Promoting preventive behaviors of sexually transmitted infections (STIs) through educational intervention based on Instructional System Design (ISD) model: Study protocol for a randomized controlled trial

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Research Article

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Abstract

Background: Sexually active women aged 18 to 48 are within the population at risk for acquiring sexually transmitted infections. Some STIs can cause serious complications, including pelvic inflammatory disease, infertility, ectopic pregnancy, cervical cancer, neonatal death, or congenital anomalies. Accordingly, the present study will investigate the impact of an educational program based on a based on Instructional System Design (ISD) model to promote preventive behaviors of sexually transmitted infections (STIs).

Methods: Women aged18–48 years that refer to Tehran Municipality Health Houses will be invited to join the study. Recruitment will continue until a sample of 150 women provides informed consent to participate. The study will be conducted using a mixed-methods protocol in three phases. In the first phase, Women's educational and learning needs about STIs will be identified using a qualitative approach. In the second phase, the results from the qualitative approach will be used to design a training program based on an ISD model. Educational intervention will be performed in the third phase. Participants will be randomly allocated into two groups: (1) intervention group (2) control group. Data will be collected using STI Four-Scale of Preventive Behaviors at baseline in 1 month and 3-month follow-up assessments. The impact of the intervention on the promotion of preventive behaviors from STIs will then be evaluated.

Discussion: This study provides an educational program for educating, empowering, and promoting behaviours that prevent sexually transmitted infections.If the interventions designed in the present study are effective, It has a high practical potential for generalization for all women aged 18-48 at risk of STIs.

Trial registration: ClinicalTrials.gov IRCT20200602047638N1.Registered on 22 May2021 with the IRCTID.

Background

In both developed and developing countries, sexually transmitted infections (STIs) are regarded as one of the most serious public health issues (1). More than a million people are infected with STIs every day around the world, and 50 million are infected with one of four curable sexually transmitted bacterial infections, namely chlamydia, gonorrhea, syphilis, and trichomoniasis (2, 3). The World Health Organization (WHO) estimated in 2008 that the total incidence of four preventable STIs in the Eastern Mediterranean region was 26.4 million(4). Although the risk of HIV infection and death has decreased in most areas of the Middle East and North Africa, the virus's prevalence is increasing. The actual prevalence of STIs in Iran is much higher than official data and records indicate (5).

The Ministry of Health and Medical Education in Iran presented alarming statistics on the rate of STIs (such as AIDS) and their rate of transmission through sexual contact. According to reports, sexual transmission has increased from 10–21%, and 38.9% of the 28 000 cases registered in 2013 acquired it through unsafe sex (6). Furthermore, 1700 cases of gonorrhea and 5500 cases of chlamydia have been

reported in Iranian men and women. These infections were found to be slightly more common in women than in men (7).

Some STIs can cause serious complications, including pelvic inflammatory disease, infertility, ectopic pregnancy, cervical cancer, neonatal death, or congenital anomalies. Meanwhile, these infections can facilitate the spread of bloodborne diseases such as the human immunodeficiency virus (HIV) and hepatitis B virus via sexual contact(8). In addition to the sexual route, blood product transfusion, mother-to-child breastfeeding, intrauterine, and delivery are all known ways for some STIs to be acquired (9). STI complications have a disproportionate impact on people of all ages, with significant consequences for women of reproductive age. Women are biologically more vulnerable to such STIs than men, and they are more likely to experience problems as a result(10). Women who engage in sexual activity are at risk for STIs (11).

From 2010 to 2013, the third national program on AIDS and STIs in Iran included four STI strategies such as education, sexual transmission prevention, treatment, and strengthening of the epidemiological care system with data management(12). Educational intervention is one of the most effective strategies for behavior change(13). The educational approach's goal is to provide people with the knowledge, information, and skills they need to adopt healthy behaviors. Behavioral approaches use preventive strategies to encourage individuals to adopt healthy behaviors (13).

Globally, the prevention of high-risk behavior and unprotected sex, as well as the promotion of healthy behavior, has been identified as the most effective solutions for STI prevention (14). The timely and rapid diagnosis of disease, complete and effective treatment, education on prevention and risk reduction, and encouraging the use of condoms are some of the principles that can control and cure STIs(15). Current efforts to prevent the spread of STIs are insufficient. Despite significant efforts to identify simple interventions for reducing high-risk behaviors, changing behavior remains a complex challenge(16). Individuals' access to effective resources has been hampered in many developing countries due to negative attitudes toward sexual health education, ineffective communication skills, insufficient educational materials, and a lack of knowledge(17). Iranians' sexual health may be jeopardized as a result of receiving incorrect sexual information from the internet and other sources(18, 19). Furthermore, discussing STIs is a cultural constraint and taboo (20).

Given the above, it seems that educational interventions based on theories that consider the learning needs of the target group will be effective in promoting preventive behaviors of sexually transmitted infections in at-risk women. Therefore, this study mixes methods will be used to design and evaluate an educational program to promote preventive behaviors of STIs to empower at-risk women.

Methods

Aim, design, and outcomes

The aim of this study is to provide a practical approach to promote preventive behaviors from STIs. An exploratory sequential mixed-methods design will be used in the study.

Primary outcome

The development of an educational program based on the findings of a preliminary qualitative study.

Secondary outcomes

The effect of our educational intervention on the preventive behavior regarding sexually transmitted infections. Consequently, the following are the primary research questions addressed in this study:

Does the educational intervention designed based on the Instructional System Design (ISD) model promote STIs preventive behaviors among Iranian?

Ethical approval

The study protocol has been approved by the Medical Ethics Research Center of Tarbiat Modares University (reference: IR.MODARES.REC.1399.039). All participants will be given complete information about their participation in the study and assured that their personal information will be kept strictly confidential. Every participant will be required to sign a written informed consent form. This will ensure that they understand that their participation is entirely voluntary and that they have the right to withdraw at any time during the study.

Participants

The research population will include women aged 18–48 years who are sexually active. To meet these inclusion criteria, recruitment will be from women who refer to Tehran Municipality Health Houses. Invitations to participate in the study will be stretched to all eligible women until we reach a sample size of 150 women who provide informed consent to participate. Table 1 contains a complete list of the inclusion and exclusion criteria.

Study design

This exploratory sequential mixed-methods study will be divided into three phases, which are described below. Table 2 shows the enrollment, interview, intervention, and assessment schedule. This protocol was developed and reported in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)(21), and the clinical trial will be carried out and reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT). A visual diagram of the study process is shown in Figure 1.

Phase 1: The qualitative exploration

The qualitative study will take 5 months to complete. To explore the educational and learning needs of at-risk women, semi-structured interviews with open-ended questions and conventional qualitative content analysis methods will be used. The interviews will take place face-to-face in a mutually convenient quiet environment. In accordance with the study's goals and objectives, an interview guide has been created. The first question is a wide, open-ended question about the participant's feelings about STIs, to which they will be asked to respond in detail. Then, based on this response, further probing questions are asked. The goal is to gain a comprehensive understanding of women's attitudes toward STIs. Each interview will be transcribed word by word immediately after each interview. The transcript will then be sent to each woman, along with a summary of key points extracted from each interview, to ensure that the interviewer has correctly interpreted their declarations (member checking), and any vague and discrepancies will be resolved. In addition, we will use the literature review to identify the educational and learning needs of women about STIs in order to gain an understanding of their needs. Finally, an educational intervention that best fits the qualitative study results will be developed using the two approaches mentioned above (interview and literature review) and the ISD model.

Phase 2: Designing the intervention program

The second phase of the study begins after the required data has been collected through qualitative research. The purpose of this step is to develope an effective educational program based on the ISD model to promote preventive behaviour from STIs among Iranian women

Conceptual framework of content development based on ISD model

Dick and Carey's (2014) Instructional System Design (ISD) model provided the framework for this program. The ISD model depicts the processes and steps we take to effectively organize all components in order to achieve our objectives(22). This model is a systematic and structured process that establishes a strong connection between stimulus (learning materials) and response (learning)(23). The role of the environment in learning is highlighted in this systematic approach. According to this model, it is necessary to first identify the sub-skills that learners should master before selecting the stimulus and strategy that are appropriate for each sub-skill(24).

Instructional System Design (ISD) model steps

The ISD includes 10 steps:

1. Identify Instructional Goals

The first stage determined what learners could accomplish after completing the educational process(25). These objectives are the result of need assessments. Need assessments are analyses of the gap between one's current status and one's desired status.

2. Conduct Instructional Analysis

When learners have achieved their instructional goals, what they should do is determined by stages in a hierarchy.

3. Analyze Learners and Contexts

In this stage, we will analyz learners' STI learning experience, preferences, traits and learning situations.

4.Write Performance Objectives

When students complete the education program, they develop a detailed action plan based on the knowledge they have gained, which is aligned with performance objectives.

5. Develop Assessment Instruments

Assessment tools determine whether or not students met their objectives.

6-Develop Instructional Strategy

The researcher determines the educational method that learners will use to achieve their ultimate learning goals during the educational strategy phase.

7- Develop Instructional materials

The researcher will choose educational materials at this stage based on the instructional strategy.

8.Design and conduct formative evaluation

At this stage, the educational content will be made available to at least 5 to 10 women outside of the research team, and the content's validity will be evaluated in terms of applicability, comprehensibility, simplicity, and attractiveness.

9-design and conduct summative evaluation

Following the evaluators' comments in Step 8, any possible and necessary corrections to the educational content will be made.

10. Final evaluation

The effect of the intervention will be evaluated at this stage in three time periods: immediately, one month, and three months after the end of the educational intervention.

Phase 3: The randomized controlled trial

Randomized controlled trials (RCTs) are the most effective way to assess public health interventions. RCT reduce the impact of confounding bias because each study participant is assigned to an intervention

or control group solely by chance (26). Figure 2 depicts the flow chart of the randomized controlled protocol.

The intervention programs

The intervention will be created using the qualitative study's phase 1 findings. Women who meet the inclusion criteria will be recruited indefinitely until the required sample size is reached.At this point, all participants will be coded and blindly allocated into one of intervention and control groups by the researchers using a permuted block randomization program: (1) intervention (2) control.

Based on the design of the randomized controlled trial intervention, the impact of the intervention program on promoting women's STI prevention behaviors will be assessed. Measurements will be taken at baseline, after one month, and after three months of following their respective program, as shown in Fig. 1. In accordance with ethical principles, the participants in the control group will also receive the most effective intervention after the final evaluation and comparisons of the three intervention groups.

Instruments

The instrument that will be used to collect the data is STI Four-Scale of Preventive Behaviors in females(2). This scale were finalized by applying 40 five-point Likert response items where the items ranged from completely agree to completely disagree; the higher the score the greater the preventive STI behaviors. The calculated Content Validity Rate (CVR) and Content Validity Index (CVI) of the four-scaleitems ranged between 0.56–1.00 and 0.83–1.00, respectively. The impact score of all items was above 1.5. Cronbach's alpha for each scale was as follows: STI knowledge (0.81), STI vulnerability (0.66), STI prevention self-efficacy (0.83) and STI prevention intentions (0.85). Cronbach's alpha and intra-class correlation coefficient were calculated for the reliability of the fourscale items and ranged between 0.66–0.85 and 0.846–0.977, respectively.

Sample size and power calculations

The sample size we require in the quantitative phase to provide sufficient power was calculated as 63 persons for each group. This sample size was calculated to be adequate at an alpha of 0.05 and a power of .80, to test for a difference between the groups. we considered a potential dropout rate of 30%. According to the formula below, we should start with a recruitment target of 75 participants in each group:

$$n = (2SD^2 \times (\ \llbracket z\_(1-\alpha\ /\ 2) + z\_(1-\beta))\rrbracket\text{^}2)/\llbracket(\mu_1 - \mu_2\rrbracket\text{^}2\ = \frac{2(2.5)^2 \times (1.96+0.84)^2}{(0.1)^2} = 63$$

$z_{0.975}$ = 1.96

$z_{0.8}$=0.84

In accordance with this approach, a total of 150 women at risk, aged 18 to 48, from the Tehran Municipality Health Houses, will be recruited using the inclusion and exclusion criteria listed in Table 1. Based on permuted block randomization, participants will be divided into two groups (one intervention group and one control group). The allocation is concealed by using opaque, sealed envelopes that are sequentially numbered and include the name of each group. The randomization process used in sampling ensures that each participant has an equal chance of being placed in each group.

Data analysis

Phase 1

To carry out the qualitative content analysis process, each interview's audio file will be listened to carefully several times on the same day and transcribed verbatimIn order to keep the data from the interviews private, each transcript will be assigned a code.To come up with overall impression of the interviews and become fully immersed in the data, the audio files and transcripts will be reviewed several times, and any ambiguities and inconsistencies will be removed by comparing the audio files and the transcripts. The interviews will be audiotaped and a summary of the key points of each interview will be then sent to each participant to ensure that the interviewer will have interpreted that participant’s comments accurately(27).The process of data analysis will be performed continuously and simultaneously with the data gathering process. All words, statements, and paragraphs that are relevent to the analysis process will be considered as a single semantic unit. After merging the semantic units, the codes will be extracted. The codes are combined to form subcategories, which are then combined to form the main categories. Finally, after the categories have been abstracted, the relevant themes will be identified. The data will be managed using MAX.QDA-ver2020 (28).

Phase 3

The collected data will be analyzed using descriptive statistics (such as frequency, frequency percentage, mean, and standard deviation) and inferential statistics in SPSS ver16. Generalized mixed models of analysis of variance for repeated measures will be used to compare the differences between the values obtained before the intervention and 1 and 3 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 tests will be run with a 0.05 significance level (p 0.05). The Kolmogorov-Smirnov test will be used to determine the data's normality.

Discussion

This paper describes the clinical trial protocol which will examine intervention program to promote preventive behaviors in at-risk women. This will be the first study to examine the impact of an educational program intervention based ISD to promote preventive behaviors from STIs in at-risk iranian women. Women in Iran account for a high percentage of the population. Despite the high prevalence of sexually transmitted infections affecting this community, low educational interventions have been made to enable

them for preventive behaviours.Therefore, this study aims to identify the educational and learning needs of at-risk women and implement a purposeful intervention program as an effective step to to promote preventive behaviors regarding STIs of Iranian women aged at 18-48 years. This study has several robust design features detailed as follows:

1. Performing a randomized controlled trial based on ISD model: This study is the first randomized controlled trial performed on women at risk of STIs to evaluate the effectiveness of the educational intervention.
2. 2Theory-based intervention: The gap in the majority of intervention studies is that they are designed based on educational needs. The present study explores the effectiveness of the training intervention over an educational framework called the Instructional system design (ISD) model.

We do recognize that this study will have some limitations in so far as we must limit the randomized controlled trial to women residing in one region of Iran. This, however, will enable us to maintain good control of the test procedure. There is a possibility of not having enough access to the questionnaire link and reducing the Response-Rate. To reduce this limitation, the link of the online questionnaire will be provided to the target group with maximum variance in different ways. Another limitation of this study is the possibility of samples falling in the final intervals of the study; It seems that considering the financial cost in exchange for completing the questionnaire in four stages (pre-test, one month later and three months after the intervention) is a good solution. Last but not least, performing educational interventions in the field of sexual health among Iranian women always faces cultural problems. Accordingly, the issue of sexually transmitted diseases is no exception to this rule. Hence, it may be difficult to accept participants to enter the study at first.

Conclusion

This study provides an educational program for educating, empowering, and promoting behaviours that prevent sexually transmitted infections. If the interventions designed in the present study are effective, It has a high practical potential for generalization for all women aged 18-48 at risk of STIs.

Trial Status

The study is ongoing. Recruitment opened in October 2020. The duration of the study period will be 2 years and will be finished in October 2022.

Abbreviations

STIs: sexually transmitted infections; ISD: Instructional System Design; RCT: Randomized controlled trial; CONSORT: Consolidated Standards of Reporting Trials.

Declarations

Acknowledgements

This protocol study is a PhD dissertation proposal of the first author in health education and promotion at the Faculty of Medical Sciences, Tarbiat Modares University.

Authors' contributions

The initial draft and edited "AKJ" and "FZ." The draft was re-edited and approved by "RM", "AH" and "SHN." The authors read and approved the final manuscript.

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The study is externally funded by Tarbiat Modares University. The study has undergone full external peer review as part of the funding process and the main funding body have had no other role in the design of the study and will not have any role in the implementation of the intervention, the data collection, data analyses, interpretation of the data, or decisions on when or where to report results.

Availability of data and materials

Not applicable. The manuscript does not report data. The datasets subsequently generated and/or analyzed during the current study may be made publicly available following conclusion of ongoing research. Requests for data may be made at any time to the corresponding author.

Ethics approval and consent to participate. The study protocol has been approved by the Medical Ethics Research Center of Tarbiat Modares University (reference: IR.MODARES.REC.1399.039). All participants will be provided with full information of their part in the study and assured that their information will be kept strictly confidential. All participants will be asked to complete a written informed consent form. This will provide a clear understanding that their participation is entirely voluntary, and they have a right to withdraw at any time during the study.

Consent for publication

This manuscript does not contain individual personal data from patients

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Women aged 18–48 years • Tend to participate with informed consent to share information, and participate • Women without cervical cancer • Women without mental disorders, drug dependence and addiction	• Absence of more than two sessions in training sessions • The participant has a special illness that is not able to participate in training sessions

Table2 Schedule of enrolment, interviews, intervention, and assessment of the Educational Intervention trial, following (SPIRIT) guidelines.

Study Timeline																
	Phase1 The qualitative exploration		**Phase2 Interventional program designing**										**Phase3 The randomized control trial**			
	Enrolment	Close-up	Step1	Step2	Step3	Step4	Step5	Step6	Step7	Step8	Step9	Step10	Enrolment	Allocation	Post-Allocation	Follow-up
Time point	**0**	**T6**	**T0-T6**	**T0-T6**	**T0-T6**	**T7**	**T8**	**T8**	**T9**	**T10**	**T11**	**T14**	**T11**	**T11**	**T14**	**T14**
Qualitative Interviews	—	—														
Qualitative content analysis	—	—														
Identify Instructional objectives			—	—	—											
Conduct Instructional Analysis			—	—	—											
Analyze Learners and Contexts			—	—	—											
Write Performance Objectives						×										
Develop Assessment Instruments							×									
Develop Instructional Strategy								×								
Develop Instructional materials									×							
design and conduct formative evaluation										×						
design and conduct summative evaluation											×					
Final evaluation												×				
Eligibility Screen Informed consent Allocation	×															
	×															
														×		
Interventions															×	
Assessments															—	—

Supplemental Data

Additional File 2 is not available with this version.

Figures

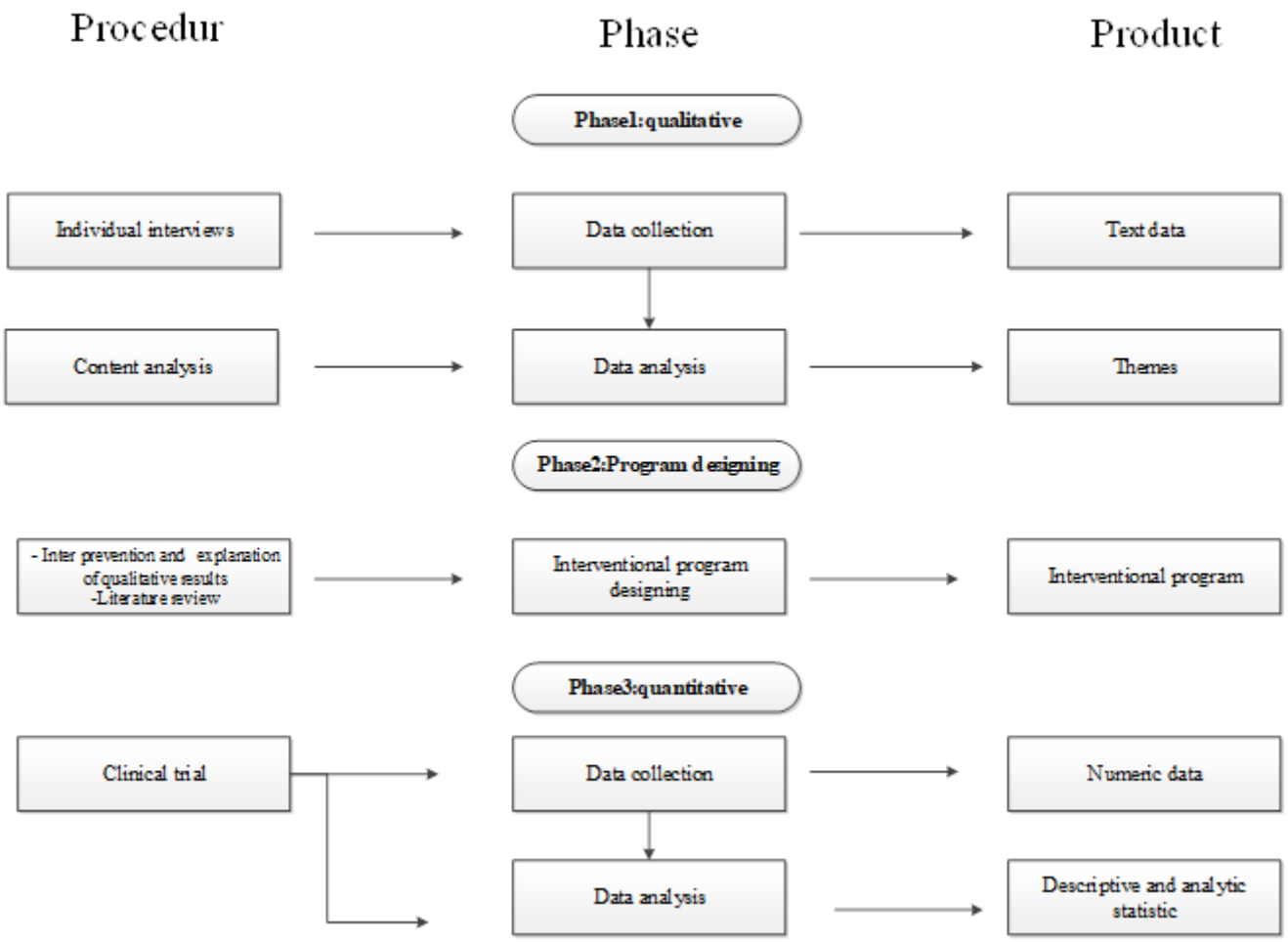

Figure 1

Study Visual Diagram

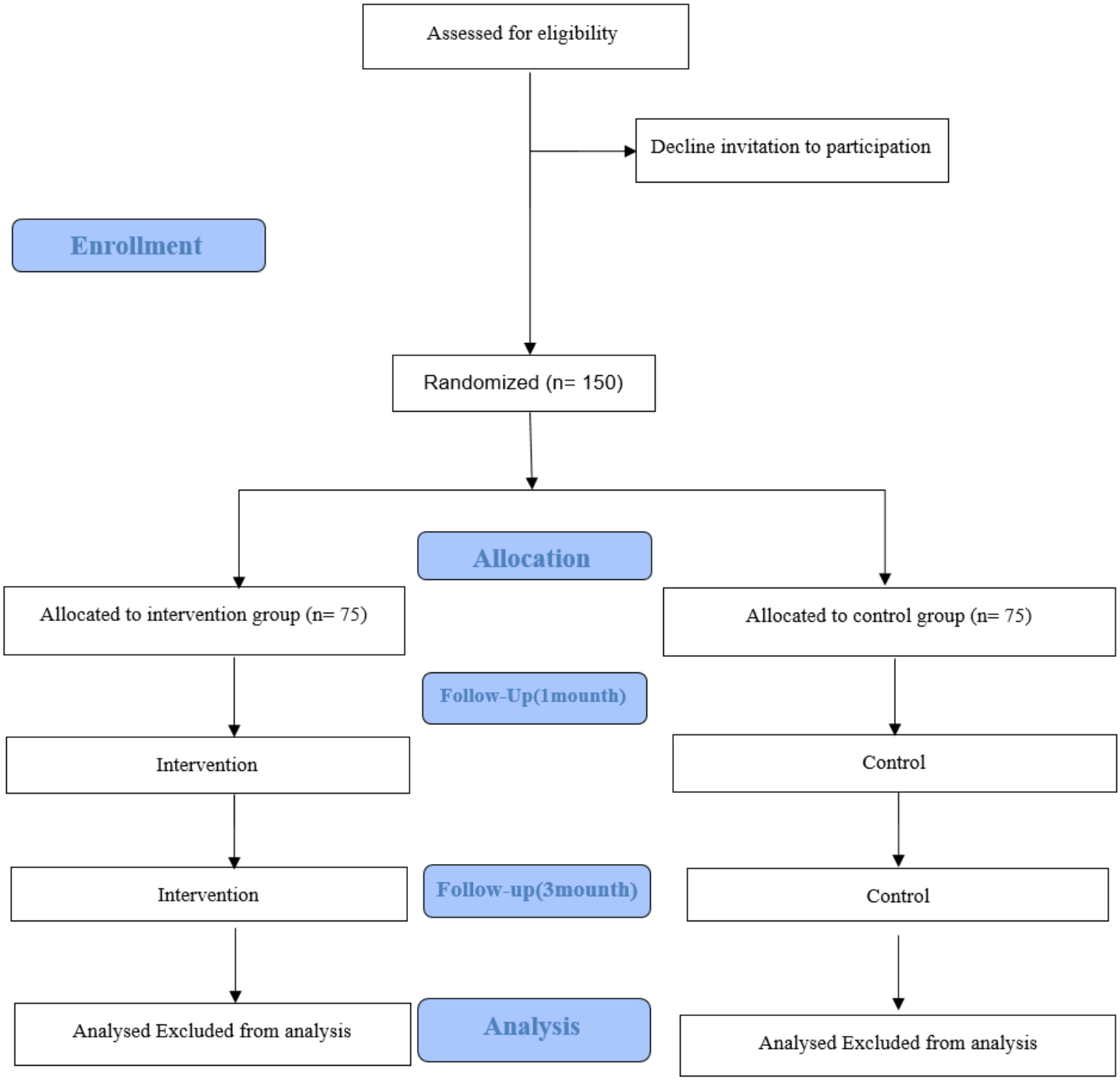

Figure 2

The flow chart of the randomized controlled protocol