

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Study on the effect of pregnant women's training about attachment behaviors on maternal-fetal attachment measure in unplanned pregnancies (a randomized clinical trial)

Protocol summary

Study aim

Determine the effect of pregnant women's training about attachment behaviors on maternal-fetal attachment measure in unplanned pregnancies

Design

A controlled randomized clinical trial, single blind, with a factorial design on 68 pregnant mothers in two group of attachment behaviors training group and the control group

Settings and conduct

Recruitment will be done in office of family physicians and health centers in Sari. After taking informed consent from eligible mothers, they will be trained about maternal-fetal attachment behaviors in small groups including 3-5 mothers for three sessions of 90 minutes, every 3-4 days. Also a booklet and check list will be given to the mothers to perform the behaviors for 4 weeks. The control group will be received only pregnancy routine cares. Demographic questionnaire, London Measure of Unplanned Pregnancy, Cranley's Maternal-Fetal Attachment Scale, Spielberger Anxiety Inventory, Edinburgh Postnatal Depression Scale and Prenatal Distress Questionnaire will be completed initially and after 4 weeks (except of demographic and London Questionnaires). Data analyzer will be blind.

Participants/Inclusion and exclusion criteria

Pregnant women with unplanned pregnancy (score 0-3 based on London measure), 20-32 weeks of gestation age, Literacy at least grade 8, Single fetus Lack of medical problems and obstetrics risk factors such as signs of preterm labor, history of infertility, history of fetal or child loss, disrupted tests of fetal health, diabetes, preeclampsia and bleeding, lack of severe anxiety, depression or worry, lack of addiction

Intervention groups

The intervention group includes pregnant mothers who will be trained about maternal- fetal attachment

behaviors. The control group are pregnant mothers who will be just received routine cares of pregnancy.

Main outcome variables

maternal-fatal attachment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091130002792N3**

Registration date: **2018-10-29, 1397/08/07**

Registration timing: **prospective**

Last update: **2018-10-29, 1397/08/07**

Update count: **0**

Registration date

2018-10-29, 1397/08/07

Registrant information

Name

Marjan Ahmadshirvani

Name of organization / entity

Mazandaran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the effect of pregnant women's training about attachment behaviors on maternal-fetal attachment measure in unplanned pregnancies (a randomized clinical trial)

Public title

Effect of training on maternal-fetal attachment in unplanned pregnancies

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Unplanned pregnancy (score 0-3 based on London measure) 20-32 weeks of gestation age Literacy at least grade 8 Single fetus Lack of medical problems and obstetrics risk factors such as signs of preterm labor, history of infertility, history of fetal or child loss, disrupted tests of fetal health, diabetes, preeclampsia and bleeding lack of severe anxiety, depression or worry lack of addiction

Exclusion criteria:

Refuse to continue participating in the study Inaccessible during follow-up Failure to implement more than 50% of recommendations during the study Occurrence of obstetrics or medical problems during the study such as preterm labor, PROM, reduce of fetal movements and indications of termination of pregnancy Losing relatives during the study or last 6 months

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization with cards (intervention group A and control group B)

Blinding (investigator's opinion)

Single blinded

Blinding description

Because blinding of participants and researcher is impossible in this study, only data analyzer will be blind.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences, Moalem sq.

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2018-09-26, 1397/07/04

Ethics committee reference number

IR.MAZUMS.REC.1397.3029

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

Maternal-fetal attachment

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3**Description of health condition studied**

Depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

4**Description of health condition studied**

Worry

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Score of maternal-fetal attachment based on the Cranley's Maternal-Fetal Attachment Scale

Timepoint

At the beginning of the study and 4 weeks later

Method of measurement

Cranley's Maternal-Fetal Attachment Scale

Secondary outcomes

1

Description

Score of anxiety based on the Spielberger Anxiety Inventory

Timepoint

At the beginning of the study and 4 weeks later

Method of measurement

Spielberger State-Trait Anxiety Inventory

2

Description

Score of depression based on the Edinburgh Depression Scale

Timepoint

At the beginning of the study and 4 weeks later

Method of measurement

Edinburgh Depression Scale

3

Description

Score of worry based on the Prenatal Distress Questionnaire

Timepoint

At the beginning of the study and 4 weeks later

Method of measurement

Prenatal Distress Questionnaire

Intervention groups

1

Description

Intervention group: mothers' Training about maternal-fetal attachment behaviors will be performed in small groups including 3-5 mothers for three sessions of 90 minutes, every 3-4 days. The training will include verbal explanations about physical and psychological changes during pregnancy and their outcomes, fetal growth, the concept of fetal attachment and its benefits, childbirth process and nutritional tips. The practical training will include touch and pat fetus from the abdomen, counting fetal movements, listen fetal heart, talk with fetus, relaxation and look at ultrasound image of fetus. For performing the mentioned training in home, a booklet and a CD including recorded voice of fetal heart,

animation of fetal growth and relaxation guide will be given to mothers.

Category

Behavior

2

Description

Control group: mothers will be received routine cares of pregnancy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of family physicians and health centers in Sari

Full name of responsible person

Parastou Mahmoudi

Street address

School of Nursing & Midwifery, Vesal St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

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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
Sari 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
Mazandaran University of Medical Sciences
Full name of responsible person
Marjan Ahmad Shirvani
Position
Lecturer
Latest degree
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

It depends on who and for what purpose they are requesting information

When the data will become available and for how long

Available from 3 months after printing results

To whom data/document is available

Researchers in academic and science centers

Under which criteria data/document could be used

To use in systematic reviews or meta analysis and use the protocol in others researches or in the health care system with respecting the rights of the researchers.

From where data/document is obtainable

Marjan Ahmad Shirvani MASHirvani@mazums.ac.ir

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

Submit an application including organization affiliation, the purpose of the request and how to observe the rights of the researchers. A request will be answered no later than one month after receipt.

Comments