Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of training based on the theory of planned behavior on the intention to have children of single-child couples

Protocol summary

Study aim

General Objective: Determine the effect of education based on the theory of planned behavior on couples' fertility intentions Specific Objectives: 1- Determine and compare the distribution of demographic variables of couples in the experimental and control groups 2- Determine and compare the average scores of knowledge, perceived behavioral control, abstract norms, attitude, and behavioral intention of couples regarding fertility intentions before and 3 months after the educational intervention in the experimental and control groups.

Design

controlled, multi-stage, single-blind, randomized, parallel-group clinical trial on 80 subjects.

Settings and conduct

The study was conducted in the city of Khomein and the people studied did not know which group they were in.

Participants/Inclusion and exclusion criteria

Participants, including married women and men of childbearing age with children one year old and older, will be excluded from the program if they do not attend the training sessions.

Intervention groups

Holding educational and counseling sessions on the importance and benefits of having children based on model structures and sending educational content and media in cyberspace to the test group.

Main outcome variables

Demographic characteristics of the participants in the study were measured separately in two experimental and control groups, and the effect of education on the constructs of attitude, abstract norms, and perceived behavioral control on fertility intention was measured through a questionnaire before the educational intervention and 3 months after the intervention.

General information

Reason for update

Acronym

IHCS

IRCT registration information

IRCT registration number: **IRCT20240215061011N1**
Registration date: **2025-12-17, 1404/09/26**
Registration timing: **retrospective**

Last update: **2025-12-17, 1404/09/26**
Update count: **0**

Registration date

2025-12-17, 1404/09/26

Registrant information

Name

Hadi Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4633 4046

Email address

h.mohammadi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

2025-05-22, 1404/03/01

Actual recruitment end date

2025-09-23, 1404/07/01

Trial completion date

2025-09-23, 1404/07/01

Scientific title
Investigating the effect of training based on the theory of planned behavior on the intention to have children of single-child couples

Public title
Investigating the effect of training based on the theory of planned behavior on the intention to have children of single-child couples

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Do not have any contraindications for pregnancy and fertility Be literate in reading and writing Women of reproductive age and not pregnant Their child's age is one year or older be married

Exclusion criteria:
illiterate people single people

Age
From **10 years** old to **54 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Multi-step method: dividing the city of Khomein into 8 regions and each region into several blocks - selecting one block from each region - random sampling of a class from each block (no children/one child/two or more children)

Blinding (investigator's opinion)
Single blinded

Blinding description
Because individuals enter the study with informed consent and must be aware of their assignment to the case and control groups, the data analyst, who is a statistical consultant, is not aware of the group assignment and only codes groups one and two, and the data is collected by interviewers who are unaware of the group assignment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Arak University of Medical Sciences

Street address
No. 34, Shahid Hashemi Alley, Shahid Sadoqi Boulevard

City
Khomein

Province
Markazi

Postal code
3881933783

Approval date
2024-05-26, 1403/03/06

Ethics committee reference number
IR.ARAKMU.REC.1403.077

Health conditions studied

1

Description of health condition studied
The effect of education based on the theory of planned behavior on the fertility intention of single-child couples

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fertility intention score in single-child couples

Timepoint
Conducting the test before the intervention and 3 months after the intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Increased childbearing in single-child couples

Timepoint
2 years after intervention

Method of measurement
Statistical information of level one health center systems

Intervention groups

1

Description
Intervention group: Educational intervention for the test group based on the results of the needs assessment and pre-test in the form of lectures, group discussions, educational videos and presentation of pamphlets and

educational books (focusing on the structures of the theory of planned behavior) regarding the child, the importance and position of the child from the perspective of religion Explaining Islam and verses of the Quran, the benefits of children, the disadvantages of having fewer children, and solutions to deal with problems related to children by midwives and psychologists, as well as regarding the formation of groups in virtual space and the provision of media and educational content for the participants in the study based on theoretical structures. The programmed behavior is carried out. The questionnaire should be completed again by two groups 3 months after the educational intervention.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
پایگاه های سلامت خمین

Full name of responsible person
هادی محمدی

Street address
No. 34, Shahid Hashemi Alley, Shahid Sadoughi Boulevard

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Postal code
3881933783

Phone
+98 86 4633 4046

Email
hady_1361@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr. Daud Hekmat Po

Street address
University Complex of the Prophet (PBUH), Basij Square, Sardasht.

City
Arak

Province
Markazi

Postal code
3848176341

Phone
+98 86 3417 3532

Email
research@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Hadi Mohammadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Health Promotion

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hadi Mohammadi

Position
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Other areas of specialty/work
Public Health

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Person responsible for updating data

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

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Other areas of specialty/work

Health Promotion

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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

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

Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

Information about the scores of the model constructs can be shared.

When the data will become available and for how long

One year after results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Master's and doctoral students for use in their dissertations

From where data/document is obtainable

Email: hady_1361@yahoo.com Mobile number: 09183661997

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

Personal request via email or phone number

Comments