# STUDY PROTOCOL Open Access

# The effect of sexual education based on the Sexual Health Model on sexual function among women living in the suburbs: study protocol for a randomized controlled trial

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#### Abstract

**Introduction** Suburban population is increasingly growing in Iran. People in the suburbs usually have limited sexual information and there are limited studies into their sexual issues. This study aims the effect of sexual education (SE) based on the Sexual Health Model (SHM) on sexual functioning among women living in the suburbs.

**Methods** This is a randomized controlled trial with two parallel groups. Seventy-six women will be selected through simple random sampling from healthcare centers in suburban areas and will be allocated to a control group (n=38) and an intervention group (n=38) with a randomization ratio of 1:1. Participants in the intervention group will receive SHM-based SE in three120 min weekly sessions which will be held using the lecture, question-and-answer, group discussion, and educational booklet methods. Data will be collected through a demographic and midwifery characteristics questionnaire, the Female Sexual Function Index, the Depression Anxiety Stress Scale, and the Sexual Quality of Life-Female, and will be analyzed through the analysis of covariance as well as the independent-sample t, the paired-sample t, and the Chi-square tests.

**Discussion** We hope this study provides a clear framework for decision-makers and healthcare providers to provide appropriate policies and interventions for SE and thereby improve the sexual health of women in the suburbs. *Trial registration*: This study was registered in the Iranian Registry of Clinical Trials on 2024.03.05 (code: IRCT20231121060133N1).

Keywords Women, Randomized controlled trial, Sexual Health Model, Sexual function, Sexual health, Suburbs

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#### Introduction

Progressive urbanization has led to the significant challenge of suburbanization throughout the world, particularly in developing countries [1]. Suburban areas have lower population density, are located around cities [2], and are known as places of disorder [3]. According to the United Nations, suburban population will reach two billion by 2030 [4]. According to the latest statistics, suburban population in Iran increased from 9,739,123 in June 2014 to 10,280,270 in 2015 [5].

Suburbs are characterized by poor social services, weak primary healthcare services, income insecurity, and unstable livelihood [6, 7]. Health-related outcomes in these areas are also poorer, particularly among women [5]. Sexual health problems are among the most common health problems of women in the suburbs [8]. Sexual health is the ability to fulfill sexual desires without exposure to sexually-transmitted infections, unwanted pregnancy, coerce, violence, or discrimination, and the ability to have an informed, pleasurable, and safe sexual life with a positive approach to sexual expression and mutual respect [9]. In the suburbs, women are more at risk for gender-based violence and sexuallytransmitted infections and have poorer access to sexual health services [8, 10]. A review study reported that the prevalence of sexual problems, particularly sexual dysfunction, among women living in urban areas in Iran was 43% in total, 42.7% in the desire dimension, 38.5% in the arousal dimension, 30.6% in the lubrication dimension, 29.2% in the orgasm dimension, 40.1% in the pain dimension, and 21.6% in the satisfaction dimension [11]. Another study in the north of India reported that 58% of women suffered from anxiety or inability to express their emotions during sex and 17% of them had problems during sex, including headache (10%), difficulty in reaching orgasm (9%), pain (7%), poor lubrication (5%), vaginitis (2%), and post-coitus infection. Some participants attributed these problems to their spouses' health problems (4%) and marital conflicts (4%) [12]. However, there are no data respecting the prevalence of sexual problems among women living in the suburbs in Iran and studies on these women mostly addressed their reproductive health status [5, 13].

Despite the high prevalence of sexual problems, public talks about sexuality and sexual desires are historically a taboo [14] and most couples feel embarrassed and guilty about expressing their sexual problems [15]. A study reported that the lack of knowledge about sexual relationships and the low prevalence of premarital sexual relationships due to sociocultural traditions in Iran cause considerable stress and anxiety for couples [15]. Therefore, the World Health Organization highlights the importance of assessing and managing sexual concerns

and problems and providing education about sexual issues in order to improve the quality of sexual care services [16].

Sexual education (SE) is one of the strategies to prevent and manage sexual health problems [17]. SE helps individuals improve their sexual knowledge, attitudes, and skills and enables couples to fulfill mutual needs and balance their personal, familial, and social life [15]. Moreover, it can lead to positive outcomes such as more effective relationships between couples, greater sexual pleasure, elimination of incorrect sexual beliefs, greater self-confidence and self-esteem, and informed decision-making [18, 19]. A study reported the great need for SE for women with sexual problems [12].

Among different methods for SE, the Sexual Health Model (SHM) seems to be more effective for those with limited sexual knowledge [17]. SHM addresses the main components of sexual health, namely talking about sex, sexual anatomy and functioning, challenges to sexual health, culture and sexual identity, sexual healthcare and safer sex, positive sexuality, body image, masturbation and fantasy, intimacy and relationships, and spirituality [20–22]. It provides individuals with a theoretical framework to improve their sexual health through improving their knowledge, personal awareness, and selfacceptance. It also enables them to communicate their sexual needs and desires with their spouses in a clear, responsible, and respectful manner [17]. A single-blind randomized controlled trial found that SHM-based SE in three ninety-minute sessions significantly improved sexual functioning among 108 women with infertility [15]. Another study found that SHM-based SE was effective in significantly improving sexual compatibility among women at risk for emotional divorce [23].

To the best of our knowledge, there are limited data respecting the sexual health of women living in the suburbs of Iran. Thus, the present study will be conducted to assess the effect of SHM-based SE on sexual functioning among women living in the suburbs of Iran.

#### **Conceptual framework**

A core component of SHM is a clear definition of SE which is provided through integrating three theoretical and empirical resources, namely the key characteristics of a fixed sexological approach to comprehensive SE, literature-based recommendations for specific cultural models and sexual health norms determined based on the experiences of the target community, and quantitative and qualitative studies into sexual attitudes, styles, and risk factors in different populations and their context for decision making about safer sexual relationship [24]. SHM provides a theoretical framework to improve overall sexual well-being and hence, is a

useful framework for the present study. The ten main components of this model are talking about sex, sexual anatomy and functioning, challenges to sexual health, culture and sexual identity, sexual healthcare and safer sex, positive sexuality, body image, masturbation and fantasy, intimacy and relationships, and spirituality [20–22]. These are the key aspects of healthy sexuality and can be used for the successful management of most sexual health concerns with different treatment options (such as cognitive behavioral therapy and problem solving). Although this model was first proposed for sexual health interventions to prevent human immunodeficiency virus infection, psychologists, psychiatrists, and family physicians have used this model in their practice [20] to treat different sexual disorders [17].

*Hypothesis* The SHM-based SE improves sexual functioning among women living in the suburbs.

#### Aim

The main aim of this study is to assess the effect of SHM-based SE on sexual functioning among women living in the suburbs. Besides, the study will assess the effect of SHM-based SE on the sexual quality of life (QOL) of these women.

# **Methods**

# Design

This is a randomized controlled trial with a control group and an intervention group and a randomization ratio of 1:1. It will compare the effects of SHM-based SE and routine SE on sexual functioning among women living in the suburbs. Both groups will receive SE for three weeks and outcome assessment will be performed before and twelve weeks after the intervention. This trial will be conducted based on the CONSORT guidelines (Fig. 1) [25]. The present protocol has been organized based on the "Standard Protocol Items: Recommendations for Interventional Trials" (SPIRIT) checklist [26].

## Date of the study

The first participant will be recruited in September, 2024.

# Study population

Study population consists of all 15–49-year-old women who live in the suburbs of Zabol, Iran.

# Study setting

The setting of the study will be four healthcare centers in the suburbs of Zabol, Iran, where women attend to receive healthcare services.

#### **Participants**

Participants will be 15–49-year-old married women who live in the suburbs of Zabol, Iran, and meet the eligibility criteria.

#### **Eligibility criteria**

The first author of the study will assess the medical records of participants for eligibility. Eligibility criteria are as follows:

- 1. Age of 15-49 years;
- 2. Matrimony;
- 3. Ability to read and write in Persian;
- 4. Affliction by sexual dysfunction (i.e., a score of less than 28 for the Female Sexual Function Index (FSFI) [27];
- 5. No pregnancy and breastfeeding;
- 6. Residence in the suburbs;
- 7. No affliction by known physical health problems;
- 8. No affliction by severe depression, anxiety, and stress (determined by scores less than 13, 9, and 18 respectively for the depression, anxiety, and stress subscales of the 21-item Depression Anxiety Stress Scale (DASS-21) [28].
- 9. History of sexual activity in the past one month;
- 10. No self-report history of husband's affliction by sexual dysfunction;
- 11. No intake of any medication for sexual dysfunction;
- 12. No substance abuse; and
- 13. No self-report history of participation in any educational course on marital problems and sexual dysfunction.

## **Exclusion criteria**

Exclusion criteria are as follows:

- 1. No willingness to stay in the study;
- 2. Pregnancy during the study;
- 3. Divorce or husband's death during the study; and
- 4. Significant life events (such as significant losses) during the study.

#### Sampling method

Sampling will be started after registering the study in the Iranian Registry of Clinical Trials, obtaining approval from the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran, and obtaining the necessary permissions from the Faculty

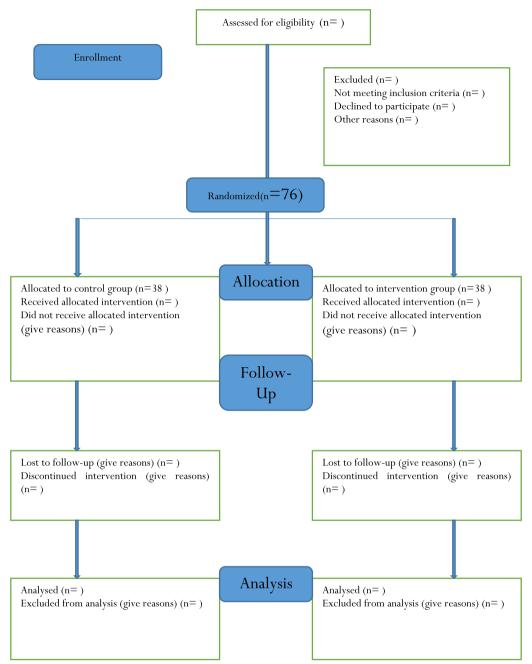


Fig. 1 Participants' flow in the study

of Nursing and Midwifery of this university. As Zabol has ten suburban areas, four areas will randomly be selected and eligible women will be selected from these centers. The aim and the methods of the study will be explained to them and their informed consent will be obtained. They will be asked to complete the study instruments and those with severe depression, anxiety, or stress and those with normal sexual functioning

will be omitted. The selected participants will be allocated to two groups through block randomization. Participants in the intervention group will receive SHM-based SE and their counterparts in the control group will receive routine SE in three weeks. All of them will complete the study instruments before and twelve weeks after the intervention. Table 1 shows the schedule of enrolment, intervention, and assessment.

**Table 1** Schedule of enrolment, interventions, and assessments

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation			Close-out	
TIMEPOINT	-t <sub>1</sub>	0	$t_1$	$t_2$	<b>t</b> <sub>3</sub>	<b>t</b> <sub>4</sub>	<b>t</b> 15
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Randomized by independent person	X						
Allocation		X					
INTERVENTIONS:							
Group A: educational intervention			•				<b>→</b>
Group B: Control							
ASSESSMENTS:							
FSFI	X						Х
S-QOL	X						Х
DASS	X						

# Sample size calculation

Using the free G\*Power software (v. 3.1.9.2) (available at www.gpower.hhu.de), sample size was calculated to be 38 per group—76 in total. Parameters for sample size calculation were a mean of  $27.19 \pm 5.56$  for FSFI in the control group at the end of the study [29], a Cohen's effect size of 0.40, a significance level of less than 0.05, a statistical power of 90% to detect a between-group

different of 5 FSFI scores at the end of the study [30], and an overall attrition rate of 10%.

# Randomization and allocation

Participants will be allocated to an intervention and a control group through block randomization. All six possible placements of the A and the B letters in foursized blocks (i.e., AABB, ABAB, BBAA, BABA, ABBA, and BAAB) will be considered and the blocks will be numbered 1–6. As the sample size is 76, the total number of the blocks will be nineteen. Then, a table of random numbers from 1 to 6 (based on the possible placement of the A and the B letters in four-sized blocks) will be generated and the blocks will be arranged according to the table. Consequently, each participant will have a unique code at the time of recruitment and allocation.

# Allocation concealment and blinding

For allocation concealment, a colleague external to the study will write the generated allocation sequence on pieces of paper, place the paper pieces in opaque envelopes, and sequentially number the envelopes. The numbered envelopes will respectively be opened and the intended participants will be allocated to the groups. The blinding of researchers and participants in this study is impossible due to the characteristics of the intervention. Yet, outcome evaluator will be blinded through employing a colleague for data collection.

# **Outcomes**

The primary outcome of the study is sexual functioning and its six dimensions, namely desire, arousal, lubrication, orgasm, pain, and satisfaction which will be measured through FSFI. The secondary outcome of the study will be participants' sexual QOL which will be measured through the Sexual Quality of life-Female questionnaire.

# **Study instruments**

The four study instruments are explained in what follows. A questionnaire will be used to collect data on participants' demographic and midwifery characteristic. Its items are on the age, educational level, and occupation of participants and their spouses as well as participants' income, age at marriage, duration of marital life, number of coituses per month, number of pregnancies, contraception method, history of preterm delivery, and history of having a low-birth-weight child. The validity of this questionnaire will be confirmed by several faculty members of the Midwifery and Reproductive Health department of Tehran University of Medical Sciences, Tehran, Iran.

Sexual functioning will be assessed using FSFI. This index has nineteen items. Each item is scored with a specific weight. The six subscales of this index are desire (two items with a weight of 0.6), arousal (four items with a weight of 0.3), lubrication (four items with a weight of 0.3), orgasm (three items with a weight of 0.4), satisfaction (three items with a weight of 0.4), and pain (three items with a weight of 0.4). Participants will answer the items on a 0–5 Likert scale on which zero stands

for no sexual activity and 5 stands for the highest level of sexual activity in the past 4 weeks. After applying the weight values, the possible total score of the index will be 2–36 [31]. The cutoff score of the index is 28 and scores less than 28 and scores more than 28 are interpreted as sexual dysfunction and normal sexual function, respectively [27]. FSFI is a standard instrument with acceptable validity and reliability [31]. The Cronbach's alpha values and the test–retest correlation coefficients of the six dimensions of the Persian FSFI in a previous study were 0.73–0.86 and 0.72–0.90, respectively [32].

DASS-21 will be used in eligibility assessment to assess depression, anxiety, and stress. Lovibond and Lovibond developed this 21-item instrument with seven items in each subscale. Items are scored from 1 ("Did not apply to me at all") to 3 ("Applied to me very much"). The score of each subscale is calculated through summing the scores of its items and is 7–21. As DASS-21 is the short form of DASS-42, the scores of DASS-21 should be doubled before interpretation. The developers of this instrument reported that the Cronbach's alpha values of its depression, anxiety, and stress subscales were 0.91, 0.81, and 0.89, respectively [28]. A study into the validity and reliability of the Persian DASS-21 reported that the Cronbach's alpha of its depression, anxiety, and stress subscales were 0.81, 0.74, and 0.78, respectively [33].

The Sexual Quality of Life-Female was developed by Symonds et al. for sexual QOL assessment [34]. This instrument has eighteen items on sexual self-esteem, emotional issues, and relationships which are scored from 1 ("Completely agree") to 6 ("Completely disagree"). Its possible total score is 18–108, with higher scores showing higher sexual QOL [34]. A study into the psychometric properties of the Persian version of this instrument found that its Cronbach's alpha and test-retest intraclass correlation coefficient were 0.73 and 0.88, respectively [35].

#### Intervention for participants in the intervention group

Participants in the intervention group will receive face-to-face SHM-based SE in three 120-min weekly sessions in 7–8-person small groups. Table 2 shows the overall content of the sessions and Table 3 shows the detailed SHM-based content of the sessions. The sessions will be held in a room in the study setting and using the lecture, question-and-answer, group discussion, and educational booklet methods. The booklet will contain the materials which will be provided at face-to-face sessions and then will be provided to participants to be used by them and their husbands. Free telephone counseling sessions will also be held for participants in order to improve their collaboration. At the end of the intervention, a comprehensive educational booklet (containing all

**Table 2** The overall content of the educational sessions

Session	Content						
First	Introduction; goals of the session; sexual issues; the effect of culture on sexual issues; sexual misconceptions and their correction; sexual anatomy and function; the sexual response cycle; answering participants' questions; provision of the educational brochure and booklet; and asking participants to study the educational brochure and booklet at home						
Second	Review of the first session; sexually-transmitted diseases and their routes of transmission, their prevention, and their treatment; common types of cancer among women (breast and cervix); group discussion about sexual health challenges and barriers; answering participants' questions; provision of the educational booklet; and asking participants to study the educational booklet at home						
Third	Review of the first and the second sessions; body image; positive sexual desires and their promotion; intimacy and marital relationship skills; the religious regulations of sexual relationships; spiritual and religious attitudes towards sexuality; provision of the whole educational booklet						

**Table 3** The content of the educational sessions based on the sexual health model

Session	Model component	Learning objective
First	Talking about sex	Participants talk about sexual relationship and thoughts in order to awaken their sexual desires Expansion of participants' sexual vocabulary to improve their ability to clearly and comfortably talk about their sexual values, attractions, and behaviors
	Culture and sexual identity	Determining the effect of sexuality and cultural heritage on participants' sexual identity, attitudes, behaviors, and health Challenging cultural beliefs about women and sexual desires and correction of misconceptions Example of misconceptions:  • Women can reach orgasm through vaginal sex • Women's sexual libido and arousal are less than men
	Sexual anatomy and functioning	Anatomy and functioning of men and women's genital organs; men and women's sexual responses; the sexual response cycle Hint: Better understanding of the anatomy of women's genital organ helps women modify their expectations and use different methods (such as indirect clitoral stimulation) to find sexual pleasure
Second	Sexual healthcare and safer sex	Better understanding of the body to determine the changes that may need medical intervention (such as diagnosis of breast cancer through self-examination and diagnosis of the symptoms of sexually-transmitted diseases); focusing on preventive behaviors such as safer sexual behaviors. The stigma of sexually-transmitted diseases can reduce libido and negatively affect orgasm (Participants should learn to cope with the pain and stigma of sexually-transmitted diseases, particularly if the disease is not completely treated)
	Challenges to sexual health	Definition and prevention of sexual abuse, sexual coercion, and sexual work (particularly among minorities and the symptoms of mental health problems such as depression and anxiety Referral of women with depression or anxiety to sex psychiatrist
Third	Body image	Challenging a limited beauty standard and encouraging self-acceptance (women can modify their attitudes toward beauty through performing physical exercise, modifying their clothing style, and living as they are really beautiful)
	Masturbation and fantasy	Body search and fantasy can help individuals communicate with their body and find the most sexually appropriate things for themselves. Therefore, participants will be encouraged to assess their body and find the things that can stimulate them and help them reach orgasm Exercise to promote arousal because understanding arousal enables women to better communicate their preferences and needs with their partners
	Positive sexuality	Focusing on the three aspects of positive sexuality, namely development of a positive approach to sexual relationship that approves life, emotion, and beauty; pluralism (i.e. individuals should personally decide what is sexually good for them); and expressing desires and what they want and what they do not want. This education helps women determine their unique sexual preferences, request them, and practice them and hence, improve their libido, arousal, and orgasm
	Intimacy and relationships	Awareness of the effect of intimacy on sexual functioning and satisfaction Assessment of the conflicts in sexual and familiar relationships and attempt to manage them and strengthen the relationships
	Spirituality and religiosity	Learning how to balance moral, mental, and spiritual beliefs as well as sexual values and behaviors (because some participants' religious beliefs may require them to be sexually accessible to their husbands irrespective of their own sexual desires or interests)  Personal coercion into sexual relationship without having adequate desire may reduce libido or even cause sexual aversion over time. Therefore, women need to be encouraged to determine how to improve their libido without self-coercion

materials provided in the sessions) will also be provided to them and they will be invited to ask their questions, if any, through either telephone contacts or face-to-face counseling sessions. The educational sessions will be held by the first author who is a PhD student in reproductive health and has a fifteen-year work experience in the area of reproductive and sexual health.

# Development and validity assessment of the intervention

The SHM-based educational intervention will be developed through reviewing the existing literature, interviewing the women who live in the suburbs, and consulting reproductive and sexual health specialists in focus group discussions. The feasibility and importance of the intervention will also be assessed and confirmed in two rounds of nominal group with specialists [36, 37]. After developing the primary draft of the educational intervention, we will carefully read and revise its content and ask ten women from the target population with different educational levels to assess and comment on its comprehensibility. Then, ten specialists in reproductive health, obstetrics, psychology, and psychiatry will assess the draft of the intervention using the second edition of the Appraisal of Guideline for Research and Evaluation (AGREE II). This appraisal has 23 items in six main areas [38].

# Intervention for participants in the control group

Participants in the control group will receive SE routinely provided to all women who refer to healthcare centers in the suburbs. For the sake of ethical considerations, SE provided to participants in the intervention group will also be provided to participants in the control group after the posttest through a face-to-face session and an educational booklet.

# Data management and analysis

After coding, the collected data will be saved in password protected computers to ensure their confidentiality. Data analysis will be performed using the SPSS software (v. 23.0). The measures of descriptive statistics such as frequency, mean, and standard deviation will be used to present the data and normality will be assessed using the Kolmogorov–Smirnov test. The analysis of covariance as well as the independent-sample t and the Chi-square tests will be employed for between-group comparisons and the paired-sample t test will be used for within-group comparisons. All statistical analyses will be performed using the per protocol analysis and at a significance level of less than 0.05.

#### Patient and public involvement statement

Interviews with women who live in the suburbs and reproductive and sexual health specialists will help us better determine the needs of these women and develop a need-based educational intervention. We intend to share the results of this study with reproductive and sexual care providers and women who live in the suburbs.

#### Discussion

This randomized controlled trial will assess the effects of SHM-based SE on the sexual functioning of the women who live in the suburbs in the east of Iran. We hope this study provides a clear framework for healthcare providers to provide SE and thereby, improve the sexual health of women in the suburbs. The theoretical benefit of this study is the use of SHM-based group education which can be as effective as individualized education. This method can be more useful in communities in which sexual problem management is in its infancy or in places where people have not received any SE during their life [17], particularly in the urban slums with limited SE [39–42].

The low prevalence of SE in the suburbs may be due to the sociocultural norms and misconceptions in these areas about SE [14]. For example, there is a prevalent misconception which holds that SE predisposes the youth to early sexual activity and considers SE in contrast with sociocultural and religious beliefs [43, 44]. Given the known positive effect of SHM-based SE, this method can be used as a component of SE in areas with poor sexual knowledge and awareness [17, 20, 23].

One of the contributing factors to the success of SHM is the positive effect of group therapy. Evidence shows the potential effectiveness of group therapy in the management of sexual dysfunction [17, 20]. Breaking the taboos on speaking about sexuality and getting familiar with the different ideas, problems, and solutions of other group members and interacting with group members who suffer from the same or severer problems can reduce the sexual concerns of the members [17]. Studies show that because of cultural considerations, Iranians consider sexual issues as private and are reluctant to speak about them, while they are interested in listening to general talks about sexuality. Therefore, group therapy may help modify their sexual attitudes and behaviors [45, 46]. Group therapy also helps reduce anxiety and normalize sexual problems for participants [47] and can be an effective alternative for the management of sexual dysfunction in healthcare settings in shorter periods of time [48].

SHM also considers different factors such as culture, sexual identity, and spiritual identity [15] and hence,

will potentially be effective in improving women's sexual functioning and QOL in the Iranian society. We will attempt to use culture-based SE in the study intervention and hope that this intervention will significantly improve family health and strengthen family relationships.

# Strengths and limitations of this study

- 1. The intervention of the study will focus on the sexual health of women living in the suburbs.
- 2. The study intervention will be designed through reviewing the existing literature, interviewing women, and consulting specialists.
- 3. Focus group discussion can be an effective alternative for the management of women's sexual dysfunction in healthcare settings.
- 4. This study can provide healthcare providers with a framework for sexual education.
- 5. Iranians consider sexual issues as private due to cultural considerations and hence, are reluctant to talk about their sexual problems. This will be a limitation of this study

#### **Abbreviations**

SHM Sexual Health Model RCT Randomized controlled trial SE Sexual education

QOL Sexual quality of life

SPIRIT Standard protocol items: recommendations for interventional

trials

FSFI Female sexual function index DASS-21 Depression anxiety stress scale

AGREE II Appraisal of guideline for research and evaluation (AGREE II)

#### Acknowledgements

The Research Administration of Tehran University of Medical Sciences, Tehran, Iran, granted this study. We would like to thank the authorities of the university for their support as well as the reviewers of this manuscript for their valuable comments.

#### **Author contributions**

MK and EE developed the initial study concept and obtained funding. All authors contributed to the design of the study and were involved in the development of sexual education based on the Sexual Health Model intervention. MK drafted the study protocol while ZB, EE, SHF and HA made important revisions. All authors have read and approved the manuscript.

#### Funding

This work was financially supported by Tehran University of Medical Sciences and Health Services with grant number 62004.

# Availability of data and materials

No datasets were generated or analysed during the current study.

## **Declarations**

# Ethics approval and consent to participate

This study received ethical approval from the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran (code: IR.TUMS.FNM. REC.1401.067) and was registered in the Iranian Registry of Clinical Trials (code: IRCT20231121060133N1). Sampling will be performed with the permission of

the Research Administration of the Faculty of Nursing and Midwifery of this university. Any change in the protocol of the study will be subject to ethical approval and will be reported in the Iranian Registry of Clinical Trials. Data confidentiality will be guaranteed through storing the data in password-protected computers, participants will be ensured of voluntary participation in and withdrawal from the study, and informed consent will be obtained from all of them. Study findings will be provided to participants and their families through healthcare centers and will be provided to healthcare providers and researchers through conferences and publication in academic journals.

#### Consent for publication

Not applicable.

#### Competing interests

The authors declare no competing interests.

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Received: 26 July 2024 Accepted: 16 August 2024 Published online: 23 August 2024

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