

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of counseling with spirituality approach on stress and anxiety during pregnancy and delivery: a randomized controlled clinical trial

Protocol summary

Summary

Objectives: To determine the effect of counseling with spiritual approach on stress and anxiety during pregnancy and delivery. **Design:** Two-armed randomized controlled trial. **Conduct:** This study will be conducted on pregnant women with gestational ages of 20 to 24 weeks referring to health centers of Maragheh city. The researcher will refer to health centers and will provide a list of women with gestational ages of 20 to 24 weeks, then will call them and if they comply with the eligibility criteria and have tendency to participate in study, they will be invited to be present at the health center. In face to face session, the questionnaires of perceived stress and anxiety will be completed and the participants will be randomly assigned into two groups (one group receiving counseling and one control group) through block randomization with block sizes of four and six. **Participants:** 112 women with gestational ages of 20 to 24 weeks. **Interventions:** For the intervention group will be provided six 60-minute group sessions once a week. The control group will receive routine prenatal cares. The main outcome variables are stress and anxiety during pregnancy and delivery that will be assessed four weeks after the end of intervention through questionnaires of perceived stress and Spielberger State-Trait Anxiety Inventory. The secondary outcomes are postpartum depression and anxiety that will be assessed through questionnaires of Edinburgh depression and Spielberger State-Trait Anxiety Inventory and also the neonatal anthropometric indices and delivery type that will be recorded according to childbirth file.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122710324N37**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-27, 1395/11/08

Expected recruitment end date

2017-10-30, 1396/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with spirituality approach on stress and anxiety during pregnancy and delivery: a randomized controlled clinical trial

Public title

The effect of counseling with spirituality approach on stress and anxiety during pregnancy and delivery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age of 20 to 24 weeks; Pregnant women with first, second and third pregnancy; Having a contact number for follow-up; Participate in at least 2 sessions of all counseling sessions; Having Edinburgh depression score less than 12 before the intervention; Desire to delivery in Shahid Beheshti hospital of Maragheh city. Exclusion Criteria: Having a physical diseases (such as epilepsy, heart disease, etc.) according to woman's expression; Having a mental illness according to woman's expression; History of hospitalization due to current pregnancy complications (such as preterm labor, placental abruption, Hemorrhage, preeclampsia, etc); History of premature labor and other risk factors for preterm labor; Detection of fetal malformations; Occurrence of recent unpleasant events in the last three months; Using of cigarette, alcohol and opiates and other drugs that affect a person's body and mind; Prior participation in spiritual counseling classes

AgeFrom **15 years** old to **49 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **112****Randomization (investigator's opinion)**

Randomized

Randomization description**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**

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Postal code**Approval date**

2017-01-09, 1395/10/20

Ethics committee reference number

IR.TBZMED.REC.1395.1064

Health conditions studied**1****Description of health condition studied**

Stress, anxiety and depression during pregnancy and puerperium

ICD-10 code

f53

ICD-10 code description

mental and behavioural disorders associated with the puerperium

Primary outcomes**1****Description**

Anxiety

Timepoint

Before intervention, 4 weeks after the intervention, during labor and 6 weeks postpartum

Method of measurement

Spielberger State-Trait Anxiety Inventory

2**Description**

Perceived stress

Timepoint

Before the intervention, 4 weeks after the intervention and during labor

Method of measurement

Perceived Stress Questionnaire

Secondary outcomes**1****Description**

Postpartum depression

Timepoint

6 weeks postpartum

Method of measurement

Edinburgh Postnatal Depression Scale

2**Description**

Neonatal anthropometric indices

Timepoint

After childbirth

Method of measurement

Childbirth file

3

Description

Delivery type

Timepoint

After childbirth

Method of measurement

Childbirth file

Intervention groups

1

Description

The control group will receive routine prenatal cares.

Category

N/A

2

Description

For the intervention group will be provided six 60-minute group sessions once a week.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in the city of Maragheh

Full name of responsible person

Masoomeh Haghighat

Street address

St. daneshsara, Maragheh city, East Azerbaijan

City

Maragheh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammadreza Rashidi

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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golasht Street, Azadi Avenue, Tabriz

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing & Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Masoomeh Haghighat

Position

MSc Student of conseling in Midwifery

Other areas of specialty/work

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PhD of Reproductive Health

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty