Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The effect of counselling on pregnancy outcomes in pregnant teenage women: a randomized controlled clinical trial

Protocol summary

Summary

1) Objectives: Objectives include pregnancy outcomes, hemoglobin and hematocrit base levels prior to and during labor, mother's weight at an early stage and in 38 weeks of pregnancy, the frequency of preterm delivery, delivery characteristics (the length of active phase and second stage of labor, intense labor pain at 6-8 centimeters cervical dilatations and receiving oxytocin during labor), and the number of prenatal visits. (2) Design: This is a clinical trial in which participants are assigned into two groups of 4 and 6 selected through randomized permuted blocking. (3) Methods and materials: This study will be conducted on 120 women aged 11 to 19 years old who have the inclusion criteria, are willing to participate in the study, and refer to Ardebil's chosen Health-treatment centers. (4) Participants of the study will be 11 to 19-year-old pregnant women with gestational age of 20-24 weeks, having their first to third pregnancy, scored below 12 according to Edinburg's Depression Scale prior to intervention, showing no signs of physical and mental illnesses according to patients, willing to give birth in Tamin Ejtemai and Alavi hospitals of Ardebil, and have never participated in physiologic childbirth classes before. (5) Interventions: In the intervention group, 60 people will take part in 5 counseling sessions from 20 to 38 weeks of pregnancy while 60 participants of the control group will only receive the routine care of pregnancy. (6) The main outcome variables will be collected through self-administered pregnancy outcomes plus demographic questionnaires, VAS pain assessment tools, and partograph form.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705146582N26**
Registration date: **2017-07-24, 1396/05/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-24, 1396/05/02

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2017-05-14, 1396/02/24

Expected recruitment end date

2017-07-15, 1396/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counselling on pregnancy outcomes in pregnant teenage women: a randomized controlled clinical trial

Public title
The effect of counselling on pregnancy outcomes in pregnant teenage women
Purpose
Prevention
Inclusion/Exclusion criteria
The inclusion criteria include 11 to 19-year-old pregnant women; with 20-24 weeks of gestational age; having their first, second, and third pregnancy; with contact numbers for future follow-up who have participated in at least 2 sessions of the total counselling sessions; have scored below 12 according to Edinburg's Depression Scale prior to intervention; and have shown willingness to give birth in Tamin Ejtemaie and Alavi hospitals of Ardebil. Exclusion criteria: Having any physical illnesses (e.g. epilepsy, heart disease, etc.); showing signs of mental illnesses according to patients; having history of hospitalization due to side effects from current pregnancy (e.g. placental abruption; hemorrhage; preeclampsia; etc.); having history of preterm delivery and the presence of other risking factors associated to preterm delivery; diagnosis of fetal abnormalities; and previous participation in physiologic childbirth classes are among the exclusion criteria.
Age
From **11 years** old to **19 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single 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
Nursing and Midwifery Faculty, Shariaty street
City
Tabriz
Postal code
Approval date
2017-05-16, 1396/02/26
Ethics committee reference number
IR.TBZMED.REC.1396.104

Health conditions studied

1

Description of health condition studied
Complications of pregnancy
ICD-10 code
(P01.-)
ICD-10 code description
Maternal complications of pregnancy

2

Description of health condition studied
Teenage pregnancy
ICD-10 code
P00.4
ICD-10 code description
Fetus and newborn affected by maternal nutritional disorders

Primary outcomes

1

Description
Delivery Characteristics (duration of active phase and second stage of labor)
Timepoint
During labor
Method of measurement
Using partograph and mother's admission forms

2

Description
Pain score
Timepoint
In 6-8 centimeters dilations
Method of measurement
Using VAS tools

3

Description
Receiving Oxytocin during labor
Timepoint
During labor
Method of measurement
Observation and assessment of mother' obstetrical chart

4

Description
Hematocrit and Hemoglobin
Timepoint

Pregnancy at early stage and during labor

Method of measurement

Cell catheter device

5

Description

Maternal weight gain during pregnancy

Timepoint

Pregnancy at early stage and during labor

Method of measurement

Adult weighing scale

6

Description

The frequency of preterm delivery

Timepoint

During labor / At the time of delivery

Method of measurement

Observation and assessment of mother' obstetrical chart

7

Description

Number of prenatal visits

Timepoint

End of pregnancy

Method of measurement

Assessment the mothers health chart

8

Description

The frequency of caesarean delivery /C-section

Timepoint

During labor / At the time of delivery

Method of measurement

Observation and assessment of mother' obstetrical chart

Secondary outcomes

1

Description

First and fifth minute Apgar score

Timepoint

Immediately and 5 minuets after birth

Method of measurement

Apgar score

2

Description

Anthropometric indicators

Timepoint

Immediately after birth

Method of measurement

Baby weighing scales, Fabric tape measure

3

Description

Postpartum Depression

Timepoint

Prior to and at the end of intervention

Method of measurement

Filling out depression questionnaire before and after intervention

4

Description

Breastfeeding

Timepoint

At the end of intervention

Method of measurement

Interview

5

Description

Family planning

Timepoint

At the end of intervention

Method of measurement

Interview

Intervention groups

1

Description

control group: Routine prenatal cares for pregnant women

Category

Other

2

Description

Intervention group: 5 sessions of group counselling will be conducted for 60 minutes in a room with comfortable and relaxing environment by the researcher. The minimum number of participants in each session will be 5 and the maximum will be 9 while the applied language for counselling will be in native. At the end of each session, individual counselling will be held for research participants upon their request. A contact number will be given to research participants in case they have any questions. The counselling content include training and consulting teenager's pregnancy symptoms, complications and introducing methods of prevention. After group introduction in the first session, participants are informed of the time and number of counselling sessions; they are further informed about pregnancy and its effective associative factors. In the second session, Participants are further counselled about the physiologic and hormonal changes during pregnancy, vaccination, and proper breathing techniques. Additional training and counselling regarding nutrition, personal hygiene, oral hygiene (mouth and dental cleanness) and pregnancy exercises along with proper breathing training will be given to them in the third session. In the fourth session, Participants are informed of the risks and complications involving teenage pregnancy (e.g. preterm labor, low

birth weight, IUGR, etc), breastfeeding counselling as well as proper breathing techniques during labor, whereas in the fifth session, participants get familiar with symptoms of labor pain and its associated risks, childbirth type and family planning. Eventually in the final stage, private counselling sessions will be held for pregnant teenagers in the presence of their husbands which is based on their questions and problems. Control group: The control group will receive the routine prenatal cares.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Health-care centers in Ardabil city and chosen hospitals

Full name of responsible person
Roya Shafagat

Street address
Health-care centers in Ardabil city and chosen hospitals

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research, University Of Tabriz Medical Sciences

Full name of responsible person
Mohammad Reza Rashidi

Street address
Research Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz, ,

City
Tabriz

Grant name

Grant code / Reference number
IR.TBZMED.REC.1396.104

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for Research, University Of Tabriz Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Master Of Sciences Of Midwifery

Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty