

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of maternal fetal attachment training on success and duration of breast - feeding of primiparous women

Protocol summary

Study aim

The present study aimed to determine the effect maternal - fetal attachment training on success and duration breastfeeding in primiparous women.

Design

In this study, 120 primigravid women referring to Health Centers are selected. Participants are randomly divided into intervention and control groups.

Settings and conduct

This study consists of two stages of prepartum and eight weeks postpartum. In the first stage, in the intervention group, 4 sessions of maternal attachment training (30 - 45 min) held and the control group receives the routine pregnancy care.

Participants/Inclusion and exclusion criteria

Being Iranian; literacy; No known medical conditions and mental illness; Being nulliparous; wanted pregnancy; gestational age of 28-34 weeks. Hospitalization of the infant or mother for medical condition; Parents' separation from baby; Postpartum Depression

Intervention groups

The intervention group takes part in four sessions of maternal fetal attachment training and the control group receives the routine pregnancy care.

Main outcome variables

The maternal fetal attachment using maternal fetal attachment scale is measured in both intervention and control groups before intervention, immediately after intervention and two weeks after the intervention. The success and duration of lactation in the 4th and 8th weeks after delivery are measured using a lactation pattern questionnaire.

General information

Reason for update

Acronym

MFA

IRCT registration information

IRCT registration number: **IRCT20120122008801N22**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **prospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8820 2517

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msimbar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2018-03-20, 1396/12/29

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of maternal fetal attachment training on success and duration of breast - feeding of primiparous women

Public title

"The effect of maternal fetal attachment on lactation"

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Age between 18 - 35 years old literacy
No known medical conditions and mental illness
Primigravida women Wanted pregnancy Gestational age
of 28-34 weeks

Exclusion criteria:

No history of infertility

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization of this study is simple
randomand. there is an individual randomization
unit.Tool of randomization is sealed envelope.

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 Shahid Beheshti University of
Medical Sciences

Street address

ValiAsr Ave, Niayesh Cross Road, Niayesh Complex,

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-01-03, 1395/10/14

Ethics committee reference number

579 .1395. IR.SBMU.PHNM

Health conditions studied

1

Description of health condition studied

Emotional relationship between mother and fetus

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

duration of breastfeeding

Timepoint

Four weeks after childbirth, Eight weeks after childbirth

Method of measurement

patterns of breastfeeding questionnaire

2

Description

success breastfeeding

Timepoint

Four weeks after childbirth, Eight weeks after childbirth

Method of measurement

patterns of breastfeeding questionnaire

Secondary outcomes

1

Description

Maternal- fetal Attachment

Timepoint

Before intervention, After the intervention, Two weeks
after the intervention

Method of measurement

Cranley's questionnaire

2

Description

Lactation success

Timepoint

Four weeks after birth, Eight weeks after birth

Method of measurement

Lactation Pattern Questionnaire

3

Description

Lactation duration

Timepoint

Four weeks after birth, Eight weeks after birth

Method of measurement

Lactation Pattern Questionnaire

Intervention groups

1

Description

The intervention group take part in four 30minute sessions of maternal-fetal attachment training.

Category

Behavior

2

Description

The control group receives the routine pregnancy care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sarem hospital

Full name of responsible person

Arash poladi

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Phase 3 , Ekbatan Settlement , Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences/
Tehran / Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Anahita Rahimi

Position

Master Student of Midwifery

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

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Position

PhD

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Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

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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