Original Article

The Effect of Sex Counseling Based on (Permission, Limited Information, Specific Suggestions, Intensive Therapy) Model on Sexual Satisfaction in Women with Cyclic Mastalgia: A Randomized Controlled Clinical Trial

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Abstract

Background: More than half of the population of women suffer from cyclic mastalgia which can interfere with women's sexual function and affect their sexual satisfaction. The current study was conducted to determine the effect of sexual counseling on sexual satisfaction in women with cyclic mastalgia. **Materials and Methods:** This randomized controlled trial study was performed on 81 women with cyclic mastalgia. The subjects were randomly divided into two groups of intervention (n = 40) and control (n = 41). Intervention was performed as Permission, Limited information, Specific suggestions, Intensive therapy (PLISSIT) sex counseling in four sessions for a maximum of 90 min in the intervention group. The demographic checklist and Index of Sexual Satisfaction (ISS) were used for data collection. Follow-up was performed 1 and 3 months after the intervention. The obtained data were analyzed using repeated-measures test. **Results:** The intervention and control groups were in good balance in terms of demographic characteristics and sexual satisfaction scores prior to the intervention and no statistically significant differences were observed. There was a statistically significant increase in the mean (SD) score of female sexual satisfaction in the intervention group: 93 (12.52), 101.15 (7.70),101.37 (5.31), ($F_{(1,39)}$ = 27.4, $p < 0.001$). We also observed a decrease in the mean (SD) score of sexual satisfaction in the control group: 93.39 (13.12), 90.68 (8.41), 90.85 (6.57), ($F_{(1,40)}$ = 11.9, $p < 0.001$) 1 and 3 months following the intervention. **Conclusions:** This study revealed that individual counseling by PLISSIT sex counseling could lead to improvement in sexual satisfaction index in women with cyclic breast pain.

Keywords: *Mastodynia, sex counseling, sexual health*

Introduction

Mastalgia could be classified into three major categories: cyclic, noncyclical, and extra-mammary. Cyclic mastalgia is thought to be related to hormonal changes. It constitutes two-thirds of female patients with breast pain, presenting most severely a week before the onset of their menstrual cycle. This corresponds with the luteal phase and often improves with the onset of menses. It is relieved during menstruation and occurs commonly during the third and fourth decades of life.[1-3] The symptoms include breast congestion, heaviness, and tenderness. Approximately 70% to 80% of women experience severe breast pain at some point in their lives and mastalgia accounts for 30%–47% of clinical breast evaluation cases.[4] In most studies, more than half of the female population has cyclic mastalgia.[4,5] The etiology of breast pain is still unknown. In many cases, the probable cause of breast pain is the changes in hormone levels or psychological stress (due to anxiety or fear of cancer).[6,7] Other causes include imbalance between hormones of estrogen, progesterone, elevation prolactin level, fat metabolism disorder, stress, anxiety, depression, breast size, weight gain, nutrition, lack of vitamins, and caffeine consumption.[8] Mastalgia could be severe enough to alter one's lifestyle.[9] Mastalgia may impair sexual activity (41%), physical activity (35%), and social activity (10%).[4]

One of the most prevalent problems of women with pain disorders is sexual dysfunction with sexual satisfaction.[10,11] Sexual satisfaction is believed to be the

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last stage of sexual function and is defined as a person's pleasant feeling of sexual intercourse free from any pain or discomfort.[12] Breast is the second sexual organ of a woman; therefore, its severe and cyclic pain can affect sexual function and consequently women's sexual satisfaction.[4,13] Any abnormalities in the sexual response process, which may impair sexual function, could potentially lead to sexual dissatisfaction.[14] Satisfying sexual needs and the accompanying satisfaction are of the most important factors of physical and mental health of individuals and increase the durability and strength of family foundations.[15] In most cases, education and counseling can solve a large percentage of couples' sexual problems and cyclic mastalgia.[2,9,16] Sex education or marital counseling plays a pivotal role in family health, enhancing positive attitudes to sexual intercourse, and thereby enhancing couples' sexual satisfaction.[17] One of the sexual health counseling models (Permission, limited Information, Specific Suggestions, Intensive Therapy) is the PLISSIT counseling model. PLISSIT model consists of four main steps, including permission to the patient, providing limited information, specific suggestion, and referrals for intensive therapy.[18] Various studies have investigated the effect of PLISSIT sex counseling model on sexual satisfaction.[19,20] In the recent studies, it has been shown that the PLISSIT model had positive effects on the individuals at different stages of life and in different circumstances.[21]

A few studies have been conducted on solving sexual problems of women with cyclic mastalgia. Accordingly, the research group decided to conduct a study aiming to investigate the effect of PLISSIT model-based sex counseling on sexual satisfaction in women with cyclic breast pain.

Materials and Methods

This study is a randomized controlled trial study registered in Iran Clinical Trial Center under the number IRCT 20180826040862. The statistical population consisted of all the women referring to four comprehensive health centers and two hospital clinics located in Qazvin city, among whom women that met the inclusion criteria were chosen. This study was conducted from September 2018 to August 2019. The inclusion criteria comprised women with mastalgia criterion equal or greater than four based on the pain scale, women whose pain lasts for more than 5 days per month based on Cardiff's breast pain score,[22] those aged from 20 years old to the menopause age, and those with regular menstruation periods. The exclusion criteria included pregnant women, lactating women, physical and mental illnesses (self-reported), history of breast hitting, history of breast surgery or sampling, history of nipple secretion, the patients with treated mastalgia during the last 3 months, and those who used hormone methods of contraception.

Considering the first type error ($\alpha = 0.5$) (Confidence level 95%) and the second type error ($\beta = 0.2$) (Test power 80%) as well as the minimum difference between the mean of case and control $d = \mu_2-\mu_1 = 95.8–88.8 = 6$, the sample size was 76 people, which was estimated 90 subjects considering a fall rate of 20%.[20]

Two-stage cluster random sampling was used to select the sampling centers in which different areas of the city were selected as the economic and social representatives of the area. This means the city was divided into five areas of northwest, northeast, southwest, southeast, and center and one comprehensive urban health center was selected from each area and in the central area, two public clinics covering all the segments of the society were selected. After referring to sampling centers, eligible individuals were selected from these centers using available sampling methods. After explaining the aims of the study to the participants, they filled out the demographic and fertility characteristics checklist. The Visual Analogue Scale (VAS) of pain and Cardiff's mastalgia table were then completed at home by the patients during 2 months. Among them, those with pain intensity equal to or more than four and pain duration more than 5 days per month were included in the research.

The study sample included 90 eligible women with cyclic mastalgia. They were then randomly selected from the health centers (15 individuals from each center). The simple random allocation method was also employed to assign women with cyclic mastalgia to either the intervention or control groups. In other words, in each health center, the two groups were previously called A and B. These letters were written on uniform and folded pieces of paper equal to the number of participants. The patients, who referred to each center, chose a letter through a lottery without paper replacement. Afterward, they were enrolled in either group A or B based on their own random selection. Therefore, the affected women were divided into an intervention group of 45 participants (those receiving the counseling) and a control group of 45 participants (those not receiving the counseling). Before the intervention, both control and intervention groups completed the Index of Sexual Satisfaction (ISS) questionnaire [Figure 1].

The data collection tools included the following cases:

1. VAS, which is applicable in physiotherapy. We used it to investigate the pain intensity. It is also like a ruler numerated from 0 to 10. Accordingly, scores of 1–3, 4–6, 7–9, and 10 represent mild, moderate, severe, and intolerable pain, respectively. The validity and reliability of this tool had been already investigated in a study.[23] In this study, the pain intensity scale of 4 and more (moderate and severe) were considered. Owing to the high validity and reliability of VAS and the need to use the instrument within a short time, it has been recommended to use it in chronic pains.[24]

2. Clinic Cardiff's mastalgia chart: it was developed by Clinic Cardiff to determine the duration of pain based on the definition of cyclic mastalgia.[22,25] It has 31 squares with scores from 1 to 31, each of which represent the same day of a month.
3. Personal-social information checklist: it includes questions about demographic characteristics, history of breastfeeding, history of breast hitting, history of breast surgery or sampling, and history of nipple secretion. They were given to five experts of the department of midwifery to determine and approve the face and content validity. Content validity was qualitative and was approved.
4. ISS was used to measure sexual satisfaction in this study. ISS was first developed by Hudson in 1981. Subsequently, it was compared by Larson and compared to other sexual satisfaction tools. Its validity and reliability have been proven in the Larson's study. Larson's sexual satisfaction questionnaire involves 25 items with answers in 5-point Likert scale (1 = not at all, 2 = seldom, 3 = sometimes, 4 = often, 5 = always). The total score of sexual satisfaction was between 25 and 125 with scores of <50 representing sexual dissatisfaction, 51–75 low satisfaction, 76–100 moderate satisfaction, and >101 high satisfactions. Moreover, its reliability was verified with $r = 0.82$.[26] The reliability of Larson's questionnaire was also determined by Bahrami *et al*.[12] with Cronbach $\alpha = 0.70$, which was reported as $r = 0.93$ using inner consistency. In addition, their reliability was verified with $r = 0.79$ in this study.

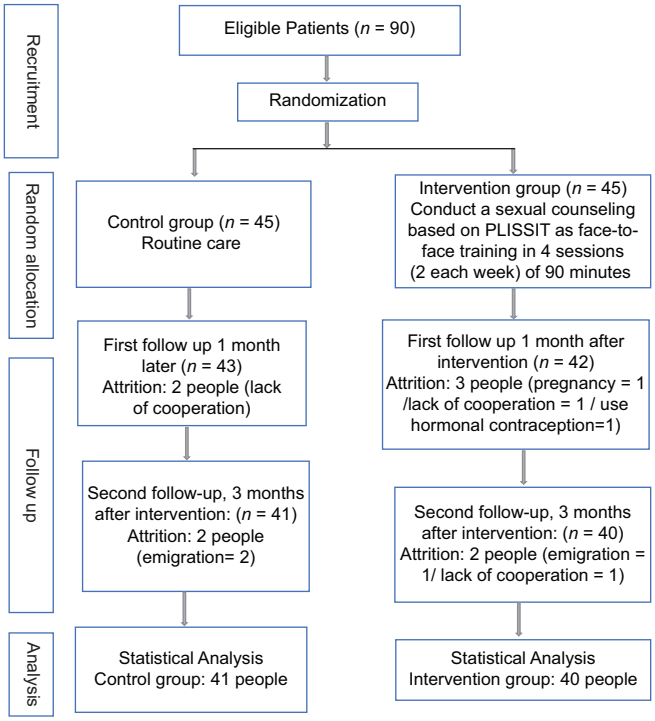

Figure 1: CONSORT flow chart of the process of study

The intervention in this study was individual counseling based on the PLISSIT model. Counseling sessions were designed and implemented in accordance with the four basic phases of the PLISSIT model (including permission, limited information, specific suggestion, and intensive therapy) at least in four sessions of 90 min each, every 2 weeks, for the intervention group [Table 1].[16] Finally, 1 and 3 months following the intervention, two groups completed again the questionnaires. The intervention was performed by a counseling student in midwifery under the supervision of a tutor. The subjects were followed up

Table 1: Model-based sex counseling program

Session	PLISSIT*	Duration (min**)	Content
1	Permission	90	Introduction and explanation on the study objectives
			Completing the checklist of personal-social and questionnaires
			Announce the schedule of counseling sessions
			Opportunity for the participants to talk about breast pain, beliefs, concerns and the assessment of the sexual problems.
			Expressing mutual goals and agreeing to achieve them
2	Limited Information	90	Review of goals
			Presenting Information on:
			Sexual problems related to breast pain and its treatment. Brief explanation of the anatomy and physiology of sexual organs
			Sexual response cycle (in desire, arousal, orgasm, natural lubrication, satisfaction and pain)
			Physiological changes and their impact on sexual satisfaction
3	Specific Suggestions	90	Education about lifestyle and how to change it to reduce pain.
			Anxiety reduction techniques, Kegel exercise, sensate focus technique, and marital skills
4	Iintensive Therapy	90	Solve problems possible, recommend specific treatments
			Completing the questionnaires

*Permission, Limited Information, Specific Suggestions, Intensive Therapy. **Minute

via phone. In order to observe ethical considerations, the control group received counseling after the intervention.

The Statistical Package for Social Sciences software (version 22.0, SPSS Inc., Chicago, IL, USA) program used for analyzing. Descriptive statistics methods were used for providing general information, independent *t test* was employed for comparison between the test and control groups before the intervention, analysis of variance with Repeated Measure test was used for the comparison between the intervention and control groups after the intervention, and Chi-square test was applied for comparing qualitative variables. The significance level was considered less than 0.05.

Ethical considerations

This study was performed after obtaining permission under the number IR.QUMS.REC.138,1397 from the Ethics Committee of Qazvin University of Medical Sciences and obtaining an introduction letter from the School of Nursing and Midwifery to participate in the research environment. The principles of ethical considerations, such as the signature of informed consent forms by the subjects, were respected.

Results

According to the CONSORT flow chart [Figure 1], in the follow-up stages, primarily five and then four out of 90 eligible people were excluded from this study due to unwillingness to continue cooperation, migration, pregnancy, and starting hormonal contraceptive methods. Ultimately, 41 cases in the control group and 40 cases in the intervention group were analyzed.

According to the results of the study, the mean (SD) age of the intervention group was 36.92 (7.83), whereas it was 37.73 (5.95) in the control group ($p = 0.60$). The mean (SD) menarche age of the intervention group was 12.77 (1.62) whereas it was 12.70 (2.05) for the control group ($p = 0.22$). The highest number of intercourses was two to three times per week for 36 (39.5%) of the subjects. There were no significant differences between the two groups in terms of demographic characteristics, age, menstrual age, duration of marriage, history of breastfeeding, education, and occupational status ($p > 0.05$). [Table 2] The normality of sexual satisfaction scores was initially evaluated with Kolmogorov-Smirnov and Shapiro test ($p < 0.05$). Prior to the intervention, the mean (SD) scores of sexual satisfaction in the intervention and control group were respectively 93 (12.52) and 96.39 (13.12). The independent *t* test showed no statistically significant differences between the two groups ($t_{79} = 1.8$, $p = 0.23$). Therefore, the change in the mean scores after the intervention in both groups was due to the intervention. One month after the intervention, the mean (SD) scores of sexual satisfaction of the intervention and control group were 101.15 (7.70) and 90.68 (8.41), respectively. The independent t-test showed statistically

Table 2: Comparison of demographic characteristics between intervention and control groups

Variable	Duration of marriage	Education level Number (%)				Job Number (%)			Pregnancy Number (%)		Lactation Number (%)	
Group	Mean (SD)	Elementary school degree	diploma	Bachelor	Higher education	Housewife	Governmental job	Self-employed	yes	no	yes	no
Intervention	12.67 (8.20)	7 (17.50)	16 (40)	17 (42.50)	0 (0)	26 (65)	11 (27.50)	3 (7.50)	32 (80)	8 (20)	31 (77.50)	9 (22.50)
Control	14.92 (8.28)	10 (24.30)	13 (31.70)	14 (34)	4 (10)	23 (56)	16 (39)	2 (5)	33 (80.40)	8 (19.60)	33 (80.5)	8 (19.50)
Statistical test	1.23		4.83			1.35			0.003		0.109	
df	79		3			df=2			df=1		1	
p	0.22***		0.10*			0.57*			0.99**		0.79**	

*Fisher's exact test, **Chi square test, ***Independent *t*-test

significant differences between the two groups (t_{79}= –5.83, p < 0.001). Three months after the intervention, the mean (SD) scores of sexual satisfaction of the intervention and control group were 101.37 (5.31) and 90.85 (6.57), respectively. The independent t-test showed statistically significant differences between the two groups (t_{79}= –7.9, p < 0.001). Sexual satisfaction score in the control group decreased over time.

Before the intervention and 1 month and 3 months following the intervention, analysis of variance with Repeated Measure test showed a statistically significant increase in the mean (SD) score of female sexual satisfaction in the intervention group: 93 (12.52), 101.15 (7.70),101.37 (5.31), ($F_{(1,39)}$ = 27.4, p < 0.001). Meanwhile, we observed a decrease in the mean (SD) score of sexual satisfaction in the control group: 93.39 (13.12), 90.68 (8.41), 90.85 (6.57), ($F_{(1,40)}$ = 11.9, p < 0.001) [Table 3 and Figure 2].

Discussion

In this study, individual PLISSIT counseling significantly increased the overall sexual satisfaction score in the intervention group compared to the control group. This study showed that the use of this model had an effect on the participants' sexual satisfaction. Certain studies have suggested that the PLISSIT model is effective on sexual problems.[16,27] Farnam *et al*. (2014),[28] after comparing PLISSIT to group counseling based on Sexual Health Models (SHM), stated that 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, particularly if the sexual problems are in the early stages and the clients have not received any sex education during their lifetime. Basically, the more complex is the problem, the more effective the use of the PLISSIT model would be.

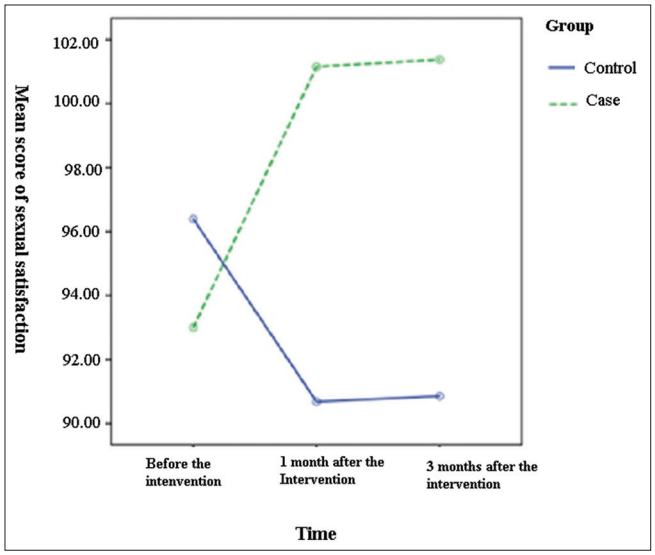

Figure 2: Trend of changes in mean sexual satisfaction scores of women in intervention and control groups before, 1 month and 3 months after intervention

The PLISSIT model was designed by Anon in 1974, who believed 70% of sexual problems in the first level of intervention (permission) and 89% to 90% of them in the first three levels of intervention (permission, limited information, and specific suggestion) can be solved.[18] Numerous sexual abnormalities are due to lack of knowledge of couples.[17] Iran is in the early stages of treating sexual problems, whereas there is a large population of couples with no knowledge of sexual health; they often have a sexual disorder.[28] The results of other studies also indicated that insufficient sexual information affects occurring sexual anomalies.[29]

In a clinical trial, which examined the effect of PLISSIT sex counseling model on the sexual performance and satisfaction of patients with type 2 diabetes, it was found that the PLISSIT sex counseling model had a significant effect on increasing female sexual satisfaction[30] In addition, a study investigated the effect of PLISSIT sex counseling model on sexual performance of women. It was concluded that applying PLISSIT sex counseling model is effective on sexual function of married women.[15] However, in this study, the dependent variable was sexual function, yet many studies have shown that there is a relationship between sexual function and sexual satisfaction.[31]

The mentioned studies are different from our study in terms of statistical population and outcome. However, in these studies, the type of study was empirical and the type of sexual counseling intervention was PLISSIT; their results were in line with the findings of our study. There are also models used for a specific statistical community, such as: The Women's Postpartum Sexual Health Program (WPSHP).[26] This program is designed with a multidisciplinary approach to women's sexual counselling in the postpartum period. Thus, it could not be applied for every statistical population.

Table 3: Comparison of sexual satisfaction score between intervention and control groups over time

Group	Before the Intervention Mean (SD)	1 month after the intervention Mean (SD)	3 months after the intervention Mean (SD)	Statistical test and p value
Intervention	93 (12.52)	101.15 (7.70)	101.37 (5.31)	$F_{1,39}$=27.4, p<0.001**
Control	96.39 (13.12)	90.68 (8.41)	90.85 (6.57)	$F_{1,40}$=11.9, p<0.001**
Statistical test and p value	t_{79}=1.8, p=0.23	t_{79}=-5.83, p<0.001*	t_{79}=-7.9, p<0.001*	

p*=Independent-t test, p**=Repeatead Measure Anova

People need to learn the skills needed to have a satisfying sex and this can be achieved through the necessary training.[32] Counseling programs used to promote sexual satisfaction increase sexual satisfaction.[26] One of the common causes of many sexual disorders and cyclic breast pains is the imbalance in an appropriate lifestyle; therefore, the inclusion of education-based counseling along with modification in lifestyle, such as nutrition, activity, and weight control can affect pain quality.[2] Moreover, providing emotional and psychological support to reduce anxiety and build self-esteem could increase pain tolerance threshold[33] and indirectly affect sexual satisfaction of women with issues in this regard.[34]

Sexual satisfaction score in the control group decreased over time. This may be due to the change in sensitivity of the control group to their sexual satisfaction after completing the questionnaire. Abedini *et al*.[35] reported this reducing effect on the sexual satisfaction score of the control group. The strength of this study lies in its longitudinal design. In this study, we were able to identify the continuing beneficial effects of our intervention on the participants. One of the limitations of the study was the lack of access to the spouses of the women participating in the study.

Conclusion

Considering the increase in the referrals of people with cyclic breast pain to comprehensive health centers, this model of sex counseling could be used as a harmless and available counseling method to promote sexual satisfaction in women with mild to moderate pain of cyclic mastalgia. Further studies could be recommended on the effect of PLISSIT model based counseling on sexual satisfaction of spouses of affected women.

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Conflicts of interest

Nothing to declare.

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