

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

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

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Full name of responsible person

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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