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ORIGINAL ARTICLE

Randomized Controlled Trial Protocol for Evaluating the Effect of Group Education on Postmenopausal Sexual Dysfunction

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Objectives: This study primarily aimed to determine the effect of group education on sexual dysfunction in postmenopausal women referred to health centers in Hamadan, Iran.

Methods: This randomized controlled clinical trial conducted on 90 postmenopausal women from October 2018 to March 2019. Postmenopausal women who met the inclusion criteria and received approval of a psychiatrist were randomly divided into intervention and control groups (n = 45 in each group). They completed the demographic questionnaire and the Female Sexual Function Index questionnaire. Thereafter, four sessions of group training were conducted for women in the intervention group; these women were followed up for 1 month after the last training session. Data were analyzed using the SPSS ver. 16 software, and descriptive statistics and ANCOVA/ANOVA test were used for data analysis.

Results: We found that the two groups were homogenous in most of the demographic variables and the data were normal. The total mean score of sexual function and standard deviation after the intervention was 23.70 ± 3.67 in the intervention group and 19.94 ± 3.64 in the control group, indicating that these scores were significantly higher in the intervention group than in the control group ($P < 0.001$).

Conclusions: Based on the results, group training is recommended to reduce sexual dysfunction in postmenopausal women at health centers.

Key Words: Group education, Menopause, Sexual dysfunction

INTRODUCTION

Menstrual onset and menopause are two important transition points in every woman's life [1]. Menopause dates back to human life and is an inevitable phenomenon [2] encountered by all women. This event has a very broad concept due to the coincidence with symptoms of aging [3].

In general, the world's population is rapidly aging and a large proportion of the change is in developing countries [4]. The transition from fertility to non-fertility is associated with some physical and psychological symptoms [5]. Some menopause complications include menopausal flushing, insomnia, changes in sexual function, mood disorders, late cardiovascular complications, and osteoporosis [6]. Sexual dysfunction is also a common complaint in menopause [7]. Sexual function means engaging in sexual intercourse as she wishes, including desire (libido), arousal (excitement), orgasm and resolution with consent and without pain. Sexual function is a part of human life and behavior and is close intertwined with one's personality; therefore, it is impossible to consider it as an independent phenomenon [8].

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According to the World Health Organization's definition of health and based on its broad dimensions as complete physical, mental, and social well-being, and not just the absence of disease, it is necessary to assess health status and evaluate health interventions by paying attention to the disease frequency and severity indices in addition to other human values of life [9]. It should be noted that sexual function is also an important part of women's health and should be considered to achieve health [10]. In a meta-analysis in Iran in 2015, the sexual dysfunction was reported as 43.9% in Iranian women [11]. According to society-based studies in different countries, the prevalence of women's sexual dysfunction is estimated to be 25% to 63%, being higher in postmenopausal women and ranges from 68% to 86.5% [12]. In many cases, sexual dysfunction can cause severe discomfort and interpersonal communication problems [13]. Studies indicate that women, who do not have good relationships with their husbands and are unable to express their sexual needs, are more likely to have sexual dysfunction [14]. If the relationship between couples is not convincing, it can lead to a sense of failure and decline in mental health [15,16]. Studies and efforts have aimed to improve the sexual function of women all over the world, and they have used various pharmacological and non-pharmacological approaches [17-19]. Results of numerous studies in different countries demonstrate the positive effect of training based on different methods on women's sexual function [20-23]. Sexual training is related to cognitive domain (information and knowledge) and emotional domain (feelings, values and attitudes) as well as behavior (communication and decision-making skills) [24]. Women's knowledge and awareness of menopause and sexual function can vary from one society to another due to age, number of births, hormonal status, socioeconomic status, culture and education [25,26].

Individual and group training has been among the common methods of training throughout history and are still the most common methods [27]. Compared to individual training, group training is economical, enables active learning, and provides an opportunity to share ideas and receive group support [28,29]. Group sessions enhance the sense of responsibility and desire to succeed by creating a welcoming environment. This reduces stress and anxiety and improves function in individuals [30]. For postmenopausal women, being in a peer group with a common problem also causes them to feel more secure and enables them to use each other's experience of sexual function and support each other [27,31]. Accurate health planning and proper education about sexual function of menopausal women can be a golden goal for all health systems [32]. Given the high prevalence of sexual dysfunction in menopause, the increase in elderly population as well as the importance of effects of this disorder on family and social health, the present study aimed to investigate the effect of group training on sexual function in postmenopausal women.

Objectives

The main aim of study was to determine the effect of group education on sexual dysfunction in postmenopausal women referred to the health centers of Hamadan, Iran.

MATERIALS AND METHODS

Study design, setting

The present study was a randomized clinical trial with a control group conducted from October 2018 to March 2019. This research was conducted in the comprehensive health centers of Hamadan, Iran.

Ethical considerations

The methodology of the study was approved by the Ethics Committee of Hamadan University of Medical Sciences (IR.UMSHA.REC.1397.399) (Grant No. 9708224837), and it was registered in the Iranian Registry of Clinical Trials (IRCT20120215009014N236). The authors would like to acknowledge the funding support of Hamadan University of Medical Sciences and the collaboration of health centers as well as postmenopausal women participating in the research.

Participants

The research participants were postmenopausal women referred to the comprehensive health centers of Hamadan city, who had inclusion criteria and were willing to participate in the study.

Inclusion criteria

Married and living with a stable spouse; age of 40 to 65 years; natural menopause; no menstruation for at least 2 and up to 3 years; no history of infertility; at least the elementary school education; no history of attendance in menopause sexual training-based classes; no spouse with sexual disability; lack of severe debilitating

diseases such as cardiovascular diseases and cancers; lack of mental illness; score lower than 28 in the Female Sexual Function Index (FSFI) questionnaire; no severe family conflict; no use of hormone replacement therapy; and no drug and alcohol addiction in the women and their husbands.

Exclusion criteria

Stressors such as serious illness and death of relatives; lack of regular attendance at counseling sessions; using drugs affecting sexual function; and withdrawal from participation in the study.

Sample size was estimated at 45 per group using the following formula and information obtained from one paper by Behboodi Moghadam et al. [33] and using the following information and accounting for 15% of the sampling loss: $\alpha = 0.05$, Power = 0.80, M1 = 25.45, M2 = 22.89, Sd1 = 3.67, Sd2 = 4.29.

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 (\delta_1^2 + \delta_2^2)}{(\mu_1 - \mu_1)^2}$$

Sampling method

In this study, multistage random sampling was used. First, the geographical regions of Hamadan city were divided into 8 districts from which a center was randomly selected. Four centers were randomly assigned to the control group and four centers to the intervention group. After obtaining the necessary licenses from Hamadan University of Medical Sciences, we referred to each of the comprehensive urban health centers, and the names of postmenopausal women in the integrated health system were extracted by coordination with authorities, and the women were invited to the centers by phone. Subsequently, postmenopausal women, who met the inclusion criteria, were identified through interviews with the approval of a psychiatrist to confirm the sexual dysfunction in individuals and, if satisfied, they were entered the study. Hamadan was geographically divided into 4 districts. Two health centers were randomly selected from each of north, south, east and west districts using the draws; and 8 health centers were selected. Then, the postmenopausal list of these centers was obtained, and allocation sequences were determined using 4th randomized blocking (Fig. 1). The sequences of individuals were assigned to the groups by the non-participant one. In this way, individuals were assigned to the intervention or control group based on the allocation sequence.

Blinding

Due to the content of training sessions, there was no possibility of blindness in this study.

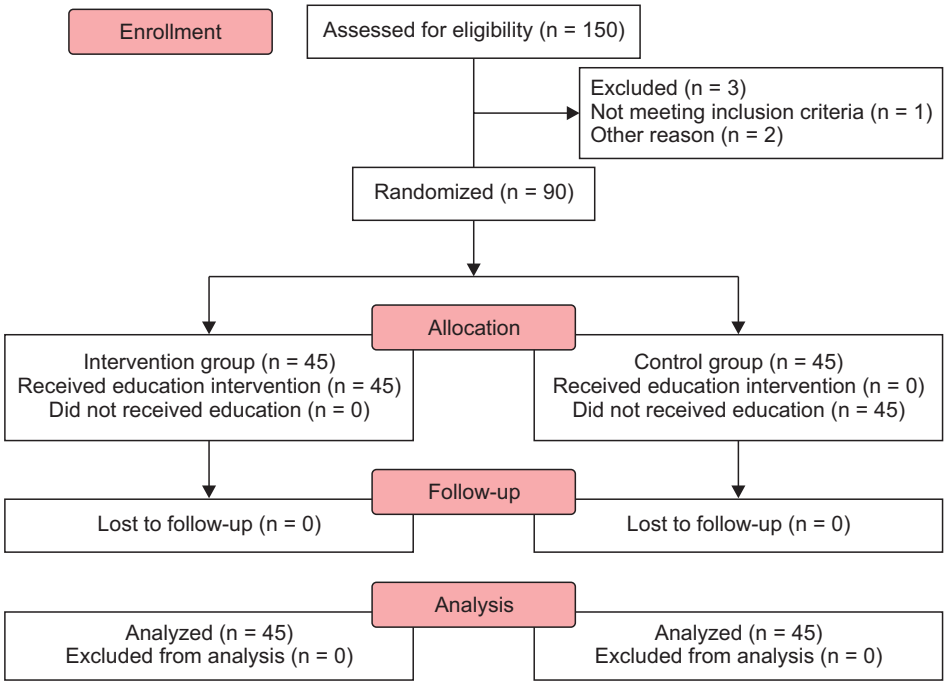

Fig. 1. Flow chart of sampling.

Instrument tools

After explaining how the study was conducted and emphasizing the confidentiality of participants' information, they completed written informed consent forms of Hamadan University of Medical Sciences and then responded to a demographic questionnaire as well as the FSFI questionnaire. Rosen et al. [34] designed the FSFI questionnaire to evaluate women's sexual function. The questionnaire includes 19 items measuring women's sexual function in 6 fields, namely desire (2 items), arousal (4 items), moisturizing (4 items), orgasm (3 items), satisfaction (3 items), and sexual pain (3 items) during the last 4 weeks. These subcategories have a response spectrum of 0 and 1 to 5. The questionnaire minimum score is 2, and the maximum score is 36. The overall cut-off point of the questionnaire is 28. In other words, scores higher than the cut-off point indicate good sexual function. The validity and reliability of this tool were determined by Mohammadi et al. [13] in Iran using the Cronbach's alpha coefficient of 0.87. Sampling continued until 90 postmenopausal women with scores lower than the cut-off point were selected.

Intervention

In the experimental group, they were informed about the time and place of training sessions, and the control group was reminded for the next visit. At the next stage, group training sessions were conducted in small groups of 5 to 6 individuals in four sessions of 45 to 60 minutes per month (a session per week). It should be noted that training was exclusively conducted by the researcher who attended the sex counseling workshop. The first 15 minutes of each session were devoted to asking and answering basic information and assessing people's awareness and answering problems and ambiguities of learned lessons in the previous session. At the end of each session, the women's possible questions were answered, and they also received information on subject of the following week (Table 1). Finally, postmenopausal women received a training booklet containing information on all issues written in the fourth training session in simple language. The control group did not receive any intervention. They received only routine training. The FSFI Questionnaire was re-completed for both groups after completion of sessions. Finally, training booklets and compact discs were given to the control group to observe ethics.

Data analyses

Data were analyzed by using the SPSS ver. 16 software (SPSS Inc., Chicago, IL, USA). The central and dispersion indices were used to describe quantitative variables. The Shapiro–Wilk test was used to investigate the distribution of quantitative variables. Results indicated normal distribution of age, and abnormal distribution of spouse's age, number of pregnancies, number of children, duration of menopause, and duration of marriage. Furthermore, the results of distribution of sexual

Table 1. Topics of training sessions

First session (45–60)	Introducing educators and clients to each other; Explaining details of training sessions and explaining goals; The importance of desirable sexual relationships in strengthening interpersonal relationships and family health; Explaining the physiology and anatomy of the female reproductive system; Explaining and showing sexually sensitive areas of women by photos and slides; Getting to know menopause changes and symptoms of this period; Impact of menopause on sexual function; Describing physiology and anatomy of the male reproductive system; The training was a lecture based and the participants' questions were answered.
Second session (45–60)	Describing the sexual cycle of women and its different stages and describing terms in the questionnaire such as desire, arousal (excitement), lubrication, orgasm, resolution, satisfaction and pain; Explaining changes in sexual processes of menopausal women and investigating misconceptions and attitudes of women and society on menopause and middle age; Teaching different types of intercourse positions, especially suitable ones for menopause by photos and slides; Explaining role of continuing intercourse to delay genital atrophy. The training was a lecture based and the participants' questions were answered by group discussion.
Third session (45–60)	Obtaining feedback from female sexual function based on previously provided information; Teaching spouse communication skills about sex and marriage issues; Importance of sexual intimacy and satisfaction between husband and wife; Teaching Kegel exercise using photos and slides and practical exercises for attendees; Recommendations for using different lubricants for ease of intercourse; Question and answer between researcher and members
Fourth session (45–60)	Teaching spouse communication and problem solving skills, especially on marital issues, intimacy, and interpersonal relationships; Getting feedback on applying recommended training and methods; Question and answer and group discussions with clients; Answering personal questions by each member of group; Sharing each woman's positive and negative experience with applying the recommendations; Giving booklets and instructional CDs containing the content that was taught in sessions.

CD: compact disc.

function data and its dimensions demonstrated that the distribution of data was normal in all domains, and sexual function was generally normal. ANCOVA was used to examine the difference between the two groups in terms of sexual function. Significance level was considered less than 0.05 in all statistical tests.

RESULTS

In the present study, 90 postmenopausal women were studied and evaluated in two groups, namely the interventional (n = 45) and control group (n = 45), and the following results were obtained. The intervention group had a mean age of 55.17 ± 4.54 years, and the control group had a mean age of 55.04 ± 4.08 years and they had no statistical significant difference. The mean

Table 2. Baseline characteristics of study patients

Variable	Intervention group	Control group	*P* value
Age (y)	55.17 ± 4.54	55.04 ± 4.08	0.88
Husband's age (y)	61.53 ± 6.30	61.48 ± 6.77	0.98
Gravid	4.20 ± 1.79	4.40 ± 1.71	0.39
Duration of menopause (mo)	77.80 ± 64.91	82.40 ± 50.59	0.31
Duration of marriage (yr)	36.75 ± 6.04	37.93 ± 6.44	0.24
Level of education			0.19
Primary	25 (55.6)	33 (73.3)	
Middle	6 (13.3)	6 (13.3)	
High	7 (15.6)	4 (8.9)	
Academic	7 (15.6)	2 (4.4)	
Husband's education			0.01
Primary	19 (42.2)	34 (75.6)	
Middle	9 (20.0)	5 (11.1)	
High	9 (20.0)	3 (6.7)	
Academic	8 (17.8)	3 (6.7)	
Job status			0.19
Employed	7 (15.6)	2 (4.4)	
Housewife	38 (84.4)	43 (95.6)	
Husband's job status			0.57
Employed	36 (80.0)	35 (77.8)	
Unemployed	9 (20.0)	10 (22.2)	
Income			0.43
Less than 10 million rials	7 (15.6)	12 (26.7)	
Between 10 and 20 million rials	31 (68.9)	27 (60)	
More than 20 million rials	7 (15.6)	6 (13.3)	
Marriage type			0.07
Traditional	45 (100)	42 (93.3)	
Non traditional	0 (0)	3 (6.7)	
Marriage satisfactory			> 0.99
Yes	39 (86.7)	39 (86.7)	
No	6 (13.3)	6 (13.3)	

Data are presented as mean ± standard deviation or number (%).

age of spouses was 61.53 ± 6.30 years in the intervention group, and 61.48 ± 6.77 years in the control group, indicating no significant difference. Comparison of job status and education level of the women were not statistical significant in both control and experimental groups. There was no significant difference between the two groups in terms of number of pregnancies, number of children, income, duration of menopause, number of years of marriage and smoking. Comparison of the demographic variables indicated no statistical significant difference between different factors, except for spouse's education (Table 2).

The mean scores of sexual function domains (desire, arousal, lubrication, orgasm, satisfaction, pain) in the interventional and control and groups before the intervention were 2.40 ± 0.83, 2.72 ± 0.91, 2.38 ± 0.90, 2.82 ± 0.88, 2.51 ± 1.01, 2.88 ± 0.96, 2.80 ± 1.06, 3.20 ± 0.96, 3.25 ± 1.24, 3.74 ± 1.04, 4.02 ± 0.90, 4.08 ± 0.86, respectively. Additionally, the mean scores of sexual function domains in the interventional and control and groups after the intervention were 3.18 ± 0.81, 2.68 ± 0.70, 3.54 ± 0.76, 2.78 ± 0.82, 3.80 ± 0.93, 2.98 ± 0.85, 3.56 ± 0.97, 3.21 ± 0.91, 4.62 ± 0.90, 3.86 ± 1.10, 4.97 ± 0.56, 4.40 ± 0.72, respectively. The results demonstrated a significant difference after the intervention between the interventional and control groups ($P < 0.001$). Furthermore, the mean scores in the sexual function domains increased after the intervention in the experimental group compared to the pre-intervention period ($P < 0.001$) (Table 3).

Owing to the significant difference in the level of education of the spouse in both groups, and the mean scores of satisfaction and arousal domains in pre-intervention, the ANCOVA test was used to assess the effect of intervention on sexual function in the interventional group (Table 4).

Table 3. Comparison of mean and standard deviation of sexual function domains between interventional and control group before and after intervention

Variable	Phase	Intervention group (n = 45)	Control group (n = 45)	*P* value
Desire	Pre-intervention	2.40 ± 0.83	2.72 ± 0.91	0.08
	Post-intervention	3.18 ± 0.81	2.68 ± 0.70	< 0.001
	P value	< 0.001	0.68	
Arousal	Pre-intervention	2.38 ± 0.90	2.82 ± 0.88	0.02
	Post-intervention	3.54 ± 0.76	2.78 ± 0.82	< 0.001
	P value	< 0.001	0.58	
Lubrication	Pre-intervention	2.51 ± 1.01	2.88 ± 0.96	0.07
	Post-intervention	3.80 ± 0.93	2.98 ± 0.85	< 0.001
	P value	< 0.001	0.19	
Orgasm	Pre-intervention	2.80 ± 1.06	3.20 ± 0.96	0.07
	Post-intervention	3.56 ± 0.97	3.21 ± 0.91	< 0.001
	P value	< 0.001	0.80	
Satisfaction	Pre-intervention	3.25 ± 1.24	3.74 ± 1.04	0.04
	Post-intervention	4.62 ± 0.90	3.86 ± 1.10	< 0.001
	P value	< 0.001	0.13	
Pain	Pre-intervention	4.02 ± 0.90	4.08 ± 0.86	0.73
	Post-intervention	4.97 ± 0.56	4.40 ± 0.72	< 0.001
	P value	< 0.001	0.06	
Sexual function	Pre-intervention	17.38 ± 4.32	19.45 ± 3.95	0.02
	Post-intervention	23.70 ± 3.67	19.94 ± 3.64	< 0.001
	P value	< 0.001	0.056	

Data are presented as mean ± standard deviation.

Table 4. Comparison of mean and standard deviation of sexual function domains between two groups and by controlling effect of spouse's education, satisfaction and arousal domains

Variable	Intervention group (n = 45)	Control group (n = 45)	F value[a]	*P* value[a]
Desire	3.18 ± 0.81	2.68 ± 0.70	25.33	< 0.001
Arousal	3.54 ± 0.76	2.78 ± 0.82	75.47	< 0.001
Lubrication	3.80 ± 0.93	2.98 ± 0.85	55.68	< 0.001
Orgasm	3.56 ± 0.97	3.21 ± 0.91	20.17	< 0.001
Satisfaction	4.62 ± 0.90	3.86 ± 1.10	51.16	< 0.001
Pain	4.97 ± 0.56	4.40 ± 0.72	17.65	< 0.001
Sexual function	23.70 ± 3.67	19.94 ± 3.64	107.2	< 0.001

Data are presented as adjust mean ± standard deviation.
[a]ANCOVA/ANOVA test.

DISCUSSION

The main aim of study was to determine the effect of group education on sexual dysfunction of postmenopausal women referred to the comprehensive health centers of Hamadan. The research results indicated that group training could affect the sexual function score and all its dimensions, through increased sexual knowledge and communication skills in postmenopausal women. The present study results were consistent with one study by Babakhani et al. [35]. According to the present study findings, group counseling affected the sexual function of women. The current study aimed to evaluate the impact of group counseling on sexual function in 15 to 45-year-old women in control and experimental groups. Comparison of information from the FSFI questionnaire indicated a significant difference between the scores of sexual function domains in the control and experimental groups before and after the intervention. In another study by Sabeti et al. [29] aiming at determining the effect of training on women's sexual function, the results demonstrated that two 90-minute training sessions significantly increased the score of the FSFI questionnaire.

Behboodi Moghadam et al. [33] in their study indicated that sex training sessions improved sexual function in women. The final findings of this study were also consistent with the results of the present study. In the study by Behboodi Moghadam et al. [33], there was a significant difference between the pre-test and post-test stages in the control group in terms of the sexual pain score. It was probably due to the age of population, including women aged 20 to 45 years. The age range might include postmenopausal women. Women may have greater intercourse pain during lactation. Results of these conditions may be a significant reason for pain scores in the control group before the intervention.

The present study results were also consistent with those obtained by Mirmohammad Aliei et al. [31] on 100 postmenopausal women in Tehran. In their study, 4 sessions of training increased all aspects of female sexual function except for orgasm. In addition, the total score of sexual function in the experimental group in the pre-intervention was significantly different from the post-intervention score. According to the results of this study, training sessions affected the sexual function of postmenopausal women.

In one study by Smith et al. [28], the results indicated that training sessions affected sexual function in women in the intervention group. Furthermore, there were a statistically significant difference between the overall scores of sexual function in the experimental group before and after the intervention. In another study by Rosen et al. [34], the results indicated a significant difference between the overall scores of sexual function in the experimental group before and after the intervention. In one study by Thomas and Thurston [36] entitled "A biopsychosocial approach to women's sexual function and dysfunction at midlife: A narrative review", the results demonstrated a significant difference between sexual function scores of middle-aged women in the control and experimental groups after the intervention. Alimohammadi et al. [37] in their study into the effect of group counseling on sexual function and satisfaction of Iranian women confirmed the present study results. In this study, sexual performance scores were significant between the experimental and control groups after the intervention by controlling the impact

of pre-test by ANCOVA. In another study by Masoumi et al. [38] on 80 pregnant women, the findings revealed a significant difference between the scores of sexual function of pregnant women in the experimental group before and after the intervention. In one study examining the impact of sexual training on sexual function of married women, Nameni et al. [39] demonstrated a significant difference between the scores of sexual function of women in the experimental group after the intervention than before the intervention [40]. According to the results of our study, the staff of health centers should educate menopausal women about the physical and the physiological changes in sexual function that occur during this period. This can somewhat prevent the psychological and social consequences of sexual dysfunction at this age.

Limitations of study

A limitation of the present study was the difficulty in inviting participants to attend classes. It was also difficult to group women in classes with participants from different geographical places of the city and unfamiliar with each other as much as possible. Holding group sessions made it difficult for women to ask questions easily.

Conclusion

Based on the present study findings, group training could have positive effects on postmenopausal women's sexual function scores.

Although, the results of the present study and other studies in Iran and other parts of the world indicated positive effects of training on women's sexual function, and different health projects aimed to investigate menopausal women's sexual function, it appears that there are not fully implemented specialized and applied sexual training services (especially in developing countries). However, addressing sexual dysfunction is a health priority during the menopause. Therefore, it is recommended that research on the women's sexual function in different climates and cultures be conducted with more samples and provide more information for health policymakers.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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