

Study protocol

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Quick Response Code:

Website: www.jehp.net
DOI: 10.4103/jehp.jehp_91_21

A reproductive and sexual health promotion program for women with heart diseases: A protocol for mixed methods study

Shahnaz Kohan¹, Nafisehsadat Nekuei², Masoumeh Sadeghi³, Minoo Movahedi⁴

Abstract:

BACKGROUND: Nowadays, for various reasons, the prevalence of heart diseases has increased in women during reproductive age. These diseases can lead to serious reproductive and sexual-related complications in the affected women. This study will conduct to develop a reproductive health promotion program for women with heart diseases.

MATERIALS AND METHODS: This is an exploratory sequential mixed methods study that will be conducted in four phases. The first phase is a qualitative research that is done using content analysis method and semi-structured individual interviews. The experiences of women with heart disease and health providers' team in educational hospitals, health centers, and private offices of physicians about reproductive health need will be explored. Purposive sampling will be continued until data saturation is reached and the conventional content analysis method will be used. In the second phase, the studies published from 2000 to 2020 will be reviewed by the matrix method and then will be analyzed by using thematic analysis. Integrating the results of these two stages, the draft of the program will be designed. In the third phase, the validation of the program will be checked by using the two-round modified Delphi method. In the fourth phase, the program will be implemented by the health system and its process will be monitored.

CONCLUSION: A life cycle reproductive health program for women with heart disease can help improve their preconception health, fertility planning, and sexual health and promote the well-being of these women in the long run.

Keywords:

Health services, heart disease, Iran, preconception care, reproductive health, women

Introduction

Today, the survival of girls with congenital heart disease was increased.^[1,2] Rising marriage age, delay in childbearing, and having an unhealthy lifestyle have been increased the number of reproductive-age women with heart disease.^[3,4] For this reason, special care for women with heart disease is also necessary for the field of reproductive health.

Pregnancy is associated with changes which can lead to cardiovascular complications in women with heart diseases.^[4] These diseases affect 1%–4% of pregnancies.^[3,5,6] In a study, it was shown that 1.57% of pregnant women had heart disease before pregnancy.^[7] Furthermore, they are the most prevalent indirect reason of maternal mortality^[8] and the cause of 15%–26% of maternal deaths worldwide.^[3,5,6,9] The death rate is reported to be 600–1000 per 100,000 live births in pregnant women with heart disease.^[3,9] Moreover, other

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How to cite this article: Kohan S, Nekuei N, Sadeghi M, Movahedi M. A reproductive and sexual health promotion program for women with heart diseases: A protocol for mixed methods study. *J Edu Health Promot* 2021;10:346.

¹Department of Midwifery and Reproductive Health, Nursing and Midwifery Care Research Centre, Isfahan University of Medical Sciences, Isfahan, Iran,
²Department of Midwifery and Reproductive Health, Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran,
³Cardiac Rehabilitation Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran,
⁴Department of Obstetrics and Gynaecology, School of Medicine, Al-Zahra Hospital, Isfahan University of Medical Sciences, Isfahan, Iran

Address for correspondence:

Ms. Nafisehsadat Nekuei, Department of Midwifery and Reproductive Health, Nursing and Midwifery Care Research Center, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezarjarib Avenue, Isfahan, Iran.
E-mail: nekuei@nm.mui.ac.ir

Received: 18-01-2021
Accepted: 25-03-2021
Published: 30-09-2021

pregnancy-related complications in these women include heart failure (11%),^[3,9,10] hospitalization during the pregnancy (26%), cesarean section (41%), fetal death (1.7%), neonatal death (0.6%), preterm birth (15%),^[11] neonatal admission to the intensive care unit (30%), postpartum hemorrhage (38%),^[12] congenital disease in the fetus, and intrauterine growth restriction.^[13] Intensive care before and during pregnancy can effectively reduce pregnancy complications in women with heart disease. Preconception care is one of the most important strategies for promoting reproductive health.^[9,14,15] The use of this service varies from 19%^[9] in one study and 63%^[12] and 55%^[16] in two other researches in women with heart diseases. In one research conducted in Isfahan, 81.82% of women with heart diseases did not receive preconception care.^[7] However, studies have shown that prepregnancy care is the best predictor of pregnancy outcome.^[12]

Another important concern is the fertility planning of these women. Restrictions on the use of some contraception methods and the risk of unwanted pregnancies should be considered. According to studies, women with heart disease do not receive adequate contraceptive services, as according to a study, 54% of these women did not receive any counseling with regard to contraception.^[16] According to another research, 21.7% of these women did not use any contraceptive method.^[17] Counseling and providing contraceptive methods in these women are necessary.^[16]

Sexual issue is another component of reproductive health in women with heart disease. Sexual dysfunction in these women (with a prevalence of 25%–41%) can negatively affect their quality of life. The cause of this problem is the nature of the disease, concern about the negative impact of sexual relation on heart disease, and drug consumption.^[18,19] In patients with congenital heart diseases, the New York association functional class may deteriorate during sexual activity.^[20] Therefore, providing adequate counseling and assessment can help them make informed decisions about this matter.^[13,21] According to a study, the use of structured educational methods and educational models by health-care providers and policy-makers leads to the empowerment of women of childbearing age to receive health care.^[22] In fact, using creative and new educational methods to teach healthy behaviors and promote the health literacy of these girls, and women can be effective.^[23] In addition, some other tools such as Perceived Health Competence Scale are also used to create simple, comprehensive, and understandable training programs for these patients.^[24]

There are several guidelines in the world to evaluate and improve the reproductive health of women with heart disease such as the guideline of the European Society

of Cardiology^[25] and the guideline for cardiovascular patients' care.^[26] In some countries, integrated clinics with a registration and follow-up system have been established in this regard.^[9,12,15,27,28] However, in many countries, these services are incomplete that is due to the lack of a comprehensive reproductive health care.^[16] For example, a joint cardiac obstetric clinic has been established in Cape Town. Mothers with heart disease are referred here from other centers and are evaluated by a multidisciplinary team. but this practice, does not include preconception care, contraceptive and sexual counseling.^[27] In another study in Iraq, due to the lack of a specialized team to evaluate mothers with heart diseases, one cardiologist is enrolled in the International EURObservational Research Program and with the cooperation of a team, performed training, and visits for mothers with heart diseases through this system. In this way, the outcome of pregnancy in these women improved. However, there were no other components of reproductive health in this registration and care system.^[29] In Iran also, the national health program of preconception care and the national guidelines for care of heart patients contain some components about the care of these women during pregnancy and childbirth.^[30] However, there is no comprehensive program for providing reproductive health services to these women in the current Iranian health-care system. Thus, the existence of a comprehensive standard team program to consider all aspects of reproductive health (i.e., care before and during the pregnancy, childbirth and after it, contraception, and sexual counseling) for these women, in accordance with the social, cultural, and health structure of Iran, seems to be essential. Based on the researcher's experiences, most Isfahanian women with heart disease do not have a proper referral for reproductive and sexual health care and the current health system does not have adequate competence and readiness to meet their needs. Deep touch of the problems caused by the health system's lack of attention to various aspects of these women's reproductive health and its resulting consequences, prompted the researcher to design this study with the aim of developing and monitoring a reproductive health promotion program for women with heart disease. In order to develop this program, first of all, the reproductive health needs of these women should be carefully evaluated. Then, the existing related programs in the world will be reviewed and the program will be developed. In addition, the views of experts and policy-makers of this field will be examined. As such, exploratory sequential mixed methods suits this study. Using several research methods, this approach leads to strong inferences. The main aim of this research is to develop and monitor a reproductive health promotion program for women with heart diseases. The objectives of the four stages of the study are as follows:

- First phase
 1. Exploring the reproductive health needs of women with heart disease from the perspective of women, health team members, managers, and policy-makers
 2. Exploring strategies for promoting reproductive health of women with heart disease from the perspective of women, health team members, managers, and policy-makers.
- Second phase
 1. Extract and prioritize the needs and strategies for promoting the reproductive health of women with heart disease based on the findings of the literature review
 2. Design the draft of the program for promoting the reproductive health of women with heart disease by integrating the results of qualitative phase and literature review.
- Third phase: Validation of the reproductive health promotion program for women with heart disease.
- **Fourth phase:** Assessing the applicability of the reproductive health promotion program for women with heart disease based on a study.

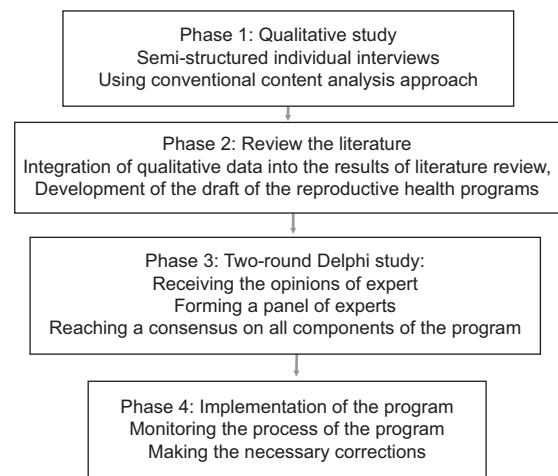
Material and Methods

Total study design

This is an exploratory sequential mixed methods study that will be conducted based on pragmatism paradigm in four phases. At the first phase with qualitative approach, needs and strategies related to the promotion of reproductive health in women with heart disease will be explored. The second phase integrates the results of the literature review with a qualitative study by using matrix method, and then, a reproductive health program for women with heart disease is developed in accordance with the structure of the health system and the available evidence. In the third phase, the program will be validated in a two-round modified Delphi method, and finally, in the fourth phase, the program will be implemented and will be monitored and modified. [Flow chart 1]

First phase: qualitative study Study design and setting

The first phase is a qualitative study which will be conducted using a conventional content analysis approach. The researcher seeks to explore needs and strategies related to the promotion of the reproductive health of women with heart disease in a specific context of Iran. In this phase, the codes are extracted directly from the interviews and concepts are obtained by categorizing the codes. Hospitals in Isfahan are divided into two general categories, including public (educational and noneducational) and private. The majority of patients with heart diseases are monitored in educational public hospitals, so research



Flow Chart 1: Total study design

setting in this study includes clinic or inpatient wards of educational hospitals of Isfahan University of Medical Sciences which provide services to women with heart diseases, the private office of cardiologists or obstetricians, comprehensive health centers, and maternal health policy units under the supervision of the Ministry of Health and Medical Education, School of Nursing and Midwifery of Isfahan University of Medical Sciences, and some other related centers in Isfahan. Based on the preference of the participants, the clinic, hospital, home, or any other suitable places will be used as the setting of the interview. According to the COVID-19 pandemic, online interviews are also used.

Study participation and sampling

The participants of the first phase of the study are women who are in the range of reproductive age (15–49 years), married, with known heart disease (at least 1 year has passed since the definitive diagnosis of the disease), Iranian, fluent in Persian, and willing to participate in the study and also health team members, managers, and policy-makers who have willingness to participate in the study, having at least 2 years professional experiences with regard to providing specialized services, and planning health program for women with heart disease.

The participants are selected using purposive and snowball sampling methods and based on the inclusion criteria until data saturation is reached and no new code is extracted from the interviews. In the selection process, maximum variation is considered in terms of age, type of heart disease, number of pregnancies, and duration of the disease. The health team is also selected from different groups such as cardiologists, obstetricians, midwives, and managers of different health-care structures.

Data collection tool and technique

In the first phase, after obtaining permission from the Vice-Chancellor for Research and Technology of

Isfahan University of Medical Sciences, the researcher will refer to the research settings and select women with heart disease who have been referred to these centers or members of the health team and the related policy-makers. After obtaining informed consent from individuals for participating in the study, the time and place as well as the manner of interview (face to face or virtual) will be determined based on the opinion of the participants. At the time of the interview, a secluded, quiet, and private place is chosen for the interview. Individual and in-depth semi-structured interviews will be conducted. Before each interview, written consent is obtained for participating in the study and audio recording. Oral consent will be recorded at the beginning of the interview. First, women with heart disease who have a history of pregnancy are selected. Then, based on the data of previous interviews, married women without children and single girls with heart disease are also interviewed in the next stage. Interviews will be recorded using a digital audio recorder. The interview process is defined by guiding questions designed based on a pilot study. The interview begins with general questions such as "Tell me about the first time you find out you have heart disease." The interview process continues with more detailed questions such as: "Did this illness affect your decisions and getting married?" and "Tell me about your planning for childbearing and contraception?" Then, the next questions will be asked based on answers to the previous ones. Through establishing a deep relationship with the participant and probing, the researcher tries to find deep and real information during the interview. The researcher also uses field notes (observation and hearing) and pays attention to the mood of the participants during the analysis. In addition, observation and taking notes of the evidence, available documents, related files and statistics, existing structure, National Health Service registration systems, and other related items (analysis of existing conditions) will be done.

Simultaneous with data collection, data analysis is performed using conventional content analysis method in three stages of preparation, organization, and reporting (Elo and Kyngäs method). So that in the first stage, after listening to each interview, the content of the interview is transcribed verbatim. Repeated listening to the sound and repeated reading of its written text lead to the selection of the unit of analysis (meaning unit) by creating a deep view (preparation stage). In the next stage, the meaning unit is compressed as much as possible and its important items are selected as code and key concepts. Then, the codes are categorized according to their relationship and similarities with each other in subcategories, (organization stage). In the third stage, the subcategories are categorized into main categories, and finally, the report of the results is presented.

The validity of the data will be strengthened using actions such as long-term engagement with the subject, conducting in-depth interviews in different times and places, proper communication with the participants before the interview, conducting interviews in the places agreed upon by the participants, selecting the participants with maximum diversity from different aspects, review of the results by the participants, review of the obtained concepts by the other colleagues of the research team, and using several data collection methods such as interviews and field notes.

To obtain transferability, the categories extracted from the study are reviewed by 3–4 people who have the characteristics of the participants without participation in the research. In this review, the similarities between their opinions and the results of the research are examined.

Second phase: the development of the program

In the second phase of the study, the review of the literature will be performed. First of all, Persian and English instructions, guidelines, and quantitative and qualitative studies of valid electronic and printed sources and databases published from 2000 to 2020 will be examined. The intended databases are as follows: PubMed, Scopus, Embase, Science Direct, Web of Science, ProQuest, OVID, Elsevier, Iran Medex, Magiran, SID, Cochran, and Iran Doc.

Studies will be searched using MeSH-matching keywords and their synonyms. Some of the keywords are as follows: preconception care, women, reproductive health, childbirth, contraceptive methods, heart disease, heart failure, prenatal care, sexual function, using the "AND" and "OR" operators.

Using the matrix method, all descriptive and interventional studies together with the systematic reviews and the related studies will be reviewed based on the thematic classification obtained from the qualitative phase. Qualitative studies are reviewed by thematic analysis, and the results of quantitative studies are used as expressions or sentences. Then, the existing guidelines, programs, and structures are reviewed by the matrix method and analyzed thematically with regard to the preconception and prenatal care, contraceptive methods, and sexual function of women, especially women with heart disease in the world, Iran, and Isfahan. In this method, the performed actions are set in four folders based on the taken steps:

1. The search process, keywords, and other components related to finding the intended texts are mentioned in the first folder
2. The existing documents are organized and arranged in the second folder
3. The documents are summarized as tables or text pages

4. A critical review of the texts is written based on the materials abstracted (G).

Then, the findings of the literature review are integrated with the results of the qualitative study, and the draft of the program for promoting reproductive health in women with heart disease is designed.

Third phase: validation of the program

The third phase of the study is performed in two rounds using the modified Delphi method.

First round

Study design and setting

The study setting of the first round of modified Delphi method is educational hospitals of Isfahan University of Medical Sciences which provide services to women with heart diseases, comprehensive health centers, and maternal health policy units under the supervision of the Ministry of Health and Medical Education, the Department of Midwifery and Reproductive Health of School of Nursing and Midwifery, Isfahan University of Medical Sciences, and other related centers in Isfahan.

Study participants and sampling

Cardiologists, obstetricians, reproductive health professionals, midwives, faculty members, managers, and policy-makers with at least 2 years of professional experience related to the manage of mothers with heart disease who have willingness to participate in the study will be selected using purposive sampling method.

Data collection tool and technique

Data collection tool at this phase of the study consists of two parts: the first part is the registration form of personal and demographic information, including age, occupation, level of education, degree, work experience, place of work, and managerial position (in policy-makers). The second part is the checklist for prioritizing and assessing the validity of the components of a reproductive health program for women with heart disease. In this checklist, program components, objectives, strategies, structure, performance, and task description are mentioned. The checklist options will be considered for ease of use and applicability, cost, time, and credibility. The scores range from 1 to 9. Score 9 corresponds to the "The advantages are expected to outweigh the disadvantages" option, and score 1 corresponds to the "The disadvantages are expected to outweigh the advantages" option. After calculating the average scores obtained for each question, the scores are categorized. Options with a score of 1–3 will be removed from the program as inappropriate options and options with an average score of 7–9 will remain in the program as suitable options. The controversial options (scores 4–6) will be reviewed in a panel of experts in the second round, and then, the main components of

the program are determined such. For data collection method after telephone or in-person contact with the research participants, if they wish to participate in the study, the subject of the study will be explained to them and written consent will be obtained from them. Then, the checklist which developed based on the results of the previous phases is provided electronically (e-mail, virtual networks, etc.) and if they wish in print to them so that they can read it and comment on it in a period of 10 days. After collecting these comments, the results are analyzed. The score of each section will be calculated. Then, the points of disagreement (score 4–6 in checklist) are examined in the panel of experts in the second round of Delphi.

Second round: The panel of experts

Study design and setting

In the second round of Delphi, after analyzing the results of the first round, the experts of the first round will be invited to be present in the panel. Setting of this stage of the study is the same as the first stage of Delphi.

Study participants and sampling

The participants in this phase of the study are the same participants in the first phase of Delphi.

Data collection tool and technique

In the face-to-face meeting and video conference, the components of the program, its structure and application, team members, prioritization of program sections, and other issues of disagreement in the first round will be discussed and the final form of the program will be presented. The content of the sessions will be recorded with the permission of the participants. The number and timing of the sessions and their structure will be arranged as required.

Fourth phase: Evaluation of the program by a pilot study

At this phase of the study, the developed program will be provided to the health system in Isfahan to be implemented for a period of 3 months. Then, the implementation process of the program will be monitored based on the indicators and scales appropriate to the program objectives and using a checklist and questionnaire from the perspective of all stakeholders. Based on the results of this phase, the necessary corrections will be applied to the program.

Ethical consideration

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences with the code of ethics, IR.MUI.RESEARCH.REC.1399. 061. In order to comply with ethical principles, written informed consent is obtained from all participants in the study. The time and place of interviews and specialized meetings are determined based on the opinion of the participants. Written and oral informed consent is obtained from the

participants in order to record audio in the interviews. All interview information will be kept confidential by the researcher.

Discussion

Consideration of the reproductive health dimension of women with heart disease, as a high-risk group, is important. Pregnancy with heart disease can lead to an increase in various complications such as arrhythmia, increased heart class, heart failure, and thromboembolism and postpartum hemorrhage.^[12] The above risks are differently demonstrated in different women and vary depending on the type of disease, individual factors, and assessment methods. In mild cases, the complications may be as severe as in women without heart disease, but the severe cases may increase mortality rate. Before pregnancy, the pregnancy-related risks should be explained to women individually and separately. In addition to the mother's intention, issues such as previous complications, the type of heart disorder, the use of teratogenic drugs, and a combination of social and medical issues should be considered by a team in deciding about a woman's pregnancy.^[11,12] The prepregnancy care of these women together with the necessary follow-ups should be considered carefully and sensitively. In preconception care of women with a heart disease, family planning counseling should be done and a reliable method of contraception should be received until the mother becomes ready for pregnancy. In fact, using a proper contraception provides an opportunity for further evaluation and care to plan for a complete prevention of pregnancy or a successful pregnancy with minimal complications.^[4] The lack of specific counseling and contraceptive methods for these women, may bring serious consequences.^[16]

Providing prepregnancy and prenatal services, contraceptive counseling, and sex-related services can improve the reproductive health of these women. In some countries, team services are provided to these women with regard to reproductive health. The provision of such services has been investigated in a study and its weaknesses have been identified.^[31]

Studies that reported a lack of reproductive health services in women with heart disease suggested that activities between cardiologists and obstetricians should be more coordinated to increase awareness, access to, and use of effective and safe contraceptive methods for these women.^[32]

In addition, it is stated that a specialized team with a comprehensive approach of patient care facilitates comprehensive education by all team members for women with heart diseases. The team should focus on

pre- and during-pregnancy care and also postpartum assessment. Based on the available evidence, an integrated and consistent approach to caring for women with heart disease reduces their mortality and morbidity. However, the cost-effectiveness of this approach and the impact of this comprehensive program on the health of women with heart disease must be carefully assessed.^[33] Other studies have highlighted the need for programs including collaboration between cardiologists and family planning to improve the conditions for providing and receiving fertility services in women with heart diseases. In their view, this issue should be considered as a priority for women of heart diseases.^[34]

Given the lack of such a program in Iran and the importance of reproductive health of women with heart disease, the present study has been designed to develop a reproductive health promotion program for women with this disease. Providing all the mentioned services in a reproductive health program will increase the efficiency and effectiveness of these services. This program can be designed and implemented through the integration of the reproductive and sexual health services into the specialized medical services provided for women with heart disease and taking into account the existing challenges. Such a program will strengthen team performance. Receiving comprehensive services in this regard is a component of reproductive rights and is based on justice in health. This study is the first mixed methods research which has been conducted in Iran with the aim of designing a reproductive health program for women with heart disease and taking into account all stakeholders. Since this program will be designed in accordance with the health structure of Iran and based on the current needs of a target group, it can be considered as a national indigenous program. This program will help policy-makers and health-care providers to improve the reproductive health of women with heart disease and reduce the fertility complications in these women.

Limitation and recommendation

Restriction in continuous and face-to-face communication of the researcher with the participants because of the COVID 19 pandemic is the limitation of this study. Other researchers are advised to use the results of the present study to design a similar program for the reproductive health of women with other chronic diseases.

Conclusion

The program is expected to, ultimately, be a method of improving the reproductive health of women with heart disease and the general health and quality of life of them and their children and families. Implementing of this program by preventing unwanted and unplanned

pregnancies can reduce fertility-related complications in women with heart disease.

This article is related to the dissertation of PhD of reproductive health that was approved by the Isfahan University of Medical Sciences with the code 3981035.

Acknowledgment

We thank the Isfahan University of Medical Sciences for the financial support.

Financial support and sponsorship

This study was financially supported by the Isfahan University of Medical Sciences, Code number: 3981035.

Conflicts of interest

There are no conflicts of interest.

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