Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

“The Effectiveness of Virtual Mindfulness-Based Counseling on Self-Efficacy and Adjustment to Unplanned Pregnancy: A Randomized Clinical Trial”

Protocol summary

Study aim

To determine the effectiveness of virtual mindfulness-based counseling on self-efficacy and adjustment in women with unplanned pregnancy.

Design

This is a randomized controlled trial with parallel groups, conducted as an open-label study. Eligible participants (n=98) will be assigned to the intervention group (virtual mindfulness-based counseling) or control group (standard prenatal care). Randomization will be done using block randomization (blocks of four) via Random Allocation Software, with allocations placed in opaque, sealed, numbered envelopes to ensure concealment. Blinding of participants and the researcher is not feasible. Trial phase: Not Applicable (Non-pharmacological / Psychological intervention)

Settings and conduct

The study will be conducted in Babol County on women with unplanned pregnancies. Intervention sessions will be in-person and online. The control group will receive standard care.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Women with unplanned pregnancy; Maternal age 18–40 years old; Literacy (able to read and write); Access to a smartphone and the internet; Willingness to participate. Exclusion Criteria: Severe physical or psychiatric disorders; High-risk pregnancy or history of high-risk pregnancy; Severe stressful events in the past three months; Unwillingness to continue participation; Absence from more than two counseling sessions; Miscarriage or pregnancy termination before intervention completion.

Intervention groups

Intervention Group (n=49): Participants will receive virtual mindfulness-based counseling. The first session is in-person, and the remaining sessions are online. Control Group (n=49): Participants will receive standard prenatal care.

Main outcome variables

Maternal self-efficacy: Measured using the General Self-Efficacy Scale (GSE). Adjustment to pregnancy: Measured using the Pregnancy Adjustment Questionnaire (PAQ).

General information

Reason for update

During the protocol update process, the start date of the patient's diagnosis was corrected. The date recorded in the previous version was incorrect due to an inadvertent error during data entry and has been replaced with the correct date. Please review and confirm the change.

Acronym

IRCT registration information

IRCT registration number: **IRCT20100510003902N8**
Registration date: **2026-03-06, 1404/12/15**
Registration timing: **prospective**

Last update: **2026-08-12, 1405/05/21**
Update count: **1**

Registration date

2026-03-06, 1404/12/15

Registrant information

Name

Farideh Mohsenzadeh

Name of organization / entity

Babol university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-04-04, 1405/01/15
Expected recruitment end date
2027-05-22, 1406/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
"The Effectiveness of Virtual Mindfulness-Based Counseling on Self-Efficacy and Adjustment to Unplanned Pregnancy: A Randomized Clinical Trial"

Public title
"The Effect of Virtual Mindfulness-Based Counseling on Self-Efficacy and Adjustment of Women with Unplanned Pregnancy"
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with unplanned pregnancy, based on the definition of the World Health Organization (WHO, 2021). Gestational age between 12 and 28 weeks (based on ultrasound examination or prenatal care records). Ability to read and write (literacy). Willingness to participate in the study. No history of chronic physical diseases (such as insulin-dependent diabetes mellitus or severe cardiovascular disease). Maternal age between 18 and 40 years. Access to a smartphone and the internet. Singleton pregnancy. Residence in Babol County and ability to attend counseling sessions (first session in person and subsequent sessions virtually). Provision of written informed consent to participate in the study
Exclusion criteria:
Severe psychiatric disorders (based on health records or physician report) History of high-risk pregnancy (such as preeclampsia, gestational diabetes, or preterm delivery in previous pregnancies). Experience of severe stressful events in the past three months (such as death of a close relative or divorce). Unwillingness to continue participation at any stage of the study. Absence from more than two counseling sessions Occurrence of miscarriage or termination of pregnancy before the end of the intervention
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: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
To prevent allocation bias, randomization will be performed by an independent statistician. The random sequence will be generated using block randomization (blocks of four) with Random Allocation Software (Saghaei, 2004). Allocation numbers will be placed in opaque, sealed, and sequentially numbered envelopes to ensure allocation concealment. After each eligible participant provides written informed consent, the researcher will open the corresponding envelope and assign the participant to either the intervention group (n=49) or the control group (n=49).
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
Health Research Institute - Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganj Afroz Street
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2026-02-02, 1404/11/13
Ethics committee reference number
IR.MUBABOL.REC.1404.249

Health conditions studied

1

Description of health condition studied
Unwanted pregnancy
ICD-10 code
Z64.0
ICD-10 code description
Problems related to unwanted pregnancy

Primary outcomes

1

Description
Adjustment to pregnancy in pregnant women, assessed using the Pregnancy Self-Evaluation Questionnaire (PSEQ).

Timepoint
Baseline (at study entry) Post-intervention (after completion of sessions)

Method of measurement
Assessed using the Pregnancy Self-Evaluation Questionnaire (PSEQ)

Secondary outcomes

1

Description
Maternal self-efficacy: The level of maternal self-efficacy in coping with pregnancy, measured using the Pregnancy Self-Efficacy Questionnaire. Assessments are conducted at baseline and immediately after the completion of the intervention.

Timepoint
Baseline (at study entry)Post-intervention (after completion of sessions)

Method of measurement
Maternal self-efficacy: Assessed in pregnant women using the Pregnancy Self-Efficacy Questionnaire at baseline and post-intervention. Pregnancy outcomes will also be evaluated.

2

Description
Pregnancy outcome

Timepoint
Baseline، Monthly follow-up until delivery، At delivery

Method of measurement
Information is collected from the mother's medical record and monthly follow-up via phone call or text message until delivery.

Intervention groups

1

Description
Intervention Group:Participants receive mindfulness-based counseling consisting of one in-person session and seven online sessions via social networks (Eitaa, WhatsApp, Google Meet). Each session lasts 90 minutes and occurs weekly.All sessions are conducted by a Master’s student in Midwifery Counseling, trained in Mindfulness-Based Interventions. Session content is based on validated scientific protocols and reviewed by a psychiatrist and research team. The intervention is supervised by the principal investigator and a psychiatric advisor to ensure consistency and participant safety.Session structure:• Session 1: Interactive mindfulness training, body scan meditation, homework: mindful raisin exercise and body scan.• Session 2: Thoughts and feelings exercises, seated meditation and mindful walking, homework: record pleasant events and practice meditation.• Session 3: Body mindfulness and 3-minute breathing space, mindfulness in daily activities, homework: selected meditation practice.• Session 4: Four-dimensional meditation, seeing and hearing exercises, homework: self-care planning and pleasant activity schedule.• Sessions 5–8: Review and practice of previous techniques, seated and four-dimensional meditation, practical exercises and homework, online feedback and practice tracking.All assessments are conducted pre- and post-intervention, and educational links are also provided to the control group after the study to ensure educational fairness.

Category
Behavior

2

Description
Control group: Participants in this group receive standard prenatal care according to local health guidelines, without any additional intervention or educational sessions.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol County

Full name of responsible person
Farideh Mohsenzadeh Ledari

Street address
Babol University of Medical Sciences, Ganj Afroz Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Reza Gadimi

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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
Farideh mohsenzadeh ledari
Position
University faculty
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available