

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the husband massage effect on pregnancy stress and postpartum blues in primiparous women

Protocol summary

Study aim

Determining the effect of massage by husband in pregnancy on pregnancy stress and postpartum grief in primiparous mothers referred to comprehensive health centers in Isfahan

Design

Randomized clinical trial with control group; single blind; on 42 patients. Even and odd numbers will be used for randomization

Settings and conduct

Study place: Health Center; Study population: Pregnant mothers referring to health center; Type of blinding: One-way blinding; How to blind: The clinician does not know for which group the massage was performed and for which group the massage was not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First pregnancy; Gestational age 30-30 weeks; Singleton pregnancy; Spouse is available (no job assignments). Non-inclusion criteria: History of specific underlying diseases; pregnancy problems (placenta previa, history of preterm delivery, collage head, fetal abnormalities); mental illness; Score 8-12 from DASS21 questionnaire

Intervention groups

The intervention group is pregnant mothers on whom massage is performed. The control group is pregnant mothers who are not massaged.

Main outcome variables

Pregnancy stress; Postpartum blues

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211219053456N1**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

roya hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3776 7885

Email address

royah2143@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-25, 1400/11/05

Expected recruitment end date

2022-02-24, 1400/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the husband massage effect on pregnancy stress and postpartum blues in primiparous women

Public title

The husband massage effect in pregnancy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

First pregnancy Gestational age 32-30 weeks Singleton

Spouse available (no job assignments) Score 12-8 from DASS21 questionnaire
Exclusion criteria:
History of specific underlying diseases Pregnancy problems (placenta previa, history of preterm delivery, cerclage, fetal abnormalities) Presence of mental illness

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: 44

Randomization (investigator's opinion)

Randomized

Randomization description

We put even and odd numbers in a sealed envelope and then every mother picks up a number at random.

Blinding (investigator's opinion)

Single blinded

Blinding description

The clinician does not know who is in the intervention group or who is in the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No.88; Karimian alley; Bagh-Daryacheh street

City

Isfahan

Province

Isfahan

Postal code

8176757791

Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.165

Health conditions studied

1

Description of health condition studied

pregnancy stress

ICD-10 code

O99.344

ICD-10 code description

Other mental disorders complicating childbirth

2

Description of health condition studied

postpartum blues

ICD-10 code

O90.6

ICD-10 code description

Postpartum mood disturbance

Primary outcomes

1

Description

The stress score in the DASS-21 questionnaire

Timepoint

31 th and 37 th week of pregnancy

Method of measurement

DASS-21 questionnaire

2

Description

Postpartum blues score in Edinburgh questionnaire

Timepoint

3 to 10 days after delivery

Method of measurement

Edinburgh questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant mothers are in 32th weeks of GA in the intervention group, who are massaged from 32-37 weeks. External hand down also the inner surface of the foot upwards from the outer surface of the foot downwards then from the bottom of the spine upwards and then towards the shoulders and again towards the spine and then downwards to the spine which for 20 minutes, three times a week for 5 weeks (15 sessions in total) This massage will be done by sweet almond oil for the mother.

Category

N/A

2

Description

Control group: Pregnant mothers are at 32th-37th week of GA without massage

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinabieh Health Center

Full name of responsible person

Roya Hosseini

Street address

No. 88; Ghaem complex; Karimian Alley; Bagh-Daryacheh Ave.

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Phone

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Email

royah2143@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Valiani

Street address

Faculty of Nursing and Midwifery; Isfahan University of Medical Sciences; Hezar Jerib Street

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valiani@nm.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Valiani

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery; Isfahan University of Medical Sciences; Hezar Jerib Street

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valiani@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Valiani

Position

assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Roya Hosseini

Position

student

Latest degree

Master

Other areas of specialty/work

Midwifery

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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