

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Maternal mood disorder and its effects on infant sleep And effect of behavioral and educational interventions on maternal and infant sleep

Protocol summary

Summary

Depression during pregnancy and after childbirth, this is causing negative effects on the infant. This is a case-control. The aim of this study was to investigate the effects of mood and anxiety disorders during pregnancy on infant sleep and behavioral and educational interventions impact on maternal and infant is sleeping. This study is conducted in two stages. At the First stage 200 women will be selected in Vali Asr Hospital and Milad Hospital. Mothers will be selected without a history of recurrent miscarriage, infertility treatment, drug or mental problems or insomnia, chronic renal failure, cardiac, hepatic, gastrointestinal, or other chronic disorders, problem-free delivery and a healthy baby. 3 times in the first quarter, the second and third trimester of pregnancy and six weeks postpartum also filled STAY anxiety and Beck depression Test. Six weeks and three months of pregnancy Pittsburgh sleep quality questionnaire completed by the mother and will also be evaluated infant sleep position. In the second phase, 44 women will be selected voluntarily. The subjects will randomly divide into two groups and the control. In the intervention group a 45-minute intervention sessions to provide information on sleep structure and strategies. Mothers in the control group, is talking about sleep hygiene only 10 minutes. The result of study assumes that lead to improved health, physical, mental, cognitive and emotional well being of babies sleep .

General information

Acronym

Mood and anxiety disorders during pregnancy on infant sleep

IRCT registration information

IRCT registration number: **IRCT2012091710746N2**

Registration date: **2013-02-04, 1391/11/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-04, 1391/11/16

Registrant information

Name

Nasrin Abedinia

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Council of Tehran University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Maternal mood disorder and its effects on infant sleep
And effect of behavioral and educational interventions on maternal and infant sleep

Public title

Maternal mood disorder and its effects on infant sleep
And effect of behavioral and educational interventions on maternal and infant sleep

Purpose

Prevention

Inclusion/Exclusion criteria

The study included women who are pregnant for the first time; they do not have history of recurrent miscarriage, infertility treatment, medication or hospitalization due to mental health problems or have insomnia; no chronic kidney disease, heart, liver, stomach and other chronic disorders; no problem with the delivery and having healthy baby and not any pregnancy complications such as gestational diabetes, pre eclampsia, premature delivery; there are not any fetal problems that lead to emergency cesarean delivery, otherwise the baby is healthy, and also there are not low birth weight or Apgar score with abnormal any chronic disease neonatal in infants.

Age

From **20 years** old to **42 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

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

Tehran University of Medical Sciences Ethics Committee

Street address

Ghods Avenu, Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2013-01-14, 1391/10/25

Ethics committee reference number

91-04-91-20330

Health conditions studied

1

Description of health condition studied

Mood disorder

ICD-10 code

F39

ICD-10 code description

Unspecified mood [affective] disorder

2

Description of health condition studied

Anxiety disorder

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Effect on maternal sleep.

Timepoint

Postpartum and 6 months after delivery

Method of measurement

1- Edinburg 2- Beck 3- STAI 4-Pittsburgh Sleep Quality Index

2

Description

Effect on infant sleeping

Timepoint

Postpartum and 6 months after delivery

Method of measurement

Questionnaire of researcher making

Secondary outcomes

1

Description

Treatment of Depression

Timepoint

6 months after delivery

Method of measurement

1- edinburg test 2- Beck Inventory

2

Description

Treatment of anxiety

Timepoint

6 months after delivery

Method of measurement

STAY test

Intervention groups

1

Description

That includes a 45-minute meeting to provide information about the structure and strategy of sleep Including maternal sleep hygiene strategies to improve maternal sleep, deep breathing and relaxation techniques, and information on the baby sleep. This manual can be read at home. In the first week to the fifth week to provide information and offer solutions to call with persons about individual problems. Mothers in the control group, only 10 minutes of sleep hygiene and 2 phone calls in weeks 3 and 5 to make contact with the group for final review. The phone does not do any advice if you have any questions will be answered.

Category

Behavior

2

Description

In the control group, only 10 minutes of sleep hygiene mother and two telephone calls at weeks 3 and 5 to make contact with the group for final review will be conducted. The phone does not do any advice you have any questions will be answered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Milad Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Tehran University of Medical Sciences - Research Center for Maternal Fetal Infan

Full name of responsible person

Mamak Shariat

Street address

Research Center for Maternal Fetal Infant

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of Tehran University of Medical Sciences - Research Center for Maternal Fetal Infan

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

Research Center for Maternal Fetal Infant

Full name of responsible person

Nasrin Abedinia

Position

MSc Clinical psychologist

Other areas of specialty/work

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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