Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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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
Isfehan
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

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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

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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
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

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Person responsible for updating data

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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
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