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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
DR Alireza Kamali
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Basij Sq., Sardasht region, Arak university of medical sciences
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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
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Person responsible for scientific inquiries

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Full name of responsible person

Mahbobeh Sajadi

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Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Mahbobeh Sajadi

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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