Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Spiritual Counseling on Pregnancy Acceptance and Reduction of Anxiety

Protocol summary

Study aim
To investigate the effect of spiritual counseling on pregnancy acceptance and anxiety reduction

Design
This study is a randomized clinical trial with control and parallel groups on 110 first trimester pregnant women in Shiraz. Allocation to intervention and control groups is done without randomization. The intervention group receives spiritual counseling and the control group receives usual care.

Settings and conduct
This study will be conducted in health centers in Shiraz. After identifying eligible first-trimester pregnant women and obtaining informed consent, participants will complete initial questionnaires. Then, individuals will be non-randomly assigned to two intervention and control groups. The intervention group will receive spiritual counseling based on a researcher-developed protocol in addition to usual care, while the control group will receive only usual care. After the intervention, the questionnaires will be completed again by the participants.

Participants/Inclusion and exclusion criteria
110 first-trimester pregnant women in Shiraz will be randomly assigned to intervention and control groups. Inclusion criteria: first-trimester pregnancy, uncertainty about pregnancy continuation or acceptance, pregnancy-related anxiety, and informed consent. Exclusion criteria: Unwillingness to participate in the study, Mother's blindness and deafness, Mental and physical retardation of the mother

Intervention groups
participants in the intervention group will receive spiritual counseling based on a researcher-developed protocol and will complete the study questionnaires before and after the intervention. Comparison group: Mothers who only received routine prenatal care and did not receive spiritual counseling

Main outcome variables
Pregnancy acceptance Pregnancy-related anxiety These outcomes will be measured using validated questionnaires before and after the intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260629070002N1**
Registration date: **2026-08-17, 1405/05/26**
Registration timing: **prospective**

Last update: **2026-08-17, 1405/05/26**
Update count: **0**

Registration date
2026-08-17, 1405/05/26

Registrant information

Name
Nasim Bozorgi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 930 167 9463

Email address
nasimbozorgi94@yahoo.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-11, 1405/06/20

Expected recruitment end date
2026-12-11, 1405/09/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spiritual Counseling on Pregnancy Acceptance and Reduction of Anxiety

Public title

The Effect of Spiritual Counseling on Pregnancy Acceptance and Reduction of Anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The mother has doubts about deciding to continue the pregnancy. No underlying disease in the mother or fetus that threatens the mother's life and requires a legal abortion Must be a resident of Fars province

Exclusion criteria:

Mental and physical retardation of the mother Mother's blindness and deafness Unwillingness to participate in the study

Age

No age limit

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Research Ethics Committee of qom medical science university

Street address

Azadegan

City

Shiraz

Province

Fars

Postal code

7154866697

Approval date

2026-06-14, 1405/03/24

Ethics committee reference number

IR.MUQ.REC.1405.089

Health conditions studied

1

Description of health condition studied

Pregnancy Acceptance and Reduction of Pregnancy Anxiety

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

At the beginning of the study and before receiving spiritual counseling, pregnancy anxiety is measured using a questionnaire. Then, two weeks after spiritual counseling, the effect of spiritual counseling on pregnancy anxiety is measured.

Method of measurement

Measuring pregnancy anxiety using the Vandenberg Pregnancy Anxiety Questionnaire

2

Description

Miscarriage

Timepoint

Before spiritual counseling, adjustment to pregnancy is measured using the Prenatal Self-Evaluation Questionnaire (PSEQ). Then, the effect of spiritual counseling on pregnancy acceptance is measured two weeks after counseling.

Method of measurement

Adaptation to pregnancy by the Prenatal Self-Assessment Questionnaire (PSEQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant women in the first trimester who refer to Shiraz health and medical centers who have doubts or have not fully accepted the continuation of pregnancy, after entering the study and becoming aware of it, complete a demographic questionnaire, a Prenatal

Self-Evaluation Questionnaire (PSEQ), a Vandenberg Pregnancy Anxiety Questionnaire (PRAQ), and a comprehensive Jaberi Spiritual Health Assessment Questionnaire, and undergo an initial assessment. They then undergo spiritual counseling according to a researcher-made protocol, meaning they receive three counseling sessions, each session lasting 30 to 45 minutes. The content of the protocol, which includes verses, hadiths, stories, and counseling, as well as using their spouse and family to support them, is completed by them again two weeks later. In the intervention, during three sessions, the content of the spiritual counseling protocol, which consists of Quranic verses and hadiths, as well as the fate of mothers mentioned in the verses and hadiths, is told to them, family support or existing support groups are provided to them, and if they are unable to visit in person, counseling will be provided over the phone. There is no other intervention group, only this intervention, which includes spiritual counseling, and the control group that was described.

Category
Lifestyle

2

Description
Control group: Mothers who only receive routine pregnancy care, meaning they do not undergo spiritual counseling sessions when visiting the clinic and after completing the questionnaire, and are only given recommendations to reduce maternal anxiety by the midwife who provides their care, as usual, and then complete the questionnaire again two weeks later.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Healthcare and Medical Centers in Shiraz

Full name of responsible person
Nahid Mehran

Street address
Enghelab

City
Shiraz

Province
Fars

Postal code
71737 75617

Phone
+98 71 3232 4805

Email
Nasimbozorgi94@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Nahid Mehran

Street address
Shahid Javad Del Azar Boulevard

City
Qom

Province
Ghoum

Postal code
7654876543

Phone
+98 25 3107 1111

Email
Nasimbozorgi94@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ghoum University of Medical Sciences

Proportion provided by this source
80

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
Ghoum University of Medical Sciences

Full name of responsible person
Nasim Bozorgi

Position
Student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Azadegan

City
Shiraz

Province
Fars

Postal code
7154866697

Phone
+98 930 167 9463

Email
Nasimbozorgi94@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Nahid Mehran

Position
Associate proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Shahid delazar

City
Qom

Province
Ghoum

Postal code
3713649373

Phone
+98 25 3456 7893

Email
Nasimbozorgi94@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Nasim Bozorgi

Position
Student

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
Azadegan

City
Shiraz

Province
Fars

Postal code
7154866697

Phone
+98 930 167 9463

Email
Nasimbozorgi94@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Data on the main outcome will be shared.

When the data will become available and for how long
4 months after results are published

To whom data/document is available
For use in research or scientific, academic, and clinical uses

Under which criteria data/document could be used
The data and documents obtained from this study will be used solely for scientific and research purposes, including data analysis and re-analysis, conducting related research, and preparing scientific articles and reports. Following completion of the study, access to the data will be possible only upon submission of a justified scientific request and approval by the principal investigator. If the data are shared with other researchers, they will be provided in an anonymized form without any identifying information, and the confidentiality of participants' information will be fully maintained. The use of the data for commercial purposes or for identifying participants will not be permitted.

From where data/document is obtainable
After printing the results, please refer to the corresponding author's email. N_mehran59@yahoo.com Dr. Nahid Mehran PhD in Reproductive Health Assistant Professor, Qom University of Medical Sciences

What processes are involved for a request to access data/document
After printing the results, please refer to the corresponding author's email. After reviewing the request and necessary correspondence with them, the corresponding author will send the data within two weeks, if deemed appropriate.

Comments
I have not decided yet.