

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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

Iran (Islamic Republic of)

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Email address

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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

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

Public title

The effect of Multidimensional Sex Education on the Sexual Knowledge and Attitude in Premarital Couples

Purpose

Education/Guidance

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

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **88**

More than 1 sample in each individual

Number of samples in each individual: **2**

1 couple

Randomization (investigator's opinion)

Randomized

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.

Blinding (investigator's opinion)

Single blinded

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.

Placebo

Not used

Assignment

Parallel

Other design features

In this study, multidimensional intervention is defined.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moalem square / Moalem street

City

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Province

Mazandaran

Postal code

4816715793

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.MAZUMS.REC.1402.148

Health conditions studied

1

Description of health condition studied

Sexual knowledge and attitude in premarital couples

ICD-10 code

Z70

ICD-10 code description

Counseling related to sexual attitude, behavior and orientation

Primary outcomes

1

Description

Sexual knowledge in premarital couples

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

Street address

Darb Hoz / Imam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

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Moallem Square_Moallem Street_Research Center of Mazandaran University of Medical Sciences

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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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Isfahan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Soghra Khani

Position

PhD / Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Position

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Latest degree

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Other areas of specialty/work

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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