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STUDY PROTOCOLS

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Psychosexual counseling intervention to improve women's genital self-image: Study protocol for a randomized controlled trial based on a multistage mixed method design

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Abstract

Background: Genital self-image (GSI) is a major barrier to reproductive and sexual health for women. This practical randomized trial aims to evaluate the effect of psychosexual counseling based on a cognitive-behavioral approach to promoting GSI for reproductive-age married Iranian women.

Methods: Married women aged 15–49 years under the coverage of health centers will be invited to join the study. The study will be conducted using a multistage mixed method design in three phases. In the first phase, semi-structured interviews with women and key informants will be conducted to understand better the GSI concept, the factors influencing it, and the interventions promoting it. Simultaneously, a literature review will be conducted by searching electronic databases to find the factors influencing GSI and the interventions to enhance it.

In the second phase, the GSI-related factors, sexual and reproductive health outcomes correlated with GSI, and intervention programs for promoting GSI in women will be extracted from the integration of qualitative study and literature review. Then, based on the expert panel's priority, a suitable program will be prepared.

In the third phase, at first, a cross-sectional study will be conducted to identify women with poor GSI and the factors relating to GSI, and then psychosexual counseling intervention will be performed. For the randomized controlled trial study, participants will be randomly allocated into two groups: (1) the intervention group and (2) the control group. Data will be collected using the Female Genital Self-Image Scale and sexual and reproductive health outcomes correlated with GSI at baseline, immediate, and 2-month follow-up assessments. The impact of the intervention on the promotion of GSI will be evaluated.

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Discussion: This study provides a counseling program for promoting GSI. If this interventional program is successful, it has practical potential to be generalized for Iranian Women with poor GSI.

KEYWORDS
genital self-image, Iran, randomized controlled trial, sexual health, women

1 | BACKGROUND

The attention and focus on female genital appearance have recently increased.[1] Individuals' perceptions and experiences of genital characteristics, including appearance, odor, and functionality, are referred to as their genital self-image (GSI), a subfield of body image research.[2,3] It seems that women are generally less satisfied with their genitalia than men.[4] Many women throughout their lives, whether generally or regarding one or more specific elements, feel unsatisfied with their genitalia. The interaction of psychological and individual factors results in GSI.[5] A person's social and cultural environment dramatically affects how they perceive their genitalia.[6] Culture, exposure to idealized images in the media, and the judgments of health care professionals, family, friends, and sexual partners—although research has not yet supported this influence—all affect how people perceive the appearance of genitalia as "normal."[7]

For instance, perceptions of desirable genital features can vary across different cultures. In some cultures, larger protuberant labia may be considered desirable, while in others, small labia may be seen as preferable.[8] The influence of mass media on the sociocultural trend of genital beautification is undeniable. Media exposure has the power to shape individuals' perceptions of their own genitalia, both positively and negatively. Although media exposure may provide some reassurance regarding one's genital anatomy, it significantly contributes to the development of beauty standards and the normalization of cosmetic enhancements.[8,9]

GSI has been linked to sexual habits, sexual satisfaction, and sexual health, whether it is positive or destructive.[10,11] Evidence suggests that negative GSI affected sexual unhappiness directly and indirectly (through low sexual self-esteem).[12] It might affect how women behave in terms of seeking out health care, such as getting regular gynecologic screenings.[11,13] According to research, women may put off getting regular gynecological exams because they are worried about how their health care providers may look at their genitalia.[10]

As a result of their ineptitude, women who feel ashamed of their genitalia may have sexual dysfunction,[14,15] be able only to have sex in the dark, or refuse to let their partner touch or see the parts of their bodies.[16]

In addition to these unfavorable attitudes toward genitalia, more women are electing to undergo genital surgery.[17,18] Female genital cosmetic surgery (FGCS) refers to a variety of nonmedically necessary treatments that try to alter the esthetic (or functional) features of women's genitalia.[18]

Infection after surgery, hematoma, asymmetry, wound dehiscence, urine retention, skin retraction, uncomfortable sex, insufficient wound healing, and injury to the bowel or bladder brought on by fistula formation are all complications of FGCS.[19]

The effectiveness of FGCS is debatable due to a lack of evidence supporting the effectiveness and safety of these operations, even though certain studies demonstrate an improvement in the negative genital image following FGCS.[20,21] Furthermore, because few patients are included in current research on surgical methods and outcomes, there is conflicting evidence regarding the effectiveness of various labiaplasty techniques and patient satisfaction.[7]

Careful evaluation and nonsurgical therapies, such as counseling and education regarding the diversity of genital appearance, can relieve worries about genital appearance.[19,21] Most medical specialists agree that women considering genital cosmetic surgery should meet with a psychiatrist or psychologist before surgery; however, it is unclear whether counseling and education successfully reduce dissatisfaction. Counseling and education could help lower the demand for procedures as the nature of patient motivation for this sort of surgery are frequently psychological.[7]

Few initiatives have been made to enhance women's GSI globally; occasionally, those made have been unsuccessful. According to research by Laan et al.,[22] women considering labiaplasty may have a more favorable GSI after being exposed to natural photos. Sex education was found to improve GSI in the population of infertile women[23] while improving GSI among healthy women between the ages of 18 and 40 was unsuccessful when employing a training program based on sex education.[24] A recent study conducted among women with Rokitansky syndrome revealed that psychosexual education was found to be effective in promoting GSI.[25] Several counseling interventions have been implemented to enhance body image (not genital image). Some notable interventions include cognitive-behavioral therapy,[26–28] acceptance and commitment therapy,[27,29] self-compassion,[30] and mindfulness-based interventions.[26] However, it remains uncertain whether these interventions are effective in addressing GSI. Therefore, according to address this conflicting information and the lack of a comprehensive program, this protocol aims to develop an interventional program to promote GSI among Iranian women.

1.1 | Hypothesis

The main aim is to assess the impact of psychosexual counseling based on a cognitive-behavioral approach to promoting GSI for Iranian women. Intervention effects will be examined at 2 months.

The research's main hypothesis is The intervention group will show a higher (better) GSI than the control group measured by mean scores.

1.2 | Trial design

The evaluation design is a parallel, randomized controlled trial (RCT), with two arms and with a 1:1 allocation ratio. The intervention arm will receive the training program starting in January 2023, and the control arm will receive the training program after the final research data collection.

2 | METHODS

2.1 | Aim, design, and outcomes

The design of this protocol is a randomized clinical trial. The final purpose is to develop and evaluate a psychosexual counseling program based on a cognitive-behavioral approach to promoting GSI among reproductive-age married Iranian women. A sequential mixed method with a multistage design will be used in the study.

2.2 | Outcome measures

The main question addressed in this study is "Does the psychosexual counseling program based on a cognitive-behavioral approach affect GSI among Iranian women?." To answer this main question following primary outcome is expected:

1. Determining and comparing the effects of a psychosexual counseling program based on a cognitive-behavioral approach on GSI among women in the target and control groups before, immediately and, 2 months after the interventions.

Consequently, we expect the effect of our counseling interventional program on sexual and reproductive health outcomes regarding GSI among women. To assess the expected secondary outcomes a self-reported assessment addressing sexual and reproductive health outcomes correlated with GSI (frequency of sexual activity, frequency of masturbation, sexual dysfunction, sexual distress, prevent risky sexual behaviors, deciding to get pregnant, deciding on the type of delivery, doing pap-test and genital examination) will be conducted. The sexual and reproductive health outcomes correlated with GSI will be extracted from integrating data in the first phase. The psychometric properties of that will also be confirmed in the second phase.

2.3 | Participants

The research population will include women of reproductive age (between 15 and 49 years) who are sexually active. Participants in the second stage of the third phase (RCT study) consisted of married women of reproductive age who chose to disagree or strongly disagree with at least one of the items of the GSI scale in the first stage of the third phase (cross-sectional study) and were willing to participate in the intervention. In the cross-sectional study, at first cluster sampling in two stages was used. The first stage involved all of Amol City's health care centers because the goal of maximal heterogeneity had been met. In the second stage, women of reproductive age were chosen randomly from each center. The sample size in each center was chosen by considering the likelihood of selection relative to the population size (or estimated population size). Invitations to participate in the study will be stretched to all eligible women until we reach a sample size of 108 women who provide informed consent to participate. Table 1 contains a complete list of the inclusion and exclusion criteria of eligible women in the third phase (cross-sectional & RCT study).

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Married women in reproductive age (15–49 years old). • Women with reading and writing literacy. • Engaged in sexual activity. • Not being pregnant. • Women without premature ovarian failure. • Not being in the first 6 months after childbirth. • Lived in Amol. • Had access to smart phones. • Tend to participate with informed consent to share information, and participate. • Women without major psychiatric disorders based on self-report (such as depression, anxiety, obsession). • Women without history of genital surgeries such as hysterectomy, oophorectomy. • Women without cancer in the genital area (like vagina cancer, cervix cancer).	• Unwillingness to continue cooperating throughout the experiment. • Absence of more than two sessions in training sessions.

2.4 | Study design

This sequential multi-stage mixed methods study will be divided into three phases. This protocol was developed and reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials, and the qualitative, cross-sectional, and clinical trial study will be carried out in accordance with the Standards for Reporting Qualitative Research,[31] Strengthening the Reporting of Observational Studies in Epidemiology guidelines,[32] and Consolidated Standards of Reporting Trials, respectively. A flow chart of the procedures in the implementation of a multistage design is shown in Figure 1. Moreover, the study visual diagram is presented in Figure 2.

2.5 | Phase 1: The qualitative study and literature review

Using semi-structured in-depth interviews with women and key informants, the researcher attempts to identify the concept and relevant determinants and interventions for fostering GSI in women at this stage. This study will employ using conventional content analysis method. This study has two types of participants: women of reproductive age and key informants. The interview will include women with the highest variance in age, education, employment, marital status, pregnancy, and delivery status, as well as women considering genital cosmetic surgery, and women receiving genital cosmetic surgery. Also participating will be health service professionals with experience delivering sexual health care, such as gynecologists, reproductive health specialists, general practitioners, midwives, psychiatrists, psychologists, and social workers. Participants will freely join in the study and provide informed consent.

They will be selected by purposeful sampling method, and interviews will continue until data saturation is reached. The interviews will be done at the participants' convenience (the research environment comprised women's health clinics, gynecological clinics, laser centers, a health care facility linked with the Mazandaran University of Medical Sciences, the offices of critical informants, etc.). All interviews is conducted in a discreet and comfortable location.

The inclusion criteria include Iranian women's willingness to engage in the study, the provision of informed permission, the ability to comprehend and articulate their experiences, and a minimum of 2 years of work experience for key informants. During this phase, data will be collected via open and semi-structured interviews and field notes. The participants' written and verbal agreement will be obtained before recording their interviews. The participant's preferences will determine the interview's timing, length, and location. The interviews will be examined using a conventional qualitative content analysis approach during data collection.[33]

In qualitative research, the sample size is undetermined, and sampling will continue until data saturation is reached.[34] Therefore, the interviews are continued until data saturation simultaneously with the qualitative study, we also will use the literature review to identify the factors influencing the genital image and the interventions to enhance it. Finally, a list of potential intervention programs will be developed using the two approaches mentioned above (interview and literature review).

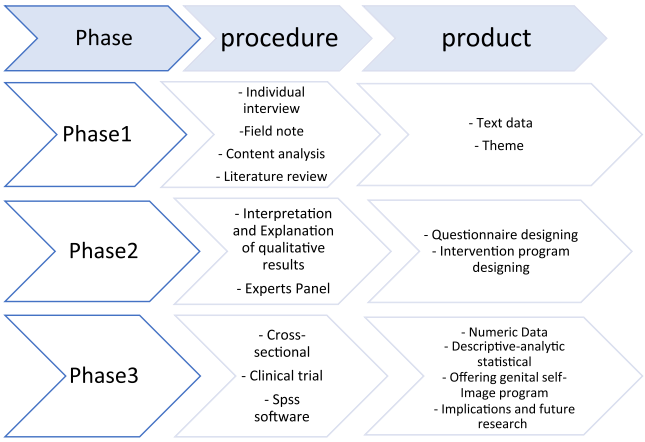

FIGURE 2 Study visual diagram.

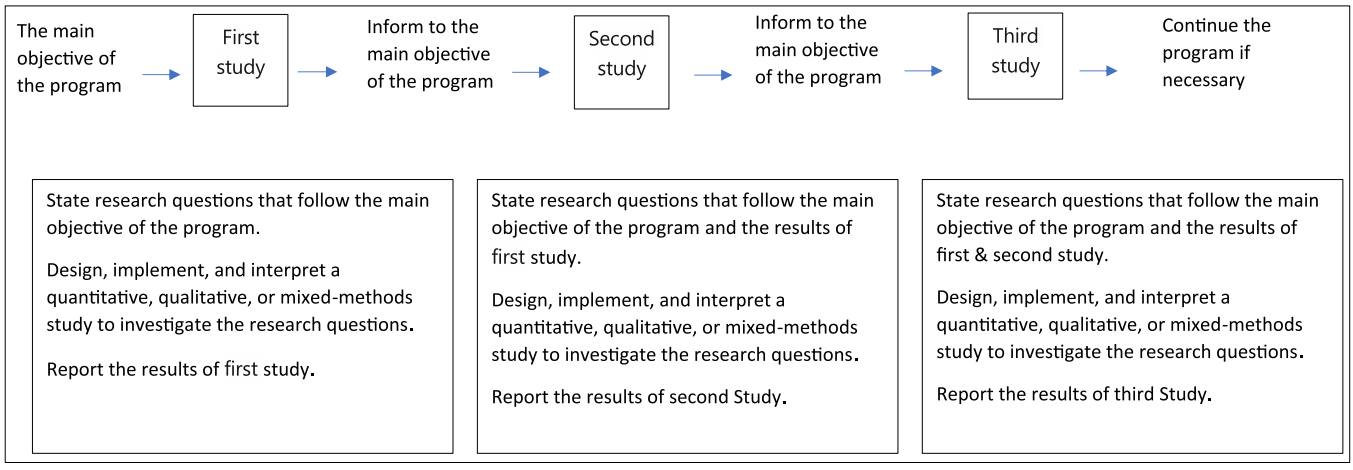

FIGURE 1 The flow chart of the usual procedures in the implementation of a multistage design.

2.6 | Second phase: Designing the questionnaire and intervention program

After gathering the necessary data through qualitative research and the literature review, the second part of the study will commence. In the second phase, two checklist will be developed using information acquired in the last phase (multidimensional checklist of the factors relating to GSI/and sexual and reproductive health outcomes correlated with GSI). Psychometry evaluation of the researcher-made questionnaires will be conducted. In addition, a list of potential intervention programs to enhance the GSI of women will be compiled based on methodologies and techniques drawn from the integrated data of the qualitative study and literature review and validated by an expert panel. The purpose of this step is to develop an effective interventional program to promote GSI among Iranian women by holding a panel of experts.

2.7 | Holding a panel of experts

At this stage, the nominal group technique (NGT) will be used to rank the strategies gleaned from the qualitative research and the literature review. The panel of experts will consist of obstetricians, psychiatrists, reproductive health professionals, community medicine professionals, a professor of urology, a general practitioner, a psychologist, and those involved in the creation of sexual health policy (these people will be selected by the research team based on their professional experiences). The experts on the NGT panel will get an email with a summary of the study's initial findings before the NGT session begins. Next, the NGT will be used to host a session with the panel experts.

Within the context of a focus group, NGT provides a systematic method for collecting useful and credible qualitative data from a panel of experts.[35] The NGT meeting is a highly organized, in-person gathering that can run up to 2 h. Some studies have used the NGT with groups bigger than the recommended 5–9 people.[36]

The routine NGT process consists of the following five steps: introduction and explanation, silent generation of ideas, idea sharing, group discussion, and voting and ranking.

Therefore, the last step entails giving the recorded answers a priority concerning the research question, which in this case was: "What is the most effective intervention to enhance women's genital image?" Participants receive immediate results in response to the question following the voting and ranking procedure, and the meeting ends with a decision made.[36]

2.8 | Phase 3: Quantitative studies (the cross-sectional and the RCT)

Two sequential quantitative studies will be carried out in this phase. The mean GSI score and its associated factors among married women of reproductive age will be determined using a cross-sectional design.

To evaluate the effectiveness of the proposed intervention, the RCT will be conducted after the initial cross-sectional investigation. RCT is the most effective way to assess public health interventions. RCT reduces the impact of confounding bias because each study participant is assigned to an intervention or control group solely by chance.[37] Figure 3 depicts the flow chart of the randomized controlled protocol.

2.9 | The implementation method

After gaining ethical permission from the Ethics Committee of Shahroud University of Medical Sciences, a permit from Mazandaran University of Medical Sciences, and conducting the required coordination with the health care center, the researcher will conduct the study. In the first step (cross-sectional study), the researcher will pick eligible women from all health care centers of Amol using a random sample method. If they are ready to cooperate, the researcher will obtain their informed consent and reassure them that the information collected will be kept secret. Finally, they will be given a questionnaire link to complete. In the next step (RCT study) the list of women who chose to disagree or strongly disagree with at least one of the items of the GSI scale in the previous step (cross-sectional study) will be retrieved. Afterward, the researcher will call these women to explain the study's goals and encourage them to join. Finally, they will be chosen using a convenience sample method with their informed consent if they are willing to participate.

2.10 | The intervention programs

Based on the findings from the previous study's phases 1 and 2, the intervention will be developed. Recruitment of eligible women will continue indefinitely until the desired sample size is reached. At that point, all participants will be coded and blindly allocated into either the intervention or control group by the researchers. This allocation will be done using a permuted block randomization program, with the groups labeled as (1) intervention and (2) control.

To evaluate the effectiveness of psychosexual counseling in enhancing women's GSI, a RCT intervention will be conducted. The counseling will be based on a cognitive-behavioral approach. Baseline, immediate, and 2-month follow-up measurements will be taken to assess the impact of the intervention on participants' GSI. In line with ethical principles, the control group participants will receive the most effective intervention after the final measurement.

2.11 | Instruments

The Female Genital Self-Image Scale (FGSIS) will be applied to assess GSI for both quantitative studies (cross-sectional and RCT). FGSIS assesses women's sentiments and views regarding their genitalia. It consists of seven questions on a Likert scale of "strongly disagree,

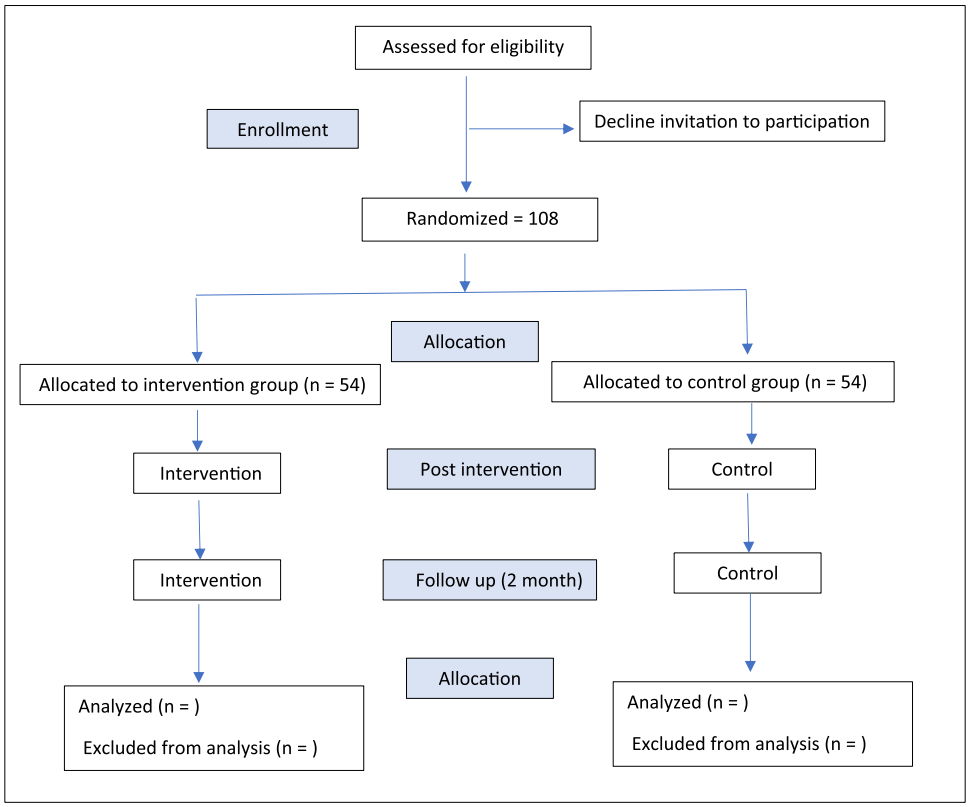

FIGURE 3 Consolidated standards of reporting trials flow diagram.

disagree, agree, and strongly agree." The scoring range is from 1 to 4. The minimum and maximum scores for GSI are 7 and 28, respectively, with higher values suggesting a more favorable GSI.[11] It has been reported that the FGSIS has great reliability and validity.[3,10] In the investigation by Felix et al.,[38] the Cronbach's α coefficient for this instrument was 0.81, indicating its good reliability. Eighty-six percent of the Persian version of the FGSIS was reliable based on Cronbach's α values and test–retest results, showing a high degree of internal consistency.[15]

Two questionnaires developed by researchers also will be used to assess the GSI-related factors in the cross-sectional study, and sexual and reproductive health outcomes correlated with GSI as the expected secondary outcomes in the RCT study. The pool of questions for the questionnaires will be derived through qualitative study and literature research in the first phase. The validity and reliability of them will be assessed in the second phase.

It should be noted that since the relationship of some variables with GSI has been proven in previous studies, apart from single questions in researcher-made questionnaires, we used reliable and validated standard questionnaires such as the six-item Female Sexual Function Index[39] for sexual function evaluation, the Female Sexual Distress Scale–revised[40] for sexual distress assessment, and the Multidimensional Sexual Self-Concept Questionnaire[41] for assessing sexual esteem and sexual satisfaction.

2.12 | Ethics approval and consent to participate

Ethical approval for this study has been obtained by the ethics committee affiliated with Shahroud University of Medical Sciences, Shahroud, Iran (IR.SHMU.REC.1398.097). Registration of this RCT has been completed with the Iranian Registry of Clinical Trials, IRCT20220302054166N1. All methods will be carried out in accordance with relevant guidelines and regulations. Moreover, the necessary permits will be obtained to attend health centers. The design, objectives, and research methods will be fully explained to the participants and informed consent will be obtained from the participants and from their parents and/or legal guardian for this study. In addition, in cross-sectional and RCT studies, Participants were required to choose the consent confirmation option before proceeding to complete the questionnaires. If they did not provide consent, they were unable to participate in the study. The control group also will have access to the educational content at the end of the intervention period. Participation will be voluntary and participants could withdraw study at any time.

It should be mentioned participation in this clinical trial offers potential benefits such as improved GSI, enhanced sexual and reproductive health, psychological well-being, empowerment, and contribution to scientific knowledge. By actively participating in the program, individuals may also experience reduced interest in

cosmetic surgery. However, there are risks involved including discomfort, embarrassment, emotional distress, and privacy concerns. It is important to note that while the intervention aims to improve GSI and related outcomes, there is no guarantee that all participants will experience positive changes. Additionally, the potential benefits and risks listed here are not exhaustive and may vary based on individual experiences and circumstances.

2.13 | Sample size and power calculations

Information taken from Smith et al.'s[42] results helped estimate the sample size of both studies (cross-sectional and RCT). The standard deviation (SD) of GSI was reported to be 3.9 using FGSI.[42] We used the formula[43] $n = \frac{z^2\sigma^2}{d^2}$ to calculate the sample size with an estimated accuracy of 30% ($d = 0.3$), with a two-tailed 5% significance difference (α) ($Z = 1.96$). The sample size was finally considered 763 in the cross-sectional study, given a drop rate of 10%.

In the RCT study, the predicted sample size for each group was 46 based on $m1 = 22.5$ and a minimum 10% rise in the mean score by the intervention in GSI ($m2 = 25.19$), SD1 = SD2 = 3.9, a significance threshold of 0.05, and a power of 95%. It was determined to recruit 54 women for each group after considering the potential 15% loss to follow-up.

2.14 | Randomization

After obtaining informed consent, participants in the RCT will be randomly assigned to either the intervention or control groups using a restricted randomized block design. Each participant will be given a unique research identification number. The eligible individuals who volunteered for the study will then be randomly allocated to the experimental and control groups using a blocking method. This random allocation will be achieved through computer-generated randomization blocks of four. A total of 108 eligible individuals will be allocated to the intervention and control groups in a 1:1 allocation ratio. The intervention group will be identified as "Group A" while the control group will be identified as "Group B." The process of random allocation will continue until the desired sample size is reached.

2.15 | Data analysis

2.15.1 | Phase 1 (qualitative analysis)

Conventional content analysis will be used to examine and interpret data.

Each interview will be transcribed, analyzed, and coded before the start of the following interview. Transcripted data will generate codes, subcategories, categories, and themes. Combinations of linked beginning codes will be labeled to create subcategories and categories. Finally, the text's hidden meaning and major themes will be retrieved. The extracted themes and key categories along with the literature review will be utilized to construct the primary item pool for the related factors questionnaire and the primary draft of recommended interventions for improving GSI. At the end, credibility, dependability, confirmability, and transferability will be applied to ensure the trustworthiness of the findings.[34]

2.15.2 | Phase 3 (quantitative analysis)

The Kolmogorov–Smirnov test will be used to determine the data's normality. In both studies, the collected data will be analyzed using descriptive statistics (such as frequency, frequency percentage, mean, and SD) and inferential statistics in SPSS ver25. Utilizing univariate analyses like Pearson correlation and analysis of variance, as well as multiple linear regression, the factors associated with GSI will be discovered in the cross-sectional study. Homogeneity between the two groups was tested using χ^2 tests, Fisher exact test, and independent t-tests. Generalized mixed models of analysis of variance for repeated measures will be used to compare the differences between the values obtained before the intervention immediately and 2 months after the intervention in each group. We will also calculate the differences in means between the independent groups, as well as their respective 95% confidence intervals. All statistical tests will be two-sided, and a $p < 0.05$ will be considered statistically significant.

3 | DISCUSSION

One crucial element in the well-being of women's sexual and reproductive health is the consideration of GSI as a significant component of body image in women. Therefore, there is a critical need for fundamental initiatives in this area. This paper describes the clinical trial protocol which will examine intervention programs to promote GSI in married reproductive-age women. This will be the first study to examine the impact of a program intervention based on a cognitive-behavioral approach to promote GSI in Iranian women.

The prevalence of poor GSI in the general population appears to be higher than anticipated. According to the available data, it has been determined that up to one-third of women are unhappy with the way their genitalia look[44] poor GSI is linked to several detrimental effects, such as decreased sexual activity behavior,[1,5,45] increased sexual distress,[46,47] increased negative cognitive-affective reactions,[5] and worse genital health decision-making.[10] It may increase the demand for cosmetic procedures, and many people with normal genitalia now have cosmetic genital surgery.[44] Although estimating the exact number of cosmetic genital surgery in Iran is not possible due to the lack of information, the demand for that, is remarkable.[48]

Therefore, this study aims to identify the best intervention program as an effective step to promote GSI and consequently, sexual and reproductive health of Iranian women aged 15–49 years. It appears that the current study's findings will first encourage

women to accept and enjoy the varied aspects of their genital systems as they are. To improve women's perceptions of their genitalia, promote sexual and reproductive health, and reduce the frequency of needless genital cosmetic surgery, legislators, managers of health deputies, and health care professionals can employ the interventional program that has been established. If this program is successful, it might become one of the most important educational guides for promoting GSI in women with poor GSI and helping them accept their genitalia.

We acknowledge certain limitations. First, the findings of the qualitative phase may not be generalized due to the nature and philosophy of qualitative research, so it cannot be considered a significant weakness. On the other hand, using a mixed method design is one of the strong points of the present protocol that can expand future research directions. Second, the RCT is restricted to recruiting participants from a specific region in Iran. However, this limitation allows for better control over the testing procedure. Third, there is a possibility of limited access to the questionnaire link, which could result in a reduced response rate. To address this, we will employ various methods of distributing the online questionnaire through social networks to reach a wider audience. Another limitation arises from cultural barriers, which may initially hinder participants' acceptance and willingness to join the study. To mitigate this, most of the intervention sessions will be conducted online using the Skyroom platform, except for the first session, which requires in-person attendance to establish trust and confidence. Lastly, there is a risk of participant attrition in the final stages of the study. To mitigate this, we will provide financial incentives as compensation for completing the questionnaire at each stage, including the pretest, immediate postintervention, and 2 months after the intervention.

4 | CONCLUSION

This study provides an psychosexual counseling program to improve women's GSI.

If the interventions designed in the present study are effective, It has a high practical potential for generalization for all reproductive-age women with poor GSI.

Moreover, it can help policymakers and health care providers understand what approach is appropriate for enhancing GSI and apply it in general or private centers/offices for sexual counseling sessions. It also can provide important information to increase the effectiveness of future policies, decision-making, and interventions. In this way, by using such counseling intervention may be possible for the demand for nonmedically indicated genital surgery to reduce.

AUTHOR CONTRIBUTIONS

Mina Malary: Conceptualization; data curation; formal analysis; investigation; methodology; project administration; resources; software; visualization; writing—original draft; writing—review and editing. **Zeinab Hamzehgardeshi**: Conceptualization; formal analysis; methodology; supervision; validation; visualization; writing—original draft; writing—review and editing. **Afsaneh Keramat**: Conceptualization; investigation; supervision; validation; writing—original draft. **Masoud Yunesian**: Conceptualization; formal analysis; methodology; supervision; writing—original draft; writing—review and editing. **Maryam Farjamfar**: Conceptualization; data curation; funding acquisition; methodology; supervision; visualization; writing—original draft; writing—review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Not applicable.

TRANSPARENCY STATEMENT

The lead author Maryam Farjamfar affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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