Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of two methods of motivational interviewing and use of peer group in promoting puberty health in adolescent girls

Protocol summary

Study aim
Comparison of the effectiveness of two methods of motivational interviewing and the use of peer group in improving the puberty health of adolescent girls

Design
Two intervention groups and one control group were designed parallel. The sample size is estimated at 100 people per group. Stratified random sampling is done.

Settings and conduct
All high schools of the first girth of Shahrood district are included in the study and are divided into intervention and control groups based on homogenization and then random selection. The analyst, and participants, have been blinded to this study.

Participants/Inclusion and exclusion criteria
Iranian nationality • Not having a specific disease that prevents from participating in the research • Lack of or history of diseases and mental disorders • No history of taking psychiatric drugs • Not having restricted attendance at meetings • Not attending similar classes outside of school • Not having a loved one's death or stressful events in the last 3 months • The desire of teenagers and parents to participate in the study and fill out an informed consent form by them

Intervention groups
In this study, there were 2 intervention groups (motivational interview and peer group) and 1 control group. The intervention group received one, five 60-minute sessions of motivational interviewing to improve the health of puberty. The intervention group is also trained by peers already trained. The control group does not have an educational intervention until the end of the intervention, but immediately after completing the intervention due to the ethical issues, they will hold educational sessions on puberty health.

Main outcome variables
puberty health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180209038675N1**
Registration date: **2018-04-03, 1397/01/14**
Registration timing: **prospective**

Last update: **2018-04-03, 1397/01/14**
Update count: **0**

Registration date
2018-04-03, 1397/01/14

Registrant information

Name
Sarah Mohamadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-04, 1397/01/15

Expected recruitment end date
2018-07-06, 1397/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of two methods of motivational interviewing and use of peer group in promoting puberty health in adolescent girls

Public title
Evaluating the effectiveness of puberty education for adolescents
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian girls without a specific disease without mental and Psychiatry disorders negative history for using psychiatric drugs Not having restrictions on attending meetings Non-attendance at similar classes outside of school- Not having a loved one's death or a tense incident for at least the past 3 months The desire of teenagers and parents to participate in the study and fill out a form of informed consent by them 11-16 years old adoescents
Exclusion criteria:
Age
From **11 years** old to **16 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is simple in the first step. Schools are non-profit based, located in the center of the city and in the margin of the city are divided into 3 classes or groups. The school is considered as a cluster on each floor. In each class, the school is randomized. Of any homogeneous group, schools are selected randomly. In each school, a class is randomly selected as a simple one. Sampling continues to the limit. Then, selected schools of each class are randomly selected and created in 3 groups: Group A, B, and C. After completing the pre-test, groups A, B, and C are randomly assigned to peer groups for control, motivational interviewing and training.
Blinding (investigator's opinion)
Single blinded
Blinding description
All the participants in the study announced that there are three groups and they are randomly assigned to a specific group. In order to prevent leakage of information from groups, there is only one group in each school (intervention 1, intervention 2 or control). Also, to blind the person collecting the information, another person who is not informed to the group is used to fill in the questionnaires after the intervention in two groups. Also, the person who analysis the data, does not know the group of people.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
7 Tir Square, Shahroud University of Medical Sciences
City
Shahroud
Province
Semnan
Postal code
۳۶۱۴۷-۷۳۹۴۷
Approval date
2017-12-20, 1396/09/29
Ethics committee reference number
IR.SHMU.REC.1396.144

Health conditions studied

1

Description of health condition studied
puberty health
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
puberty Health Questionnaire
Timepoint
Evaluation of puberty health before the intervention - immediately after the intervention and one month after the intervention was completed.
Method of measurement
puberty Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To conduct motivational interviewing sessions to improve the puberty health of girls' at intervals of one week and 5 sessions 60 minutes. The day of the meetings is discussed with the participants beforehand and will be served after the meeting.

Category
Behavior

2

Description
Intervention Group 2: In this group, peer educators will be selected by students with conditions such as higher score in the puberty health questionnaire than others, approved by the school administrator and teachers. Elderly peers see a training session by the researcher on puberty health behaviors and then they will be given a pamphlet of the same material to remind them. Then, one session will be held to introduce peer educators to others and a brief explanation of their puberty health by the presence of a researcher in the classroom. Continuing education is informal and can provide training in any environment. 1 month is given to peer educators to transfer information to others.

Category
Behavior

3

Description
Control group: This group does not receive any counseling and training until the end of the interventions. However, in order to observe ethical issues after completing the interventions and completing post tests, two educational sessions will be held with the content of puberty health and to promote puberty health by the researcher for this group.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Governmental and nonprofit Schools (first-year girls' high schools),

Full name of responsible person
Ali Akbar Jalali

Street address
Koodak park Ave., 22 Bahman street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
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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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Sarah Mohamadi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available