Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effects of adolescent health promotion training package on treatment of poly cystic ovary syndrome

Protocol summary

Study aim

Evaluation of the effects of adolescent health promotion training package on treatment of polycystic ovary syndrome

Design

This study is a longitudinal clinical trial.

Settings and conduct

In this study, 100 adolescents with poly cystic ovary syndrome (50 in each group) were randomly selected from the students in Tehran high schools. In the intervention group the training was done by lecture method and the second group was control (no training).

Participants/Inclusion and exclusion criteria

inclusion criteria: 14-18 years old girls, signed written consent form by parents and student; no history of disease; no drug use, no drug addiction. exclusion criteria: Unwillingness of the teenager or her parents to participate in the study, Lack of teen participation in one-third of educational classes, Adolescent drug use

Intervention groups

Face-to-face teaching to poly cystic ovary syndrome adolescents is conducted in eight 60-minute sessions of lecture, question and answer provided by the researcher. The adolescent health promotion package was designed based on the Nice Clinical Guidelines Model. Based on this model, the package was designed after searching the guides, books, sexual health packages of various countries as well as available articles. Then, Delphi method was used to validate the sexual health package by specialists and experts in different cities of Iran. Designed in two parts for the adolescent and adolescent lifestyle educator, the package is designed to include the most important aspects of adolescent health during education years.

Main outcome variables

• Changes in nutritional status score) FFQ, recall 24 h questionnaire(• Changes in physical activity status score (Caspian questionnaire) • Changes in the status of blood bio markers • Changes in status of ultrasound items • Changes in the quality of life of adolescents(kids Screening Questionnaire)

General information

Reason for update

Due to the conditions of school closures and changes in the implementation of this plan in Tehran girls' high schools, it is necessary to express it in this section as well.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200114046123N1**
Registration date: **2020-01-23, 1398/11/03**
Registration timing: **prospective**

Last update: **2022-02-28, 1400/12/09**
Update count: **1**

Registration date

2020-01-23, 1398/11/03

Registrant information

Name

somayeh abdolahian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4429 8292

Email address

abdolahian.s@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of adolescent health promotion training package on treatment of poly cystic ovary syndrome

Public title
Evaluation of the effects of adolescent health promotion training package on treatment of poly cystic ovary disease
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Written parental and student agreement Girls ages 14 to 18 who are single and without sexual relation At least 2 years passed from the juvenile menarche According to ASRM criteria, 2 items of PCOS symptoms were diagnosed Be healthy in terms of all diseases including liver, kidney, thyroid, heart and skeletal diseases Have not taken any female hormone or metformin medication for at least three months before entering the study Have no smoking at least three months before the intervention Do not use drugs or alcohol Not have severe mental illness (which requires medication) Do not exercise professionally or attend school sports team Do not follow a specific diet
Exclusion criteria:
Adolescents who failed to perform 1/3 of the recommended physical activities per month for any reason Adolescents who for any reason failed to attend 1/3 of the classes held at the school. Adolescents who have not completed any form of physical activity and diet assessment for at least one month for any reason. Adolescents who affected by a specific illness or need to take a particular drug after entering the plan. Adolescents who they or their parents are reluctant to continue in the project for any reason.
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
The sampling method is random cluster sampling in the educational districts of Tehran. At first Tehran are divided into five educational districts (East, West, North, South and Center). The areas in the five districts are written separately on paper and were drawn randomly. Then again, in each cluster, the girls' secondary schools are written separately on a single paper and randomly drawn. In the draw, the first school name in each district is placed in the intervention group respectively; the second school name in that district is placed in the control group (two schools in each district).
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 Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2018-07-02, 1397/04/11
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.100

Health conditions studied

1

Description of health condition studied
poly cystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
life style modification in adolescent with poly cystic ovarian syndrome
Timepoint
before intervention, 6 and 12 after intervention
Method of measurement

diet and physical activity questionnaire

2

Description
menstrual cycleregularity,
Timepoint
Before intervention and 6, 12 months after intervention
Method of measurement
Menstrual cycles are <21 or more than 35 days or have <8 cycles per year will be considered irregular

3

Description
Hirsutism status
Timepoint
Before intervention and 6, 12 months after intervention
Method of measurement
The Ferriman–Gallwey scale will be used for Hirsutism status; a score of 1–4 is given for nine areas of the body. A total score <9 is considered normal, a score of 9–15 indicates mild Hirsutism, and a score >15 indicates moderate or severe Hirsutism

4

Description
Anthropometric index
Timepoint
Before intervention and 6, 12 months after intervention
Method of measurement
weight,height, waist, and hip circumstance

Secondary outcomes

1

Description
Blood bio markers
Timepoint
before intervention and after 12 months
Method of measurement
Blood test

2

Description
Sonography Items
Timepoint
before intervention and after 12 months
Method of measurement
Transabdominal Sonography

Intervention groups

1

Description
"Intervention group:" Face-to-face teaching polycystic ovary syndrome adolescents are conducted in eight 45-minute sessions of lecture, question and answer provided by the researcher. The adolescent health promotion package was designed based on the Nice Clinical Guidelines Model. Based on this model, the package was designed after searching the guides, books, sexual health packages of various countries as well as available articles. Then, Delphi method was used to validate the sexual health package by specialists and experts in different cities of Iran. Designed in two parts for the adolescent and adolescent lifestyle educator, the package is designed to include the most important aspects of adolescent health during education years.
Category
Lifestyle

2

Description
"Control group: " The control group receive only routine care and receive no intervention and training packages. Routine care includes blood pressure control, weight measurement, blood biomarkers and ultrasound measurement.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Girls' High School in Tehran
Full name of responsible person
Somayeh Abdolahian
Street address
Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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Abdolahian.s@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Somayeh Abdolahian
Position
PhD candidate
Latest degree
Master
Other areas of specialty/work
Reproductive Health
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Not applicable

Title and more details about the data/document

one report include: introduction, methods, results and discussion

When the data will become available and for how long

12 months after published manuscript

To whom data/document is available

Academic researchers are allowed access to data

Under which criteria data/document could be used

Citing the source

From where data/document is obtainable

Correspondence with responsible author by email

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

The application letter should include the name of the applicant, the use and the scientific title of the research project or article in question.

Comments