

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 2026

### Investigating the Impact of an Educational Program Based on the Transtheoretical Model on Fertility Preferences and Childbearing Motivations Among Married Students

#### Protocol summary

##### Study aim

This study aims to evaluate the effectiveness of a transtheoretical model-based educational program in modifying fertility preferences and childbearing motivations among married students at Islamic Azad University, Isfahan (Khorasgan) Branch (2024).

##### Design

A randomized, non-blinded, parallel-group controlled clinical trial will be conducted on 60 married students. Block randomization will be used for allocation.

##### Settings and conduct

The study will be conducted at Islamic Azad University in Isfahan. The study population consists of married students. No blinding procedure will be implemented in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Voluntary participation consent; Ability to read and write in Persian; Currently married (legally or traditionally); Living with spouse at time of study.

Exclusion criteria: Diagnosis of a chronic illness; any medical contraindication for childbearing.

##### Intervention groups

The intervention group will receive seven educational sessions on fertility preferences, childbearing motivations, and self-care based on the transtheoretical model, while the control group will only receive standard university education.

##### Main outcome variables

Reproductive preferences; childbearing motivations

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250530065982N1**

Registration date: **2025-07-06, 1404/04/15**

Registration timing: **prospective**

Last update: **2025-07-06, 1404/04/15**

Update count: **0**

##### Registration date

2025-07-06, 1404/04/15

##### Registrant information

###### Name

Hedieh Kamrava

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3535 4001

###### Email address

hediehkamrava1377@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-07-12, 1404/04/21

##### Expected recruitment end date

2025-09-17, 1404/06/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Impact of an Educational Program Based on the Transtheoretical Model on Fertility Preferences and Childbearing Motivations Among Married Students

##### Public title

The effect of educational programs on reproductive preferences and childbearing motivations

### **Purpose**

Education/Guidance

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Willingness to participate in the study Literacy (ability to read and write) Being married Living with one's spouse Age range: 18-35 years Using a contraceptive method No current or immediate future pregnancy planning

#### **Exclusion criteria:**

Diagnosis of a chronic illness Any medical contraindication for childbearing

### **Age**

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

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Participants were randomly assigned to either the intervention or control group. Each group consisted of 30 participants, and block randomization was employed for allocation. The blocking scheme included the following six permutations: CTTC, CTCT, CCTT, TCCT, TCTC, and TTCC, where "T" denotes the intervention group and "C" represents the control group. To generate the allocation sequence, random numbers between 0 and 6 were produced using the RANDBETWEEN function in Microsoft Excel. Based on the generated number, one of the predefined blocks was selected, and participants were allocated accordingly. This randomization method ensured equitable and systematic distribution of participants between the two groups, minimizing selection bias and enhancing the validity of the study.

### **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 Islamic Azad University-Yazd Branch

### **Street address**

Shohadaye Gomnam boulevard, Safaieh, Yazd

### **City**

Yazd

### **Province**

Yazd

### **Postal code**

8915813135

### **Approval date**

2025-03-13, 1403/12/23

### **Ethics committee reference number**

IR.IAU.YAZD.REC.1403.107

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Educational program based on a meta-theoretical model on reproductive preferences and childbearing motivations in married students

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### **1**

#### **Description**

Individuals' desire and planning to have children

#### **Timepoint**

Before the start of the intervention, immediately after the intervention, 1 month after the start of the intervention, 3 months after the start of the intervention

#### **Method of measurement**

Childbearing Motivation Questionnaire

### **2**

#### **Description**

The score each participant receives from the Fertility Preferences Questionnaire

#### **Timepoint**

Before the start of the intervention, immediately after the intervention, 1 month after the start of the intervention, 3 months after the start of the intervention

#### **Method of measurement**

Reproductive Preferences Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: The intervention group participated in a 7-session educational program (1-2 hours per session) grounded in the Transtheoretical Model, designed to modify fertility preferences, enhance

childbearing motivations, and promote self-care behaviors. Immediately following the intervention, both groups completed standardized questionnaires assessing fertility preferences and childbearing motivations. Follow-up evaluations were conducted at 1-month and 3-month intervals post-intervention to examine sustained effects. Participants requiring additional support received individualized counseling sessions, delivered either in-person or via telephone. Throughout the study period, the control group received only standard institutional education while undergoing identical assessment procedures at matching timepoints. This rigorous methodology ensured systematic evaluation of the intervention's effectiveness while maintaining ethical standards of participant care.

**Category**

Behavior

**2****Description**

Control group: This group didn't receive any new training and only received routine university training and classes.

**Category**

Behavior

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Islamic Azad University, Isfahan (Khorasgan) Branch

**Full name of responsible person**

Dr. Payam Najafi

**Street address**

Islamic Azad University, Isfahan (Khorasgan) Branch,  
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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Ahmad Shajari

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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**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Hedieh Kamrava

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University  
**Full name of responsible person**  
Dr. Mahsa sadat Mousavi  
**Position**  
Associate Professor  
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Ph.D.  
**Other areas of specialty/work**  
Midwifery  
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## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Hedieh Kamrava  
**Position**  
Student  
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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

Not applicable

### Title and more details about the data/document

All study data will be made shareable after complete de-identification of participants.

### When the data will become available and for how long

The access period begins 6 months after the results are published.

### To whom data/document is available

Researchers

### Under which criteria data/document could be used

By citing a logical reason, citing the source, and conducting analyses.

### From where data/document is obtainable

Researchers may request the data by contacting Dr. Mahsa Al-Sadat Mousavi via email: mousavi1315@gmail.com

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

Following a 6-month post-publication period, data may be obtained by submitting a formal request with valid justification to the corresponding author, Dr. Mahsa Al-Sadat Mousavi. Approved requests will be fulfilled within 10 business days.

### Comments