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The Effect of Sexual Counseling Based on EX-PLISSIT Model on Improving the Sexual Function of Married Women with Systemic Lupus Erythematosus: A Randomized Controlled Trial

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Abstract

Systemic Lupus erythematosus (SLE) is a multisystem autoimmune disease. This disease triggers sexual dysfunction due to physiological, cognitive and mental effects. Since sexual function is often ignored in these patients, this study aimed to investigate the effect of sexual counseling based on EX-PLISSIT model on improving the sexual function of married women with SLE. This clinical trial was conducted on 101 married women suffering from SLE (18–49 years) residing in Tehran. Randomization was performed by random block allocation with six blocks in a rheumatology clinic. A demographic questionnaire, the Depression, Anxiety, Stress Scales-21 Items (DASS-21), and the female sexual function index were used to collect the data. The intervention group received counselling sessions every week while the control group (n=55) received routine care for the disease. Eight and twelve weeks after completion of counselling sessions, outcomes compared between the intervention and control groups, using independent ttest, paired t-test, repeated measures and Chi-squared test. The scores of sexual function in both groups did not differ significantly before the intervention ($p > 0.05$). At the first follow-up session, the score of all sexual function domains except sexual pain increased significantly in the intervention group while a significant reduction was observed in all domains of sexual function in the control group ($p < 0.05$). In the second follow-up, sexual function significantly increased in the intervention group whereas it significantly decreased in the control group ($p < 0.05$). According to the findings of this study, counseling based on EX-PLISSIT model positively affected the sexual function of women with SLE. Therefore, this model can be used as a cost-effective and simple counseling method to improve the sexual functions.

Keywords Systemic lupus erythematosus · Sexual function · EX-PLISSIT model · Sexual counseling · Women · Islamic Republic of Iran

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Introduction

Systemic Lupus erythematosus (SLE) is an autoimmune disease where the immune system attacks its own tissues [1]. According to a community-based study, the prevalence of SLE in Iran was estimated to be 40 per 100,000 individuals [2]. More women, particularly those at reproductive ages (15–44 years) are affected by SLE than men (estimates range from 4 to 12 women for every 1 man) [1, 3]. In Akbarian et al.'s study on 2280 patients with SLE in Iran, women with a mean age of 24 years were found to be affected 9 times more than men [4].

The effect of SLE on women's sexual function has been investigated in many studies [5, 6]. In these patients sexual dysfunction is multifactorial and can be caused by physical symptoms such as pain, fatigue, joint stiffness and psychological reactions to chronic diseases such as depression and anxiety [7]. It seems that sexual dysfunction in these women is more related to vaginal pain during intercourse. On the other hand, fatigue, which is one of the consequences of SLE, leads to sexual dysfunction [8, 9]. According to a study by Shen et al., 64.1% of their SLE patients had sexual dysfunction [10] while Zhang et al. reported the prevalence of sexual dysfunction in healthy Chinese women to be 29.7% [11]. The prevalence of sexual dysfunction in women affected by SLE in Iran according to the study of Behboodi Moghadam et al. was 85.9%. The results of this study showed that 14.1% of patients scored more than 26.55 in the female sexual function index (FSFI), while this score was obtained by 73.5% of healthy women [5].

Research has shown that couples' knowledge could be promoted by solving problems caused by their misconceptions and misinformation [12]. According to the World Health Organization (WHO), identifying and addressing sexual concerns and problems, as well as providing education to address sexual dysfunction, are essential factors in improvement of sexual health care. However, sexual health is often overlooked by health care providers [13, 14]. In addition, SLE patients do not seek help from their physicians about sexual health [15].

Consulting based on the Permission-Limited Information-Specific Suggestion-Intensive Therapy (PLISSIT) model which was first described by Anon [16] has been reported to have positive effects on sexual function and sexual problem-solving skills [17]. EX-PLISSIT model is an extended form of PLISSIT model in which all stages start with Permission, and the patient is offered opportunity to ask questions or voice their concerns to increase self-awareness. Some characteristics of PLISSIT model, which have been expanded in the EX-PLISSIT, are providing feedback and re-review, offering Intensive Therapy at any stage, and changing the PLISSIT model from a one-way process into a two-way process by reviewing interventions with clients [18].

According to the literature, the EX-PLISSIT model is effective in treatment of sexual dysfunction in some diseases or after some operations [19–21]. To the best of our knowledge, no study has yet investigated the effects of different interventions on the sexual functioning of women with SLE. Therefore, with regard to the prevalence of sexual dysfunction in SLE patients and the scarce data on the effects of EX-PLISSIT model, the aim of this study was to determine the effect of counselling based on the EX-PLISSIT model on improving sexual function of married women suffering from SLE in Iran.

Methods

This randomized controlled study trial was conducted on 110 married women with SLE referring to the Lupus Association of Tehran and the Rheumatology Clinic of Shariati Hospital affiliated to Tehran University of Medical Sciences, Iran from April to October 2021 to answer the question of whether sexual counseling is effective in improving the sexual function of women with SLE. Eligible participants were literate and sexually active married Iranian women of reproductive age (18–49 years), with confirmed diagnosis of SLE made by a rheumatologist, having no history of chronic disease (a part from SLE) as diagnosed by a rheumatologist (affected by SLE while the main organs such as the heart, kidneys, etc. are not involved), and having Internet access. Due to the cultural restrictions with respect to sexual activities of single people in Iran, the study was conducted only on married women. Women experiencing severe depression, anxiety and stress (obtaining scores less than 13, 9 and 18 on constructs of the Depression, Anxiety and Stress Scale (DASS)–21 questionnaire, respectively), having intrapersonal problems according to their own statement, experiencing physical or mental illnesses that could affect sexual activity, participating in any sexual training classes during the study period, receiving any treatment for sexual function, being pregnant, and having a history of drug abuse and using any other kinds of medicines which could affect sexual functioning except those their rheumatologist prescribed for their disease were excluded from the study.

Sample Size

Based on an estimate of 25% change in baseline scores in intervention group and 5% change in mean baseline scores of the control group, and considering 95% confidence interval ($\alpha = 0.05$) and 80% test power ($\beta = 0.2$), 49 participants were calculated for each group. Assuming a 10% attrition rate, the number of samples in each group was considered to be 55 people. Therefore, in this study, 110 patients were randomly assigned to two groups of 55. Because of patient flow and budget constraints, we did not initially conduct a pilot study.

Sampling

The trial was conducted after receiving approval from the Ethics Committee of Tehran University of Medical Sciences (Ref. ID: IR.TUMS.FNM.REC.1399.136), being registered in the Iranian Registry for Clinical Trials (IRCT20120414009463N63) and obtaining permission from the authorities of Rheumatology *Research Center*. During a meeting, the participants were assured that their information would remain confidential, were briefed on the importance and the methods of the study, and were requested to sign informed written consents. Of the 126 patients who were willing to participate in the study, 25 were excluded due to exclusion criteria. Therefore, a total of 101 female SLE patients were enrolled in the study. The participants completed the pre-test questionnaires including a demographic questionnaire, Depression Anxiety and Stress Scale 21 (DASS-21), and Female Sexual Function Index (FSFI). Participants with severe depression, anxiety and stress (according to DASS-21) were excluded from the study and referred to a psychiatrist. Afterward, patients were allocated into two groups using a randomized block design. At first, based on the arrangement of the patients in the two groups, namely Group A (intervention) and Group B (control), six blocks were identified and numbered. Then, the numbers of blocks

were selected randomly by a person who was not involved in the sampling process to reach the intended sample size. Fifty-five females were assigned to each group. All participants answered the questionnaires at baseline and after 8 and 12 weeks. The physicians involved in the clinical evaluations were blinded to the patient group allocation. Due to the nature of the intervention, blinding participants to group assignment was not possible.

The intervention group (IG n = 55) was divided into eight subgroups, with a maximum of ten and minimum five patients according to each patient's preferred schedule for the first consultation session. Control group (CG n = 55) only received standard medical care according to the outpatient Rheumatology Clinic schedule. The IG continued to receive routine medical treatment throughout the study.

Nine patients dropped out of the study (five in IG and four in CG). In IG, one patient became pregnant, two stopped attending the counseling sessions, one suffered the loss of her husband, and one needed intensive therapy and was referred to a psychologist. In CG, four patients dropped out of the study due to failure in cooperating in the study and not completing the questionnaires in the follow-up sessions.

Data Collection Tools

The demographic questionnaire included information about the participants' and their husband's age, educational attainment, and occupation, socio-economic status, length of marriage, duration of disease, age at onset of the disease, type of medications taken, etc.

DASS-21 consists of 21 items and was developed by Lavibund and Lavibund (1995) [22]. The questions address three components of depression, anxiety and stress, with each component containing 7 questions. The final score of each subscale (component) must be doubled. The validity and reliability of this questionnaire were examined by Samani et al. [23], who found the reliability for the subscales of depression, anxiety and stress to be 0.80, 0.76 and 0.77, respectively, and obtained Cronbach's alphas of 0.81, 0.74 and 0.78 for the subscales of depression, anxiety and stress, respectively.

In this study, sexual function was measured by FSFI. This 19-item questionnaire assesses six areas of sexual desire, sexual arousal, lubrication, orgasm, sexual satisfaction, and dyspareunia. according to the weighting of the domains, the maximum score for each domain is 6 and the maximum total score is 36. In this questionnaire, the clinical cut-off point for the overall score is 26.55. A score below 26.55 indicates sexual dysfunction, and a score above 26.55 indicates normal sexual function. FSFI is a standard tool that reliability and validity were confirmed by Rosen et al. in 2000 [24]. The validity and reliability of the Persian version of this questionnaire was calculated and confirmed by Fakhri et al. (2012). The reliability coefficient of test and retest for each domain of this questionnaire was (0.73–0.86), and the internal consistency was between 0.72 and 0.90 which is in the acceptable range [25].

Intervention

After completing the demographic and social characteristics checklist, the DASS-21, and FSFI by the both groups, sexual counseling based on the EX-PLISSIT model was conducted in the intervention group (55 patients) by the first author who was a trained midwife. Due to the COVID-19 pandemic, all counseling sessions except the first session were held via Skype and WhatsApp. A previous study has shown that virtual education and counseling have a positive effect on self-efficacy and other variables in SLE patients

[26]. Sessions were held on a weekly basis. The number of meetings held for each participant was according to their specific needs. In this way, 20 patients received counselling in three sessions of 60–100 min, 30 patients received three 90 min sessions, and five patients attended two 100 min sessions. The difference in the number and length of sessions was based on the request of the individuals and the recognition of the researcher in terms of answering their questions, satisfying their needs, and providing appropriate guidance.

First, based on the first step of the model (Permission), the participants were given opportunity to talk about themselves and their views and opinions about sex and marital relationships in general. In this face-to-face session, in order to enhance the participants' learning, images (e.g., body anatomy, diagrams, and other images) in form of PowerPoint slides and educational clips were used. Information about the SLE process and its impact on sexual function as well as the anatomy and physiology of the female sexual organ and the psychological aspects of the disease was given to patients. The subsequent sessions were held individually on Skype or WhatsApp. Then, based on the second step of the model (Limited Information), people were told to raise their questions and concerns privately so that the second session could be arranged individually. In the second session, by giving the participants limited information including the outline of the four stages of sexual response, the researcher tried to answer the participants' questions and convey the necessary information to them. For example, one of the participants' concerns was the effect of the drugs she was taking for Lupus on her sexual function. Another common question of the participants was about the type of contraceptive method, indicating their limited information about the advantages and disadvantages of each method with respect to their disease. Following that, based on the third step of the model (Specific Suggestion), specific suggestions about the participants' sexual problems were made. A few examples include using lubricants for those who had problems with lubrication or sexual pain, teaching suitable and different intercourse positions for those who had problem with orgasm or intercourse positions, avoiding sexual activity when tired, and using Kegel exercises. Patients who still had mental disorders and interpersonal conflicts related to sexual function despite the previous three stages entered the Intensive Therapy phase, at which point they were referred to a psychologist and excluded from the study.

The Permission phase was considered in all counseling sessions, and the participants were offered opportunity to talk about their worries in the consultation process. The counseling process involved providing feedback and review, exchange and discussion about the topics to be learned, and monitoring the comprehension of the patients during the counseling. Women were encouraged to enhance their relationship with their husband and tell them about their concerns and issues. The control group only received standard medical care according to the schedule of the outpatient rheumatology clinic.

In the last session, in addition to summing up the previous sessions and examining the positive and negative aspects of the counseling process, any remaining ambiguities or questions were addressed, and follow-up sessions were scheduled. The contact number of the researcher was also provided to answer any possible question the participants might have had. Finally, 8 and 12 weeks after the last counseling session, the FSFI questionnaire was completed by individuals in both groups.

Statistical Analysis

The data were analyzed using SPSS software version 23. After collecting the data, normality of data was examined using Kolmogorov–Smirnov test. In order to compare the two groups,

quantitative variables were compared using independent t-tests and paired t-test, whereas qualitative variables were compared using Chi-squared test. Repeated measures ANOVA was used to compare sexual function and its six domains over time. One-sample and paired t-tests were used in groups. In all tests, $p < 0.05$ was considered statistically significant. All analyses were done based on per-protocol.

Results

One hundred and one women were ultimately selected for this study (Fig. 1). The mean age of the participants in the intervention and control group was 34.3 ± 5.74 and 35.2 ± 6.62 years, respectively. The mean length of marriage in the intervention group was 12.2 ± 7.28, and that in the control group was 14.2 ± 6.72. The mean duration of the disease in the intervention and control group was 9.5 ± 5.36 and 10.8 ± 6.45 years, respectively. The variety of medications taken by both groups were identical. No statistically significant difference was found ($p > 0.05$) between the demographic characteristics of the participants in both groups (Table 1). Moreover, there was no significant difference between the mean score of depression, anxiety and stress in the intervention and control groups (Table 1).
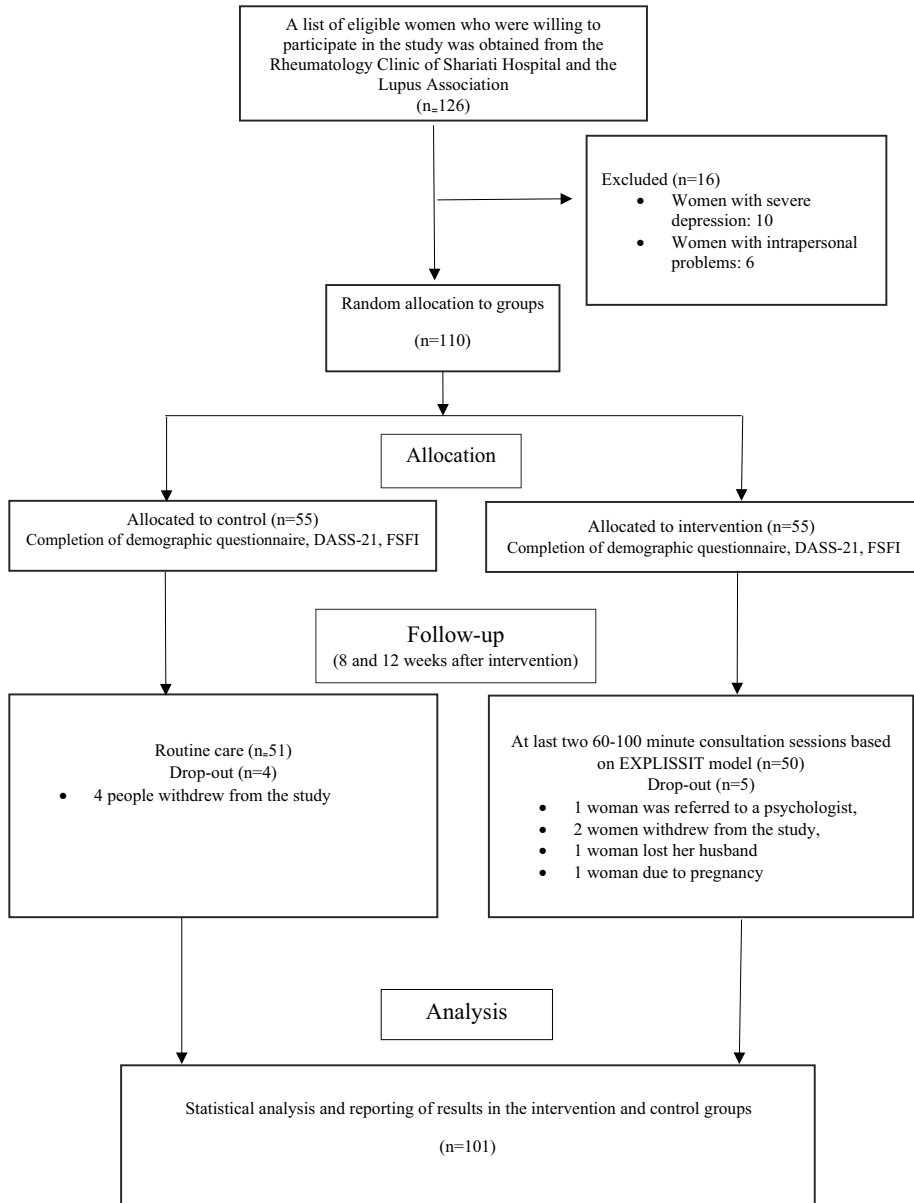
Prior to intervention, no statistically significant difference was found ($p = 0.581$) between the groups regarding FSFI score and all its dimensions (Table 2). The mean total score of FSFI in the intervention group increased from 21.0 (5.68) before intervention to 23.5 (5.43) eight weeks after intervention. The same value in the control group decreased from 20.3 (6.19) before intervention to 17.2 (4.79) eight weeks after intervention. These changes were significant in both groups ($p < 0.0001$). Based on the results of independent t-test, the mean total score of FSFI in the intervention group was significantly more than that in the control group 8 weeks after intervention ($p < 0.0001$). All domains ($p < 0.0001$) in both groups, except pain ($p = 0.673$) in the intervention group, underwent significant changes, with an increasing trend in the intervention group but a decreasing trend in the control group.

A comparison of the mean total score of FSFI twelve weeks after intervention (25.4 ± 3.85) with that at baseline (21.0 ± 5.68) showed that there was a significant increase in the intervention group ($p < 0.0001$). In contrast, a significant decrease (20.3 ± 6.19 before intervention compared to 16.1 ± 4.39 twelve weeks after intervention) was observed in the control group ($p < 0.0001$). The total score of FSFI and all its domains significantly increased twelve weeks after intervention (25.4 ± 3.85) compared with eight weeks after intervention (23.5 ± 5.43) in the intervention group ($p < 0.0001$). However, in the control group Sexual desire ($p = 0.710$), Sexual arousal ($p = 0.815$), and Orgasm ($p = 0.188$) did not change significantly twelve weeks after intervention compared with eight weeks after intervention (Table 2).

Overall, by using repeated measures ANOVA, a significant increase ($p < 0.0001$) in the total score of sexual function and all its domains was seen in the intervention group during the two follow-up sessions. In contrast, a significant decrease ($p < 0.0001$) was observed in the control group (Table 2, Fig. 2).

Discussion

The main purpose of this study was to determine the effect of counseling based on the EX-PLISSIT model on improving the sexual function of married women with SLE. In this study, the demographic information and clinical features related to the disease (which have

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                    │ A list of eligible women who were │
                    │ willing to participate in the     │
                    │ study was obtained from the       │
                    │ Rheumatology Clinic of Shariati   │
                    │ Hospital and the Lupus Association │
                    │            (n=126)                │
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Excluded (n=16)
- Women with severe depression: 10
- Women with intrapersonal problems: 6

Random allocation to groups
(n=110)

Allocation

Allocated to control (n=55)
Completion of demographic questionnaire, DASS-21, FSFI

Allocated to intervention (n=55)
Completion of demographic questionnaire, DASS-21, FSFI

Follow-up
(8 and 12 weeks after intervention)

Routine care (n=51)
Drop-out (n=4)
- 4 people withdrew from the study

At last two 60-100 minute consultation sessions based on EXPLISSIT model (n=50)
Drop-out (n=5)
- 1 woman was referred to a psychologist,
- 2 women withdrew from the study,
- 1 woman lost her husband
- 1 woman due to pregnancy

Analysis

Statistical analysis and reporting of results in the intervention and control groups
(n=101)

Fig. 1 Flowchart of the study

been considered as variables affecting the sexual function of SLE patients in some studies) were collected, and an effort was made to examine all patients in terms of these variables to see if the women in the two groups were similar or not. Therefore, the participants in both groups were homogenous with regards to these variables.

Our findings revealed the positive effect of sexual counseling on sexual function and all its six subscales in the married women with SLE. Of course, the average total sexual

Table 1 Comparison of demographic factors of patients in intervention and control groups

Variable	Groups (number/percentage)		p-value*
	Intervention n=50 (%)	Control n=51 (%)	
Participant's educational attainment			0.389
Primary	7 (14.0)	7 (13.7)	
Secondary	9 (18.0)	15 (29.4)	
University	34 (68.0)	29 (56.9)	
Husband's educational attainment			0.429
Primary	8 (16.3)	10 (19.6)	
Secondary	9 (18.4)	14 (27.5)	
University	32 (65.3)	27 (52.9)	
Participant's occupation			0.961
Housewife	40 (80.0)	41 (80.4)	
Employed	10 (20.0)	10 (19.6)	
Husband's occupation			0.984
Unemployed	2 (4.0)	2 (3.9)	
Employed	48 (96.0)	49 (96.1)	
Economic status			0.803
Good	4 (8.0)	4 (7.8)	
Moderate	36 (72.0)	34 (66.7)	
Poor	10 (20.0)	13 (25.5)	
Medication			0.567
Anti-malaria and corticosteroid	21 (42.0)	21 (41.2)	
Anti-malaria and corticosteroid and Immunosuppressive	22 (44.0)	23 (45.1)	
Anti-malaria and corticosteroids and Bisphosphonates	2 (4.0)	4 (7.8)	
Corticosteroids and immunosuppressive	2 (4.0)	3 (5.9)	
Corticosteroids	2 (4.0)	0 (0)	
Corticosteroids, immunosuppressive, anti-malaria and bisphosphonates	1 (2.0)	0 (0)	
Method of contraception			0.530
Condom	14 (28.0)	13 (25.5)	
Hormonal (OCPs, DMPA and etc.)	3 (6.0)	2 (3.9)	
IUD (Intra uterine devices)	2 (6.0)	7 (13.7)	
TL and Vasectomy	4 (8.0)	3 (5.9)	
None	27 (54.0)	26 (51.0)	
The average number of coitus per month			0.589
4 times	29 (58.0)	27 (52.9)	
8 times	13 (26.0)	19 (37.3)	
12 times	6 (12.0)	4 (7.8)	
16 times and more	2 (4.0)	1 (2.0)	
Variable	Mean (SD)		p-value**
Woman's age (year)	34.3 (5.74)	35.2 (6.62)	0.432
Husband's age (year)	39.2 (5.81)	39.9 (7.02)	0.597
Marriage duration (year)	12.2 (7.28)	14.2 (6.72)	0.160
Disease duration (year)	9.5 (5.36)	10.8 (6.45)	0.295

Table 1 (continued)

Variable	Mean (SD)		*p*-value**
Age of onset of systemic lupus erythematous	24.8 (6.99)	24.6 (6.68)	0.912
Number of pregnancies	1.9 (0.82)	1.8 (0.86)	0.739
Number of alive children	1.6 (0.73)	1.6 (0.75)	0.806
Depression	7.3 (3.53)	7.9 (3.37)	0.384
Anxiety	5.3 (2.19)	5.4 (2.37)	0.910
Stress	12.6 (4.32)	12.6 (4.6)	0.976

*Chi square test

**Independent t test

function score we obtained was still less than 26.55, which is the cut-off point of FSFI. However, our purpose was promotion sexual function after counseling, not raising it above the cut-off point. Moreover, our results showed that lack of sexual counseling is associated with reduced sexual function score and all of its dimensions in women with SLE 8 and 12 weeks after intervention.

This was the first study conducted based of the EX-PLISSIT model on women with SLE in Iran. As for validating these findings in this study, we could refer to the studies conducted by Behboodi Moghadam et al. and Schmalzing et al. [27, 28]. Results of other studies conducted in the world showed that EX-PLISSIT model-based sexual counseling decreased the sexual problems of women with other chronic diseases [19–21, 29].

Khakbazan et al. reported a significant increase in the mean score of all dimensions of FSFI except pain in their intervention group, 2 and 3 months after sexual counseling based on PLISSIT model on 90 women with MS attending three 1 h sessions [30]. Another study by Rezaei Fard et al. showed that three 45 min sexual counseling sessions once a week for 44 spinal cord injury (SCI) women reduced sexual problems and increased the mean score of sexual function significantly [29]. Daneshfar et al. studied the influence of EX-PLISSIT model on intimacy and sexuality of married women with multiple sclerosis. They reported decreased sexual dysfunction in the studied women after intervention ($p < 0.05$) [20]. Another study by Kazemi et al. examined the effect of PLISSIT model counseling on the sexual quality of life of married women with multiple sclerosis. Their results showed the positive effect of this model on sexual quality of life in M.S women [31]. Consistent with our results, the mean score of sexual function after intervention in their study was not more than 26.55 either. This similarity can be explained by the fact that both SLE and MS patients suffer from neurological problems [32] which are still a barrier to the full promotion of sexual function in these patients. Therefore, we should not expect women with SLE to attain the same cut-off point and it must be reconsidered for this community. However, no studies have yet been done to specify the cut-off point of FSFI for SLE patients or develop a new questionnaire for these patients.

In this study, there was a significant difference between the two groups in the mean scores of sexual function and its different dimensions ($p < 0.0001$) except sexual pain ($p = 0.065$), 8 weeks after intervention. Also, the mean score of the total sexual function and all its subscales significantly improved 12 weeks after counseling in the intervention group compared with the control group ($p < 0.0001$). These results are consistent with those of Rezaei Fard et al. who also found a significant difference between the two groups after intervention in SCI women [29]. Furthermore, Mahmoodi Dangesaraki et al. in their study of 80 women with hysterectomy showed that counseling based on EX-PLISSIT model had

Table 2 Female sexual function index and its dimensions in intervention and control groups

Sexual function	Groups	Before intervention Mean±SD	After 8 weeks of intervention Mean±SD	After 12 weeks of intervention Mean±SD	**p value (between before and 8 weeks)	**p value (between 8 and 12 weeks)	**p value (between before and 12 weeks)	***p value (between before, 8 and 12 weeks)
Sexual desire	Intervention	3.1±0.92	3.9±0.89	4.2±0.65	<0.0001	0.004	<0.0001	<0.0001
	Control	3.1±1.06	2.4±0.93	2.4±0.86	<0.0001	0.710	<0.0001	<0.0001
		*p=0.902	*p<0.0001	*p<0.0001				
Sexual arousal	Intervention	3.2±1.09	3.9±0.99	4.2±0.72	<0.0001	0.004	<0.0001	<0.0001
	Control	3.1±1.27	2.6±1.09	2.6±1.07	<0.0001	0.815	0.003	<0.0001
		*p=0.734	*p<0.0001	*p<0.0001				
Vaginal lubrication	Intervention	4.0±1.59	4.3±1.31	4.62±1.13	0.006	0.012	<0.0001	<0.0001
	Control	3.6±1.55	3.0±1.26	2.7±1.01	<0.0001	0.011	<0.0001	<0.0001
		*p=0.180	*p<0.0001	*p<0.0001				
Orgasm	Intervention	3.4±0.86	3.9±0.94	4.4±0.71	<0.0001	<0.0001	<0.0001	<0.0001
	Control	3.6±0.82	3.0±0.84	2.8±0.96	<0.0001	0.188	<0.0001	<0.0001
		*p=0.340	*p<0.0001	*p<0.0001				
Sexual satisfaction	Intervention	4.2±1.53	4.8±1.39	5.0±1.03	<0.0001	0.012	<0.0001	<0.0001
	Control	4.3±1.71	3.9±1.36	3.4±1.14	<0.0001	0.008	<0.0001	<0.0001
		*p=0.805	*p=0.002	*p<0.0001				
Sexual pain	Intervention	2.6±0.87	2.6±0.91	2.8±0.81	0.673	0.024	0.013	<0.0001
	Control	2.4±0.87	2.3±0.80	2.0±0.64	0.001	0.001	<0.0001	<0.0001
		*p=0.485	*p=0.065	*p<0.0001				
Total score of sexual function	Intervention	21.0±5.68	23.5±5.43	25.4±3.85	<0.0001	<0.0001	<0.0001	<0.0001
	Control	20.3±6.19	17.2±4.79	16.1±4.39	<0.0001	0.035	<0.0001	<0.0001
		*p=0.581	*p<0.0001	*p<0.0001				

*Independent t test

**Paired t test

***Repeated measures
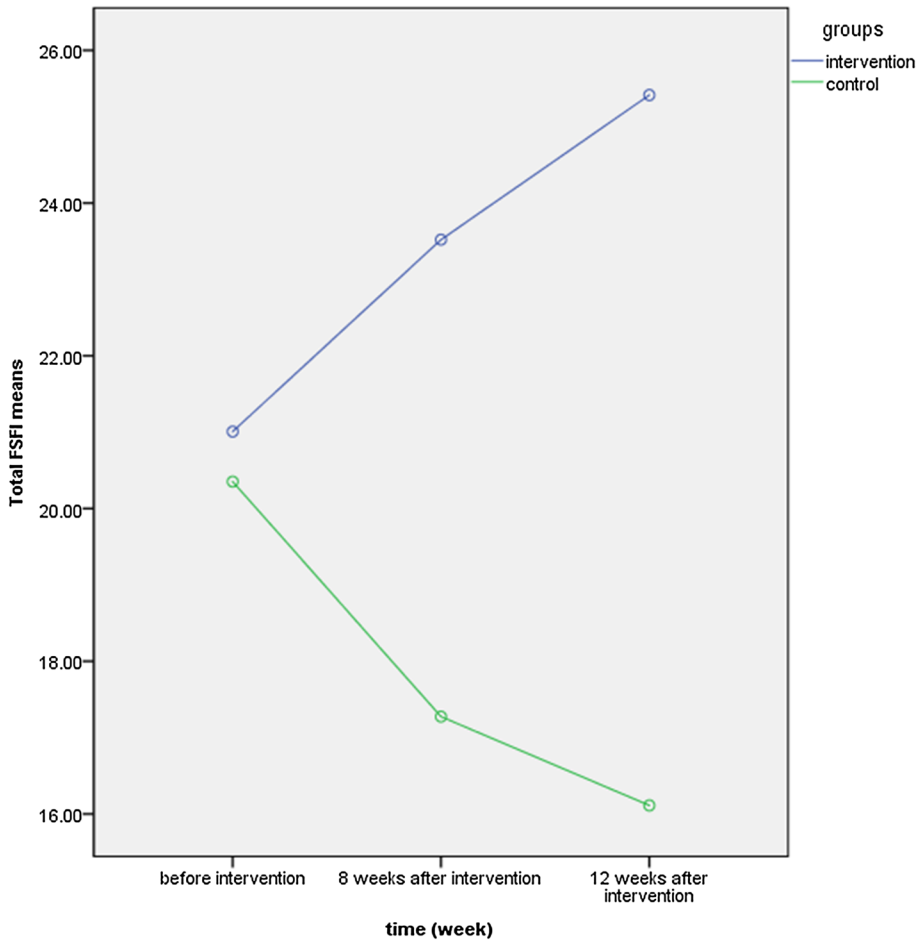
Fig. 2 Total FSFI score changes during the study

a positive effect on these women's sexual functioning and sexual quality of life ($p < 0.001$) 8 weeks after the counseling [21]. Farnam et al. used PLISSIT model to evaluate its effect on sexual problems of women in Tehran. Their results showed the positive effect of this model of counseling on improving sexual function and decreasing sexual distress, which is in line with the results of our study [33].

Consistent with the results of the present study, the results of two studies using this method to study sexual function in married women with chronic disease showed a significant difference in terms of sexual function [19, 20]. Another study by Merghati Khoei et al. demonstrated that sexual counseling based on PLISSIT model in women suffering from breast cancer had a positive effect on sexual problems of these women by improving their sexual capacity, sexual function, and sexual behavior [34]. In their study, group and individual sexual counseling was done. Esmkhani et al. compared the effect of the individual PLISSIT model versus group therapy according to Sexual Health Model on the quality of women with breast cancer and reported that the quality of both methods had similar effects on improving the quality of life, sexual function, and sexual pleasure of these women [35].

Nho also examined the effect of a PLISSIT-based sexual health enhancement program on women with gynecological cancers and their husbands and concluded that using these programs in four 90 min sessions could be effective in promoting sexual function and marital intimacy, reduce women's sexual distress, and increase their husbands' happiness [36].

In their study on sexual function of women who had hysterectomy surgery, Tutuncu and Yildiz examined the effect of PLISSIT sex education in four stages (two times before surgery, then 3 and 6 months after surgery). Comparison of the mean FSFI score showed that the score of patients before surgery was similar in the two groups. In both postoperative follow-up stages, the FSFI score was higher in the intervention group compared to the control group, and women in the intervention group were more successful in dealing with sexual problems associated with their surgery [37]. The results of a study by Perz et al. also indicated that sexual education based on PLISSIT model was useful and efficacious according to couples, as the implementation of this counseling increased their awareness of sexuality, improved their relationship, and helped them to manage sexual changes [38].

As far as sexual pain is concerned, despite the increase in the FSFI score of the intervention group after counseling, there was no statistically difference between the two groups 8 weeks after counseling ($p=0.065$). Asadi et al. [39] studied the effect of counseling based on PLISSIT model on sexual function of HIV-positive married women and observed that there was no significant difference between the two groups in terms of sexual pain one month after a program of 3 h weekly counseling ($p=0.28$). Therefore, it can be argued that sexual pain, compared with other subscales of FSFI, takes longer to improve and couples need more practice and time to work on this dimension of sexual function. In our study, 12 weeks after the counseling program ended, a significant increase was seen in the intervention group in terms of the subscale of sexual pain. Besides, pain needs more physical or drug treatment than other domains of sexual function. As Daneshfar et al. put it, EX-PLISSIT intervention could not improve physical changes due to diseases [20].

In this study, the mean scores of total sexual function and all subscales in the control group 8 and 12 weeks after counseling significantly were reduced compared to those obtained at baseline before counseling. In contrast, two studies conducted by Mehrabi et al. and Daneshfar et al. found no significant change in the mean scores in the control group, which could be due to the environmental conditions present during the research. This study was performed during the Covid-19 pandemic, and according to Fuchs et al. [40], Yuksel et al. [41], and Schiavi et al. [42], among many others, following the Covid-19 pandemic, there have been significantly lower scores obtained on the female sexual function index and all subscales compared with before the pandemic.

This study had several limitations. That the participant`s husbands were not included in counseling sessions was our first limitation. Previous studies have demonstrated that Iranians are reluctant to talk about their sexual problems because of cultural considerations making sex-related topics a private issue, but they are still interested in listening to general topics related to sexual issues. Therefore, the presence of each couple can be somewhat effective in changing their behavior and attitude, but the presence of both couples together, providing general information and expressing their problems in this area can be more effective for them [43]. The large number of questions in our data collection tools along with the fatigue associated with SLE women was another limitation of this study. Because of the numerous personal concerns and problems of these women, it was difficult to persuade them to participate in study, and most of them were not initially willing to participate in counseling sessions. Sexual problems are considered private issues in the Iranian culture. The researcher reduced somewhat this limitation by building trust and stating the research objectives before the commencement of the counseling sessions. Recruiting

married women because of cultural restrictions with respect to sexual activities of single people in Iran is another limitation of this study, which can affect the generalizability of the results. In spite of these limitations, this study was worthwhile given its design which was randomized controlled trial and the use of standard questionnaires whose validity and reliability has already been firmly established.

Conclusion

According to the findings, sexual counseling based on EX-PLISSIT model has a positive effect on the sexual function of SLE women. In addition, we found that sexual counseling and providing useful information about the disease and its problems play an important role in promoting women's sexual function, improving their relationship with their husbands, and providing useful solutions to their difficulties. Therefore, this model is recommended as a cost-effective and simple counseling method to improve the sexual health and function of these women. Moreover, given the significant decrease in the mean score of sexual function in the control group, future studies are recommended to use a third group including healthy women to serve as the second control group.

Data Availability Data of this study will be available upon the request from the corresponding author.

Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval This study was approved by the Ethics Committee of Tehran University of Medical Sciences. IR.TUMS.FNM.REC.1399.136. It has been registered with the Iranian Registry for Clinical Trials. IRCT20120414009463N63.

Informed Consent Informed consent was obtained from participants.

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