Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Maraghegh 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

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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 Maraghegh 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
Age
From **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 Univercity 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
Percieved 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
Maraghegh

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
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
City
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
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Street address
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Person responsible for updating data

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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