Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Quran voice with and without meaning on stress, anxiety and depression during pregnancy: a randomised controlled trial

Protocol summary

Summary

Objectives: This study aims to determine the effect of Quran voice with and without meaning on stress, anxiety and depression during pregnancy. Design: Tree parallel arm Randomized Controlled Trial Setting and conduct: This study will be conducted in Urmia health centers. Eligible women will be selected with convenience sampling and will be randomly assigned into 3 groups of 56 subjects with block sizes of 3 and 6. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Participants: 168 pregnant women with gestational age 25-28 weeks Interventions: First intervention group will receive Surah Maryam with the Persian meaning and the second group will receive Surah Maryam without meaning for 20 minutes weekly by researcher. The CD of Surah Maryam with and without meaning will be provided for both intervention groups, respectively in order to listen it at home. Also, the both intervention groups will receive routine prenatal care. The control group only will receive routine prenatal care. Main outcome measures: Stress, anxiety and depression will be assessed by the Perceived Stress Scale (PSS), the Spielberger State-Trait Anxiety Inventory (STAI) and Edinburgh Postnatal Depression Scale (EPDS), respectively at baseline, 4 and 8 weeks after starting the intervention. Secondary outcomes include the frequency of preterm delivery, cesarean delivery, and anthropometric indicators of newborn that will be assessed after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021710324N16**

Registration date: **2014-06-04, 1393/03/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-04, 1393/03/14

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Quran voice with and without meaning on stress, anxiety and depression during pregnancy: a randomised controlled trial

Public title
The effect of Quran voice with and without meaning on stress, anxiety and depression during pregnancy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Aged 18 to 35 years; First and second pregnancy (no history of abortion and stillbirth); Singleton pregnancy and healthy fetus based on ultrasound; Gestational age of 25-28 weeks; Being literate; Willingness to participate in the study and regular attendance to receive the intervention and completion of questionnaires; Having a contact number for follow-up; Being Muslim and belief in Qur'an.
Exclusion criteria: Having history of psychiatric problems; Having history of drug abuse, smoking and addiction; Experiencing severe stressors such as the death of first-degree relatives, divorce and other problems in last three months; Having history of essential disease; Having complicated pregnancy such as hemorrhage, placenta previa, placental abruption and ...; Having depression score higher than of 12 based on Edinburgh scale; Having of sensorineural deafness.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **168**
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, and East Azerbaijan
City
Tabriz
Postal code
-
Approval date
2014-03-03, 1392/12/12
Ethics committee reference number
92231

Health conditions studied

1

Description of health condition studied
stress, depression, anxiety
ICD-10 code
F31, F32,
ICD-10 code description
Mood [affective] disorders

Primary outcomes

1

Description
Stress score
Timepoint
Before intervention, 4 and 8 weeks afterintervention
Method of measurement
Percieved Stress Scale

2

Description
Depression score
Timepoint
Before intervention, 4 and 8 weeks after intervention
Method of measurement
Edinburgh Postnatal Depression Scale (EPDS)

3

Description
State-Trait anxiety score
Timepoint
Before intervention, 4 and 8 weeks after intervention
Method of measurement
Spielberger Anxiety Inventory (STAI)

Secondary outcomes

1

Description
Preterm labour
Timepoint
After delivery
Method of measurement
Frequency

2

Description
Caesarean section
Timepoint
After delivery
Method of measurement
Frequency

3

Description
Anthropometric indicators of newborn
Timepoint
After delivery
Method of measurement
Centimeter

Intervention groups

1

Description
The first intervention group will receive Surah Maryam with the Persian meaning for 20 minutes weekly for sequential three weeks by researcher. The CD of Surah Maryam with meaning will be provided for this group in order to listen it at home.
Category
Other

2

Description
The second group will receive Surah Maryam without meaning for 20 minutes weekly for sequential three weeks by researcher. The CD of Surah Maryam without meaning will be provided for this group in order to listen it at home.
Category
Other

3

Description
The control group only will receive routine prenatal care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia health centers
Full name of responsible person
Batoul Jabbari
Street address
Nursing & Midwifery Faculty, South Shariati Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Rashidi Mohammad Reza
Street address
Research department, third floor, central construction number 2, Tabriz medical science university, 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
Batoul Jabbari
Position
MSc student in Midwifery
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mojgan Mirghafourvand

Position
PhD of reproductive health

Other areas of specialty/work

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Person responsible for updating data

Contact

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