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# Design, development, and evaluation of a self-care program for women with osteoporosis: The protocol of a mixed-method study

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## Abstract:

**BACKGROUND:** Osteoporosis, the fourth most common disease in the world, affects the elderly and postmenopausal women and imposes a great financial and social burden on individuals and society. Furthermore, it has a significant impact on the quality of patients' life. This study tries to take an effective step toward improving the quality of patients' life by developing and evaluating the self-care program of women with osteoporosis.

**MATERIALS AND METHODS:** In this research, a hybrid sequential design of quantitative and qualitative type consisting of three phases is used. This mixed-method study aimed to develop and evaluate a self-care program for women with osteoporosis.

**CONCLUSION:** Familiarity with the needs of these patients and the use of self-care programs and considering social, cultural, and psychological factors could be effective steps to improve the health of women with osteoporosis. These steps can improve the quality of life and reduce the costs of treatment for this group of women.

## Keywords:

Osteoporosis, program, protocol study, self-care, women

## Introduction

Osteoporosis is the most common metabolic bone disease, which increases the fragility of the bone by reducing bone density and loss of bone microstructure, and consequently increases the risk of fracture.<sup>[1,2]</sup> The World Health Organization identifies osteoporosis as the fourth most common enemy of humans after cancer, heart attack, and stroke.<sup>[3,4]</sup> It is also recognized as one of the chronic diseases.<sup>[5]</sup> Due to the significant increase in life expectancy, the prevalence of osteoporosis is increasing in different parts of the world. The prevalence of osteoporosis in women is 4-1 compared to men. Moreover, in European societies,

one person fractures due to osteoporosis every 30 min.<sup>[6]</sup> According to statistics, about 70% of women over 50-year-old and 50% of men over 50-year-old in Iran suffer from osteoporosis and osteopenia.<sup>[7]</sup>

Fifty-year-old women are about 30%–40% at risk for osteoporotic fractures during their lifetime. The mortality risk from osteoporosis during a woman's lifetime is equal to the mortality risk from breast cancer and about four times higher than dying from uterine cancer.<sup>[3]</sup> A 3-year follow-up in Iran has shown that a significant number of patients with pelvic fractures have been women, and this rate has increased with age.<sup>[8]</sup> Generally, it can be said that the

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incidence of pelvic fractures in women and men is 4.2% and 2.04%, respectively, and it is estimated that this rate will reach 61,635 by 2020 and 100,465 by 2050.<sup>[9]</sup> Thus, about 85% of the global burden of osteoporosis and 12.4% of the burden of osteoporotic fractures in the Middle East are related to Iran.<sup>[10]</sup>

Moreover, the economic costs of osteoporosis are very high, and in the United States, the direct cost of a fracture due to osteoporosis is between 12 and 18 billion dollars, and indirect costs are added to it. These costs are increasing due to the high prevalence of osteoporosis.<sup>[11]</sup> Osteoporosis mortality and the burdens have always been significant due to frequent bone fractures, treatment costs, and hospitalization. Prevention has played an important role in improving the quality of life, reducing mortality rate, and decreasing medical expenses.<sup>[8,12]</sup>

Due to the high number of patients and the impact of osteoporosis on women's quality of life, self-care can be effective in treating and controlling the disease. Self-care includes learned, purposeful, and conscious actions that people take daily to maintain and improve their health so that they can meet their physical, mental, and social needs and prevent illness and incidents.<sup>[7]</sup>

By emphasizing patients' potential abilities instead of relying on disabilities, the self-care program empowers patients to take care of themselves, reduces intangible costs, and improves the quality of life and the level of daily activities.<sup>[13]</sup> Self-care also focuses on physical, mental, and social activities to maintain health and well-being.

The self-care program in women with osteoporosis can improve the quality of their life and reduce costs, and prevent or delay the acute and chronic complications of osteoporosis. In many societies, women usually do not prioritize self-care and thus are affected by cultural, financial, and social factors. Developing a self-care program for women with osteoporosis is highly demanding but there is still no program in this field in a country like Iran. Therefore, the present study is proposed to design and develop a self-care program for women with osteoporosis.

### Goals of the study

This mixed-method study aims to develop and evaluate a self-care program for women with osteoporosis. This study is carried out in three phases as follows:

- The first phase of the study (qualitative phase) explains and identifies the needs, opportunities, and barriers of self-care for women with osteoporosis
- The second phase (program design) designs a self-care program for women with osteoporosis

- The third phase (program evaluation) evaluates the content of self-care program for women with osteoporosis using the modified Delphi RAM technique.

## Materials and Methods

In this research, a hybrid sequential design of quantitative and qualitative types consisting of three phases has been used. In the first phase, a qualitative study begins with the aim of identifying the self-care needs of women with osteoporosis, and the content analysis method is used to analyze the data. In the second phase, the initial design of the self-care program for women with osteoporosis is designed using the findings of the first stage and a review of the texts. In the third phase, the modified Delphi technique is used to evaluate the program. All steps are shown in Figure 1.

### Phase one: Qualitative study

In this phase, the needs of women with osteoporosis are identified using in-depth and semi-structured interviews. Then, the data are analyzed using qualitative content analysis.

### Participants

In the present study, the selection of participants is done purposefully. Thus, after obtaining the necessary permissions for visiting the endocrinology and metabolism center at Isfahan University of Medical Sciences, patients and experts who meet the inclusion criteria in the field of care for women with osteoporosis are selected. Then, after obtaining written consent, the context for conducting interviews with them is provided. The researcher continues to select and interview the participants until the data are saturated. The interviews are continued until the new interviews do not add any new data to the previous ones. In

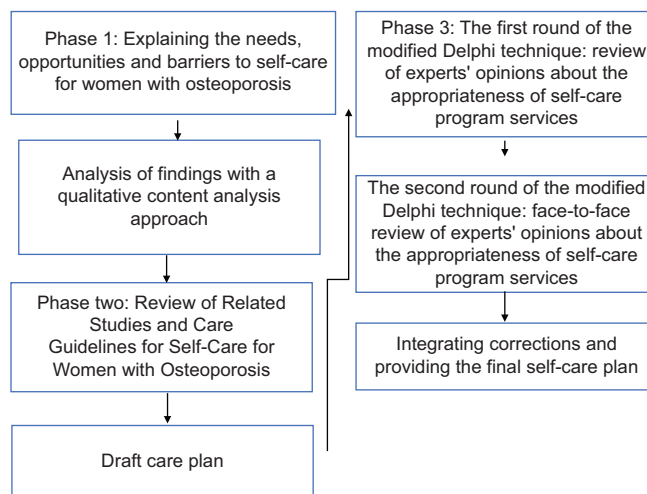


Figure 1: All steps the program

qualitative research, the number of participants is determined during the study. The method of selecting participants in qualitative research is nonrandom and purposeful, which may be based on inclusion criteria and continue gradually until saturation is achieved.<sup>[14]</sup> Participants also become highly involved in the study as they have no new ideas to state. Therefore, in these studies, there is no need to estimate the number of participants in advance, and the purposeful sampling method is often used.

### Inclusion criteria

Women with osteoporosis, managers, physicians, nurses, faculty members, and all those who are in a way involved with these patients and want to participate in the study and have the required communication skills are selected. This means that they should be able to willingly and freely exchange their experiences, feelings, and information with the researcher.

### Data collection method

After selecting eligible participants purposefully and obtaining the required consent, they are invited to record an in-depth, semi-structured, and individual interview. The first few interviews are conducted to familiarize the researcher with how to interview. Using the information obtained, general questions are identified for subsequent semi-structured interviews. In semi-structured interviews, there are no fixed and predetermined questions, and they are based on the interview process. Interview guide questions are reviewed after several interviews and new ideas are obtained. The duration of each interview depends on the situation and environmental conditions and the agreement of the parties, the subject of the interview, and the method used. Interview and sampling continue until data saturation is obtained.

The method of data analysis in the qualitative stage:

In this research, the content analysis method is used to analyze the data.<sup>[15]</sup>

Accuracy and robustness of qualitative data:

Credibility, transferability, dependability, and conformability are used for data accuracy.<sup>[16]</sup>

### Phase two: Initial design of self-care program for women with osteoporosis

At the beginning of this stage, to initially design a self-care program for women with osteoporosis, the findings obtained in the first stage are used. Then, by reviewing texts and similar studies in the field of self-care for women with osteoporosis, the existing care are extracted. A narrative review of texts includes the search

of library and electronic resources to gain knowledge in this field. At the end of this phase, using the findings of the qualitative stage and review of the texts, the initial design of the self-care program for women with osteoporosis is created.

### Phase three: Evaluate the content of the self-care program for women with osteoporosis

RAM is a two-stage modified Delphi approach in which, in the first round, the scoring of the care indications is done individually by the relevant experts, and in the second round, the scoring is done in a face-to-face group discussion.<sup>[17]</sup>

Based on the results obtained from the qualitative stage and review of texts, a list of women's self-care cases is compiled in a table, sent to specialists for further analyses. Based on the RAM technique, each of the actions in the table is evaluated based on four criteria, "relevance, intelligibility, usefulness, and feasibility" and based on a scale of 1–9. Usefulness means, to what extent is the proposed action considered useful to achieve the goal? Clarity means, to what extent does the executor understand the writing of this phrase? Feasibility means, to what extent is it possible to provide this action? Relevance means, to what extent the proposed action is considered appropriate?<sup>[18]</sup>

Based on the scores obtained, each action is rated as "appropriate," "unspecified," or "inappropriate." Measures with average scores in the range of 1–3/9 are considered "inappropriate," in the range of 4–6/9 as "Unspecified or uncertain," and in the range of 7–9 as "appropriate." Below each action, a line is placed for the comments suggested by the panel members regarding how to write the action. Thus, if the action is not clear, they can submit their opinion for correction. At the bottom of each table, a few blank rows are inserted so that, if necessary, specialists can add other actions that they are interested in.<sup>[17]</sup>

The average final score assigned to each program action is calculated based on the scoring of the criteria in the RAM scale. The proposed actions that have a "suitable" score 7–9 are included in the final guide. If actions in the program do not score "appropriate," they will be reevaluated in the second round of consensus. In fact, in the second consensus, which is formed in the school of nursing, members are asked to comment on actions that the members do not agree on, in the first round, based on the content of the second evaluation program. At this stage, they are asked to comment on the removal or maintenance of the action, and if they wish to maintain that action, they should write strategies to improve its implementation. Finally, the necessary corrections should be taken into action based on the experts'

feedback to develop the final format of the self-care program for women with osteoporosis.

### Ethical considerations

The researcher will introduce himself/herself to the participants before the start of the study and after obtaining the approval of the Research Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.RESEARCH.REC.1399.450.), will explain the aims and method of the study. Assures them that their information will be confidential.

### Discussion and Conclusion

Osteoporosis is a universal and common disease that affects the elderly and postmenopausal women and imposes a heavy financial and social burden on individuals and society.<sup>[12]</sup> Evidence shows that about half of patients with chronic diseases do not follow their diets, indicating that social, cultural, and psychological factors are involved in these diseases.<sup>[19]</sup> In this regard, studies show that many women have no awareness about osteoporosis; and they need to be aware of the complications of osteoporosis and its management.<sup>[14]</sup> They also need to grow their knowledge and awareness of preventive measures for osteoporosis.<sup>[20]</sup> Developing a self-care program taking into account social, cultural, and psychological factors can be an effective step to improve and maintain the health of women with osteoporosis, which can consequently improve the quality of life and reduce the costs of treatment for this group of women. According to the purpose of this study, which is to develop and evaluate a self-care program for women with osteoporosis, an effective step can be taken to help these patients. The results of the present study can also be used by physicians, nurses, and treatment teams to help these patients.

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### Conflicts of interest

There are no conflicts of interest.

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