Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effectiveness of educational -cognitive-behavioral therapy for the prevention and reduction of postpartum depression

Protocol summary

Summary

The purpose of this study was to investigate the effects of educational -cognitive-behavioral therapy for the prevention and reduction of postpartum depression. 135 at risk mothers from two hospitals in Tehran were participated in the research. Participants who meet inclusion criteria including aged 18 -32 years, had a single birth and an uncomplicated pregnancy completed the pretests comprised of Beck Depression and Anxiety Questionnaires as well as Edinburgh Postnatal Depression Scale. Those who use antidepressant/anti-anxiety medications were excluded. Following completion of the pretests participants were randomly assigned to the CBT intervention and control condition. In this study, intervention was introduced in the third trimester of pregnancy and post test was conducted 2 weeks after delivery. The intervention group received 8 session of educational- cognitive behavioral program completed weekly, which composed of two parts including component imparting information about the realities of parenthood and normal infant development problems and cognitive behavioral therapy, focusing on improving depressing mood and negative thinking and problem solving skills.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014040617134N1**
Registration date: **2014-05-20, 1393/02/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-20, 1393/02/30

Registrant information

Name
Ahmad Ahmadi
Name of organization / entity
University of Tehran
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Behavioral Sciences Research Center

Expected recruitment start date

2012-08-26, 1391/06/05

Expected recruitment end date

2013-03-15, 1391/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of educational -cognitive-behavioral therapy for the prevention and reduction of postpartum depression

Public title

Prevention and reduction of postpartum depression

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: participants aged 18-32 years; had a single birth; an uncomplicated pregnancy Exclusion criteria: using Antidepressant/Anti-anxiety medications

Age

From **18 years** old to **32 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics committeeof Baghiatallah University of Medical Sciences

Street address

Tehran,

City

Baghiatallah University of Medical Sciences, Molasadra Street, Vanak Square, Tehran, Iran

Postal code

Approval date

2012-04-24, 1391/02/05

Ethics committee reference number

22/340/س

Health conditions studied

1

Description of health condition studied

postpartum depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Depression

Timepoint

pretest Before introducing the intervention and before delivery, posttest after delivery

Method of measurement

Beck Depression Inventory, Beck Anxiety Inventory, Edinburgh Postnatal Depression Scale

Secondary outcomes

1

Description

Anxiety

Timepoint

preters Before Delivery, post testafter Delivery

Method of measurement

Beck Anxiety Inventory

Intervention groups

1

Description

The intervention group received 8 session of educational-cognitive behavioral program 40 to 60 minutes per sessions which composed of two parts including component a) imparting information about the realities of parenthood and normal infant development problems and b) cognitive behavioral therapy, focusing on improving depressing mood and negative thinking and problem solving skill. The intervention was designed and delivered by a multidisciplinary team. The intervention takes place in the hospital along with educational guide booklet and films.

Category

Behavior

2

Description

Participants in the control group will continue to be under the normal care of their midwife/GP and received usual antenatal education. There were no restrictions on the treatment that they can receive.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatollah Hospital

Full name of responsible person

Ahmad Ahmadi

Street address

Baghiatollah Hospital, Molasadra Street, Vanak Square,Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for research of Baqiyatallah University of Medical Sciences

Full name of responsible person
Dr Ali Fathi-Ashtiani

Street address
Baqiyatallah University of Medical Sciences, Sheikh Bahaei Street, Molasadra Street, Vanak Square, Tehran

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 Baqiyatallah University of Medical Sciences

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

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Position
PhD student

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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