

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Designing and evaluating the effectiveness of the intervention based on the educational needs of adapting to the parental role in first-time parents, a multi-stage study

#### Protocol summary

##### Study aim

Determining the effect of an education program on adaptation to parenting role in first-time parents

##### Design

The clinical trial will have a control group, with a parallel design, without blinding, on 176 pregnant women and their spouses (88 people in each group). For randomization, 4 and 6 random blocks will be used with an allocation ratio of 1:1. After listing all the possible states of blocks 4 and 6 and assigning a number to each of them using a computerized random number table, people will be divided into two groups receiving the training program and routine care with a ratio of 1:1.

##### Settings and conduct

This study will be conducted in Iran, Ahvaz health centers. Participants will be eligible pregnant women and their husbands. Pregnant women will be randomly divided into intervention and control groups, the intervention group will receive an educational program and the control group will receive routine pregnancy care. Then, the degree of parenting sense of competence, maternal role adaptation, and paternal role adaptation will be compared following the two mentioned methods.

##### Participants/Inclusion and exclusion criteria

Including criteria: First-time parents, 33-34 weeks of pregnancy, 18-45 years, low-risk and singleton pregnancy, Wanted pregnancy, willingness to participate in the study, Ability to speak and understand the Farsi language. Exclusive criteria: Drug abuse, medical problems (such as preterm labor, GDM, preeclampsia...), healthy fetus, chronic maternal and physical disease in parents

##### Intervention groups

The intervention group will receive a parenting education program and the control group will receive routine prenatal care.

#### Main outcome variables

Parenting Sense of Competence Adapting to the maternal role Adapting to the paternal role

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221206056729N1**

Registration date: **2022-12-29, 1401/10/08**

Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**

Update count: **0**

##### Registration date

2022-12-29, 1401/10/08

##### Registrant information

##### Name

Iran Talebi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2223 9245

##### Email address

25farzanehh58@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-05, 1401/10/15

##### Expected recruitment end date

2023-05-22, 1402/03/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Designing and evaluating the effectiveness of the intervention based on the educational needs of adapting to the parental role in first-time parents, a multi-stage study

**Public title**

Effect of the training program on adaptation to the parental role in first-time parents

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

First-time parents 18-45 years low risk and singleton pregnancy Wanted pregnancy willingness to participate in the study Ability to speak and understand Farsi language 33-34 weeks of pregnancy

**Exclusion criteria:**

Drug abuse Medical problems (such as preterm labor, GDM, preeclampsia...) Healthy fetus Chronic maternal and physical disease in parents

**Age**

From **18 years** old to **45 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **176**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After the initial selection of the samples by easy sampling, they will be divided into two groups using a random block of 4 and 6, with an allocation ratio of 1:1. After listing all the possible states of blocks 4 and 6 and assigning a number to each of them using a computerized random number table with a ratio of 1:1, people will be divided into two groups receiving training and routine care. To conceal the allocation, the type of intervention will be written on paper and placed in sequentially numbered opaque envelopes. The researcher and the participant will not know how to group and intervene until the start of the study.

**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**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Room 4, Ground floor, Vice President of Research and Technology Development, Jundishapur University of Medical Sciences of Ahvaz, University City, Golestan Blvd.

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

61357-15794

**Approval date**

2021-08-28, 1400/06/06

**Ethics committee reference number**

IR.AJUMS.REC.1400.472

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

Parenting educational program

**ICD-10 code**

F43.2

**ICD-10 code description**

Adjustment disorders

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

Maternal role adaptation

**Timepoint**

4 weeks after the intervention

**Method of measurement**

Maternal Role Adaptation Questionnaire

**2****Description**

Paternal role adaptation

**Timepoint**

4 weeks after the intervention

**Method of measurement**

Paternal Adaptation Questionnaire

**3****Description**

Parenting Sense of Competence

**Timepoint**

Before the intervention, immediately after the intervention and 4 weeks after the intervention

**Method of measurement**

Parenting Sense of Competence Scale

**Secondary outcomes**

**1**

**Description**

The rate of exclusive breastfeeding

**Timepoint**

After the baby is born and 4 weeks after the intervention

**Method of measurement**

A questionnaire made by the researcher

**Intervention groups**

**1**

**Description**

Intervention group: In the intervention group, women with 33-34 weeks of pregnancy and their husbands, who have been referred to health centers in Ahvaz for perinatal care, are invited to enter the study. They will be offered three face-to-face training sessions at 34, 35, and 36 weeks. In group classes of 4 to 8 people, each session will last 45-60 minutes. The educational content will be on psychological issues, the embodiment of maternal and paternal roles, infant interaction skills, and general infant care. The educational information of the sessions will be presented to the group members through lectures, discussions, role plays, and whiteboards.

**Category**

Behavior

**2**

**Description**

Control group: Women with 33-34 weeks of pregnancy and their husbands, who have been referred to Ahvaz health centers for perinatal care, will be received pregnancy care from the health centers. Providing care in this group is routine, and the researcher will not interfere in their pregnancy care.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Comprehensive health centers affiliated to Jundishapur University of Medical Sciences of Ahvaz

**Full name of responsible person**

Zahra Abbaspoor

**Street address**

Ahvaz University of Medical Sciences, Golestan Blvd.

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehdi Ahmadi Moghadam

**Street address**

Vice President of Research and Technology Development, Jundishapur University of Medical Sciences of Ahvaz, Golestan Blvd.

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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**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Zahra Abbaspoor

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Department of Midwifery, School of Midwifery  
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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Forough Talebi

**Position**

Phd student of midwifery

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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No. 5, Payam Alley, East Soleimani Ave., Chizar.

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**

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**Position**

Phd student of midwifery

**Latest degree**

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**Other areas of specialty/work**

Midwifery

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**Email**

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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**

Not applicable

**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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The data can be published after the completion of the thesis.

**When the data will become available and for how long**

One year after finishing the thesis.

**To whom data/document is available**

Ahvaz Jundishapur University of Medical Sciences,  
hospital and university researchers.

**Under which criteria data/document could be used**

After analysis, the data will be available to others  
through publication in scientific research journals.

**From where data/document is obtainable**

Forough Talebi, email: 25farzanehh58@gmail.com

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

Information will be available through printing the article.  
But if the person wants more information, he can express  
his request through email.

**Comments**