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Original Article

The effect of extended PLISSIT model-based counseling on sexual satisfaction in women with systemic lupus erythematosus: A randomized controlled trial

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ABSTRACT

Background & Aim: Systemic Lupus Erythematosus has physiological, cognitive, and mental effects on sexual satisfaction in afflicted women. This study aimed to investigate the effect of sexual counseling based on the EX-PLISSIT model on sexual satisfaction in this group of patients.
Materials & Methods: A randomized controlled trial was conducted on 120 married women with SLE in Ahvaz, Iran. Eligible women were randomly assigned to the intervention group (four weeks of psychosexual counseling sessions based on EX-PLISSIT) and the control group, using block randomization with a 1:1 allocation ratio. Before the intervention and eight and twelve weeks after the completion of counseling sessions, the Larson Sexual Satisfaction Questionnaire was administered. Data was analyzed using independent t-tests, paired t-tests, Chi-square test, and repeated measures ANOVA.
Results: There was no significant difference in sexual satisfaction scores between the two groups before the intervention ($p=0.718$). Following the intervention, the mean sexual satisfaction score in the intervention group significantly increased (from 93.8±15.59 to 104.5±13.32 after 12 weeks), while a significant decrease was observed in the control group. At the 12-week follow-up, the mean satisfaction in the intervention group was significantly higher than the control group ($p<0.0001$). Repeated Measures ANOVA confirmed a significant difference in the trend of changes between the two groups over time ($p<0.0001$).
Conclusion: The results demonstrated that sexual counseling based on the EX-PLISSIT model significantly enhanced sexual satisfaction in married women with SLE compared to the control group. Therefore, this type of counseling is recommended as an effective and simple adjunctive therapeutic service for enhancing sexual satisfaction in women with SLE.

Trial registration: This study has been registered with the Iranian Registry for Clinical Trials (IRCT20230626058592N2).

Introduction

Sexual satisfaction is a key component of sexual health and a predictor of relationship satisfaction. The World Health Organization recognizes it as both a sexual right and an outcome of sexual well-being (1). Beyond reproduction, sexual activity now plays a vital role in initiating and maintaining intimate relationships (2, 3). Chronic diseases and their treatments directly and indirectly affect sexual satisfaction (4, 5). Systemic Lupus Erythematosus (SLE), a multisystem autoimmune disease, is more common in women of reproductive age, with a female-to-male ratio of 9:1 (6, 7). Its prevalence is estimated at 23 per 100,000 in the U.S. and 40 per 100,000 in Iran (8, 9).

While SLE can be effectively managed with medications, attention must also be paid to the patient's quality of life (QoL). On the other hand, sexual life is an important aspect of individuals' quality of life (8). Reported sexual problems among women with SLE include loss of libido, dyspareunia, vaginal atrophy, orgasmic disorders, and decreased sexual

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pleasure (5, 10). In a case-control study, significantly higher sexual dissatisfaction was reported among women with SLE compared to the control group (11). In another study, the prevalence of sexual dissatisfaction in SLE patients was reported at 89.7% (12). Low levels of testosterone and dehydroepiandrosterone (DHEA) in SLE patients are associated with sexual desire and satisfaction. In addition, low estrogen levels in these patients lead to vaginal dryness, burning, and dyspareunia, which can negatively affect sexual satisfaction (8, 13).

Sexual education and counseling have been shown to improve sexual satisfaction and reduce divorce rates, with studies attributing a large portion of divorces and infidelities to sexual dissatisfaction (14-16). Therefore, educational and counseling interventions for these patients have been proposed as potentially useful approaches due to their overall cost-effectiveness. However, the evidence base for effective interventions remains limited and sometimes inconsistent. While studies have demonstrated that sexual counseling based on the EX-PLISSIT model improves sexual function in married women with SLE (5) and sexual satisfaction in other condition like multiple sclerosis and cancer (17-19), a critical distinction must be made. The study focusing on women with SLE (5), primarily utilized the Female Sexual Function Index (FSFI) questionnaire, which measures sexual function (e.g., lubrication, orgasm, pain) rather than the individual's subjective experience of sexual satisfaction. Sexual function and satisfaction are related but distinct concepts, and improved function does not automatically guarantee increased satisfaction (3).

The EX-PLISSIT model, a four-level intervention, was first described by Anon and focuses on determining the type and amount of assistance needed for a specific individual. This model has proven beneficial for sex therapy and counseling, with approximately 80-90% of sexual concerns addressable using the first three levels of this model (5). Given the high reported prevalence of sexual dissatisfaction (up to 89.7%) in women with SLE (12) and the lack of studies directly evaluating the efficacy of the EX-PLISSIT model on the subjective experience of satisfaction in this population, a significant research gap exists. Therefore, the present study specifically employed the Larson Sexual Satisfaction Questionnaire to evaluate the effect of EX-PLISSIT-based sexual counseling on sexual satisfaction in married women with SLE. This study was conducted to fill this important gap and provide targeted evidence for developing effective, satisfactory interventions.

Methods

Study design

This study was a randomized controlled trial with a single-blind design (outcome assessor blinded), conducted on 120 married women with SLE who attended the rheumatology clinic of Imam Khomeini Hospital in Ahvaz for their routine follow-up visits from January to May 2024, aimed to assess the effect of sexual counseling based on EX-PLISSIT model on improving sexual satisfaction in these women.

Participants

Participants were women with confirmed diagnosis of SLE made by a rheumatologist. Inclusion criteria consisted of: married Iranian, women of reproductive age (18-49 years) and self-reported sexual dissatisfaction by the patient. Exclusion criteria included: pregnancy; physical or psychological problems affecting sexual function; severe depression, anxiety, and stress defined according to standardized cutoff scores on the DASS-21 questionnaire in the baseline (20); interpersonal problems according to patient self-report; participation in any sexuality education classes during the study; receiving any treatment for sexual problems; and a history of any psychoactive substance use and addiction.

It is noteworthy that the DASS questionnaire consists of 21 items comprising a set of 3 self-report scales designed to assess depression, anxiety, and stress with a Likert scale from 0 to 3 (20). According to the guideline, the resulting rankings are categorized as "normal, mild, moderate, severe, or extremely severe". The reliability coefficients of the Persian version

of DASS-21, examined by Samani and colleagues, were reported as 80%, 76%, and 77% for the domains of depression, anxiety, and stress, respectively, indicating acceptable reliability and validity among Iranian samples (21).

Sample Size

Based on the previous study (5), we estimated a mean difference between the intervention and control groups. Specifically, we anticipated an increase of 24% in the intervention group and a 5% change in the control group, with 80% power (β=0.2) and 95% confidence level (α=0.05), the sample size in each group was determined to be 54 individuals using the formula, considering a 10% dropout rate, the sample size in each group was considered to be 60 individuals. Although the primary outcome was analyzed as a continuous variable, sample size estimation was based on proportion differences due to the reporting format of the reference study, which presented outcomes as percentage changes. This approach was used as a conservative estimation method.

Sampling method

To ensure the assessment of baseline characteristics and pre-intervention scores were not affected by the immediate medical visit, data collection for eligible participants began prior to their receipt of routine follow-up care at the clinic on that day. A total of 130 patients expressed interest in participating in the study, of which 3 were excluded due to study withdrawal criteria. Therefore, 127 SLE patients were enrolled in the study. Participants completed pre-test questionnaires including a demographic questionnaire, the Depression Anxiety Stress Scale-21 (DASS-21), and the Larson Sexual Satisfaction Questionnaire. According to the results of the DASS-21 questionnaire, 7 more individuals were excluded from the study due to severe depression, anxiety, or stress, and were referred to a psychiatrist. Then, the remaining individuals (120) were randomly divided into two groups using block randomization method. Randomization was performed using randomly generated sequences within blocks of six with a 1:1 allocation ratio to either intervention or control group. Group A was designated as the control group, and group B as the intervention group. Subsequently, all possible combinations of letters A, A, B, B were written, and the number of blocks required was determined based on the sample size. Then, one combination was randomly selected. For example, according to the combination (AAABBB/ABABAB), the seventh individual was placed in the control group (A). In order to conceal random allocation, the group names were placed in opaque, sealed envelopes with numbered seals. A non-participant was asked to select the envelopes during the sampling process. Finally, 60 individuals were assigned to each group. Consort diagram was shown in figure 1.

All participants completed all questionnaires before the intervention and then again at 8 and 12 weeks after the last counseling session. Due to the nature of the intervention, participant blinding was not feasible (an unblinded trial). However, the outcome assessor, who administered and scored the questionnaires, was blinded to group allocation to reduce assessment bias (a single-blind trial). Fifteen individuals (8 from the intervention group and 7 from the control group) dropped out. In the intervention group, two individuals lost their spouses, and six individuals did not complete the questionnaires during follow-ups. In the control group, three individuals became pregnant, and four individuals did not complete the questionnaires during follow-ups.

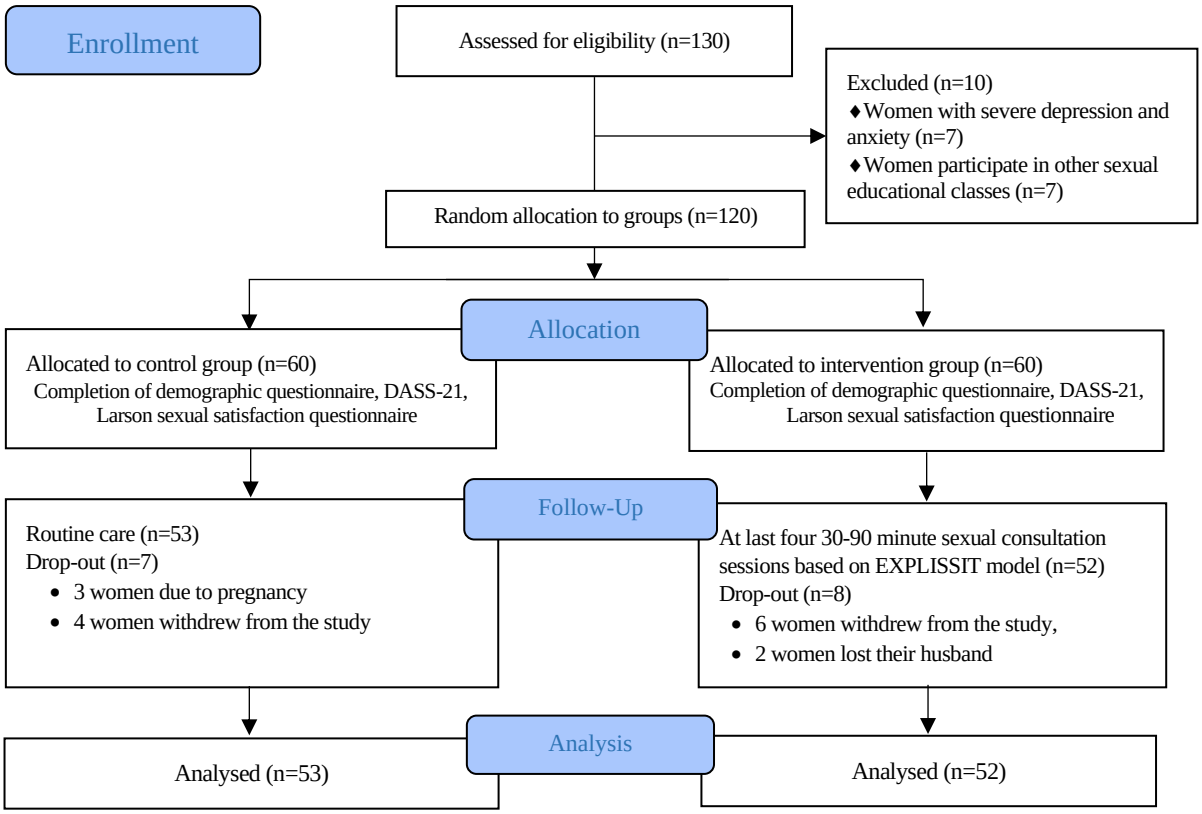

Figure 1. Flow diagram of the study

Research instruments

A demographic information questionnaire included information about the age, level of education and occupation of women and their spouses, socio-economic status, duration of marriage and diagnosis of the disease, age at onset of illness, types of medications used, and so on.

The Larson Sexual Satisfaction Questionnaire consists of 25 questions introduced by Larson and colleagues in 1998 (22). This questionnaire is designed on a Likert scale (1=never, 2=seldom, 3=sometimes, 4=often, 5=always). Scores of 25-50 (sexual dissatisfaction), 51-75 (low sexual satisfaction), 76-100 (average sexual satisfaction), and 101-125 (high sexual satisfaction). Hudson and colleagues reported the reliability of the original version of the questionnaire with a Cronbach's alpha coefficient of 0.91, which they reported as 0.93 after retesting one week later (23). The validity and reliability of this questionnaire were assessed by Bahrami and colleagues among Iranian couples. The Cronbach's alpha coefficient for the questions was above 0.70, indicating internal consistency of the questionnaire and the correlation between questions (24).

Intervention

Following obtaining informed consent, demographic questionnaires, DASS-21, and Larson's Sexual Satisfaction were completed by the both intervention and control groups. Counseling based on the EX-PLISSIT model was conducted for the intervention group by a midwife who had completed sexual counseling course. The control group received only routine care. Counseling sessions were conducted weekly, with a minimum of 4 sessions lasting 30-90 minutes for each participant. These sessions were held in a private and calm environment in the rheumatology clinic according to the steps of the EX-PLISSIT model. Based on this model, permission was obtained at the beginning of each session and before introducing any new stage of the counseling process. The first session focused on establishing rapport and allowing participants to express their experiences,

concerns, and views regarding sexual issues, including their own and their spouse's sexual concerns. Participants and the counselor worked together to define mutual goals and strategies to achieve them. In the second session, participants first reviewed their progress and were asked for permission to proceed. The session provided structured education about the impact of SLE on sexual satisfaction, physiology, and behavior. It also addressed common misconceptions and sexual myths, and aimed to increase sexual awareness and communication skills. Physical symptoms (e.g., joint pain, fatigue), psychological changes (e.g., body image, sexual self-esteem, depression), and spousal reactions to these issues were also discussed. In some cases, spouses were invited to participate in this session. The third session focused on Specific Suggestions, tailored to the individual concerns raised in previous sessions. After reviewing goals, participants received recommendations such as exploring non-sexual forms of intimacy, practicing pelvic floor exercises, improving communication skills, and enhancing sexual pleasure and body awareness. In the fourth session, participants reviewed their progress toward previously defined goals. If deeper psychological or interpersonal challenges were identified, they were referred to a psychologist or sex therapist, and consequently excluded from further participation in the study (Table 1).

After the completion of the counseling sessions, the Larson Sexual Satisfaction questionnaire was completed again by individuals in the intervention and control groups 8 and 12 weeks after the last counseling session. After completion of the final questionnaire by individuals in both groups, in order to thank the participants in the control group, an educational video on the anatomy of reproductive organs, sexual response cycle, and some information and misconceptions about sexual issues were sent to them via WhatsApp. The outcome assessor, who administered and scored the questionnaires, was blinded to group allocation to reduce assessment bias.

Table 1. Counseling sessions and their contents

Session	Content	Duration of Session (minutes)	Participants	EX-PLISSIT level	Tools and methods
1	- Discussing sexual issues and concerns - Expressing mutual goals	90	women	Permission	Discussion, Speech, and Interview
2	- Review of Goals - Education on SLE-related sexual problems - Misconceptions correction - Increasing sexual awareness and skills. - Physical/psychological changes and partner's response	90	Women and in some cases both spouses and women	Permission + Limited information	Speech, Discussion, Image, Moulage, PowerPoint and Video
3	- Review of Goals - Personalized suggestions (e.g., pelvic floor exercises, non-sexual intimacy) - Communication training - Enhancing body and sexual enjoyment	60	women	Permission + Specific suggestion	Speech, Discussion, Film, Moulage, Poster
4	- Review of Goals - Reviewing progress toward desired goals - Referral to Sex Therapy or Psychologist if needed	30	women	Permission + Intensive therapy	Speech and Discussion

Statistical methods

Data were analyzed using SPSS version 23 software (IBM Corporation, USA). Baseline comparisons between the intervention and control groups were performed using independent samples t-tests for continuous variables and chi-square tests for categorical variables. To evaluate changes in sexual satisfaction over time and differences between groups, a mixed model (between–within) analysis of variance (ANOVA) was conducted, with group (intervention vs. control) as the between-subject factor and time (baseline, 8 weeks, and 12 weeks) as the within-subject factor. The interaction effect between group and time was examined to determine whether changes in sexual satisfaction differed

significantly between the two groups across measurement points. A p-value< 0.05 was considered statistically significant.

Data were analyzed using a per-protocol (PP) approach, including only participants who attended all counseling sessions. This approach was employed given the low attrition rate, which fell within the predefined margin of the sample size calculation.

Ethical considerations

This study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences. (Ref. ID: IR.AJUMS.REC.1402.333). It has been registered with the Iranian Registry for Clinical Trials. IRCT20230626058592N2. Informed consent was obtained from participants.

Results

Socio-demographic characteristics of the participants showed that the majority of women had university education and were housewife. The mean age of women in the intervention and control groups was 33.9±5.91 and 35.4±6.56, respectively. The mean duration of marriage in the intervention group was 11.9±7.29 and in the control group was 14.4±6.85. Both groups were similar in terms of types of medications used. Overall, no statistically significant differences were observed in demographic characteristics between the two groups (p> 0.05) (Table 2).

Table 2. Comparison of demographic factors of patients in intervention and control groups

Variable	Groups (number/percentage)		P-value*
	Intervention n= 52 (%)	Control n= 53 (%)	
Participant's educational attainment			
Primary	7 (13.5)	7 (13.2)	0.394
Secondary	9 (17.3)	15 (28.3)	
University	36 (69.2)	31 (58.5)	
Participant's occupation			
Housewife	42 (80.8)	43 (81.1)	0.579
Employed	10 (19.2)	10 (18.9)	
Economic status			
Good	4 (7.7)	5 (9.4)	0.735
Moderate	38 (73.1)	35 (66.1)	
Poor	10 (19.2)	13 (24.5)	
Medication			
Anti-malaria and Corticosteroid	23 (44.2)	22 (41.5)	0.421
Anti-malaria and Corticosteroid and Immunosuppressive	9 (17.3)	6 (11.3)	
Anti-malaria and Corticosteroids and Bisphosphonates	0 (0.0)	4 (7.6)	
Corticosteroids and Immunosuppressive	13 (25.0)	14 (26.4)	
Corticosteroids	4 (7.7)	5 (9.4)	
Corticosteroids, Immunosuppressive, Anti-malaria and Bisphosphonates	3 (5.8)	2 (3.8)	
Method of contraception			
Condom	14 (26.9)	13 (24.5)	0.530
Hormonal (OCPs, DMPA and etc.)	3 (5.8)	2 (3.8)	
IUD (Intra uterine devices)	2 (3.8)	7 (13.2)	
TL and Vasectomy	4 (7.7)	3 (5.7)	
None	29 (55.8)	28 (52.8)	
The average number of coitus per month			
4 times	29 (55.8)	29 (54.8)	0.593
8 times	14 (26.9)	19 (35.8)	
12 times	7 (13.5)	4 (7.5)	
16 times and more	2 (3.8)	1 (1.9)	
Variable	**Mean (SD)**		**P-value****
Woman's age (year)	33.9 (5.91)	35.4 (6.56)	0.224
Husband's age (year)	38.9 (5.91)	40.0 (6.96)	0.355
Marriage duration (year)	11.9 (7.29)	14.4 (6.85)	0.083
Disease duration (year)	9.4 (5.31)	11.1 (6.80)	0.165
Age of onset of Systemic Lupus Erythematous	24.5 (7.02)	24.4 (6.92)	0.972
Number of pregnancies	1.9 (0.82)	1.8 (0.85)	0.762
Number of alive children	1.6 (0.73)	1.6 (0.75)	0.925
Depression	8.5 (2.68)	8.3 (3.16)	0.680
Anxiety	5.8 (1.96)	6.4 (1.78)	0.123
Stress	12.3 (4.82)	12.7 (4.29)	0.662

* Chi square test; ** Independent t test

Before the intervention, the two groups did not differ significantly in terms of mean sexual satisfaction (p=0.718). Following the intervention, the mean sexual satisfaction score in the intervention group increased from 93.8 (±15.59) before the intervention to 98.3 (±15.77) 8 weeks after the intervention. In the control group, a decreasing trend from 92.7 (±16.86) before the intervention to 89.1 (±14.32) 8 weeks after the intervention was observed, and these changes in both groups were statistically significant based on paired t-test results (p< 0.0001). By comparing the two groups at the first follow-up (8 weeks after the intervention), it was evident that the mean sexual satisfaction score in the intervention group (98.3±15.77) was significantly higher than the control group (89.1±14.32) according to independent t-test (p=0.002). Similarly, the changes in sexual satisfaction score between the two groups at the second follow-up (12 weeks after the intervention) were also significant (p< 0.001) (Table 3).

Overall, the mixed model ANOVA revealed a significant group × time interaction, indicating a differential change in sexual satisfaction between the intervention and control groups over time (p < 0.001) (Table 3) (Figure 2).

Table 3. Changes in sexual satisfaction scores over time in intervention and control groups

Time point	Intervention (Mean ± SD)	Control (Mean ± SD)	Between group P-value *	Time×Group P-value**
Baseline	93.8 ± 15.59	92.7 ± 16.86	0.718	p < 0.001
8 weeks	98.3 ± 15.77	89.1 ± 14.32	0.002	
12 weeks	104.5 ± 13.32	85.6 ± 9.74	p < 0.001	

* Independent samples t-test; **Mixed model (between–within) ANOVA

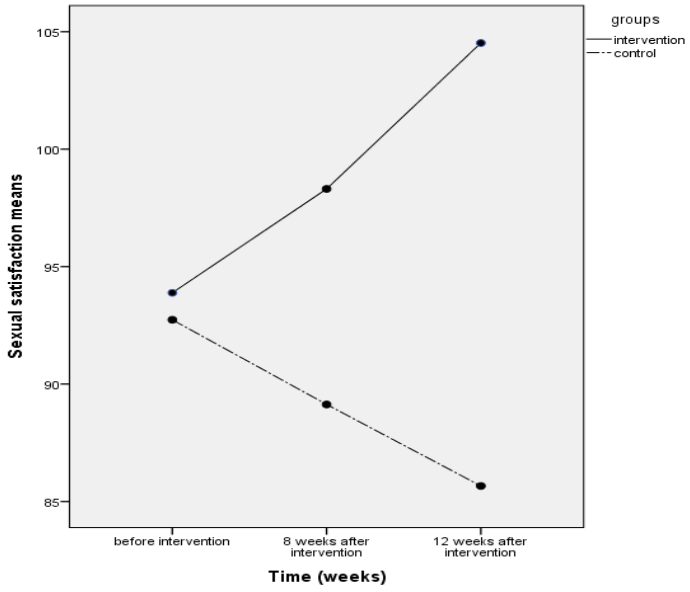

Figure 2. Sexual satisfaction changes during the study

Discussion

This study aimed to investigate the effect of sexual counseling based on the extended PLISSIT model on the sexual satisfaction in married women with SLE and as it was shown sexual counseling in these women can be effective in increasing women's sexual satisfaction.

Demographic information and clinical characteristics related to the disease which have been considered in some studies as potential variables affecting the sexual satisfaction of SLE patients were compared. For example, Shami et al. conducted study on women with SLE and included factors such

as patient and spouse age, age at diagnosis, contraceptive method, types of medications, stress, anxiety and depression, economic status, and frequency of sexual intercourse per month when investigating sexual function (5). Accordingly, in our study, all patients were examined in terms of these variables, and there was no significant difference between the two groups, indicating that the participants were homogeneous in this regard. Our findings indicated a positive effect of sexual counseling on improving the sexual satisfaction of married women with SLE, with an improvement from moderate sexual satisfaction to high sexual satisfaction, whereas in the absence of counseling, sexual satisfaction tended to decline.

The validity of the results of this study can be demonstrated by referring to studies conducted on the sexual health of women with SLE in Iran (5, 25). The positive impact of sexual counseling on improving the sexual function of SLE women has been shown in the study by Shamieh and colleagues (5). Similarly, results from other studies have shown that sexual counseling based on the EX-PLISSIT model can enhance the sexual satisfaction of women with specific conditions (17-19, 26). On the other hand, the more complex the sexual problem, the more effective the use of the EX-PLISSIT model will be in enhancing sexual satisfaction (27).

Nazari and colleagues demonstrated that four weekly sessions of sexual counseling based on the EX-PLISSIT model significantly increased sexual satisfaction in women with M.S ($p<0.001$) (18). Consistent with these results, group sexual counseling, conducted in women with M.S over 6 sessions, had a positive effect on enhancing their sexual satisfaction (28). Psychological impairments such as reduced self-esteem and depression seen in patients with M.S appear similar to issues present in patients with SLE, impacting the sexual satisfaction of these patients (29). Several clinical studies have shown that SLE patients often have lower levels of testosterone and dehydroepiandrosterone (DHEA) (13). Androgen status has been shown to be associated with sexual function including desire and sexual satisfaction in patients with M.S and SLE (13, 30). Furthermore, low levels of estrogen lead to vaginal dryness, burning, and dyspareunia, which can negatively impact sexual satisfaction (8). Impairments in movement, fatigue, stiffness, and knee or thigh joint pain also restrict sexual activity (13). Conversely, in SLE patients, due to exacerbation of disease symptoms, external estrogen cannot be used to alleviate symptoms of dyspareunia, vaginal dryness, and burning (8). Therefore, similar to the content of our counseling sessions, counseling interventions that include strategies for preparing women and increasing sexual arousal to enhance sexual desire, reduce vaginal dryness, increase self-esteem, improve relationships with spouses, and reduce family tension can be effective in enhancing sexual satisfaction. However, in a clinical trial conducted by Ghaffari et al. on 72 married women with M.S, following four weekly sessions of sexual counseling based on the BETTER model, no statistically significant difference ($p=0.06$) in mean sexual satisfaction scores was reported between the two groups at 8 and 12 weeks post-intervention. It appears that the BETTER model may be more effective in improving sexual performance than sexual satisfaction (31).

Zangeneh et al. reported a significant increase in sexual satisfaction among breast cancer survivors following sexual counseling based on the EX-PLISSIT model. However, this increase did not elevate the average sexual satisfaction to high satisfaction levels (19), contrary to our findings. It seems that the reason for this difference might be the target population of this study. Breast cancer survivors often face more severe and permanent anatomical changes compared to SLE patients, which may explain why the EX-PLISSIT model, while effective, did not achieve the 'High Satisfaction' level found in our SLE cohort. Similarly, Bilge and Aslan also reported similar results following four sessions of PLISSIT model-based sexual

counseling in women undergoing surgery for uterine, ovarian, or cervical cancer (17). As studies indicate, patients with SLE and cancer survivors experience body image disturbances (32, 33). Moreover, body image disturbance negatively impacts sexual satisfaction and sexual health (34). Our counseling sessions included information on improving body image, thus providing such information to these women can positively impact their sexual satisfaction.

In a clinical trial examining the effects of EX-PLISSIT model-based sexual counseling on sexual function in women with SLE, it was found that this counseling model significantly improves the sexual function of these women (5). Although their reported variable was sexual function, some studies have shown a relationship between sexual function and sexual satisfaction (35, 36).

It has been shown that pelvic floor and stretching exercises, yoga, Pilates, and aerobic exercises enhance sexual satisfaction in women with SLE (37, 38). A study teaching exercise to 40 women with SLE showed a significant reduction in fatigue and depression three months after the intervention, along with an increase in their physical activity (39). Our counseling sessions included information on sexual issues, correcting sexual misconceptions, solutions for problems in emotional and sexual relationships, pelvic floor exercises, and techniques to improve sexual satisfaction. Thus, our study's results demonstrated that the solutions provided in the counseling sessions, including stretching exercises, pelvic floor exercises, and Kegel exercises, are effective in improving the sexual satisfaction of women with SLE in the intervention group.

As our study results indicated, sexual satisfaction in the control group had significantly decreased over time. It seems that besides the disease itself, which affects sexual satisfaction, the medications received by these patients also contribute to reducing their sexual satisfaction. As reported in studies, glucocorticoids and nonsteroidal anti-inflammatory drugs (NSAIDs) may disrupt sexual satisfaction (13, 40). Glucocorticoids may exert inhibitory effects on sex hormones. High doses of glucocorticoids can decrease testosterone levels, which play a crucial role in reducing sexual satisfaction. Cyclophosphamide can also interfere with DNA repair mechanisms and cause gonadal toxicity and decreased sexual desire (8, 13). Additionally, this study was conducted during the post-COVID-19 pandemic period, and as shown in studies, the COVID-19 pandemic had a negative impact on the sexual satisfaction of couples, which, despite the end of this pandemic, still persists (41). Therefore, it is recommended that professionals should consider the sexual health of these patients alongside other healthcare services provided to them.

Strengths and limitations

To the best of our knowledge, this study is the first to examine the effect of the extended PLISSIT sexual counseling on the sexual satisfaction of married women with SLE. The strengths of the study include adherence to the principles of randomized controlled trials, including random allocation and allocation concealment. Additionally, the use of standardized questionnaires with established validity and reliability was another strength of this study. This study, however, had limitations. One of them was the impossibility of blinding the participants and the counselor due to the nature of the intervention (performance bias). Although we used assessor blinding to mitigate detection bias, the lack of participant blinding remains a potential limitation in self-reported outcomes. The other was the lack of counseling for all sessions with male partners due to cultural constraints. Therefore, it is recommended that similar studies be conducted on male partners and also in other regions of Iran with different cultures to use their results in designing appropriate counseling and sexual education programs for these individuals, emphasizing cultural issues. Furthermore, in this study, due to cultural constraints regarding the sexual activity of unmarried individuals in Iran, only

married women were included in the study, which could affect the generalizability of the results. Moreover, sample size estimation was based on a proportion-based formula rather than a mean-difference approach, which should be considered when interpreting the results.

Conclusion

This study demonstrated that sexual counseling based on the extended PLISSIT model significantly and positively improved sexual satisfaction in married women with SLE. This positive effect, contrasting sharply with the decline observed in the control group over 12 weeks, suggests the intervention is an effective strategy for helping these women adapt to their disease and mitigate relationship conflicts. Given that the study was limited to married women, the findings suggest that the effective and cost-efficient EX-PLISSIT model may be considered for integration into the routine care provided by healthcare centers to this specific patient group.

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Conflict of interests

The authors declare that they have no conflict of interest.

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Contributions

M.SH. and M.J. are the primary investigators of the study and provided comments and ideas. M.SH. and A.Gh. participated in the data collection. M.SH., A.M., Z.BM. and M.J. did data analysis, drafted, and revised the manuscript. M.SH., M.J., Z.BM and A.M. provided comments and ideas, and helped revised the manuscript. All authors read and agreed on the final revision of the manuscript.

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