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
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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.
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Province
Khouzestan
Postal code
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

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Latest degree
Master

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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