Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Religion-Based Spiritual Self-Care Education on Fear of Childbirth and Pregnancy Experience Among Pregnant Women: A Randomized Controlled Trial

Protocol summary

Study aim
To determine the effect of religion-based spiritual self-care education during pregnancy on fear of childbirth and pregnancy experience

Design
Three assessment stages: 1) before the intervention (at enrollment, weeks 20–24 of gestation), 2) immediately after the end of the intervention, and 3) four weeks after the end of the intervention.

Settings and conduct
(gestational weeks 20–24, W-DEQ-A ≥ 66 ≥66). Randomization: 1:1 allocation to intervention and control via block randomization and opaque envelopes. Intervention & Follow-up: 5 training sessions vs. routine care; blinded outcome assessment (Tabriz, Iran).

Participants/Inclusion and exclusion criteria
Major Eligibility Criteria Before Randomization Inclusion criteria: Residing in Tabriz. Having a singleton pregnancy at 20–24 weeks of gestation. Scoring ≥66 on the initial childbirth fear assessment. Being committed to religious beliefs and practices. Being able to read and write. Physical or mental disability (based on self-report). History of difficult labor. Known fetal anomalies. History of depression (based on maternal self-report and medical records review).

Intervention groups
Intervention Group (

Main outcome variables
Fear of childbirth and pregnancy experience.

General information

Reason for update

Acronym
W-DEQ-A & PRAQ

IRCT registration information
IRCT registration number: **IRCT20240128060831N3**
Registration date: **2026-10-29, 1405/08/07**
Registration timing: **prospective**

Last update: **2026-10-29, 1405/08/07**
Update count: **0**

Registration date
2026-10-29, 1405/08/07

Registrant information

Name
Reyhaneh Ivanbagha

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3479 6770

Email address
ivanbagha@tbzmed.ac.ir

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-11-21, 1405/08/30

Expected recruitment end date
2027-05-21, 1406/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Religion-Based Spiritual Self-Care Education on Fear of Childbirth and Pregnancy Experience Among Pregnant Women: A Randomized Controlled Trial

Public title

The effect of religion-based spiritual self-care education on fear of childbirth and pregnancy experience in pregnant women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Major Eligibility Criteria Before RandomizationInclusion criteria Having a singleton pregnancy at 20–24 weeks of gestation Residing in Tabriz..Scoring ≥66 on the initial childbirth fear assessment. Being committed to religious beliefs and practices Being able to read and write.

Exclusion criteria:

Age
From **5 months** old to **6 months** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated to the intervention and control groups using block randomization (with block sizes of 4 and 6, and a 1:1 allocation ratio). Randomization will be stratified based on parity (primigravid and multigravid) and the severity of fear of childbirth (high fear and severe fear). The random allocation sequence will be generated using a computer-based Randomizer software. Allocation concealment will be ensured by an individual not involved in participant recruitment and data collection; the allocation sequence will be written on slips of paper and placed in sequentially numbered, opaque, sealed envelopes, which will be opened in order of participants' entry into the study."

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessors and the data analyst will be blinded to participants' group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences

Street address
University Square, Tabriz University of Medical Sciences

City
tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2026-10-20, 1405/07/28

Ethics committee reference number
IR.TBZMED.REC.1405.52

Health conditions studied

1

Description of health condition studied
Fear of childbirth and pregnancy experience

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fear of childbirth and pregnancy experience.

Timepoint
20-24 w

Method of measurement
W-DQE-A PES

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in this group receive routine prenatal care along with five 90-minute weekly sessions of religion-based spiritual self-care education conducted in groups of 6 to 8 participants.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Selected health centers in Tabriz.

Full name of responsible person

mahnaz mohsenzadeh
Street address
Tabriz Nesf-e Rah Health Center
City
tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3443 8797
Email
info@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Reyhaneh Ivanbagha
Street address
South Shariati street
City
،abriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3477 0648
Email
ivanbagha@tbzmed.c.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
mahnaz mohsenzadeh
Position
midvife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
south shariyati street
City
tabriz
Province
East Azarbaijan
Postal code
5138997977
Phone
+98 41 3477 0649
Email
mahnazmohsen3@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
reyhaneh ivanbagha
Position
lecture
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
sourth shahnaz street
City
tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3477 0649
Email
r.ivan1347@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Reyhaneh ivanbagha
Position
Lecturer
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, South Shariati Street, Tabriz, Iran
City

tbriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

r.ivan1347@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Individual participant data will not be made publicly available in order to protect confidentiality and privacy. De-identified data and study documents may be provided upon reasonable request, subject to approval by the principal investigator and compliance with ethical requirements. No information that could identify participants will be shared.

When the data will become available and for how long

5years

To whom data/document is available

Qualified researchers who submit a reasonable request may access the de-identified data and study documents only after approval by the principal investigator and in compliance with ethical and confidentiality requirements. Identifiable participant information will not be shared.

Under which criteria data/document could be used

De-identified data may be used only for research purposes related to maternal health, scientific analysis or re-analysis, and systematic reviews. Use of the data to identify participants or for commercial purposes is not permitted.

From where data/document is obtainable

Requests for access to the de-identified data and study documents should be directed to the principal investigator, [full name], at [email address or telephone number]. Access is subject to the principal investigator’s approval and compliance with ethical and confidentiality requirements.

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

Applicants must submit a written request to the principal investigator, specifying the purpose of the proposed use, the data required, and how confidentiality will be protected. The principal investigator will review the request for scientific and ethical appropriateness. If approved, the relevant de-identified data and study documents will be provided subject to agreed terms of use and compliance with ethical and confidentiality requirements. No identifiable participant information will be provided

Comments

Data and study documents will be shared only in de-identified form. Requests will be reviewed individually, and access is subject to the principal investigator’s approval and compliance with ethical and confidentiality requirements. No information that could identify participants will be shared.