

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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; reluctance 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.

City

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Postal code**Phone**

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Person responsible for scientific inquiries

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Full name of responsible person

Zahra Abedian

Position

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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**

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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