Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the effectiveness of childbearing education/counseling guidelines based on the Kirkpatrick model among service providers and its impact on knowledge, attitude, reproductive behavior, and motivation for childbearing in women

Protocol summary

Study aim
Evaluating the effectiveness of childbearing education/counseling guidelines based on the Kirkpatrick model among service providers and its impact on knowledge, attitude, reproductive behavior, and motivation for childbearing in women

Design
This study is a randomized clinical trial with 300 women, including two intervention groups (multimedia and existing guidelines) and a control group. Random assignment based on behavior change stages and separate delivery of sessions limits information exchange between participants.

Settings and conduct
The intervention is based on the behavior change model and is carried out in 17 similar health service centers in Bastak city. After a pre-test, participants are grouped based on the stages of behavior change and are continuously selected from among eligible women.

Participants/Inclusion and exclusion criteria
Participants must be married Iranian women living together, aged 18 to 45, at least literate, and willing to participate in the study. They must not have chronic physical or mental illnesses, and must meet certain conditions such as at least 6 months of marriage, a child aged 12 to 18 months, mental readiness after a miscarriage or at least 6 months of stillbirth, no contraception, and access to a smartphone. Withdrawal from the study will occur in the event of marital breakdown, infertility diagnosis, or withdrawal and absence from intervention sessions.

Intervention groups
This study includes three groups: the first group receives multimedia training, the second group receives training with existing instructions, and the control group receives no training during the study but receives training after completion.

Main outcome variables
Improving women's awareness, attitudes, reproductive behavior, and motivation to have children

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250818066902N1**
Registration date: **2025-08-29, 1404/06/07**
Registration timing: **prospective**

Last update: **2025-08-29, 1404/06/07**
Update count: **0**

Registration date
2025-08-29, 1404/06/07

Registrant information

Name
Farzaneh Banihashemi

Name of organization / entity
Tarbiat Modares University

Country
Iran (Islamic Republic of)

Phone
+98 76 4432 1610

Email address
banihashemi.farzaneh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-22, 1404/07/30

Expected recruitment end date
2026-03-19, 1404/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effectiveness of childbearing education/counseling guidelines based on the Kirkpatrick model among service providers and its impact on knowledge, attitude, reproductive behavior, and motivation for childbearing in women

Public title
Evaluating the effectiveness of childbearing education/counseling guidelines based on the Kirkpatrick model among service providers and its impact on knowledge, attitude, reproductive behavior, and motivation for childbearing in women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women must be married, have a husband, and live together.Be between the ages of 18 and 45.
Exclusion criteria:
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
To determine the effect of the new educational intervention based on new technologies, intervention group 1 will receive parenting education according to new methods, intervention group 2 will receive parenting education/counseling according to existing methods and content, and in the control group, individuals who have not received this education for any reason or may continue to receive it until the end of the year will be included in the study. In this study, all comprehensive health service centers covered will be included in the study, and the study will be conducted in each center on all three intervention groups 1, intervention 2, and the control group. In this study, random allocation of participants to three intervention groups 1, intervention 2, and control will be performed using the Stratified Random Allocation method. First, the entire sample will be divided into 17 blocks (based on the number of centers) based on comprehensive health service centers. Then, at each center, participants will be randomly assigned to one of three groups using a block randomization method, so that each center has a representative sample of all three groups. Randomization will be performed using the household file number in the SIB system and statistical software (such as Random Allocation Software or the randomization feature in SPSS) or a list of computer-generated random numbers. This method maintains a balance in the number of people in each group across all centers and allows for fair comparisons of interventions.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants do not know which intervention or control group they are in.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tarbiat Modares University
Street address
Jalal Al-Ahmad Highway - No. 7 Street, Tarbiat Modares University
City
Tehran
Province
Tehran
Postal code
141115111
Approval date
2025-07-27, 1404/05/05
Ethics committee reference number
IR.MODARES.REC.1404.78

Health conditions studied

1

Description of health condition studied
Improving women's knowledge, attitudes, reproductive behavior, and motivation to have children
ICD-10 code
-
ICD-10 code description
-

Primary outcomes

1

Description
Improving women's awareness, attitudes, reproductive behavior, and motivation to have children

Timepoint
Study of knowledge, attitude, reproductive behavior and motivation to have children in women at the beginning of the study and three months after the end of the educational intervention.

Method of measurement
Using the Knowledge, Attitude, Fertility Behavior, and Childbearing Motivation Questionnaire

2

Description
Improving women's knowledge, attitudes, reproductive behavior, and motivation to have children

Timepoint
At the beginning of the study and three months after the end of the educational intervention

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Changing awareness, attitudes, reproductive behavior, and childbearing motivation in women

Timepoint
After the end of the intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: The samples will be distributed to the intervention centers based on which of the 5 stages of behavior change they are in and will receive training in accordance with the Ministry of Health’s guidelines based on the Behavior Change Approach (SOC) and with full knowledge of the client. This approach helps the trainer/counselor to discover which stage of behavior change a woman eligible for childbearing is currently in and then adjusts their training content to suit that stage based on the Ministry of Health’s guidelines and presents it to the client. This training/counseling in intervention group 1 will be conducted in person and virtually, multimedia-based, in 10 60- and 30-minute training sessions.Intervention group 2 will also receive this training routinely based on the existing guidelines in 15 to 20 minutes.The control group will include eligible married women who have not received this training for any reason or may continue to receive it by the end of the year.Given the fact that training will be less effective if it is not model-based, the topics of the training session of this study will be based on the structures of the stages of change approach, which include the following:1) Pre-contemplation stage: In this stage, the individual has no intention or intention to change behavior in the next 6 months. Lack of information, motivation, resistance to change, and lack of readiness for intervention are the reasons for remaining in the pre-contemplation stage.2) Thinking stage: In the thinking stage, the individual intends to change behavior in the next 6 months, but these people constantly change their minds, it may take several weeks or months, or they may not even move on to the next stage. The educated classes stay in this stage more often.3) Preparation stage: In this stage, people have active plans for change in the next month. They have taken steps, however small, in this direction and are adjusting their lives accordingly. These people think whether they have the ability to change behavior? So, it is necessary to work on their self-confidence and remove obstacles from their path or help them remove obstacles.4) Action stage: In this stage, people have made a clear change in their behavior. Therefore, these people need encouragement and social and family support to remain in this stage and move on to the next stages.5) Continuation stage: In the continuation stage, people try to prevent a return to the previous behavior. More than 6 months have passed since the behavior change, this stage indicates the continuation of the new lifestyle. These people enjoy the resulting change and their self-confidence increases.

Category
N/A

2

Description
Control group: It will not receive any intervention and after the end of the study, educational content will also be provided to the control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
This study will be conducted in all comprehensive health service centers of Bastak city in western H

Full name of responsible person
Farzaneh Bani Hashemi

Street address
Vali Asr Street

City
Bastak

Province
Hormozgan

Postal code
7961973649

Phone
+98 917 364 4951

Email

Banihashemi.farzaneh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares University, Tehran
Full name of responsible person
Najmeh Tehranian
Street address
Jalal Al Ahmad Highway, Street 7
City
Tehran
Province
Tehran
Postal code
141115111
Phone
+98 912 327 0155
Email
N_tehranian@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University, Tehran
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
Tarbiat Modares University
Full name of responsible person
Farzaneh Bani Hashemi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Jalal Al Ahmad Highway, Street 7
City
Tehran
Province
Tehran
Postal code
141115111
Phone
+98 76 4432 2262
Email
Banihashemi.farzaneh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Farzaneh Bani Hashemi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Jalal Al Ahmad Highway, Street 7
City
Tehran
Province
Tehran
Postal code
141115111
Phone
+98 76 4432 2262
Email
Banihashemi.farzaneh@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Farzaneh Bani Hashemi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Jalal Al Ahmad Highway, Street 7
City
Tehran
Province
Tehran
Postal code
141115111
Phone
+98 76 4432 2262
Email
Banihashemi.farzaneh@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

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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

After submitting the request via email and obtaining permission from the professors, information will be sent to the applicant.

Under which criteria data/document could be used

If confidentiality is maintained and the request is reasonable

From where data/document is obtainable

Farzaneh Banihashemi, student
Banihashemi.farzaneh@gmail.com

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

After sending the request via email and obtaining permission from the professors, information will be sent to the applicant.

Comments