

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Assessing the effectiveness of a fertility education program on the motivation of childbearing among girls attending premarital counseling centers: a randomized controlled trial

Protocol summary

Study aim

Assessing the impact of a fertility education program on the motivation of childbearing among girls attending premarital counseling centers

Design

Eighty participants will be randomly assigned to two groups: an intervention group that will receive both routine premarital counseling and a fertility education program, and a control group that will receive only routine premarital counseling.

Settings and conduct

This study will be conducted at the premarital counseling center in Babol city. Eligible participants, identified as girls about to get married, will be invited to participate after providing written informed consent. Demographic information, fertility knowledge, motivation to childbearing and attitudes will be assessed using questionnaires following an explanation of the study's objectives and importance.

Participants/inclusion and exclusion criteria

Inclusion criteria include Iranian girls aged 18 to 35 referring to the premarital counseling center. Exclusion criteria include medical sciences students or employees and those with known chronic physical or mental illnesses.

Intervention groups

The intervention group will receive both routine premarital counseling and a 3-week virtual fertility education program consisting of text messages and short films. The control group will receive only routine premarital counseling. Upon study completion, the control group will have the option to access the fertility education program content.

Main outcome variables

Fertility knowledge; Fertility motivation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056451N3**

Registration date: **2024-10-04, 1403/07/13**

Registration timing: **prospective**

Last update: **2024-10-04, 1403/07/13**

Update count: **0**

Registration date

2024-10-04, 1403/07/13

Registrant information

Name

Fatemeh Bakouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3232 2589

Email address

bakouei2004@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-11, 1403/07/20

Expected recruitment end date

2025-01-29, 1403/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effectiveness of a fertility education program on the motivation of childbearing among girls attending premarital counseling centers: a randomized controlled trial

Public title

The effectiveness of an educational program on the motivation of childbearing among girls

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian citizenship At least elementary education Age 18 to 35 years Attending to pre-marriage counseling centers Having access to a phone equipped with an application required to send educational content Having a desire to participate in the study

Exclusion criteria:

Medical sciences students or staff Known chronic physical and mental diseases

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants will be randomly assigned to either the control or intervention group using a 1:1 block randomization method with blocks of four. To ensure concealment of allocation, only the first supervisor will have access to the randomization list, which will be generated using Random Allocation Software. The researcher will communicate participant eligibility to the supervisor, who will then provide the group assignment based on the block file prepared by the statistics consultant.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Health Research Institute - Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afroz Ave, Babol

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2024-09-08, 1403/06/18

Ethics committee reference number

IR.MUBABOL.HRI.REC.1403.105

Health conditions studied

1

Description of health condition studied

Motivation to have children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fertility knowledge

Timepoint

Before and one month after the intervention

Method of measurement

Cardiff Fertility Knowledge Scale

2

Description

Fertility motivation

Timepoint

Before and one month after the intervention

Method of measurement

Miller's Fertility Motivation Questionnaire

Secondary outcomes

1

Description

Attitude to fertility

Timepoint

Before and one month after the intervention

Method of measurement

Questionnaire of attitudes towards fertility and child bearing

Intervention groups

1

Description

Intervention group: The intervention group will receive both routine premarital counseling and a 3-week virtual fertility education program based on the latest guidelines from the American Society of Reproductive Medicine, the European Society of Human Reproduction and Embryology, and the Iranian Ministry of Health and Medical Education. The program will consist of text messages and short films of one to two minutes.

Category

Behavior

2

Description

Control group: The control group will receive only routine premarital counseling

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Premarital counseling center of Babol city

Full name of responsible person

Fatemeh Bakouei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology: Dr. Mehdi
Rajab Nia

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Bakouei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available