O EFEITO DO PROGRAMA EDUCACIONAL BASEADO NO CONCEITO DE INTIMIDADE SEXUAL ATRAVÉS DE SMARTPHONE EM MULHERES PÓS-MASTECTOMIA: UM ESTUDO CLÍNICO RANDOMIZADO CONTROLADO

THE EFFECT OF EDUCATIONAL PROGRAM-BASED ON SEXUAL INTIMACY CONCEPT VIA SMARTPHONE IN WOMEN FOLLOWING MASTECTOMY: A RANDOMIZED CONTROLLED TRIAL

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RESUMO

A malignidade mais comum entre mulheres em todo o mundo é o câncer de mama. A mastectomia é um dos tratamentos de câncer de mama mais comumente usados, com impacto direto no desempenho sexual desses pacientes. O objetivo deste estudo foi examinar o impacto do programa Educacional por meio do *smartphone* na intimidade sexual de mulheres com câncer de mama. Em um estudo controlado randomizado, 60 mulheres com mastectomia foram encaminhadas ao Hospital Imam Khomeini entre abril e julho de 2018 e foram divididas aleatoriamente em duas intervenções (intimidade sexual com educação de rotina em mastectomia e quimioterapia) e grupos de controle (mastectomia de rotina e educação em quimioterapia) usando quatro blocos aleatórios. Foram realizadas seis sessões via *smartphone* para ambos os grupos; o questionário de intimidade sexual foi preenchido pelos participantes antes e após a intervenção. Os dados foram analisados pelo SPSS 21 em nível de significância de $p < 0.05$. De acordo com os achados, o escore médio da intimidade sexual geral antes da intervenção não foi significativamente diferente ($p = 0.143$) entre os dois grupos. No entanto, após a intervenção, o escore médio da intimidade sexual geral foi significativamente diferente nos grupos controle e intervenção, sendo maior no grupo intervenção ($p < 0.001$). O presente estudo mostrou que a educação via *smartphone* foi eficaz para melhorar a intimidade sexual de mulheres com câncer de mama e, consequentemente, melhorar as relações sexuais dos casais.

Palavras-chave: Educação sexual; Intimidade sexual; Smartphone; Mastectomia;

ABSTRACT

The most common malignancy among women around the world is breast cancer. Mastectomy is one of the most commonly used breast cancer treatments, which has a direct impact on the sexual performance of these patients. The purpose of this study was to examine the impact of Educational program through Smartphone on the sexual intimacy of women with breast cancer. In a randomized controlled trial, 60 women with mastectomy referred to Imam Khomeini Hospital from April to July 2018 and were randomly divided into two intervention (sexual intimacy with routine mastectomy and chemotherapy care education) and control groups (routine mastectomy and chemotherapy care education) using four randomized blocks. Six sessions via smartphone were held for both groups the sexual intimacy questionnaire was completed by participants before and after the intervention. The data were analyzed by SPSS 21 at a significance level of $p < 0.05$. According to the findings, the mean score of overall sexual intimacy before intervention was not significantly different ($p = 0.143$) between the

two groups. However, after the intervention, the mean score of total sexual intimacy was significantly different in the control and intervention groups being higher in the intervention group ($p < 0.001$). The present study showed that education via smartphone was effective in improving the sexual intimacy of women with breast cancer and consequently enhancing the couples' sexual relations.

Keywords: Sex education; Sexual intimacy; Smartphone; Mastectomy;

1. INTRODUCTION:

Breast cancer is one of the most common malignancies among women and has the highest mortality rate in this group throughout the world. More than 7 million people in the world are currently affected by breast cancer, and the number of new cases is expected to reach 10-15 million by 2020 (Hummel *et al.*, 2018, Ghoncheh *et al.*, 2016, Li *et al.*, 2016).

This malignancy accounts for 33% of all cancers in women, and its prevalence in the general population is estimated to be between 8% and 10% in different countries (Boyd *et al.*, 2007, Society, 2017, Khalkhali *et al.*, 2019). Evidence suggests that about 60% of breast cancer cases in Iran occur in women under the age of 50 (Esfandiari *et al.*, 2015).

Mastectomy is one of the most commonly used treatments for this malignancy that directly affects the sexual performance of these patients (Rojas *et al.*, 2017; Pérez *et al.*, 2010). In this method, the body image of patients is affected, and this has a profound effect on their mental status (Traun-Vogt and Herdina, 2010; Safarpour *et al.*, 2018; Fouladi *et al.*, 2018). This disease is associated with many problems that can affect mental health and quality of life of these patients (Berek, 2002, Norouzirad *et al.*, 2018; Moghaddam Tabrizi *et al.*, 2018,). These individuals also have difficulties in their sexual and marital relationships, and this significantly affects the relationship between women and men and their families (Galbraith *et al.*, 2005, Kaviani *et al.*, 2014, Boquiren *et al.*, 2019, Brandão *et al.*, 2017, Male *et al.*, 2016).

One of the most critical factors affecting sexual function is sexual intimacy (Cairo Notari *et al.*, 2018; Nordvig *et al.*, 2019; Bois *et al.*, 2016). Sexual intimacy is the need to share and express sexual thoughts, feelings, and imagination with the spouse. (Kalra *et al.*, 2011) This kind of intimacy is mainly in the direction of sexual stimulation and requires communication, and exchange and expression of thoughts, feelings tendencies, and imaginations that have sexual nature (Ali *et al.*, 2004). Sexual intimacy is a complex subject that needs special attention because satisfaction from

sexual intimacy affects other relationships in couples (Bagarozzi, 2014; Tat *et al.*, 2018).

Lack of proper information and inadequate training on sexual activity, and consequently the inappropriate communication, wrong sexual beliefs, and anxiety about sexual performance play an essential role in the emergence and continuation of these disorders (Hummel *et al.*, 2017, Perz *et al.*, 2013, Crowley *et al.*, 2016). Findings show that sexual intimacy helps to reduce the burden of cancer diagnosis and treatment and the recovery process (Weijmar Schultz and Van de Wiel, 2003; Ussher *et al.*, 2013).

There are different ways to increase sexual intimacy, including education and sexual counseling on marital relationships, which help healthy sexual growth, marital health, interpersonal relationships, affection, sex, body image and gender roles (Jun *et al.*, 2011, Zareipour *et al.*, 2018, Boswell and Dizon, 2015). Different methods that are used for patient counseling include written, oral, photo, film, telephone, internet, and other means. The upward trend in mobile phone use in human societies had caused this device to be considered as a new tool in care, education, and counseling, which can be used from a distance for communication between patients and health care providers (Barak, 2003, Yazdani *et al.*, 2019).

This process is similar to in-person counseling and psychotherapy, but there are some differences. In this method, there are no barriers that are usually caused by social status, geographical location, and physical and emotional characteristics. Therefore, it can be instrumental in improving sexual problems (Barak and Cohen, 2002). This study aimed to investigate the impact of sexual counseling by Smartphone on the sexual intimacy of women attending the selected center of Tehran.

2. MATERIALS AND METHODS:

2.1. Design

A Parallel randomized clinical trial was conducted on women with breast cancer attending

the Imam Khomeini Hospital in Tehran from April to July 2018. This center is a referral for patients with cancer. Human rights were respected following the Helsinki Declaration 1975, as revised in 1983. The informed consent was taken from the participants. The Medical Ethics Committee has approved current studies of Alborz University of Medical Sciences and Health Services on 23 December 2017 (code: 1396.147)

2.2 Participants and recruitment

Sample size was determined based on the previous study of Shahkarami *et al.* By considering type I and II errors (0.05, 0.2), the mean change (standard deviation) score of sexual intimacy before and after intervention were 6.6(5.2) and 0.5(10.80) in intervention and control groups respectively, and a 10% attrition rate determined a sample size of 35 subjects in each as described in equation 1.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta} \right)^2 (\delta_1^2 + \delta_2^2)}{(\mu_1 - \mu_2)^2} \quad \text{eq.1}$$

2.3 Inclusion criteria

There were included in this study 20 to 60 years old married woman, having a mastectomy due to breast cancer, not having prosthesis, having reading and writing skills, not having chronic diseases (heart, diabetes, kidney, liver), obtaining medium to low score based on gender intimacy questionnaire, having access to Smartphone and internet, knowing how to use Smartphone, and having the consent of spouse. In this study, information was collected by using a standard sexual intimacy questionnaire (Botlani *et al.*, 2010), and a personal-social information checklist.

Sexual intimacy questionnaire is a one-dimensional questionnaire, which consists of 30 questions and is analyzed based on the score obtained from the survey. So that, the score between 30 and 50 indicate the low level of sexual intimacy, between 50 and 100 shows the moderate level of sexual intimacy, and rating of above 100 reflects the high level of sexual intimacy (Botlani *et al.*, 2010). In Iran, the reliability of the components of this questionnaire was obtained by Cronbach's alpha (0.84) for the entire poll (Botlani *et al.*, 2010).

The sociodemographic checklist included questions about age, level of education, occupation, income level, number of partners,

marital status

2.4 Processors

After obtaining the necessary permissions, the researcher attended the cancer center of Imam Khomeini Hospital and selected 60 eligible participants, between 80 patients, by convenience sampling, then, the study objectives were expressed to them, and if they wished to participate in the study, written consent was obtained from them and their spouses. The patients were then asked to complete the Sexual Intimacy Questionnaire.

This information was used as a baseline score for comparison and also for identifying qualified individuals. If the score of the subjects was moderate and low (scores of 100 and less), they were included in the study and randomly divided into the intervention and control groups by using Permuted block randomization. Before allocating people in each group, a telegram channel was designed by the researcher, and she was the only one who had access to the telephone numbers of the participants.

The participants did not have access to each other's phone number. In the next step, to allocate people in the groups, the researcher obtained the telephone number from each participant for education. The intervention group received sexual intimacy education under the supervision of a sexologist along with routine mastectomy and chemotherapy care education according to the protocol of the cancer center. They received this intervention twice a week through the telegram channel, which allowed them to enter into discussions and express their comments. The control group underwent routine mastectomy and chemotherapy care education according to the protocol of the center through the telegram channel.

To observe ethic, an educational package related to sexual intimacy (all contents presented in the intervention group) was given to the control group at the end of an informative session. An admin managed the telegram channel for one month for six educating sessions (two sessions per week) and related contents were uploaded. The materials included audio files, text file and associated images. In order to ensure that the participants have used the topics uploaded to the telegram channel in each session, several questions were asked from each participant privately by the researcher, which were related to the subject, of course. If any participant needed more advice or had question, their need was met

individually on their page, but general questions were answered in the group (Table 1).

At the end of the sessions, (After the six-session) the participants were contacted again and both groups were asked to complete the sexual intimacy questionnaire once again. After completion, the post-intervention scores were kept for analysis. The information of 60 people was analyzed in both groups (Figure. 1). To make the participants communicate more with each other and use each other's experiences, another telegram channel was designed for their peers.

2.5 Statistical Analysis

Intention to treat analysis (ITT) considered dealing with noncompliance and missing. Outcomes in this randomized controlled trial (RCT) were sexual intimacy, and the collected data were analyzed by SPSS software using independent and paired t-tests.

3. RESULTS AND DISCUSSION:

In the present study, 60 women with mastectomy due to breast cancer who remained until the end of the research in the intervention and control groups were examined. After examining the normality by K-S, variables tested by Fisher exact test and chi-square test, no significant difference was found between the two groups in terms of mean age, education level, and duration of breast cancer diagnosis. In other words, the two groups were homogeneous. (Table 2)

There was no significant difference between the mean overall score of sexual intimacy in the control and intervention groups before the study. In other words, both groups were similar in terms of sexual intimacy. However, after the intervention, the comparison of the mean overall score of sexual intimacy was significantly different between the two groups ($p = 0.000$), so that the mean score of sexual intimacy in the intervention group was significantly higher than the pre-intervention time. This difference indicated the positive impact of counseling (Table 3).

To examine the hypothesis of the study, "sexual counseling affects the sexual intimacy of women with breast cancer," the covariance analysis was used. After reviewing the premises, the result of the test indicated the significance of F for the scores of sexual intimacies. Accordingly, the zero hypotheses were ruled out and we could conclude that the mean scores of the two groups (control and intervention groups) after the intervention (after moderating the pre-intervention

scores) were significantly different from each other (Table 4).

Breast cancer is associated with many individual, social, and familial complications for patients and their families. (Wassermann *et al.*, 2019, Ataollahi *et al.*, 2015) For example, it can be a significant contributor to sexual problems due to the weakening of physical strength, decreasing ability to perform daily activities, hospitalization, and cancer-induced depression (Kwait *et al.*, 2016, Alappattu *et al.*, 2015).

In the present study, after considering the individual-social and familial variables of the participants in the two groups, we found that the majority of variables such as; age, education, occupational status, first gestation age, number of children, history of breastfeeding, duration of marriage, type of contraception, type of medications used during treatment, time of filling the questionnaire, level of income, age of the first menstruation, place of residence, history of breast cancer in the family, and duration of the disease, were not significantly different from each other. In other words, the two groups were homogeneous in terms of the variables mentioned earlier, and this was one of the strengths of the study.

According to the findings of the study, there was no significant difference in the score of sexual intimacy before consultation in the two groups of control and intervention. In other words, the two groups, at the time of entering the study, were homogeneous in terms of sexual intimacy. However, after the intervention, the mean of overall sexual intimacy score in the intervention group showed a significant increase compared to the control group.

Study of Moradi *et al.* (2014) entitled: "Investigating the Impact of Consultation on the Sexual Function of Women with Type 2 Diabetes in 2014" showed that counseling improves the sexual function of women with type 2 diabetes. They found a significant difference between the mean sexual performance scores before and after the intervention in the intervention group compared to the control group (Moradi *et al.*, 2016).

Also, Mohammad Shakarami *et al.* (2013) researched the effect of sexual education on the sexual intimacy of married women attending the Hamyaran center of Bojnourd. They found a significant difference between the mean scores of sexual intimacy in the intervention and control group in the post-test and follow up stages. They also found that sexual education increased the sexual intimacy of women in the intervention group

(Shakarami *et al.*, 2014).

The results of the present study are also consistent with the findings of an investigation by Jennifer Barski *et al.* (2015). They conducted a study as a randomized pilot trial on sexual intimacy and concerns of patients with colorectal cancer. They found a positive effect of internet intervention on sexual performance and self-efficacy of the participants(Reese *et al.*, 2014).

Women's sexual satisfaction is closely related to psychological intimacy than physical acts of sexual intercourse(Gilbert *et al.*, 2013), and The result of this study is similar to Masoumi and *et al.* (2017). They expressed sexual education can be used as a method of intervention in the sexual relationship of spouses particularly in marital dissatisfaction(Masoumi *et al.*, 2017).

One of the leading causes of sexual problems after cancer is the problem in establishing communication and expressing needs and wishes (Zee *et al.*, 2008). According to studies, modern communication technologies provide a new opportunity for individuals to create a private space in cyberspace, where people communicate with one another and form a wide range of online relationships in social networking channels(Ebert *et al.*, 2015). On the other hand, concerning the culture of patients, speaking about sexual problems with someone else in a face-to-face manner can be difficult for some patients, and that is why the use of these social networks such as telegrams can have a more significant effect during information gathering, evaluation and treatment (Taylor and Luce, 2003). According to Marlene Elias, online counseling is the most controversial change that has taken place in the consultation and treatment(Barak and Cohen, 2002).

4. CONCLUSIONS:

Consultation as an effective procedure of solving problems can improve the quality of sexual life, and the social networks, especially mobile phones, are everywhere and have been well accepted as a communication tool. The results of the present study indicated the effectiveness of sexual intimacy education on marital problems of women after mastectomy. Education by health cares like nurses and midwives can help to increase the sexual intimacy of women and their spouses, as the primary care providers of women, Also, considering the expansion of cyberspace and convenient of access to Smartphone, the use of such device is useful for reducing costs, and

resolving time and space constraints for educating. In the present study, we tried to homogenize the participants, but the existence of other social networks could be considered as a limitation of this study.

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Table1. The content provided in each educating session

Number of sessions	Content of each Session
Session 1	Welcome to the group, the goals and rules of the channel are expressed, self-introduction, determination of communication, importance of marital relations, education of sexuality and marital affairs
Session 2	Teaching the correct sexual relations technique, sexual aspects of life and behaviors which can lead to marital satisfaction .
Session 3	Familiarity with the common sexual disorders of women
Session 4	Familiarity with Physiology of Sexual Exercise, Physical Education
Session 5	Focusing skills training, Attention and awareness of sensory symptoms, Expression of expression, Sexual self-expression
Session 6	Confronting Negative Thought and Reviewing Past Sessions. open Chanel for one heure in order to ask their question

Table 2. Distribution of demographic characteristics of women with breast cancer

Variables		Intervention group (n=30)	Control group (n=30)	Total (n=60)	P
		n (%)	n (%)	n	
Age	Less than 40 years old	11(36.7)	9(30)	20	0.768
	40 to 44	6(20)	8(26.7)	14	
	45 to 49	6(20)	4(13.3)	10	
	50 and above	7(23.3)	9(30)	16	
Education	Reading and writing	6(20)	6(20)	12	0.670
	Secondary school	8(26.7)	10(33.3)	18	
	High school diploma	11(36.7)	12(40)	23	
	Bachelor and master degree	5(16.7)	2(6.7)	7	
Employment	Housekeeper	24(80)	26(86.7)	50	0.748
	Clerk	5(16.7)	3(10)	8	
	Others	1(3.3)	1(3.3)	2	
Age at the first menstruation	8-13years	24(80)	20(66.7)	44	0.382
	>14 years	6(20)	10(33.3)	16	
Age at the first pregnancy	Below 18 years old	4(13.3)	3(10)	7	0.640
	18 to 20 years old	11(36.7)	10(33.3)	21	
	21 to 35 years old	12(40)	15(50)	27	
	35 and above	0(0)	1(3.3)	1	
	No answer	3(10)	1(3.3)	4	
History of	Yes	23(76.7)	25(83.3)	48	
	No	7(23.3)	4(13.3)	11	

lactation	No answer	0(0)	1(3.3)	1	0.386
History of breast cancer in the family	Yes	4(13.3)	6(20)	10	0.731
	No	26(86.7)	24(80)	50	
Type of medication	Tamoxifen	3(10)	6(20)	9	0.352
	Letrozole	5(16.7)	2(6.7)	7	
	Other	5(16.7)	8(26.7)	13	
Duration of cancer diagnosis	Less than one year	17(56.7)	14(46.7)	31	0.795
	More than one year	16(53.3)	18(60)	34	

Table 3. Comparison of the mean overall score of sexual intimacy in the two groups of control and intervention before and after the intervention in women with breast cancer

Variable		Before intervention	After intervention	p*
Sexual intimacy	Control group	69.10±9.7	68.57±9.70	0.118
	Intervention group	72.37±6.86	80.33±5.55	0.000
p **		0.14	0.000	

*= pair T-test ** = In depended test

Table 4. Testing the hypothesis of the effect of sexual counseling on the sexual intimacy of women with breast cancer based on covariance analysis

Reference	Sum of squares	Degree of freedom	Mean of squares	F value	P-value
Modified model	4898.421	2	2449.211	220.048	0.000
The width from the origin	199.625	1	199.625	17.935	0.000
Before intervention	2821.605	1	2821.605	253.506	0.000
group	1183.516	1	1183.516	106.333	0.000
Error	634.429	57	11.130	-----	-----
Total	338101	60	-----	-----	-----

Figure 1. CONSORT flow diagram of the participants