

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of a designed educational-consulting program based on artificial intelligence technology on fertility attitudes and motivation in childless married women: A randomized controlled trial

Protocol summary

Study aim

Determining the effect of a designed educational-consulting program based on artificial intelligence technology on fertility attitudes and motivation in childless married women

Design

Eighty participants will be randomly allocated to each of the two groups: an intervention group will receive parenting counseling via an AI chat bot, and the control group will receive routine parenting counseling.

Settings and conduct

This study will be conducted among women who attend comprehensive health centers in Mahmudabad city to receive health services. Participants will be screened according to the study's inclusion and exclusion criteria. Eligible women will be provided with information about the study objectives and a brief description of the procedures. Those who agree to participate will complete and sign a written informed consent form.

Participants/Inclusion and exclusion criteria

The inclusion criteria include married women aged 18-40 years, Iranian nationality, first marriage, childless (women who have been married for at least 6 months and are not currently pregnant), low or average desire to have children, access to the Internet and a smartphone, and having at least 9 years of education and exclusion criteria include women with maternal or fetal medical contraindications to pregnancy, known chronic physical and mental illnesses, speech and hearing disorders, drug addiction and unwillingness to participate in the study.

Intervention groups

The intervention group will receive the designated childbearing counseling content for service providers through an AI chat bot intervention delivered in four weekly sessions at times scheduled by the study participants. The control group will receive the same content routinely by healthcare providers.

Main outcome variables

Attitudes towards fertility and childbearing, childbearing motivation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056451N7**

Registration date: **2025-11-14, 1404/08/23**

Registration timing: **prospective**

Last update: **2025-11-14, 1404/08/23**

Update count: **0**

Registration date

2025-11-14, 1404/08/23

Registrant information

Name

Fatemeh Bakouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3232 2589

Email address

bakouei2004@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2026-06-10, 1405/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of a designed educational-consulting program based on artificial intelligence technology on fertility attitudes and motivation in childless married women: A randomized controlled trial

Public title

An educational-consulting program based on artificial intelligence technology on the fertility attitude and motivation of childless married women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women aged 18-40 years Iranian nationality First marriage Childless (women who have been married for at least 6 months and are not currently pregnant) Low or average desire to have children based on a fertility preference question score below 8 Access to the Internet and a smartphone Having at least 9 years of education

Exclusion criteria:

Women with maternal or fetal medical contraindications to pregnancy Known chronic physical and mental illnesses Speech and hearing disorders (preventing communication with the researcher) Drug addiction according to the individual's statements Unwillingness to participate in the study

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible women will be randomly assigned to either the control or intervention group using a 1:1 block randomization method with blocks of four. To ensure concealment of allocation, only the first supervisor will have access to the randomization list, which will be generated using Random Allocation Software. The researcher will communicate participant eligibility to the supervisor, who will then provide the group assignment based on the block file prepared by the statistics consultant.

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 Health Research Institute - Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganj Afroz Ave, Babol

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2025-11-09, 1404/08/18

Ethics committee reference number

IR.MUBABOL.HRI.REC.1404.172

Health conditions studied**1****Description of health condition studied**

Attitudes and motivation towards childbearing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Attitude to fertility

Timepoint

Before and one month after the intervention

Method of measurement

Questionnaire of attitudes towards fertility and child bearing

2**Description**

Fertility motivation

Timepoint

Before and one month after the intervention

Method of measurement

Miller's Fertility Motivation Questionnaire

Secondary outcomes

1**Description**

Fertility knowledge

Timepoint

Before and one month after the intervention

Method of measurement

Cardiff Fertility Knowledge Scale

Intervention groups**1****Description**

Intervention group: Participants randomized to the intervention arm will receive a structured educational-counseling program based on artificial intelligence technology through an AI-powered chat bot platform, delivered across four weekly sessions scheduled at each participant's convenience. The intervention protocol begins with a standardized set of researcher-developed questions derived from the National Guidelines for Childbearing Counseling for Healthcare Providers, which are embedded within the chat bot interface. Following this initial structured interaction, participants will have the opportunity to pose personalized questions to refine their understanding and receive tailored advice.

Category

Behavior

2**Description**

Control group: Participants allocated to the control arm will receive conventional childbearing counseling as specified in the National Guidelines, administered through standard in-person consultations with trained healthcare providers.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Comprehensive health centers in Mahmudabad city

Full name of responsible person

Fatemeh Bakouei

Street addressBabol University of Medical Sciences, Ganj Afroz Ave,
Babol**City**

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 5313

Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible personVice President of Research and Technology: Dr. Reza
Ghadimi**Street address**Babol University of Medical Sciences, Ganj Afroz Ave,
Babol**City**

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 7667

Email

r.ghadimi@mubabol.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Bakouei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street addressBabol University of Medical Sciences, Ganj Afroz Ave,
Babol**City**

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 5313

Email

bakouei2004@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Bakouei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Ganj Afroz-Babol university of medical sciences

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3232 2589

Fax**Email**

bakouei2004@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Bakouei

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Ganj Afroz

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Phone

+98 11 3232 2589

Email

bakouei2004@yahoo.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