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# Sexual health promotion interventional program for women undergoing breast cancer treatment: Protocol for a mix-methods study

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## Abstract:

**BACKGROUND:** Women undergoing breast cancer treatment, especially those of reproductive age, experience sexual health challenges. The aim of this study is to design an interventional program for promoting the sexual health of women undergoing breast cancer treatment.

**MATERIALS AND METHODS:** This is a mixed qualitative-quantitative exploratory study consisting of four phases. In the first phase, the needs and strategies for promoting sexual health of Iranian women with breast cancer in Isfahan city will be identified through a qualitative study. The patients will be selected using purposive sampling method and the data will be collected through semi-structured interviews. In the second phase of the study, the relevant literature will be reviewed. In the third phase, the initial version of the program will be designed based on the results of qualitative study and review of literature, the appropriate strategies are prioritized by the members of the panel of experts, and then, the final interventional program is prepared. In the fourth phase, the designed interventional program will be conducted as a quasi-experimental study in two groups of intervention and control and the effectiveness of the program on sexual quality of life, sexual satisfaction, and sexual function of women undergoing breast cancer treatment will be evaluated. The type of the intervention will be selected based on the results of the previous phases and the opinion of the expert panel.

**CONCLUSIONS:** The results of this study are expected to contribute to the design of an interventional program based on the needs of women undergoing breast cancer treatment and promote health and meet the sexual health needs of breast cancer patients.

## Keywords:

Breast cancer, mixed method, sexual health, study protocol

## Introduction

Breast cancer is one of the most prevalent malignant tumors in women and the second leading cause of cancer-related death.<sup>[1]</sup> Based on the latest report of the WHO, breast cancer accounts for 12.5% of all cancers among Iranian women.<sup>[2]</sup> It is estimated that the incidence of breast cancer is increasing among under 40-years-old Iranian women.<sup>[3]</sup> The diagnosis of cancer is considered as a crisis in women's lives

which lowers the quality of their life.<sup>[4]</sup> Today, although the 5-year survival rate of breast cancer patients is about 90%,<sup>[5]</sup> cancer survivors face challenges in their sexual function. The type of treatment, the use of chemotherapy and hormone therapy, through ovarian failure and decreased estrogen and testosterone, leads to vaginal atrophy, decreased vaginal moisture and vascular congestion and decreased sexual desire.<sup>[6]</sup> Studies have shown that sexual dysfunction, with an prevalence of 85%,

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is one of the most common problems in breast cancer patients.<sup>[7,8]</sup>

In cancer patients, sexual health should be considered not only during their treatment but also years after their being treated.<sup>[9-11]</sup> To evaluate the effect of cancer on sexual health, physical function, and sexual dysfunction as well as other factors that affect sexual health should be considered.<sup>[12,13]</sup> The role those societies, especially traditional ones, have defined for women affects their sexual self-concept and sexual dysfunction occurs when they lose the perception of the role assigned to them by the society.<sup>[14]</sup> In some countries, such as Iran, women are usually more conservative in talking about their sexual problems, as a result of which their sexual needs remain unanswered.<sup>[15]</sup> There is the problem, particularly in Asian countries, when most approaches are targeted to treatment of cancer disease itself.<sup>[16]</sup> In some societies, the social belief is that sexuality is only important to healthy people and those with cancer should only think about survival, family and children. Accordingly, patients feel ashamed to talk about sexual problems with health-care professionals.<sup>[17]</sup> Health-care providers are concerned that talking about sexual issues may invade the patients' privacy and cause psychological distress to them.<sup>[18,19]</sup> Differences in supportive care priorities and unmet needs of breast cancer patients in Asian and Western countries show that the needs of patients are under the influence of the culture of each country and its health services.<sup>[20]</sup> The results of some studies showed that the need for cancer patients for sexual health services is not well met due to the unavailability of sexual health services and lack of attention to socio-cultural factors.<sup>[21-23]</sup> Although, in other countries a sexual health guidelines such as American Cancer Society / American Society of Clinical Oncology Breast Cancer Survivorship Care Guideline, Cancer Care Ontario guideline and Sexual Function in Cancer Survivors guideline have been developed for cancer patients but the racial, religious beliefs, and cultural factors of patients were not considered in the sexual health guidelines of the health system and these do not fully met the sexual health needs of all patients.<sup>[13,24]</sup> Given that sexual dysfunction in women with breast cancer can have consequences such as impaired marital satisfaction, sexual violence, and broken family foundations also lack of sexual health program for the Iranian women with breast cancer, the present study is designed to identify the sexual health needs of women undergoing breast cancer treatment and design an interventional program for promoting their sexual health.

## Materials and Methods

### Study design and setting

The present mixed study is a sequential qualitative-quantitative exploratory study.<sup>[25]</sup> Inspired

by a pragmatic approach, the researcher first identifies the needs and strategies for promoting sexual health of women undergoing breast cancer treatment in a qualitative study. Then, an interventional program will be designed based on the results of the qualitative part, review of the literature and the results of the panel of experts. Finally, the program will be implemented through a quantitative study. The setting of this study isomid hospital and Ala Charity Center in Isfahan city.

### Phase I: Qualitative study

The aim of this phase is to explain the needs and strategies for promoting the sexual health of women undergoing breast cancer treatment. To achieve this goal, semi-structured interviews will be conducted with participants. After data analysis, the needs and strategies for promoting sexual health of women undergoing breast cancer treatment will be extracted through conventional qualitative content analysis.

### Study participants and sampling

Eligible participants included 18–50-years-old women with breast cancer, married (at least 1 year of cohabitation), 6 months after treatment period, not being in advanced stage of the disease, be able to communicate and conduct interviews, willingness to participate in the study and no history of sexual dysfunction before breast cancer will be selected using purposive sampling method and considering maximum variation in terms of age, occupation, level of education, type of treatment, and the time elapsed since the diagnosis. The inclusion criteria for healthcare teams who provide services to women with breast cancer is having at least 1 year of experience in providing services to such women. Exclusion criteria include unwillingness to continue cooperation and leaving the research at any stage of it. Sampling will be continued until data saturation is reached. Saturation is reached when no new information is obtained while analyzing and encoding data.

In the present study, participants include Iranian women with breast cancer who go to the centers for a routine treatment or follow-up of their disease and have a medical record. In addition, the husbands of the women undergoing breast cancer treatment, the health-care team that provides services to these women including oncologists, psychiatrists, gynecologists, reproductive health specialists, psychologists, midwives, oncology nurses and managers and health policy-makers of Isfahan province in will be among the participants of the study. Interviews will be conducted in locations where agreed upon by the researcher and participants.

### Data collection tool and technique

The researcher will purposefully refer to the centers where the participants will be available for sampling. According

to the inclusion criteria, eligible individuals will be selected from the list of patients and the researcher will call them for participating in the study. The researcher will invite the participants to participate in the study after introducing herself and gaining their trust. After obtaining the consent of the individuals for participating in the study, the interview will be conducted in a private and quiet place. The semi-structured interview begins by asking questions about the sexual health needs of women with breast cancer and the impact of the disease on their sexual health, for example, what needs do you feel in your sexual life since the diagnosis? and based on your experience, what problems do breast cancer patients face in terms of sexual health? will continue according to the interview guide. Probing questions such as “Can you explain more?” or “Can you give an example?” will be asked of the participants for deeper evaluations. In addition, the researcher will use field notes in such a way that she will record what she sees and hears, as well as the postures and movements of the participants separately. She will pay attention to them during the analysis of the findings.

### Data analysis

In this stage of the study, data analysis will be performed simultaneously with data collection using the conventional qualitative content analysis method. After each interview, it is listened to and transcribed verbatim. Then, the unit of analysis will be selected (preparation stage). This stage of analysis will be the basis for the data collection process in later stages. In this process, cycle back and forth between the stages of data collection and analysis, makes the study richer. Listening to the interviews and reading the text over and over, the researcher tries to immerse herself in the data and gain an in-depth overview of them, and meaning units are formed accordingly. In the next stage, the meaning unit will be as concise and compressed as possible and its important words will be selected as prominent code and key concepts. Then the codes will be categorized according to their relationship to each other and placed under sub-subcategories which will be put in subcategories based on their similarities and differences with each other (organization stage). Then, the main categories will appear and the report of the results will be presented.

### Rigor and trustworthiness of qualitative data

To ensure the trustworthiness of qualitative data, four important criteria of credibility, dependability, transferability, and conformability should be considered.<sup>[26]</sup> For the credibility of the data, long-term engagement with the research subject, in-depth interviews, selection of participants with maximum variation, and review by participants and professors will be used by the researcher. In order to confirm the dependability of the data, accurate record of research

stages, providing examples of how to extract categories, and provision of excerpts from the interview texts will be provided for each category. To investigate the transferability of the data, the external review of the individuals with the characteristics of the study participants who are not present in the study will be used. Conformability of the data will be done by preserving the documents in all phases of the research and providing the texts of some interviews and extracted categories to some faculty members who are not a member of the research team and they are asked to examine the accuracy of the coding process and extraction of the categories.

### Phase II: Literature reviews

After analyzing qualitative data and explaining the needs and strategies for promoting sexual health of women undergoing breast cancer treatment, the related literature will be reviewed. The aim of the literature review is confirm and complete the needs and strategies explained in the first phase of the research and determine the content of sexual health program. Using keywords such as (sexual health or sexual health promotion or sexual function or sexual dysfunction or sexual experiences or sexuality) and (breast cancer or breast neoplasms or breast tumors or breast carcinoma) and mastectomy and lumpectomy, the articles and texts which have been published during 2000–2021 and are available in known Persian and English databases, such as PubMed, Science Direct, and Web of Science, Cochrane Library, Scopus, Pro Quest, Ovid, Magiran, SID, MEDLINE Embase CINAHL will be reviewed. The findings of this phase will be analyzed using the matrix method. The stages consist of four stages: Searching and keywords, organization of the existing documents, summary of the documents as tables or texts, and review of the critical texts will be written in the first to fourth folders respectively.<sup>[26]</sup>

### Phase III: Design of the interventional program

In this phase of the study, sexual health needs and strategies will be extracted using the results of the first and second phases of the study. Then, in order to prioritize the strategies, a checklist will be prepared and will be sent to the panel members by E-mail. Panel members include oncologists, psychiatrists, gynecologists and reproductive health specialists, psychologists, midwives, oncology nurses and managers, and health policy-makers. After collecting checklists and reviewing the opinions of experts, the initial version of the program will be designed and reviewed in meetings with members of the panel of experts. The interventional program is expected to be finalized in three rounds after reviewing the opinions of panel members.

### Phase VI: Quantitative study

The aim of the quantitative study is to determine the effect of implementing the sexual health promotion

interventional program on sexual quality of life, sexual satisfaction and sexual function of women undergoing breast cancer treatment. The quantitative study will be a quasi-experimental and two-stage study with pre- and postintervention design and a sample size of 60 participants. The type of the intervention will be selected based on the results of the previous phases and the opinion of the expert panel.

### Study environment and population

The research environment will be clinics, hospitals or centers that provide services to women undergoing breast cancer treatment. The target population of the quantitative study consists of women with breast cancer who refer to these centers or have a medical record there.

### Inclusion and exclusion criteria

The inclusion criteria for this phase of the study include women with breast cancer that at least 6 months have passed from their treatment period, aged between 18 and 50 years, married (with at least 1 year of marital life), and being not in advanced stages of the disease. The exclusion criteria include unwillingness to continue co-operation and leaving the study at any stage of the research.

### Data collection method

In this phase of the study, data will be collected by means of questionnaire. To measure the quality of sexual life of women undergoing breast cancer treatment, the sexual scales of The European Organization for Research and Treatment of Cancer QLQ-BR23 will be used. This questionnaire includes functional and symptomatic scales. The functional scales include body image, sexual function, and sexual pleasure. The symptomatic scales include arm symptoms, breast symptoms, discomfort caused by hair loss, and treatment side effects.

The Rosen Female Sexual Function Index, which is a multidimensional self-report questionnaire, will be used to assess the sexual function of women undergoing breast cancer treatment. This tool measures women's sexual function by 19 questions in the dimensions of sexual desire, sexual arousal, vaginal lubrication, orgasm, sexual satisfaction, and dyspareunia. The Larson standard sexual satisfaction questionnaire will be used to assess sexual satisfaction. This questionnaire consists of 25 questions including 13 negative and 12 positive questions. The answers will be scored based on a 5-point Likert scale. Answers to the options "never" and "always" are scored one and 5, respectively. A score of <50 indicates sexual dissatisfaction, 51–75 low sexual satisfaction, 76–100 moderate sexual satisfaction, and a score higher than 100 means high sexual satisfaction. The validity and reliability of the questionnaires used in studies have been confirmed in Iran.<sup>[27-29]</sup>

### Data analysis

The collected quantitative data will be analyzed using the descriptive and inferential statistical methods by the SPSS version 21 software (IBM CompanyUSA). Independent *t*-test will be used to compare quantitative baseline characteristics in the intervention and control groups, and Mann–Whitney test will be used to compare the qualitative baseline characteristics. Multivariate analysis of variance will be used to compare the mean scores of sexual quality of life, sexual satisfaction, and sexual function between the intervention and control groups.

### Ethics approval and consent to participate

Ethical approval for this study has been obtained by the ethics committee affiliated with Isfahan University of Medical Sciences, Isfahan, Iran (IR.MUI.RESEARCH.REC.1399.501). Participation in this study was completely anonymous and based on written informed consent.

### Ethical considerations

The researcher starts study after obtaining approval from the ethics committee of Isfahan University of Medical Sciences and the necessary coordination with the officials of the sampling centers. Introduces herself to the participants and research units, explains the purpose of the research to them, and oral and informed consent will be obtained before entering the study. Participants will be assured of the confidentiality of the information collected and the anonymity of the participants' names. Participants are also reminded that they can withdraw from the study at any stage of the study. Participants are reminded that the study does not pose a particular risk to them and can benefit from further training if desired.

## Discussion

As breast cancer targets one of the sexual organs of women and is directly related to their sexual identity, it can disrupt their sexual function and satisfaction and affect the foundation of the family.<sup>[30]</sup> In most societies, breasts are considered as more than just an organ. Feminine identity, a sense of femininity, sexual orientation, attractiveness, and breastfeeding are concepts which are directly related to the breasts.<sup>[31]</sup> Accordingly, breast loss has negative consequences on one's body image and self-concept.<sup>[32]</sup> Continued sexual intercourse is an important aspect of quality of life for patients with cancer, especially in young women. Thus, communication and participation in sexual activity can make them feel normal and improve their relationship with their sexual partner.<sup>[33]</sup> The social structures and stereotypical roles expected by society sometimes cause women with breast cancer, especially those who had mastectomy, to be affected by social stigmas and lose their femininity and self-concept. Given the fact that



sexual desire is influenced by biological, cultural, social, and cognitive factors, breast cancer can impair the sexual function of these women.<sup>[34]</sup> In some cultures, sexuality is conceptualized based on gender characteristics, in which women deny their sexual desire, while talking about sexual issues is considered normal for men.<sup>[35]</sup> Studies have shown that many sociocultural factors such as marital status, quality of marital relationship, economic issues, financial support, traditions, isolation, stigma, fear of rejection, communication problems with the sexual partner, changes in intimacy between couples, education level of patients and their spouses, religion, and incorrect information affect the sexual health of patients with cancer.<sup>[36,37]</sup> As such, improving the sexual quality of life of patients with cancer requires intervention programs focusing on physical, psychological and communication interventions.<sup>[38,39]</sup> Cancer patients regardless of gender, age, and type of cancer need to receive sexual health services and access to sexual health services should be provided for these patients.<sup>[40]</sup> Therefore, recognizing the sexual health needs of patients with cancer can help to remove barriers and providing sexual health services for them in the health system.<sup>[41]</sup> The mixed method, is like a bridge between the gap between quantitative and qualitative research.<sup>[42]</sup> In which the distance between the two objective and subjective views is covered and due to the combination of the two views, the study becomes stronger and a deeper understanding is created. In fact, in cases where the researcher can not answer the research question based on a quantitative or qualitative perspective, by combining the two perspectives can gain a better understanding of the research problem and this is the basis of the combined approach. By combining both quantitative and qualitative perspectives, the researcher can achieve different perspectives and stronger results.<sup>[43]</sup> We hope that by conducting, will be recognized and by implementation of this interventional program in healthcare centers the sexual health needs of patients will be met and their sexual health will be promoted.

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### Conflicts of interest

There are no conflicts of interest.

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