Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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
I submitted the manuscript protocol to a journal. The reviewers suggested that I add the inclusion criterion "ability to interact with AI/digital platforms". Since I haven't started sampling yet, if possible, this criterion should be added. In addition, the editor asked me to complete the data sharing section and update the expected recruitment start date, so I added the relevant content in the relevant section. Thanks

Acronym

IRCT registration information
IRCT registration number: **IRCT20221109056451N7**
Registration date: **2025-11-14, 1404/08/23**
Registration timing: **prospective**

Last update: **2026-06-13, 1405/03/23**
Update count: **1**

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
Not yet recruiting

Funding source

Expected recruitment start date
2026-08-23, 1405/06/01
Expected recruitment end date
2027-03-19, 1405/12/28
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 ability to interact with artificial intelligence/digital platforms
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

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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

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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

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

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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
Yes - There is a plan to make this available

Title and more details about the data/document
Deidentified Individual Participant Data (IPD) – This includes all deidentified participant data related to primary and secondary outcome measures, will collect through questionnaires and clinical records. Study Protocol – Full finalized protocol submitted to the ethics committee. Statistical Analysis Plan (SAP) – Final version describing the statistical methods used for primary and secondary outcomes. Informed Consent Form – Blank version of the informed consent form used for participant enrollment. Analytic Code – R/Stata/SPSS scripts used for statistical analysis. Data Dictionary – A detailed guide to the variables, definitions, formats, and codes used in the dataset.

When the data will become available and for how long
The documents and data files will be available starting 6 months after the main publication and will remain accessible for at least 5 years.

To whom data/document is available
Data and documents will be made available to researchers affiliated with academic or nonprofit institutions, with a clear and valid research purpose. Requests from commercial entities may be considered case-by-case.

Under which criteria data/document could be used
Data/documents can be used only for secondary analyses related to reproductive health, fertility, or public health. Proposals will be reviewed by the principal investigator and research ethics coordinator. Data will be shared via secure data transfer.

From where data/document is obtainable

Requests should be directed via email to: Dr. Fatemeh Bakouei Babol University of Medical Sciences Email: bakouei2004@yahoo.com

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

Interested researchers should submit: A short proposal (max 1 page) Ethics approval (if applicable) Signed data use agreement Requests will be reviewed within 2–4 weeks. Access will be granted after approval and agreement signature.

Comments

None at this time.