

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Investigating the effect of reciting the Quran on COVID-19 anxiety in women with gestational diabetes

Protocol summary

Study aim

Investigating the effect of reciting the Quran on corona anxiety in women with gestational diabetes

Design

Clinical trial with a control group, with parallel groups, a blind strain, randomized on 64 patients. Sealed Envelope software will be used for randomization.

Settings and conduct

This study will be conducted in the health centers of Khomein city. After the intervention, the anxiety level of the intervention group is measured and recorded. Only the analyzers do not know how the samples are placed in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age 24-32 weeks, Being a firstborn, Lack of experience in participating in problem solving training courses, Lack of history of participating in stress control methods and yoga in the last 6 months, Absence of hearing impairment, Having a smartphone!
Exclusion criteria: Having a history of abortion, having a history of stillbirth, receiving sedatives and painkillers, not being able to read and write

Intervention groups

Intervention group: The samples are requested to listen to the audio file of Surah Al-Rahman with the resonance of Sheikh Al-Qamidi for 4 consecutive weeks, 3 times a week and each time for 15 minutes, through the WhatsApp software of their mobile phones. The intervention will be followed by the researcher and through Soroush virtual software. After the intervention, the Corona Anxiety Questionnaire (CDAS) will be completed by the participants in the intervention group.
Control group: In this group, there was no intervention in this regard and they only receive routine pregnancy care according to the normal routine.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221102056383N1**

Registration date: **2022-11-26, 1401/09/05**

Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**

Update count: **0**

Registration date

2022-11-26, 1401/09/05

Registrant information

Name

zeynab beheshti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4634 3493

Email address

zeynabbeheshti7941@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of reciting the Quran on COVID-19 anxiety in women with gestational diabetes

Public title

Investigating the effect of reciting the Quran on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 24-32 weeks Being a firstborn Lack of experience in participating in problem solving training courses Lack of history of participating in stress control methods and yoga in the last 6 months Absence of hearing impairment Having a smartphone

Exclusion criteria:

History of abortion Having a history of stillbirth Receiving sedatives and painkillers 3 hours before the intervention Inability to read and write

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to groups in the order of arrival and based on the randomization sequence that will be generated in advance. This sequence is unpredictable and does not have a specific pattern, and its arrangement is completely random. To assign the samples to two groups, the block randomization method will be used with a block size of 4, so that by using the random number generation software in the block method, the randomization sequence will be produced according to the required sample size for the two groups. First, all the states where two letters A and B can be arranged together in a block of 2 are created, and a block is randomly selected by placing it between the blocks, and from the arrangement pattern in that block for patient allocation is used then this block will be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups that the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer will not know how the samples are placed in the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak university of medical sciences

Street address

Arak university of medical sciences, Basij Sq., Sardasht region

City

Arak

Province

Markazi

Postal code

3848176593

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.ARAKMU.REC.1401.193

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Average anxiety score

Timepoint

Before the intervention and 40 days after the start of the first intervention, the anxiety level of each patient is measured.

Method of measurement

At the beginning and end of the study, the demographic questionnaire and the Corona Disease Anxiety Scale (CDAS) are completed by the patients of both groups, and based on this, the anxiety level of the patients is determined.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The samples are requested to listen to the audio file of Surah Al-Rahman with the resonance of Sheikh Al-Qamidi for 4 consecutive weeks, 3 times a week and each time for 15 minutes, through the WhatsApp software of their mobile phones. The intervention will be followed by the researcher and through Soroush virtual software. After the intervention, the Corona Disease Anxiety Scale (CDAS) will be completed by the participants in the intervention group.

Category

Other

2

Description

Control group: In the control group, there was no intervention in this regard and they only received routine pregnancy care according to the normal routine.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health and treatment centers of Khomein city

Full name of responsible person

Mahbobeh Sajadi

Street address

Basij Sq., Sardasht region, Arak university of medical sciences

City

Khomein

Province

Markazi

Postal code

3819693345

Phone

+98 918 599 7635

Email

golmehrsharafati@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

DR Alireza Kamali

Street address

Basij Sq., Sardasht region, Arak university of medical sciences

City

Arak

Province

Markazi

Postal code

3848169417

Phone

+98 86 3417 3524

Email

golmehrsharafati@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Basij Sq., Sardasht region, Arak university of medical sciences

City

Arak

Province

Markazi

Postal code

38815171

Phone

0098 86 46337801-8

Email

golmehrsharafati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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38815171

Phone

0098 86 46337801-8

Email

golmehrshefati@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Associate professor

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only the part of the data related to the original outcome will be able to be shared.

When the data will become available and for how long

Since the spring of 2023

To whom data/document is available

Researchers and students in this field

Under which criteria data/document could be used

In order to reduce anxiety

From where data/document is obtainable

Vice chancellor for education and research, Arak university of medical sciences

What processes are involved for a request to access data/document

These documents will be available on the website of Arak university of medical sciences.

Comments