

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of counseling on health behaviors of adolescent girls in Tabriz: a randomized controlled Field Trial

Protocol summary

Summary

The goal is to determine the effect of counseling on adolescent girls' health behaviors. Inclusion criteria: Students aged 18 to 14, students who have experienced menarche, have less pre-test scores. Exclusion criteria: having physical and mental illness, having a specific diet, having physical activity limits. Methods: This clinical trial will be carried out on 120 high school girl students in Tabriz. Sampling will be multistage clustering. Thus, out of a total of 180 school girls for ten schools (from each district of two schools) and 12 students from each school, they will be randomly selected. One school in each district will be randomly selected from the control group and the other school of intervention. Qualified students will complete demographic questionnaires, nutrition and physical activity questionnaires, menstrual health questionnaire, and social and economic status questionnaires. Individuals who have a lower pre-test score will be included in the study. Advice in the intervention group. Educational content will include proper nutrition, appropriate physical activity, and compliance with menstrual health. The counseling is training-based and will be carried out in three sessions for 45-60 minutes. The control group will not receive any intervention. Primary outcomes: Increasing the mean nutritional, physical activity and menstrual health scores 8 weeks after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052034052N1**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name

Niloofer Sattarzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 2699

Email address

sattarzadehn@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Tabriz University of Medical Science

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling on health behaviors of adolescent girls in Tabriz: a randomized controlled Field Trial

Public title

The effect of counseling on health behaviors of adolescent girls

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Students aged 18 to 14 years; enrolled high school students who are educating; students who have experienced menarche; having willingness to participate in the study; having parents' permission to attend in the study; having a contact number to follow up; earning a pre-test scores less than a cut off.
Exclusion criteria: having physical and mental illness; having a specific diet; having physical activity limitations.

Age

From **14 years** old to **18 years** old

Gender

Female

Phase

N/A

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

Regional Ethics Committee

Street address

Department of Research and Technology, third floor,
Central Building, No. 2, Tabriz University of Medical
Sciences, Golgasht,

City

Tabriz

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.TBZMED.REC.1396.177

Health conditions studied

1

Description of health condition studied

Persons encountering health services for other

counselling and medical advice, not elsewhere classified

ICD-10 code

Z71.9

ICD-10 code description

Counselling, unspecified

Primary outcomes

1

Description

physical activity

Timepoint

Before intervention, 8 weeks after intervention

Method of measurement

IPAQ questionnaire

2

Description

nutrition

Timepoint

Before intervention, 8 weeks after intervention

Method of measurement

FFQ questionnaire

3

Description

hygien menstruation

Timepoint

Before intervention, 8 weeks after intervention

Method of measurement

hygien menstruation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, counseling is done on a training-based basis. Educational content will include proper nutrition, appropriate physical activity, and compliance with menstrual health. Consultation takes place for up to 45 minutes in the relevant counseling room for three consecutive sessions. The number of participants in each session will be 10-8 people, and the last 20 minutes will be devoted to answering questions and answers. The content of the first session of puberty and menstruation is the content of the second session on nutrition and the third session of physical activity. The number of sessions will increase as needed. 8 weeks after the end of the intervention, the nutrition and physical activity (short form) and menstrual health questionnaire will be provided to the students and will be completed by the students.

Category

Lifestyle

2

Description

The control group will not receive any intervention. If the results of the research are positive, after the completion of the research, the training content will be provided to the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Education Department of East Azarbaijan province

Full name of responsible person

Jafar Pashaie

Street address

South Army Street, Police Station Street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research, Tabriz University of Medical Science

Full name of responsible person

Dr. Mohammadreza Rashidi

Street address

3rd floor, Central building number 2, Tabriz University of Medical Science , Golgasht St.

City

tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research, Tabriz University of Medical Science

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

Tabriz University of Medical Science

Full name of responsible person

Raana Aghanezhad Nozari

Position

MSc Student of counseling in Midwifery

Other areas of specialty/work

Street address

End of Dr. Shariati Avenue, Faculty of Nursing and Midwifery

City

Tabriz

Postal code

Phone

+98 41 3477 2699

Fax

Email

raana_nozari@yahoo.com

Web page address

http://nursing.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Midwifery, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Niloofar Sattarzadeh

Position

PhD in reproductive health

Other areas of specialty/work

Street address

End of Dr. Shariati Avenue, Faculty of Nursing and Midwifery

City

Tabriz

Postal code

Phone

+98 41 3477 2699

Fax

Email

sattarzadehn@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Raana Aghanezhad Nozari

Position

MSc Student of counseling in Midwifery

Other areas of specialty/work

Street address

End of Dr. Shariati Avenue, Faculty of Nursing and Midwifery

City

Tabriz

Postal code

Phone

+41 34772699

Fax**Email**

raana_nozari@yahoo.com

Web page address

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

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