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Original Article

Effects of Saffron on Erectile Dysfunction in Men: A Randomized Controlled Trial

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Abstract

Background and Aim: According to previous research, about 30% of men report certain forms of sexual dysfunction. Saffron is one of the medicinal herbs which is considered of high value in Iranian culture. The effect of saffron on the improvement of sexual function has been studied in various studies, but the results of these studies have revealed several challenges. This study aimed to investigate the effect of saffron on erectile dysfunction in men.

Materials and Methods: In this randomized clinical trial study, 24 men with erectile dysfunction who worked in industrial companies from June to September 2021 were enrolled. The participants were randomly divided into the intervention and control groups (n=12/each). The intervention group received 2 capsules of 15 mg of saffron daily twice for 4 weeks. The control group did not receive any treatment. Demographic variables were measured at the beginning of the study, and then the international index of erectile function scale were assessed before and at the end of the intervention. The data were analyzed, using chi-square, Fisher's exact, Mann-Whitney, and Wilcoxon tests.

Results: The average score of all dimensions of erectile dysfunction (erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction) in the intervention group increased significantly after consuming saffron capsules (p-value<0.05), while there was no significant difference in the control group (p-value>0.05). Moreover, the comparison of the mean relative change of all dimensions of sexual function except orgasmic function between the treatment and control groups with the Mann-Whitney test showed a statistically significant difference between the two groups (P<0.05). In the dimension of orgasmic function, the average changes between the intervention and control groups did not indicate a statistically remarkable distinction (P=0.178).

Conclusion: The findings of this study indicated that saffron could affect all aspects of erectile dysfunction. Thus, saffron could be used for the recovery of sexual performance.

Keywords: Crocus, Saffron, Sexual dysfunction, Erectile dysfunction

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Introduction

Sexual dysfunction is a global health issue that negatively affects people's health and quality of life (1). Sexual dysfunction might be concealed under the influence of personality, socio-cultural, and family factors. In some cases, it becomes evident with other signs and symptoms such as physical discomfort, depressive disorder, lack of marital satisfaction, family breakdown, and divorce (2). According to previous studies conducted in Iran, between 10-30% of men reported some forms of sexual dysfunction (3, 4), and one of the most common sexual disorders in men is erectile dysfunction (5).

Erectile dysfunction is described as the failure to keep an erection long enough to perform a satisfying sexual act (6). In this case, findings of several studies conducted in Iran have shown that between 18.6 and 40.4% of men have erectile dysfunction (3, 5). In some cases, phosphodiesterase 5-inhibitors such as sildenafil, tadalafil, and vardenafil are effective in treating erectile dysfunction in men, but for various reasons, including the side effects of these drugs, high costs and drug interactions, the use of these drugs is limited (7). Saffron is a significant medicinal plant in Iranian culture. The effect of saffron on the improvement of sexual function has been studied in various studies, but the results of these studies have shown several challenges (8).

For example, in studies conducted by Abedimanesh *et al*. (9) and Safarinejad *et al*. (10), saffron did not affect sexual dysfunction. However, the results of research carried out by Mohammadzadeh-Moghadam *et al*. (7) and Maleki-Saghooni's (11) revealed that saffron could not be effective in the treatment of male sexual dysfunction. These differences might be due to various conditions that affect the implementation of these studies, such as the way saffron is used, the amount of saffron consumed, underlying diseases of individuals, and other factors. Thus, despite the the positive effects of saffron reported in some studies, its beneficial impacts on male sexual dysfunction are still questionable (8, 12). Moreover, the physiological effects of saffron on some organs of the body such as the reproductive system are not yet fully known (13). It appears that these effects are due to the modulation of neurotransmitters in the CNS and antioxidant properties (14, 15). Furthermore, antioxidants can control the activity of free radicals, thereby increasing blood circulation to the genitals and consequently improving erectile function in men. Moreover, saffron and its derivatives increase the secretion of gonadotropin-releasing hormone which leads to increased libido in men (16).

Therefore, considering the therapeutic effects of saffron and its ingredients, in this study we aimed to examine the impact of saffron capsules on erectile dysfunction in men. Given the high occurrence of erectile dysfunction among men as well as the lack of sufficient studies on the use of complementary methods in improving sexual function in men with erectile dysfunction, researchers decided to study the effect of saffron capsules on erectile dysfunction in men.

Materials and Methods

Study Design and Participants

In this randomized clinical trial study, 36 men with erectile dysfunction who worked in industrial companies from June to September 2021 were enrolled. The reason for choosing this center was the absence of a urology department in the city where the study was conducted. More importantly, this center was selected because of the results of previous studies (17-19) that revealed a close relationship between insufficient sleep at night and sexual dysfunction. Since the employees in this center worked at the night shift for 15 consecutive days and experienced continuous nocturnal awakenings, the research team decided to conduct this study in this industrial company according to the mentioned evidence.

The inclusion criteria were: 1) married men aged >18 years old, 2) the patients who could swallow food and did not have digestive and oral difficulties that might interfere with taking the capsules, 3) those who had not used alternative treatments such as hormonal drugs, 4) willingness to participate in the research, and, 5) getting a score in the mild and mild to moderate range from the international index of erectile function (IIEF) scale. The exclusion criteria were: 1) willingness to continue participating in the study, 2) a history of allergy to herbal medicines, 3) addiction to

drugs and alcohol and painkillers, 4) the use of neuropsychiatric drugs, 5) severe depression or anxiety, 6) a history of physical diseases such as diabetes and cardiovascular disorders, and 7), having intense physical activity and working as a professional athlete.

Sample size

The PASS 15 software was used to specify the sample size and compare two independent means, in which the average of the international index of erectile function questionnaire score in the first group was 44.32 ± 3.90, the average of the dependent variable in the second group was 37.56 ± 3.68 (7), the alpha was set at 0.01 and, and the power was considered about 0.95. Finally, the sample size was estimated about 12 individuals in each group.

Randomization

First, people were included in the study using convenience sampling, and then the randomized block method was used to assign people into two intervention and control groups. According to the final sample size, which was composed of 24 people, 6 blocks of 4 were used. Thus, 12 people were placed in each group at the end of random allocation.

Intervention

The samples were divided into the intervention and control groups, and data collection tools included the demographic characteristics form and the international index of erectile function (IIEF) scale. The IIEF scale was completed before the start of treatment (the first day of visit) and one month after the beginning of the intervention. Then, the intervention group received 2 capsules with 15 mg of saffron twice daily orally for 4 weeks (11, 12). In previous studies, the toxic effect of saffron was observed in some tissues (kidneys and lungs), particularly at a dose of 0.5 ml/kg (20). Saffron of the Qaenat brand was purchased individually from a reputable store. The control group did not receive any treatment.

Outcome

The IIEF measure was completed in two groups before and in the last day of the intervention. An outcome evaluation was performed by the principal investigator of the project. The key measured result was the recovery of erectile function based on the increase in the whole score of the IIEF Questionnaire.

Information Collection Tools

Demographic and IIEF questionnaires were used to collect the data.

The IIEF consists of 15 questions. This scale evaluates male erectile function in 5 areas as follows:

- Erectile function consists of questions 1, 2, 3, 4, 5, 15 (scores range from 0-30),
- Orgasm function includes questions 9 and 10 (scores range 0-10),
- Sexual desire is composed of questions 11 and 12 (scores range from 1-10),
- Sexual satisfaction includes questions 6, 7 and 8 (scores range from 0-15),
- Overall satisfaction consists of questions 13 and 14 (scores range 1-10).

The answers were graded from 0-5 on a 6-point Likert scale and from 1-5 on a 5-point Likert scale. The whole score was between 5-75. A score below 25 indicates erectile dysfunction for the erectile function field of the IIEF measure. For mild erectile dysfunction, a score limit of 22-25, for mild to moderate erectile dysfunction, a score limit of 17-21, and for moderate erectile dysfunction, a score limit of 11-16 were considered (21). IIEF helps general practitioners prepare a sexual history from the patient, but the scores of the questionnaire for specialists have not separated the etiologies of vascular erectile dysfunction(22). The validity of the Farsi version of this scale has been confirmed in previous research. The scale and its Persian abridged version have been used in cross-cultural studies, and its reliability and validity have been approved with 88% sensitivity, 82% specificity and 82% positive predictive value, as well as having a Cronbach's α value of 0.90% (23).

Statistical Analysis

The frequency table, central tendency indices (mean), and dispersion indices (standard deviation) were used to express descriptive statistics. The chi-square test and Fisher's exact test were applied to compare qualitative data in the intervention and control groups. The Wilcoxon nonparametric test was used for intragroup comparison before and after the scores. Moreover, the relative change analysis approach was used in order to decrease the impact of covariates. Subsequently, the changes between the two groups

were analyzed with the Mann-Whitney test. SPSS software version 25 was used for data analysis. The confidence interval in this study was 95% and the level of alpha was considered 0.05.

Results and Discussion

In this study, initially, 36 men were enrolled in the study. Twelve participants were excluded because they did not meet the inclusion criteria. The remaining participants were randomly assigned into the intervention and control groups (n=12/each). There were no dropouts in any of the groups, and the analysis was performed on 24 participants. The flowchart for the study has been presented in Figure 1. The mean age and standard deviation of the participants were 35.25±5.37 years in the intervention group and 36.42±6.40 years in the control group. According to Table 1, a comparison of the mean rank of age, height, weight, and body mass index (BMI) between the two groups did not reveal a remarkable distinction (P>0.05). Furthermore, according to Table 1, the two groups were analogous in items of qualitative variables of education level and smoking (P>0.05). The results of comparing the mean of sexual function and its dimensions (erectile function, orgasmic function, sexual desire, intercourse satisfaction, overall satisfaction) between the two groups of intervention and control have been presented in Table 2.

The results of the Wilcoxon test in the treatment group showed a statistically significant difference between the pre-test and post-intervention stages, but in the control group, the comparison of these two stages did not reveal a significant difference. Moreover, the comparison of the mean relative change of all dimensions of sexual function except the orgasmic function between the treatment and control groups with the Mann-Whitney test showed a statistically significant difference between the two groups (P<0.05). In the dimension of orgasmic function, the

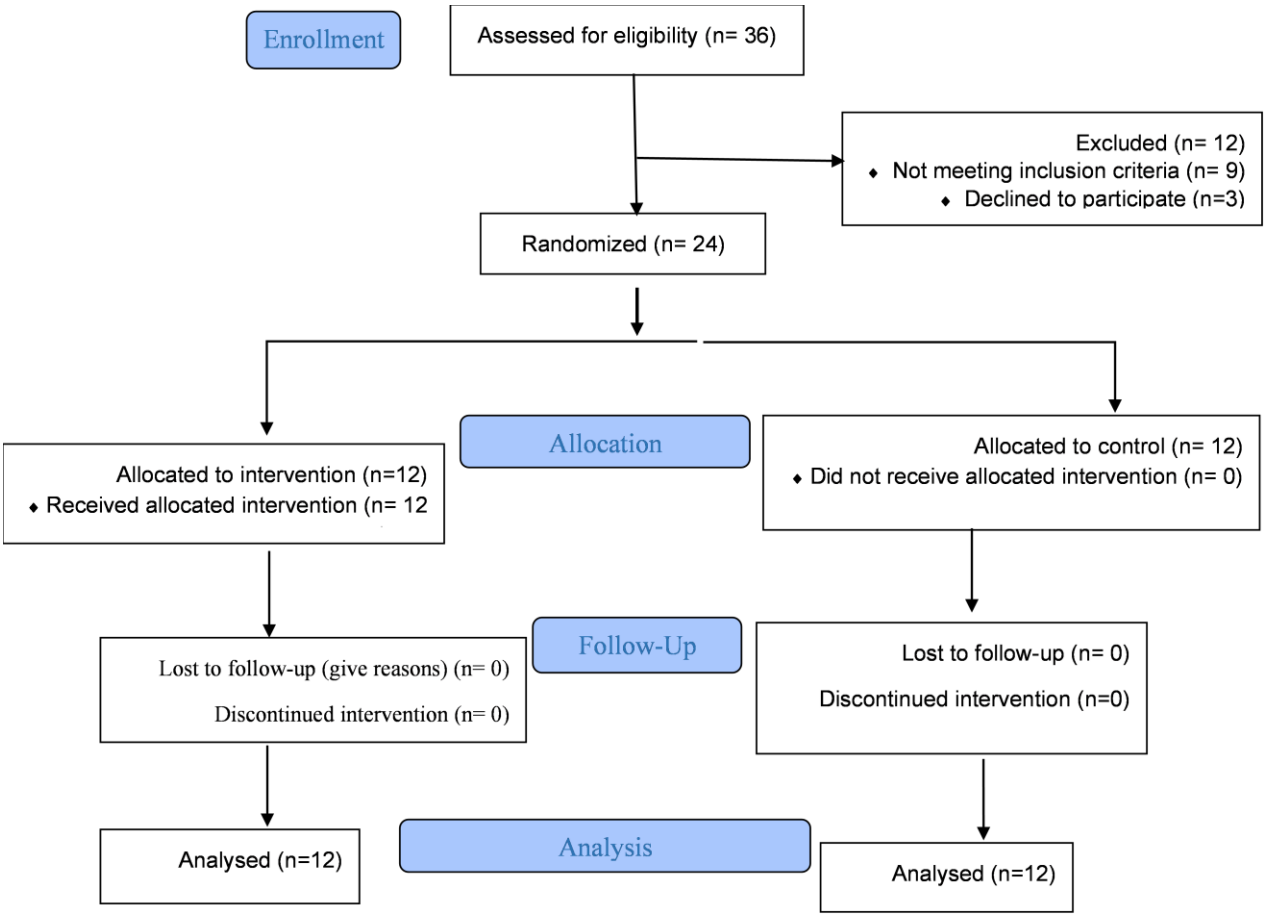

Figure 1. Consort diagram.

Table 1. Demographic characteristics of the participants in the two study groups.

Variables	Intervention group (n = 12)	Control group (n = 12)	P-value
Age (yr) *	35.25±5.37	36.42±6.40	0.685
High (cm)*	173.08 ± 4.99	171.42 ± 5.01	0.728
Weight (kg) *	70.42 ± 9.31	66.58 ± 7.14	0.839
BMI (kg/m) *	23.44 ± 2.43	22.75 ± 3.16	0.603
Number of cigarettes per day*	0.08±0.28	0.00±0.00	0.328
Education**			
Under diploma	4 (44.40)	5 (55.60)	0.809
Diploma and above	8(53.30)	7 (46.70)	

*The data have been presented as Mean ± SD. Mann-Whitney U test. **The data have been presented as n (%). Fisher's exact test. BMI: Body mass index.

average changes between the intervention and control groups did not show a statistically significant difference (P=0.178).

This study investigated the impact of saffron on sexual dysfunction in men. The results indicated a statistically significant difference in the mean scores of the IIEF between the intervention and control groups one month after the intervention. The mean scores of the erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction were significantly higher in the intervention group than in the control group.

The results of the present study showed that the use of saffron had a positive effect on the erectile function score, and there was a significant difference in the intervention group pre- and post-saffron therapy (p = 0.003). The mean score in the control group decreased after the intervention, and this difference was not significant (p = 0.132). This reduction indicates that if this important function is neglected, we will face a reduction in performance over time. In line with the results of the present study, Modabbernia *et al*. (2012) found that the use of saffron resulted in considerably better recovery in the erectile function, sexual intercourse satisfaction fields, and the whole scores. The results for the consumption of saffron did not significantly change from that of placebo in the orgasmic function, overall satisfaction, and sexual desire field scores(12).

Orgasmic dysfunction in men can be categorized based on three key signs that may adversely affect a man's perception of orgasm: (1) the presence, timing and power of ejaculation, (2) urinary incontinence at the time of orgasm, and (3) the orgasm itself. If orgasm is not related to ejaculation, it is occasionally referred to as "dry orgasm." (24). The mean score of the orgasmic function significantly increased after the intervention (p = 0.013), while in the control group, this difference was not significant (p = 0.132). Kashani *et al*. (2013) reported that women in the saffron consumption group exhibited better recovery states in whole FSFI, lubrication, arousal, and pain fields of FSFI, but not in tendency, satisfaction, and orgasm domains (25).

Mohammadzadeh-Moghadam (2015) studied the effect of saffron on the erectile dysfunction and concluded that saffron had positive influences on entire fields of erectile dysfunction (7). The effect of saffron in all dimensions might have been due to its topical use. However, Shamsa *et al*. (2009) who used saffron tablets also found positive effects in all the dimensions (26).

Sexual tendency is usually clear as the personal psychological status to begin and keep human sexual behavior triggered by internal and/or external stimuli (27). The mean score of sexual desire improved after the intervention in the intervention group and this difference was significant (p = 0.011). The mean score of sexual desire in the control group was examined after the intervention but no noticeable alteration was observed. Moreover, this difference was not statistically significant (p = 0.480). Abedimanesh (2017) (9) stated that saffron had no significant effect on men's sexual tendencies, but in the study conducted by Rahmati *et al*. (2017), a significant difference was observed between their excitement and tendency four weeks after the beginning of the treatment (28).

Bravi *et al*. (29) concluded that the relationship between erectile function and sexual satisfaction was mediated by sexual desire. Thus, different dimensions were related to each other. The results of another study revealed that females had sexual arousal and orgasm

issues and males had erectile dysfunction as well as ejaculation problems which affected sexual satisfaction (24). Intercourse satisfaction scores improved in the intervention group after the intervention, and this difference was statistically significant (p = 0.007).

After the trial mean score in the control group, no noticeable change was made in comparison with before the intervention (p = 0.317). Therefore, an increase in sexual satisfaction was evident in the saffron group compared with the controls. Moreover, the overall satisfaction score in the intervention group was statistically higher than the control group after the intervention (p = 0.009). Many psychological and physical factors affect the level of sexual satisfaction of individuals. The results of the study conducted by Khan *et al*. (2020) showed that saffron could be used as a safe remedy to treat depression, inflammation, pain, and the coagulation system. They also indicated that saffron was an important and efficient source of bioactive compounds with excellent potential as a nutraceutical with health benefits (30). Furthermore, saffron and crocin might be able to recover the function of the central nervous system and mental health conditions through organizing the synthesis of chemical neurotransmitters in the brain, including dopamine, norepinephrine, and serotonin (31).

The total score of the IIEF scale in the intervention group at pre-intervention was 49.67±2.640, but it increased to 58.42±4.795 after the intervention.

This score represents the effect of saffron on the improvement of erectile dysfunction. Leone *et al*. (2018) studied the phytotherapic use of Crocus sativus L. (Saffron) and its potential applications in a brief overview. They concluded that the total positive impact was detected with a meaningful growth in erectile and orgasmic functions such as sexual

Table 2. A comparison of the study findings in the two study groups.

Variable	Intervention group (n = 12)	Control group (n = 12)	P-value*
Erectile Function			
Pre-intervention	22±2.089	22.17±2.082	0<0.001
Post-intervention	24.58±2.503	21.75±2.137	
P-value*	0.003	0.132	-
Orgasmic Function			
Pre-intervention	8.58±0.515	8.42±0.996	0.178
Post-intervention	9.42±0.669	8.50±0.798	
P-value*	0.013	0.705	-
Sexual Desire			
Pre-intervention	5.67±0.888	5.42±0.900	0<0.001
Post-intervention	6.92±1.084	5.25±1.138	
P-value*	0.011	0.480	-
Intercourse Satisfaction			
Pre-intervention	7.75±1.712	7.50±1.624	0<0.001
Post-intervention	10 ±2.174	7.25±1.960	
P-value*	0.007	0.317	-
Overall Satisfaction			
Pre-intervention	5.67±0.985	5.25±1.485	0<0.001
Post-intervention	7.50±1.732	5.67±1.155	
P-value*	0.010	0.166	-
Total score			
Pre-intervention	49.67±2.640	48.75±1.138	0<0.001
Post-intervention	58.42±4.795	48.40±2.811	
P-value*	0.002	0.414	-

The data have been presented as Mean±SD. *Wilcoxon test, ** In order to reduce the effect of covariates, the relative change analysis approach was used, and then the changes between the two groups were analyzed with the Mann-Whitney test

tendency and overall satisfaction (32). Cai *et al*. (2013) compared the effect of serenoa repens and a commercial formula including serenoa, pinus massoniana, and saffron on 129 patients with lower urinary tract signs and erectile dysfunction associated with benign prostatic hyperplasia in a prospective, multicenter, stage three research. It was revealed that the commercial formula was able to noticeably recover the quality of life of patients, particularly in terms of sexual function (33). Khalatbari –Mohseni *et al*. (2019) found that crocin was elicited and crystallized from saffron stigmas, and also significantly improved IIEF rather than placebo (31). Moreover, Mzabri *et al*. (2019) (34) concluded that saffron had a beneficial impact on sexual function with an increase in the number and duration of erections in patients with erectile dysfunction even after treatment for only 10 days.

In this regard, as it was reported in the research carried out by Razak *et al*. (2017), many studies have presented the beneficial effect of saffron on sexual dysfunction, but long-term consequences have not been documented (35). In contrast, Safarinejad *et al*. (2010) highlighted the absence of its beneficial impact on sexual dysfunction (10). José Bagur *et al*. (2018) (36) reported that some authors have noted that saffron could not have any effect on as sexual activity. Allahmadi (2020) (37), Maleki- Saghooni (2018) (11), and Irani (2018) (38) stated that there is still a controversy about the efficacy of saffron in the management of erectile dysfunction as there were different consequences in other research. Furthermore, Ranjbar and Ashrafizaveh (2018) explained that saffron could contribute to the improvement of sexual dysfunction. This influence was dissimilar in different fields of sexual dysfunction (8). Further research is necessary to confirm these primary findings.

Although the present study showed the beneficial effects of saffron on sexual disorders, the researchers confronted certain limitations. One of the major limitations of the study was the impossibility of blinding the study participants, which may have affected the results of the study. Due to the close relationship between the staff of companies and establishing interactions with each other, there was no possibility of blinding. Irregular consumption or non-consumption of the product was another limitation of this study, which should be considered in other studies. Finally, no placebo group was used in this study. It is suggested to be used in other studies.

It is suggested that similar research with larger samples and different populations be performed for definitive conclusions. Moreover, since this scale deals with people's mentality and self-reports, it is suggested to examine people's attitudes, cultural influences, expectations of individuals, and influencing factors about sexual satisfaction.

Conclusion

The findings of the present research indicated that saffron could affect all dimensions of erectile dysfunction. Due to the safety of this herbal medication, saffron could be consumed for the recovery of sexual efficiency. Since only a few studies have been conducted on the influence of saffron on sexual dysfunction, the results of this study can raise our awareness about the efficiency of saffron in the improvement of the erectile function. Even though saffron and its ingredients can be clinically used, further investigations are required to approve the practical use of the “Red Gold” and its applications in clinical practice.

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Conflict of Interest

The authors declare that they have no conflict of interest.

Funding

None.

Availability of Data and Materials

The datasets used and/or analyzed during the current

study are available from the corresponding author on reasonable request.

Consent for Publication

Not applicable.

Ethical Considerations

The objective of the research was explained to the samples and all of them completed the informed agreement form which was prepared based on the Declaration of Helsinki. This research was approved by the ethics committee of Larestan University of Medical Sciences (IR.LARUMS.REC.1399.016). Registration ID in IRCT: IRCT20090304001742N9 (update: March 11, 2023).

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