Clinical Trial Protocol
Iranian Registry of Clinical Trials
31 May 2022

The effect of midwife support (Doula) on childbirth experience of adolescent pregnant women: a randomised controlled clinical trial

Protocol summary

Study aim
The effect of midwife support (Doula) on childbirth experience of adolescent pregnant women: a randomised controlled clinical trial.

Design
After explaining the objectives and methods of research to adolescents mothers, after receiving written consent, Social and midwifery questionnaires will be completed then participants will be assigned doula support and control groups with the use of random block sizes the size of four- and six- blocks.

Settings and conduct
In the intervention group, continuous support includes emotional support (constant presence on the client’s bed, reassurance, encouragement and positive motivational sentences) physical support (back massage, breathing techniques and muscle relaxation, quenching thirst and hunger, helping to change position and encourage physical activity). Will provide information about the stages of labor and the mechanism of labor pain). Maternity care in both groups will be provided by the delivery room staff. In both groups, cares will continue for up to two hours after delivery. Childbirth experience will be measured using the Labor Agentry Scale, Support and control questionnaire, The Childbirth Fear Questionnaire, Postpartum hemorrhage and the baby’s Apgar score, The length of the delivery process will be checked.

Participants/Inclusion and exclusion criteria
Pregnant teens under 19 years of age; Being primitive; Pregnancy age 37 to 41 weeks; Initiation of the active phase of labor, Being single Having a partner during the labor

Intervention groups
Intervention group during the active phase of labor supported by a trained midwife and The control group that receives routine ward care.

Main outcome variables
Childbirth experience score, support and control in childbirth, fear of childbirth, duration of the active stage of labor, newborn Apag score, postpartum hemorrhage

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20200628047944N1
Registration date: 2020-11-21, 1399/09/01
Registration timing: retrospective

Last update: 2020-11-21, 1399/09/01
Update count: 0

Registration date
2020-11-21, 1399/09/01

Registrant information
Name
Leila Abdoli Najmi
Name of organization / entity
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Iran (Islamic Republic of)
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+98 41 3475 0798
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abdoli@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-21, 1399/04/31
Expected recruitment end date
2020-11-19, 1399/08/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Scientific title
The effect of midwife support (Doula) on childbirth experience of adolescent pregnant women: a randomised controlled clinical trial

Public title
The effect of midwife support (Doula) on childbirth experience of adolescent pregnant women: a randomised controlled clinical trial

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
1- Pregnant teens under 19 years of age
2- Being primitive
3- Pregnancy age 37 to 41 weeks
4- Initiation of the active phase of labor (dilatation 4 cm onwards)
5- Being single
6- Having a partner during the leader

Exclusion criteria:
History of any systemic, heart or lung disease
2- Infertility history
3- Rupture of the water bag for more than 18 hours
4- Having physical activity contraindications (heart disease, lung disease, insufficient cervix, high-risk multiple pregnancies, persistent bleeding, placenta previa after 26 weeks, gestational hypertension)
5- Having cesarean section indications

Age
From 13 years old to 18 years old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 54

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to two intervention groups (mobile midwifery support and trained mobile support) using randomized block sizes of four- and six-block blocks.

Blinding (investigator's opinion)
Not blinded

Blinding description
Not used

Placebo
Not used

Assignment
Parallel

Secondary outcomes

Primary outcomes

Health conditions studied

Description of health condition studied
Pregnancy, childbirth and the puerperium

ICD-10 code
094

ICD-10 code description
Pregnancy, childbirth and the puerperium

Sample size
Target sample size: 54

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to two intervention groups (mobile midwifery support and trained mobile support) using randomized block sizes of four- and six-block blocks.

Blinding (investigator's opinion)
Not blinded

Blinding description
Not used

Placebo
Not used

Assignment
Parallel

Secondary Ids
empty

Ethics committees

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of medical Sciences

Street address
681–Manzareye sq-

City
Tabriz

Province
East Azarbaijan

Postal code
5375134484

Approval date
2020-06-21, 1399/04/01

Ethics committee reference number
IR.TBZMED.REC.1399.291
Description
Control group: 24 adolescent pregnant mothers who receive routine care during labor.

Category
Other

Recruitment centers

1
Recruitment center
Name of recruitment center
Taleghani Hospital, Rah- Ahan Sq, Tabriz
Full name of responsible person
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mohammad Samiei
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Person responsible for general inquiries

Contact
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data related to the study can be published without observing the ethics of the participants by observing the ethics in the research.
When the data will become available and for how long
Start access 4 months after printing results
To whom data/document is available
Researchers working in the academic and research center
Under which criteria data/document could be used
Dear researchers, after authentication by observing ethical issues, if they wish, with the opinion of the research team, they will have access to the study data for analysis and other studies.
From where data/document is obtainable
Department of Midwifery, School of Nursing and Midwifery, Tabriz University of Medical Sciences
What processes are involved for a request to access data/document
Contact the author Submit a written request Design and review the application in the research team Approval of the faculty officials Provide documentation
Comments