Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Street address
Shahid Rastegari Street

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3221 5633

Email
Javadifar-n@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Badavi

Street address
Golestanstreet Ahvaz university of medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8383

Email
javadifar-n@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Shahin Moradi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Golestan street; Ahvaz university of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8383

Email
moradi_sh@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Nahid Javadifar

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Golestan street; Ahvaz university of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3373 8331

Email
javadifar-n@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences
Full name of responsible person
Shahin Moradi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Golestan street; Ahvaz University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8331
Email
moradi_sh@ajums.ac.ir

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