Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of Cognitive behavioral therapy and Neurofeedback in pregnant women on perinatal Concern, Depression, Anxiety, Stress and postpartum Depression

Protocol summary

Study aim

General aim: to investigate the effect of Cognitive behavioral therapy and Neurofeedback in pregnant women on perinatal concern, depression, anxiety, stress and postpartum depression

Design

In this study, those with mild and moderate concern, depression, stress and anxiety were randomly treated using block random sampling in two experimental groups and a control group.

Settings and conduct

This research will be carried out on pregnant women who refer to health centers in Ardabil for mental health screening. Demographic questionnaire, pregnancy distress questionnaire (PDQ) and DASS 21 (depression, anxiety and stress scale) and standard Beck depression questionnaire will be administered as a pre-test for the participants and those who have mild and moderate concern, depression, stress and anxiety, randomly, they will be treated in two experimental groups, Cognitive behavioral therapy (and midwife support) and Neurofeedback and a control group (30 people in each group).

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Primiparous pregnant women; pregnant women who have mild and moderate worry, depression, anxiety and stress The non-entry criteria are having severe worry, depression, anxiety and stress

Intervention groups

The first experimental group will receive Cognitive behavioral therapy (and midwife support) for 15 sessions, the second experimental group will receive 30 sessions of Neurofeedback therapy, and the control group will receive only the usual pregnancy care without intervention.

Main outcome variables

Reducing perinatal concern; anxiety; stress; depression and postpartum depression in pregnant women with Cognitive behavioral therapy (and midwife support) and Neurofeedback

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231220060478N1**
Registration date: **2023-12-26, 1402/10/05**
Registration timing: **prospective**

Last update: **2023-12-26, 1402/10/05**
Update count: **0**

Registration date

2023-12-26, 1402/10/05

Registrant information

Name

Roya Motavalli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3371 1060

Email address

mr.motavalli@iau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of Cognitive behavioral therapy and Neurofeedback in pregnant women on perinatal Concern, Depression, Anxiety, Stress and postpartum Depression

Public title
Investigating the effect of Cognitive behavioral therapy and Neurofeedback in pregnant women on Worry, Depression, Anxiety, Stress during pregnancy and postpartum Depression
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous pregnant women Those who do not have communication problems Those who do not have a high-risk pregnancy (multiple pregnancy, pregnancy, premature birth, preeclampsia, etc.) Those who volunteer to participate in the research Those who have not received psychological treatment and support in the last 6 months Those who did not receive neurofeedback treatment before Those who have undergone the second mental health screening in the 16-20 week of pregnancy
Exclusion criteria:
Those who have severe worry, depression, stress and anxiety and need drug treatment
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, those with mild and moderate depression will be treated in two groups of Cognitive behavioral therapy (and midwife support) and Neurofeedback and a random control group. The samples will be determined using the block random sampling method (The number of samples allocated to each of the studied groups(each group 30 people) will be equal). In this way, we will create blocks of three ABC using random numbers generated from 1 to 90 by the software and randomly divide the random numbers into three equal groups and select the groups based on the way ABC is arranged and will study it. Group A will be treated with Cognitive behavioral therapy (and midwife support), group B will be treated with Neurofeedback. Group C, as a Control group, will not receive any intervention except routine prenatal care.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This research will be of experimental type in the form of pre-test-post-test with a control group. The statistical population of this research consists of all pregnant women referring to health centers in Ardabil city.11-question demographic questionnaire, Pregnancy Distres Questionnaire (PDQ), DASS 21 (Depression, Anxiety, Stress Scale) and Beck's Standard Depression Questionnaire will be administered as a pre-test for the participants in this study.In this study, those who have mild and moderate concern, depression, stress and anxiety will be randomly assigned to two experimental groups, Cognitive behavioral therapy (and midwife support) and Neurofeedback, and a control group (30 people in each group). After completing the therapeutic interventions, all the participants will be administered the questionnaires and the data will be collected.To evaluate postpartum depression, in the research samples, the Edinburgh postpartum depression questionnaire will be administered to all groups on days 10-15 and 30-42 days after delivery, who refer to health centers for mental health screening.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic Azad University-Ardabil Branch
Street address
Islamic Azad University, Ardabil Branch, Basij Square
City
Ardabil
Province
Ardabil
Postal code
5615731567
Approval date
2023-11-28, 1402/09/07
Ethics committee reference number
IR.IAU.ARDABIL.REC.1402.106

Health conditions studied

1

Description of health condition studied
Perinatal worry, depression, anxiety, stress and postpartum depression
ICD-10 code

F41.2

ICD-10 code description

Mixed anxiety and depressive disorder

Primary outcomes

1

Description

Pregnancy Distress score: In the pregnancy Distress questionnaire, the highest score that can be obtained from the questionnaire is 48 and the lowest score is zero. A high score in the questionnaire shows that worry is high during pregnancy, if the score is low and close to zero, it means that worry is low during this period.

Timepoint

Before starting therapeutic interventions in pregnant women at 16-20 weeks of pregnancy, a pre-test will be conducted using a pregnancy distress questionnaire, and in research samples with mild and moderate concern, therapeutic interventions will continue until the 30th week of pregnancy and a post-test after treatment. , will be used to measure the investigated variable.

Method of measurement

Pregnancy Distress Questionnaire(PDQ)

2

Description

Depression score: In the DASS 21 questionnaire, scores between 0-4 are normal, scores between 5-6 are mild depression, scores 7-10 are moderate depression, scores 11-13 are severe depression, and scores 14 and above are considered very severe depression.In the Beck depression questionnaire, a score between 0 and 21 indicates mild depression, a score between 21 and 31 indicates moderate depression, and a score above 31 indicates severe depression.

Timepoint

Before starting therapeutic interventions in pregnant women at 16-20 weeks of pregnancy, a pre-test will be conducted using the DASS 21 questionnaire and the Beck depression questionnaire, and after diagnosis in the research samples with mild and moderate depression, the therapeutic interventions will continue until the 30th week of pregnancy. After the treatment, the post-test will be used to measure the studied variables.

Method of measurement

DASS 21 questionnaire and Beck depression questionnaire

3

Description

Postpartum depression score: In the Edinburgh Postpartum Depression Questionnaire, a score below 10 means that the person is healthy, a score of 10 or more means depression. Question number ten needs attention if the answer is yes, there is a possibility of mother's suicide.

Timepoint

To evaluate postpartum depression on days 10-15 and 30-42 days after delivery, the test will be performed with a questionnaire.

Method of measurement

Edinburgh Postpartum Depression Questionnaire

4

Description

Anxiety score: In the DASS 21 questionnaire, scores of 0-3 are normal anxiety, scores of 4-5 are mild anxiety, scores of 6-7 are moderate anxiety, scores of 8-9 are severe, and scores of 10 and above are considered very severe anxiety.

Timepoint

Before starting therapeutic interventions in pregnant women at 16-20 weeks of pregnancy, a pre-test will be conducted using the DASS 21 questionnaire, and after diagnosis in research samples with mild and moderate anxiety, therapeutic interventions will continue until 30 weeks of pregnancy. After the treatment, the post-test will be used to measure the studied variables.

Method of measurement

DASS 21 questionnaire

5

Description

Stress score: In the DASS 21 questionnaire, scores of 0-7 are normal stress, scores of 8-9 are mild stress, scores of 10-12 are moderate stress, scores of 13-16 are severe stress, and scores of 17 and above are considered very severe stress.

Timepoint

Before starting therapeutic interventions in pregnant women at 16-20 weeks of pregnancy, a pre-test will be conducted using the DASS 21 questionnaire, and after diagnosis in research samples with mild and moderate stress, therapeutic interventions will continue until the 30th week of pregnancy. After the treatment, the post-test will be used to measure the studied variables.

Method of measurement

DASS 21 questionnaire

Secondary outcomes

1

Description

Reducing the score of worry

Timepoint

The level of worry will be measured 15 sessions after cognitive behavioral therapy (and midwife support) and 30 sessions after neurofeedback treatment and at 34 weeks of pregnancy.

Method of measurement

Pregnancy Distres Questionnaire (PDQ)

2

Description

Reducing the score of stress

Timepoint

The level of stress will be measured 15 sessions after

cognitive behavioral therapy (and midwife support) and 30 sessions after neurofeedback therapy and at the 34th week of pregnancy.

Method of measurement

DASS 21 Questionnaire

3

Description

Reducing the score of anxiety

Timepoint

The level of anxiety will be measured 15 sessions after cognitive behavioral therapy (and midwife support) and 30 sessions after neurofeedback therapy and at the 34th week of pregnancy.

Method of measurement

DASS 21 Questionnaire

4

Description

Reducing the score of depression

Timepoint

The level of depression will be measured 15 sessions after cognitive behavioral therapy (and midwife support) and 30 sessions after neurofeedback therapy and at the 34th week of pregnancy.

Method of measurement

DASS 21 Questionnaire and Beck's Standard Depression Questionnaire

5

Description

Reducing postpartum depression

Timepoint

Postpartum depression will be measured on days 10-15 and 30-42 days after delivery.

Method of measurement

Edinburgh Postpartum Depression Questionnaire

Intervention groups

1

Description

In this study, those with mild and moderate concern, depression, stress and anxiety will be randomly treated in two experimental groups, Cognitive behavioral therapy (and midwife support) and Neurofeedback and a control group. First intervention group: For the first experimental group, Cognitive behavioral therapy (and midwife support) will be used by a psychologist and a midwife. Cognitive behavioral therapy (and midwife support) is performed for each person from the sixteenth week of pregnancy for 15 sessions. The sessions are 50 minutes each week and will continue until the 30th week of pregnancy. The second intervention group: For the second experimental group, Neurofeedback treatment will be performed by a psychologist. Each person will receive 30 Neurofeedback sessions from the 16th week of pregnancy, 2 sessions a week, each session lasts 40 minutes and will continue until the 30th week of pregnancy.

Category

Treatment - Other

2

Description

Control group: The control group will receive only usual pregnancy care and no intervention or treatment.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers of Ardabil city

Full name of responsible person

Roya Motavalli

Street address

Administrative complex of Ardabil University of Medical Sciences., university street

City

Ardabil

Province

Ardabil

Postal code

5618985991

Phone

+98 45 3353 4790

Fax

Email

portal@arums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Zaefizadeh

Street address

Islamic Azad University, Ardabil Branch., Basij square

City

Ardabil

Province

Ardabil

Postal code

5615731567

Phone

+98 45 3372 8024

Email

mazefi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Roya Motavalli
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 50, Janbazan 4., Hafez Street
City
Ardabil
Province
Ardabil
Postal code
5615748911
Phone
+98 45 3371 1060
Email
Mrmotavalli@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Roya Motavalli
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 50, Janbazan 4., Hafez Street
City
Ardabil
Province
Ardabil
Postal code
5615748911
Phone
+98 45 3371 1060
Email
Mrmotavalli@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Roya Motavalli
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 50, Janbazan 4., Hafez Street
City
Ardabil
Province
Ardabil
Postal code
5615748911
Phone
+98 45 3371 1060
Email
Mrmotavalli@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available