior in male rats; The authors attributed these effects to the saponins, flavonoids, and alkaloids.

It was indicated that co-administration of DPP or vanadyl folate in carbofuran-treated rats mitigated the toxic effects of this toxicant on reproductive functions and improved fertility index in male rats. The authors posited that these positive effects might be related to flavonoids, glycosides, steroids, saponins, estradiol, and several types of vitamins, such as vitamin A, vitamin E, and minerals such as manganese, zinc, and selenium in DPP. Indeed, these constituents can increase levels of LH, and testosterone consequently leads to improve sexual behavior (Kobeasy, El-Naggar, & Abdallah, 2015). In postmenopausal and aged women, non-hormonal approaches such as vitamin E and vitamin A have been used vaginally to increase lubrication; Moreover, vitamin E has a vasodilatory feature that contributes to supply adequate blood flow to the sex organs (Qureshi et al., 2007). Despite various experimental studies, there are a few human studies regarding the effect of DPP on sexual dysfunction in the literature. Therefore, for the first time, we sought to evaluate the impact of 300 mg DPP supplementation on female sexual function in Iranian non-menopausal women. We hypothesized that DPP supplementation could improve female sexual function.

## 2. Methods

### 2.1. Study design

We conducted a double-blinded randomized clinical trial. The proposed clinical trial was held at the Khalkhal University of Medical Science for 35 d to assess the efficacy of 300 mg DPP supplementation on female sexual function in Iranian non-menopausal women (Fig. 1).

### 2.2. Outcomes

The primary outcome consists of female sexual function. The secondary outcome is the association between the coitus and preintervention FSFI domains scores and overall score.

### 2.3. Ethics and trial registration

This study, approved by the Medical Ethics Committee of Khalkhal University of Medical Sciences, was conducted in accordance with the Declaration of Helsinki (approval number: IR.KHALUMS.REC. 1398.001). Moreover, the present interventional study was registered in the Iranian Registry of Clinical Trials (IRCT registration number: IRCT2016070928853N1).

### 2.4. Sample size and randomization

The sample size was estimated based on the study by Sadeghi et al. ( $\alpha = 0.05$ ,  $\beta = 0.2$ ,  $S1 = 1.3$ ,  $S2 = 0.8$ ,  $\mu1 = 3.2$ ,  $\mu2 = 4.4$ ) (Sadeghi Goghari, Yousefzadeh, Rakhshandeh, Dadghar, & Mazloom, 2018). Finally, with considering a loss of 20% of the participants, 35 subjects were recruited for the intervention group and 35 subjects for the placebo group. Next, the subjects were randomly stratified using a permuted block randomization procedure by Random Allocation Software (RAS) and assigned to one of the two study groups: control (placebo group,  $n = 35$ ) and intervention (palm pollen group,  $n = 35$ ). Moreover, randomization was concealed in sequentially numbered, sealed, opaque envelopes, and kept by the researcher.

### 2.5. Participants

Following referral to the health centers in the city of Khalkhal, married volunteers meeting the inclusion criteria were recruited in this trial study (October 2019 to December 2019). Then, each participant signed an informed consent form prior to participation. The inclusion criteria in this study were aged 30–45 years old, and using the Intrauterine Device (IUD) for contraception at least six months before. Participants with any of the following criteria were excluded from the study: having abortion within the past six months, having psychological or systemic disorders influencing sexual function, menopause, lactation, pregnancy, and food allergies, taking psychiatric and hormonal drugs and herbal products affecting sexual function, taking alcohol and tobacco. Moreover, the suspension criteria in this study were unwilling to continue, becoming pregnant during the study, and consuming <90% of the total administered supplements.

### 2.6. Intervention

The intervention group received a palm pollen capsule (300 mg) per day for 35 d. Also, each subject in the control group received placebo capsules daily. DPP was purchased from the palm lands of Khuzestan Province, Iran, and was used after verification (Herbarium code: 373846). Both palm pollen and placebo capsules were provided by the Pharmacy Laboratory of the Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, Iran. The starch powder was used to prepare the placebo capsules. The placebo was similar to the palm pollen capsules in appearance. At baseline, demographic information, including education, husbands' education, economic status, type of delivery (childbirth), history of infertility, having own bedroom, the job of participant and partner, ethnicity, language differences, housing, the age of the participant and her husband, gravida, the number of family members, duration of the marriage, and the amount of intercourse per week was collected by the researcher via a questionnaire. The participants were fully informed about the study's protocol. The subjects were asked to consume supplements regularly and record the time of supplement intake (Javid et al., 2019). To ensure that subjects consumed the supplement appropriately, participants were contacted every 5 d by a researcher.

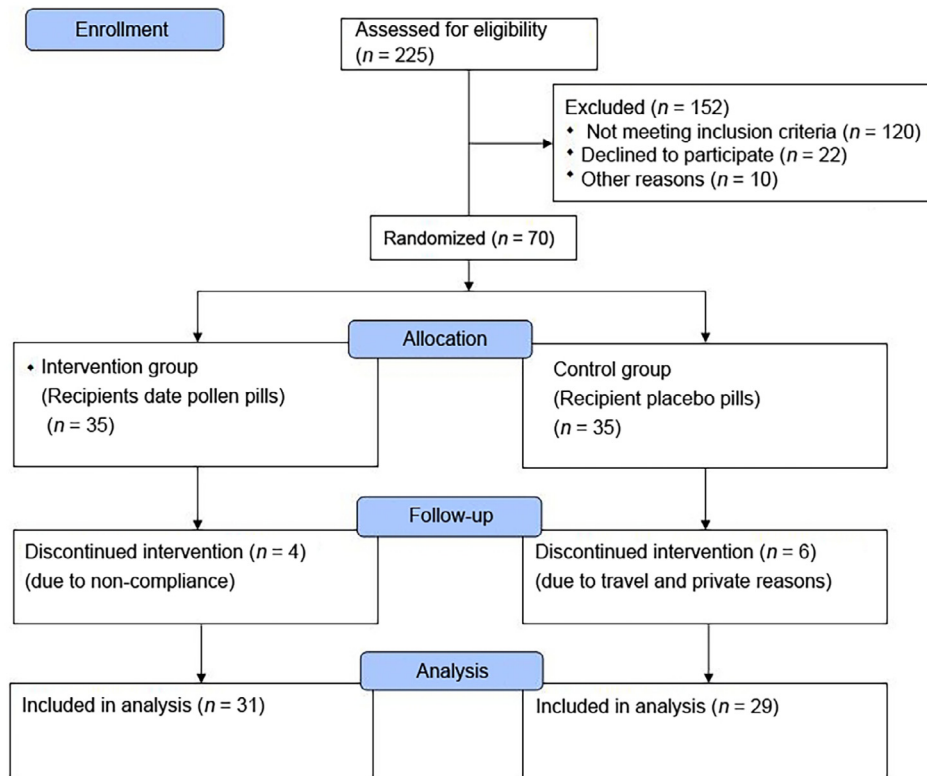


Fig. 1. CONSORT flow diagram of present RCT.

### 2.7. Female sexual function assessment

To assess sexual function, we applied the Persian translation of the female sexual function index (FSFI) at the baseline and the end of the trial; this instrument, developed by Rosen et al., is a multi-dimensional self-report instrument for the assessment of female sexual function (Rosen et al., 2000). The FSFI was normed and validated on a sample of women with clinically diagnosed female sexual arousal disorder (FSAD) (Heydari & Faghihzadeh, 2008). The FSFI contained 19 self-reported items and seven domains including desire (questions 1, 2), arousal (questions 3, 4, 5, and 6), lubrication (questions 7, 8, 9, and 10) orgasm (questions 11, 12, and 13), satisfaction (questions 14, 15, and 16), pain (questions 17, 18, and 19). The scale of each domain ranged from 0 or 1 to 5, and each domain score was attained by the summing of each domain questions scores and multiplied by the domain factor. Finally, scores of domains were summed to ascertain an overall score (2 to 36). Good reliability of the FSFI was shown by Rosen et al., with Cronbach's alpha = 0.82 and higher (Rosen, 2000). The CONSORT Flow Diagram of the present RCT is shown in Fig. 1.

### 2.8. Statistical analysis

The data were analyzed using SPSS version 24 (IBM SPSS Statistics, Armonk, USA). All the categorical and numeric parameters were displayed as a number (percentage) and mean (standard deviation), respectively. The Kolmogorov-Smirnov test was applied to determine the normality of variables. A chi-square test was used to compare the categorical data between treatment groups at the baseline. Independent sample *t*-test and Mann-Whitney test were applied to compare parametric continuous and nonparametric data between the groups, respectively. Paired sample *t*-test or Wilcoxon signed-rank test were used to compare

data within the groups. A *P*-value of <0.05 was, a priori, regarded to be statistically significant. We restricted the analyses to only those individuals who completed the intervention.

## 3. Results

The mean age of the total population was  $(37.24 \pm 4.92)$  years, and the demographic characteristics of the subjects in the study groups are presented in Table 1. Accordingly, no significant difference in any demographic characteristics was observed between the groups ( $P > 0.05$ ). As shown in Table 2, after DPP supplementation, the increase in desire and lubrication domains and the overall score were statistically significant compared to the placebo group ( $P = 0.002$ ,  $P = 0.000$ , and  $P = 0.042$ ; respectively), and the mean scores of other domains were not significantly different (arousal:  $P = 0.763$ ; orgasm:  $P = 0.370$ ; satisfaction:  $P = 0.474$ ; pain:  $P = 0.259$ ). Following 35 d of intervention, scores of all domains (except for pain domain) and overall scale, significantly improved in the intervention group compared to baseline ( $P < 0.05$ ). Although, in the placebo group, only changes in the desire and arousal domains were significant at the end of the study compared to baseline ( $P = 0.017$ ;  $P = 0.020$ , respectively) (Table 2).

Additionally, univariate general linear modeling was applied to control pre-intervention scores of each domain effect. Accordingly, no significant differences between the groups in endpoint domains and overall scores were evident, even after adjustment for pre-intervention scores of each domain effect ( $P > 0.05$ ), except for the lubrication domain ( $P = 0.04$ ).

There was a statistically significant positive correlation between the Coitus and preintervention levels of desire ( $P = 0.038$ ), arousal ( $P = 0.021$ ), lubrication ( $P = 0.011$ ), orgasm ( $P = 0.025$ ), satisfaction ( $P = 0.022$ ), and overall scores ( $P = 0.018$ ). (Table 3).

**Table 1**  
Baseline characteristics of participants by study group.

Variables	Intervention group (n = 31)	Control group (n = 29)	Statistical indicators <sup>c</sup>
<b>Education<sup>a</sup></b>	4	3	
Illiterate	(57.1)5	(42.9)8	
Guidance school	(38.5)15	(61.5)14	0.6
Diploma	(51.7)7	(48.3)4	
Post diploma	(63.6)	(36.4)	
<b>husband Education<sup>a</sup></b>	6	7	
illiterate	(46.2)8	(53.8)6	
Guidance school	(57.1)9	(42.9)8	0.94
Diploma	(52.9)8	(47.1)8	
Post diploma	(50.0)	(50.0)	
<b>Economic Status<sup>a</sup></b>	8	8	
Equal Income And expense	(50.0)16	(50.0)16	0.44
Income More Than Expense	(50.0)	(50.0)	
Income Less Than Expense	7 (58.3)	5 (41.6)	
<b>Type of delivery<sup>a</sup></b>	17	16	
NVD	(51.5)8	(48.5)7	
CS	(53.3)	(46.7)	0.92
NVD & CS	6 (50.0)	6 (50.0)	
<b>History of infertility<sup>a</sup></b>	2	1	
Yes	(66.7)29	(33.3)28	0.24
No	(50.9)	(49.1)	
<b>Own bedroom<sup>a</sup></b>	27	23	
has	(56.0)4	(44.0)6	0.56
has not	(40.0)	(60.0)	
<b>Job<sup>a</sup></b>	28	26	
Housekeeping Employee	(51.9)3	(48.1)3	0.86
(50.0)	(50.0)		
<b>husband Job<sup>a</sup></b>	1	0	
Unemployed manual worker	(100.0)3	(0.0)7	0.40
(30.0)11	(70.0)		
Employee	(55.0)14	9 (45.0)	
Marketing jobs	(53.8)2	12	
other	(100.0)	(46.2)0	
		(0.0)	
<b>Ethnic difference<sup>a</sup></b>			
Yes	3 (50.0)28	3 (50.0)	0.82
No	(51.9)	26	
		(48.1)	
<b>Language difference<sup>a</sup></b>	1	3	
Yes	(25.0)30	(75.0)26	0.22
No	(53.6)	(46.4)	
<b>Whats your relation to your spouse?<sup>a</sup></b>	7	4	
Family	(63.6)24	(36.3)25	0.31
(51.0)	(49.0)		
Stranger			
<b>Housing<sup>a</sup></b>	20	19	
Private home	(51.3)7	(48.7)7	
Rental home	(50.0)4	(50.0)3	0.46
Family home	(57.1)	(42.9)	
<b>Age<sup>b</sup></b>	37.54 (4.75)	36.88	0.62
		(5.19)	
<b>Husband Age<sup>b</sup></b>	43.77 (6.46)	41.50	0.19
		(6.38)	
<b>Gravida<sup>b</sup></b>	2.48 (0.92)	2.88	0.20
		(1.45)	
<b>Number of family members<sup>b</sup></b>	4.25 (0.85)	4.51	0.34
		(1.18)	
<b>Duration of marriage<sup>b</sup></b>	17.06 (5.77)	16.61	0.79
		(6.66)	
<b>Number of intercourses per week<sup>b</sup></b>	1.85 (0.76)	2.22	0.12
		(0.86)	

NVD: normal vaginal delivery; CS: cesarean section.

<sup>a</sup> Number (%).<sup>b</sup> Mean (standard deviation).<sup>c</sup> Independent t-test for numeric variables and Pearson Chi-Square test for categorical variables.**Table 2**  
FSFI domains scores of study groups at baseline and end of intervention.

Variables	Intervention group (n = 31)	Control group (n = 29)	P <sup>b</sup>
<b>Desire</b>			
Before	3.21 (1.02) <sup>a</sup>	3.31 (0.90)	0.701 <sup>b</sup>
After	4.54(0.60)	3.84 (0.80)	<b>0.001&gt;</b>
P <sup>c</sup>	<b>0.001&gt;</b>	<b>0.017</b>	
<b>Arousal</b>			
Before	3.32(1.13)	3.46(1.18)	0.654 <sup>b</sup>
After	4.21(0.75)	4.14(1.11)	0.763
P <sup>c</sup>	<b>0.001&gt;</b>	<b>0.020</b>	
<b>Lubrication</b>			
Before	4.15(1.07)	3.98(1.21)	0.591 <sup>b</sup>
After	5.02(0.70)	4.24(1.09)	<b>0.002</b>
P <sup>c</sup>	<b>0.001&gt;</b>	0.375	
<b>Orgasm</b>			
Before	4.10(1.18)	4.31(1.01)	0.478 <sup>b</sup>
After	4.77(0.68)	4.57(0.96)	0.370
P <sup>c</sup>	<b>0.004</b>	0.274	
<b>Satisfaction</b>			
Before	4.23(1.32)	4.54(1.07)	0.337 <sup>b</sup>
After	4.78(0.75)	4.60(1.12)	0.474
P <sup>c</sup>	<b>0.039</b>	0.783	
<b>Pain</b>			
Before	4.42(1.32)	4.00(1.08)	0.190 <sup>b</sup>
After	4.77(1.18)	4.00(1.31)	0.259
P <sup>c</sup>	0.71	0.230	
<b>Total Score</b>			
Before	23.45(5.89)	23.62(5.23)	0.908 <sup>b</sup>
After	28.11(3.46)	25.81(5.09)	<b>0.042</b>
P <sup>c</sup>	<b>0.001&gt;</b>	0.099	

P-values of statistical significance ( $P < 0.05$ ) are presented in bold.<sup>a</sup> Mean (standard deviation).<sup>b</sup> Independent Samples Test.<sup>c</sup> Paired Samples Test.**Table 3**  
Correlation between Coitus and preintervention FSFI domains scores and overall score.

Variables	r	P
Desire	0.298	0.038
Arousal	0.328	0.021
Lubrication	0.361	0.011
Orgasm	0.320	0.025
Satisfaction	0.327	0.022
Pain	0.011	0.943
Overall scores	0.338	0.018

Correlations were assessed using Pearson correlation coefficients.

P-values of statistical significance ( $P < 0.05$ ) are presented in bold.

#### 4. Discussion

This study highlighted that 300 mg DPP supplementation, for 35 d, in women using the IUD for contraception, led to a significant improvement in the desire and lubrication domains of FSFI and the overall score, as compared to the placebo group. A study by Sidi et al. found that lack of lubrication was the strongest predictor for sexual dysfunction; Indeed, sufficient vaginal lubrication is necessary for a healthy sexual response cycle (Sidi, Puteh, Abdullah, & Midin, 2007). Since the physiological reduction of estrogen and androgen during menopause leads to vaginal dryness and dyspareunia (Krapf, Belkin, & Goldstein, 2013), it was hypothesized that supplementation with DPP might reduce these menopausal symptoms due to the historical reports of the aphrodisiac properties of DPP. In Sadeghi et al study, supplementation of 350 mg DPP for 35 d contributed to improved vaginal lubrication and decreased

dyspareunia in menopausal women (Sadeghi Goghari et al., 2018). These effects could be due to the effect of DPP on the increase of sex hormones, such as estradiol, progesterone, and testosterone. Menopause in women initiates a period characterized by some changes caused by a physiological deficiency of estrogens. Vaginal epithelium undergoes thinning, the cells become flattened, their content of glycogen is reduced, and epithelial-connective papillae disappear (Sawczuk, Gołębiewska, Mazurek, & Chyczewski, 2017). Marbut et al. showed that 500 mg DPP powder supplementation for three months in 25 infertile men increased serum levels of LH, follicle-stimulating hormone (FSH), testosterone, and sexual desire; The authors concluded these effects might be due to the presence of steroid precursors in DPP (Marbut, Al-Snafi, & Marbeen, 2005). Moreover, the conception of the treated men wives increased, a result that could be attributed to the improvement of sexual desire and semen quality. DPP is rich in flavonoids, alkaloids, sterols, and steroids, all of which can enhance and regulate sexual behavior (Abedi, Karimian, Parviz, Mohammadi, & Roudsari, 2014; Tahvilzadeh, Hajimahmoodi, & Rahimi, 2016). Alkaloids in DPP have ergogenic properties that can induce vasodilatation of blood vessels, which occurs in erection and sexual response (Gauthaman & Ganesan, 2008).

DPP administration, as a dopamine agonist, can also increase dopamine-releasing from the accumbance nucleus. As previously mentioned, DPP can raise the plasma levels of sex hormones such as testosterone and estradiol. These hormones induced dopamine release through increasing nitric oxide (NO) synthesis, which can stimulate catecholamine release and prevents its reuptake (Orshal & Khalil, 2004). Subsequently, DPP can facilitate sexual function, including desire, arousal, and orgasm (Abedi et al., 2014; Baldwin & Mayers, 2003). Administration of DPP contributed to improve sexual arousal due to further increases in dopamine release, where the authors attributed these effects of DPP to the presence of steroids, alkaloids, and flavonoids (Abedi et al., 2014). Dopamine has a pivotal role in sexual parameters as it raises intromission frequency (IF) and decreases intromission latency (IL) and mount latency (ML) (Abedi et al., 2013). Dopamine can affect motor activity in the mesolimbic tract and facilitates several sexual behavior and genital stimulation. Historically, the sexuality-enhancing effect of dopamine in humans was first confirmed in Parkinson's patients treated with Levodopa (L-DOPA), where Levodopa administration improved libido and sexual activity (Giuliano & Allard, 2001).

Karimi Jashni et al. evaluated the effects of Palm pollen extract administration for 21 consecutive days on induced- polycystic ovary syndrome (PCOS) in rats. Accordingly, the authors observed that 400 mg/kg palm pollen extract minimized the number of cystic follicles and increased the number of corpus luteum. The authors noted improvement in hormonal and histological may be related to the antioxidant properties of the extract (Karimi Jashni, Kargar Jahromi, & Bagheri, 2016). The results of researches showed that levels of reactive oxygen species (ROS) in ovarian tissue are raised in PCOS and the balance between oxidant and antioxidant system is interrupted (Shirsath, Aundhakar, & Kamble, 2015). Oxidative substances and free radicals weaken regular growth and apoptosis in Theca interstitial layer. This layer is necessary for normal ovarian function (Sohrabvand, Shirazi, Shariat, & Mahdiyin, 2013). A direct association between reduced oxidative stress and elevated maturation of oocytes is indicated in women with infertility and PCOS. So antioxidants administration can modify PCOS symptoms by a decrease in oxidative stress (Chattopadhyay et al., 2010; Karadeniz et al., 2008).

One of the principal limitations of this study was that we were unable to directly measure the sex hormones due to funding complications. Because Orgasmometer-F was not validated in the Iranian population, we couldn't use it in the present study.

Moreover, due to a lack of available clinical trials, we applied DPP extract dose and study duration based on a prior study, which could have contributed to null-effects being observed in some factors. Although the participants were followed by the researcher every 5 d, we still had 10 participants lost to attrition. Despite these limitations, our results were strengthened by the robust double-blinded method. Furthermore, to the best of our knowledge, this RCT is the first to have evaluated the effect of the DPP capsules on female sexual function in non-menopausal women. Further researches with more study duration and using other tools, such as Orgasmometer-F are needed. Also, further researches are needed to determine the effect of DPP on sex hormones. Finally, during the intervention, no adverse effects were reported by participants.

## 5. Conclusion

We found that 300 mg DPP supplementation for 35 d in non-menopausal women could improve the lubrication and desire domains of FSFI. Thus, DPP as an effective, cheap, and safe therapeutic agent seems to improve sexual function in non-menopausal women.

## Authors' contributions

R S., V A. and contributed to the conception and design of the study and the study protocol. K N., R S. and Y J. managed the running of the study. V A. and K N. conducted data analysis and all authors helped with data interpretation. V A., C.C. and R S. wrote this manuscript with input from all co-authors. All authors read and approved the final version of the manuscript.

## Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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