Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of infant massage by mother on postpartum blues in primiparous women: A Randomized clinical trial with control group

Protocol summary

Summary

The Clinical trial was randomly done with the aim of determining the effect of Infant massage on postpartum blues of primiparous women on 54 target group who had Natural Vaginal Delivery during early November to mid December 2016. Inclusion criteria To have scores lower than 10 in Edinburg questionnaire in the day of delivery, the infant to be term and healthy, to have Apgar score higher than 7 and with the weight above 2500 gram, general situation of mother should be fine, and does not have the history of sever mental disorders and stress. Exclusion criteria are as follows: hospitalization of mother with infant for any reason during research, non-execution of massage during two consecutive days, lack of mother`s medical stability due to one of her relative`s death in accident in a way that prevent the massage to be done. Intervention group should massage their infants for about 15 minutes per day until the tenth day after delivery, massage their infant. In Control group, there was no intervention.The postpartum blues levels in the first, fourth and tenth day after delivery, and attachment mother and infant in the first and tenth day after delivery were assessed and compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121931475N1**
Registration date: **2017-01-25, 1395/11/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-25, 1395/11/06

Registrant information

Name

Solmaz Kouhestani Mianji

Name of organization / entity

Mashhad University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

Email address

kouhestanis921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2016-10-29, 1395/08/08

Expected recruitment end date

2016-12-01, 1395/09/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of infant massage by mother on postpartum blues in primiparous women: A Randomized clinical trial with control group

Public title

The effect Of infant massage on postpartum blues

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Be primiparous; natural vaginal delivery must be done; to have Iranian nationality and be resident of Mashhad City; to have scores lower than 10 in Edinburg questionnaire in the day of delivery; the infant to be term and healthy; to have Apgar score higher than

7 and weight above 2500 gramme; pregnancy must be singleton and wanted; be educated(Learned); general situation of mother be fine; does not have the history of sever mental disorders and stress; does not have the history of two or more abortions, still births and infertility; do not suffer from undesirable pregnancy precussion. Exclusion criteria: Hospitalization of either mother or infant for any reason during research; non-execution of massage during two consecutive days; reluctancy of mother to continue cooperation; lack of mother`s medical stability due to one of her relative`s death in accident in a way that prevent the massage to be done, mothers being sick in away that fails to massage.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **54**

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
Mashhad University Of Medical Sciences

Street address
College of Nursing and midwifery, Ibn-Sina street, Doctori crossroads, Daneshgah street, Mashhad, Iran.

City
Mashhhad

Postal code
13944-91388

Approval date
2016-09-24, 1395/07/03

Ethics committee reference number
IR.MUMS.REC.1395.350

Health conditions studied

1

Description of health condition studied
Postpartum Blues

ICD-10 code
F53

ICD-10 code description
Mental and behavioural disorders associated with the puerperium

Primary outcomes

1

Description
Postpartum Blues

Timepoint
1ST, 4th, 10th after delivery

Method of measurement
Edinburg Questinory

Secondary outcomes

1

Description
Attachment Of Infant and Mother

Timepoint
First and 10th day after Delivery

Method of measurement
Questionary

Intervention groups

1

Description
Infan massage for 15 minutes per day until the tenth day after delivery with Field techniqe in intervention group

Category
Prevention

2

Description
There was no intervention in Control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Omolbanin hospital

Full name of responsible person

Street address
Omolbanin hospital,16th Bahjat street, Ayatollah Bahjat avenue, Mashhad, Iran

City
Mashhad

2

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Street address
Imam Reza hospital, Ibn-Sina street, Doctori crossroads, Daneshgah street, Mashhad, Iran.
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zahra Abedian
Street address
Mashhad University Of Medical Sciences, College of Nursing and midwifery, Ibn-Sina street, Doctori crossroads, Daneshgah street, Mashhad, Iran.
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Name of organization / entity
Mashhad University Of Medical Sciences
Full name of responsible person
Zahra Abedian
Position
MSc
Other areas of specialty/work
Street address
Mashhad University Of Medical Sciences, College of Nursing and midwifery, Ibn-Sina street, Doctori crossroads, Daneshgah street, Mashhad, Iran.
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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University Of Medical Sciences
Full name of responsible person
Solmaz Kouhestani
Position
MSc of Midwifery
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
Web page address

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