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ORIGINAL ARTICLE

Effectiveness of sexual counseling using PLISSIT model on sexual function of women with type 2 diabetes mellitus: results from a randomized controlled trial

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Abstract

Background Sexual problems are very common in patients with type 2 diabetes mellitus and due to its chronic nature may affect women's sexual quality of life.

Objectives To study the effect of permission, limited information, specific suggestions, intensive therapy (PLISSIT) model sexual counseling on sexual function of women with type 2 diabetes.

Methods This study is a randomized clinical trial that was conducted on 100 married women aged 35-55 year old with type 2 diabetes referred to endocrinology clinic. The subjects were randomly assigned to the intervention and control groups. In the intervention group, individual counseling was designed based on PLISSIT model, in at least three sessions. The control group received a general health training pamphlet at the end of the study. Before the first session and then 4 and 8 weeks after the intervention, questionnaires of demographic information, Brief Sexual symptom checklist for women (BSSC-W), and Female sexual Function Index (FSFI) were completed for two groups.

Results Total FSFI score of the patients improved after sexual counseling ($p < 0.001$) and in subscales; sexual desire ($p = 0.009$), lubrication ($p = 0.004$), orgasm ($p < 0.001$), and sexual satisfaction ($p < 0.001$). Also sexual function in all subscales except for arousal ($p = 0.181$) and pain ($p = 0.783$) were increased significantly. Although pain was decreased significantly in intervention group over the time, no difference was seen between two groups ($p = 0.783$). The effect size of intervention to promote FSFI was determined 0.42.

Conclusion Considering the effectiveness of a PLISSIT model sexual counseling on sexual function of women with type 2 diabetes, the results of the present study, can be used to promote sexual health of diabetic patients.

Keywords Diabetes mellitus · Women's sexual function · PLISSIT · Sexual counseling

Background

Chronic diseases, especially type 2 diabetes, which have a high prevalence in Iran, have a significant effect on women's sexual life [1, 2]. Although sexual dysfunction is very prevalent, patients with type 2 diabetes are more likely to have sexual dysfunction, pain, and reduced sexual arousal [3, 4]. The total prevalence of sexual dysfunction in type 2 diabetic women in Iran has been reported 78% [5]. In women with type 2 diabetes mellitus, sexual dysfunction and vaginal lubrication problems have been reported 46–82% and 37–70%, respectively. Prevalence of arousal disorder has been 68%, orgasm disorder 38–84%, and painful sex 43–46% [6].

The quality of sexual life and sexual health of diabetic women was reported significantly lower than that of women without this disorder [7, 8]. Sexual disorder is more common in women than men and it has not been related to age, duration of diabetes, and hypertension [9]. Another study also confirmed this result [2].

In the country's healthcare system, despite high capacity, there is still no place to screen sexual problems. The World Health Organization (WHO), emphasizing the integration of sexual health in primary health services, considers sexual issues' training of people and health workers as essential for the

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promotion of sexual health [10]. Regarding the high prevalence of diabetic patients' sexual problems, it seems that diagnosis of sexual problems and counseling about these problems with patients should be more carefully planned in the healthcare system. In some other countries also, health services often are not organized for the needs of diabetic patients, and health workers lack the knowledge and skills to manage such diseases [11].

Regarding high prevalence of sexual dysfunction in type 2 diabetic patients and the effect on the quality of life, it seems very necessary to have sexual counseling. PLISSIT model is the most commonly used tool for studying and evaluating sexual function and can be used by all people. This model was developed by psychologist Jack Annon (1974) to be used by healthcare providers in visits to assess the patients' sexual health needs [12]. The sexual counseling model has a four-stage framework, including a patient permission to start talking about sexual problems, providing limited information, specific suggestions, and intensive care to resolve the sexual problems of the patients. This counseling model has been studied in patients with stoma, breast cancer, multiple sclerosis, uterine, and vaginal cancer, as well as in patients undergoing surgeries such as hysterectomy or cardiac surgery and in all of these patients, it has been proven useful in solving and managing patients' sexual problems [13–16]. Due to scarce evidence about this counseling model in diabetic patients, this study aimed to assess the effect of sexual counseling using PLISSIT model on sexual function of type 2 diabetic women.

Methods

Design

The present study was a parallel randomized clinical trial that was conducted on 100 middle-aged diabetic women (50 in the intervention group and 50 in the control group) referred to endocrinology clinic of Imam Ali hospital in Karaj. The study protocol was reviewed and verified by a sexologist of the research team. Eligible patients randomly assigned to the control and intervention groups after providing consent to participate in the study. Randomization took place by a colleague outside of the research.

Study participants

Diabetic women aged 35 to 55 years participated in this study and the inclusion criteria were as follows: Iranian women with type 2 diabetes, ages 35–55, women with at least one sex problem based on Brief Sexual symptom checklist for women (BSSC-W), reading literacy in Persian to fill in questionnaires, and no medical conditions other than diabetes that affects sexual function. Participating in similar training counseling sessions, pregnancy, and/or lactation, as well as sexual dysfunction in men, were the study exclusion criteria. Assuming the equality of variance in two groups and the mean difference of 0.7 between the two groups, using the following formula with the 0.05 probability error of type 1, and the power of 80%, 50 samples were calculated. In addition, we accounted for a 10% dropout. A total of 55 patients in each group were needed [17].

$$n = \frac{2 \times \left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 S^2}{(d)^2}$$

Simple randomization (card/envelops shuffling) was the method for randomization in this study. The participants were selected randomly (3 days per week every other day) among patients who had the study inclusion criteria referred to endocrinology clinic of Imam Ali hospital. Random allocation was performed by 110 cards that were encoded and placed in a container from 1 to 110, so that 55 envelopes for the intervention group and 55 envelopes for the control group could be extracted. Then, the envelopes were randomly pulled out. Two separate containers were considered for the intervention and control. According to the previous process, the first envelope was placed for the control group and the one for the intervention group, and this was done until the allocation process was complete. To conceal the randomization, the envelopes were sealed as well as we asked an assistant outside the study team to assign the envelopes. The study flowchart based on CONSORT 2010 was illustrated in Fig. 1.

Intervention

At least three sessions of 45 min of individual sexual counseling were designed and developed to improve sexual function based on PLISSIT model in the intervention group. Educational pamphlet for the control group included general care in diabetes and related therapies, nutrition, physical activity, and sexual health. Sexual function questionnaire was completed for both groups before the first session and then 4 and 8 weeks after the intervention.

Permission The researcher asks the patient for permission to enter the sexual discussion and allows him to ask questions in a comfortable and private environment. A sample question asked is "I ask all diabetics about their sexual problems, is it okay to ask you such questions?" or for example "do you have questions about sexual problems to ask me?" [18].

The second stage is to provide *limited information*. The researcher provided brief information to the patient about the effect of diabetes and its side effects on sexual function. The third stage is *specific suggestions* for the given problem. After taking a thorough history and discovering patients' problems, strategies such as administering lubricant and/or introducing a special position for sex and changes in lifestyle can help the person to

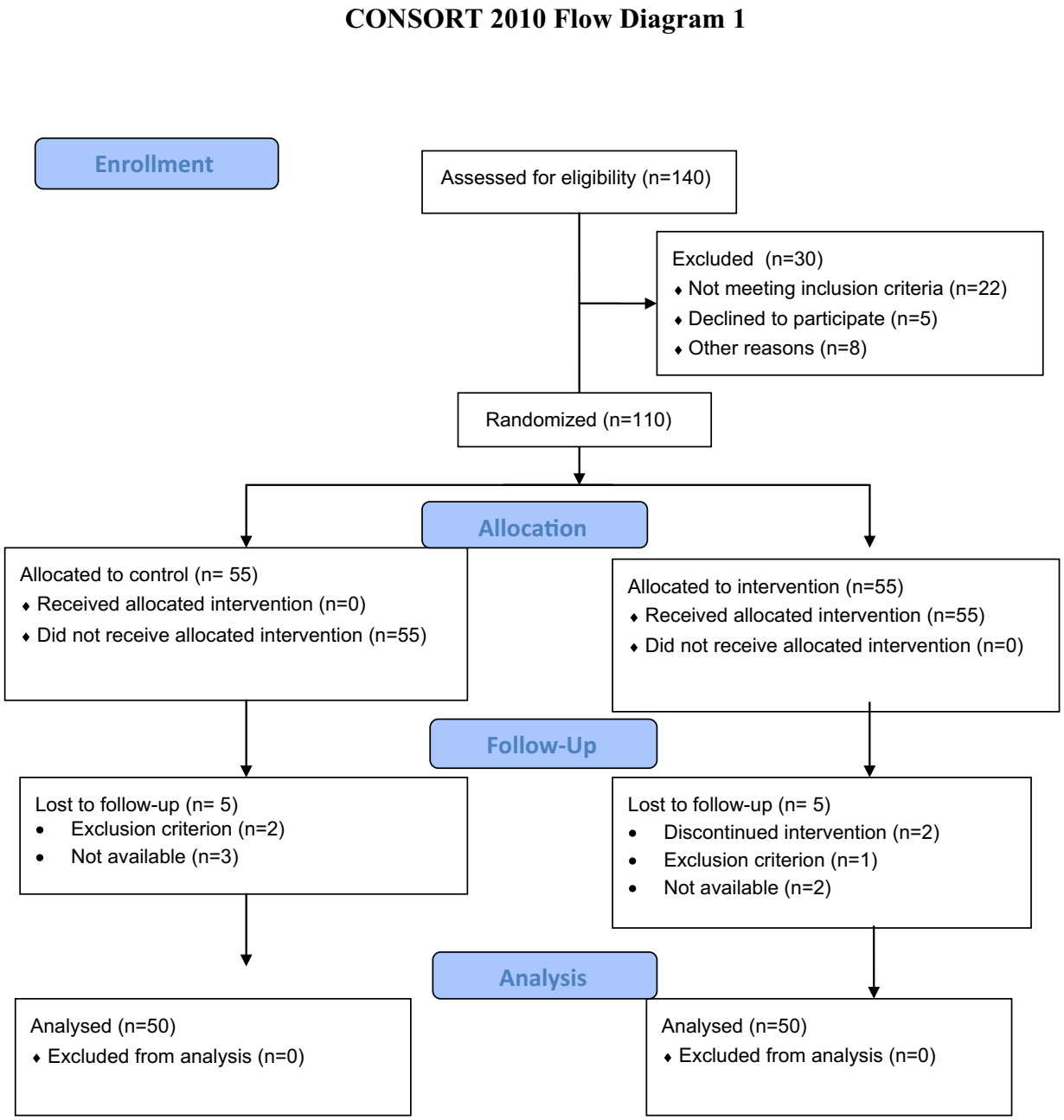

Fig. 1 CONSORT 2010 flow diagram 1

resolve the problem. Exercises can be used such as sensate focus, Kegel exercise, and others, depending on the type of problem and patient's need. The fourth stage is *intensive care*, which identifies any difficulty and sometimes requires referral to other professionals such as a psychiatrist or family consultant.

The first session started with permission, introduction, providing an intimate and comfortable environment for the patient, and asking questions about the onset of the disease and how it was treated. The second session provided limited information on genital anatomy and physiology with images and models, sexual response cycle and changes in life cycle, and the effect of diabetes on the sexual function and life of a person. At this stage, we attempt to correct the information about the changes that may occur sexually in a diabetic person, and/or the mutual effect of a healthy sexual relationship on a diabetic person life, as well as her sexual misconceptions.

The third session offered specific suggestions for the patient's problem, including regular daily walks, recommendations for taking lubricant, Kegel regular exercise, hormonal medications such as Premarin (if necessary under a doctor's control), sensate focus, and changes in sex position [18]. The first author as a female midwife-counselor has conducted sessions and gathered data. Study duration lasted 18 weeks from the first counseling

session of the first participant and the last counseling session of the last participant.

Measures

In this study, data collection tool was a questionnaire that was completed as self-administered. The questionnaire consisted of three parts as below:

Demographic characteristics

Demographic characteristics include marital status, age, education, occupation of the patient and her spouse, duration of the patient's diabetes and type of treatment, level of HbA1c, family income, and body mass index.

Brief Sexual symptom checklist for women

BSSC-W with forward-backward procedure was applied to translate the questionnaire from English to Persian with the author's permission. It consists of six questions; the first question begins with the question of the degree of satisfaction with sexual function, which, if negative, the next question is asked.

Female Sexual Function Index

Female Sexual Function Index (FSFI) questionnaire by Rosen et al. evaluates sexual function of women in six independent fields of sexual desire, sexual stimulation (arousal), lubrication (vaginal wetness), orgasm, satisfaction, and sexual pain with 19 questions [19]. A higher score indicates better sexual function. This tool evaluates women's sexual function over the past 4 weeks. For scoring, the scores of each field are obtained by summing the scores of questions in each field and multiplying them in the factor number. A zero score indicates that the person did not have sexual activity during the last 4 weeks. The maximum score for each domain is 6 and for the whole scale is 36. Validity and reliability of this tool were confirmed in Iranian studies and Cronbach's alpha coefficient for each of the fields and the whole scale was 0.70 and higher [20].

Data analysis

To compare the quantitative variables between the two groups, we used *t* test and for comparing the qualitative variables in two groups, chi-square or Fisher's tests were used. The mean scores of sexual function between the intervention and control groups before 4 and 8 weeks after the intervention were compared using repeated measure ANOVA. *p* value less than 0.05 was considered significant. Cohen *d* was used to determine effect size. Data analysis of this study was done using software SPSS version 19.

Results

The mean age of women was 47.88 ± 5.44 and 48.02 ± 6.03 in the intervention and control groups respectively ($p = 0.903$). Husbands' age mean was 54.46 ± 6.75 in the intervention and 55.36 ± 8.24 for the control group ($p = 0.552$). The highest number in both groups (56%) was for junior and high school without significant difference between the two groups ($p = 0.061$) about income. The duration of the disease in the intervention group was 7.62 ± 5.270 and 7.35 ± 3.995 in the control group ($p = 0.773$). The mean of HbA1C in the intervention group was 8.23 ± 1.52 and 8.170 ± 1.24 in the control group ($p = 0.813$). Eleven women (22%) of the intervention group were in menopausal situation and four of them (18%) needed hormone therapy. Other variables are shown in Table 1.

Repeated measures ANOVA showed that the sexual function mean score had a significant change over time ($p = 0.000$) and a significant difference was observed between the two groups ($p = 0.000$). All subscales of sexual function in the intervention group improved except for pain and arousal (Table 2). Figure 2 shows the trend of the total mean scores of the FSFI in participants of intervention and control groups.

Discussion and conclusion

The present study is a randomized controlled clinical trial that was conducted on type 2 diabetic women and showed that

Table 1 Demographic characteristic of the participants

Variable	Intervention group $N = 50$, N (%)	Control group $N = 50$, N (%)	p value
Kind of therapy			
Insulin	6 (12)	4 (8)	$p = 0.542$
Tablet	33 (66)	38 (76)	
Both	11 (22)	8 (16)	
Number of children			
1–2	10 (20)	9 (18)	$p = 0.101$
3–5	38 (79)	29 (65)	
6 and more	2 (4)	2 (4)	
Body mass index (BMI)			
18.5–24.9	3 (6)	6 (120	$p = 0.421$
25–29.9	29 (58)	31 (62)	
30 and more	18 (36)	13 (42)	
Menopause			
Yes	11 (22)	14 (28)	$p = 0.424$
No	39 (78)	36 (22)	

Table 2 Total FSFI scores in different points of evaluation in the intervention group and control group

FSFI and subscales	Group	Before intervention	4 weeks after intervention	8 weeks after intervention	Test statistics p value	
					Within group	Between group*
Desire	Intervention	3.300 ± 0.019	3.276 ± 0.019	3.708 ± 0.007	$F = 3.04$, $p < 0.05$	$F = 4.861$, $p < 0.01$
	Control	3.336 ± 0.018	3.318 ± 0.018	3.300 ± 0.018		
Arousal	Intervention	4.160 ± 0.013	4.164 ± 0.013	4.226 ± 0.010	$F = 0.75$, $p = 0.928$	$F = 1.723$, $p = 0.181$
	Control	4.242 ± 0.013	4.218 ± 0.013	4.158 ± 0.012		
Lubrication	Intervention	3.852 ± 0.025	3.786 ± 0.025	4.380 ± 0.012	$F = 7.766$, $p < 0.01$	$F = 5.81$, $p < 0.01$
	Control	3.936 ± 0.025	3.876 ± 0.025	3.942 ± 0.024		
Orgasm	Intervention	3.344 ± 0.017	3.464 ± 0.018	4.488 ± 0.018	$F = 33.714$, $p < 0.001$	$F = 23.16$, $p < 0.001$
	Control	3.400 ± 0.017	3.472 ± 0.018	3.536 ± 0.018		
Satisfaction	Intervention	3.152 ± 0.014	3.200 ± 0.015	4.632 ± 0.015	$F = 85.85$, $p < 0.001$	$F = 40.160$, $p < 0.001$
	Control	3.088 ± 0.014	3.104 ± 0.014	3.368 ± 0.018		
Pain	Intervention	5.120 ± 0.018	5.408 ± 0.014	5.656 ± 0.008	$F = 19.908$, $p < 0.001$	$F = 0.285$, $p = 0.783$
	Control	5.064 ± 0.020	5.400 ± 0.014	5.528 ± 0.012		
FSFI (total score)	Intervention	22.932 ± 0.045	23.298 ± 0.050	27.130 ± 0.035	$F = 3.47$, $p < 0.01$	$F = 4.86$, $p < 0.001$
	Control	23.066 ± 0.043	23.438 ± 0.048	23.832 ± 0.050		

Data are presented as mean ± SE

*According to two-way repeated measure ANOVA test

sexual counseling with PLISSIT approach increased the sexual function score and most of its field (except arousal and pain) in women with type 2 diabetes 8 weeks after the intervention significantly. This was the first study conducted based on PLISSIT model for women with type 2 diabetes in Iran.

Although sexual counseling can be done in a variety of ways, PLISSIT model can be very useful, given the potential for its application by doctors and midwives to its third stage. Consistent with the results of the present study, this model of sexual counseling has been performed in various groups of patients including patients with breast cancer, cardiovascular, hysterectomy, and multiple sclerosis, which have been shown to be effective in all cases [13–16]. The results of a study showed that PLISSIT based sexual counseling was effective in improving sexual function of women after hysterectomy and oophorectomy surgery [15]. Other studies conducted in Iran showed that counseling with this model reduced women sexual problems [21, 22].

PLISSIT model-based sexual counseling in the present study increased all domains of sexual function, except for sexual excitement and pain. In the study of Khakbazan et al., also PLISSIT model-based sexual counseling did not have a significant effect on the sexual excitement of women with multiple sclerosis during three 1-h sessions [13]. Diabetic neuropathy, in addition to affecting the sense of pleasure in sex, also affects the sexual excitement [23]. Regarding high prevalence of diabetic sexual problems and the effect on quality of life, it seems that this disorder should be identified more accurately in the healthcare system [5].

In a study examining the effect of sexual counseling in six 1-h sessions based on PLISSIT model on women with sexual problems in Tehran, sexual function and distress of women reduced in the intervention group 7 months after the intervention [22]. But in a systematic and meta-analytic study aimed to study the effectiveness of therapeutic interventions on women's sexual dysfunction, it was found that there is still

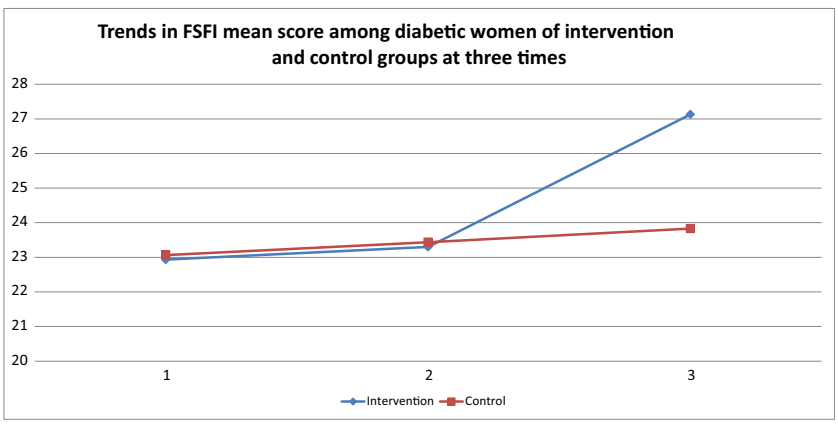

Fig. 2 Trends in FSFI mean score among diabetic women of the intervention and control groups. Axis X shows different times; time 1 is related to before intervention, time 2 and 3 are related to 4 and 8 weeks after intervention respectively. Axis Y shows mean score of FSFI

no reliable evidence to suggest the effectiveness of the various types of interventions [24].

Consistent with the results of the present study, which showed that PLISSIT model-based sexual counseling has increased lubrication, in a study that used this approach to study sexual function of married women with sexual problems, the results showed a significant difference in terms of lubrication [21].

The present study showed that sexual counseling could affect the orgasm of diabetic women, which is consistent with the results of a study that was conducted based on PLISSIT model, in which during three weekly sessions, women sexual function and orgasm increased [25]. Also, Almedia et al. considered sexual counseling based on PLISSIT model as effective on marital intimacy and sexual intimacy and orgasm in mastectomized women [26].

A significant difference was found in the satisfaction domain in the intervention group over time, and also observed between two groups. A study was conducted on sexual satisfaction of 60 women with stoma with PLISSIT model and showed that sexual counseling based on this model can reduce the sexual problems of women and increase their sexual satisfaction [27]. Sexual counseling in the present study in addition to providing appropriate strategies that could lead to better control of blood glucose in women and prevent or control sexual dysfunction, sexual desire, and lubrication improved with techniques, and pain reduced which showed an effect on orgasm improvement as well as satisfaction with sex. Good sex can be a powerful motivation for controlling diabetes and maintaining health [26].

A significant different was found in the variable pain over time, but no significant difference was observed between the intervention and control groups. Consistent with the results of this study, Khakbazan et al. showed that PLISSIT model-based sexual counseling was effective on sexual function of women with multiple sclerosis in three sessions immediately after the intervention and 2–3 months after the intervention but failed to reduce pain in women with multiple sclerosis [13]. A study had evaluated the effect of PLISSIT model-based sexual counseling on sexual function of women with cancers; all of sexual function subscales improved except for arousal and pain that is in line with our study [28]. Pain score was a domain that did not increase in a sexual education program that was conducted in the four 60-min sessions with 1-week interval in another study [29]. In our study, husbands of the participants were not included in intervention; maybe, the presence of them could impact on sexual function of women especially on pain reduction that was showed in a study [30].

One of the limitations of the present study, like other studies focusing on sexual problems, is the multifactorial nature of sexual problems, as well as the effect of mental and emotional conditions on sexuality. This study would be a good guide for the midwifery counseling group and physicians to address the sexual problems of diabetic patients.

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Compliance with ethical standards

Ethical approval The present study was approved by Abzums.Rec.1396.6 code at the Ethics Committee of Alborz University of Medical Sciences, as well as the registration number of IRCT2017070231662N4 in Iranian Clinical Trial System.

Conflict of interest The authors declare that there is no conflict of interest.

Informed consent Informed consent was obtained from all individual participants.

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