Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of exercise counseling on the quality of life of students with polycystic ovary syndrome

Protocol summary

Study aim
Determining the effect of exercise counseling on the quality of life of the students with polycystic ovary syndrome in Hamadan city universities

Design
A controlled clinical trial with randomized parallel groups on students with polycystic ovary syndrome

Settings and conduct
Notifications are posted in the student dormitories of universities in Hamedan city in Iran and students with polycystic ovary syndrome who wish to participate in the study are requested to call the phone number mentioned in the notice. After obtaining informed consent, they will be asked to complete the demographic questionnaire and the World Health Organization Quality of Life Short Questionnaire (WHO-QOL-BREF) and the Iranian version of the Health-Related Quality of Life Questionnaire for Polycystic Ovary Syndrome (MPCOSQ) in a self-report manner. Intervention group (in groups of 10-15 people) will be counseled for 2 weeks; 2 times a week and they will do sports exercises for 45 to 60 minutes under the supervision of the trainer. Then the students will do sports exercises at their residence for a period of 4 months and 3 times a week. To ensure compliance with the exercise regimen during this period, the researcher will send SMS reminders and place 2-3 weekly phone calls.

Participants/Inclusion and exclusion criteria
Participants: 18-35-year-old students with polycystic ovary syndrome who are not pregnant or breastfeeding; have no known mental or medical illness and physical disability; do not use hormonal drugs, and do not exercise regularly.

Intervention groups
Randomly for the intervention group, sports counseling will be done in groups of 10-15 people for 2 weeks, and then they will do sports exercises at their residence for 4 months and 3 times a week. The control group will continue their normal daily routine.

Main outcome variables
Quality of life (general); Health-related quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240326061367N1**
Registration date: **2024-04-26, 1403/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-26, 1403/02/07**
Update count: **0**

Registration date
2024-04-26, 1403/02/07

Registrant information
Name
Rafat Bakht
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 0535
Email address
r.bakht@umsha.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-19, 1403/01/31
Expected recruitment end date
2024-09-04, 1403/06/14
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of exercise counseling on the quality of life of students with polycystic ovary syndrome

Public title
The effect of exercise counseling on the quality of life of students with polycystic ovary syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
She has polycystic ovary syndrome She should be 18 to 35 years old She should be physically and mentally able to do exercise

Exclusion criteria:
She is pregnant or breastfeeding According to her own statement, she has known medical diseases such as: diabetes, Cushing's syndrome, hyperplasia of adrenal glands, high blood pressure, thyroid disorders, hyperprolactinemia According to her own statement, she has a mental illness She uses hormonal contraceptives or drugs She has physical disability, deafness, and blindness She exercise regularly during the week

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Four control and intervention dormitories will be randomly selected from the girls' dormitories of the universities in Hamadan city, and from each dormitory, people will be randomly assigned to the intervention groups of 10-15 people (50 people) or the control group (50 people).

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
Research Ethics Committees of Hamadan University of Medical Sciences

Street address
Faculty of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamadan, Iran.

City
Hamadan

Province
Hamadan

Postal code
6517838698

Approval date
2024-03-08, 1402/12/18

Ethics committee reference number
IR.UMSHA.REC.1402.768

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Quality of life

Timepoint
Measuring the quality of life at the beginning of the study and 2 months and 4 months after the study

Method of measurement
The short version of the world health organization quality of life instrument (WHO-QOL-BREF) and the Iranian version of health-related quality of life polycystic ovary syndrome questionnaire (MPCOSQ)

Secondary outcomes

empty

Intervention groups

1

Description
Students with polycystic ovary syndrome living in the dormitories of universities in Hamadan, who are randomly assigned to the intervention group, are asked to complete demographic and quality of life questionnaires. Then, they will be given exercise counseling in groups (in groups of 10-15 people) for 2

weeks and they will do exercises (which were taught by the trainer) at their residence for 4 months and 3 sessions every week. They are also asked to complete the quality of life questionnaires 2 months and 4 months after the consultation.

Category

Lifestyle

2

Description

Control group: Students with polycystic ovary syndrome living in the dormitories of universities in Hamadan city, who are randomly placed in the control group, are asked to complete the demographic and quality of life questionnaires before studying and quality of life questionnaires 2 , 4 months after the intervention group's exercise counseling.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitories of universities in Hamadan city

Full name of responsible person

Solmaz Javadi Yeganeh

Street address

Faculty of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamadan, Iran.

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dr.solmazzz.yeganeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Reza Shokoohi

Street address

Shadid Fahmideh Blvd

City

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Hamadan

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6517838678

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Email

Fanavari@umsha.ac.ir

Web page address

https://research.umsha.ac.i

Grant name

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Rafat bakht

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Faculty of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamadan, Iran.

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Email

rbakht@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Rafat Bakht

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Assistant professor

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Person responsible for updating data

Contact

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
In case of the approval of Hamشdan University of Medical Sciences, the individual data of the participants (non-identifiable) and the summary report of the methods and results of the study without data analysis will be provided to the participants and researchers who request it.

When the data will become available and for how long
If Hamadan University of Medical Sciences agrees, the access period will start 6 months after the publication of the results

To whom data/document is available
Participants and requesting researchers

Under which criteria data/document could be used
In order to increase the awareness and improve the health level of the participants from the results of the study in which they participated and the researchers to use it in the design of studies in the future

From where data/document is obtainable
Hamedan University of Medical Sciences Research and Technology Vice-Chancellor

What processes are involved for a request to access data/document
Submitting an application to the Research and Technology Vice-Chancellor of Hamadan University of Medical Sciences, submitting the application to the University Research Council, and in case of approval, providing the data files and a summary report of the methodology and study findings to the participants

Comments