

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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:** Three 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 envelopes 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

###### Email address

mirghafourvandm@tbzmed.ac.ir

##### 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 after intervention

**Method of measurement**

Perceived 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**

##### **Street address**

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-

## Person responsible for scientific inquiries

### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

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**Web page address**

<http://nursing.tbzmed.ac.ir>

## 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*