

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of cognitive-behavioral counseling on maternal-fetal attachment in adolescent mothers

Protocol summary

Study aim

Determining the effect of cognitive-behavioral counseling on mother-fetus attachment in adolescent mothers

Design

Clinical trial with intervention and control groups and the volume of each group was 6 people, randomized by blocking method

Settings and conduct

Samples will be selected from pregnant women referring to Dayyer city health centers by available sampling method. Those who scored low on the Cranley's Maternal Attachment Questionnaire will be selected. The samples are randomly divided into twelve blocks of six and are assigned to the intervention and control groups. In the intervention program, individuals are divided into groups of six.

Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous mothers, maternal age from 15 to 19 years, no maternal physical or mental illness confirmed by a doctor and psychiatrist, having at least a Middle school degree, gestational age of at least 28 weeks and mother-fetus attachment Low (based on the score of the first quarter questionnaire) and exclusion criteria: cancellation of further research, incomplete completion of questionnaires, absence of more than two sessions in counseling sessions, fetal death and divorce.

Intervention groups

In the intervention group, in addition to receiving routine pregnancy care, women also participate in 6-person group sessions of cognitive-behavioral counseling. In the control group, women receive only routine pregnancy care.

Main outcome variables

Maternal-fetal attachment in adolescent mothers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220605055078N1**

Registration date: **2022-06-14, 1401/03/24**

Registration timing: **prospective**

Last update: **2022-06-14, 1401/03/24**

Update count: **0**

Registration date

2022-06-14, 1401/03/24

Registrant information

Name

Somayeh Mohammadsoori

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 3665 4015

Email address

smsoori.as@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-19, 1401/03/29

Expected recruitment end date

2022-10-20, 1401/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive-behavioral counseling on maternal-fetal attachment in adolescent mothers

Public title

The effect of counseling on maternal-fetal attachment in adolescent mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Primiparous mothers Mother age from 15 to 19 years The mother does not have an underlying physical or mental illness confirmed by a doctor and psychiatrist Have at least a Middle school diploma Gestational age at least 28 weeks Existence of low attachment (based on the score of the first quarter questionnaire score 48)

Exclusion criteria:

Withdrawal from continuing research Incomplete of questionnaires Absence of more than two sessions in counseling sessions Fetal death Divorce

Age

From **15 years** old to **19 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by continuous sampling and will be divided into intervention and control groups by Block Balanced Randomization (BBR). The allocation sequence will be done using the free web system <http://www.randomization.com/>. In this way, the number of subjects in each block is determined by 6 people and the letter A will be considered for the intervention group and the letter B will be considered for the control group. The assignment sequence will be created for 72 samples by combining the letters A and B. Finally, the cards containing the blocks will be placed inside the standard envelope, and as a result, the Allocation Concealment will be considered and observed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ahwaz Jundishapur University of Medical Sciences

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Ahvaz Jundishapur University of Medical Sciences,
School of Nursing and Midwifery, Golestan St

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Province

Khouzestan

Postal code

6135715794

Approval date

2022-05-30, 1401/03/09

Ethics committee reference number

IR.AJUMS.REC.1401.094

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

Relationship between cognitive-behavioral counseling on maternal and fetal attachment in adolescent mothers.

ICD-10 code

F69

ICD-10 code description

Unspecified disorder of adult personality and behavior

Primary outcomes**1****Description**

Maternal-fetal attachment score of adolescent mothers in Cranley fetal-maternal attachment questionnaire

Timepoint

Completion of maternal-fetal attachment questionnaire before intervention, end of intervention and one month after intervention.

Method of measurement

Cranley's Maternal-Fetal Attachment Questionnaire

Secondary outcomes

empty

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

Intervention group: Adolescent women with low maternal attachment score to the fetus receive 8 sessions of cognitive-behavioral counseling for 8 consecutive weeks. The number of people in the groups will be 6 and the duration of each session will be about 45 minutes. Each session has an educational purpose and during the session, they perform cognitive-behavioral change techniques. Homework is also recommended for women to permanently change the behavior appropriate to the topic of each session to increase maternal-fetal attachment to women.

Category

Behavior

2

Description

Control group: Receive routine prenatal care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Urban health centers

Full name of responsible person

Somayeh mohammadsoori

Street address

Moallem Boulevard in front of the radio and television, Dayyer city health Network

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

معاونت تحقیقات و فناوری دانشگاه علوم پزشکی جندی شاپور اهواز

Full name of responsible person

Mehdi Ahmadimoghadam

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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

معاونت تحقیقات و فناوری دانشگاه علوم پزشکی جندی شاپور اهواز

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

Ahvaz University of Medical Sciences

Full name of responsible person

Somayeh mohammadsoori

Position

Master student of counseling in midwifery

Latest degree

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Other areas of specialty/work

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Full name of responsible person

Mojgan javadnoori

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

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Position

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Latest degree

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Other areas of specialty/work

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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