Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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 labar

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 Apgar 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

Country

Iran (Islamic Republic of)

Phone

+98 41 3475 0798

Email address

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

Trial completion 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

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

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

Health conditions studied

1

Description of health condition studied
Pregnancy, childbirth and the puerperium

ICD-10 code
094

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
childbirth experience of adolescent pregnant women

Timepoint
24 hours after delivery

Method of measurement
labor agentry scale

Secondary outcomes

1

Description
support and control during labar

Timepoint
24 hours after birth

Method of measurement
support and control questionnaire

Intervention groups

1

Description
Intervention group: 24 teenage pregnant mothers who are supported by a midwife during the active phase of labor.

Category
Other

2

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
Leila Abdoli Najmi
Street address
Taleghani Hospital, Rah- Ahan Sq, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
51976154113
Phone
+98 41 3442 4420
Email
leilanajmi97@gmail.com
Web page address
https://taleghanihosp.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Mohammad Samiei
Street address
Vice Chancellor for Research and Technology Central Building No. 2 ,Tabriz University of Medical Sciences, Golgasht St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5375134484
Phone
+98 41 3335 7310
Email
Samiei.moh@gmail.com
Web page address
https://taleghanihosp.tbzmed.ac.ir/
Grant name
Approved budget of Tabriz University of Medical Sciences research project
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Leila Abdoli Najmi
Position
Instructer
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No.681, Manzariye, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5375134484
Phone
004134750798
Email
leilanajmi97@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Leila Abdoli Najmi
Position
Instructer
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No.681, Manzareyeh, Tabriz
City
Tabriz
Province
East Azarbaijan

Postal code
53751-34484
Phone
+98 41 3475 0798
Email
leilanajmi97@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Leila Abdoli Najmi
Position
Faculty instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
Taleghani hospital, Rah-Ahan Sq, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5375134484
Phone
+98 41 3475 0798
Email
leilanajmi97@gmail.com
Web page address
https://taleghanihosp.tbzmed.ac.ir

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