Reproductive Health

STUDY PROTOCOL

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Improving the sexual health of couples with diabetes: study protocol of an action research study

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Abstract

Background One of the most serious problems that threatens the sexual health of couples is diabetes. Diabetes is a global public health crisis affecting more than 0.5 billion adults worldwide. Inefficiency in implementing family planning or childbearing, sexually transmitted infections and sexual disorders in these patients can lead to psychological problems such as feelings of inadequacy, despair, loss of self-esteem and psychological consequences. Action research has the dual purpose of action, to bring about change in society or an organization or program, and research to increase the understanding of the researcher or the people involved with the problem, or both, in the wider community. Therefore, this study was designed with the aim of improving the sexual health of couples with diabetes with an action research approach.

Methods This study will be done with an action research approach in four phases and several steps. In the first phase (planning), which includes 4 steps, during which the needs and challenges of sexual health of couples with diabetes are explained ([with a qualitative and quantitative approach), the literature review of databases, the explanation of suitable and practical solutions, the prioritization of strategy improve sexual health Diabetic couples and development of sexual health promotion program for diabetic couples and Identifying sexual function and sexual satisfaction before implementing the program [before action]will be done. In the second phase (action), the program resulting from the first phase will be implemented, and in the third and fourth phases, the program will be continuously observed and reflected in order to adjust and improve the program. Qualitative data analysis using conventional content analysis method, quantitative data analysis will be done with SPSS 27 statistical software.

Conclusion Since diabetes affects the sexual health and marital satisfaction of couples, and considering that providing sexual health is one of the duties of reproductive health practitioners, and considering that the study of strategic action research is accepted to change attitudes, behavior and performance in the system. It seems that the application of the technical action research method opens the field for the entry of a research team consisting of various relevant experts to implement the plan resulting from It is the participants' own needs and strategy open.

Keywords Diabetes, Couple, Sexual health, Solution, Challenges and needs, Action research study

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Plain language summary

Sexual dysfunction is more common in people with diabetes compared to the general population. Also, diabetes can increase the risk of transmission of sexually transmitted diseases (STDs), HIV infection and hepatitis, especially type C between affected couples. The lack of a specific comprehensive health care program for matters related to the sexual health of this group can also lead to the above cases. This study will be done with an action research approach in four phases and several steps. In the first phase [planning], during which the needs and challenges of sexual health of couples with diabetes are explained the suitable and practical solutions and development of sexual health promotion program for diabetic couples. In the next phase, we intend to practically implement and then evaluate the prepared program. Considering that the study of strategic action research is accepted to change attitudes, behavior and performance in the system. It seems that the application of the technical action research method opens the field for the entry of a research team consisting of various relevant experts to implement the plan resulting from It is the participants' own needs and strategy open. In this study, to obtain data, couples with diabetes, personnel of d clinics related to diabetes, and health system policymakers will be interviewed. Methods such as semi-structured and structured, standardized and researcher-made questionnaires, literature review will be used. After examining the strengths and weaknesses of the implemented program, we will develop a final program to improve the sexual health of couples with diabetes.

Introduction

According to the Cairo action plan, sexual health is defined as couples being able to have enjoyable sexual relations, away from discrimination, violence, and fear of unwanted pregnancy and sexually transmitted diseases, in a way that leads to the creation and Promote love between couples [1]. Many factors affect sexual health, including chronic diseases, psychological and communication factors, and sexual infections [2–4]. One of the most serious chronic diseases that threatens the sexual health of couples is diabetes [5–12]. Over the past 20 years, in 2021, 1 out of every 10 adults 20 to 79 had diabetes, and in low- and middle-income countries, this statistic reaches 3 out of 4 people, which leads to many physical, social, and economic consequences. Such that 11.5% of global health costs are spent on diabetes. Overall, the global burden of diabetes has increased significantly since 1990. 6.7 million deaths related to diabetes have been reported in 2021, and 1 person dies every 5 s due to the complications of this disease [13]. 67.9 million disability-adjusted life years [DALYs] associated with diabetes were reported [14]. According to the report of the Ministry of Health in Iran, there are about 7.5 million people with diabetes and 9 million people at risk of diabetes [Iran's population is currently estimated at 89 million people]. The annual growth rate of diabetes in Iran ranks second in the Middle East region; this issue has attracted the attention of policymakers and experts to deal with diabetes in Iran [15].

Sexual dysfunction is more common in people with diabetes compared to the general population. The prevalence of sexual dysfunction in women with diabetes is estimated between 20 and 80% [16]. In men, the primary side effects are erectile dysfunction, ejaculation disorder, and loss of sexual desire, and in women, it manifests as a decrease in sexual desire, painful intercourse, and orgasm disorder [17]. Diabetes is considered a risk factor for urinary and genital tract infections, especially in the setting of uncontrolled hyperglycemia [18]. Also, diabetes can increase the risk of transmission of sexually transmitted diseases [STDs] between affected couples [19]. There is a perceived association between HIV infection and diabetes [20]. Also, there is evidence that the prevalence of hepatitis, especially type C, is higher in people with diabetes than in the general population [21]. In addition to these, another concern that threatens the sexual health of couples with diabetes, as well as women with diabetes, is unwanted pregnancy. Since the prognosis of pregnancy in these women is related to blood sugar control, especially hemoglobin A1c, having sex should be done without worrying about unwanted pregnancy and entering a high-risk pregnancy [22]. The type of contraception in patients with diabetes is controversial. Some studies reported that the longer the use of birth control pills, the higher the possibility of insulin resistance and increased fasting blood sugar [23, 24]. However, another study on 1940 women completely disagrees with this result and does not consider the use of birth control pills as a reason for increased blood sugar [25]. Regarding intrauterine devices such as IUDs, even though their safety has been proven in women with diabetes [26], only 15.5% of women with diabetes around the world use this method [27]. Access and adequacy of medical services, early referral to a specialized center, and rapid diagnosis and treatment of complications are among the effective factors in reducing and preventing the occurrence and treatment of sexual disorders managing the non-occurrence and transmission of sexually transmitted diseases, and

preventing the occurrence of unwanted pregnancy in patients with diabetes [28, 29].

The lack of a specific comprehensive health care program for matters related to the sexual health of this group can also lead to the above cases. It is difficult to meet the complex needs of patients with diabetes through private practices or public hospitals. These issues have been taken into consideration in different countries of the world, which point out that to provide the sexual health components of women and men with diabetes, there is a need for integrated clinics that are provided by a team with different specialties in all aspects of health. Sex should be offered to these people along with diabetes treatment [30, 31]. Despite the great importance of sexual health in creating marital satisfaction, maintaining the foundation of the family, and improving the quality of life, often due to cultural barriers and the taboo of raising sexual issues by patients, even treatment personnel, providing training in this field by service providers People with diabetes are usually neglected. Based on the preliminary research conducted by the researcher, a special program or structure to provide comprehensive sexual health services to women and men with diabetes was not found in the health system of our country, and for various reasons, the current structure of the health and treatment system meets the sexual health needs of these people. It is not [32, 33]. So, the existence of a coherent program to evaluate and provide continuous sexual health services to these people according to the social, cultural, and health structure of the country seems necessary. In the analysis of the existing conditions, it was concluded that the provision of sexual health services to these patients requires a broad perspective and a consistent standard program with the cooperation of a team with special skills. This issue clarifies the necessity of designing a native program in the country's socio-cultural context. In this regard, different methods of individual education, research based on people's participation, strengthening individual skills in self-care, individual improvements, and healthy lifestyles, and strengthening the capacity of society are among the strategies to promote health, and since qualitative studies are in-depth and understanding People pay attention to a problem and search for its solution, it seems logical to use this type of research to build capacity and improve sexual health in couples with diabetes [34]. Action research is used with the dual purpose of action, to bring about a change in society or organization or program and research, to increase the understanding of the researcher or the client or both in the wider society. The purpose of action research is to generate knowledge, propose and create change, and improve performance in the service delivery system. It is also a factor in empowering practitioners with the phenomena they face. In addition, wherever there is a need to solve a problem or to provide a platform to improve people's health conditions, the action research approach is a logical choice. [34]. Among the types of action research, the technical type is a scientific research method for solving practical and social problems and testing theories in practice, and the researcher, as a skilled expert, conducts the research with professional experts and acts as a facilitator provides recommendations regarding performance. In this type of study, the research team can act to create change and implement the designed program or intervention [35]. Since diabetes is one of the most populous diseases in the world, and it affects the sexual health of couples and can affect the entire marital satisfaction of couples, considering that providing sexual health is one of the duties of reproductive health professionals and Considering that the study of action research is an accepted strategy for changing attitudes, behavior, and performance in health systems, for which there is currently no fair and logical solution, and by applying the technical action research method, the field for the entry of a research team consisting of Various relevant experts are opened to implement the program resulting from the needs and strategy of the participants themselves. This study was designed to improve the sexual health of couples with diabetes with an action research approach to sexual health.

General aim

Improving the sexual health of couples with diabetes.

Specific aims

1. Explaining the sexual health needs and challenges of couples with diabetes
2. Clarifying the prioritization of solutions and designing a plan to improve the sexual health of couples with diabetes
3. Identifying the implementation issues and problems of the program through the feedback of people participating in the program
4. Explanation of the participants' experiences of the effectiveness of the sexual health promotion program for couples with diabetes after the implementation of the program

Main research questions

1. What are the challenges and sexual health needs of couples with diabetes?
2. What is the appropriate program to improve the sexual health of couples with diabetes?

3. Are the participants satisfied with the implementation of the sexual health promotion program?
4. How are the participants' experiences of the effectiveness of the sexual health promotion program for couples with diabetes after the implementation of the program? Improving the sexual health of couples with diabetes

Research paradigm

Paradigm comes from the Greek word Paradigm. Paradigm is a comprehensive term that includes all the acceptances of the agents of a scientific field and provides a framework for scientists to solve scientific problems in that field. Systematic research is often guided under two general paradigms, positivist and naturalist. Recently, another paradigm has occurred in research methodology, which is called pragmatism. During this study, we will benefit from the paradigm of pragmatism. The word pragmatism means action. This term was first used by Charles Sanders Pierce. His purpose of using this word was a method to solve and evaluate intellectual problems [36–39]. Action research requires action as a complementary and necessary part of the research process itself. Interaction between researchers, participants, and research samples is a characteristic of action research and empowers people who work in the research process to solve real-world problems. The purpose of action research is to add practical knowledge and empower practitioners about social and educational phenomena. The process of empowerment, participation, joint efforts and the principles of the community development approach cannot be achieved without proper and good communication. Poor formal communication is a barrier to interprofessional collaboration and information exchange. Since action research; It has a situational, group, collaborative and self-evaluation nature, it causes cooperation and authority in people and reduces the distance between theory and practice. In this method, unlike other researches, which at the end only lead to a recommendation from the researcher, the researcher tries to make changes; strengthen the systematic attitude; It promotes the spirit of teamwork and creates commitment in the application of the results in the researcher and is actually working in the real world. In other words, the four basic features of action research are finding solutions for functional problems related to work, collaboration between researchers and employees, applying changes in practice, and creating local or indigenous theory or practice based on context [40–42].

There are three approaches to action research that are relatively simple and include technical, practical and liberating action research. Under this umbrella, there are several established methods. Each of these methods is based on a number of steps to collect and interpret information. The types of action research can be placed on a spectrum, which shows that different types of action research are not different from each other in terms of methodology, but their differences are in their underlying assumptions and the worldview of the participants [43]. Technical action research is a scientific research method for solving practical and social problems and testing theories in practice. In this type of action research, the participants' behavior is considered objective and verifiable and can be generalized and predictable. The nature of the partnership between the researcher and the participants is facilitative and technical. The flow of communication is primarily between the facilitator and the group; so that ideas can be transferred to the group [44]. Regarding the level of cooperation, it can be said that in technical research, the participants are responsible and role models. Regarding the concept of change in action research, it should be said that in technical action research, the source of power for action is the idea, and since the idea often belongs to the facilitator [researcher], it is the facilitator who controls the power in the project [45]. In this study, technical action research will be used to change the attitude, behavior and performance of people with diabetes in order to improve their sexual health.

Method

Study design and setting

In this study, the technical action research method will be used to improve the sexual health of couples with diabetes. In technical action research, the researcher, as a skilled expert, conducts research with professional experts, acts as a facilitator, and provides recommendations regarding performance [45]. The commission model will be used in this study among the different action research models. In this model, a four-phase process, including planning, action, observation, and reflection, has been proposed in action research [40]. In the first phase [planning], which includes 4 steps, during which the needs and challenges of the sexual health of couples with diabetes are explained (with a qualitative and quantitative approach). The literature review of the databases, the appropriate and practical strategy are explained, and the sexual health improvement strategies are prioritized. Couples suffering from diabetes and developing a plan to improve the sexual health of couples suffering from diabetes and identifying sexual function and sexual satisfaction before implementing the program [before action] will be done will be done. In the second phase (action), the program resulting from the first phase will be implemented, and in the third and fourth phases, the program will be continuously observed and reflected in order

to adjust and improve the program (Fig. 1. Approach of action research). The four stages of the study are as follows:

– The first phase [planning]:

The aim of the study in the planning stage, explanation needs and challenges and suitable strategy improve the sexual health of couples with diabetes will be. The stage of planning will be four steps:

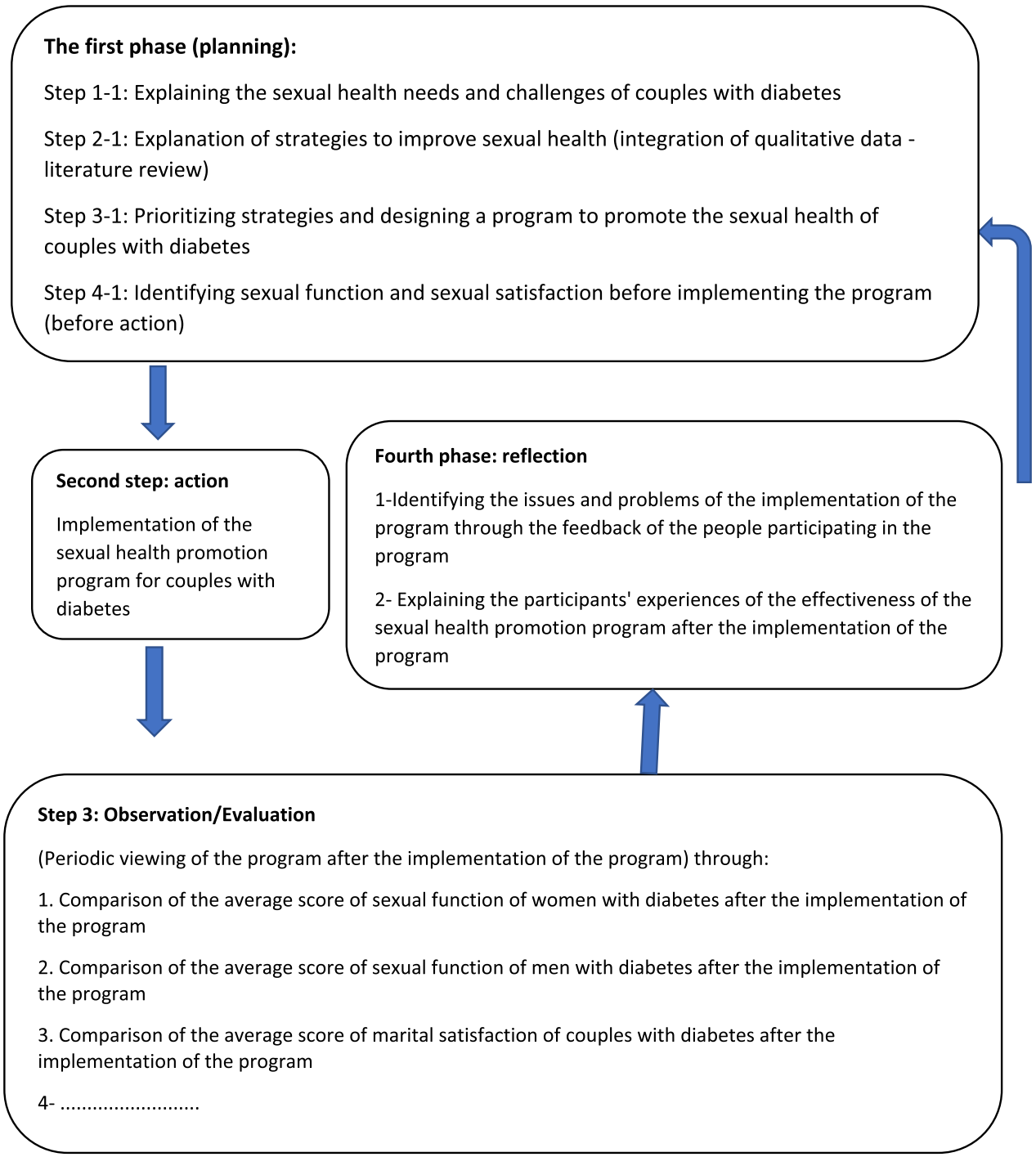

Fig. 1 Approach of an action research

Step 1-1: Explaining the sexual health needs and challenges of couples with diabetes: The purpose of this phase is to explain the challenges and needs of improving the sexual health of couples with diabetes, as well as explaining the strategies for improving the sexual health of these couples. Participants, includes couples with diabetes [one or both of them have diabetes], doctors, specialists, providers of services to patients with diabetes in centers related to different levels of diabetes prevention, treatment and rehabilitation, and policy makers and planners in the field of diabetes. The selected environment of this research is Diabetes clinic and Endocrine Center of Sedige Tahereh Hospital, Isfahan. In order to analyze the data in the first step, observation methods and semi structure interviews will be used.

Participatory observation requires the researcher to participate in the studied society and actually see, hear, and experience the reality. In this study, the researcher was present in the research environment (Sediqeh Tahera Endocrine Center and Diabetes clinic) and took notes on the process of providing services, service process, situation analysis, the condition of patients with diabetes and the services provided to them, etc. So, a semi-structured in-depth individual interview method will be used in the present study. The interview location will be determined with the participants' agreement, at Diabetes clinic and Sedige Tahereh Center, and if they do not wish to, at their workplace, comprehensive health service centers near their home or university headquarters. The duration of the interviews will be between 45 and 60 min. At the beginning of individual interview sessions, consent will be obtained to record the sessions and it will be assured that no personal identity information such as name will be included in the content. Then the objectives of the study will be explained to them. The key questions of the individual interview include: What is your experience with diabetes? What information do you have about sexual health? How would you describe your sexual health since you got diabetes? What issues have you faced in relation to sexual health? What services related to sexual health are provided in the center you visited? Which of these services do you need and why?, And what do you think is a way to improve your sexual health?

Sample interview guide questions with service providers are describe the usual care method in this clinic? In your opinion, what are the challenges and sexual needs of couples with diabetes? What strategy do you suggest to overcome these obstacles? And in the current situation, what is your solution to improve the sexual health of couples with diabetes?

Step 2-1: Literature review [extracting solutions]: After conducting the interviews and forming the focus group, related documents and texts related to the strategies for improving the sexual health of couples with diabetes in Iran and other countries will be reviewed and potential strategy will be identified. For this purpose, Persian and English language electronic databases in the field of health and library resources including SID, Iran Medex, Magiran, IranDoc, Medlib, Google Scholar, Scopus, PubMed, Web of Sciences, Cochrane Database of Systematic Reviews with keywords Diabetes Mellitus, Men and women, sexual health, approach or strategy, challenge, needs, action research study and their Persian equivalents It is searched.

Step 3-1: Prioritizing strategies and designing a program to promote the sexual health of couples with diabetes: The aim of implementing this step will be to prioritize solutions and design empowerment programs for couples with diabetes, which will be extracted through the interviews conducted in step 1-1. Deciding on priority solutions is one of the most important and perhaps even the most important task of participants in a project or study. The presence of different and sometimes conflicting influential criteria will make decision makers look for methods that will provide an acceptable answer by considering all the criteria and their importance. In this regard, methods known as multi-criteria decision-making methods have been developed. In this study, SFF method will be used. The SFF method was first proposed by Landsberg. This matrix includes 3 criteria, such that the criterion of proportionality or the importance of the importance and necessity of each solution in the direction of empowering couples with diabetes in order to improve sexual health, the criterion of ease of implementation the degree of ease of implementation of each solution according to the resources, the number of people, the required cost and time (and the flexibility criterion) means the flexibility of each solution against unwanted and unforeseen results and incidents, the possibility of changing and adjusting the solution while doing the work. Each criterion will be assigned a score of 1 to 3 (high = 3, medium = 2, and low = 1). And in this way, any index or solution can have a score of 3 to 9 [46]. In order to prioritize the strategies to improve the sexual health of couples with diabetes, a panel of experts and a focus group method will be used. It will be like this that at first, the empowerment solutions extracted in step 1-1 were set according to the SFF matrix. Then, the panel of experts will be identified based on their expertise and activities related to people with diabetes. And then the solutions questionnaire will be presented to 40 people in person or via email. These people will include people with diabetes, doctors specializing in endocrinology and metabolism, personnel working in endocrinology and metabolism centers, a clinical psychology expert focusing on sexual health, a urologist and a sociologist focusing

on community health. Two focus group meetings will be held. According to the opinion of the research team, any solution that gets a score of 6 or higher will be prioritized for action. In the next step, the researcher will review all the questionnaires that he will receive from the expert panel members in the focus group interview session, and enter the scores given by the participants based on the SFF matrix into the SPSS version 22 software, and the average of each solution in It will evaluate the promotion of sexual health of couples with diabetes.

Step 4-1: Identifying sexual function and sexual satisfaction before implementing the program (before action): In step 4-1, in the planning phase and before starting the action (in the second phase), people with diabetes (who will not necessarily be the same people in step 1-1) are invited to participate in the action phase. Since the evaluation of the efficiency of a program such as action research in a large community such as people with diabetes, it is not possible to randomly divide people into two intervention and control groups. In such a case, quasi-experimental studies can be used. Also, since in the current study, there is only one group in the action phase, the I plan will be used. In the fourth step of the planning phase, before starting. The action stage will be used for comparison with the results obtained after the action stage using a semi-experimental method in a group before and after, and it is possible that other cases will be investigated according to the results of the qualitative study in step 1-1.

In the current study, the participants are couples with diabetes, one or both of them have diabetes. The chosen environment of this research is the Diabetes clinic and the research center for glandular and metabolic diseases (located in the Sedige Tahereh Research Center, Isfahan). This environment seems appropriate due to providing comprehensive services to people with diabetes. To collect information in this phase of the study, data collection was done using the standard questionnaires of the Standard Scale of Sexual Function (FSFI for women and IIEF for men) [47, 48] and Larson's sexual Satisfaction questionnaire [49] and possibly a researcher-made questionnaire for the variables that the qualitative step will be discovered. The tools made by the researcher after compiling the questionnaire will be face validity, content validity [validity ratio, validity index] and reliability.

– Second phase: action [execution of the program]:

The program designed in the previous phase will be completed according to the conditions of couples with diabetes as well as their needs and requests. To implement the program, first, after obtaining the necessary permits, the researcher will go to the research environment and select the participants who meet the study entry criteria in the available method, and after explaining the research objectives and working methods, they will be invited to participate in the study and consent A written letter will be obtained to participate in the study. Also, the participants [couples with diabetes] will be assured that they can withdraw from the study at any time of the research if they do not want to continue cooperation. During the implementation of the sexual health promotion program, structural changes may be made in the program, which will be taken into account and, if necessary, necessary planning will be done. The chosen environment of this research will be the Diabetes clinic and the research center for glandular and metabolic diseases (located in the Sedige Tahereh Research Center of Isfahan). Because these two centers are the only comprehensive centers providing services to people with diabetes in Isfahan city.

Inclusion criteria for participants in the second phase: Have written consent to participate in the study, At least one of the couples has type 2 diabetes, Be Iranian and resident of Isfahan city, 4. The minimum and maximum age for women with diabetes is considered to be 30 and 50 years, respectively [50], The minimum and maximum age for men with diabetes are 35 and 60 years, respectively [51], At least 3 years have passed since the onset of diabetes, Absence of physical and mental illness reported by participants or medical centers and Have the ability to express their opinions and expectations.

Criteria for not entering the study in the second phase: Suffering from ACVD (acute cardiovascular disease), Suffering from advanced kidney disease and kidney patients who are in the final phase and need dialysis or kidney transplant, Suffering from any other endocrine disorder that interferes with sexual intercourse or leads to menstrual disorders in women, such as uncontrolled hypothyroidism, hyperprolactinemia, Cushing's, etc., Any incident that causes a physical problem for a person that interferes with having sex (unless it is related to diabetes),Participate in another research study at the same time. According to the nature of the work in the second phase, other entry and exit criteria may be determined during the study.

Exclusion criteria: Women's pregnancy, Death or complete absence of one of the spouses, Acute cardiovascular disease (ACVD) during the operation, Suffering from advanced kidney disease and kidney patients who are in the final phase and need dialysis or kidney transplant; That this happens during action, Suffering from any other endocrine disorder during the procedure that interferes with sexual intercourse or leads to menstrual disorders in women, such as uncontrolled hypothyroidism, hyperprolactinemia, Cushing's, etc. during the procedure and Any

incident that physically causes a problem for the person during the act that interferes with having sex (unless it is related to diabetes). The procedure will be as follows during a call at Diabetes Center and Sedige Tahereh Endocrine Center, a research project was introduced and couples with diabetes were invited to participate. Then, these couples will be selected according to the records they have in the mentioned centers and according to the goals, the prevalence of diabetes, and the sample size formula.

– The third phase [observation]:

The observation phase is the action evaluation phase in the form of program implementation. This phase will be done with the aim of evaluating the program through the following:

1. Comparison of the average score of sexual function of women with diabetes after the implementation of the program.
2. Comparison of the average score of sexual function of men with diabetes after the implementation of the program.
3. Comparison of the average score of marital satisfaction of couples with diabetes after the implementation of the program.

In the third phase, the average scores of men's and women's sexual performance and marital satisfaction will be determined using a quasi-experiment study (that the stage before its action was explained in the fourth step of the planning stage). This phase is a one-group, multi-variable study and data will be collected in several phases. It should be noted that currently in the observation, semi- structure interviews, according to the review of the literature, the study of sexual function and marital satisfaction is emphasized because of its role in sexual health. But since sexual health has various dimensions, according to the qualitative interviews that will be conducted in the planning phase and depending on the participants' statements, other variables will be added and subsequently the necessary questionnaires will be developed or introduced. Research community Including all couples with diabetes, one or both of them have diabetes and The Research environment will be the endocrinology center of Sedigeh Tahereh Hospital and Diabetes clinic of Isfahan. Inclusion and exclusion in the third phase will be the same as the action phase. The sample size was estimated as follows that using the statistical software G*Power [52] based on the analysis of variance test with repeated measures, to perform the test at a significance level of 5% ($\alpha = 0.05$), with the power of the test 90% ($\beta = 0.1$), and the average effect size ($d = 0.25$) [53] was obtained equal to 36 people (18 couples). Considering 4 extra people due to the possible distortion of the results or dropping out of the study, 40 people will be examined in the form of 20 couples with diabetes. In this phase of the study, data collection using standard questionnaires of the standard scale of sexual function (FSFI for women and IIEF for men) and Larson's sexual Satisfaction Scale and probably the researcher-made questionnaire derived from the themes extracted from the planning phase, interviews It will be qualitative.

– The fourth phase [Reflection]

Reflection is one of the important steps in the action research cycle. Reflection makes the impact of the action on the participants' insight and action, the problems of the program to be determined, the program to be modified, and ultimately, the probability of its success to increase. This phase includes a general plan evaluation based on the previously agreed criteria [54, 55]. The objectives of the fourth phase in this study are:

A.A.A. Identifying the problems and implementation problems of the program through the feedback of people participating in the program.

Methods of collecting information:

1- Self-report: It is the most common method of data collection in clinical studies, which is very powerful due to its immediacy, and through it the researcher obtains information that is difficult to obtain with other methods [56, 57].
2- Notes in the field: Notes are used to document observations. In order to observe, the full participatory observation method will be used. In this study, the researcher, with the participants in the research as well as some people who are not participants [evaluation by colleagues], notes his observations in the field of study in different situations and times after the implementation of the sexual health promotion program, to identify the challenges and problems. The implementation of the program should be reviewed. The research team will continuously analyze these data along with other data collected in the study, and necessary measures will be considered in this regard.
3- Review meetings: holding regular meetings of the research team from the beginning of the study to its final phases is one of the effective and efficient methods of obtaining the opinions, views, suggestions, and criticisms of the participants and also presenting the results of the study steps to the members of the research group. These meetings will be held once

every 2–3 weeks, the researcher and the research team, together with the participants in the study, will examine the problems and proposed strategist each phase of the study.

B. Explaining the participants' experiences of the effectiveness of the sexual health promotion program after the implementation of the program (second qualitative study).

Objectives of the qualitative study in the second qualitative study including "Evaluation of the results and effects of the implemented sexual health promotion program from the perspective of the participants" and "Explaining the opinions and suggestions of the participants in order to improve the sexual health promotion program of couples with diabetes". Participants will be diabetic couples, doctors, specialists, providers of services to diabetic patients in centers related to different levels of diabetes prevention, treatment, and rehabilitation, and policymakers and planners in the field of diabetes. Focus group meetings and structure interviews are held with the participants' participation in the program's implementation. The interviews will continue until data saturation. Finally, at the end of the meeting, there will be a reception and a final summary. The meetings will be held according to the request of the participants and with their coordination at the times and places where attendance is possible. At the beginning of the first session, the purpose of the study and the working method will be explained; and then all the participants will complete a written consent form to participate in the study to record the conversations. The key questions in this phase will include the following: then meetings with open questions including: How do you evaluate your own experience of implementing the sexual health promotion program for couples with diabetes? In order to continue the sexual health promotion program for couples with diabetes, what do you suggest? From your point of view, what facilitators can be used in the better implementation of the program? Finally, according to the results of the four stages of the study, the final program will be compiled by the research team.

Data analysis with a qualitative approach

In this study, the analysis of the recorded interviews will be done simultaneously with the data collection. In the current study, qualitative content analysis method will be used in the conventional way to analyze the qualitative data [58]. All the descriptions and stories of the participants and the texts are studied in order to gain a general insight/understanding of their statements in order to get a general understanding of them. The study is noted. This step is repeated several times until as many relevant titles as possible are written in the margins of the text so that it can cover all aspects of the text. Then all these titles are written on coding sheets and grouped. For each group, a title is considered that includes all the titles within the group. Finally, these groups and classes are placed in larger classes as much as possible. The purpose of creating larger classes is to gain new knowledge and increase the understanding and complete description of the phenomenon.

Data analysis with a quantitative approach

In the fourth step from the first step, descriptive analysis will be used to analyze the data. So that the average and standard deviation indicators of sexual performance and sexual satisfaction are used before taking action for the people who will be invited to participate in the study. So, in third phase, data analysis will be done on two descriptive and inferential levels. At the descriptive level, average and standard deviation indicators are used. At the inferential level, according to the research plan, the analysis of variance model with repeated measures will be used to compare the average score of sexual performance, marital satisfaction of couples, etc. The Post hoc Bonferroni test is used to make pairwise comparisons. The assumption of normality of data distribution is checked by Shapiro-Vrill tests. The assumption of homogeneity of error variance is checked by Levine's test. If this assumption is not established, Friedman and Mann–Whitney non-parametric tests are used to answer the research questions. The tests are performed at a five percent error level using SPSS software version 27.

Validity and robustness of data with a qualitative approach

The main purpose of checking validity, accuracy and robustness of qualitative research is to ensure that the study accurately reflects the experiences of the participants in the research [59]. Four criteria of believability (credibility), reliability (reliability), neutrality and objectivity of data (validity) and transferability are used to evaluate qualitative data [59, 60]. In addition, in order to increase the accuracy and strength of qualitative studies data, it should be considered that there are three types of threats to the accuracy and strength of qualitative studies, which are researcher bias, participant bias and activism. Although in studies based on interviews, long-term engagement is not possible, but by conducting more than one interview, it will be done in order to fulfill this goal [61]. The participants had an in-depth interview and interviewed more than one face-to-face meeting in order to reach a deep understanding about each participant. Then, for the validity of the findings, the researcher took the text of the interview and took his own interpretation of the data in the form of codes

resulting from the analysis. And the analysis will be presented to some participants and their opinions will be sought. Supervisor review is another method that is used to confirm the validity of qualitative research [62]. The text of the interviews along with the emerging codes and classes, in addition to the respected professors and advisors, are presented to 3 colleagues who are not involved in the research. To check the flow of data analysis and comment on its accuracy, and the researcher applies the most agreed opinions after collecting the opinions. Reliability means the stability of data over time and similar conditions and is a criterion related to the research process. In order to provide this criterion, the researcher will try to accurately record and report the stages of the research and the decisions made during it. and records the analysis of the data in a part-by-part manner, which is included both in the 6-month report presentation sessions and in the text of the thesis, so that it is possible for others to follow up the research if needed. Findings, making it clear He will use a tape recorder that will record all the people's speech during the interview.

The validity and reliability of the quantitative data

The questionnaires used are the standard questionnaires of sexual function of women and men (FSFI for women and IIEF for men) and the Larson sexual satisfaction scale, as well as researcher-made tools that in the action stage after formulating the questionnaire, face validity, content validity (validity ratio], reliability index) have been checked. So, if the researcher-made questionnaire is compiled according to the results of the interviews extracted from step 1 to 1 of the planning stage regarding the promotion of sexual health in couples with diabetes, using content validity (ratio and validity index content) and Cronbach's alpha above 85%, its validity and reliability will be considered.

Discussion and conclusion

Diabetes is one of the most serious problems that threatens the sexual health of couples. Diabetes increases the risk of erectile dysfunction in men by 3 times by causing vascular disorder and relaxation of smooth muscles in the penis. The presence of oxidative stress in diabetes and the reduction of antioxidant activity leads to the destruction of vascular endothelium, which is responsible for the production of nitric oxide, a vasodilator, which is the cause of erectile dysfunction in men [63]. In women with diabetes, due to vascular problems and neuropathy caused by diabetes, sexual dysfunction occurs and leads to a decrease in sexual desire and arousal and pain during sexual activity, which causes stress, disruption in marital relations, and a decrease in the quality of life of couples [64]. Several studies have conducted various interventions to improve sexual disorders in people with diabetes, which includes increasing sexual literacy and awareness [65]. Using the PLISSIT sexual counseling technique [66]. There is also evidence in favor of the use of complementary medicine to improve sexual performance in couples with diabetes [67, 68]. Counseling in connection with the method of contraception in women with diabetes has become a challenge. Compared to non-diabetic women, these women fail to receive these consultations and use a safe and reliable method of contraception. While they should choose the best contraceptive method based on their needs and related risk factors [27]. The lack of a comprehensive healthcare program dedicated to the issues related to the sexual health of this group can also lead to irreparable complications in the continuation of the married life of couples with diabetes. It is difficult to meet the complex needs of patients with diabetes through private practices or public hospitals [31]. For this reason, the provision of sexual health services to these patients requires a broad perspective and a coherent and local standard program in the country's socio-cultural context. Since qualitative studies pay attention to the depth and perception of people about a problem and the search for its solution, using this type of research to build capacity and promote sexual health in couples with diabetes seems logical [34]. Action research causes change in society or organization or program and research and knowledge production, proposing and creating change and improving performance in the service delivery system [34]. Among the types of action research, the technical type is a scientific method for solving practical and social problems and testing theories in practice. Action research at the system design level, self-management, support, decision-making, health care, and clinical information systems has been improved [44]. In an action research study, they examined and compared the effectiveness of the health and medical personnel empowerment program in the education and control of type 2 diabetes. He suggested implementing the health personnel empowerment program and using experienced personnel due to the important role they play in the health system's mission to improve diabetes control indicators [69]. In most of the research conducted on people with diabetes, other aspects of their lives, such as sexual experiences [34], sexual adaptation [35], and sexual violence [45], have been addressed. As a result, research on the needs and challenges of people with diabetes and ways to improve it can be an effective step in the development and improvement of diagnosis, treatment, lifestyle changes, and sexual problems. The results of this study can be used for specialized training and counseling for women and reproductive health specialists, midwives, psychiatrists and psychologists, endocrinology

and metabolism specialists, and urologists who work in the field of sexual health. [Mousavi]. Since diabetes affects the sexual health and marital satisfaction of couples, and considering that providing sexual health is one of the duties of reproductive health practitioners, and considering that the study of strategic action research is accepted to change attitudes, behavior, and performance in the system. It is a health issue for which no fair and logical solution exists. It seems that applying the technical action research method opens the field for the entry of a research team consisting of various relevant experts to implement the plan resulting from the needs and strategy of the participation to open it.

Expected achievements

Considering the importance of improving the sexual health of couples with diabetes in maintaining fertility and sexual ability and maintaining the foundation of the family, it is hoped that this research can lead to the improvement of the quality of sexual life of these people. It is also hoped that the results of this research can provide information that will be the basis for better planning by managers to improve the sexual health of these loved ones.

Limitations

Although action research leads people to self-improvement, it also has disadvantages and problems. One of them is the issue of time, the duration of the research is a problem that can be minimized with the cooperation and sincere communication of the members of the research group. Another limitation that can be mentioned for this type of study is the absence of a control group and the unpredictability of the work process and results.

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Author contributions
Z.B. conceived the idea, design the study and wrote the first draft of protocol and this manuscript "M.S.D." provided technical assistance during the design of trial, sample size calculation, protocol write-up and revision of this manuscript "F.Z.M., P.S. and N.G." assisted and guided during protocol development, interview's structure, measurement tools and questionnaires and also in revision of the manuscript. All authors read have read and approved the manuscript.

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Availability of data and materials
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
Yes. The code of ethics was obtained from Isfahan University of Medical Sciences Ethics Committee (IR.MUI.REC.1403.028). All procedures for the participants will be carried out according to ethical standards and under the supervision of Isfahan Medical Sciences Ethics Committee. Informed consent will be obtained from the participants before participating in each phase of the research, and they will be assured of privacy and non-disclosure of their identification information, and the audio file will be destroyed after the data is released. In case of non-participation and cooperation, there will be no restriction and deprivation in the care of the participants, and if necessary, referrals will be made to specialized levels of treatment.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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