Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of Group Prenatal Care on Adolescent Pregnancy Outcomes and explaining the experience of this model of prenatal care: A Mixed method study

Protocol summary

Study aim

The Effect of Group Prenatal Care on Adolescent Pregnancy Outcomes and explaining the experience of this model of prenatal care; A Mixed method study.

Design

The randomized clinical trial with a control group and parallel design, without blinding, will be conducted on 294 pregnant women (147 women in each group). For randomization, 4 and 6 random blocks with a 1: 1 allocation ratio will be used. Thus, after listing all possible situations of blocks 4 and 6 and assigning a number to each of them using a computer random number table with a 1: 1 ratio, participants will be allocated into two groups of routine care and group prenatal care. For allocation concealment, the type of intervention will be written on paper and will be kept in a series of opaque envelopes.

Settings and conduct

This study will be performed in health centers and hospitals in Ahvaz. Eligible adolescent pregnant women will be recruited. Eligible pregnant women will be randomly divided into intervention and control groups, the intervention group will receive group prenatal care and the control group will receive routine prenatal care.

Participants/Inclusion and exclusion criteria

Inclusion criteria; Adolescent pregnant women (15-19 years old); first and second pregnancies; gestational age 16 to 20 weeks;, low risk pregnancy; singleton and desired pregnancy. Exclusion criteria; High-risk pregnancy and unwillingness to participate in the study.

Intervention groups

The intervention group will receive group prenatal care and the control group will receive routine prenatal care.

Main outcome variables

Average of maternal weight gain; preterm labor; mean duration of labor; mode of delivery; mean score of women's empowerment; mean score of fear of childbirth; mean weight of neonate; mean duration of hospital stay in neonatal intensive care; Apgar score at 5 and 10 minute; Type of feeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210703051764N1**
Registration date: **2021-07-15, 1400/04/24**
Registration timing: **prospective**

Last update: **2021-07-15, 1400/04/24**
Update count: **0**

Registration date

2021-07-15, 1400/04/24

Registrant information

Name

Fatemeh Malchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8331

Email address

f.malchi@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Group Prenatal Care on Adolescent Pregnancy Outcomes and explaining the experience of this model of prenatal care: A Mixed method study

Public title
The Effect of Group Prenatal Care on Adolescent Pregnancy Outcomes.
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
15-19 years old First and second pregnancies Singleton pregnancy low-risk pregnancy Gestational age 16-20 wk
Exclusion criteria:
Unwanted pregnancy
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: **294**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible women will randomly assigned into two groups of routine (individual) prenatal care or group prenatal care using block randomization with a block size of 4 and 6 and allocation ratio of 1:1. Thus, after listing all possible situation of 4 and 6 blocks and assigning a number to each of them using a computer random number table with a 1: 1 ratio, participants will be allocated into two groups, namely routine prenatal care and group prenatal care. For allocation concealment, each woman will received a code and all codes will be kept in an opaque envelope until the time of intervention. Sequencing of allocation and preparation of envelopes will be done by a person that will not involve in sampling and data collection. The researcher and the participant will not aware of the groups and the intervention that they received until the commencement of intervention.
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
Golestan Blvd, University Campus, Research Deputy of Ahvaz Jundishapur University of Medical Sciences, Ground Floor, Room No: 4
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2021-07-02, 1400/04/11
Ethics committee reference number
IR.AJUMS.REC.1400.235

Health conditions studied

1

Description of health condition studied
Group prenatal care
ICD-10 code
O36.7
ICD-10 code description
Maternal care for viable fetus in abdominal pregnancy

Primary outcomes

1

Description
Average weight gain of adolescent pregnant mothers
Timepoint
End of the intervention(38-40 wk)
Method of measurement
scale

2

Description
Preterm labor
Timepoint
During the intervention
Method of measurement
mean gestational age

3

Description
Duration of first and second stage of labor
Timepoint
End of the intervention(labor)
Method of measurement
Measuring the mean of the first and second stages of

labor (minutes)

4

Description
Select the type of delivery
Timepoint
End of the intervention
Method of measurement
type of delivery(normal vaginal delivery or cesarean delivery)

Secondary outcomes

1

Description
Empowerment of pregnant adolescents
Timepoint
End of the intervention
Method of measurement
Kameda Empowerment Questionnaire

2

Description
Fear of child birth
Timepoint
Before and after delivery
Method of measurement
Wijma Delivery Expectancy/Experience Questionnaire version A and B

3

Description
Apgar score of the 1st and 5th minutes after birth
Timepoint
End of the intervention(at child birth)
Method of measurement
Apgar score

4

Description
Birth weight
Timepoint
End of the intervention(at birth)
Method of measurement
Scale

5

Description
Duration of neonate hospitalization in Neonatal Intensive Care Unit
Timepoint
After the intervention (after the child birth)
Method of measurement
Mean duration of hospitalization

6

Description
Type of feeding
Timepoint
After the end of intervention (after the child birth)
Method of measurement
Questionnaire

Intervention groups

1

Description
In the intervention group from 16 to 20 weeks of pregnancy, 5 to 6 pregnant adolescents women will be allocated in a group, and will receive 4 or 5 prenatal care (weeks 16-20, 30-24, 34-31, 37-35, 38). The first 30 to 45 minutes of each prenatal care session will be included measuring uterine height and fetal heart rate, which will be performed by the researcher. The fetal heart rate will be heard and recorded by one of the women in the group using Sonicaid. Then, weight and blood pressure will be measured in groups by adolescent pregnant women under the supervision of the researcher. Adolescent pregnant women will be taught how to take blood pressure using a digital sphygmomanometer, as well as how to measure weight, so that women can measure each other's blood pressure and weight. Pregnant women will be given the opportunity to discuss learning this skill. Then, the prenatal care education will be done in the form of group discussions, according to the educational content specific to each week of pregnancy in the booklet prepared by National Instruction of the Ministry of Health and Medical Education. In each session, the researcher will encourage women to participate in prenatal care education discussions through open-ended questions. In order to express their information, knowledge and experiences in the field of care, their information and knowledge will be evaluated by the researcher. The necessary information and strategies to promote health, will be provided by the researcher in simple language.
Category
N/A

2

Description
Control group; Pregnant women in the control group will receive routine prenatal care from health care centers, and the researcher will not be involved.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health care centers affiliated to Ahvaz Jundishapur

University of Medical Sciences

Full name of responsible person
Parvin Abedi

Street address
Golestan Blvd; Ahvaz Jundishapur University of Medical Sciences

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2

Recruitment center

Name of recruitment center
Razi hospital affiliated to Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
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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

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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
Parvi Abedi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Golestan Blvd; Department of Midwifery; Nursing and Midwifery School; Ahvaz Jundishapur University of Medical Sciences

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Fatemeh Malchi

Position
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Person responsible for updating data

Contact
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Full name of responsible person
Fatemeh Malchi
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)
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 accomplishment of the dissertation
When the data will become available and for how long
One year after completing the dissertation
To whom data/document is available
Ahvaz Jundishapur University of Medical Sciences; Hospital and University researchers
Under which criteria data/document could be used
Data will be available after publication in journals.
From where data/document is obtainable
Fatemeh Malchi; Email; machi.fatemeh52@gmail.com
What processes are involved for a request to access data/document
The information will be available through the publication of the article. But if more information is needed, the request should be sent via email
Comments