Original Article

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Quick Response Code:

Website: www.jehp.net

DOI: 10.4103/jehp.jehp_870_22

Vitagnus an estrogen-riched herbal remedy used in sexual dysfunction: A randomized clinical trial

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Received: 20-06-2022
Accepted: 01-10-2022
Published: 31-08-2023

Abstract:

BACKGROUND: Sexual dysfunction is a common problem in the postmenopausal period. Vitagnus is a phytoesterogen containing herb, which can bind to estrogen receptors and modulate their function. In this study, we evaluated the efficacy of oral vitagnus solution on sexual dysfunction improvement among postmenopausal women in North Khorasan Province, Iran.

MATERIALS AND METHODS: The present study was a double-blind clinical trial on 60 retired female teachers who visited the retirement center of North Khorasan Province from December 2019 until January 2021. Sampling was done in a convenience sampling. Allocation of intervention and placebo groups was done randomly by marking as A and B codes, respectively. Eligible married women aged 50–70 years had received 40 drops of vitagnus or placebo daily for 8 weeks. Female Sexual Function Index was filled on the first day, fourth, sixth, and eighth week after the intervention. Data were analyzed using SPSS V.23 and independent *t*-test, Mann–Whitney U, Chi-square, Fisher's exact test, and repeated measure ANOVA were used for analyzing descriptive and inferential data. $P < 0.05$ was considered as a statistically significant threshold.

RESULTS: Data from Bonferroni *post hoc* test indicated that the mean total sexual function did not differ between the two groups before and at the end of the fourth week of intervention, but scores of total sexual function showed a significant difference at the end of the sixth ($P = 0/003$) and eighth week ($P = 0/001$) of intervention.

CONCLUSION: Vitagnus drops, as a simple, cheap, and available herbal supplement, could affect the sexual function of women aged 50–70 and improve it.

Keywords:

Herbal medicine, menopause, sexual activities, vitex agnus-castus, women

Introduction

Sex function is a major concern of aging that has been in less attention. Research on the sexual behavior of elderly people has often been neglected; hence, there is relatively less information about the sexual behavior of people over the age of 60.[1] Sexual functions refer to behaviors and procedures by which a human experience and express his/her sexual desire.[2]

Sexual dysfunction may remain hidden under the influence of personality, sociocultural, and familial factors and manifests itself with other symptoms such as physical discomfort, depression, and dissatisfaction with marital life, and sometimes may lead to severe family disputes and separation.[3] Some evidence indicate that people who have more satisfactory sexual activity have a longer life span; on the other hand, the mental health and well-being of those who suffer sexual dysfunctions will be endangered.[4]

How to cite this article: Zohreh A, Robabeh A, Peiman A, Hamid NS, Zakiyeh A. Vitagnus an estrogen-riched herbal remedy used in sexual dysfunction: A randomized clinical trial. J Edu Health Promot 2023;12:268.

Unfortunately, despite the high prevalence of sexual dysfunctions among elderly people, this issue is usually not given importance in clinical care. Studies showed that many women consider old age as a period of liberation due to the end of their fertile years because, in addition to a reduction of responsibility for their children,[5-7] they no longer worry about pregnancy and feel more comfortable in comparison to premenopausal period. Albeit they seem more sexually active than before, due to menopause and serum estrogen level reduction, they experience vaginal dryness and atrophy, and subsequently dyspareunia, which unintentionally keeps them away from sexual affairs.[8,9]

According to the abovementioned cases, even though sexual health is important, it is neglected as a component of older patients' care. Various therapeutic methods have been used to prevent sexual activity impairments and improve sexual function during menopause and old age. These interventions are divided into hormone therapy and alternative medicine.[10]

There is an unprecedented growth in the popularity of alternative medicine to manage menopausal symptoms, and postmenopausal women have become the greatest users of alternative medicine. They consider such therapies much safer than hormone therapy. Their main concerns about hormone replacement therapy are the increased risk of some types of malignancies and uterine bleeding.[10] Utilizing vitagnus (vitex agnus-castus), which contains estrogen-like compounds (phytoestrogens), is a nonhormonal method.[11] Phytoestrogens affect sex hormones and also have antioxidant, antiallergic, antiinflammatory, and antineoplastic properties. Even though their exact pathway of molecular action has not been proven, their effects are reduction of follicle-stimulating hormone and prolactin release and increase leutinizing hormone secretion by affecting the hypothalamic-pituitary axis.[12] The essential oil of vitagnus has been traditionally used to treat many problems such as menstrual cramps, general pain, inflammation, sexual dysfunction, and nervous disorders. Mirzaeinajmabadi in 2016 reported that consumption of vitagnus improved sexual function in women during menopause.[13] Zamani, in 2017, found that vitagnus extract was effective not only in growth but also in the reproduction of xiphophorus. It also induced a noticeable delay in sexual maturation.[14]

Previously mentioned studies showed that sexual health is important, but unfortunately, it is often neglected as a component of health care for elderly patients. Since sexual affairs are considered as taboo by a high majority of society, they are ignored and not taken into account in the evaluation of patients, while they have profound effects on the individual and the family health.[15] Based on a rich field of alternative medicine background in gynecologic therapies and due to the indigenous and available vitagnos plant in Iran, this study was conducted to determine the effect of vitagnos drops on improving the sexual function of women after menopause in order to increase life quality.

Materials and Methods

Study design and setting

The present study was a double-blind clinical trial (IRCT20190528043736N1) in Bojnurd in 2021. This study was approved by the ethics committee of North Khorasan University of Medical Sciences. The study population visited the retirement center of North Khorasan Province from December 2019 until January 2021.

Study participants and sampling

The statistical population consisted of all women who visited the retirement center of North Khorasan Province. The sample size was 56 according to G power 3.1 software and it increased to 60 (30 in each group) according to the probability of loss and proportional distribution in age groups [effect size f = 0.2, α err prob = 0.05, power (1–β err prob) =0.95, number of groups = 2, number of measurements = 4, correction among rep measures = 0.5, nonsphericity correction ε =1]. Due to the irregular use of drops, five individuals were excluded from the study. Finally, the analysis was performed on 27 members of the intervention group and 28 members of the placebo group [Figure 1].

Data collection tool and technique

Research tools of the present study included a form of researcher-made demographic information and clinical and obstetric record and the Female Sexual Function Index (FSFI) by Rosen. The FSFI consisted of 19 questions for examining people in six dimensions, namely, sexual desire (two questions), arousal (four questions), lubrication (four questions), orgasm (three questions), sexual satisfaction (three questions), and dyspareunia (three questions). The questions were scored based on the scoring system of 0–5, and the score of a dimension is obtained from adding scores of questions of each dimension (a higher score indicates better sexual function). Therefore, we had six points. The minimum score for answering questions was 2 and the maximum was 36. Subsequently, scores less than 10 indicated severe sexual dysfunction, 11–17 moderate dysfunction, 18–23 mild dysfunction, and above 23 no sexual dysfunction.

The sexual function questionnaire was first designed in 2000 by Rosen,[16] and then, it was carried out in psychometrics studies by Mohammadi and Fakhri,[17,18]

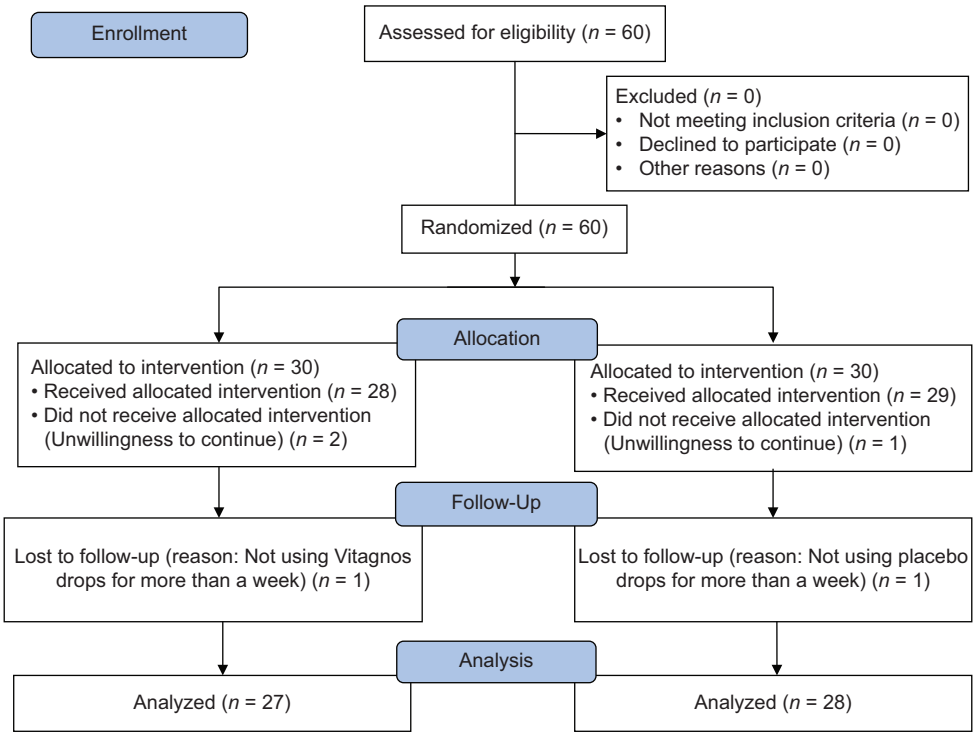

Figure 1: Flow chart for this study

subsequently, it has been used in several studies.[13,19,20] In the present study, the reliability of the questionnaire was assessed by internal consistency (Cronbach's α: 0.84) and the test–retest method, and calculating the correlation coefficient and intracluster correlation index between two test times, which was 0.79.

The researcher invited all 50-70-year-old female teachers after proposal approval and legal permission obtainment. All of the invited retired teachers should had all of inclusion criteria as: A. alive husband and living with him, B. no known mental and emotional disease in the last 6 months, C. no use of hormonal, herbal, and neuroleptic drugs, D. no use of estrogen hormone or other phytoestrogens that affected the status of hormones during the research period, E. no active cancer, F. no vaginal bleeding, G. husband's without any obvious sexual disorders, and H. a sexual function score of under 23 based on Rosen index. All the invited cases were given the necessary explanations of the study and signed written consent forms.

Sampling was done in convenience sampling among the visitors to the research environment during the presence of the researcher. Allocation of research units to intervention and placebo groups was done randomly by removing codes A and B. Both the researcher and the research unit did not know about the codes of the groups. After selecting the research units and completing the questionnaires by them, a training class was simultaneously held on sexual activity in old age by a reproductive health specialist for both groups. Codes were assigned to the individuals. At the end of the session, vitagnus and placebo drops (both prepared by Poursina Pharmaceutical Company in similar bottles in appearance and only with letters on them) were given to the members under the supervision of an alternative medicine specialist, and the necessary explanations (40 drops of vitagnus or placebo every morning on fasting with a cold drink for 8 weeks) were provided for both groups. The research units were followed up in person or by phone every 2 weeks, and the required drops were given to them for another 2 weeks. By this way, the individuals were examined in terms of quality and quantity of drop consumption. They were advised to present the empty bottle to the researcher on the next visit. At intervals of 4, 6, and 8 weeks from the beginning of the intervention, the sexual function questionnaire was completed for the research units. Their questions were also answered and, if necessary, they were referred to a gynecologist or alternative medicine specialist. The individuals were advised to inform the researcher if they observed any abnormal finding. One of the exclusion criteria of this study was more than 1 week of disusing the medicine. Data analysis was done using statistical software (version 23 SPSS Inc, Chicago, IL, USA). First, the normality of quantitative variables was determined using the Kolmogorov–Smirnov test. According to the study's objectives, descriptive and inferential statistics, independent *t*-test, Mann–Whitney U-test, Chi-square test, Fisher's exact test, and analysis of variance with repeated measures were used. In all

tests, 95% confidence interval and a significance level of 0.05 were considered.

Ethical consideration

Ethical aspects of this study were approved by the North Khorasan University of Medical Sciences (IR.NKUMS.REC.1398.007). All of the subjects were informed about being free to participate in the research and nondisclosure of personal information. They all signed written informed consent.

Results

According to the research information, all participants were in the age range of 50–69 years. They were in four age groups, 50–55 years (n = 36), 55–60 years (n = 11), 60–65 years (n = 5), and 65–69 years (n = 3). Tables 1 and 2, present the participants' information after examining the homogeneity of quantitative and qualitative variables.

We used the repeated measures analysis of variance (ANOVA) to investigate the effect of drops on sexual function in the two groups in four time periods and found that sexual function changed at the measurement times (P < 0.001). The scores were also different in the experimental and placebo groups (P = 0.001). The results of the Bonferroni *post hoc* test indicated that scores of sexual functions did not differ between the control and experiment groups before the intervention and in the fourth week after the intervention, but they were significantly different in the sixth (P = 0.003) and eighth weeks (P = 0.001). Furthermore, sexual desire, lubrication, satisfaction, and dyspareunia were significantly different between the two groups at 4 and 6 weeks from the beginning of the intervention. In terms of sexual satisfaction, the difference was significant only 8 weeks after the intervention (P = 0.009) but was insignificant in terms of orgasm and mental arousal in both groups in any period after the intervention; however, the results were better in the vitagnus drop group [Table 3].

Table 1: Comparison of the mean of demographic information (quantitative variables) of the research unit in the experimental and placebo groups

Quantitative variables	Group		*P**
	Experimental *n*=27 Mean±Standard deviation	Placebo *n*=28 Mean±Standard deviation	
Age	54.44±5.13	55.17±4.86	0.976
Spouse age	57.70±5.99	57.75±5.30	0.289
Number of children	2.70±1.06	2.75±0.84	0.766
Gravida	2.66±6.72	2.85±1.04	0.293

Discussion

Results of previous studies indicated that sexual function in elderly women declines with age, and there is a nonsignificant association between poorer sexual function and decreasing sexual desire.[21] Based on the results of the present study, the time required to start the effect of vitagnus drops was 6 weeks after starting the intervention. In other words, there was no difference between the two groups in terms of sexual function and dimensions of sexual function (desire, dyspareunia, and vaginal lubrication) in week 4, but there were significant differences in all the above dimensions in two groups in the weeks 6 and 8 and also differences in satisfaction in week 8. Even though the scores for orgasm and mental arousal increased at week 8 after the initiation of intervention, the increase was not significant. Based on the cut-off point in the drug group, they experienced a better status than other groups. Unfortunately, despite the widespread use of

Table 2: Frequency distribution of the research unit in terms of demographic information (qualitative variables) in the experimental and placebo groups

Qualitative variables	Category	Group				*P*
		Experimental *n*=27		Placebo *n*=28		
		Frequency	Percentage	Frequency	Percentage	
Age	50–55	18	66.7	18	64.3	0.289*
	55–60	5	18.5	6	21.4	
	60–65	3	11.1	2	7.1	
	65–70	1	3.7	2	7.1	
Condition Marriage of children	Married	6	22.2	5	17.9	0.046*
	Single	9	33.3	9	32.1	
	Married and Single	12	44.4	14	50.0	
Education level	Diploma	11	40.7	10	35.7	0.704**
	University	16	59.3	18	64.3	
Income	Less than enough	4	14.8	8	28.6	0.262*
	Enough	22	81.5	19	67.9	
	More than enough	1	0.73	1	3.6	
Smoking	Yes	26	96.3	28	100.0	0.231***

*Mann–Whitney *U*–test; **Chi-square test; ***Fisher's exact test

Table 3: The mean score of sexual function in the two groups before and after the intervention (Comparison between and intragroup)

Sexual function	Stage of test	Groups		*P**
		Experimental group Mean±SD *n*=27	Placebo group Mean±SD *n*=28	
sexual desire	before of intervention	2.84±0.71	2.97±0.66	0.474
	4 weeks	3.20±0.57	2.80±0.74	0.034
	6 weeks	3.64±0.36	2.82±0.90	0.001
	8 weeks	3.62±0.48	2.74±0.87	*P*<0.001
arousal	before of intervention	3.11±0.67	3.32±0.43	0.171
	4 weeks	3.42±0.74	3.21±0.50	0.229
	6 weeks	3.62±0.73	3.34±0.81	0.187
	8 weeks	3.72±0.87	3.41±0.75	0.174
lubrication	before of intervention	3.17±0.71	3.36±0.37	0.228
	4 weeks	3.31±0.74	3.33±0.61	0.909
	6 weeks	3.98±0.94	3.40±0.62	0.009
	8 weeks	4.02±1.05	3.49±0.69	0.033
orgasm	before of intervention	3.21±0.46	3.32±0.40	0.338
	4 weeks	3.51±0.61	3.60±0.76	0.638
	6 weeks	0.59±3.52	3.55±0.71	0.862
	8 weeks	3.51±0.61	3.60±0.76	0.638
sexual satisfaction	before of intervention	3.54±0.89	3.67±0.70	0.551
	4 weeks	3.88±0.92	3.84±0.63	0.857
	6 weeks	4.25±1.22	3.87±0.73	0.016
	8 weeks	4.35±1.28	3.87±0.77	0.009
dyspareunia	before of intervention	3.15±1.04	3.40±0.69	0.309
	4 weeks	3.77±0.68	3.62±0.72	0.439
	6 weeks	4.42±1.04	3.41±0.76	*P*>0.001
	8 weeks	4.84±1.00	3.78±0.74	0/.001
Total scores	before of intervention	19.04±2.90	20.06±1.75	0.119
	4 weeks	21.10±2.87	20.42±2.29	0.337
	6 weeks	23.46±3.96	20.42±3.19	0.003
	8 weeks	24.07±4.13	20.91±2.71	0.001

*weeks after the start of the intervention *repeated measures ANOVA

phytoestrogens in women's menopause problems, there are few studies on sexual affairs in older people, and there is only one study on the effect of vitagnus on sexual function by Mirzaeinajmabadi in Shahrud, Iran. In her study on the effect of vitagnus on the sexual function of postmenopausal women, she found that the use of vitagnus drops for 16 weeks could improve the total sexual function scores of postmenopausal women.[13] The results of her study were confirmed by the present study. Therefore, similar studies were used in the discussion section of the present study. Ruth *et al*.[21] demonstrated a significant decrease in the ratio of women who were sexually active over the age of 60.

Taghizadeh *et al*.[22] indicated that the use of estrogen replacement therapy or phytoestrogen for 3 months led to vaginal dryness and dyspareunia due to lower vaginal atrophy, and these factors could play important roles in improving sexual function in women. Management of vaginal atrophy in menopausal phase is often neglected, while it is estimated that 90% of women are affected by its symptoms such as dryness, itching, dysuria, and dyspareunia; thereby, it is an important factor that adversely affects sexual function and urogenital system health.[23]

Estrogen improves mucosa, increases elasticity and blood flow of the vulva and vagina, reduces the sensory threshold of the vulva and vagina, increases sexual pleasure, and improves arousal.[24] In a study by Pebdani *et al*., it was found that Gingko biloba extract, which is a phytoestrogen, did not affect the sexual function of postmenopausal women aged 50–60 years, and there was no difference between the drug and placebo groups. In their study, the intervention lasted for 4 weeks, and the Sabbatsberg Sexual Self-Rating Scale was the research instrument; hence, there was no information about the dimensions of sexual function. Their results were also confirmed by our study because there was no difference between experimental and placebo groups in sexual function scores according to repeated measurements of score 4 weeks after using vitagnus. Due to the fact

that herbal medicines need more duration of time to reach their effect than chemical medications, their study is suggested to increase the time of administration of Gingko biloba extract; moreover, their data was also confirmed by our study. In the current study, the effectiveness of the vitagnus was observed after 6 weeks.[5]

Ahangarpour studied the effect of vitagnus drops on antioxidants and sex hormone levels in female rats and reported an improvement in the reproductive system function of female rats.[25]

The results of a study by Jabbari confirmed the results of our study too. In Jabbari's study, the consumption of Ginkgo biloba for 6 weeks increased sexual function.[26] In their study, scores of all dimensions of sexual function showed a significant increase after drug consumption, so their results were in the same direction as the present study in terms of mental arousal and orgasm. Based on numerous studies, women's sexual dysfunction associated with the orgasmic disorder, requires the most difficult types of treatments, because orgasm is multifactorial in women and depends on the cognitive background and experiences of women in marital life; on the other hand, orgasm is more dependent on psychological factors.[26] In the recently mentioned study, the participants had 45–55 years of age, so they had better sexual status than women in our study with 50–70 years of age.

In another study on the use of red clover isoflavone, which is a type of phytoestrogens, Tedeschi reported positive results from the administration of this plant on early menopausal symptoms as well as vaginal cytology. Red clover isoflavones improved mucosal density and vaginal atrophy as well as menopausal symptoms by binding to beta-estrogen receptors. Even though their study did not directly examine the women's sexual function, it is expected that vaginal atrophy would disappear due to the improvement of vaginal cytology and indirectly reflect the improvement of sexual function. It is obvious that phytoestrogens positively affect women's sexual function.[27]

Lipovac *et al*.[28] also reported that administration of red clover isoflavone as a source of phytoestrogens can improve functions of vaginal appendages and mucus, libido, mood, and depression in postmenopausal women.

In a meta-analysis by Ghazanfarpour *et al*.[29] on the results of two clinical trial studies, soy isoflavones were effective in improving vaginal dryness. The data of these two studies were also consistent with the present study.

The strengths of the study included the use of the random allocation method to prevent selection bias, the use of the blinding method to reduce the risk of bias in data collection, receiving both drops and placebo from Porsina pharmaceutical company in coded form, phone follow-up of participating people in order to ensure the correct consumption of drops, and timely interventions by the researcher for the management of drug side effects. One of the weaknesses of the study was the selection of samples from a retirement center, which can restrict the generalizability of the results. The innovation of the research also includes determining the effectiveness of the drug and the minimum time required to use the vitagnos plant to improve sexual function.

Limitation and recommendation

Due to cultural reasons and the sensitivity of the topic, the research subjects might avoid the precise expression of their sexual information. The participants were assured that by using sealed envelopes to place the completed questionnaires anonymously, all their information would remain confidential. Also, it was not possible to accurately monitor the consumption of drops by the researcher, but the research units were given sufficient training for consumption, and every 2 weeks, the research units visited and delivered empty bottles and were provided new medicine bottles in order to provide highest confidence rate for monitoring standard drug consumption. It is suggested to compare different medicinal forms of the vitagnos plant to determine the most effective preparation. It is also suggested that vitagnos plant be compared with various medicinal plants which are effective on sexual dysfunction.

Conclusion

Problem solving without using drugs and simple, low-risk methods are the most important features of healthcare and midwifery. The optimistic goal of any research is the practical use of its results in order to improve the current status and help to solve remaining problems. The results of the present and similar studies in menopausal care may be the best opportunity to improve the physical, psychological, and sexual health of women and their husbands, which leads to a higher quality of family health.

Acknowledgements

We hereby express our gratitude and appreciation for the guidance of the North Khorasan University of Medical Sciences, and all women who had cooperated with the researcher to conduct this research.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in

the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Financial support and sponsorship

This study has been conducted as part of master Thesis, which is funded by North Khorasan University of Medical Sciences. This study is reviewed by the ethics committee of the School of nursing of the North Khorasan University of Medical Sciences and approved by the code IR.NKUMS.REC.1398.007.

Conflicts of interest

There are no conflicts of interest.

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