Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation of the effectiveness of an intervention program to improve the sexual competence of young adult women about to get married

Protocol summary

Study aim
Determining the effectiveness of an intervention program to improve sexual competence in young adult women about to get married

Design
The study is a controlled clinical trial, with parallel groups,double-blind, randomized, phase II study on 35 women about to get married. The allocation of samples to the control and intervention groups will be done by simple randomization. A random number table will be used.

Settings and conduct
The sexual competence program developed will be implemented for 35 young women on the verge of marriage who refer to the Ibn Sina and Gol Yas premarital counseling centers in Isfahan. A researcher-made sexual competence questionnaire will collect data in the intervention and control groups before, immediately, and 2 months after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Young adult women between the ages of 18 and 25. Exclusion criterion: unwillingness to participate in the study.

Intervention groups
The intervention and control groups will consist of women aged 18-25 who are about to get married. The sexual competence training program will be implemented in 4 sessions in a specific sequence for the intervention group. The control group will receive the usual training during marriage in government pre-marriage classes. At the end of the study, the training provided to the intervention group will also be implemented for the control group.

Main outcome variables
Outcome variable: Sexual competence of young adult women about to get married.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231103059937N1**
Registration date: **2025-08-22, 1404/05/31**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-22, 1404/05/31**
Update count: **0**

Registration date
2025-08-22, 1404/05/31

Registrant information

Name
Zahra Sadat Mousavi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3361 3598
Email address
mousavi@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-11, 1404/04/20

Expected recruitment end date
2025-10-12, 1404/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effectiveness of an intervention program to improve the sexual competence of young adult women about to get married

Public title
Investigating the effectiveness of the intervention program to improve the sexual competence of young adult women about to get married
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research Age between 18 and 25 years Iranian nationality
Exclusion criteria:
Unwillingness to continue cooperation in every stage of the research Incomplete questionnaires
Age
From **18 years** old to **25 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, the allocation of samples in two control and intervention groups will be done by a simple randomization method. The unit of randomization is individual and people will be divided into two groups using a table of random numbers. In this way, first, all the group members are numbered from 1 to 70. Then the researcher, with his eyes closed, places the pointer on the numbers of the random table and moves from the same number in the corresponding row to the right. Even numbers will be assigned to the control group and odd numbers to the intervention group. Also, for concealment, central randomization will be used. This way, a random sequence is given to a specific person, and sampling is done. Based on the order in which the participants entered the study, the researcher communicated with the relevant person by phone and asked about the random allocation of the participants to the intervention and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher will prepare the questionnaire. Then the questions will be provided to the teacher of sexual competence classes. The teacher will hold the class, and the questionnaires will be completed after the class without the researcher's knowledge. The instructor will not be at fault in allocating samples and analyzing data. Next, the lecturer puts the supplementary questionnaires in the envelope and gives them to the researcher. At the end, the researcher will give the questionnaires to the outcome assessor without mentioning the names of the control and intervention groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medical Sciences (Research
Street address
Soffe Terminal. Beginning of the National Highway. Zeytoun Residential Complex 1
City
Isfahan
Province
Isfehan
Postal code
84137-33993
Approval date
2023-12-25, 1402/10/04
Ethics committee reference number
IR.MUI.NUREMA.REC.1402.160

Health conditions studied

1

Description of health condition studied
Examining the level of sexual competence in young adult women (18-25 years old)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The score of sexual competence in the researcher-made questionnaire
Timepoint
The sexual competence score in young adult women will be measured before, immediately and 2 months after the implementation of the sexual competence promotion program
Method of measurement
Questionnaire made by the researcher

2

Description

information of sexual competence

Timepoint

before, immediately and 2 months after the intervention

Method of measurement

Questionnaire

3

Description

motivation for Acquisition of sexual competence

Timepoint

before, immediately and 2 months after the intervention

Method of measurement

Questionnaire

4

Description

behavioral skills for for Acquisition of sexual competence

Timepoint

before, immediately and 2 months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, the intervention will include training in a sexual competence enhancement program for young adult women, which was obtained from a combination of a qualitative study and literature review, and a panel of experts in the first phase of the study. The content of the first training session will include sexual competence, its positive and negative consequences, the second session will correct false sexual beliefs and expectations, the third session will teach safe sex and discuss and evaluate people's beliefs and attitudes regarding the negative effects of unsafe sexual behavior on health, and the fourth session will teach assertiveness skills, saying no, and effective conversation. 4 training sessions will be conducted in a weekly sequence after the intervention group is called to the training location. Before the start of the first session, a pre-test will be taken from the samples. The duration of the classes will be 90 minutes, of which the first 60 minutes will be related to presenting educational content using lecture and question-and-answer methods, and the last 30 minutes will be dedicated to answering the samples' questions. At the end of the 4 sessions and also 2 months later, a post-test will be taken.

Category

Lifestyle

2

Description

Control Group: In this study, the control group will receive 2-hour sexual education that is routinely provided to all couples in premarital centers. This education includes education on contraception, abortion, and sexual anatomy and physiology. Pre-test and post-test will be administered before and after the premarital center educational classes. After completing the study and completing the questionnaire, the sexual competence enhancement program will also be implemented for the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Ibn Sina premarital counseling centers in Isfahan city

Full name of responsible person

Zahra Sadat Mousavi

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Phone

Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
zahra sadat mousavi

Position
PhD student at the Ministry of Health

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available