Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of infant massage on postpartum blues and mother-infant attachment in primiparous women: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of infant massage on postpartum blues and mother-infant attachment in primiparous women

Design
This is a randomized clinical trial, in which 90 eligible primiparous women will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible primiparous women who will refer to the Comprehensive Health Centers of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Aged 20 to 35; Score of blues between 15 and 10 based on the Edinburgh questionnaire; Term pregnancy; Uncomplicated normal delivery; Being literate; The stability of couples' life; Satisfaction with the baby's gender Exclusion criteria: Psychological problems; History of depression in the first-degree family

Intervention groups
Intervention group: Routine care and massage of the baby by touching the baby's body tissue with regular movement for 15 minutes daily for 6 weeks to improve the functioning of the nervous system of the body, muscle, skin, joints and circulation Control group: Just routine care

Main outcome variables
Primary outcome: Assessing the score of postpartum blues

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N254**
Registration date: **2018-12-15, 1397/09/24**
Registration timing: **registered_while_recruiting**
Last update: **2018-12-15, 1397/09/24**
Update count: **0**

Registration date
2018-12-15, 1397/09/24

Registrant information

Name
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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-06, 1397/09/15

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of infant massage on postpartum blues and mother-infant attachment in primiparous women: a randomized clinical trial

Public title
Effect of infant massage on postpartum blues and mother-infant attachment in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 20 to 35; Score of blues between 15 and 10 based on the Edinburgh questionnaire; Term pregnancy; Uncomplicated normal delivery; Being literate; The stability of couples' life; Satisfaction with the baby's gender

Exclusion criteria:

Psychological problems; History of depression in the first-degree family

Age

From **20 years** old to **35 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

Random assignment of the patients to the intervention, and control groups through the drawing of lots

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 Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Province

Hamadan

Postal code

6517838695

Approval date

2018-11-17, 1397/08/26

Ethics committee reference number

IR.UMSHA.REC.1397.556

Health conditions studied

1

Description of health condition studied

Postpartum blues

ICD-10 code

O90.6

ICD-10 code description

Postpartum mood disturbance

Primary outcomes

1

Description

Assessing the score of mother's postpartum blues

Timepoint

Before intervention and at second, forth, and sixth weeks after intervention

Method of measurement

Using Edinburgh standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care and massage of the baby by touching the baby's body tissue with regular movement for 15 minutes daily for 6 weeks to improve the functioning of the nervous system of the body, muscle, skin, joints and circulation

Category

Treatment - Other

2

Description

Control group: Just routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers of Hamadan City

Full name of responsible person

Fatemeh Rezji

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
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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