

Compare the Effectiveness of PLISSIT and Sexual Health Models on Women's Sexual Problems in Tehran, Iran: A Randomized Controlled Trial

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ABSTRACT

Introduction. Sexuality is an important aspect of human life and sexual problems are common, but there is limited evidence for cost-effective treatments of women's sexual dysfunctions.

Aims. The aim of this study was to assess whether group therapy such as Sexual Health Model (SHM) can be as effective as individual therapy like Permission, Limited Information, Specific Suggestions, and Intensive Therapy (PLISSIT) model in women with sexual problems.

Methods. A randomized controlled trial was conducted between May 2012 and September 2013 in five Tehran, Iran health clinics. Eighty-four consecutive married women aged 20–52 years, with sexual problems who were admitted for the first time, were recruited and randomized into two groups. The intervention included two therapeutic models: the SHM, which consisted of two sessions of 3 hours of group education, and the PLISSIT model, which required a total of 6 hours of one-on-one consultation at an interval of 1–2 weeks.

Main Outcome Measures. Sexual function and sexual distress were assessed, respectively, with the Brief Index of Sexual Function for Women and Female Sexual Distress Scale Revised questionnaires.

Results. Seven months after intervention, the mean (SD) of the sexual distress score decreased and sexual composite score increased significantly in both groups ($P < 0.001$). The overall analysis of repeated measure MANOVA revealed borderline significance differences for combined outcomes between two groups ($P = 0.051$).

Conclusions. Due to the considerable human resource, time, and cost spent conducting the PLISSIT, it seems that group education based on SHM could be more cost-efficient and nearly as effective. This conclusion may be more applicable in communities where the treatment of sexual problems is in the beginning stages and where people have not received any sexual education or knowledge during their lifetime. **Farnam F, Janghorbani M, Raisi F, and Merghati-Khoei E. Compare the effectiveness of PLISSIT and Sexual Health Models on women's sexual problems in Tehran, Iran: A randomized controlled trial. J Sex Med 2014;11:2679–2689.**

Key Words. RCT; PLISSIT Model; Sexual Health Model; Interventions in Sexual Health; Female Sexual Dysfunction; Iran

Introduction

Sexuality is an important aspect of human life. It plays a vital role in one's well-being and health, in general. There are significant relationships between sex-related problems and quality of life [1,2]. Female sexual dysfunction (FSD) refers to a problem during any phase of the sexual response cycle that prevents the individual or couple from experiencing satisfaction from sexual activity. The sexual response cycle has four phases: excitement, plateau, orgasm, and resolution. FSD includes sexual interest/desire disorder, disorders of subjective and genital arousal, orgasm disorders, vaginismus, and dyspareunia [3]. FSD is a major women's health problem worldwide, and the data suggest that more than 40% of women experience sexual problems and 20% have sexual stress [2,4,5]. The reported prevalence of FSD in Iran varied between 31% and 72% [6–9]. One study in Iran showed that women with sexual dysfunction had more somatic, social, and psychological problems than sexually healthy women [10]. In spite of these adverse effects and its high prevalence, little attention has been paid to FSD treatment [11,12], few studies have investigated treatment, and no consensus exists on how or where possible treatment should be given. Iran is in its beginning stages of the treatment of sexual problems, and we are confronted with massive numbers of patients with very little sexual information. Although the clinical trials showed that the Permission, Limited Information, Specific Suggestions, and Intensive Therapy (PLISSIT) model is one of the most useful models for the treatment of sexual problems [13–15], we need to find alternative cost-effective models, at least in the early stages. According to the aforementioned aspects and considering the culture of the country, we chose the Sexual Health Model (SHM). This model, in addition to its ability to run in groups, is education based, culturally specific [16], and can be used as a treatment model [17]. One clinical trial indicated the efficacy of SHM in prevention of HIV [18], but no studies have been done to assess the efficacy of SHM, nor has it been compared with standard models such as PLISSIT in a clinical setting.

Aim

We designed this randomized, controlled trial to test the hypothesis that the SHM, as compared with PLISSIT, would reduce sexual stress and promote sexual function in women who seek treatment for FSD.

Methods

We conducted a multicenter, randomized, single-blinded, parallel-group clinical trial in Tehran, Iran.

Setting

Iran's capital, Tehran, is the most populous city in the country, with over 8 million inhabitants. The mean ages of marriage for men and women in Tehran are 29.6 and 25.9, respectively. Approximately 17% of women have some academic education [19] and the Internet penetration rate in 2013 was almost at 80% [20]. Tehran has the country's highest divorce rate (one out of three marriages) [21], and many studies show that sexual dysfunctions are among the most important contributing factors to divorce in Iran [22]. Socio-economic and educational progress in Iran during the last two decades has increasingly transformed women's roles from traditional spheres of housework toward productive occupations leading to financial independence, participation in family decision-making, and a more proactive role in society [23]. Legally, any emotional or sexual contact between man and woman prior to marriage is forbidden, but in many cases, these relationships exist, especially with regard to emotional contact [24]. In Iran, there is a lack of access to appropriate information regarding sexual matters due to the absence of sex curriculums. This lack of information extends to the private sphere, where sexual issues are generally not even discussed within families or society at large [25]. The dearth of reliable knowledge extends to the Internet; where governmental filtering of "key words" means that access to any content on sexual matters (even academic journals and articles) is denied. The main reason for these censorship is fear of the propagation of premarital or extramarital sex and overall sexual promiscuity. This censorship also formed misconceptions and in many cases negative and erroneous beliefs and attitudes toward sexual issues that can lead to sexual dysfunctions in youth [26].

Tehran University is the oldest Medical Sciences University in Iran and caters to nearly 4 million of its inhabitants. Normally, people from low to middle socio-economic status get served at university clinics, but our sample was very heterogeneous and included patients from a range of socio-economic statuses, due to a dearth of private centers for the treatment of sexual problems. In

our study, all clinical interventions were undertaken by a female specialist.

Participants

We studied 84 consecutive patients who were admitted for the first time to five health clinics of Tehran University of Medical Sciences, Iran, from May 2012 to September 2013. Our sample was gathered through local announcements (self-referred) to these centers as well as professional referral. Primary screening included women who described themselves as healthy, in general, aged 20 and above, with a history of a self-reported sexual problem. Women were recruited for participation with the following criteria: married and living with husband; stable, monogamous relationship with husband; diagnosis of FSD; presence of a sexual problem during the last 2 months; a Female Sexual Distress Scale Revised (FSDS-R) score of 11 or above; and the ability to speak, read, and understand the Persian language. Exclusion criteria were any major cognitive disorder; reluctance to participate; current serious relationship in conflict with husband; alcohol or drug abuse; and serious medical conditions such as diabetes or heart disease. Eligible candidates were invited to a clinical appointment that included an assessment by a qualified psychiatrist to rule out major psychological disorders.

Study participants were apprised of the nature of the trial, and they were given a study number. Verbal and written informed consent was obtained prior to randomization. Participants were randomized to one of two study groups, SHM or PLISSIT. The patients were unaware of the treatment assigned. The tenets of the current version of the Declaration of Helsinki were followed; the study protocol was approved by the Ethics Committee of Isfahan University of Medical Sciences (approval No. 391026 dated May 2012).

Randomization Scheme

A total of 90 participants were eligible for inclusion. Six patients were excluded because of family issues. Before randomization, pretreatment evaluation was undertaken for all 84 participants to obtain demographic and clinical data including (i) age, (ii) marital status, (iii) education level, (iv) history of psychological or psychiatric disorders, (v) history of sexual and medical problems, (vi) status of present sexual problem, (vii) sexual stress and relationship status, (viii) use of psychiatric medications, and (ix) smoking status. The questionnaires were answered on a self-reported basis.

The 84 participants were assigned randomly to one of the two groups according to a preexisting list produced by a computer program that differed from a random number generator only in that it assigned an equal number of patients to each treatment group. The group assignments were concealed in a sealed, opaque envelope until clinic admission.

Intervention

The intervention included two therapeutic models: the SHM and PLISSIT model. Both programs were delivered by a trained sexual health provider (FF). Subjects in the SHM group attended two sessions of group education, each lasting 3 hours, at an interval of 1 month (up to eight women in each group). Education was conceptually based on 10 key components of Robinson's SHM [16], although we modified it according to our culture and problems. This model is a holistic, flexible, and culturally based program for improving sexual health and empowerment. Its aims are to solve sexual concerns through accurate knowledge, personal awareness, and self-acceptance; the ability to be intimate with a partner and express explicitly sexual needs and desires; to act responsibly and respectfully and be free from unwanted behaviors or disease. During the sessions, participants were encouraged to discuss their questions, experiences, and solutions. The PLISSIT group received a total of 6 hours of one-on-one consultation at an interval of 1–2 weeks that was adapted from four therapeutic stages: permission, limited information, specific suggestions, and intensive therapy of the Annon PLISSIT model [27], which has been widely used by health care practitioners to address the sexual health needs of clients [28]. In this model, the consultant lets the patient talk freely about her sexual concerns, and permission is given for those nonproblematic sexual behaviors that the subject has already experienced. Providing limited information based on the patient's concerns and dispelling widespread sexual myths are parts of the next step. With specific suggestion, the consultant offered specific recommendations to enable the client to manage her sexual issues. The last stage, intensive therapy, was performed for women who still needed more intervention. The researcher was in contact with the participants of both groups regularly to prevent subjects from missing follow-ups as well as addressing their concerns related to the therapy. Each participant was contacted at least three times.

Outcome Measurements

Patients were evaluated at baseline, at 10 weeks and at 28 weeks after clinic admission with structured interviews, during which they completed a (23-item) questionnaire for demographic and clinical characteristics, the Brief Index of Sexual Functioning for Women (BISF-W) [29] for sexual function assessment, and the FSDS-R Questionnaire [30] for sexual distress assessment. The last two instruments were translated into Persian and then translated back into the original language. The 22 item's questionnaire of BISF-W was originally developed in 1994 by Taylor et al. [31], then modified in 2000 to a new scoring algorithm [29]. This new version scored from -16 to +75, and had seven dimension scores, including D1 (thought/desire), D2 (arousal), D3 (frequency of sexual activity), D4 (receptivity/initiation), D5 (pleasure/orgasm), D6 (relationship satisfaction), and D7 (problem affecting sexual function). The possible score ranges for different dimensions were as follows: D1–D6 (0–12), D7 is (0–16). The total score for sexual function (composite score) was obtained by summing up D1–D6 items and subtracting the seventh domain. In D1–D6 and the composite score, the higher score indicates better sexual function, but in D7, it is the opposite. The FSDS-R is a 13-item instrument for measuring sexual distress. The FSDS-R scoring ranges from 0 to 48; the higher the score, the greater the intensity of sexual distress: mild, <11; moderate ≥ 11 . Both questionnaires used widely and had psychometric properties including internal consistency, test–retest reliability, and validity [30,31]. Validity and reliability of the Persian version of FSDS-R have been confirmed [32].

Statistical Analysis

The sample size was calculated when the study was designed. We calculated that 42 women per treatment group would be required to provide the study with 80% power (with a two-sided alpha of 0.05) to detect a mean difference in sexual satisfaction score of 2.0 between PLISSIT and SHM groups, given an anticipated dropout rate of 20%. Statistical analyses were based on the intention-to-treat principle. The results for the groups that received PLISSIT or SHM intervention were compared with Student's *t*-test for independent samples and analysis of variance with repeated measures over time; the results at baseline and after 7 months within each group were compared with paired Student's *t*-tests. We used the χ^2 or Fisher's exact test to compare proportions. The

results are expressed as the mean (standard deviation [SD]), and $P < 0.05$ was considered statistically significant. All statistical tests were two sided, and all analyses were done with the SPSS version 21 for Windows (SPSS IBM, New York, USA).

Results

Baseline Data

A total of 84 patients were randomized: 42 to the PLISSIT group and 42 to the SHM group (Figure 1). All 84 patients who completed treatment were available for follow up at 7 months. Mean (SD) age in the PLISSIT and SHM groups was 31.6 (7.4) and 32.6 (7.0) years, respectively. In 33 women (39.3%), the main reason for referrals was low desire, in 26 (31%) it was orgasm problems, in 15 (17.9%) dyspareunia, in 14 (16.7%) arousal problems, in 12 (14.3%) primary vaginismus (unconsummated marriage), in 2 women (2.4%) secondary vaginismus, and in 2 women (2.4%) it was sexual aversion. Twenty-five (30%) of the women complained of husband's sexual dysfunctions; among them, husband's low desire (13%) was the most frequent grievance. However, following the initial problem, women experienced many problems in other sexual aspects (Table 1). The two treatment groups were generally well matched at baseline with regard to age, marital status, education, and other characteristics except the duration of the marriage for which participants in the SHM group had a higher mean ($P < 0.05$) (Tables 1 and 2).

Also, sexual distress score and all domains of sexual function were matched at baseline except for pleasure/orgasm domain, in which participants

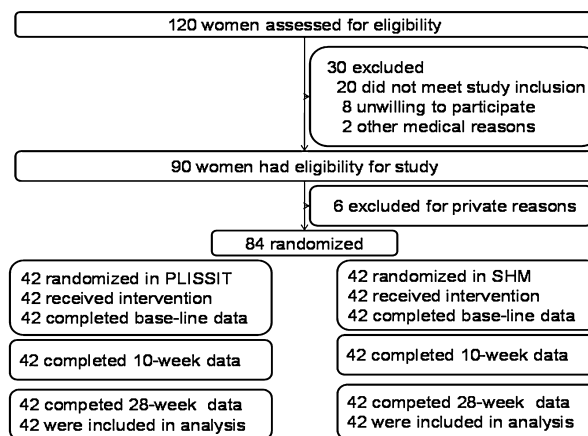


Figure 1 Flow diagram of patient's selection process.

Table 1 Baseline characteristics and prevalence of sexual dysfunction in men and women in PLISSIT or sexual health model (SHM) groups (assessment with a 23-item questionnaire)

Characteristics	PLISSIT (N = 42) mean (SD)	SHM (N = 42) mean (SD)	Difference 95% CI
Women's age (year)	31.6 (7.4)	32.6 (7.0)	-1.0 (-4.1, 2.1)
Husband's age (year)	34.3 (7.3)	36.8 (6.8)	-2.5 (-5.6, 0.6)
Duration of marriage (year)	7.2 (7.7)	11.0 (8.2)	-3.8 (-7.3, -0.5)*
Years of education	13.2 (4.0)	12.6 (3.2)	0.7 (-0.9, 2.2)
Number of children	0.9 (1.1)	1.2 (0.9)	-0.3 (-0.8, 0.1)
	No (%)	No (%)	
Women's sexual problem			
Low desire	18 (42.9)	15 (35.7)	7.2 (-13.7, 28.0)
Arousal problems	8 (19.0)	6 (14.3)	4.7 (-11.1, 20.7)
Orgasm problems	14 (33.3)	12 (28.6)	4.7 (-15.0, 24.5)
Dysparounia	8 (19.0)	7 (16.7)	2.3 (-14.8, 18.8)
Primary vaginismus	8 (19.0)	4 (9.5)	9.5 (-5.3, 24.4)
Secondary vaginismus	2 (4.8)	0 (0.0)	4.8 (-1.7, 11.2)
Sexual aversion	1 (2.4)	1 (2.4)	0.0 (-6.5, 6.5)
Husband's sexual problem			
Low desire	6 (14.3)	5 (11.9)	2.4 (-12.0, 16.8)
Erectile dysfunction	3 (7.1)	2 (4.8)	2.3 (-7.7, 12.5)
Premature ejaculation	5 (11.9)	12 (28.6)	-16.7 (-33.5, 0.1)
Retarded ejaculation	0 (0.0)	2 (4.8)	4.8 (-11.2, 1.7)
Hyper sexuality	0 (0.0)	2 (4.8)	4.8 (-11.2, 1.7)

* $P < 0.05$

PLISSIT = Permission, Limited Information, Specific Suggestions, and Intensive Therapy

in SHM had higher mean ($P < 0.05$). Mean (SD) sexual distress scores on a scale of 0–48 measured with the FSDS-R at the start of the intervention were 22.7 (9.8) in the PLISSIT group and 22.0 (8.4) in the SHM group. Mean (SD) sexual functions (composite score) on a scale of -16 to +75 measured with the BISF-W at the start of the intervention were 25.8 (10.1) in the PLISSIT group and 27.5 (9.5) in the SHM group. There were no statistically significant differences between the two groups (Table 3).

Summary of Results

Changes in mean sexual distress and all eight dimensions of sexual function, from baseline to 7 months after the study, in the two groups are shown in Table 3. In both groups, the average composite score increased significantly ($P < 0.001$). The average increases from baseline were -7.1 points (95% CI, -10.1, -4.2) in the PLISSIT and -5.3 points (95% CI, -8.0, -2.5) for the SHM. In both groups, the mean sexual distress score decreased significantly ($P < 0.001$). The mean (SD) sexual distress decreased in the PLISSIT from 22.7 (9.8) at baseline to 6.8 (7.5) at the end of the study period and in the SHM from 22.0 (8.4) to 11.7 (10.5).

Sexual distress and all dimensions of sexual function were measured for PLISSIT and SHM group at three time points: baseline, at 10 weeks,

and at 28 weeks. Repeated measure MANOVA analyses confirmed that there were borderline significance multivariate effects for group ($P = 0.05$), a significant effect of treatment week ($P = 0.001$), and a significant interaction between group and treatment week ($P = 0.004$).

Univariate between-group analyses indicated that the PLISSIT group had significantly lower "problems affecting sexual function" and "sexual distress" than the SHM group ($P < 0.05$). Within-group univariate analyses revealed that sexual distress and all dimensions of sexual function except of initiation/receptivity were significantly improved ($P < 0.001$) between baseline and week 28 (regardless of group type).

There was a significant interaction between group and treatment week for pleasure/orgasm, relationship satisfaction, and sexual distress. Further analyses showed that there was a greater improvement in "pleasure/orgasm," "relationship satisfaction," and "sexual distress" score across time for PLISSIT than SHM ($P < 0.01$). Changes from baseline in all dimensions of sexual function and sexual stress are shown in two groups (Figure 2).

Discussion

This randomized controlled trial (RCT) demonstrated that both the PLISSIT and SHM were

Table 2 Baseline characteristics of women with sexual dysfunction in PLISSIT or sexual health model (SHM) groups (assessment with a 23-item questionnaire)

Characteristics	PLISSIT (N = 42) No (%)	SHM (N = 42) No (%)	Difference 95% CI
Contraceptive			
None	21 (50.0)	10 (23.8)	26.2 (6.3, 46.1)*
Withdrawal	8 (19.0)	13 (31.0)	-12.0 (-30.2, 6.4)
Other method	13 (31.0)	19 (55.2)	-24.2 (-34.8, 6.3)
Pre-menopause	41 (97.6)	40 (95.2)	2.4 (-5.6, 10.3)
Occupation			
Household	29 (69.0)	27 (64.3)	4.7 (-15.4, 4.9)
Part-time job	8 (19.0)	6 (14.3)	4.7 (-11.4, 20.7)
Full-time job	5 (11.9)	9 (21.4)	-9.5 (-25.3, 6.3)
Consent of marriage			
Couples and families consent	33 (78.6)	31 (73.8)	4.8 (-13.4, 23.0)
Just couple consent	5 (11.9)	9 (21.4)	-9.5 (-25.3, 6.3)
Just family consent	4 (9.5)	2 (4.8)	4.7 (-6.2, 15.7)
20-minute walking or any exercise			
Every day	11 (26.2)	11 (26.2)	0.0 (-18.8, 18.8)
Three times weekly	13 (31.0)	12 (28.6)	2.4 (-17.2, 21.9)
One time or fewer	18 (42.9)	19 (45.2)	-2.3 (-23.6, 18.8)
Women estimate of general life stress			
Low	4 (9.5)	2 (4.8)	4.7 (-6.2, 15.2)
Moderate	15 (35.7)	21 (50.0)	-14.3 (-35.2, 6.7)
Severe	23 (54.8)	19 (45.2)	9.6 (-11.8, 30.8)
Medical disease			
Mild depression	3 (7.1)	2 (4.8)	2.3 (-7.8, 12.5)
Mild anxiety	5 (11.9)	8 (19.0)	-7.1 (-22.5, 8.3)
Other	8 (19.0)	9 (21.4)	-2.4 (-19.6, 14.8)
Drug abuse			
Cigarette smoking	1 (2.4)	2 (4.8)	-2.4 (-10.3, 5.5)
Alcohol consumption	1 (2.4)	2 (4.8)	-2.4 (-10.3, 5.5)
Medications			
OCP	4 (9.5)	6 (14.3)	-4.8 (-18.6, 9.1)
Anxiety or depression	4 (9.5)	5 (11.9)	-2.4 (-15.6, 10.8)
Other	1 (2.4)	2 (4.8)	-2.4 (-10.3, 5.5)
Violence in current marriage			
Rarely	3 (7.1)	3 (7.1)	0.0 (-11.0, 11.0)
Sometimes	3 (7.1)	7 (16.7)	-9.6 (-23.2, 4.2)
Frequently	1 (2.4)	1 (2.4)	0.0 (-6.5, 6.5)
Child abuse	4 (9.5)	2 (4.8)	4.7 (-6.2, 15.7)
Adultery abuse	3 (7.1)	2 (4.8)	2.3 (-7.7, 12.5)
Sexual knowledge at marriage time			
None	18 (42.9)	25 (59.5)	-16.6 (-37.7, 4.4)
Low	17 (40.5)	8 (19.0)	21.5 (2.4, 40.4)*
Moderate	3 (7.1)	7 (16.7)	-9.6 (-23.2, 4.2)
High	4 (9.5)	2 (4.8)	4.7 (-6.2, 15.7)
Homo or transsexual orientation	0 (0.0)	0 (0.0)	—
Sexual activity			
Few times a year	3 (7.1)	1 (2.4)	4.7 (-4.3, 13.8)
One time a month	4 (9.5)	4 (9.5)	0.0 (-12.6, 12.6)
Two to three times a month	5 (11.9)	9 (21.4)	-9.5 (-25.3, 6.3)
One to two times weekly	20 (47.6)	20 (47.6)	0.0 (-21.4, 21.4)
Three to four times weekly	10 (23.8)	8 (19.0)	4.8 (-12.8, 22.3)
Marital satisfaction			
Low	2 (4.8)	3 (7.1)	-2.3 (-12.5, 7.7)
Moderate	12 (28.6)	21 (50.0)	-21.4 (-41.8, -1.1)*
High	28 (66.7)	18 (42.9)	23.8 (3.1, 44.5)*

*P < 0.05

PLISSIT = Permission, Limited Information, Specific Suggestions, and Intensive Therapy

associated with improvement in all dimensions of sexual function (except receptivity) over time in women with sexual problems. This was accompanied by a significant decrease in sexual distress scores, demonstrated by the FSDD-R, and self-

report after interventions. These findings are in line with the literature that supports counseling, sexual therapy, and education such as the PLISSIT model or any other educational program as the first line of nonmedical management for women

Table 3 Mean (SD) for sexual function (BISF-W) and sexual distress (FSDS-R) of PLISSIT vs. SHM groups at baseline and at 28 weeks

		Baseline (N = 42) mean (SD)	Last follow-up (N = 42) mean (SD)	Difference 95% CI
BISF-W questionnaire				
Thought/desire	PLISSIT	4.0 (2.1)	4.7 (2.0)	-0.7 (-1.5, 0.1)
	SHM	4.2 (2.2)	4.9 (2.0)	-0.7 (-1.4, -0.0)*
Difference 95% CI		-0.2 (-1.1, 0.8)	-0.2 (-1.1, 0.6)	
Arousal	PLISSIT	4.6 (1.7)	5.3 (1.6)	-0.7 (-1.2, -0.2)*
	SHM	5.1 (1.4)	5.6 (1.8)	-0.5 (-0.9, -0.0)*
Difference 95% CI		-0.5 (-1.2, 0.2)	-0.3 (-1.0, 0.5)	
Frequency of sexual activity	PLISSIT	3.4 (1.7)	4.1 (1.5)	-0.7 (-1.2, -0.2)**
	SHM	3.7 (1.8)	4.1 (1.8)	-0.4 (-0.9, 0.1)
Difference 95% CI		-0.3 (-1.1, 0.4)	0.0 (-0.7, 0.7)	
Receptivity/initiation	PLISSIT	8.4 (3.0)	8.8 (2.9)	-0.5 (-1.3, 0.3)
	SHM	8.7 (2.8)	9.2 (2.7)	-0.5 (-1.3, 0.3)
Difference 95% CI		-0.3 (-1.6, 0.9)	-0.4 (-1.6, 0.8)	
Pleasure/orgasm	PLISSIT	3.1 (1.8)	4.2 (2.0)	-1.1 (-1.6, -0.5)***
	SHM	4.0 (2.0)	4.5 (2.1)	-0.5 (-1.1, 0.1)
Difference 95% CI		-0.9 (-1.7, -0.1)*	-0.3 (-1.2, 0.6)	
Relationship satisfaction	PLISSIT	7.5 (2.3)	9.6 (2.0)	-2.0 (-2.7, -1.4)***
	SHM	8.0 (2.1)	8.8 (2.3)	-0.8 (-1.3, -0.2)**
Difference 95% CI		-0.5 (-1.4, 0.4)	0.8 (-0.1, 1.7)	
Problems affect. sex. function	PLISSIT	5.4 (2.3)	3.8 (2.3)	1.5 (0.9, 2.0)***
	SHM	6.3 (2.2)	4.4 (1.8)	1.9 (1.2, 2.6)***
Difference 95% CI		-1.0 (-2.0, 0.0)	-0.5 (-1.4, 0.3)	
Composite score	PLISSIT	25.8 (10.1)	32.9 (10.0)	-7.1 (-10.1, -4.2)***
	SHM	27.5 (9.5)	32.8 (10.2)	-5.3 (-8.0, -2.5)***
Difference 95% CI		-1.7 (-2.0, 0.0)	0.1 (-4.2, 4.5)	
FSDS-R questionnaire				
Sexual distress score	PLISSIT	22.7 (9.8)	6.8 (7.5)	16.0 (13.1, 18.9)***
	SHM	22.0 (8.4)	11.7 (10.5)	10.2 (7.6, 12.9)***
Difference 95% CI		0.7 (-3.2, 4.8)	-5.0 (-8.9, -1.0)*	

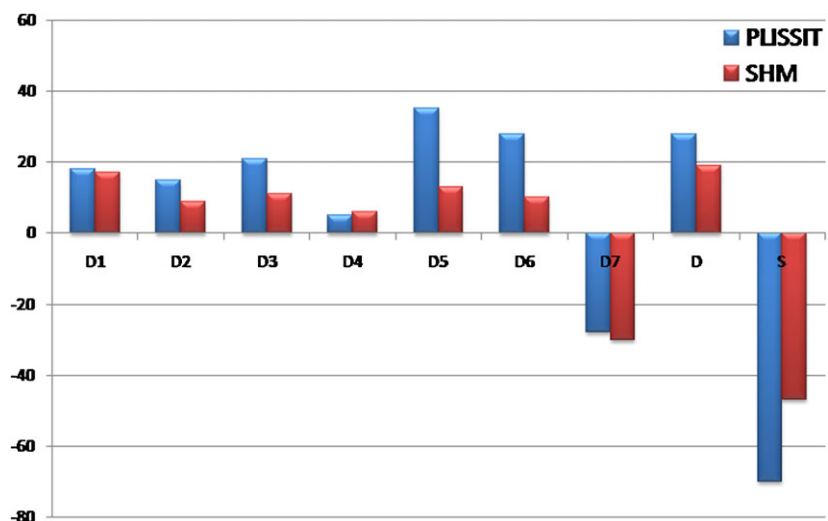
*P < 0.05, **P < 0.01, ***P < 0.001

SHM = Sexual Health Model; PLISSIT = Permission, Limited Information, Specific Suggestions, and Intensive Therapy; Brief Index of Sexual Functioning for Women; Female Sexual Distress Scale Revised

with sexual problems [33,34]. Similar to previous RCT [15,35] and non-RCT reports [13,14], we found significant effects in the treatment of women's sexual concerns by using the PLISSIT.

Our research adds a new dimension to previous studies of Robinson [17], which demonstrated improvement in sexual problems by using the SHM in a case study. As the first RCT, we con-

Figure 2 Percentage change from baseline in two groups. D1/thought desire; D2, arousal; D3 frequency of sexual activity; D4, receptivity/initiation; D5, pleasure/orgasm; D6, relationship satisfaction; D7, problem affecting sexual function; D, composite score; S, sexual distress score (negative growth in S and D7 reflecting positive outcome).



firmed the efficacy of the SHM and also its comparable efficacy with a standard model like the PLISSIT. Our results revealed a borderline significant difference ($P = 0.051$) between the two groups in sexual function and distress at the end of the study. Due to the staffing limitation and considerable cost and time needed to conduct the PLISSIT, and in regard to the significant decrease in sexual problems of women in the SHM group over the time of the study (Table 3), it seems that group therapy based on the SHM could be quite efficient at least in a society with our particular culture and situations.

To better understanding the SHM's effects in our study, considering the level of sexual knowledge in our country is very helpful. In this study, 81% of participants stated that their sexual knowledge, at the time of marriage, was zero or negligible, although the average number of years of schooling in our sample was 12.9. Similarly, in Javadnoori et al.'s study, participants narrated that the taboo surrounding sexuality resulted in sexual silence, censorship, or emphasis on negative aspects of sexuality [36]. Moreover, Goshtasebi et al. reported that low education was a significant risk factor for female sexual difficulty [8]. McHugh, in her report against the "medicalization of female sexuality" focused on the role of a lack of sexual knowledge and cultural messages in creating sexual problems [34]. A lack of correct information and a low incidence of premarital sexual relationships (because of our religious and cultural tradition) cause considerable stress and anxiety in couples [37]. It is reasonable that in such conditions, educational programs can be effective [38,39] because in many cases, the problems are not so severe. Hawton reported that the absence of major psychiatric disorders leads to positive treatment outcomes [40]. Review of the demographic characteristics of our patients (Table 2) revealed that many complex factors that cause sexual problems, such as child abuse, forced marriage, frequent physical or mental violence in a current marriage, and being highly unsatisfied with marriage, were not common.

Another factor in the success of SHM model is the positive therapeutic function of group therapy. It has been shown that group therapy in treatment of FSDs can be quite effective [41–43]. Removing the taboo of talking about sexual problems, becoming aware of the ideas, difficulties and solutions of other participants, and observing other people with similar or even more severe problems can lead to decrease sexual concerns by

normalizing thoughts and behaviors. Similarly, Bergeron et al. reported that attendance in a group may reduce anxiety and help the normalization of sexual problem [41]. Spence believed that removing the taboo of talking about sexual concerns in a group setting can act as an impetus to self-expression and self-disclosure, and consequently to sexual communication with the husband [44]. Also, most of these interventions were conducted in individual therapy with PLISSIT, but in group therapy, participants can realize these issues through direct experiences of other people and more active and practical situations instead of theoretical concepts of the therapist. Smith et al. have shown that group therapy can be an effective alternative option for the treatment of sexual concerns by health care with limited time [45].

Some differences were observed between the two models in treatment of sexual problems. The "problems affecting sexual function" and "sexual distress" scores were significantly lower in PLLISIT group than in the SHM group. It seems that some problems or distress were so specific and private that they may be addressed better in individual therapy than in group therapy. These findings show that although group therapy is an effective method, few individual sessions to address specific problems of each woman would lead to more positive outcomes. These results are in line with the general consensus that suggests that treatment should be individualized to a patient's problem [46].

Apart from the significant improvement in overall sexual function, it is noteworthy to highlight the lack of impact of our interventions on the "receptivity/initiation" domain. It is very interesting that the other two RCTs, which used BISF-W as an outcome assessment, found similar results. This domain had the minimum positive change after medical therapy with bupropion in women with hypoactive desire [47] and no significant change in response to testosterone therapy in women after oophorectomy [48]. This can be attributed to the tendency of women to love instead of participating in sexual activity. Similarly, Brotto et al. showed that experiencing emotional intimacy was the most important goal of women's sexual desire and what may be labeled as a "dysfunction" on a questionnaire—like lack of initiation—may not be a dysfunction in real life [49]. This result may also indicate that the women's sexual roles have been formed in an androcentric context [50].

A number of limitations are acknowledged in this study. First, in using the single-blinded design, the inherently different natures of the two treatment modalities made it impossible to blind the observer due to the treatment group allocation. Second, the sample size was small. However, there was sufficient power to identify a significant positive effect of PLISSIT and SHM on FSD. Assessing the efficacy of this intervention in larger samples is therefore warranted. In this study, selection bias was controlled by randomization with concealed treatment allocation, and observation bias was probably marginal because the results were analyzed in a single-blinded manner. The present results clearly need to be replicated and extended across multiple centers and investigators. Sexual health arises from an appropriate mutual relationship between women and men. The lack of attendance of men in our research is another limitation.

Conclusion

The findings of this study have important clinical implications in that they further reinforce that culturally appropriate and educational-based interventions have potential benefits in treatment of female sexual disorders. Our data have important clinical implications for communities; in that the treatment of sexual problems is in the beginning stages, people have not received any sexual education or knowledge during their lifetime and the deficiency of expert clinicians in the treatment of sexual issues is obvious. SHM is a cost-effective, flexible, and user-friendly model.

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