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# A comprehensive interventional program for promoting sexual function in postmenopausal women: Protocol for a mixed methods study

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## Abstract:

**BACKGROUND:** Menopause is a natural event in women's life that leads to physical, psychological, and social consequences. A fundamental health concern in postmenopausal women is problems with their sexual function. This study aims to design an interventional program to promote sexual function in postmenopausal women.

**MATERIALS AND METHODS:** This sequential exploratory mixed methods study will be conducted in three phases. The first phase will be a qualitative study with a content analysis approach. The participants will be selected using a purposive sampling in Isfahan, Iran. The data will be collected through in-depth interviews and field notes and analyzed using conventional content analysis. In the second phase, the intervention will be designed and finalized to promote sexual function in postmenopausal women using the results of qualitative study and literature review, asking experts' opinions, and holding specialized panels. In the third phase, the intervention will be implemented (in the form of a quasi-experimental study) and the effect of the intervention will be determined. In this phase, the data will be collected using the female sexual function index. Finally, an appropriate interventional program will be presented.

**CONCLUSION:** It is hoped to promote sexual function in postmenopausal women by conducting this study and implementing an appropriate interventional program that is culturally sensitive. If it is proved that the intervention is effective, a basis for health policy-making to promote sexual health in postmenopausal women can be provided by presenting evidence and increasing the knowledge in this field of health.

## Keywords:

Iran, menopause, mixed methods study, postmenopause, sexual function, women

## Introduction

Menopause is a natural event in women's life that leads to physical, psychological, and social consequences and can affect women's quality of life.<sup>[1]</sup> Today, the number of postmenopausal women has increased with the increase in the number of women in the world, so it is predicted that by 2030 there will be 1.2 billion menopausal women in the world.<sup>[2]</sup>

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A fundamental health concern for menopausal women is problems in their sexual function.<sup>[3]</sup> Sexual dysfunction in women after menopause is a complex disorder that has several causes such as biological, psychological, interpersonal, and sociocultural.<sup>[4,5]</sup> In addition, other menopause-related changes such as the body image, psychological health, and lifestyle affect sexual function in women.<sup>[6]</sup> In general, physical and psychological changes after menopause affect women's understanding of their efficiency, potential, and abilities in sexual situations.<sup>[7]</sup>

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According to several studies, sexual function considerably decreases in women after menopause.<sup>[8-11]</sup> Studies have indicated that between 25% and 85% of postmenopausal women experience sexual dysfunction.<sup>[12,13]</sup> Despite the high prevalence of sexual dysfunctions in women with age, most middle-aged women (aged between 40 and 60 years) are sexually active and sex is important to them.<sup>[14]</sup> However, middle-aged women have negative attitudes toward sexual issues and believe that the end of fertility means the end of sexual life, and despite the inner desire for sex, they refuse to express their sexual needs.<sup>[15]</sup> In many societies, women avoid talking about sex and related topics. In the Iranian culture, talking about sexual issues is considered taboo and based on cultural norms, Iranian women refrain from expressing sexual thoughts and desires, especially during menopause, affecting their sexual desire.<sup>[16]</sup> Finding solutions to improve sexual health seems very important because it predicts happiness and satisfaction in life.<sup>[17]</sup> Desirable sex life is an important element in human wellbeing, especially in the postmenopausal period.<sup>[18]</sup> Therefore, it is important to consider preventive measures to decrease complications and improve sexual satisfaction. However, several studies have been mostly focused on determining the effect of educational programs on improving the quality of life in postmenopausal women.<sup>[19]</sup>

In many studies, educational and consulting programs have been limited to coping methods for controlling the symptoms of menopause.<sup>[20,21]</sup> Menopause is a transient biological event; however, it shows a social change with different levels of importance in cultures. Therefore, the sociocultural history may affect women's understanding and experience of sexual function in menopause.<sup>[22]</sup> Developing programs to improve health especially culturally sensitive issues such as sex, as well as considering the attitudes and beliefs of society can increase the effectiveness of such programs. Thus, there is a need to conduct a deep study to design and implement native interventions to promote sexual function in postmenopausal women. In this regard, this mixed methods study aims to design an interventional program to promote sexual function in postmenopausal women.

## Materials and Methods

This study is an exploratory mixed methods study with a consecutive (qualitative-quantitative) design. It will consist of three phases. In the first phase, a qualitative study will be conducted. Then, an interventional program to promote sexual function in postmenopausal women will be designed. To do so, the results of qualitative studies and a review of the literature will be used. The obtained strategies will be adjusted by the Delphi method and prioritized by experts and

then the draft of the program will be designed. Then, in a panel of experts, the required modifications will be applied to the draft and the final version of the intervention will be prepared. In the third phase, the interventional program will be implemented in the form of a quasi-experimental study and its effectiveness will be determined [Figure 1].

### First phase: Qualitative study

#### Objectives

- Explaining postmenopausal women's perceptions and experiences of sexual relations. Explaining appropriate solutions to promote sexual function in postmenopausal women.

This phase will be designed for answering the question of: "How are the perceptions and experiences of postmenopausal women about their sexual relations?" and "What are the appropriate strategies to improve the sexual function of postmenopausal women?" from the viewpoint of participants. This phase will be conducted using a qualitative content analysis method.

**Participants:** Participants consist of postmenopausal women, midwives, gynecologists, reproductive health professionals, psychiatrists, and psychologists who are willing to take part in the study in Isfahan, Iran.

**Sampling method:** Participants will be selected with a purposeful sampling method. Postmenopausal women will be selected based on maximum variation strategy

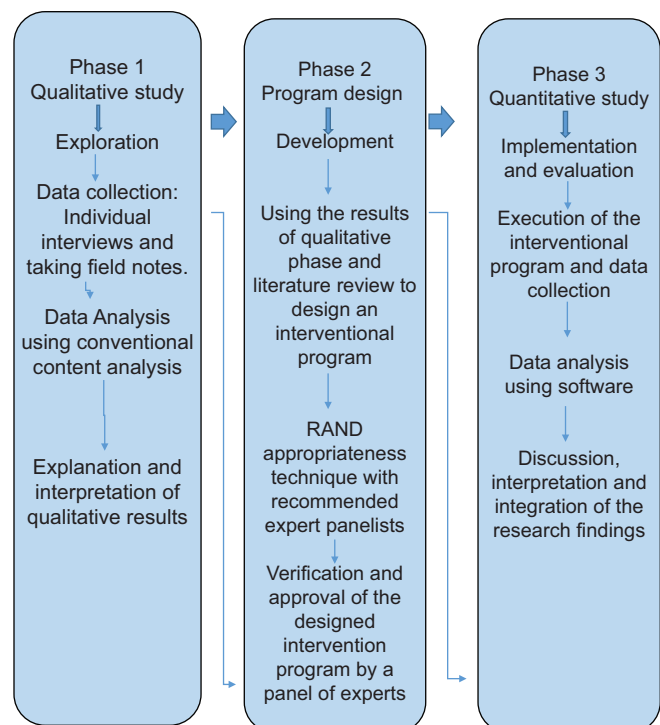


Figure 1: Study visual diagram

in educational level, socioeconomic status, job, age, and duration of the onset of menopause.

#### *Inclusion criteria for postmenopausal women*

- Natural menopause.
- The age range between 40 and 60 years.
- Having primary and higher education. Being married and living stably with a husband.
- At least 1 year has passed since the permanent marriage and that the woman is the only wife of her husband. Not having a history of diagnosed major psychological problems undergoing drug treatments.
- Absence of a history of drug and alcohol abuse in both wife and husband.
- Absence of premature ejaculation or impotence in husband according to the self-reports.
- Absence of a history of surgery in the participants and their husbands, such as prostatectomy, hysterectomy, oophorectomy, mastectomy, and other breast surgeries.
- Absence of unpleasant events during the last 6 months, such as the death of parents, etc.
- Not having any chronic diseases affects sexual function in the participants and their husbands (including systemic diseases such as liver, kidney, and lung failure), cardiovascular diseases, malignant diseases, psychological diseases, mood disorders (depression, anxiety), ulcerative colitis, vasculitis, thyroid and adrenal cortex diseases, diabetes, high blood pressure, central nervous system disorders, infectious, and sexually transmitted diseases.
- Not using the most common groups of medications that can cause sexual problems.

#### *Inclusion criteria for healthcare providers:*

- Having at least 2 years of work experience.

*The research setting:* Access to the participants will be through comprehensive healthcare centers, gynecologic clinics of educational hospitals affiliated with Isfahan University of Medical Sciences, sexual health clinics, private offices of gynecologists and psychiatrists, psychology and counseling centers, and midwives' offices.

*Data collection process:* After obtaining permission from the Isfahan University of Medical Sciences, the researchers will select the participants by referring to research environments. After selecting each participant, the researcher will introduce herself and state the main objectives of the study to gain participant's trust to ensure the confidentiality of the interviews. After explaining the goals and methods of the study, the researcher will obtain the written consent forms for participating in the study, interviews, and recording the interviews. In the qualitative phase, data collection methods include individual, in-depth, and semi-structured interviews and

field notes. The interviews will be conducted at the place and time chosen by the participants for their convenience and will be recorded using an MP4 device. The researchers will ensure that the participants are free to discontinue their cooperation with the study whenever they want. In the semi-structured individual-interviewing method, the first several interviews are conducted to get acquainted with probable and unpredicted issues. The interviews will be started with open questions such as "What effect has menopause had on your sexual relations?" and then will be continued based on the answers. After the end of each interview, the interview will be transcribed at the earliest time and data analysis will be carried out simultaneously with data collection. Data collection will be continued until data saturation that is, when no new data code is extracted. In this stage, the saturation of data will be confirmed.

*Data analysis:* Conventional content analysis method proposed by Graneheim and Lundman (2004)<sup>[23]</sup> will be used for data analysis. In this study, each interview will be immediately written word by word after recording. After extracting its general idea, the text will be read line by line, meaning units will be determined, and from these units, compressed meaning units and codes will be extracted. After extracting the initial code, data reduction will be done, and eventually subcategories, categories, and the main categories, respectively, will appear from these codes.

*Rigor and trustworthiness:* To assure the rigor of the data, four criteria are suggested: credibility, dependability, transferability, and confirmability.<sup>[24]</sup> Different measures will be considered to improve credibility of the data, such as selecting the participants with maximum variation, spending sufficient amount of time on data collection, performing in-depth interviews in different locations and times, and mixing multiple data collection methods including individual interviews and field noting. For verification of extracted codes or their modification, they will be reviewed by the participants. To confirm the reliability of the findings, some examples of code extraction methods and their corresponding interview narratives will be reviewed by an external supervisor to control the accuracy of researcher's perception and to find contradictory cases. For increasing transferability, study findings will be presented to people who have similar characteristics with the participants to compare the results of this study with their own experiences. Regarding verification, the researcher will explain the whole procedure, including recording, transcription, code extraction, and categorization. To verify the coding procedure, some of the research colleagues and faculty members who are acquainted with qualitative research analysis are asked to review the procedure.

## Phase II: Designing the interventional program

### Objectives:

- Identifying promoting strategies for sexual function in postmenopausal women according to the literature.
- Prioritizing the promoting strategies of sexual function in postmenopausal women (obtained from the qualitative study and review of the literature) by experts.
- Developing a draft of an interventional program to promote sexual function in postmenopausal women and determining the opinions of experts regarding the appropriateness of its content.

### A: Literature review.

After collecting data using a qualitative method, the second phase of the study will be started. This phase will be aimed at designing the interventional program to promote sexual function in menopausal women. Explaining the postmenopausal women's perceptions and experiences of sexual relations and explaining the appropriate strategies from the participants' points of view, the research will review the literature. The literature will be reviewed to confirm and complete the interventional strategies obtained in the qualitative stage to design the interventional program. The method of review will be narrative review with searching in electronic and library resources, including reference books and theses. Multiple databases are available for searching the related papers, such as Scopus, MEDLINE, Ovid, ProQuest, Cochrane Library, Science Direct, Web of Science, PubMed, Embase, Springer, Google Scholar (as a search engine), CINAHL, WHO, Magiran, SID, and Iranmedx. All the studies published between 2000 and 2022, both in English and Persian languages with qualitative, quantitative, and mixed methods studies and with the keywords: sexual function, sexual dysfunction, sexual health, sexuality, sexual relations, sexual satisfaction, menopause, and women, will be studied and analyzed.

### B: Concluding the results of the literature review and the findings of the qualitative study, and prioritizing the strategies.

In this stage, the strategies from the literature review and qualitative study will be adjusted using the Delphi method<sup>[25]</sup> and prioritized by experts. To do so, a decision matrix will be used; the draft of strategies obtained from the review of the literature and qualitative study will be developed in the form of the decision matrix and presented to 10 to 15 experts (reproductive health specialists, gynecologists, and health promotion specialists) to prioritize the strategies in terms of importance, requirement, and applicability. Each dimension will have a point between 1 and 3. After

completing the decision matrix by experts, collecting opinions and strategies will be prioritized based on the score of each member for each dimension. Then, the strategies with high prioritization will be identified and appropriate interventional methods will be selected.

### C: Holding a panel of experts.

After designing and compiling the draft of the interventional program, a panel of experts including reproductive health specialists, gynecologists, health education and health promotion experts, and other specialists if necessary (based on the draft of the intervention) will be held. The experts will be asked to express their opinions about the designed interventional program. Finally, the required amendments will be applied and the final version will be presented.

## Phase III: The implementation of the intervention program (quantitative study)

### Objectives:

- Determining the effect of the interventional program on promoting sexual function in postmenopausal women.

**Type of the study:** The interventional program will be implemented in the form of a quasi-experimental study consisting of two groups (intervention and control) at the individual level to determine the effectiveness of the intervention.

**Research population:** The population consists of all postmenopausal women, and their husbands if necessary, who will refer to the research settings during the study.

**Research sample:** The research samples will be postmenopausal women, and their husbands if necessary, who have the inclusion criteria.

**Research environment:** The research setting includes comprehensive healthcare centers, gynecologic clinics affiliated with Isfahan University of Medical Sciences, sexual health clinics, private offices of gynecologists and psychiatrists, and midwives' offices in the city of Isfahan.

**Sample size and sampling method:** The sample size calculation will be based on the results of previous studies, considering 95% confidence interval, 80% test power,  $S = 0.1-0.25$ , and 10% loss. Afterward, the postmenopausal women with inclusion criteria will be selected from each center via convenience sampling method.

### Inclusion criteria:

- Obtaining a score of less than 28 from the female sexual function index questionnaire.

Other inclusion criteria will be the same as the qualitative study.

**Exclusion criteria:**

- Diagnosis of other diseases in the participants or their husbands during the program and follow-up process, which will affect their sexual function.
- Unwillingness to continue cooperation at each stage of the research.
- Failure to receive 50% of the intervention for any reason.
- Failure to complete the questionnaire completely.

**Research variables:** The designed intervention will be considered as an independent variable, and the sexual function of postmenopausal women will be considered as dependent variable.

**Data collection tools:** Data will be collected using appropriate tools (such as female sexual function index questionnaire) and will be completed before and after the intervention.

**The implementation method:** The researcher will implement the designed program after obtaining permission from ethics committee of Isfahan University of Medical Sciences and performing the necessary coordination with the designated centers' officials. This is done by referring to the centers and presenting a letter of introduction to the authorities of those centers regarding research objectives. After that, the researcher will be allowed to access the phone numbers of postmenopausal women, call them to explain research objectives, and invite them to participate in the research. If the women are willing to cooperate and have all the inclusion criteria, they will be selected by convenience sampling method with their informed consent. Before intervention, the questionnaires will be filled by women in each of the two groups. After the implementation of the intervention program, the questionnaires will be completed again in the intervention and control groups.

**Data analysis:** The collected data will be analyzed by descriptive statistical methods (mean, standard deviation, minimum, and maximum), inferential statistics (paired *t*-test, Chi-squared test, Fisher's exact test, analysis of variance, Wilcoxon test, and Mann-Whitney test), and by using SPSS v20 software.

**Ethical considerations**

The Ethics Committee of the Isfahan University of Medical Sciences, Isfahan, Iran, approved the protocol of this study (code number: IR.MUI.NUREMA.REC.1401.165). Informed consent, anonymity, confidentiality of information, and the right to withdraw at any time will

be observed. Also, the reasons for the study will be explained before each individual interview.

**Discussion**

In general, the population aging is progressing at a rapid pace worldwide. Healthy aging is the right of all human beings, and what modern knowledge focuses on is not only prolonging life but also it should be noted that the prolonged life should be spent in peace and physical and psychological health. Otherwise, scientific advances to ensure longer life will be inefficient.<sup>[26]</sup> Considering increased life expectancy as a current trend, most women spend about a third of their life in the postmenopausal period.<sup>[27]</sup> Therefore, promoting sexual health in this period is of great importance and it is necessary to consider the health problems such as sexual problems in this group of women.<sup>[28]</sup> In this mixed methods study, a sequential exploratory approach will be used for providing an interventional program sensitive to the culture and conditions of Iranian society to improve the sexual function of postmenopausal women. Sequential exploratory approach is a known method for researching, especially when little information is available about the study subject. It is an appropriate method for achieving participants' experiences. When one method is not sufficient for revealing the study subject, it is better to use a combination of two methods.<sup>[29]</sup> Using a mixed methods study will help the researcher gain a more comprehensive understanding of the phenomenon and relate its different aspects with each other.<sup>[30,31]</sup> Since the present research question has a new multidimensional nature and the researcher is not able to predict the factors that will affect the subject, therefore, it seems that the use of a mixed methods study and the application of both the qualitative and quantitative methods will be an appropriate way to reach the goals of the study. It is expected to improve the sexual health of menopausal women by conducting this exploratory mixed methods study, designing and implementing an appropriate, native, and culturally sensitive interventional program. If it is proved that the intervention is effective, a basis for health policy-making and planning programs to promote sexual health in postmenopausal women can be provided by presenting evidence and increasing the knowledge in this field of health.

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**Conflicts of interest**

There are no conflicts of interest.

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