

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of infant massage on maternal depression and fatigue in mothers referred to selected clinics of Iranshahr University of Medical Sciences

Protocol summary

Study aim

Determining the effect of maternal massage by mother on depression and maternal fatigue in referring to selected clinics of Iranshahr University of Medical Sciences in 1397-1396

Design

72 mothers with inclusion criteria are randomly assigned to intervention or control groups. The intervention group will receive infant massage training, while the control group will receive routine care only.

Settings and conduct

A total of 72 mothers with healthy infant who had mild to moderate depression, were randomly assigned to control and intervention group. The multidimensional fatigue questionnaire and Edinburgh Depression questionnaire were used before and 4 weeks and 8 weeks after the intervention. In this study, the field massage technique will be used as the intervention. The infants in the intervention group will receive the intervention 15 minutes a day, for 8 weeks. The control group will receive routine care.

Participants/Inclusion and exclusion criteria

Entry criteria: It wants to cooperate Non-entry criteria: Having addicted and divorced

Intervention groups

Massage will be given to the mothers In the intervention group who come to the first postnatal care. Moms massage their baby for 8 weeks every day for 15 minutes. Field massage technique is used. The control group receives routine care.

Main outcome variables

Depression score; Fatigue score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180618040135N1**

Registration date: **2018-11-02, 1397/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-02, 1397/08/11**

Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

khoshid rigi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3722 0483

Email address

shahnavazi.a@irshums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-05, 1397/04/14

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of infant massage on maternal depression and fatigue in mothers referred to selected clinics of

Iranshahr University of Medical Sciences

Public title

The effect of infant massage on maternal depression and fatigue in mothers referred to selected clinics of Iranshahr University of Medical Sciences

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

It wants to cooperate

Exclusion criteria:

Having addiction divorced

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

First, they are sampled in a class, that is, half of the samples will be primiparous and the other half will be multiple. Block randomization method was used. To implement this method, two letters A and B represent the intervention and control group.

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 Shiraz University of Medical Sciences

Street address

opposite Palestine Street, Zand Ave, Central Building of Shiraz University of Medical Sciences, shiraz

City

shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2018-05-09, 1397/02/19

Ethics committee reference number

IR.SUMS.REC.1397.147

Health conditions studied

1

Description of health condition studied

Postpartum Depression

ICD-10 code

F53.0

ICD-10 code description

Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Edinburgh Depression Score

Timepoint

Before starting the intervention 4 and 8 weeks after the intervention

Method of measurement

Edinburgh Depression Inventory

2

Description

Fatigue score

Timepoint

Before starting the intervention 4 and 8 weeks after the intervention

Method of measurement

Fatigue Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Baby massage Daily for 15 minutes for 8 weeks with Mom by Field Massage Technique

Category

Prevention

2

Description

Control group: Routine care is done

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Iranshahr University of Medical Sciences

Full name of responsible person

Khorshid Rigi

Street address

No. 46, Imam Khomeini Street, Iranshahr School of Medical Sciences and Health Services

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research of Shiraz University of Medical Sciences

Full name of responsible person

dr.younes ghasemi

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No. 8, Central Building of Shiraz University of Medical Sciences, Opposite to Palestine Street, Zand Ave, shiraz

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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

Deputy of Research of Shiraz 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**

Iranshahr University of Medical Sciences

Full name of responsible person

Khorshid Rigi

Position

Non-faculty trainer

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Position

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Other areas of specialty/work

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Fax**Email**

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