



The effects of psychosexual counseling on sexual quality of life and function in Iranian breast cancer survivors: a randomized controlled trial

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Abstract

Background Considering different dimensions of life, special sex life for survivors of breast cancer (BC) is important because their life expectancy has increased.

Objective We designed this study to improve the sexual function, satisfaction and quality of sexual life.

Methods In a randomized controlled clinical trial study, from a total 286 breast cancer survivors (BCS), 118 women enrolled to the study. After providing informed consent, the participants were randomly assigned either to the intervention group or to the waitlist control group. The intervention consisted of six weekly psychosexual counseling sessions that lasted from 90 to 120 min. Data were collected by the demographic and clinical forms, Beck Depression Inventory, Female Sexual Function Index (FSFI), Larson Sexual Satisfaction Questionnaire and sexual quality of life-female (SQOL-F) questionnaire.

Results Mean age of patients in control and intervention groups were 43.8 ± 6.6 and 44.84 ± 6.7 , respectively. More than 65% of the patients in the both groups were either normal or showed a low level of depression. Sexual function (FSFI) scores and sexual quality of life (SQOL-F), showed a significant statistic differences after intervention ($P < 0.001$ in both tools). Sexual satisfaction (Larson) has showed improvement in some subclasses, however, change in total score was not statistically significant ($P = 0.073$).

Conclusions The psychosexual intervention program was effective in improving sexual function and quality of sexual life among BCS. This intervention has clinical significance as it provided an opportunity for the women to discuss their sexual issues.

Keywords Breast cancer · Sexual quality of life · Psychosexual counseling · Iran

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Introduction

Cancer is considered an issue related to health all around the world [1]. Breast cancer (BC) is the most common cancer in women all over the world [2, 3]; this disease kills 411,000 people around the world every year [4]. Its global incidence is 38 in 100,000 and it is 20 in 100,000 in Iran [5]. In 2006, 6466 Iranian women were involved with this disease [5] and it is the most common cancer in women in Mazandaran province with the expression age of 24.9 years [6].

Despite improvement in management of patients with BC, quality of life and sexual quality of life have been negatively affected in breast cancer survivors (BCS) [4, 7–11].

The most commonly used method for BC is mastectomy [12]. This treatment, by disturbing the body image, inducing a sense of weakness and reducing attractiveness, can lead

to multiple sexual dysfunctions in women's BCS. Previous studies have shown that sexual dysfunction is present in a wide range of BCS [13].

Treatment such as chemotherapy is relevant to dyspareunia (the most common sexual disorder) and orgasm disorder [14]. Dyspareunia, which causes a decrease in vaginal lubricating, can lead to decrease in sexual desire [10], however, sexual desire, sexual arousal and sexual satisfaction also were reported to reduce in other studies [8, 15].

The World Health Organization has defined quality of life as each individual's perception of life, values, purposes, standards and interests [16]. On the other hand, sexual desires such as emotions in relationship are related to body image, femininity mode, fertility competence and sexual performance [17]; therefore, any undesirable and harmful changes in sexual performance might reflect problems in all fields related to life quality and psychosocial aspects, which can cause physical symptoms, emotionality and sensitivity, self-confidence, self-perception, feeling healthy, life satisfaction and social communication [18, 19], which all affect people's life quality.

In a study, 26% if the sexual performance disorders were reported to be related to surgeries which bring disorders in slippery vagina, sexual desire, orgasm and arousal [12].

Therefore, the medical association advises all survivors of cancer receive a regular care program so these cares provide practical information about after-treatment consequences and care activities related to cancer and psychosocial compatibility for the survivors [20]. Therefore, interventions such as psycho-educational and psychosocial interventions are used. From these interventions, the psychosexual one is a special treatment technique which is performed by

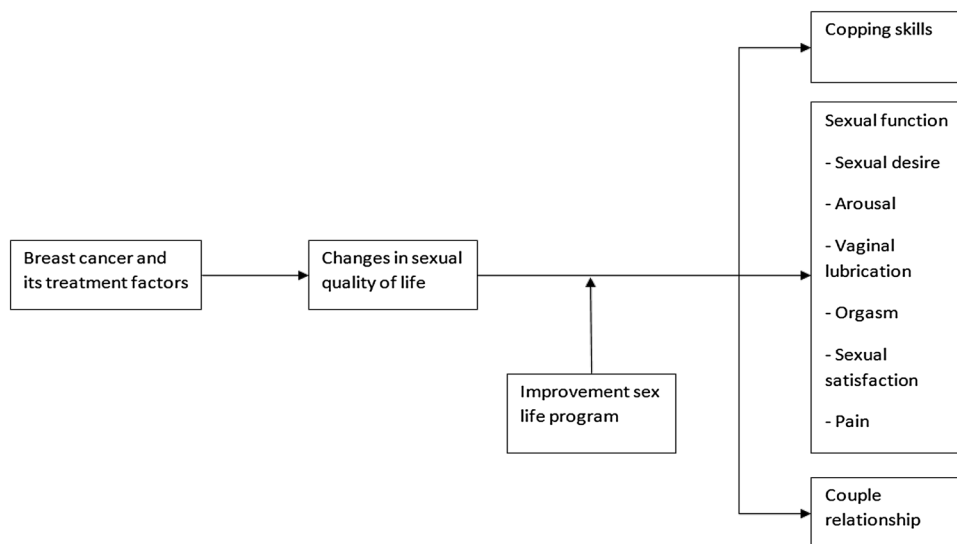
consultants or specialists. These interventions help patients with psychological, sexual and other types of problems or a combination of them [21] For example, a study in 2013 about the sexual function of a young women under the treatment of BC in Poland showed that awareness of the diagnostic effects of BC and its treatment on the sexual performance of young women and their spouses during the course of treatment and recovery was necessary [22].

Another study showed that 42% of patients consider it important to talk with their nurses about sexual desires. Moreover, findings state that acquiring information about the consequences of the disease and its treatment decreases the danger of negative effects on the couple's relationship [21]. Considering that studies conducted about the effects of counseling are limited to the method of psychosexual field on the sexual life quality of women under BC treatment, researchers decided to investigate the effects of intervention through psychosexual counseling on the sexual life quality of women with BC.

Conceptual framework

This study was mainly based on Ganz and colleagues' [23] conceptual framework. The conceptual framework proposes that BC and its treatments including mastectomy, chemotherapy, radiotherapy, and anti-hormone therapy influence on sexual quality of life in BCS. In this study, a sexual quality of life improvement intervention was proposed to maintain couple relationship, coping skills and improve sexual function which may ultimately lead to a change in sexual quality of life in BCS (Fig. 1).

Fig. 1 Conceptual framework of study



Materials and methods

Design

This is a randomized controlled clinical trial study, conducted in October 2015 on 118 women with BC referring to the cancer center located in Imam Khomeini hospital in Sari city, North of IRAN.

Ethics

This project was fully approved by ethics committee of the Shahroud University of Medical Sciences and received an ethics code (IR.SHMU.REC.1394.115), and granted approval by Mazandaran University of Medical Sciences. All participants were requested to complete the informed consent. The study was registered in the Iranian Center for Registration of Clinical Trials (IRCT 2016060528278N1) and study protocol is available in <http://en.search.irct.ir/view/30649>.

Sample and setting

To determine the sample size, a pilot study was conducted and according to the results, the sample size using G-POWER software program was calculated to be 100 people and by applying 20% attrition, the sample size was obtained for about 120 people. Participants in the study were BC patients from Imam Khomeini hospital in Sari, north of Iran. All the files of BCS were investigated, then 286 women, who were potentially eligible for the study (Fig. 2), were contacted by a counselor to assure candidates met the study criteria. Finally 118 samples were entered to the study according to the inclusion and exclusion criteria. The inclusion criteria were: married women living with their husband having a history of BC, mastectomy experienced and no hormone therapy experience, age up to 60 years, are still not candidates for breast reconstruction surgery, patients' being sexually active before BC, lack of addiction to psychotropic drugs or narcotics in the couple. The exclusion criteria were: cancer stage IV, having cardiovascular diseases, diabetes, asthma and other chronic diseases affecting sexual activity, taking drugs that affect sexual function, having a history of other malignancies, participating in educational and counseling sessions of sexual disorder and having diagnosed psychological disorders such as depression. Participants were allocated randomly into the intervention and control groups via permuted block randomization. Out of 118 patients enrolled to the study, 59 of them were placed in the intervention group and the rest in the control group. Eligible patients were invited to attend a meeting in

Educational-Medical Center of Imam Khomeini Hospital in Sari city to become familiar with the type and purposes of the study. Patients filled in informed consent forms at the first. Then, the researcher evaluated the patients to examine the past and present of the participants qualitatively about sexuality by Schover's Score, which is based on a multi-dimensional model of sexuality assessment, including having sexual activity and role and relationships between partners [24].

Intervention

After providing informed consent, the participants were randomly assigned either to the immediate intervention group or to the waitlist control group. The intervention consisted of 6 weekly counseling sessions that lasted from 90 to 120 min. The participants in the intervention group were informed of the time and number of sessions of the support program.

The structures of the counseling sessions are presented in Table 1. The content of the psychosexual counseling for patients with BC was developed on the basis of the Schover's sexual assessment method. The general content of the sessions consisted the initial meeting and familiarity, describing the anatomy of sexual organs and sexual cycles in both genders, the consequences of BC and its treatment effects on sexual relationships and the relationship with the spouse and the effects on sexual relationship, and providing solutions based on Master and Johnson's sex therapy principles to deal with sexual problems [25].

Measures

All participants completed self-administered questionnaires at the beginning of the study, after the final session of the intervention, and at 3 months following the intervention.

Data collecting tools

1. The demographic and clinical data which includes: patient's and spouse's age, patient's and spouse's education, length of marriage, method of contraception, number of pregnancies and deliveries, type of delivery, engaged breast, number of chemotherapy sessions, the last period of chemotherapy, old treatment regimen or type of treatment at the present time.
2. Beck Depression Inventory that was previously normalized regarding its validity and reliability. The inventory has 21 items on a 4-point Likert scale which ranges from 0 to 3. Each item consists of four statements. The scores of 1–10 mean natural, 11–16 mean a little depressed, 17–20 mean requiring counseling, 21–30 mean relatively depressed, 31–40 mean severe depression and more than 40 mean too depressed [26, 27].According

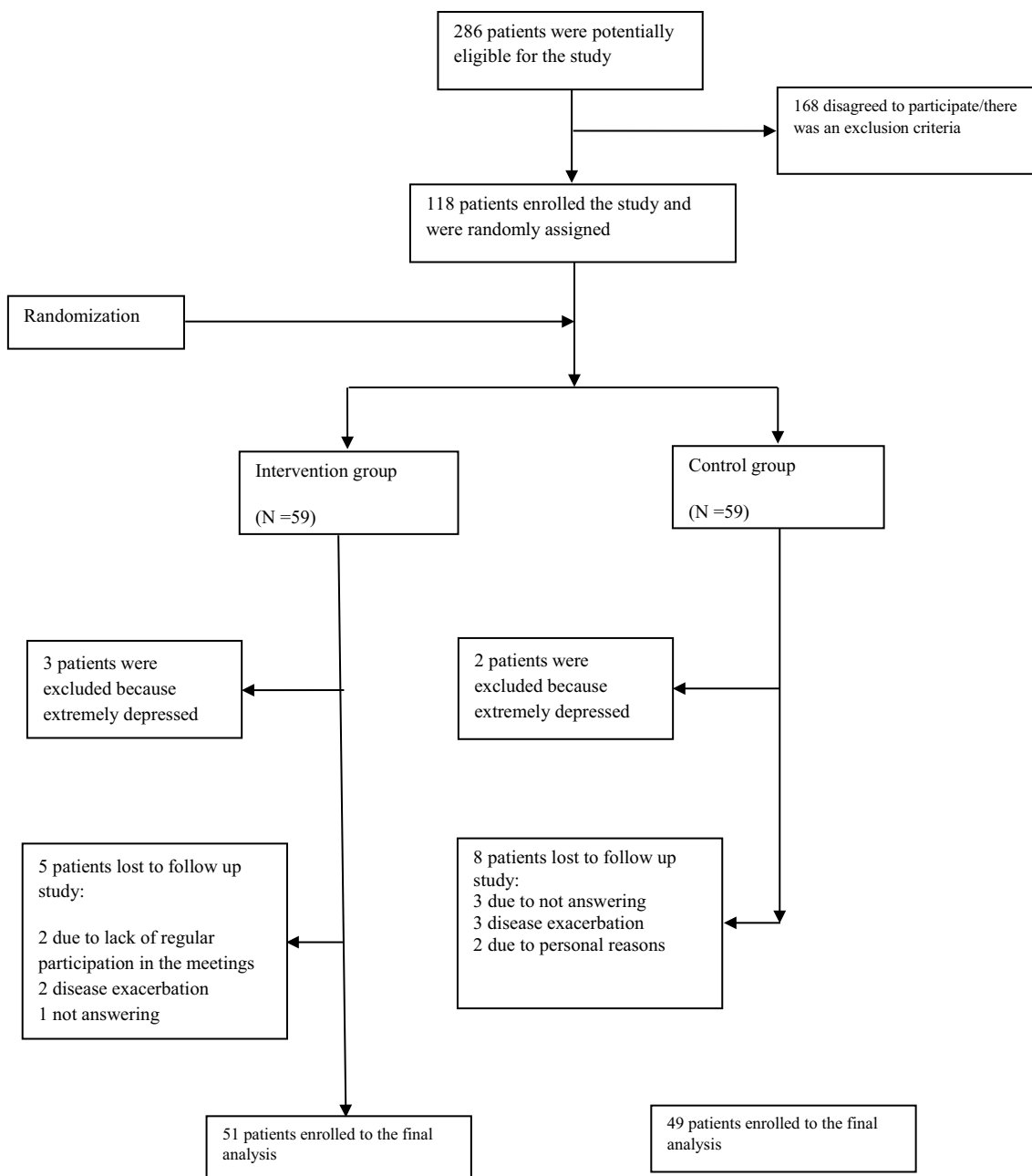


Fig. 2 Trial profile

to the results, patients with intense depression were excluded from the study and referred to healthcare centers.

3. The Female Sexual Function Index (FSFI) is a six-dimensional questionnaire that contains 19 items in which that validated in Farsi version in 2008 and 2013 with Cronbach's alpha about 0.7 [28]. Baser, Li, and Carter [29] validated the use of the Female Sexual Functioning Index (FSFI) in a cancer survivor population. The score considered for each question are sex appeal

(1–5 points) and for the dimensions of sexual stimulation, vaginal moisture, orgasm, sexual satisfaction and pain (0–5 points). The range of sexual scores is $\frac{1}{2}$ to 6 points and other dimensions are 0 to 6 points. The overall range of sexual dysfunction score is between $\frac{1}{2}$ to 36 points. Higher scores in this tool indicate better sexual function, and an overall score of ≤ 26.55 denotes sexual dysfunction [30].

4. The questionnaire of sexual quality of life-female (SQOL-F): SQOL-F was first presented in 1998 and was

Table 1 Content overview of intervention counseling sessions

Session	General goals	Topics covered
1	Sexual activities and function	Sexual anatomy and physiology
2	Identification of sexual goals, desires and knowledge	Engaging in the sexual activities Any sexual practices that they would like to know
3	Impact of cancer and its treatment factors on sexual activities and function, body and physical structure	Cancer and sexual activities and function Cancer treatment and sexual activities and function Developing a positive body image
4	Coping skills	Adjustment to the effects of treatment Finding ways to overcome this problem
5	Sexual relationships	Communicating sexual values and needs Sexual communication and assertiveness
6	Cancer and relationships	Disclosing the cancer experience to others Cancer affecting on sex life

revised and validated by Simonds et al. in 2005 [31]. The SQOL-F questionnaire consists of 18 questions with a 6 points Likert response spectrum. The minimum score of this tool is 18 and up to 108. A higher score indicates a more favorable level of sexual quality of life. According to the response spectrum, up to 36, as poor grade, score 37–72 was classified as a middle class and the score of 73–108 was classified as a good class. The Farsi version of this tool was translated and validated by Masumi et al. in 2013 ($\alpha=0.73$) [32].

- To determine sexual satisfaction, Larson Inventory of Sexual Satisfaction (ISS) was used. The standard questionnaire has 32 items with 16 negative and 16 positive items. Iranian version of ISS with good validity and reliability consists of 25 items and includes a 5-option Likert scale as follows: never, rarely, sometimes, often, and always (in a 0–4 score range). Based on the scores obtained, each group was placed into four sub-groups: completely satisfied (101–128), relatively satisfied (76–100), slightly satisfied (50–75), and dissatisfied (<50) [33].

Data analyses

Frequency, percentage and Mean \pm SD were used as descriptive statistics. Independent T and Chi square tests were also carried out for variable analyses. All the analyses were conducted in SPSS version 18, and 0.05 was considered to correspond with significance.

Findings

One hundred and eighteen patients entered the study and 100 included in analyses. By 3-month follow-up, 18 women dropped out of the initial counseling with a loss to follow-up rate about 15.25%. The investigated demographic and

medical profile is presented in Table 2 for each of the intervention and control groups. In the baseline characteristics of the women including patient and spouse's age, patient and spouse's education, length of marriage, method of contraception, number of pregnancies and deliveries, type of delivery, engaged breast, treatment regimen or type of treatment at the present time, there is no statistically significant difference.

Mean age of patients in control and intervention groups were 43.86 ± 6.6 and 44.84 ± 6.7 (mean \pm standard deviation) without a significant statistical differences ($P=0.461$), respectively, and also, the ages of the patients' spouses were 46.93 ± 7.2 and 47.82 ± 7.8 in the control and intervention groups which did not show a significant statistical differences ($P=0.557$).

The time elapsed since the last chemotherapy (in month) with 10.40 ± 3.7 and 11.14 ± 5.3 in control and intervention groups, respectively and, the number of implemented chemotherapy sessions with 7.88 ± 1.5 and 7.43 ± 2.2 in control group and intervention groups, respectively, did not have a significant statistical difference ($P=0.234$, 0.232 , respectively).

The Beck test scores in BCS in the two groups of intervention and control were presented in Table 3. The results did not show a significant difference between the two groups ($P=0.736$). Furthermore, more than 65% of the patients in the both groups were either normal or showed a low level of depression.

The measurement results of the tools were used in the study including FSFI, Larson and those dimensions and SQOL-F questionnaires in patients with BC have been presented in Table 4 according to the time of the measurements (baseline and after 3-month follow-up) in intervention and control groups. There were no significant statistical differences at the baseline of all variables in this study (Sexual function "FSFI", $P=0.198$, Level of sexual satisfaction "Larson", $P=0.073$, Sexual quality

Table 2 Demographic and clinical characteristics by group assignment ($N=100$)

Demographic/clinical profile	Control group ($n=49$) Number (%)	Intervention group ($n=51$) Number (%)	<i>P</i> value
Patient's education			
Under diploma	26 (53.1)	26 (51)	0.461
Diploma	15 (30.6)	18 (35.3)	
University	8 (16.3)	7 (13.7)	
Spouse's education			
Under diploma	23 (46.9)	19 (37.2)	0.587
Diploma	16 (32.7)	21 (41.2)	
University	10 (20.4)	11 (21.6)	
Duration of marriage			
1–5 years	1 (2.1)	1 (2.0)	0.067
6–10 years	3 (6.1)	5 (9.8)	
11–15 years	8 (16.3)	5 (9.8)	
16–20 years	16 (32.7)	6 (11.8)	
20<years	21 (42.9)	34 (66.6)	
Number of pregnancies			
Without pregnancy	2 (4.1)	4 (7.8)	0.574
1–3	40 (81.6)	37 (72.6)	
4–6	7 (14.3)	9 (17.6)	
6<	0	1 (2.0)	
Type of delivery			
Without delivery	2 (4.1)	4 (7.8)	0.387
NVD*	26 (53.1)	33 (64.7)	
CS**	12 (24.5)	9 (17.7)	
CS/NVD	9 (18.3)	5 (9.8)	
History of contraception method			
Withdraw method	20 (40.8)	19 (37.2)	0.797
OCP	22 (44.9)	26 (51)	
IUD	2 (4.1)	3 (5.9)	
Condom	5 (10.2)	3 (5.9)	
Drug treatment regimen			
Hormone therapy	37 (75.5)	40 (78.4)	0.513
Herceptin	3 (6.1)	1 (2.0)	
Herceptin plus hormone therapy	8 (16.3)	10 (19.6)	
Without medicine	1 (2.1)	0	
Side of the engaged breast			
Right	28 (57.1)	26 (51)	0.259
Left	20 (40.8)	20 (39.2)	
Both	1 (2.1)	5 (9.8)	

*Normal vaginal delivery

**Cesarean section

of life “SQOL-F”, $P=0.414$). In both intervention and control groups, sexual function resulted from FSFI is low compared with the cut point of the tool and also, over 75%

of patients in both groups for sexual satisfaction either is dissatisfied or slightly satisfied.

Sexual function (FSFI) scores and sexual quality of life (SQOL-F), showed a significant statistic differences after intervention. Sexual satisfaction (Larson) has showed improvement in some subclasses, however, change in total score was not statistically significant.

Discussion

After 12 weeks, we have demonstrated the efficacy of psychosexual counseling, to improve sexual quality of life and sexual function, among BCS, although sexual satisfaction did not show improvement.

Considering the sexual health is one of the most important aspects of personal and social life, multiple studies have designed to improve the sexual function in BCS. Consistent with existing findings in the literature we have showed, the most observed sexual dysfunction in BCS is in the field of sexual desire. Applying psychosexual counseling intervention in the present study was based on that, woman's emotions and stress could effect on sexual desire and arousal [34] and mastectomy, in particular, result in the woman's negative image of body [35] and cause a sense of loss of femininity and sexual interest [36, 37]. Our research based on psychosexual counseling, which provide proper information and support in mental and sexual fields [38] showed that it could be effective in improving the sexual quality of life in BCS.

For sexual function, the scores in all of the sub-domains of FSFI at baseline in both groups were similar. Similar to the results of the present study, several studies have shown that the prevalence of sexual dysfunction in BCS is high. Findings indicate that sexual dysfunction may occur as a common concern for BCS [39].

The sexual dimensions that showed the most problems were desire, satisfaction, and pain. This findings are similar to Boquiren et al.'s study [39].

After psychosexual counseling, our findings show an improvement in all areas of sexual function, so that the total score of the FSFI measure increased by about 150% in the intervention group. The results of our study are similar to Young Jun et al.'s study [40], although they used the sexual dysfunction subscale of CARES, instead of FSFI. Also similarly, the scores of sexual function in a study by Faghani's et al. showed increasing in all dimensions of FSFI after the intervention [38].

In terms of sexual quality of life, the scores of SQOL-F at baseline in both groups were similar. In accordance with the findings of other studies, we observed improvement in sexual quality of life following psychosexual counseling intervention such that the SQOL-F score increased by 300% approximately, although, in the study of Faghani's et al.

Table 3 Measures participants' mood status by group assignment at the beginning of the study

Clinical profile depression index	Control group	Intervention group	<i>P</i> value
	(<i>n</i> = 49)	(<i>n</i> = 51)	
	Number (%)		
Not depressed	22 (44.9)	24 (47)	0.736
A little depressed	11 (22.4)	14 (27.4)	
Need for consultation with a counselor	9 (18.4)	8 (15.7)	
Somewhat depressed	7 (14.3)	5 (9.8)	
Extremely depressed	0	0	

Table 4 Measures participants' sexual function status by group assignment at the beginning of the study

Clinical profile	Baseline		<i>P</i> value	3-month follow-up		<i>P</i> value	Cut point of test
	Control group (<i>n</i> = 49)	Intervention group (<i>n</i> = 51)		Control group (<i>n</i> = 49)	Intervention group (<i>n</i> = 51)		
	Mean (SD)		Mean (SD)				
Sexual function (FSFI)							
Sexual desire	2.17 (1.1)	1.94 (1.1)	0.211	2.13 (1.0)	4.14 (1.0)	<0.001	3.3
Arousal	2.33 (1.7)	2.41 (1.5)	0.239	2.27 (1.6)	4.24 (1.3)	<0.001	3.4
Vaginal lubrication	2.23 (1.6)	2.79 (1.4)	0.128	2.20 (1.6)	3.10 (1.0)	0.014	3.4
Orgasm	2.59 (2.0)	2.42 (1.9)	0.398	2.23 (1.7)	3.14 (1.1)	0.011	3.4
Sexual satisfaction	2.86 (1.7)	2.34 (1.6)	0.153	2.90 (1.5)	3.12 (1.5)	0.010	3.8
Pain*	2.32 (1.9)	2.26 (1.6)	0.359	2.26 (1.3)	3.20 (1.4)	0.017	3.8
Total score	14.52 (9.2)	14.81 (8.1)	0.198	14.10 (8.1)	21.49 (6.7)	<0.001	28
Level of sexual satisfaction (Larson)							
Completely satisfied	0	0	–	0	0	–	–
Relatively satisfied	0	0	–	0	1 (1.9)	<0.001	–
Slightly satisfied	9 (18.4)	12 (23.5)	0.317	11 (22.4)	26 (51.0)	0.044	–
Dissatisfied	40 (81.6)	39 (76.5)	0.390	38 (77.6)	24 (47.1)	0.020	–
Total score	43.86 ± 6.9	44.11 ± 10.5	0.893	46.20 ± 4.0	44.89 ± 6.20	0.073	–
Sexual quality of life (SQOL-F)							
	41.35 ± 8.2	42.57 ± 6.6	0.414	38.23 ± 10.6	91.01 ± 17.9	<0.001	–

*Getting higher scores in this area is equivalent to less pain

intervention was carried out based on the PLISSIT model, and Julia et al. used psycho-educational group intervention [38, 41]. Similarly, another study was focused on the effects of group counseling on the sexual function and quality of life in patients with BC showed that the counseling method is effective in improving the patients' health and quality of life because the presence of a counselor and provision of information and support, can improve sexual function indexes, body image and sexual satisfaction [42]. Leo'n-Pizarro C. et al. in their study, investigated the effects of psychosocial interventions on patient's quality of life with cancer [43]. They reported, counseling has been a useful strategy to reduce patient concerns, and it was claimed that intervention, considering the focus on sexual function, is useful in people's attitude toward improving health and quality of life.

In the present study, sexual satisfaction did not show significant changes in participants after psychosexual

intervention. However, 6 weeks of psycho-educational group intervention in the Rowland et al. study has led to an increase in relationship adjustment and communication and increase in satisfaction with sex [41]. Although in the recent study, samples who had the least sexual satisfaction before study, reported most improvement in sexual satisfaction, we could not show such a feature as well. It seems, the sexual satisfaction, which is a subjective concept, may be more affected by the increase in partner intimacy relationships. As a difference, we did not apply any specific interventions to improve couples' intimacy relationships. Another study, conducted by Young et al. in BCS, showed improvement in sexual satisfaction after 6 weeks of intervention [40]. Although two studies by Chang and colleagues and Moon were shown improvement in sexual satisfaction following intervention, their samples were healthy married women [44, 45].

Limitations of study

The lack of participation of patient's husbands in the study has limited the strong effectiveness of intervention, especially on marital intimacy. Due to the limited duration of patient's follow-up period, to 3 months, commenting on the long-term effects of psychosexual intervention cannot be made easily.

Conclusions

The psychosexual intervention program was effective in improving sexual function and quality of sexual life among BCS. Although some findings were not statistically significant, this intervention has clinical significance as it provided an opportunity for the women to discuss their sexual issues.

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Compliance with ethical standards

Conflict of interest No authors on this manuscript declare a conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. This study approved by ethics committee of the Shahrood University of Medical Sciences and received an ethics code (IR.SHMU.REC.1394.115).

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