Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Virtual Education Program Based on the Theory of Planned Behavior on Childbearing Intentions among Single-Child's Women

Protocol summary

Study aim

Determining the Effect of a Virtual Education Program Based on the Theory of Planned Behavior on Childbearing Intentions among Single-Child's Women

Design

Semi-experimental clinical trial; intervention and control groups; non-blinded; stratified random allocation; 70 participants per group; 12 health centers across three socioeconomic levels (four per stratum), two centers for intervention and two for control.

Settings and conduct

This semi-experimental trial will be conducted in Zanjan among married women aged 18–45 with one child. Participants from 12 health centers will be selected by socioeconomic status and randomly assigned to intervention or control groups. Eligible individuals will be identified via the "Sib" system. The educational intervention, based on the Theory of Planned Behavior, will include six online sessions with short videos and virtual groups for interaction.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Iranian nationality, residence in Zanjan, literacy, married women aged 18–45, one child (≥1 year, 11 months, 29 days), access to phone or computer with Telegram and Bale, pre-contemplation or contemplation stage. Exclusion Criteria: More than one child, pregnancy, infertility history or diagnosis, medical contraindication to pregnancy, major psychiatric disorder, permanent contraception, participation in similar programs in past six months, severe physical or mental illness.

Intervention groups

In the experimental group, virtual training is delivered over six sessions via messaging platforms, with each session containing one or two pre-recorded educational videos of up to 15 minutes. In the control group, participants can only contact the researcher to ask midwifery-related questions to encourage participation.

Main outcome variables

Attitude, subjective norm, perceived behavioral control, and intention toward childbearing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039436N18**
Registration date: **2025-12-16, 1404/09/25**
Registration timing: **prospective**

Last update: **2025-12-16, 1404/09/25**
Update count: **0**

Registration date

2025-12-16, 1404/09/25

Registrant information

Name

Leila Amiri Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1139

Email address

l.amirifarahani@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Virtual Education Program Based on the Theory of Planned Behavior on Childbearing Intentions among Single-Child's Women

Public title
The Effect of Virtual Education Program Based on the Theory of Planned Behavior on Childbearing Intentions among Single-Child's Women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Having Iranian citizenship Residing in the city of Zanjan Being literate in reading and writing Married women aged 18 to 45 years Having only one child whose minimum age is 1 year, 11 months, and 29 days Having access to a mobile phone or computer capable of installing and using the Telegram and Bale messaging apps until the end of the study Being in the precontemplation or contemplation stage according to the Stages of Change model

Exclusion criteria:
Having more than one child Being pregnant at the time of enrollment in the study Having a history or diagnosis of infertility in the woman or her husband Having a medical contraindication to pregnancy Having a major psychiatric disorder (based on self-report) Using permanent contraceptive methods (such as tubal ligation or vasectomy) Participation in similar educational programs within the past six months Having severe physical or mental illnesses that impede understanding the training or making informed decisions

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Health centers in Zanjan were stratified into three economic levels: high, medium, and low. Four centers were selected from each stratum. Allocation of centers to the intervention and control groups was performed using simple randomization, with two centers from each stratum assigned to the intervention group and two to the control group. Eligible participants were then identified from the “SIB” database, and written informed consent was obtained electronically. Participant recruitment continued continuously and proportionally within each center until the target sample size was achieved.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery-Iran University of Medical Sciences

Street address
Hemmat Highway - next to Milad Tower

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2025-10-13, 1404/07/21

Ethics committee reference number
IR.IUMS.NURSE.REC.1404.007

Health conditions studied

1

Description of health condition studied
Management and planning of fertility and procreation

ICD-10 code
Z31

ICD-10 code description
Encounter for procreative management

Primary outcomes

1

Description
Attitude toward childbearing

Timepoint
At three time points, including before the start of the interventions (at the beginning of the study), immediately after the sessions related to each theoretical construct, and two months after the intervention.

Method of measurement
Theory of Planned Behavior Questionnaire

2

Description

Subjective norm toward childbearing

Timepoint

At three time points, including before the start of the interventions (at the beginning of the study), immediately after the sessions related to each theoretical construct, and two months after the intervention.

Method of measurement

Theory of Planned Behavior Questionnaire

3

Description

Perceived behavioral control toward childbearing

Timepoint

At three time points, including before the start of the interventions (at the beginning of the study), immediately after the sessions related to each theoretical construct, and two months after the intervention.

Method of measurement

Theory of Planned Behavior Questionnaire

4

Description

Childbearing intention

Timepoint

At the beginning of the study, to identify eligible participants (in the precontemplation or contemplation stages), and at the end of the study, to assess the extent of participants' progress to higher stages of childbearing.

Method of measurement

Stages of Change Model Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This study is a semi-experimental clinical trial with two groups (intervention and control) designed to determine the effect of virtual education based on the Theory of Planned Behavior (TPB) on fertility intention among women with only one child. After approval of the proposal and obtaining ethical clearance from the university ethics committee, an official letter will be obtained to conduct the study in urban comprehensive health centers. The study setting will include urban comprehensive health centers under the coverage of the university. The target population consists of married women aged 18 to 45 years who have only one child and reside in Zanjan.Inclusion criteria are Iranian nationality, continuous residence in Zanjan, having only one child aged at least one year and 11 months, minimum literacy skills, and being in the pre-contemplation or contemplation stage according to the Transtheoretical Model (TTM) questionnaire. Exclusion criteria include having more than one child, being pregnant at the time of enrollment, lacking intention for a second child, history or diagnosis of infertility, medical contraindication to pregnancy, major psychiatric disorders, use of permanent contraceptive methods, participation in similar educational programs in the past six months, and severe physical or mental conditions that prevent comprehension of the education or informed decision-making. Criteria for withdrawal from the study include unwillingness to continue participation, absence from more than one educational session, pregnancy during the study, experiencing severe stressful events, major family conflicts, and diagnosis of infertility or chronic or mental illnesses preventing pregnancy.The sampling method involves selecting 12 centers from a total of 19 urban comprehensive health centers in Zanjan, classified into three socioeconomic levels (high, medium, low). Four centers from each level will be selected, with two centers randomly assigned to the intervention group and two to the control group. Eligible women's information will be extracted from the database and they will be invited by phone to participate in the study. Written consent will be obtained virtually, and sampling will continue until the target sample size of 70 participants per group (considering potential attrition) is achieved.Random allocation of clusters will prevent contamination between groups and maintain internal validity. Due to the nature of the intervention, blinding of participants and center staff is not feasible; however, data management will be conducted confidentially. Data collection will occur within a specified timeframe and data analysis will follow the CONSORT guidelines for interventional studies.The educational intervention will be structured based on the four components of the TPB and delivered in six virtual sessions through dedicated messaging groups. Each component will be covered in two sessions to ensure comprehensive content delivery and effectiveness. Each session will include one or two pre-recorded educational videos of up to 15 minutes, and virtual groups will facilitate interaction, Q&A, and experience sharing.The educational sessions are structured as follows:Session 1 (Attitude – Part 1): Positive effects of having children, benefits of multiple children, pregnancy, natural childbirth, and breastfeeding.Session 2 (Attitude – Part 2): Adverse effects of having a single child, side effects of contraceptive methods, and abortion consequences.Session 3 (Subjective Norm – Part 1): Addressing medical and educational misconceptions regarding fertility.Session 4 (Subjective Norm – Part 2): Addressing economic misconceptions, analyzing national population aspects, and highlighting maternal dignity.Session 5 (Perceived Behavioral Control): Teaching life skills and informed decision-making, introducing social support, and reviewing challenges and strategies to overcome fertility barriers.Session 6 (Behavioral Intention): Planning for childbearing, addressing remaining concerns, and reinforcing intentional and informed commitment.Data collection tools include three validated questionnaires:Demographic and reproductive health questionnaire, adapted from the official Ministry of Health form, used to collect baseline descriptive

data.Transtheoretical Model (TTM) questionnaire to assess participants' stage (pre-contemplation, contemplation, preparation, action, or maintenance), completed at baseline and at the end of the study.Theory of Planned Behavior (TPB) questionnaire to assess attitude, subjective norm, perceived behavioral control, and fertility intention, completed at three time points: before the intervention, immediately after each session, and two months post-intervention.

Category

Behavior

2

Description

Control group: Participants in the control group will not receive this educational program. Their contact with the researcher will only be facilitated to encourage participation in the study and to answer couples' questions regarding midwifery.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban Health Services Center No. 1

Full name of responsible person

Fatemeh Mojtabazadeh-Hasanloei

Street address

Adjacent To Zanjan County Health Center, Amirkabir Intersection, Imam Street, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4514937117

Phone

+98 24 3326 0154

Email

f.mojtabazadeh@outlook.com

2

Recruitment center

Name of recruitment center

Urban Health Services Center No. 3

Full name of responsible person

Fatemeh Mojtabazadeh-Hasanloei

Street address

Sosan Alimoradian Comprehensive Health Center, Beginning Of Saadi North Street, Saadi Intersection, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4514937117

Phone

+98 24 3425 1805

Email

f.mojtabazadeh@outlook.com

3

Recruitment center

Name of recruitment center

Urban Health Services Center No. 5

Full name of responsible person

Fatemeh Mojtabazadeh-Hasanloei

Street address

Zolfaghari Street, Sarcheshmeh Saadi Vassat Neighborhood, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4514937117

Phone

+98 24 3336 2025

Email

f.mojtabazadeh@outlook.com

4

Recruitment center

Name of recruitment center

Urban Health Services Center No. 6

Full name of responsible person

Fatemeh Mojtabazadeh-Hasanloei

Street address

Near Municipality Executive Office, Shahid Hossein Hassani Street, Ayatollah Sadooghi Shomali Street, Eslam Abad Neighborhood, Janbazan Town, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

4514937117

Phone

+98 24 3352 5102

Email

f.mojtabazadeh@outlook.com

5

Recruitment center

Name of recruitment center

Urban Health Services Center No. 7

Full name of responsible person

Fatemeh Mojtabazadeh-Hasanloei

Street address

Between Ahmad Takhti Alley and Farshad Abbasi Alley, Corner of 9th Gharbi Etemadieh Street, Jomhouri Eslami Street, Zanjan, Iran

City

Zanjan

Province
Zanjan
Postal code
4514937117
Phone
+98 24 3342 0067
Email
f.mojtabazadeh@outlook.com

6

Recruitment center
Name of recruitment center
Urban Health Services Center No. 9
Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei
Street address
Ahmad Mahdavi Health Center, Between Shahpour Esmaeili Alley and Honarju Alley, Fateh Street, Honarestan Neighborhood, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4514937117
Phone
+98 24 3377 2610
Email
f.mojtabazadeh@outlook.com

7

Recruitment center
Name of recruitment center
Urban Health Services Center No. 10
Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei
Street address
Opposite Ansar Bank, Parvin Alley, Mohammadiyeh Square, Jomhouri Eslami Street, Southern Side of Sheikh Fazlollah Nouri Street, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4514937117
Phone
+98 24 3345 7015
Email
f.mojtabazadeh@outlook.com

8

Recruitment center
Name of recruitment center
Urban Health Services Center No. 11
Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei
Street address
2nd Floor, University of Applied Science and Technology, Next to Gas Station, 45 Metri Golshahr Street, Golshahr Neighborhood, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4514937117
Phone
+98 992 963 5114
Email
f.mojtabazadeh@outlook.com

9

Recruitment center
Name of recruitment center
Urban Health Services Center No. 13
Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei
Street address
Opposite Ghaem Honarestan, Near Palestine Boulevard, Khayyam Street, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4514937117
Phone
+98 24 3336 1804
Email
f.mojtabazadeh@outlook.com

10

Recruitment center
Name of recruitment center
Urban Health Services Center No. 14
Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei
Street address
4th West Street, Phase 2, Karmandan Town, Zanjan, Iran
City
Zanjan
Province
Zanjan
Postal code
4514937117
Phone
+98 24 3344 7054
Email
f.mojtabazadeh@outlook.com

11

Recruitment center
Name of recruitment center
Urban Health Services Center No. 15
Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei
Street address
1st Yasaman Street, Yasaman Street, Golha Square,

Farhang Neighborhood, Zanjan, Iran

City
Zanjan

Province
Zanjan

Postal code
4514937117

Phone
+98 24 3353 3660

Email
f.mojtabazadeh@outlook.com

12

Recruitment center

Name of recruitment center
Urban Health Services Center No. 17

Full name of responsible person
Fatemeh Mojtabazadeh-Hasanloei

Street address
Plot 5792, Next to Vali Asr Mosque, Eqbal 3 Alley, Erfan Street, Mirza Shirazi Boulevard, Amir Kabir Square, Amir Kabir Town, Zanjan, Iran

City
Zanjan

Province
Zanjan

Postal code
4514937117

Phone
+98 24 3376 4144

Email
f.mojtabazadeh@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Majid Safa

Street address
Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 2504

Email
info@iums.ac.ir

Web page address
https://iums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Leila Amiri Farahani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
In front of Khatamol anbiaa Hospital., Rashid Yasemi Ave., Valiasr Ave., Tehran., Iran

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 4365 1000

Email
l.amirifarahani1100@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Leila Amiri Farahani

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
In front of Khatamol anbiaa Hospital., Rashid Yasemi Ave., Valiasr Ave., Tehran., Iran

City
Tehran

Province
Tehran

Postal code
1996713883
Phone
+98 21 4365 1000
Email
l.amirifarahani1100@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Leila Amiri Farahani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
In front of Khatamol anbiaa Hospital., Rashid Yasemi Ave., Valiasr Ave., Tehran., Iran
City
Tehran
Province
Tehran
Postal code
1996713883
Phone
+98 21 4365 1000
Email
l.amirifarahani1100@gmail.com

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