Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the Effectiveness of Cognitive Behavioral Therapy Based on Virtual Content with Drug Therapy in Postpartum Depression in Improving Weight Indices in Children Up to 4 Months

Protocol summary

Summary

This research is a randomized clinical trial study. The target community will have mothers who have given birth to their children last week and have a score of over 13 in Edinburgh's Depression Test and have the right to participate in the research. The sample size will be 110 people who will be randomly divided into two groups, both of which will be identical in terms of age. In first group we will use drug therapy. In the second group, cognitive-behavioral therapy will be implemented based on virtual content, in which behavioral-cognitive behavioral techniques including depression symptoms, anxiety and depression control, ways of coping, the role of negative thoughts and emotional relationship with it, problem-solving skills, He will be trained in creating and improving depressed mood, teaching legless, and teaching effective communication styles. At 2 and 4 months of age, Edinburgh's Depression test will be tested again in mothers and the degree of improvement will be compared in the two groups. On the other hand, the weight of newborns born at birth, 2 months and 4 months of age will be measured. The second consequence is the weight gain of the child and the initial outcomes of the depression. The target community will be the mothers who gave birth to their children last week and have a score of over 13 in Edinburgh's depression. They also have to be able to read and write and work with the telegram. Other criteria for research include the singularity statement, lack of problems with pregnancy; being treated without depression, having no thoughts of harm to yourself and others to enter the research is required. Exit criteria: If they do not respond to treatment or worsen, they will be excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071826484N3**
Registration date: **2017-09-11, 1396/06/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-11, 1396/06/20

Registrant information

Name

Ghazal Shariat Panahi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 5448

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Recruitment status

Recruitment complete

Funding source

Grant Thesis of Tehran University of Medical Sciences.

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of Cognitive Behavioral Therapy Based on Virtual Content with Drug Therapy in Postpartum Depression in Improving Weight Indices in Children Up to 4 Months

Public title
Comparison of the Effectiveness of Cognitive Behavioral Therapy Based on Virtual Content with Drug Therapy in Postpartum Depression in Improving Weight Indices in Children Up to 4 Months

Purpose
Treatment

Inclusion/Exclusion criteria
The target community will be the mothers who gave birth to their children last week and have a score of over 13 in Edinburgh's depression; they also have to be literate and able to work with the telegram; other criteria of research The sentence is monogamous; lack of pregnancy problems; being treated without depression; having no thoughts of harm to yourself and others to enter the research. Exit criteria: double-ended; problems with pregnancy or illness; previous treatment due to depression; having thoughts of harm to yourself or others

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The sample size is randomly divided into two groups, of which two groups will be in terms of maternal age. In one group, a previous routine therapy will be implemented, and in the second group, cognitive-behavioral therapy will be implemented based on virtual content, in which behavioral-cognitive behavioral techniques including depression, anxiety and depression control, coping strategies, the role of negative thoughts And emotional relationship with it, problem-solving skills, peer-tracking and depressive mood development, lexical education, and effective communication styles training will be provided and these content will be taught to be virtual. In two groups, three sessions will be held in person, one meeting will be held at the beginning of the project,The second session on the second month of treatment (to find exacerbated cases or suicidal thoughts) and one session at the age of 4 months. During this period, counseling is also available 5 days a week from Saturday to Wednesday from 8 am to 4 pm Patients will be able to call in case of a problem. At 2 and 4 months of age, the Edinburgh questionnaire for mothers will be completed to compare mothers' depression in two groups. On the other hand, the weight of newborns at 2 months and 4 months of age will be measured in two groups by health care and calibrated. Also, the birth weight of newborns will be recorded on the apple system.In order to compare the mean of weight variations in two groups, ANCOVA analysis will be used.If the need for the sexually transmitted infant, the type of breastfeeding, birth rotation, and BMI of mothers will be considered in the covariance analysis model, for comparison. The efficacy of treatments for the improvement of postpartum depression, taking into account the outcome of the study as a variable, two (improved and unrecognized) and comparing two therapies, taking into account the confounding variables, of multiple logistic regression will be used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Zhiyin Hospital, Midan Fallah, Around the municipality of district 17, Abuzar,

City
tehran

Postal code

Approval date
2017-07-31, 1396/05/09

Ethics committee reference number
9421744011

Health conditions studied

1

Description of health condition studied
depression

ICD-10 code
f32.1F32.و

ICD-10 code description
mild and moderate depression

Primary outcomes

1

Description
weight gaining
Timepoint
0, 2 and 4 months after childbirth
Method of measurement
scale

Secondary outcomes

1

Description
depression improving
Timepoint
0, 2 and 4 months of age
Method of measurement
Edinburg questionnaire

Intervention groups

1

Description
In one group, a routine treatment, or drug treatment, will be performed, and the drug will be used according to the conditions The patient will have 20-40 fluoxetine. And the duration of the treatment is 4 months
Category
Treatment - Drugs

2

Description
Cognitive Behavioral Therapy Based on Virtual Content, which will be provided to the patients by telegrams and patients will send us feedback on the exercises of this content.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeean Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Science
Full name of responsible person
Mrs. Ghazal Shariat Panahi
Street address
Zhiyin Hospital, Midan Fallah, Around the municipality of district 17, Abuzar,
City
Tehran
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 of Tehran University of Medical Science
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
Tehran University of Medical Science
Full name of responsible person
Azam Ahadpour Khaneghah
Position
Family doctor assistant
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Person responsible for scientific inquiries

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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