

# 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)

##### Phone

+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

**Street address**

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

**City**

Ahwaz

**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

##### City

Dayyer

##### Province

Boushehr

##### Postal code

7557174373

##### Phone

+98 77 3542 3676

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##### Email

smsoori.as@gmail.com

## 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

##### Street address

Golestan St. Jundishapur University of Medical Sciences

##### City

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##### Province

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##### Phone

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##### Email

ahmadi-m@ajums.ac.ir

##### 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

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

Ashuri Street

##### City

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mojgan javadnoori

##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

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**Person responsible for updating data****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**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Ashuri Street

**City**

Kangan

**Province**

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7557174373

**Phone**

+98 66 3665 4015

**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