

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of self-care counseling on health practices of adolescent pregnant women: a randomized controlled trial

Protocol summary

Study aim

Comparison of mean health practice score in adolescent pregnant women in counseling and control groups

Design

Randomized controlled trial with two parallel arms

Settings and conduct

54 adolescent pregnant woman will be chosen from health centers of Tabriz city and will be allocated in two groups of counseling and control with block randomization method. randomization will be conducted by person non involved in the sampling and data collection. The counseling group will receive 6 sessions of self care counseling in groups of 5 to 7 people. The questionnaires will be done before and 1 month after the intervention. Only data analyser will be blinded from the received intervention by groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Residency in Tabriz, Having a file in health centers (SIB system), Age between 10-19, Having at least a secondary or higher education, The desire to attend in counseling sessions, Gestational age 18-24 weeks Having a home and cell phone number Exclusion criteria: High risk pregnancies including diabetes, high blood pressure and etc., Mental disorders or history of them or hospitalization because of them, Experiencing a terrible event in the past three months, Health conditions in which the pregnant woman should not have physical activity such as heart or pulmonary disease and etc.

Intervention groups

The intervention group will receive 6 self-care counseling sessions and an educational booklet. The control group will only receive routine pregnancy care.

Main outcome variables

Mean score of health practices in adolescent pregnant

dormitories, the study was needed to be done in home town of researcher.

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N54**

Registration date: **2020-03-02, 1398/12/12**

Registration timing: **prospective**

Last update: **2021-04-29, 1400/02/09**

Update count: **1**

Registration date

2020-03-02, 1398/12/12

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6969

Email address

mirghafourvandm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-01-09, 1399/10/20

Actual recruitment start date

2020-07-22, 1399/05/01

Actual recruitment end date

2021-01-27, 1399/11/08

Trial completion date

2021-02-18, 1399/11/30

Scientific title

General information

Reason for update

because of pandemic situation of corona virus and closed

The effect of self-care counseling on health practices of adolescent pregnant women: a randomized controlled trial

Public title
The effect of self-care counseling on health practices of adolescent pregnant women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Residency in Bukan Having a file in health centers (SIB system) Age between 10-19 Having at least a secondary or higher education The desire to attend in counseling sessions Gestational age 18-24 weeks Having a home and cell phone number
Exclusion criteria:
 High risk pregnancies including diabetes, high blood pressure, chronic illnesses effecting on pregnancy such as cardiovascular or pulmonary diseases Mental disorders or history of them or hospitalization because of them Experiencing a terrible event that can effect on mental health in the past three months including death of a member of the family Health conditions in which the pregnant woman should not have physical activity such as heart or pulmonary disease, cervical incompetence, high risk multiple pregnancy, continuous vaginal bleeding, placenta previa after 26 weeks of pregnancy and high blood pressure

Age
From **10 years** old to **19 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **54**
 Actual sample size reached: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
 Participants will be allocated to self-care counselling or control groups with an allocation ratio of 1:1.
 Randomization will be conducted using the website www.random.org and through block randomization method. The block sizes will be 4 and 6. Consecutively numbered opaque sealed envelopes will be used to conceal the allocation sequence. The sequence generation and the envelop preparation will be done by a person not involved in the participant recruitment, intervention implementation, or collection or analysis of data.

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

Faculty of Nursing Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2019-11-25, 1398/09/04

Ethics committee reference number

IR.TBZMED.REC.1398.913

Health conditions studied

1

Description of health condition studied

Health practices in adolescent pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Health practices

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

Health Practices Questionnaire-II

Secondary outcomes

1

Description

Attitudes towards motherhood and pregnancy

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

Attitudes towards motherhood and pregnancy questionnaire

2

Description

Pregnancy symptoms

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

Pregnancy Symptoms Scale

Intervention groups

1

Description

For intervention group, self-care counseling as six 60-90 minutes group sessions will be held in health centers of Tabriz by researcher from 25th week of pregnancy. The interval of sessions will be one week. The contents of counseling sessions will include providing information about pregnancy and childbirth, prenatal care, effect of adequate rest and sleep, appropriate physical activity, accurate diet, accurate health practices and their importance and benefits, signs and symptoms of pregnancy and training of necessary self-care behaviors to control of annoying symptoms.

Category

Behavior

2

Description

Control group: The control group will receive routine pregnancy care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Boukan city

Full name of responsible person

Ronya Rezaie

Street address

Nursing and Midwifery faculty, South Shariati street

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+98 41 3479 6969

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rorezaie08@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz

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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

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

Ronya Rezaie

Position

M.Sc student of counseling in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

<http://nursing.tbzmed.ac.ir>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data of participants are confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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 results of clinical study will be published as article.

When the data will become available and for how long

Immediately after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article

From where data/document is obtainable

Email: mirghafourvandm@tbzmed.ac.ir

What processes are involved for a request to access data/document

Maximum one week after the communication by email.

Comments