

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the effect of pregnancy yoga Exercises on breastfeeding self-efficacy in primiparous mothers referring to selected comprehensive health centers

Protocol summary

Study aim

Comparison of the mean score of breastfeeding self-efficacy on the first day and after the intervention of one, two and four, 8 weeks and 6 months after delivery

Design

The clinical trial has a control group which is initially stratified according to the available method and then randomly stratified according to the education level of the mothers in two groups. The number of samples in each group is 45. The sealed envelope technique is used for randomization.

Settings and conduct

The environment is selected comprehensive health centers in the Isfahan. This study was not blinded. The researcher will do yoga exercises in groups in 12 sessions in these centers and the questionnaires in six stages after delivery (the first week after delivery and 2 ,4 ,8 weeks and six months after delivery) will be completed.

Participants/Inclusion and exclusion criteria

Mothers who are literate. Mothers who had a normal body mass index at the beginning of pregnancy. Mothers who do not have a history of systemic diseases (diabetes/hypertensive/intrauterine death/multiples) etc. during their pregnancy. Mothers who do not have medical contraindications to exercise and perform yoga stretching exercises Mother's willingness to breastfeed after delivery Mothers who do not have breast diseases and anomalies Mothers who have not been subjected to domestic violence Mothers who have participated in childbirth preparation classes. Mothers who have no history of participating in yoga classes and professional sports (regular daily walking, swimming, etc.)

Intervention groups

Yoga sessions will be held as a group at the venue of birth preparation classes in selected centers, twice a week and for one hour each time from the 34th week of

pregnancy to 8 weeks after delivery (12 sessions).

Main outcome variables

Breastfeeding status: contextual variable Breastfeeding self-efficacy score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120923010913N2**

Registration date: **2024-01-27, 1402/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2024-01-27, 1402/11/07**

Update count: **0**

Registration date

2024-01-27, 1402/11/07

Registrant information

Name

Masoume Pirhadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1357 9577

Email address

pirhadi@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2025-01-19, 1403/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of pregnancy yoga Exercises on breastfeeding self-efficacy in primiparous mothers referring to selected comprehensive health centers

Public title

pregnancy yoga Exercises and breastfeeding self-efficacy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Mothers who sign the informed consent form. Mothers who are literate. Mothers who had a normal body mass index at the beginning of pregnancy. Mother's willingness to breastfeed after delivery Mothers who have no history of systemic diseases during their pregnancy (diabetes/hypertensive/intrauterine death/multiples) etc. Mothers who do not have medical contraindications to exercise and do yoga stretches. Mothers who do not have Breast anomalies. Mothers who have no history of infertility (primary, secondary). Mothers who have not been subjected to domestic violence Mothers who have participated in childbirth preparation classes. Mothers who have no history of participating in yoga classes and professional sports (regular daily walking, swimming, etc.)

Exclusion criteria:

The impossibility of natural childbirth Mother's physical inability to do exercises

Age

No age limit

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

Stratified random assignment based on education level into two groups The selection of samples will be based on the available method at first, and then they will be randomly divided into intervention and control groups and matched according to their education level. In order to assign samples in each group, they were asked to choose one of the sealed envelopes. Envelope number one is assigned to the control group and number 2 to the intervention group. Then, based on the education level of the mothers, sampling will continue until the level of education in the two groups is equal.

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**

Nursing, Rehabilitation and Management schools- Isfahan University of medical Sciences

Street address

Hezar JeribAve, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-12-19, 1402/09/28

Ethics committee reference number

IR.MUI.NUREMA.REC.1402.151

Health conditions studied**1****Description of health condition studied**

breastfeeding self-efficacy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

breastfeeding self-efficacy score

Timepoint

The first day after delivery, week 1, 2, 4, 8, the sixth month after the intervention

Method of measurement

Dennis and Fox BSES breastfeeding self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Yoga sessions will be held in groups in selected centers, twice a week and for one hour each time from the 34th week of pregnancy to 8 weeks after delivery (12 sessions).

Category

Behavior

2

Description

Control group: Samples in this group only receive routine pregnancy care in comprehensive health centers

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Hamzeh Comprehensive Health Center

Full name of responsible person

Pirhadi Masoume

Street address

6th Ave, Amirieh town

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7592

Email

pirhadi@nm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Pirhadi Masoume

Street address

Faculty of Nursing and Midwifery - Isfahan University of Medical Sciences - Hazar Jerib St

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7592

Email

pirhadi@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

1

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

Pirhadi Masoume

Position

Academic member, Instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Faculty of Nursing and Midwifery - Isfahan University of Medical Sciences - Hazar Jarib St

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7592

Email

pirhadi@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

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Esfahan University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Pirhadi Masoume

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Faculty of Nursing and Midwifery - Isfahan University
of Medical Sciences - Hazar Jarib St

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable