

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of father- fetus attachment education on mother's mental health

Protocol summary

Summary

The goal of this study is to evaluate the effect of education father- fetus attachment on mental health of primipregnant mothers. This is a clinical trial research. Inclusion criteria mothers: first pregnancy; age between 18-35; ability to read and write; gestational age 32-28 weeks; single pregnancy; mental health score less than 23. inclusion criteria fathers :Complete a consent form; at least read and write; monogamy and The first experience of fatherhood .exclusion mothers criteria: history of psychological problems; history of acute or chronic medical conditions; infertility; high risk pregnancy ; Grief and stressful incidents occurred during the last 6 months. exclusion fathers criteria: history of drug and alcohol use; history of mental problems .This research was done on 60 pregnant mothers and their husbands who visit for prenatal care in the health centers of Mashhad city In the year of 1394-95. Couples randomly placed in two groups of 30 each for intervention and contro.Fathers intervention group receive father-fetal attachment training in the form of three session of 120 minute classes weekly. The woman in control group received routine prenatal care only. immediately and after 3 weeks (follow-up) Both intervention and control groups evaluate by father- fetus attachment questionnaires and Goldberg mental health questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010225808N1**
Registration date: **2016-08-18, 1395/05/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-18, 1395/05/28

Registrant information

Name

Nassim Khajavian

Name of organization / entity

Departeman Biostatistic

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of father- fetus attachment education on mother's mental health

Public title

The effect of father- fetus attachment to the mother's mental health

Purpose

Supportive

Inclusion/Exclusion criteria

Mothers inclusion criteria: to complete the consent form,

is of Iranian origin and resident of Mashhad, is the first pregnancy, gestational age based on LMP and ultrasound between 32-28 weeks of the first quarter, chronological age is 35-18 years; singleton pregnancy have twins, have the ability to read and write is not less than 22 mental health score. Inclusion criteria fathers: to complete the consent form, is of Iranian origin and resident of Mashhad, have the least literate; his first become fathers is to be monogamous..Mothers exclusion criteria: history of psychological problems, a visit to the psychiatric clinic, effective drugs, or admitted to the psychiatric hospital is facing, have a history of acute or chronic medical condition, have a high risk pregnancy, current drug use and alcohol during pregnancy, have a history of infertility, grief and traumatic and stressful events occurred during the last 6 months. Exclusion criteria fathers: drug and alcohol use have; a history of mental problems, referring to psychiatric clinics, psychiatric drugs that have or hospitalization, bereavement, traumatic and stressful events occurred during the last 6 months there is, in the absence of more than a training session

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

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
Regional Committee for Medical Research Ethics
Mashhad University of Medical Sciences

Street address
Vice President of Research and Technology, next to the cinema curb, Daneshgah Avenue, Mashhad, Iran

City
Mashhad

Postal code

Approval date
2015-12-05, 1394/09/14

Ethics committee reference number
IR.MUMS.REC.13940542

Health conditions studied

1

Description of health condition studied
pregnancy

ICD-10 code
z34

ICD-10 code description
Supervision of normal pregnancy

2

Description of health condition studied
Mother's mental health

ICD-10 code
F99

ICD-10 code description
Mental disorder, not otherwise specified

Primary outcomes

1

Description
Mother's mental health

Timepoint
At the beginning of intervention, intervention, follow-up

Method of measurement
Form Goldberg mental health

2

Description
Mental health of mothers

Timepoint
At the beginning of intervention, intervention, follow-up

Method of measurement
Weaver father-fetus attachment questionnaire

Secondary outcomes

1

Description
Effect of intervention

Timepoint
Three weeks after the intervention

Method of measurement
Natan H marital satisfaction questionnaire modified
igneous - Social Support Questionnaire modified Cassidy

Intervention groups

1

Description

In the intervention group training 3 times a parent-baby attachment to parents (weekly) First session: Understanding the stages of fetal development problems, common physical changes pregnant women, Second session: Introduction to psychological changes and the importance of maternal mental health and its impact on the health of the family, duties of the spouses during pregnancy. Third session: Introduction to mental and physical changes in pregnancy. Fourth session : The role of the father, the concept of attachment and attachment parents - embryos, since the formation of parent-baby attachment, links to the fetus and mother-baby attachment behavior

Category

Other

2

Description

No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center staff

Full name of responsible person

Nosraty Ashraf

Street address

22 Aleey, Rostami street, Mashhad, Iran

City

Mashhad

2

Recruitment center

Name of recruitment center

Heath Center 22 Bahman

Full name of responsible person

Nosraty Ashraf

Street address

32 Alley, Mohammad Abad, Mashhad, Iran

City

Mahhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tafaghodi Mohsen

Street address

Vice President of Research and Technology, next to

the cinema curb, Daneshgah Avenue, Mashhad, Iran

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ashraf Nosraty

Position

Consultation on midwifery, Master

Other areas of specialty/work

Street address

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NosratyA1@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Kobra Mirzakhani

Position

Master of Midwifery

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty