Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of efficacy of internet- based cognitive behavior therapy alone versus combination CBT with well-being therapy for improvement of depressive symptoms of pregnant women

Protocol summary

Study aim
Determination of the effect of internet-based cognitive behavior therapy (iCBT) alone vs a combination of iCBT with Well being therapy (WBT) on depressive symptoms of pregnant women

Design
A clinical trial with randomized, four parallel groups on 408 patients. R software version 3,6,1 will be used for randomization

Settings and conduct
In a multicluster randomized clinical trial of equality type, 408 pregnant women with depressive symptoms are divided into four groups of psychotherapy models (iCBT with reminder sessions - iCBT without reminder sessions - iCBT combination with iWBT without reminder sessions - iCBT and iWBT combination therapy with reminder sessions). The content of four types of treatment is prepared online in 8 sessions. The validity of the content will be confirmed by the research team. Reminder groups will receive a reminder dose during pregnancy monthly until the end of pregnancy, and at postpartum every two months until the first year of birth. Outcomes of this study are Edinburgh Depression, Psychiatric Symptoms (BSI-18), Specific Pregnancy Stress (NuPDQ), Psychological well-being, Maternal-Child Postnatal Attachment, Ages and Stages Questionnaire (ASQ).

Participants/Inclusion and exclusion criteria
Inclusion: Gestational age less than 30 weeks, Edinburgh depression score higher than 10 for low-risk pregnancies and higher than 7 for high-risk pregnancies, access to computers and the Internet, Educational level higher than primary school, consent to enter treatment
Exclusion: Current substance abuse or dependence, currently using depressant drugs, recently receiving psychotherapy (<6 months), having a severe psychiatric, having suicidal ideations.

Intervention groups
Group 1: Only iCBT Group 2: Combined iCBT with WBT Group 3: iCBT with reminder doses. Group 4: Combined iCBT and iWBT with reminder doses.

Main outcome variables
Symptoms of depression and anxiety

General information

Reason for update

Acronym
ICBT: Internet-based Cognitive behavior therapy IWBT: Internet-base well-being treatment

IRCT registration information
IRCT registration number: **IRCT20110228005931N12**
Registration date: **2022-06-05, 1401/03/15**
Registration timing: **prospective**

Last update: **2022-06-05, 1401/03/15**
Update count: **0**

Registration date
2022-06-05, 1401/03/15

Registrant information

Name
Mahbobeh Faramarzi

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of internet- based cognitive behavior therapy alone versus combination CBT with well-being therapy for improvement of depressive symptoms of pregnant women

Public title

Effect of Internet cognitive-behavioral psychotherapy with psychological well-being on depression of pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age of less than 30 weeks Edinburgh depression score higher than 10 for low-risk pregnancies and higher than 7 for high-risk pregnancies Access to computers and the Internet Educational level higher than primary school Consent to enter treatment

Exclusion criteria:

Current substance abuse or dependence Current use of antidepressant drugs, or recent psychotherapy for depression/anxiety (<4 weeks) Women with severe depression disorders who require medical treatment Severe psychiatric disorders or suicidal ideations Childbirth before the end of the treatment period

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: **408**

Randomization (investigator's opinion)

Randomized

Randomization description

After checking inclusion and exclusion criteria, participants are allocated randomly into four groups by permuted block randomization method. The block size is 4 and each block of each intervention group will be repeated once. Then, will be generated 102 blocks with 4 sizes and a total of 408 sequences using the statistical program in R software environment version 3,6,1. The participants will be assigned to four groups of the study by a randomly generated list.

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

Ethic Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz Avenue, Babol, Mazandaran, Babol, Iran

City

Babol

Province

Mazandaran

Postal code

47745-47176

Approval date

2021-10-06, 1400/07/14

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.084

Health conditions studied

1

Description of health condition studied

Depressive Disorder

ICD-10 code

F32.9

ICD-10 code description

Depression NOS

Primary outcomes

1

Description

Depression

Timepoint

Before intervention, immediately after intervention, follow-ups 6 and 12 months after intervention

Method of measurement

Edinburgh Postnatal Depression Inventory

2

Description

Anxiety

Timepoint

Before intervention, immediately after intervention, follow-ups 6 and 12 months after intervention

Method of measurement

Brief Symptoms Inventory (BSI-18)

Secondary outcomes

1

Description
Pregnancy stress
Timepoint
Before the intervention, at end of the intervention, and follow- ups of 1 and 6 months after the end of intervention
Method of measurement
Revised Prenatal Distress Questionnaire (NuPDQ)

2

Description
Mother and child attachment
Timepoint
After the birth of a child at 4 and 12 months
Method of measurement
Mother-child attachment questionnaire

3

Description
Child development
Timepoint
After the birth of a child at 4, and 12 months
Method of measurement
Ages and Stages Questionnaire (ASQ)

4

Description
Psychological well-being
Timepoint
Before the intervention, at end of the intervention, and follow- ups of 1 and 6 months after the end of intervention
Method of measurement
Ryff psychological well-being questionnaire

Intervention groups

1

Description
Intervention group 1: Participants in this group receive online cognitive behavioral therapy in 8 sessions of 90 minutes, once a week.
Category
Treatment - Other

2

Description
Intervention group 2: Participants in this group receive combined online cognitive-behavioral therapy with psychological well-being in 8 sessions of 90 minutes, once a week.
Category
Treatment - Other

3

Description
Intervention group 3: Participants in this group receive Internet cognitive behavioral therapy in 8 sessions of 90 minutes, once a week, with reminder sessions.
Category
Treatment - Other

4

Description
Fourth intervention group: Participants in this group receive combined online cognitive-behavioral therapy with psychological well-being in 8 sessions of 90 minutes, once a week, with reminder sessions.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rouhani and Yahya Nejad Educational and Medical Center and private offices in Babol
Full name of responsible person
D.zahra basirat
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Sponsors / Funding sources

1

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Grant name
Research Project
Grant code / Reference number
724133475
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
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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