

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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 Agency 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 agency scale

**Secondary outcomes****1****Description**

support and control during labor

**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

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##### 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, Goltasht St, Tabriz

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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

Instructor

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

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## Person responsible for scientific inquiries

#### Contact

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Tabriz University of Medical Sciences

##### Full name of responsible person

Leila Abdoli Najmi

##### Position

Instructor

##### Latest degree

Master

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Latest degree**  
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**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