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The Effect of Counseling Based on EX-PLISSIT Model on Sexual Dysfunction and Quality of Sexual Life of Married Women with Multiple Sclerosis: A Randomized Controlled Clinical Trial

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Abstract

Sexual dysfunction is one of the most common complaints of patients with multiple sclerosis (MS). The study aimed to determine the effect of counseling based on the extended PLISSIT model (Permission, Limited Information, Specific Suggestion, and Intensive Therapy) on sexual dysfunction and the quality of sexual life of married women with MS. This randomized clinical trial was performed on 70 married women with MS aged between 18 and 45 years referring to the MS Association of Tabriz, Iran. The data were collected using a demographic questionnaire, Multiple Sclerosis Intimacy and Sexuality Questionnaire-19 (MSISQ-19), Sexual Quality of Life for a Female, Fatigue Severity Scale, and Beck Depression Inventory-Short Form Items (BDI-13). A neurologist rated the disability level using the Expanded Disability Status Scale. Using randomization, the participants with a score of 4 or 5 in each item of MSISQ-19 were assigned to counseling and the control group, with block sizes of four and six and allocation ratio of 1:1. The intervention group attended a counseling session or more if needed, based on the EX-PLISSIT model. Data were analyzed using SPSS software (Version 25). Independent t test and ANCOVA were used to analyze the data. After intervention, there was a significant difference between the two groups in terms of primary and tertiary sexual dysfunctions [AMD, -7.84; 95% CI -14.82 to -0.86; P=0.02]. Despite an increased mean score of quality of sexual life in the intervention group after counseling, there was no statistically significant difference between the two groups [AMD, 9.29; 95% CI -1.46 to 20.04; P=0.08]. Although counseling based on EX-PLISSIT had a positive effect on decreasing sexual dysfunction, it could not improve the quality of sexual life of women suffering from MS. Applying sexual counseling approaches with a focus on couple counseling is suggested for improving the quality of sexual life.

Keywords Multiple sclerosis · Sexual dysfunction · Quality of sexual life · EX-PLISSIT model · Islamic Republic of Iran

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Introduction

Multiple sclerosis (MS) is one of the most common chronic neurological diseases causing inflammation and demyelination of the central nervous system [1]. The global prevalence is about 30 (95% CI 5–80) per 100,000 people and its incidence is 3–4 times more in women than men [1–4]. The prevalent age of the disease is between 20 and 35 years [4]; therefore, women of reproductive age are the most vulnerable to the disease [5, 6]. The incidence in Iran is 20–60 per 100,000 people [4].

With an incidence of 40–85%, sexual dysfunction is one of the most common complaints of patients with MS [7–9]. Sexual function is the result of interaction between three physical, emotional, and psychological factors [10]. Changes in the sexual function of patients with MS are classified into three areas. Primary sexual dysfunction is rooted in physical changes that are caused by the disease and directly affect sexual responses or senses. Secondary sexual dysfunction includes physical changes that indirectly affect sexual responses, such as urinary excretion disorders, intestinal problems, muscle cramps and weakness, attention and concentration deficit disorders, and movement problems. Tertiary sexual dysfunction is related to the psychological, emotional, cultural, and social aspects of the disease, which can interfere with sexual senses and responses. Depression, anxiety, decreased self-esteem, poor communication and social functioning, and concerns about body image and feminine attractiveness are a few of the tertiary sexual dysfunctions [11, 12].

Quality of life is affected by the changes in sexual function [13]. The quality of sexual life is defined on the basis of physical, emotional, and interpersonal assessment of the individual in relation to her partner [14]. The quality of sexual life is one of the key issues in the field of sexual and reproductive health, and similar to the quality of life, it defines as one's understanding of her sexuality in terms of culture, expectations, standards, and priorities. The quality of sexual life involves the sexual attraction, interest and engagement in sexual activity, and understanding of the sexual performance [13]. A review of non-pharmacological interventions shows that only few studies have been done on improving sexual function in women with MS [15-18]. One of the simplest recommended sexual counseling approaches has been PLISSIT model. PLISSIT model includes four components of Permission, Limited Information, Specific Suggestion, and Intensive Therapy [19]. Considering the limitations of the PLISSIT counseling approach, an extended model (EX-PLISSIT) was used to differentiate between a simple and solvable problem and an issue requiring more serious and specialized support. In this model, the permission-giving is core feature of all stages, and techniques such as Review and Reflection are used to increase the clients' self-awareness [20].

In a study by Khakbazan et al. [16], which used the PLISSIT model, the Female Sexual Function Index (FSFI) was utilized to measure sexual dysfunction of women who suffered from MS, while FSFI is unable to differentiate between the three areas of sexual dysfunction [21, 22].

Considering that the most of patients with MS are young women of childbearing age and due to the disabling nature of MS and the high prevalence of sexual dysfunction which causes poor quality of life, this study was designed to determine the effect of counseling based on the Extended PLISSIT model on sexual dysfunction and the quality of sexual life of married women with MS.



Materials and Methods

Study Design

This study was a randomized controlled clinical trial on 70 patients with MS referred to the MS Association of Tabriz, Iran during October–November 2018. Qualifying criteria for enlisting in the study were sexually active married women of reproductive age (18–45 years), passing at least 1 year of married life, living at least 6 months with MS, having at least middle-school level of literacy, obtaining score 4 or 5 in each item of the MS Intimacy and Sexuality Questionnaire-19 [11], having auditory and verbal abilities, having a phone number for follow-up, and a lack of extensive disability (Expanded Disability Status Scale < 7) [23].

Exclusion criteria included pregnant and breastfeeding women, relapse or history of hospital admission because of the progression of MS during the past month, history of other illnesses affecting sexual functioning (diabetes, cardiovascular diseases, thyroid disorders, etc.), drug addiction and smoking, taking medications that affect sexual function (oxybutynin, clonazepam, gabapentin, beta-blockers, and sildenafil), women under treatment for sexual dysfunction, and women with a depression score of 16.0 or higher according to short form of Beck Depression Inventory [24].

Sample Size

To determine the sample size, G Power software was used. According to the article published by Rostamkhani et al. [25], and taking into account: m1=25.3, m2=29.4, SD1=4.88, SD2=4.28, two-sided $\alpha=0.05$, and power=95%, sample size of about 35 people in each group was calculated.

Sampling

After obtaining approval from the Ethics Committee of Tabriz University of Medical Sciences (IR.TBZMED.REC.1396.115) and registering the research at Iran's Center for Clinical Trials (IRCT2017051833834N2), the process of selecting the subjects was started. The Association for the Support of Patients with MS in Tabriz provided a list of married women in reproductive age (18-45 years old) with MS. Through phone calls, the goals of the study were explained, and qualified individuals were invited to participate in the study. During a meeting, the participants were assured that their information will be treated confidentially, the importance and the methods of the study were explained, and signed consents for participation in the study were obtained. Additionally, the participants completed the pre-test questionnaires including demographic data, Sexual Quality of Life for Female (SQOL-F) questionnaire, Beck Depression Inventory-13 item short form (BDI-13), MS Intimacy and Sexuality Questionnaire-19 (MSISQ-19), and Fatigue Severity Scale (FSS). Using Expanded Disability Status Scale (EDSS), the exact level of disability was measured by a neurologist. The participants with severe depression (score 16 and above according to BDI-13) were excluded from the study and referred to a psychiatrist. Because fatigue has been reported to be associated with sexual dysfunction in patients with MS [26, 27]; therefore, in the present



study, fatigue as a confounding variable along with two other confounding variables of depression and disability were compared in the two groups.

After that, 70 women who had scored 4 or 5 in each item of the MSISQ-19 questionnaire were assigned into intervention and control groups by blocked randomization using Random allocation software with block sizes of four and six and the allocation ratio of 1:1. The type of assignment was written on paper and placed in opaque envelopes numbered from 1 to 70 based on the allocation sequence (allocation concealment). The envelopes were opened by a non-involved person in the sampling process.

Data Collection Tools

Demographic characteristics questionnaire included age, number of children, subject's and spouse's education, occupation, family income, housing status, duration of marriage, duration of illness, contraceptive method, type of medications, etc.

MSISQ-19 consists of 19 questions with a minimum score of 19 and a maximum of 95. Five questions (12, 16, 17, 18, 19) are related to primary sexual dysfunction, nine questions (1, 2, 3, 4, 5, 6, 8, 10, 11) to secondary sexual dysfunction, and five questions (7, 9, 13, 14, 15) to tertiary sexual dysfunction; This questionnaire asks the subjects to rate how various MS symptoms have interfered with their sexual activity or interaction over the last 6 months. Responses are based on a five-point Likert scale: 1—never, 2—rarely, 3—sometimes, 4—most times, and 5—always. A score of 4 or 5 for any of the items indicates sexual dysfunction. A higher score indicates more sexual dysfunction [11]. The psychometric properties of Persian version of this questionnaire was evaluated by Mohammadi et al. [28] and the Cronbach's alpha coefficient was reported 0.9.

Moreover, the quality of sexual life was measured by SQOL-F. This 18-item questionnaire assesses four areas of psycho-sexual feelings, sexual and relationship satisfaction, self-worthlessness, and sexual repression. Based on the Likert spectrum, each question is scored from *totally agree* (1) to *totally disagree* (6). The overall score is between 18 and 108, and a higher score indicates a higher quality of sexual life [13]. The psychometric properties of Persian version of this questionnaire was evaluated by Masoumi et al. [29] and the Cronbach's alpha coefficient and Intraclass correlation coefficient (ICC) were reported 0.73 and 0.88, respectively.

In this study, the disability level of women with MS was measured by a neurologist using EDSS, which is a gold standard for evaluating the neurological damage of patients with MS. EDSS scores range from 0 to 10; a score of greater than 7 indicates people who cannot walk and rely on wheelchairs for mobility [23]. Intraclass correlation coefficient of EDSS was reported 0.86 [30].

The fatigue of the subjects was evaluated using FSS. This tool contains nine items. Responses are based on the 7-point Likert spectrum, with a score of 1 for *totally disagree* and a score of 7 for *totally agree*. The score range is 9–63. High scores represent more severe [31]. The psychometric properties of Iranian version of the instrument in patients with MS showed a Cronbach's alpha coefficient of 0.96 and an ICC of 0.93 [27].

The short form of BDI consists of 13 questions and is based on the 4-point Likert spectrum of 0–3; the lowest total score is 0 and the highest total is 39. A score of 0–4 is normal, 5–7 is mild depression, 8–15 is moderate depression, and 16–39 is severe depression [24]. In the Iranian version of the inventory by Rajabi [32], the Cronbach's alpha coefficient was 0.89 and the correlation coefficient between the short form and the 21-item form of the BDI was 0.67.



Intervention

After filling the pre-test questionnaires by the both groups, sexual counseling based on the EX-PLISSIT model in the intervention group (35 subjects) was conducted during a 60–90 min session. Further counseling was performed based on the need and considering the concerns, difficulties, and needs of the participants. After receiving permission from the participants for starting the discussions, relevant information regarding the relationship between MS and sexual problems was provided and recommendations such as the use of lubricants were made.

Counseling included obtaining permission to start a discussion by the counselor; providing limited information such as outlining the four stages of sexual response and explaining the factors affecting sexual satisfaction; giving specific suggestions including different intercourse positions considering early fatigue in patients with MS; offering effective techniques for achieving orgasm and sexual pleasure; avoiding sexual activity when tired; reducing the duration of sexual activity, and using lubricants in case of vaginal dryness, training Kegel exercises, and finally, referring two subjects to a psychiatrist.

The control group received the usual care of the disease. 8 weeks after the intervention, the participants of the both groups were called on by telephone and invited to attend the MS association site in order to complete the SQOL-F and MSISQ-19 questionnaires.

Statistical Analysis

The data were analyzed using SPSS software version 25. The normality of data was examined using Kolmogorov–Smirnov test. To examine the homogeneity of the study groups, Chi square, and independent *t* test were used. To compare the mean scores of sexual dysfunction, as well as the quality of sexual life between the groups, before the intervention, independent *t* test, and 2 months after the intervention, ANCOVA were used while controlling for the effects of baseline values. There was no attrition rate in follow up. All analyses were done based on intention to treat (ITT). ITT analysis is usually described as "once randomized, always analyzed".

Results

In this clinical trial, 85 women were assessed for eligibility and 70 women were ultimately selected (Fig. 1). The mean (standard deviation: SD) of the age of the intervention and control groups was 36.56 (5.99) and 36.70 (5.97), respectively. The mean age of the spouses of the subjects in the intervention and control groups was 42.44 (8.53) and 43.76 (7.93) years, respectively. The mean duration of marriage in the intervention and control groups was 16.12 (7.16) and 16.93 (7.17) years, respectively. Most of the participants in the both groups were housewives. The mean duration of diagnosis in the intervention group was 4.2 (18.1) and in the control group was 5.23 (3.86) years. Before the intervention, the mean number of sexual intercourses during the previous month in the intervention and control group was 2.36 (0.7) and 2.30 (0.65), respectively. There were no significant differences between the demographic characteristics of the groups



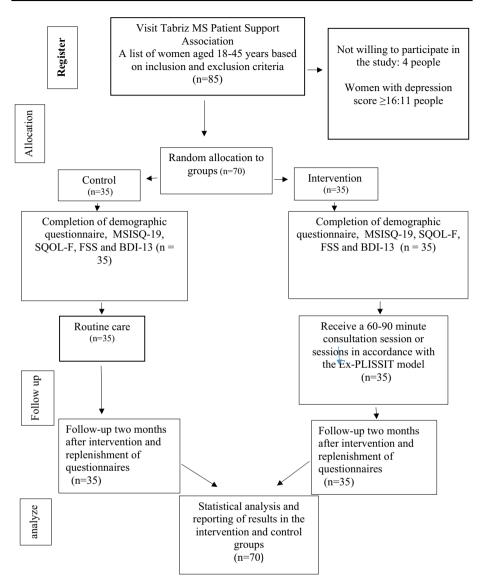


Fig. 1 Flowchart of the study steps

(Table 1). Moreover, there was no significant difference between the mean scores of depression, disability, and fatigue in the intervention and control groups (Table 2).

Prior to intervention, there was no significant difference between the groups regarding sexual dysfunction (P=0.12). The mean score of sexual dysfunction in the counseling group was reduced from 51 (15.57) before to 41.03 (14.02) after the intervention. The same value in the control group reached from 51.55 (11.95) before to 48.88 (16.41) after the intervention. Using the general linear model and by controlling for baseline



Table 1 Comparison of socio-demographic characteristics of study groups	o-demographic	characteristics of study gr	sdno				
Variable	Intervention group $(n=35)$	Control group (n=35)	Ь	Variable	Intervention group $(n=35)$	Control group (n=35)	35) P
Age (years)*	36.56 (5.99)	36.70 (5.97)	0.93**	Spouse smoking			0.448
Spouse's age (years)*	42.44 (8.53)	43.76 (7.93)	0.55**	Yes	10 (28.57)	12 (34.28)	
				No	25 (71.42)	23 (65.71)	
Length of marriage (years)* 16.12 (7.16) 16.93 (7.17)	16.12 (7.16)	16.93 (7.17)	0.67**				
				Housing			0.09
Education			0.12#	Personal	25 (71.42)	21 (60.0)	
Guidance	10 (28.57)	11 (31.42)		Leased	10 (28.57)	9 (25.71)	
High school	1 (2.85)	3 (8.57)		Parental or spouse home	0 (0)	1 (2.85)	
Diploma	18 (51.42)	10 (28.57)		Others	0 (0)	4 (11.42)	
Academic	6 (17.14)	11 (31.42)		Number of Pregnancies*	1.68 (1.06)	2.07 (1.41)	0.26**
Spouse's education			0.77#	Number of deliveries*	1.52 (0.77)	1.83 (1.14)	0.25
Illiterate	0 (0)	1 (2.85)		Duration of diagnosis (year)*	4.18 (2.1)	5.23 (3.86)	0.44
Elementary/gui	15 (42.85)	11 (31.42)		Frequency of intercourse during the last	2.36 (0.7)	2.30 (0.65)	0.74**
				monur.			
High school/diploma	13 (37.14)	14 (40.0)		Spouse alcohol use			0.92
Academic	7 (20.0)	9 (25.71)		Yes	3 (8.57)	2 (5.71)	
Occupation			#60.0	No	32 (91.42)	33 (94.28)	
Work at home	4 (11.42)	0 (0)		Exposed to wife violence			$0.16^{\$}$
Employed	1 (2.85)	5 (14.28)		Yes	8 (22.85)	14 (40.0)	
Housewife	30 (85.71)	30 (85.71)					
Spouse's job			0.12#	No	27 (77.14)	21 (60.0)	
Unemployed	0 (0)	0 (0)		Level of understanding and emotional support of the spouse			0.36#
Employee	13 (37.14)	6 (17.14)		Much	11 (31.42)	12 (34.28)	
Manual worker	13 (37.14)	10 (28/57)		Middle	13 (37.14)	7 (20.0)	
Free	9 (25.71)	19 (54/28)		Low	11 (31.42)	16 (45.71)	



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Variable	Intervention group $(n=35)$	Control group (n=35) P	Variable		Intervention group $(n=35)$	Control group (n=35) P	P
Income adequacy level		9.0	4# Level of	0.64* Level of spouse cooperation at home			0.79#
Inadequate	15 (42.85)	14 (40.0)	Much		14 (40.0)	18 (51.42)	
			Middle		13 (37.14)	14 (40.0)	
Relatively enough	20 (57.14)	20 (57.14)	Low		8 (22.85)	3 (8.57)	
Enough	0 (0)	1 (2.85)	Contrace	Contraception method			0.12#
			IUD		4 (11.42)	6 (17.14)	
MS types		#80.0		и	7 (20)	7 (20)	
RRMS	18 (51.42)	27 (77.14)	Tubectomy	omy	1 (2.85)	6 (17.14)	
PPMS	14 (40.0)	5 (14.28)	Withdrawal	awal	23 (65.71)	16 (45.71)	
SPMS	0 (0)	2 (5.71)					
PRMS	3 (8.57)	1 (2.85)					

*Mean (SD), **independent t test, #Chi-square, \$Fisher exact test



Table 2 Comparison of mean scores of confounding variables between the two groups

Variable	Intervention group (n=35) Mean (SD)	Control group (n=35) Mean (SD)	t	P*
Depression	8.24 (4.8)	6.87 (4.6)	2.02	0.23
Disability	6.37 (5.48)	5.39 (3.56)	0.84	0.40
Fatigue	40 (10.8)	39.73 (9.6)	0.09	0.07

^{*}Independent t test

values, the mean score of sexual dysfunction in the intervention group was significantly lower than the control group [AMD, -7.84; 95% CI -14.82 to -0.86; P = 0.02].

Before counseling, there was no significant difference between the two groups regarding the primary, secondary, and tertiary sexual dysfunctions. However, 8 weeks after intervention, there was a significant difference between the two groups in terms of primary (P=0.003) and the tertiary (P=0.02) sexual dysfunction (Table 3). Overall, primary sexual dysfunction decreased from 68 before to 44% after the intervention, the secondary dysfunction from 90 before to 80% after the intervention, and tertiary dysfunction from 93 before to 46% after the intervention.

Before the intervention, there was no significant difference between the groups regarding the mean score of quality of sexual life (P=0.51). The quality of sexual life in the intervention group increased from 74 (22.73) before to 78.37 (21.63) after the intervention. The same value in the control group reached from 69.29 (22.06) before to 69.08 (23.13) after the intervention. Using the general linear model and by controlling for baseline values, the mean score of the quality of sexual life was not significantly different between the groups [AMD, 9.29; 95% CI – 1.46 to 20.04; P=0.08]. (Table 4)

Discussion

The purpose of this study was to determine the effect of EX-PLISSIT model on the sexual dysfunction and quality of sexual life of married women with MS. The findings reflected the positive effect of intervention on the primary and tertiary levels of sexual dysfunction of the women with MS.

In a study by Daneshfar et al. [17] on 60 women with MS, a significant decrease in all three levels of sexual dysfunction, 8 and 12 weeks after intervention with the EX-PLISSIT method was reported. In our study, primary sexual dysfunction decreased from 68 before to 44% after EX-PLISSIT-based counseling. This suggests that recommendations such as the use of lubricants and so on could reduce primary sexual dysfunction. Secondary sexual dysfunction decreased from 90 before to 80% after the intervention; counseling had no significant effect on muscle weakness, and urinary and intestinal problems in the intervention group. This is a logical consequence, because these side effects of MS require drug therapy and rehabilitation. Tertiary sexual dysfunction decreased from 93 before to 46% after intervention, indicating the positive impact of counseling on the psychological aspects of sex, self-esteem, and self-efficacy enhancement of women in interaction with their husbands, as well as the effectiveness of recommendations.

Other study by Khakbazan et al. [16] regarding the effect of PLISSIT model on sexual dysfunction in women with MS showed significant decreases in the sexual dysfunction of the experimental group, 2 and 3 months after the intervention, in comparison with the



Table 3 Comparison of mean scores of sexual disorders between two groups, before and 8 weeks after intervention

Variable	Pre-test intervention group (n=35) Mean (SD)	Control group (n=35) Mean (SD)	<i>p</i> *	Post-test intervention group (n=35) Mean (SD)	Post-test intervention Control group (n=35) group (n=35) Mean (SD) Mean (SD)	CI 95%	P^**
Primary SD	17 (3.89)	16.44 (3.80)	0.46	11.01 (3.86)	14.70 (4.65)	-3.68 (-6.02 to -1.35)	0.003
Secondary SD	22.52 (7.41)	22.16 (8.84)	0.15	20.21 (6.95)	21.76 (7.73)	-1.54 (-5.05 to 1.95)	0.37
Tertiary SD	11.48 (5.94)	12.94 (4.39)	0.88	9.89 (5.04)	12.25 (5.88)	-2.36 (-4.33 to -0.38)	0.02
MSISQ-19 score	51 (15/57)	51.55 (11.95)	0.12	41.03 (14.02)	48.88 (16.41)	7.84 (-14.82 to -0.86)	0.02

*Independent t test, **ANCOVA test with control of the effect of baseline score



Table 4 Comparison of mean scores of sexual quality of life between two groups, before and 8 weeks after intervention

Variable	Pre-test interven- Control gro tion group (n=35) Mean (SD) Mean (SD)	Pre-test interven- Control group (n=35) P* Post-test interven- Control group (n=35) CI 95% tion group (n=35) Mean (SD) Mean (SD) Mean (SD)	b*	Post-test interven- Control gro tion group (n=35) Mean (SD) Mean (SD)	Control group (n = 35) Mean (SD)	CI 95%	p**
Psycho-sexual feelings	28.33 (10.08)	27 (9.29)	99.0	29.70 (9.82)	26.24 (10.85)	3.46 (-1.90 to 8.82) 0.19	0.19
Sexual and communication satisfaction	20.41 (5.80)	20.29 (5.59)	0.94	22.62 (4.65)	21.08 (5.81)	1.54 (-0.89 to 3.98)	0.20
Feeling of worthlessness	13.16 (4.02)	11.88 (4.92)	0.36	13.12 (4.42)	11.04 (4.75)	2.07 (-0.37 to 4.19)	0.054
Suppression of sexual expression	12.8 (4.78)	10.11 (3.96)	0.17	12.83 (3.81)	10.75 (4.69)	2.07 (-0.36 to 4.51)	0.09
SQOL-F score	74 (22.73)	69.29 (22.06)	0.51	0.51 78.37 (21.63)	69.08 (23.13)	9.29 (-1.46 to 20.04) 0.08	80.0

*Independent t test, **ANCOVA test with control of the effect of baseline score



control group [16]. In that study, the FSFI was used to measure the subjects' sexual dysfunction, which was unable to distinguish between primary, secondary, and tertiary sexual dysfunctions.

Regarding the quality of sexual life, despite an increased score in the intervention group after counseling, there was no statistically significant difference between the two groups. Consequently, the reduction of sexual dysfunction could not improve the quality of sexual life as an outcome measure in a short-term follow-up. In systematic reviews where significant quality of life improvements were noted for patients receiving an intervention, improvements tended to be seen at 6 or 12 months follow up [33, 34].

There were no significant differences between two groups in terms of spouse smoking or alcohol use, wife abuse, and contraception method; accordingly they were not entered in comparison of sexual function and quality of sexual life between two groups as covariate.

The design of the study as a randomized clinical trial, the absence of attrition bias, and applying standard questionnaires were strengths of the present study. The limitation of this study was its short follow-up period.

Conclusions

Although counseling based on EX-PLISSIT had a positive effect on decreasing sexual dysfunction, it could not improve the quality of sexual life of women suffering from MS. So, longer follow-up periods (6–12 months) are suggested for future studies to evaluate the long-term effectiveness of the intervention. Moreover, applying sexual counseling approaches with a focus on couple counseling is suggested for improving the quality of sexual life.

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Compliance with Ethical Standards

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

Ethical Approval Regarding Research Involving Human Participants All procedures performed in this study were in compliance with the ethical standards of the National Research Committee and with the 1964 Helsinki Declaration and its subsequent amendments or comparable ethical standards.

Informed Consent Informed consent was obtained from each participant.

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