

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of empowerment program on mother infant attachment in nulliparous women

Protocol summary

Study aim

Effects of an empowerment program on the mother infant attachment in nulliparous mothers

Design

In this clinical trial study, 80 nulliparous mothers who are eligible to enter the study are selected. The mothers are randomly divided into two groups of control and intervention.

Settings and conduct

This clinical trial will be done in the women ward of Imam Sajjad Hospital and Sohrab Ali Bakhshi Health Center in Shahriar city. An empowerment educational program will be done for the mothers in the experimental group at last month of pregnancy, while the mothers in the control group only received the routine care of during pregnancy. Then, the first day of birth of the neonates in the hospital, using maternal attachment questionnaire to the neonate, observed and recorded the mother's attachment behaviors during lactation and without mother's knowledge within 15 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnancy is monogamous; The age range of the mother is between 16-35 years old; All mothers have normal delivery; The baby is not from IVF or infertility. Exclusion criteria: Pregnancy is Polygons; Mothers aged less than 16 years or more From 35 years of age; Cesarean section delivery; The neonate born to IVF or infertility.

Intervention groups

An educational program will be conducted by a researcher and lecture and a group using a projector video for mothers. The training includes the first session: Primary care education for the newborn, Second session: Training the symptoms of the risk and disease in the newborns, and the third session: Developmental care education.

Main outcome variables

Attachment of nulliparous women to their neonates.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140604017972N8**

Registration date: **2017-12-25, 1396/10/04**

Registration timing: **retrospective**

Last update: **2017-12-25, 1396/10/04**

Update count: **0**

Registration date

2017-12-25, 1396/10/04

Registrant information

Name

Zahra Godarzi

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of iran univercity of medical science

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment program on mother infant attachment in nulliparous women

Public title

The effect of empowerment program on mother infant attachment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Pregnancy is monogamous; Pregnancy asked; Not being pregnant (gestational hypertension, gestational diabetes, bleeding, etc.); The mother's lack of medical and mental illness and depression; Being Iranian ; Mother's Not Addicted to Alcohol and Drugs; The baby is not from IVF or infertility; The baby is a family member; mother has no history of abortion and baby death; The age range of the mother is between 16-35 years old; All mothers have normal delivery.

Exclusion criteria:

Exclusion criteria: Pregnancy is Polygons; unwanted pregnancy; mother has to Pregnancy Diseases (gestational hypertension, gestational diabetes, bleeding, etc) ; Maternal affliction to medical and psychological illnesses and depression; non-Iranian mothers; maternal addiction to alcohol and drugs; neonate born to IVF or infertility; mother has a history of abortion and stillbirth; mothers aged less than 16 years or more From 35 years of age; Cesarean section delivery; Severe and prolonged labor and rupture grade 3 and 4 Perinal; Neonate disease and abnormalities; Premature infant; Infant death

Age

From **16 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The choice of mothers in two groups of control and Intervention is done randomly using a random number table of statistics reference books. the first researcher will put a finger on the table while his eyes are closed and the touching number will be the starting point, then the researcher moves up and down, and right and left, respectively, from the numbers to obtain the sample size of use he does.

Blinding (investigator's opinion)

Single blinded

Blinding description

Mothers participating in research. The mothers of each group are unaware of the other group and the

interventions they are doing.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemat Road

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-12-21, 1395/10/01

Ethics committee reference number

IR.IUMS.REC.1395.28807

Health conditions studied

1

Description of health condition studied

Mother infant attachment in nuliparousn women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Maternal attachment score

Timepoint

The first day of the birth of baby

Method of measurement

The avant mother infant attachment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: An educational program will be

conducted by a researcher and lecture and a group using a projector video for mothers during the last month of pregnancy. The training includes the first session: Primary care education for the newborn and follow-up vaccination and heel screening, Second session: Training the symptoms of the risk and disease in the newborns, and the third session: Developmental care education (touch, massage, sleepiness, lullaby, Kissing, grooming, the importance of skin-to-skin contact).

Category

Behavior

2

Description

Control group: The mothers in the control group only received the routine care of during pregnancy.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam sajad hospital

Full name of responsible person

Masoumeh askari

Street address

Valiasr street, Imam sajad hospital

City

Shahriar

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Tehran

Postal code

3351636434

Phone

+98 21 6522 6041

Email

askari.mas28@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed kazem malakoti

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Next to Milad Tower, Hemmat Highway, Iran University of Medical Sciences

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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

Iran 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

Iran University of Medical Science

Full name of responsible person

Masoumeh askari

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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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