

The effect of hydro-alcohol extract of *Tribulus terrestris* on sexual satisfaction in postmenopause women: A double-blind randomized placebo-controlled trial

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ABSTRACT

Introduction: Increasing life expectancy in women and having menstrual problems and hormone-associated complications have led people to use complementary and alternative medicine. In menopause, the reduction in estrogen and androgen physiologically leads to a decrease in blood flow in the vulvuleous and vaginal zone, resulting in a reduction in sexual desire and arousal. Sexual satisfaction plays an important role in mental health. The aim of this study was to investigate the effect of *Tribulus terrestris* on sexual satisfaction in postmenopausal women. **Methods:** This double-blind clinical trial was conducted in 2017 with the aim of investigating the effect of hydro-alcohol extract of *T. terrestris* on sexual satisfaction of postmenopausal women on 60 women referred to health center number 1 in eastern Ahvaz. A total of 60 postmenopausal women were randomly assigned into two groups of 30 to receive a syrup containing *T. terrestris* extract at a concentration of 0.9 mg and placebo for 8 weeks. Sexual satisfaction was calculated based on Larsson questionnaire. Data were analyzed by SPSS software (version 22) and *t*-test was used for comparing two groups in quantitative variables and Chi-square test was used for qualitative variables. *P* value less than 0.05 was considered significant. **Findings:** After intervention, the mean of sexual satisfaction in the intervention group was significantly higher than in the preintervention group ($P < 0.005$), and a significant increase in sexual satisfaction was observed in the tetanus syrup group. **Results:** Taking *T. terrestris* syrup increased sexual satisfaction in postmenopausal women.

Keywords: Menopause, sexual satisfaction, *Tribulus terrestris*

Introduction

Woman is one of the most important members of both families and society, and the health of both family and society is based on meeting women's medical, cultural, and economic needs.^[1] Quite a lot has been said about women's personality and social value. Women have a variety of important role and responsibilities in

the family and society. Fulfilling these roles and responsibilities call for having complete physical and mental health. Women go through various crises in her life and throughout her development stages. Women's crises in life including maturity, menstruation, sexual intercourse procedure, pregnancy, delivery, and menopause are interdependent on one another like the rings of a chain, and women's mental and even physical health is inevitably dependent on them.^[2] Throughout their lives, women are dealing with special issues arising from their natural and

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physiological conditions including menopause.^[3] Menopause is the most important event for middle-aged women. It is of significant personal, cultural, and social importance, and since women spend one-third of their lives after menopause, it is of special significance as one of the health issues of reproductive health.^[4] The population of postmenopausal women will have reached 1 billion by the year 2030.^[5] In Iran, the Management and Planning Organization has predicted that by the year 2021 as many as 5 million people will be in menopausal age.^[6] With the end of fertility in women, numerous changes will occur in their hormonal, physical, and metabolic processes that have significant effects on postmenopausal women's quality of life and health.^[7] In menopausal stage, most of the women experience changes that are likely to lead to reduced estrogen as a result of sensual and blood flow changes.^[8] In postmenopausal women who are sexually active, vaginal atrophy is less than that of women without sexual activity.^[9] Masters and Johnson maintain that sexual activity is of great importance for postmenopausal and even elderly women.^[10] In comparison to other women, women who pay less attention to their postmenopausal sexual intercourses and have less sexual intercourses are more likely to suffer from vaginal dryness and atrophy, and they are personally more isolated than others.^[9] Lexically speaking, sexual satisfaction refers to the individual's pleasant feeling from sexual intercourse. A high level of sexual satisfaction will result in an increased quality of marital life leading to marital stability throughout life.^[11] Sexual satisfaction includes the individual's judgment of his or her sexual behavior that he or she assumes to be pleasurable.^[12] According to Freud, satisfaction is a mental feeling and experience that can be identified through behaviors such as facial expression and gestures or physiological indicators such as heart beat changes, blood pressure, and post-sex relaxation that express the satisfaction more properly.^[13] Some degrees of sexual satisfaction have to do with the good or poor sexual performance of women; most of the studies indicate that sexual desire and arousal disorders are closely related to women's sexual dissatisfaction.^[14] According to World Health Organization, sex is not the same as sexual intercourse, and its aim is not merely experiencing orgasm. Sexual intercourse and its importance in marital life is more important than a physical relationship. Sexual intercourse is a kind of energy that arouses the individuals to establish love, emotion, and intimacy between one another. Sexual intercourses of marital life are sensual as they are sexual and physical.^[15] In the past, hormone replacement therapy was the selected treatment for improving menopausal symptoms.^[16] Despite the advantages of hormone therapy for postmenopausal women, the findings of the researches in this regard indicate that these methods are not completely harmless.^[17] This has made the researchers search similar drugs with fewer complications.^[18] Alternative medicine is one of the therapeutic methods that is now of significant popularity among postmenopausal women. One of the methods used in alternative medicine is herbal medicine.^[18,19] Different kinds of plants have long been used for the treatment of different kinds of disease. Nowadays, as many as 60% of the world population use medicinal plants for the treatment of their diseases.^[20] At present, as much as 25% of the drugs

prescribed by doctors contain herbal combination that have fewer complications than other kinds of drugs.^[21] One of the plants that has been introduced to improve the sexual performance is *Tribulus terrestris*.^[22] *T. terrestris* is an annual herbaceous plant.^[23] This plant and its various products are widely used in Indian and Chinese traditional medicine for the treatment of various chronic diseases including urinary system and cardiovascular diseases, gastrointestinal disorders, and improving male sexual performance.^[22,24] This plant is known as an Aphrodite plant that brings about spermatogenesis and increased testosterone by having estradiol.^[25,26] The study conducted by Carlos *et al.* (2014) in Brazil indicated that *T. terrestris* is effective for the treatment of female sexual dysfunction at reproductive age and increases the dehydroepiandrosterone sulfate levels.^[27] Moreover, the study conducted by Postigo *et al.* (2016) in Brazil indicated that a 3-month consumption of pills containing *T. terrestris* was proved to be effective on the sexual problems of postmenopausal women and resulted in improved lust and sexual desire.^[28] Since providing preventive healthcare services and medicinal interventions in the menopausal age can offer more healthy years for women and promote their quality of life.^[29] Moreover, given the findings of some clinical trials conducted on the effectiveness of *T. terrestris* on men's sexual performance and women's improved sexual interest in menopausal age, this study was conducted to investigate the effectiveness of *T. terrestris* on postmenopausal women's sexual performance and satisfaction.

Materials and Methods

This double-blind randomized placebo-controlled trial was conducted in 2017 on 60 postmenopausal women referred to health center number 1 in eastern Ahvaz with their husbands to conduct premarital tests. The inclusion criteria of this study are as follows: women who had passed 1–5 years since their last menstruation; women whose menopause was natural; women who were married; and women with the ability of reading and writing. The exclusion criteria of this study include the following: body mass index (BMI) of 30 kg/m² and higher; using hormone therapy over the past two months; consuming alcohol or drugs; using herbal supplements or phytoestrogens; taking antidepressants or similar drugs; having any kind of mental or psychological diseases; the history of breast cancer in the participants or family members; and having Pap smear or abnormal mammography at the time of referral. After acquiring the permission needed from Ahvaz Jundishapur University of Medical Sciences (code of ethics: IR. AJUMS. REC.1395.519), registering the website of the Iranian Registry of Clinical Trials (IRCT2016121131340N1), and making the coordination needed with health center number 1 in eastern Ahvaz, the postmenopausal women were invited to participate in the study. The postmenopausal women who were willing to participate in the study and qualified to enter the study were asked to fill out informed consent letter to participate in the study, demographic information questionnaire, and sexual satisfaction questionnaire. These individuals were selected as samples of the study. The drug used in this study was supplied

by the Faculty of Pharmacy of Ahvaz Jundishapur University of Medical Sciences. Since this study was double-blind, the drugs used in this study were coded by a third party unaware of the subject of the research and type of drugs. For preparing the drug, the dried fruit extract of *T. terrestris* was bought. For preparing a syrup with concentration of 0.9%, first the hydro-alcohol extract of *T. terrestris* was measured and weighed and heated at 75°C. Then, sodium benzoate was added as a preservative, and as much as 30 mL of water was added so that it can be dissolved. Then, a sufficient amount of sugar was added, so that it could be dissolved. Now, a sufficient amount of the formulated water was poured into another container, and some citric acid was added. Citric acid was mixed until it was completely dissolved. The extract was then added to be completely dissolved. When the container containing the syrup reached the room temperature, the second container was added to the first one. In the end, it reached the intended volume using distilled water. For preparing the placebo, all the above-mentioned stages were conducted, but there was no *T. terrestris* extract. Instead, a filling material such as mannitol or calcium carbonate was used instead of *T. terrestris*. The medicinal packages were randomly distributed among the samples. The samples were randomly assigned into two groups: intervention group (receiving *T. terrestris* extract at a concentration of 0.9 mg) and control group (placebo). The samples used the coded drugs for 8 weeks twice a day. At the end of the eighth week, the samples were provided with the sexual satisfaction questionnaire. Throughout the study, the samples were followed by the researcher by making phone calls in terms of reminding them to take the drugs, the incidence of side effects, awareness of their unwillingness to continue cooperation, and responding their questions. The data collected were then analyzed using Statistical Package for the social sciences (IBM Company in Chicago, USA, 2009). For analyzing the data collected, the demographic variables applied central tendency indicators and distribution such as mean and standard deviation for all the questions of the questionnaire as well as research variables. Moreover, at the inferential level, *t*-test was used for comparing the two groups in terms of the quantitative variables, and Chi-squared test was applied for comparing the two groups in terms of qualitative variables.

Findings

In this study, the two groups were not significantly different in terms of sociodemographic characteristics ($P > 0.05$). According to Table 1, the mean age of *T. terrestris* and placebo groups was 1.8 ± 52.53 and 1.8 ± 51.55 years, respectively. Moreover, the mean age of menopause was 1.71 ± 48.28 years in the *T. terrestris* group and 2.26 ± 47.51 years in the placebo group. The mean BMI of *T. terrestris* and placebo groups was 12.85 ± 26.4 and 2.49 ± 26.0 kg/m², respectively. The frequency of sexual activity was 1.15 ± 2.82 in the *T. terrestris* group and 1.29 ± 2.74 for the placebo group. Other characteristics are presented in Tables 1 and 2.

The mean score of sexual satisfaction of individuals consuming *T. terrestris* syrup was 34.8 ± 4.25 before the intervention, while it was 37.56 ± 6.65 after the intervention [Table 3]. The

Table 1: Demographic characteristics of the individuals studied in the two groups of the study

Demographic indicator	Group (mean±SD)		P
	<i>Tribulus terrestris</i> group	Placebo group	
Age	1.8±52.53	1.8±51.55	0.056
Weight (kg)	12.66±80.71	11.35±78.62	0.524
Height (cm)	9.66±154.2	9.01±150.5	0.157
BMI	12.85±26.4	2.49±26.0	0.866
Age of marriage	1.88±14.00	1.67±13.77	0.646
Number of children	2.06±4.14	1.69±4.22	0.877
Menopausal age	1.71±18.28	2.26±47.51	0.161
Number of sexual intercours	1.15±2.82	1.29±2.74	0.808
Husband's age	10.12±66.07	8.84±62.81	0.210
Age difference with one's husband	10.17±13.53	9.25±11.25	0.390

SD: standard deviation; BMI: body mass index

Table 2: Demographic characteristics (qualitative) of the individuals studied in the two groups

Demographic indicator	Group Frequency (%)		P
	<i>Tribulus terrestris</i> group	Placebo group	
Educational level			
Academic	1 (1)	0 (0)	0.453
High school diploma	10 (3.8)	6 (5.7)	
Junior high school diploma	11 (10.5)	12 (11.4)	
Elementary school	6 (5.7)	9 (8.6)	
Occupational status			
Housewife	24 (22.9)	24 (22.9)	0.913
Employed	1 (1)	1 (1)	
Retired	3 (2.9)	2 (1.9)	

Table 3: Comparison of sexual satisfaction before the intervention and 8 weeks after the intervention in *Tribulus terrestris* and placebo groups

Sexual satisfaction scores	Group (mean±SD)	
	<i>Tribulus terrestris</i> group	Placebo group
Before the intervention	25.4±8.34	35.2±6.50
After the intervention	37.56±6.65	36.34±6.23
Level of significance	0.001	0.197

SD: standard deviation

postintervention score was significantly higher than that of preintervention ($P < 0.05$), and it was measured based on the *t*-test [Figure 1].

Discussion

In this study conducted to investigate the effect of hydro-alcohol extract of *T. terrestris* on sexual satisfaction of postmenopausal women, the consumption of *T. terrestris* had a positive effect on increasing sexual satisfaction of postmenopausal women, and this difference was statistically significant. In menopause, reduced estrogen and androgen physiologically resulted in reduced blood flow of vulva and vagina and thus reduced arousal.

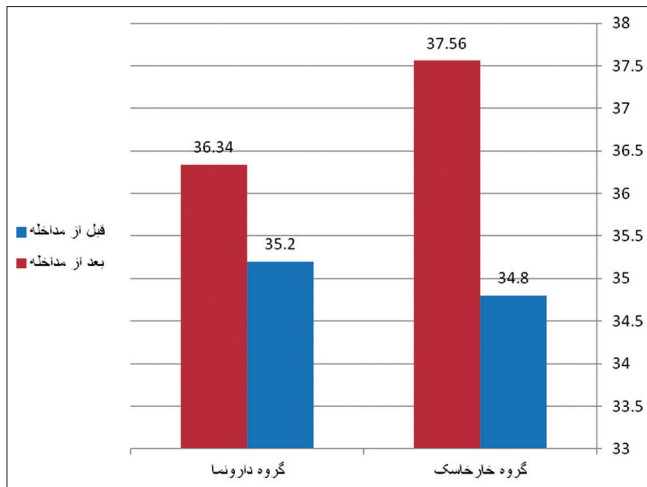


Figure 1: The diagram of mean score of sexual satisfaction before and after the intervention in *Tribulus terrestris* and placebo groups

Vaginal dryness results in reduced genital sensory threshold, dyspareunia, and reduced sexual desire. Reduced sexual desire in the primary years of menopause is estimated to be 40% and even more in some cases.^[30] *T. terrestris* brings about increased testosterone by having estradiol glycosides, the most important of which is protodioscin. As mediators, natural estradiols are likely to facilitate the pathway for androgen production through estradiol^[31] and bring about increased testosterone. Moreover, *T. terrestris* has unsaturated fatty acids.^[32] Unsaturated fatty acids increase the activity of 17 β -hydroxysteroid dehydrogenase enzyme, and this enzyme is involved in the production of testosterone (androgen), and thus testosterone level increases.^[32] In the study conducted by Clinton *et al.* (1997), it was reported that these acid combinations control aromatase activity. Since this enzyme (aromatase) turns androgen to estrogen, controlling its activity results in an increased level of androgen (testosterone) in the blood.^[33] The effect of testosterone on women's improved sexual desire in reproductive age and the process of its increase has been confirmed in various studies.^[34] Moreover, testosterone is remarkably effective on women's improved sexual desire.^[35] According to the study conducted by Akhtari *et al.* (2014), it was indicated that *T. terrestris* is effective on increasing women's sexual factors in reproductive age, and it will result in increased sexual desire ($P < 0.001$). The main factor behind this increase is likely the interactive and positive effect existing between *T. terrestris* and luteinizing hormone–follicle-stimulating hormone mechanism.^[36]

Furthermore, in the study conducted by Carlos *et al.* (2014), it was indicated that 90-day consumption of *T. terrestris* 250 mg extract will affect the total score of women's sexual function in reproductive age ($P < 0.001$). In their study, 144 women suffering from sexual disorders (based on Female Sexual Function Index questionnaire) were divided into two equal groups of *T. terrestris* and placebo. The preintervention sexual satisfaction score was 2.90, and it was reported to be 3.45 after the intervention ($P < 0.0001$). Moreover, the total score of sexual function questionnaire was 16.57 before the intervention and 19.93 after the intervention; the difference was statistically significant ($P < 0.0001$). This

indicates the positive effect of *T. terrestris* on the treatment of sexual disorders in reproductive age.^[27]

Postigo *et al.* (2016) conducted a study in Brazil to investigate the effect of *T. terrestris* on postmenopausal women's sexual performance. In this study, conducted as a double-blind clinical trial, patients with sexual performance disorder (based on Sexual Quotient-female version) consumed a 250-mg pill containing *T. terrestris* three times a day for 90 days. The findings reported a significant increase in the level of comfort in postmenopausal women's sexual intercourse. The score of comfort in sexual intercourse was 5.7 ± 2.8 before the intervention and 8.0 ± 1.9 after the intervention ($P < 0.05$).^[28] Moreover, the mean score of sexual desire was 7.4 ± 3.3 before the intervention and 10.2 ± 3.2 after the intervention; the difference was statistically significant ($P < 0.05$). The total score of preintervention sexual function was 49.5 ± 19.1 , and it was 70.9 ± 17.6 after the intervention ($P < 0.05$). Thus, the findings of their study are consistent with those of this study.

The findings of the clinical trials released indicate the positive effect of *T. terrestris* on women's sexual satisfaction. Given the significant effect of the syrup containing the hydro-alcohol extract of *T. terrestris* on sexual satisfaction of postmenopausal women, their increased sexual desire, and the lack of any side effects reported by the participants of this study, using this extract for postmenopausal individuals can promote their health and consequently promote the health and economy of the entire society.

Conclusion

Taking the syrup containing the extract of *T. terrestris* for 8 weeks will result in postmenopausal women's increased sexual satisfaction. Moreover, as reported by the participants of this study, this syrup has no side effects.

Acknowledgments

This study is the outcome of a master's thesis in midwifery registered at the Iranian Registry of Clinical Trials with the registration code of IRCT2016121131340N1. This study was also confirmed at Ethics Committee of Ahvaz Jundishapur University of Medical Sciences with the code of ethics of IR.AJUMS.REC.1395.519. Hereby, the researchers greatly appreciate the cooperation provided by all women who participated in this study.

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Conflicts of interest

There are no conflicts of interest.

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