Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of cognitive behavioral therapy on health promoting lifestyle in students with premenstrual syndrome

Protocol summary

Study aim
Determining the effect of CBT on health-promoting lifestyle in students with PMS.

Design
A clinical trial with control and intervention groups with parallel groups, randomized,Rand function of Excel software on 72 girls.

Settings and conduct
After the screening of girls with PMS and eight sessions of cognitive-behavioral counseling, the analysis of the final statistics for the control and intervention groups and the impact of CBC on lifestyle and PMS will be done.The place of conducting research and consulting is in Behbahan Faculty of Natural Resources.

Participants/Inclusion and exclusion criteria
Eligibility criteria: 1. Girls aged 18-30 years 2. Single 3. Suffering from moderate and severe type of premenstrual syndrome 4. Having regular menstruation with intervals of 24-35 days 5. Obtaining a score of less than 156 from the health promoting lifestyle questionnaire Exclusion criteria: 1. Existence of mental stress in the last three months, such as the death of relatives 2. Surgery (Performing surgeries that require sedation during the recovery period and performing uterine and ovarian surgeries, or surgeries that require chemotherapy or radiation therapy afterward) 3. Suffering from physical diseases 4. Abnormal bleeding 5. History of mental illness 6. Taking antidepressants and hormonal drugs 7. Having regular sports activities 8. Any special treatment to treat PMS

Intervention groups
Eight sessions of cognitive-behavioral counseling and its effect on improving the lifestyle of girls with PMS and after of sessions and statistical analysis, two sessions of CBC should be held for the control group.

Main outcome variables
Lifestyle, which includes aspects of spiritual growth and self-actualization, responsibility in health, interpersonal relationships, stress management, exercise, and dimensions of PMS, which includes psychological, behavioral, and physical dimensions.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240813062743N1**
Registration date: **2024-08-24, 1403/06/03**
Registration timing: **prospective**

Last update: **2024-08-24, 1403/06/03**
Update count: **0**

Registration date
2024-08-24, 1403/06/03

Registrant information

Name
Azadeh Moteraghi

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
2024-12-21, 1403/10/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of cognitive behavioral therapy on health promoting lifestyle in students with premenstrual syndrome

Public title
The effect of cognitive behavioral therapy on health promoting lifestyle in students with premenstrual syndrome

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-30 years Single Suffering from moderate and severe type of premenstrual syndrome Having regular menstruation with intervals of 24-35 days Obtaining a score of less than 156 from the health promoting lifestyle questionnaire

Exclusion criteria:
The presence of mental stress in the last three months, such as the death of relatives Surgery (Surgeries that require sedation during the recovery period and uterus and ovary surgery or operations that require chemotherapy or radiation therapy afterwards.) Suffering from physical diseases Abnormal bleeding History of mental illness Taking antidepressants Taking hormonal drugs Having regular sports activity Any specific treatment for Premenstrual syndrome(PMS)

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling in a non-probability way and by the method of randomly assigning the intervention of people and by the method of randomized permutation blocks with a random block size of 4 (using the table related to random permutations) with one-to-one allocation (18 to 4 blocks)) is The randomization list will be prepared by the statistician. The intervention used in this research is allocated according to the randomized list by a person outside the study who is not aware of the research objectives and according to the corresponding codes in the closed envelopes, and any measure to hide the sequence until the interventions are determined is done.Allocation concealment and blinding According to the nature of this study, it is not possible to blind researchers and participants, but after randomization, the codes assigned to each of the participants are kept by an unknown person in order to hide the expertise, so neither the participants nor The researcher is not aware of the order of allocation until the start of the intervention.

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 Jundishapur Ahvaz University

Street address
Farazmand Manzel, Azadegan Bridge, Vetri Square, Khuzestan, Behbahan

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Province
Khouzestan

Postal code
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Approval date
2024-08-11, 1403/05/21

Ethics committee reference number
IR.AJUMS.REC.1403.208

Health conditions studied

1

Description of health condition studied
Premenstrual syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Cognitive-behavioral counseling on reducing premenstrual syndrome by filling out the premenstrual syndrome questionnaire and reducing the behavioral, psychological and physical symptoms of this syndrome- and the effect of this counseling on lifestyle and changing dimensions and spiritual growth and self-fulfillment, responsibility in health, relationships between Individual, stress management, physical activity and nutrition by filling in the questionnaire of Walker et al.

Timepoint
. Before the start of the intervention, immediately after the start of the intervention, one month and two months

after the intervention, the effect of cognitive behavioral counseling on the dimensions of premenstrual syndrome.

Method of measurement

PSST premenstrual syndrome questionnaire [2]: This questionnaire has two parts and 19 questions, the first part contains 14 questions about mood-behavioral and physical symptoms, and the second part contains 5 questions about the effect of premenstrual symptoms on performance. It examines people's lives. In this questionnaire, 4 main criteria are mentioned for each question: not at all, mild, moderate and severe, which are scored based on a Likert scale from 0 to 3. For each question, 4 criteria were mentioned: not at all, mild, moderate and severe, which were graded from 0 to 3. In order to diagnose moderate or severe PMS, the following three conditions must be present together: 1- From options 1 to 4, at least one case should be moderate or severe, 2- In addition to the previous case, from options 1 to 14, at least 4 cases should be moderate or severe and 3- In the section on the impact of symptoms on life (the last 5 options), there should be a moderate or severe case. In order to diagnose PMDD, the following three conditions must be present together: 1- From options 1 to 4, at least one case should be severe. 2- In addition to In the previous case, from options 1 to 14, at least 4 cases should be moderate or severe, and 3- there should be a severe case in the impact of symptoms on life (last 5 options). In this study, moderate and severe cases are included in the study. Lifestyle questionnaire: this questionnaire has 52 questions and 6 dimensions of spiritual growth and self-actualization (11 questions, from questions 1 to 11), responsibility for health (13 questions, from questions 12 to 24), interpersonal relationships (8 questions, from questions 25 to 32), stress management (6 questions, from questions 33 to 38), sports and physical activities (7 questions, from questions 39 to 45) and nutrition (7 questions, from questions 46 to 52). In this questionnaire, usually 4 answers are considered for each question and a score is given to each answer. A score of 1, 2, 3, and 4 is given to each of the questions in the questionnaire, respectively, for the answers of never, sometimes, most of the time, and always. The minimum score is 52 and the maximum is 208. The lifestyle score can be divided into three levels: a score of less than 103 is a poor lifestyle, 104-155 is an average lifestyle, and a score of 156 and above is considered a good lifestyle.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group: cognitive behavioral counseling for 8 sessions and the duration of each session is 60 minutes. group.

Category

Behavior

2

Description

Control group: no intervention is done, only two sessions of cognitive behavioral counseling are done as a thank you.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Behbahan Faculty of Natural Resources

Full name of responsible person

Moteraghi Azadeh

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Email

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Web page address

https://irct.behdasht.gov.ir/user/trial/78524/update/recruitment_center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Doctor Zakerkish mehrnoosh

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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
Ahvaz 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
Ahvaz University of Medical Sciences
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Azadeh Moteraghi
Position
Master student
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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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
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
After conducting the research, the data file can be shared for all researchers and professors to access the main result and the second result after de-identifying people.
When the data will become available and for how long
After one year from the time of printing the results, it will be possible to access up to 10 years after the printing of the results.

To whom data/document is available

The ways are accessible to all people who need them.

Under which criteria data/document could be used

Any condition or analysis that in any way causes this research to contribute to the progress of other research or to help other researchers in retrospective research or review articles.

From where data/document is obtainable

azadehmoteaghi@gmail.com Mobile phone number 00989161720249

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

As soon as we know about the request of people to receive documents, we will send the documents via email or mobile phone number.

Comments