

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Effectiveness of mindfulness-based intervention on breastfeeding self-efficacy and mother-infant attachment in primiparous women

Protocol summary

Study aim

1-Determining the effectiveness of mindfulness-based intervention on breastfeeding self-efficacy and mother-infant attachment in primiparous women

Design

Clinical trials with control group at 3-5 days after giving birth: Randomized

Settings and conduct

The study will be done on 46 primiparous women with a score of their self-efficacy less than 49 who were referred to Ahwaz Medical Center No. 1. The study will be a randomized controlled trial with two intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First time pregnancy; breast feeding: lactating self-efficacy less than 49 Exclusion criteria: : Use of prohibited drugs on breastfeeding; and having neonate with galactosomia

Intervention groups

Intervention group will receive mindfulness-based education weekly during 8 weeks by researcher: while control group will receive only routine care. (No intervention)

Main outcome variables

Mother's attachment: Lactation self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181031041516N1**

Registration date: **2019-01-17, 1397/10/27**

Registration timing: **retrospective**

Last update: **2019-01-17, 1397/10/27**

Update count: **0**

Registration date

2019-01-17, 1397/10/27

Registrant information

Name

Shahin Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3447 0164

Email address

moradi_sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2018-12-08, 1397/09/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of mindfulness-based intervention on breastfeeding self-efficacy and mother-infant attachment in primiparous women

Public title

The Effect of Mindfulness on the Breastfeeding self-efficacy and Mother's Attachment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

First time pregnancy Literacy at least third of middle The age range of the mother is between 18-35 years old

Normal delivery Just breastfeed singleton neonate Agree to take part in the study Lactation self-efficacy score is less than 49

Exclusion criteria:

Use of prohibited drugs on breastfeeding Newborn with Galactosomia Maternal addiction to alcohol

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified mothers were randomly divided into two groups of intervention and control group with the using four-way blocks and a one-to-one assignment ratio. To avoid bias Twenty-three of the four-digit paired numbers were selected as codes of participants in the intervention group and Twenty-three of the four-digit individuals were selected as the control group code from the random numbers table. To hide the allocation, the number of intervention and control groups were arranged in block envelopes, respectively. Eventually, The envelopes were given to the participants by an accidental crash center.

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 Ahvaz University of Medical Sciences

Street address

Golestan Ave, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-11-09, 1397/08/18

Ethics committee reference number

IR.AJUMS.REC.1397.601

Health conditions studied

1

Description of health condition studied

Breastfeeding self-efficacy and maternal-infant attachment

ICD-10 code

Z39.1

ICD-10 code description

Encounter for care and examination of lactating mother

Primary outcomes

1

Description

Breastfeeding self-efficacy

Timepoint

Measure self-efficacy before intervention and measure one month and two months after the intervention

Method of measurement

Breastfeeding self-efficacy questionnaire

Secondary outcomes

1

Description

Maternal-infant attachment

Timepoint

Before Intervention and After Intervention

Method of measurement

Avant review checklist

Intervention groups

1

Description

Intervention group:for this group 8 sessions of 120 minutes counseling of mindfulness will be held weekly.The content of sessions will be as follow: First and second session :introduction and orientation with group members: explain the relationship between the physiology of breastfeeding and mindfulness: explaining the basics of maternal attachment . Third and fourth sessions: management of attachment skills to meet the needs of the baby and breastfeeding will be taught. Fifth and sixth sessions:encouraged to Exclusive breastfeeding. Seventh and eighth sessions: principles of counseling of mindfulness will be reinforced.

Category

N/A

2

Description

Control group: For this group, control group will receive only routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Around the east of Ahwaz

Full name of responsible person

Nahid Javadifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

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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

Ahwaz 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

Ahwaz University of Medical Sciences

Full name of responsible person

Shahin Moradi

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nahid Javadifar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available