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Placebo-controlled effect of topical Qust (Costus) oil on postmenopausal women's sexual desire disorder: a double-blind, randomized clinical trial

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Abstract

Decreased libido and anorgasmia are common problems for women after menopause that reduce the quality of life of couples. This study examined the effect of topical Qust oil on sexual desire disorder in postmenopausal women. In this double-blind, randomized, clinical trial, 110 postmenopausal women with decreased sexual desire visiting a Traditional Medicine Center and Hazrat Rasool Akram Hospital (affiliated to Iran University of Medical Sciences) were selected by convenience consecutive sampling and randomly assigned to experimental and control groups. The experimental group received qust oil, while the control group was given a placebo (liquid paraffin); they were instructed to massage the product topically on their pubic area and perineum daily. The sexual function of both groups was assessed and compared before the intervention and four weeks after the intervention using the Female Sexual Function Index. The mean and standard deviation of the improvement of sexual function post-intervention were 37.66±32.52% and 11.96±11.18% in the experimental and control groups, respectively ($p<0.001$). In terms of the improvement of components of sexual function, a significant difference was observed between the two groups in the sub-scales of sexual desire [57.05±42.99% *vs.* 21.25±27.85%, $p<0.001$], arousal, orgasm, and satisfaction ($p<0.001$ for all); however, no significant difference was observed in terms of lubrication ($p=0.25$) and pain during intercourse ($p=0.776$). In postmenopausal women with sexual dysfunction, massaging the pubic area and perineum with qust oil for at least four weeks significantly improves desire, arousal, orgasm, and sexual satisfaction.

Key Words: sexual desire, menopause, costus oil, Persian medicine.

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Most women spend more than a third of their life with menopause, and the population of postmenopausal women in the world will increase to 1,000,300,000 by 2030[1]. Hot flashes, circadian rhythm disorders, mood disorders such as decreased concentration, depression and anxiety, tachycardia, headache, musculoskeletal pain, and sexual disorders are common problems during menopause[2]. The onset of menopause is associated with changes in sex hormones, including a decrease in estrogen, increase in FSH (Follicle-Stimulating Hormone), decrease in LH (Luteinizing Hormone) and consequently a decline in progesterone and cessation of menstruation[3]. Despite the numerous advances in the prevention and treatment of menopause complications, decreased libido and anorgasmia are still among the most common problems experienced by postmenopausal women that can decrease their quality of life[4]. Sexual functioning is an important component of quality of life[5]. The high prevalence of sexual dysfunction, its undeniable impact on marital disputes and the ensuing social problems, and the patients' refusal to discuss their sexual problems out of shame highlight the need to delve deeper into this subject[6].

The prevalence of sexual dysfunction is reported to be about 72% in postmenopausal women in Iran, with 75% affecting the women's arousal and 62% their desire[7]. Sexual dysfunction leading to divorce has been reported to be about 40% in Iran. Meanwhile, lack of sexual satisfaction can lead to problems such as depression and deterioration of the family's mental health[8]. Sexual responses and desires are multifactorial, influenced by psychological, social, environmental, and learned factors. Sexual dysfunction is often accompanied by other psychological disorders such as anxiety, depression, personality disorder,

and schizophrenia[4]. Currently, two modalities, namely sex therapy and drug therapies, are used to treat female sexual dysfunction[9]. Drug therapies include estrogen and testosterone compounds and anti-anxiety and anti-depressant medications, which have side effects and may interact with other drugs taken by the patient during menopause[10]. The American Endocrine Society has recommended against excessive prescription of androgens for treating female sexual problems, citing side effects such as increased risk of breast cancer and cardiovascular diseases[11]. In traditional medicine references, the reasons for poor sexual desire include weaknesses of the main body organs (heart, brain, and liver)[12]. The corroboration of the comorbidity in the increased prevalence of sexual dysfunction and psychological problems based on new statistical studies is somewhat aligned with this view held by traditional medicine[13]. The treatments mentioned in accessible sources of traditional medicine include a wide range of commonly-used substances, from libido-enhancing single ingredients to compounds containing numerous elements. Despite the increasing availability of effective conventional medical treatments, herbal remedies continue to be a popular alternative for men and women looking to improve their sexual functioning. Nevertheless, the efficacy of most herbal agents in treating sexual problems remains unclear[14]. Out of the proposed treatments, this study examines a simple and accessible drug that can be used topically to avoid interfering with the drugs used by postmenopausal women, who are often middle-aged and might be taking multiple drugs to manage other chronic diseases. Oil massage has been mentioned in many references of traditional medicine as a mechanism for stimulating sexual desire[15]. Qust (Costus) oil is derived from Iranian books of traditional medicine. It contains bitter qust root, Chinese cinnamon, marjoram, valerian root, cloves, nutmeg fruit, *Acorus calmus* root, *Ferula gummosa* gum resin, olive oil, grape vinegar, and water[15]According to traditional medicine, this product is *muhalal* and *musakhan* and a tonic for the nerves, organs, and sexual desire[15]When topically used, simple qust oil, which is the main part of this product, is a tonic for the nerves, organs, and sexual desire, a strong *muhalal* and reliever of melancholic and phlegmatic fever and chills[15]Although it is mostly used to strengthen the nerves and organs, it was chosen in this study due to the effects of its constituent plants on sexual desire.

Materials and Methods

This was a double-blind, randomized, clinical trial on postmenopausal women aged 40-65 years with sexual dysfunction visiting a traditional medicine center and Hazrat Rasool Akram Hospital, affiliated to Iran University of Medical Sciences.

Sample size was calculated based on type-I error of 0.05 and study power of 80%. Since there was no information about the effect of this drug, and assuming the equality of the standard deviation (SD) of changes in sexual desire in the two groups, the effect size index and Cohen's formula were used to determine the sample size, and the effect size was taken as 0.6.

$$n = \frac{2\left(\frac{Z_\alpha + Z_\beta}{2}\right)^2}{d^2} \quad d = \frac{\mu_1 - \mu_2}{\sigma}$$

The sample size was thus estimated as 44 per group. After adding 20% attrition, the required sample size was increased to 55.

Inclusion criteria

Menopause (at least 1 year since the last menstruation), age 40 to 65 years, complaining of decreased sexual desire, having an emotionally satisfying relationship with a stable and sexually active husband within at least the last 6 months, normal pelvic examination, and providing informed consent for participation in the study.

Exclusion criteria

Vaginal infection, vaginal bleeding, a serious physical medical condition or chronic illness requiring constant care, consuming any chemical or herbal medicines known to affect sexual desire, smoking, or any substance abuse.

Attrition criteria

Breakdown of the satisfactory emotional relationship with the husband during the study, unwillingness to continue participating in the study, using other treatments for sexual dysfunction or other problems during the study, low compliance or adherence to instructions, and developing skin allergy or other intolerable complications.

The participants were selected from eligible women using convenience consecutive sampling. After explaining the objectives of the study, the women who were willing to participate first reported their age, age of marriage, education level, and sexual functioning. Then, by block randomization, they were randomly assigned to the experimental or control groups.

In the experimental group, qust oil (Tooba Company) was delivered to the patients, who were instructed to massage 20 drops on the pubic area, twice a day for 4 weeks, in a back and forth motion for 5 minutes (superficial and without pressure) and 3 drops on the perineum for 1 minute in a circular motion. In the control group, liquid paraffin (manufactured by Merck) was delivered to the patients, who were instructed to massage 20 drops on the pubic area, twice a day for 4 weeks, in a back and forth motion for 5 minutes (superficial and without pressure) and 3 drops on the perineum area for 1 minute in a circular motion. Both groups were followed up by phone every week to monitor their regular use of the drugs and to check any side effects. At the end of the fourth week, the two groups were again examined in terms of sexual functioning and severity of menopausal symptoms. The primary outcome was change in sexual desire, and the secondary outcome was arousal, lubrication, orgasm, satisfaction, pain during intercourse, and overall sexual function, as evaluated by the FSFI four weeks after the start of the intervention[14].

Data analysis

SPSS v. 27 was used for the data analysis. Chi-square test and Fisher's exact test were used in order to compare the

two groups in terms of qualitative variables (education level, occupation, and complications). In order to compare the group in terms of sexual functioning, the normality of the data distribution was first checked using the Kolmogorov-Smirnov test. Based on the test result and rejection of the null hypothesis of normal data distribution, Mann-Whitney U test was used to compare the two groups. The significance level was set at 95% (P<0.05).

Results

Among 120 postmenopausal women with sexual dysfunction, ten were excluded due to not meeting the inclusion criteria, and 110 women were included in the study in two groups of 55. Three women from the experimental group and six from the control group dropped out during the study. Finally, 52 women in the experimental group and 49 in the control group remained until the final analysis (Figure 1).

The mean and SD of the age of the participants was 54.35±5.06 years (range: 43-65 years) and the duration of marriage was 31.66±8.21 years (range: 1.47 years). In terms of education level, in both experimental and control groups, most of the participants had a high school diploma, followed by higher education. In terms of occupation, in both groups, most women were homemakers. No significant difference was observed between the experimental and control groups in terms of occupation and education level (Table 1).

There was no significant difference between the two groups in terms of sexual function before the treatment, except for satisfaction. The level of sexual satisfaction of the women was significantly lower in the experimental compared to the control group (p=0.039). After the intervention, significant differences were observed between the experimental and control groups in sexual functioning in the domains of sexual desire (p<0.001), arousal (p<0.001), orgasm (p<0.001),

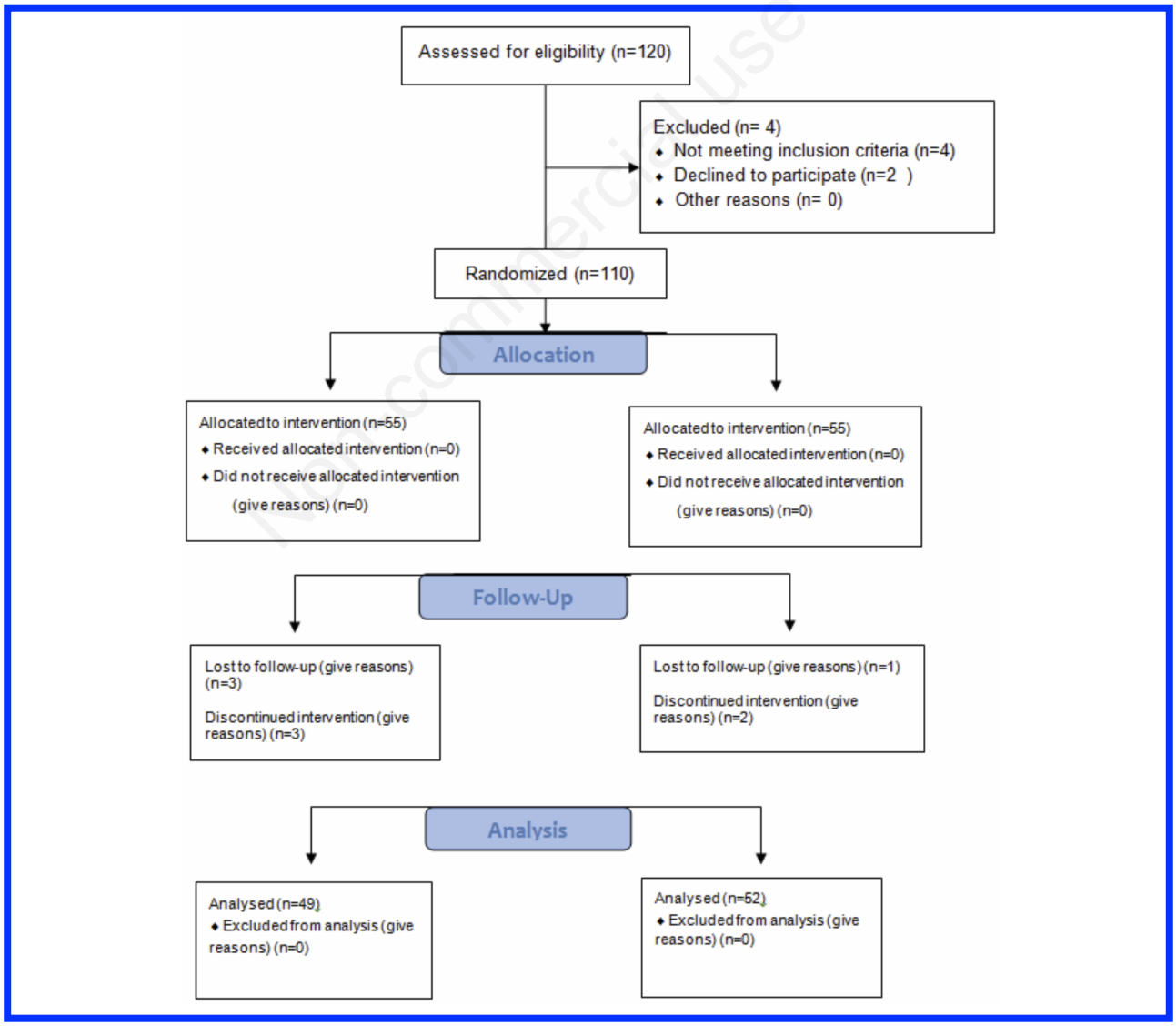

Figure 1. *CONSORT diagram of sample selection.*

satisfaction, and overall score (p<0.001). Meanwhile, no significant difference was observed in lubrication and pain during intercourse (Table 2, Figure 2).
One woman (2.0%) from the experimental group had complications (hives), which improved with oral treatment. No complications were observed in the control group. No significant difference was observed between the two groups in the frequency of complications (p=0.485).

Discussion

In the present study, the topical use of qust oil by postmenopausal women with sexual dysfunction for four weeks significantly increased sexual desire, arousal, orgasm, satisfaction, and overall sexual functioning; however, no significant difference was observed in lubrication and pain during intercourse. The researchers' search of electronic databases yielded no relevant or similar papers that had used

Table 1. *Frequency of the participants' education level and occupation divided by group.*

Variable	Group		P-value
	Experimental number (%)	Control number (%)	
Education level			
Below high school diploma	5 (9.6)	9 (18.4)	0.302
High school diploma	28 (53.8)	20 (40.8)	
Associate or bachelor's degree	9 (17.3)	13 (26.5)	
Master's degree or higher	10 (19.3)	7 (14.3)	
Total	52 (100)	49 (100)	
Occupation			
Homemaker	33 (63.5)	35 (71.4)	0.120
Self-employed	7 (13.5)	1 (2.0)	
Governmental employment	12 (23.1)	13 (26.5)	
Total	52 (100)	49 (100)	

Table 2. *The mean and standard deviation of the pre-intervention sexual functioning score by group.*

Variable	Group		P-value
	Experimental Mean±sd	Control Mean±sd	
Pre-intervention			
Desire	1.47±4.23	1.45±3.76	0.103
Arousal	3.08±7.40	2.74±8.73	0.283
Lubrication	2.73±9.47	2.95±9.68	0.667
Orgasm	2.28±7.07	2.72±6.65	0.293
Satisfaction	2.48±7.44	2.57±6.44	0.039
Pain during intercourse	2.71±8.03	2.54±7.67	0.380
Overall	11.59±44.67	13.51±41.94	0.277
Post-intervention			
Desire	1.31±6.13	1.53±4.41	0.001>
Arousal	2.42±12.37	2.80±7.80	0.001>
Lubrication	2.19±11.85	3.20±11.14	0.250
Orgasm	1.64±9.21	2.52±6.37	0.001>
Satisfaction	1.66±10.08	2.24±7.32	0.001>
Pain during intercourse	2.71±8.92	2.21±8.80	0.776
Overall	8.44±58.83	11.84±45.84	0.001>

**Mann-Whitney U test.*

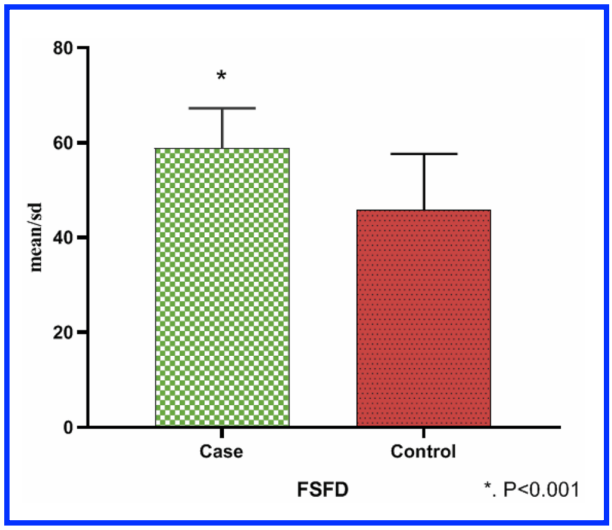

Figure 2. *The mean and standard deviation of the post-intervention overall score of sexual functioning by group.*

qust oil topically to treat women's sexual dysfunction. Two human studies, *i.e.*, carried out by Sadeghi *et al.* (2020) on the oral effect of carrot seed and by Akhtari *et al.* (2014) on the effect of *Tribulus terrestris* extract on reduced sexual desire in women of reproductive age, reported favorable results in terms of increasing libido[14, 16]. Similarly, two human studies were conducted by Preedy *et al.* (2021) and Akbar e*t al.* (2020) on the effect of olive oil and valerian (a component of qust oil), respectively. Preedy *et al.* (2021), who examined the effect of olive oil on physical health, observed that short-term massaging with olive oil can increase sexual desire[17]. Akbar *et al.* (2020) examined the effects of *Valeriana jatamansi* and found that the root of this plant increases libido while reducing anxiety, depression, seizures, headaches, and menstrual cramps[18] In-vitro animal studies have investigated the medicinal effects of qust oil or each of its components separately, yielding promising results[19-22].Muchtaromah (2020) examined the combined protective and therapeutic effects of three herbs, including garlic, turmeric, and *A. calmus* (a component of qust oil), on mice. This combination increased the animal subjects' endometrial thickness, secretion of sex hormones, and fertility[19] . Mehanna *et al.* (2020) examined the oil extract of marjoram (a component of qust oil) and observed that with its strong antioxidant effects, this substance increases spermatogenesis and testosterone levels in male rats suffering tissue damage and necrosis of the testicular cells[20]. Mishra *et al.* (2016) examined clove extract (a component of qust oil) and showed that its administration at low doses (15 mg) has androgenic effects, increases testosterone levels, and rejuvenates sex genes[21]. As can be observed, each component of qust oil has been examined in human and animal studies, showing androgenic effects and influencing the sex hormones, testosterone levels, fertility, and sexual function. Our study was conducted on a human sample, and instead of examining the individual effects of the mentioned medicinal plants, we studied their combined effect (valerian, marjoram, cloves, *F. gummosa*, olive, nutmeg, *A. calmus*, bitter qust, and Chinese cinnamon) through a product known as qust oil, which significantly improved the sexual functioning of postmenopausal women; it can be argued that these substances have had a synergistic effect.

Another difference between the present study and most of the cited studies was the different method of qust oil administration (topical use via massage versus oral use). Regarding the positive effect of massage therapy on sexual desire, Chia *et al.* (2011) examined the therapeutic effect of massage on sexual desire and reported that massaging the pubic area increases libido and sexual desire.[22] Therefore, the therapeutic effects of qust oil alone in sexual dysfunction and its massaging on the pubic area may increase the effectiveness of this compound. Meanwhile, this route of administration will have no side effects potentially arising through oral consumption. As for other uses of qust oil, the results of studies have shown that rubbing qust oil on the pubic area is effective in treating bed wetting in children[23]and urinary incontinence in women[24]. In two review studies and meta-analyses, Karimi *et al.* and Zalchour *et al.* investigated the effect of medicinal plants on sexual functioning. The review study by Karimi *et al.* (2023) in Iran carried out a systematic review of clinical trials to investigate the effect of medicinal plants on sexual functioning in Iranian postmenopausal women. The studied plants included *Ginkgo biloba*, fennel, *Hypericum perforatum*, date palm pollen, Aphrodite, fenugreek, common hop, black cohosh, lavender, ginseng, saffron, red clover, *T. terrestris*, *Nigella sativa,* and *Vitex agnus-castus*, and combined aromatherapy (fennel, *Heracleum persicum*, common sage, bitter orange, lavender, and geranium). The results showed that most plants were effective in improving sexual functioning[25]. In a review and meta-analysis by Zalchour *et al.* (2023), the effect of medicinal plants on the sexual functioning and satisfaction of postmenopausal women in Iran and other countries was investigated. The meta-analysis showed that herbal medicines significantly increase the overall sexual functioning score and the sexual satisfaction score of postmenopausal women[26]. To investigate the pharmacological and phytochemical properties of qust oil, Kumari *et al.* (2024) carried out a phytochemical analysis of the product in India and showed that *Saussurea costus* (Falc) Lipsch contains a large number of bioactive compounds, including sesquiterpenes, flavonoids, and essential oils, which are responsible for its numerous medicinal properties. Pharmacological studies have shown anti-inflammatory, antioxidant, anti-cancer, hepatoprotective, and immune-modulating effects for this product. As a result, it is widely used in the treatment of diseases such as asthma, digestive disorders, and skin diseases. *S. costus* has significant therapeutic potential, mainly owing to its rich phytochemical composition. The convergence of its traditional uses and modern pharmacological findings offers promising avenues for future research, especially in drug development and understanding its mechanism of action in various diseases[27].According to the study by Bahrami *et al.* (2018) on the characteristics of thick vessels, energy channels, meridians, and

chakras, it can be concluded that massaging and stimulating the second pair of the thick vessels lead to connection and balance of the cephalo uterin axis and favorable results in the treatment of decreased sexual desire[28]. In the present study, no complications (itching, rash, burning, or hives) were observed as a result of qust oil massaging on the pubic and perineal area, which suggests the safety of the topical use of qust oil to treat sexual dysfunction in postmenopausal women.

Conclusions

In postmenopausal women with sexual dysfunction, massaging the pubic area and perineum with qust oil for at least four weeks has no side effects and significantly improves the components of desire, arousal, orgasm, and sexual satisfaction.

List of abbreviations

FSFI, Female sexual function index
FSH, Follicle-Stimulating Hormone
LH, Luteinizing Hormone

Conflict of interest

The authors declare no potential conflict of interest, and all authors confirm accuracy.

Ethics approval

The Ethics Committee of Iran University of Medical Sciences under the code of ethics IR.IUMS.REC.1402.378 . The Iranian Registers of Clinical Trial (lRCT) code IRCT 2023730058969NI. The study is conformed with the Helsinki Declaration of 1964, as revised in 2013, concerning human and animal rights.

Informed consent

All patients participating in this study signed a written informed consent form for participating in this study.

Patient consent for publication

Written informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

Availability of data and materials

all data generated or analyzed during this study are included in this published article.

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