

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the Effect of Multidimensional Sex Education with Routine Classes of Education during Marriage on the Sexual Knowledge and Attitude in Premarital Couples

Protocol summary

Study aim

Comparing the effect of multidimensional sex education with routine classes of education during marriage on the knowledge and sexual attitude in premarital couples

Design

A clinical trial with a control group, with parallel groups, one-sided blind, randomized, assigning samples to groups using the randomized block method.

Settings and conduct

Refer to the health center of Kashan city that conducts marriage classes, identify eligible people, ask eligible people to participate in the study if they wish to complete the questionnaires, divide the patients into two control and intervention groups in a randomized block manner, complete Questionnaires by both groups, implementation of training in Skyroom, the statistical analyst has no knowledge of intervention and control subjects.

Participants/Inclusion and exclusion criteria

First marriage, being Iranian, having a smart phone, being literate, consenting to participate in the study / not having general health (according to the GHQ questionnaire), couples who previously attended sex education classes except the class of this center, temporary marriage With another spouse, cohabitation begins immediately after marriage

Intervention groups

After obtaining informed consent from the couple and completing the pre-test, the intervention sessions will be carried out in 4 sessions of 45-60 minutes with an interval of one week. It will be next month. In the control group, after completing the study, during a PowerPoint session containing educational materials on sexual, religious and psychological dimensions, they will be provided.

Main outcome variables

Sexual knowledge and attitude in premarital couples

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161126031117N14**

Registration date: **2023-08-12, 1402/05/21**

Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Soghra Khani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Other design features In this study, multidimensional intervention is defined.
Scientific title Comparison of the Effect of Multidimensional Sex Education with Routine Classes of Education during Marriage on the Sexual Knowledge and Attitude in Premarital Couples	Secondary Ids empty
Public title The effect of Multidimensional Sex Education on the Sexual Knowledge and Attitude in Premarital Couples	Ethics committees
Purpose Education/Guidance	1
Inclusion/Exclusion criteria Inclusion criteria: First Marriage Being Iranian Having a Smartphone Being Literate in Reading and Writing Consent to Participate in the Study Exclusion criteria: Lack of General Health (according to the GHQ questionnaire) Couples who previously Attended Sex Education Classes Except the Class of this Center Temporary Marriage with Another Spouse Starting Cohabitation Immediately after Marriage	Ethics committee Name of ethics committee Ethics committee of Mazandaran University of Medical Sciences Street address Moalem square / Moalem street City Sari Province Mazandaran Postal code 4816715793
Age No age limit	Approval date 2023-07-11, 1402/04/20
Gender Both	Ethics committee reference number IR.MAZUMS.REC.1402.148
Phase N/A	Health conditions studied
Groups that have been masked • Outcome assessor • Data analyser	1
Sample size Target sample size: 88 More than 1 sample in each individual Number of samples in each individual: 2 1 couple	Description of health condition studied Sexual knowledge and attitude in premarital couples
Randomization (investigator's opinion) Randomized	ICD-10 code Z70
Randomization description Random block method will be used to assign samples to groups. In this method, couples will be considered as blocks. Blocks will be considered in the form of 4 (in each block 2 pairs for each group) and finally 22 different blocks will be used to assign 44 pairs to two groups. The selection of the block type will be determined by the software 2 Random Allocation.	ICD-10 code description Counseling related to sexual attitude, behavior and orientation
Blinding (investigator's opinion) Single blinded	Primary outcomes
Blinding description Outcome assessor: Due to being nameless Questionnaires (assignment of a code), the outcome assessor does not know about the allocation groups of the participants. The statistician also does not know about the groups because the groups are named with A and B codes.	1
Placebo Not used	Description Sexual knowledge in premarital couples
Assignment Parallel	Timepoint Determining the sexual knowledge of couples about to get married before the intervention, after and three months after the intervention
	Method of measurement Snell et al.'s sexual awareness questionnaire (1991)
	Secondary outcomes
	1
	Description sexual attitude in premarital couples
	Timepoint Determining the sexual attitude of couples about to get

married before the intervention, after and three months after the intervention

Method of measurement

Ezgoli et al. sexual attitude questionnaire (1379)

Intervention groups

1

Description

Intervention group: Couples intervention sessions will be conducted after completing the pre-test for 45-60 minutes and in 4 sessions with an interval of one week. During the 3 months, the couple will be contacted once a week to follow up and make sure they have completed their homework, whether they have started living together, and whether they have attended the training class or not. Immediately after the completion of the post-test intervention sessions and the follow-up and re-evaluation of the two groups in terms of sexual knowledge and attitudes, it will be 3 months later.

Category

Behavior

2

Description

Control group: The control group receive routine training in pre-marital education classes. After completing the study, during a PowerPoint session containing educational materials about the knowledge and sexual attitude of the couples about to get married, they will be provided to them.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golabchi Kashan Health Center

Full name of responsible person

Dr. Soghra Khani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Mazandaran University of Medical Science

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

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Seyri

Position

Master's student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information related to the research is shared with the aim of keeping the names of the people and keeping their identities confidential and complying with the 31 codes of ethics.

When the data will become available and for how long

Since 2024

To whom data/document is available

All researchers and those interested in research

Under which criteria data/document could be used

To conduct review and supplementary research and to use educational classes during marriage

From where data/document is obtainable

In order to receive data or documents, the responsible author can be reached by e-mail khanisog343@gmail.com and the e-mail of the counseling student in midwifery can be reached by e-mail fateme.seyri96@gmail.com. If the article is published, you can refer to it according to the journal's address.

What processes are involved for a request to access data/document

First, you should send an email to the responsible author of the article and make your request, and if the responsible author and the research team deem it appropriate, the documents and files will be provided in a short period of time.

Comments