

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Investigating the Effect of Educational Program Based on The Theory of Planned Behavior on The Childbearing Intention in Childless Couples

#### Protocol summary

##### Study aim

Determining the effect of educational program based on the theory of planned behavior on the childbearing intention in couples without children

##### Design

Randomized parallel groups clinical trial with control group, phase 3 on 116 participants, without blinding. A table of random numbers is used for randomization.

##### Settings and conduct

The target population is couples referring to Andimeshk health centers, the research environment of Andimeshk Comprehensive Health Centers. The research samples will be selected from the centers. They will be randomly divided into two control and intervention groups (58 people in each group). two questionnaires of demographic and constructs of the Theory of Planned Behavior will be completed by participants. The intervention group will receive 3 sessions of 45-60 minute focusing on the constructs of the Theory of Planned Behavior. Immediately and one month after the end of the sessions, both groups will complete questionnaire and finally the scores of both groups will be compared to evaluate the effect of education.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 45 years, not having children, Having been married for 2 years or more, unwilling to have children in the next 2 years, and exclusion criteria: pregnancy, having contraindications to pregnancy

##### Intervention groups

The intervention group will receive three educational sessions focusing on the constructs of the Theory of Planned Behavior. The control group will receive routine care.

##### Main outcome variables

Measuring the score of the constructs of the Theory of Planned Behavior Questionnaire before, immediately and one month after the intervention in the intervention and control groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20250111064350N1**

Registration date: **2025-01-21, 1403/11/02**

Registration timing: **prospective**

Last update: **2025-01-21, 1403/11/02**

Update count: **0**

##### Registration date

2025-01-21, 1403/11/02

##### Registrant information

##### Name

Nazanin Nikfard

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3311 0000

##### Email address

nazanin.nikfard1373@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-02-19, 1403/12/01

##### Expected recruitment end date

2025-07-06, 1404/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the Effect of Educational Program Based on The Theory of Planned Behavior on The Childbearing Intention in Childless Couples

#### Public title

Effect of Educational Program Based on The Theory of Planned Behavior on The Childbearing Intention

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 18 to 45years Not having children Being Literate Having been married for 2 years or more Unwillingness to have children in the next 2 years

##### Exclusion criteria:

Pregnancy Having contraindications for pregnancy Unwilling to participate in the study

#### Age

From **18 years** old to **45 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **116**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The samples are selected by convenience sampling method, then divided into two groups using simple randomization method (random number table), one group is considered as control group and one group is considered as intervention group. To conceal allocation, the type of intervention is written on paper and numbered consecutively inside opaque envelopes (numbers 0-4 for the first group, numbers 5-9 for the second group) and will be delivered by the center secretary to the people referring to 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

Ethics committee of Jundi Shapour Ahvaz University of Medical Sciences

###### Street address

Esfand Estreet, Golestan highway

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

00986135715794

##### Approval date

2024-12-21, 1403/10/01

##### Ethics committee reference number

IR.AJUMS.REC.1403.513

### Health conditions studied

#### 1

##### Description of health condition studied

childbearing intention

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

The score of childbearing intention based on the theory of planned behavior

##### Timepoint

Before intervention, immediately after intervention and one month after intervention

##### Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

#### 2

##### Description

The score of attitude based on the theory of planned behavior

##### Timepoint

Before intervention, immediately after intervention and one month after intervention

##### Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

#### 3

##### Description

The score of subjective norms based on the theory of planned behavior

##### Timepoint

Before intervention, immediately after intervention and one month after intervention

##### Method of measurement

Researcher made questionnaire based on the Theory of Planned Behavior

#### 4

##### Description

The score of behavioral control based on the theory of planned behavior

**Timepoint**

Before intervention, immediately after intervention and one month after intervention

**Method of measurement**

Researcher made questionnaire based on the Theory of Planned Behavior

**5****Description**

The score of intention based on the theory of planned behavior

**Timepoint**

Before intervention, immediately after intervention and one month after intervention

**Method of measurement**

Researcher made questionnaire based on the Theory of Planned Behavior

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The educational intervention for the test group will consist of three 45-60 minute sessions (lecture, group discussion, educational video, and presentation of pamphlets and educational books) focusing on the structures of the theory of planned behavior regarding children, the importance and status of children from the perspective of the religion of Islam and the verses of the Quran, the benefits of children, the disadvantages of childlessness, and strategies for dealing with problems related to children.

**Category**

Behavior

**2****Description**

Control group: receive routine care

**Category**

Behavior

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

Selected health centers of Andimshek city

**Full name of responsible person**

Nazanin nikfard

**Street address**

Andimshek Health and Treatment Network, in front of Sarvandi Stadium, Enghelab street

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 4263 0401

**Email**

hn-ank@ajums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoush Zaker Kish

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Esfand Street, Golestsn highway

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ahvaz

**Province**

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aduaum@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Zahra Abbaspoor

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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Esfand Estreet, Golestan highway

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

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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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