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 address
Babol University of Medical Sciences, Ganj Afroz Ave, Babol
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 5313
Email
bakouei2004@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Vice 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 address
Babol 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 mrdical 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 Afrooz
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