

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### 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

##### City

Hamadan

##### 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

##### Street address

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

##### City

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##### Province

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6517838695  
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fatemeh.razaji6599@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr Saeid Bashirian  
**Street address**  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave  
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6517838695  
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info.research@umsha.ac.ir

#### 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

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Rezji  
**Position**  
Midwifery Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Midwifery

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Parisa Parsa  
**Position**  
Specialist of Community Health  
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Ph.D.  
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Midwifery  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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Professor of Epidemiology  
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**Other areas of specialty/work**  
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**Email**

poorolajal@umsha.ac.ir

**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