Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Promoting Childbearing Intention WithTeach-Back Method: The Role of Attitudes and Perceived Behavioral Control Among Married Women

Protocol summary

Study aim

The Effect of the Teach-Back Educational Method on Childbearing Intention Based on the Theory of Planned Behavior Among Married Women in Khoy

Design

This study was a parallel-group, open-label, cluster quasi-experimental controlled trial conducted on 150 eligible women (75 intervention, 75 control). To prevent contamination, allocation was performed at the cluster level across eight comprehensive health centers, randomly assigning four centers to the intervention group and four to the control group, followed by simple random sampling of participants from each center

Settings and conduct

Conducted on TPB-based fertility intention across 8 urban health centers in Khoy. Cluster allocation of centers into intervention and control groups (4 each). Baseline face-to-face interview surveys. Intervention received four 45-minute Teach-Back sessions; control received routine care. Follow-up after 3 months. Unblinded due to educational intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women of reproductive age (15–49 years); no medical contraindication for pregnancy; having an active health record at a comprehensive health service center; willingness to participate and providing informed consent. Exclusion Criteria: Pregnancy during the study period; infertility in either partner.

Intervention groups

Intervention Group: Participated in four 45-minute sessions (25 minutes of TPB-based education and 20 minutes of Teach-Back) to improve fertility knowledge, attitudes, subjective norms, and perceived behavioral control. Control Group: Received routine care with no specific intervention during the study period; educational materials were provided only after the 3-month follow-up (to uphold ethical principles).

Main outcome variables

Fertility intention; Reproductive knowledge; Attitude toward childbearing; Subjective norms; Perceived behavioral control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251129068147N2**
Registration date: **2026-10-11, 1405/07/19**
Registration timing: **retrospective**

Last update: **2026-10-11, 1405/07/19**
Update count: **0**

Registration date

2026-10-11, 1405/07/19

Registrant information

Name
Leila Asadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-31, 1403/05/10

Expected recruitment end date

2024-10-01, 1403/07/10

Actual recruitment start date

2024-07-31, 1403/05/10

Actual recruitment end date

2024-12-04, 1403/09/14

Trial completion date

2025-04-03, 1404/01/14

Scientific title

Promoting Childbearing Intention WithTeach-Back Method: The Role of Attitudes and Perceived Behavioral Control Among Married Women

Public title

The Impact of Teach-Back Educational Interventions on Childbearing Intentions: Evaluating Attitudes and Perceived Behavioral Control

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

being within reproductive age (15–49 years) having no medical contraindication for pregnancy having an active health record at a comprehensive health service center

Exclusion criteria:

pregnancy during the study period and infertility in either partner

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was conducted using a multistage cluster-randomized design. Khoy city was initially divided into two geographic zones based on municipal divisions. From each zone, four urban comprehensive health service centers were randomly selected (total of 8 centers). Within each zone, two centers were randomly allocated to the intervention group and two centers to the control group (resulting in 4 intervention clusters and 4 control clusters). In the final stage, 20 eligible women from each health center were selected using simple random sampling from the center’s registry list. The primary unit of randomization for group allocation was at the cluster level (comprehensive health service centers) to prevent contamination and information exchange between groups, while the secondary selection of participants was at the individual level. Stratified randomization was applied based on the two municipal geographical regions of Khoy city as strata to ensure socioeconomic and geographical balance across study arms. The random allocation sequence for both cluster assignment and individual participant sampling was generated using a random number table. Cluster allocation was determined prior to participant enrollment. Eligible participants were unaware of the alternative group allocation across other centers during recruitment and consent, and geographical separation between health centers ensured effective concealment and prevented contamination across study arms.

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

Research Ethics Committees of Khoy University of Medical Sciences

Street address

15th of Khordad Blvd., Shahid Fahmideh Sq., Ostad Shahriar St.

City

Khoy

Province

West Azarbaijan

Postal code

5814743343

Approval date

2024-07-24, 1403/05/03

Ethics committee reference number

IR.KHOY.REC.1403.019

Health conditions studied

1

Description of health condition studied

Fertility Intention,Reproductive Health,Health Education,Reproductive Behavior

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Fertility Intention

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Data were collected using a structured questionnaire consisting of three main sections: (1) demographic characteristics, (2) knowledge related to childbearing, and (3) constructs of the Theory of Planned Behavior

(TPB) associated with fertility intention

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The educational intervention consisted of four 45-minute training sessions (one session per week) conducted for the intervention group. Each session included 25 minutes of structured education based on the constructs of the Theory of Planned Behavior (TPB) (including attitudes, subjective norms, and perceived behavioral control regarding childbearing) and 20 minutes of practice and feedback using the Teach-Back method to ensure comprehension.

Category

Behavior

2

Description

Control group: .The control group received routine health center care and no educational intervention during the study period (3-month follow-up). The educational content was provided to the control group after the completion of the 3-month follow-up period.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban Health Centers in Khoy, Iran

Full name of responsible person

Morad Ali Zareipour

Street address

Headquarters of Khoy University of Medical Sciences and Health Services, Ostad Shahriar St., Shahid Fahmideh Sq., 15th of Khordad Blvd., Khoy, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoy University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology, Khoy University of Medical Sciences

Street address

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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

Khoy 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

Khoy University of Medical Sciences

Full name of responsible person

Morad Ali Zareipour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the sensitivity of the study topic and the potential risk of re-identification of participants within a small-scale sample, we are unable to share individual participant data in order to strictly protect participant confidentiality and privacy.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available