

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Education of Attachment Skills on Maternal Fetal Attachment of Pregnant Women

Protocol summary

Study aim

To Assess the Effect of a Training Program about Maternal Fetal Attachment (MFA) Skills on Prenatal Attachment among Iranian First Time Pregnant Women

Design

A clinical trial with a control group, with parallel groups, one blind and randomized

Settings and conduct

From selected health care centers eligible pregnant women were selected purposively and was randomly divided into two groups; Intervention group: received a training program on two MFA skills. Face to face education about touching the fetus, counting and recording the daily fetal movement was provided by the researcher in the intervention group. Control group: received the routine antenatal care. Using Cranley's Maternal Fetal Attachment Scale (MFAS) the data were collected at baseline (28th weeks of pregnancy) and after intervention. The data analyst was blinded regarding to the division of the groups and type of intervention in every group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Iranian women; First time pregnancy; Being 18-35 years old; Having Literacy; Having no medical problem during pregnancy or a history of mental disorders; Normal pregnancy without use of assisted reproductive treatments; Singleton pregnancy; Gestational age between 20-22 weeks. Non-inclusion Criteria: Life threatening event during last 6 months; Pregnancy with assisted reproductive treatment; Multiple pregnancy; Substances abuse before and during pregnancy

Intervention groups

Intervention: In addition to prenatal care, Intervention group was taught to touch and count their fetal movement after consuming breakfast for 30 minutes in left lateral position for one month from 28 weeks of pregnancy. Control: In the control group, the usual education about prenatal care and fetal movements

were done.

Main outcome variables

Maternal Fetal Attachment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100516003936N4**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **retrospective**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Kobra Salehi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-06-22, 1394/04/01

Actual recruitment start date

2015-05-22, 1394/03/01

Actual recruitment end date

2015-07-16, 1394/04/25

Trial completion date

2015-09-23, 1394/07/01

Scientific title

The Effect of Education of Attachment Skills on Maternal Fetal Attachment of Pregnant Women

Public title

Effect of Education on Maternal Fetal Attachment

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian women First time pregnancy Being 18-35 years old Having Literacy Having no medical problem during pregnancy or a history of Mental disorders Normal pregnancy without use of assisted reproductive treatments Singleton pregnancy Gestational age between 20-22 weeks

Exclusion criteria:

Life threatening event during last 6 months Pregnancy with assisted reproductive treatments Multiple pregnancy Drugs abusing before or during pregnancy

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget sample size: **56**Actual sample size reached: **53****Randomization (investigator's opinion)**

Randomized

Randomization description

Eligible pregnant mothers randomly allocated into two groups of intervention and control using table of random numbers. Being odd or even for the intervention group was selected through drawing.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study group was labled as A and B; So the data analysor was blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib Ave.

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Isfahan

Province

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Postal code

8174673461

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

293259

Health conditions studied**1****Description of health condition studied**

Emotinal Relationship between Mother and Fetus

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Maternal Fetal Attachment

Timepoint

Before intervention and one month afetr begining the intervention

Method of measurement

Cranly Maternal Fetal Attachment Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In addition to prenatal care, intervention group was taught to touch and count their fetal movement after consuming breakfast for 30 minutes in left lateral position for 1 month from 28 weeks of pregnancy.

Category

Behavior

2**Description**

Control group: In the control group, the usual education about prenatal care was done.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amirieh Health Care Center

Full name of responsible person

Kobra Salehi

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Web page address<http://isfhealth2.mui.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Shaghayegh Haghjoo Javanmard

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Email

research@mui.ac.ir

Web page address<http://research.mui.ac.ir/fa/>**Grant name**

293259

Grant code / Reference number

293259

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

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**

Esfahan University of Medical Sciences

Full name of responsible person

Kobra Salehi

Position

PHD Candidate of Reproductive Health

Latest degree

Master

Other areas of specialty/work

Midwifery

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Some parts of the data, such as information about the main study outcome, will be shared.

When the data will become available and for how long

Access to the information will be started at 6 months after printing the results.

To whom data/document is available

Researchers working in academia and scientific institutions

Under which criteria data/document could be used

The data will be available for midwifery experts on the reasonable and acceptable reasons and analysis of the data will be possible with obtaining the written permission from the research team.

From where data/document is obtainable

Information will be shared by sending a request to the responsible person for the study. k_salehi@nm.mui.ac.ir

What processes are involved for a request to access data/document

If the request contains the causes of the use of the data and the requesting person clearly introduces his/her professional identity and after confirmation of his/her identity, this information will be provided to him/her at the earliest opportunity. This documentation will be in Persian.

Comments