

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of couple education on maternal-fetal attachment in pregnant women

Protocol summary

Study aim

The aim of this study was to determine the effectiveness of couple education on maternal-fetal attachment.

Design

A randomized controlled clinical trial will be performed on 110 pregnant mothers. We will use central method for Concealment of allocation sequences.

Settings and conduct

Training is done through cyberspace. The control group is divided into 5 groups of 11 people. Each group is assigned one session (45-60 minutes) per week of training and interaction.

Participants/Inclusion and exclusion criteria

Admission requirements: Age between 18 and 35 years, minimum primary education and gestational age between 18 to 28 weeks, Non-entry requirements: A history of mental illnesses, Drug abuse, Taking psychiatric medications, History of marital problems or conflicts

Intervention groups

In the intervention group, 4 training sessions are held on the role of spouse, attachment and gender preferences for couples. And the control group receives routine care.

Main outcome variables

The main outcome of this study is the degree of maternal attachment to the fetus.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210329050788N1**

Registration date: **2021-05-06, 1400/02/16**

Registration timing: **prospective**

Last update: **2021-05-06, 1400/02/16**

Update count: **0**

Registration date

2021-05-06, 1400/02/16

Registrant information

Name

Elieh Abasi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of couple education on maternal-fetal attachment in pregnant women

Public title

The effect of couple education on mother-fetus attachment

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 35 years Minimum basic education

Gestational age between 18 to 20 weeks

Exclusion criteria:
A history of mental illnesses Drug abuse Taking psychiatric medications History of marital problems or conflicts

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of assigning mothers to intervention and control groups will be used using the allocation sequence produced based on the block method in volume 4. Because participants enter the study from different centers over time, how to hide the allocation sequence will be a central method. In this way, the allocation sequence will be escaped in the hands of someone outside the research team. Upon each person entering the study at each center, the person will be contacted and asked about assigning the person to the correct group. The person with the sequence determines the group of participants using a central list based on the individual code (the individual code is determined by the order in which they entered the study).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study has two groups of intervention and control. In addition to routine care, the intervention group receives the mentioned training and the control group receives only routine care.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shahroud University of Medical Sciences

Street address

Yas Apartment, Piroozi 34 Alley, Piroozi Avenue, Sari, Iran

City

Sari

Province

Mazandaran

Postal code

4818884554

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SHMU.REC.1398.019

Health conditions studied

1

Description of health condition studied

Maternal Fetal Attachment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Maternal Fetal Attachment

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Cranley Maternal Fetal Attachment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant Women- For the intervention group, 4 training classes will be held during 4 weeks. The duration of each session is 60 minutes. Session 1: Teaching about paternal role, how the spouse supports his pregnant wife and advice to do these behaviors - Session 2: Attachment to the fetus and attachment behaviors, teaching the spouse about strategies to increase attachment and advice to do these behaviors - Session 3 Parents' preferences about children's gender and its causes, factors affecting sexual preferences a) Historical, cultural and social dimensions b) Demographic and psychological dimensions (age, education, religious beliefs, beliefs, attitudes, etc.) c) Homework presentation : Advantages and disadvantages of having gender preference - Session 4: Explaining gender preferences and its psychological and social consequences to inform couples, analyzing the answers given about the advantages and disadvantages of gender preference .

Category

Prevention

2

Description

Control group: The control group receives routine care.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 12

Full name of responsible person

Fatemeh Logmani

Street address

Health Center No. 12, Shahid Nozari Alley, Tabarestan St.

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2

Recruitment center

Name of recruitment center

Shahid Adibi Health Center

Full name of responsible person

Soori Mahmoodi

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Shahid Adibi Health Center, between Azadegan 2 and 4, Imam Reza Boulevard

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3

Recruitment center

Name of recruitment center

Shahid Ghasemi Health Center

Full name of responsible person

Masoumeh Karimilagab

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Shahid Ghasemi Health Center, Salanfarsi Ave.

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4

Recruitment center

Name of recruitment center

Health Center No. 7

Full name of responsible person

Atosa Kialashki

Street address

Health Center No. 7, Keshavars 6, Keshavars Blvd

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shamisakia@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

7 tir Square, Shahroud University of Medical Sciences

City

Shahroud

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Semnan

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3614773955

Phone

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Email

vcr@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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**

Shahroud University of Medical Sciences

Full name of responsible person

Elieh Abasi

Position

PhD Student

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Elieh Abasi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Elieh Abasi

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Latest degree

Ph.D.

Other areas of specialty/work

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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

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

In the case of data files, information about the main outcome can be shared. The study protocol is shareable. The methods used in statistical analysis can be shared. The clinical study report can be shared in the form of an article. The code used in the analysis and data classification system can be shared. All of the above can be shared via email if there is an individual request.

When the data will become available and for how long

Six months after the results were published

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Just to help with future research. Data and documentation are provided only to inspire working methods, especially in review studies, and the type of use should be reported by the applicant after use.

From where data/document is obtainable

elieh abasi email address: elieh_abasi@yahoo.com

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

The requested file and the reason for the request and the

type of use should be sent via email. Files that are received six months after the publication of the article and the reason and type of use is justified, the requested

information will be sent to them within a maximum of one week.

Comments