Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Web-Based Counseling with Cognitive-Behavioral Approach on Premenstrual Syndrome: a randomized controlled trial

Protocol summary

Study aim
To determine the effect of web-based counseling with cognitive-behavioral approach on premenstrual syndrome

Design
Randomized controlled parallel trial: 92 students with moderate or severe PMS or PMDD will be randomized into two groups; receiving the web-based counselling or receiving no intervention; using block randomization, 1:1 assignment ratio, stratified by the syndrome severity.

Settings and conduct
Students with moderate or severe PMS or PMDD who are resident in governmental or non-governmental dormitories of Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria
Inclusion criteria 1.Healthy women aged 18-35 years 2.Resident in governmental or non-governmental dormitories of Tabriz University of Medical Sciences 3.Regular menstrual periods of 25 to 35 days over the past 6 months 4.Having moderate or severe premenstrual syndrome (PMS), or premenstrual dysphoric disorder (PMDD), diagnosed by the Daily Record of Severity of Problems chart (DRSP) filled in prospectively in the following two cycles 5.Not receiving drugs (except supplements) for treatment of PMS/PMDD 6 Good cooperation in completion of the study questionnaires at the preliminary stage Exclusion criteria 1.Being a professional athlete 2.Pregnancy or the first year after childbirth 3.Breast-feeding 4.Having severe depression (score 29 or higher on the Beck Depression Inventory) 5.History of severe depression, anxiety or eating disorders during the past two years 6. Having severe chronic diseases 7 Current drug user or history of its use during the last two years

Intervention groups
Intervention group: receiving web-based counseling with cognitive-behavioral approach Control Group: No intervention

Main outcome variables
premenstrual syndrome symptoms; Quality of life in luteal and follicular phase of menstruation; Disability rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100414003706N34**
Registration date: **2019-06-19, 1398/03/29**
Registration timing: **prospective**

Last update: **2019-06-19, 1398/03/29**
Update count: **0**

Registration date
2019-06-19, 1398/03/29

Registrant information

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Sakineh Mohammad-Alizadeh-Charandabi

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
2019-06-22, 1398/04/01

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Web-Based Counseling with Cognitive-Behavioral Approach on Premenstrual Syndrome: a randomized controlled trial

Public title
Effect of Web-Based counseling on Premenstrual Syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy women aged 18-35 years Resident in governmental or non-governmental dormitories of Tabriz University of Medical Sciences Regular menstrual periods of 25 to 35 days over the past 6 months Having moderate or severe premenstrual syndrome (PMS) or premenstrual dysphoric disorder (PMDD), based on the DRSP questionnaire filled in two following cycles Good cooperation in filling the questionnaires at the preliminary stage of study (before randomization) Having experience in using Internet Regular access to Internet during study period Having a phone number for follow-up

Exclusion criteria:
Being a professional athlete Pregnancy or the first postpartum year Breast-feeding Having severe depression (score 29 or higher on Beck Depression Inventory) Having a history of severe depression, anxiety or eating disorders in the past two years, self-report Drug use or history of drug use during the last two years, self-report Use of antidepressants, benzodiazepines, anticancer drugs, oral contraceptives or hormones in the past three months, self-report Having chronic diseases (such as epilepsy, or severe digestive, cardiovascular, kidney, or gonadal disorders), self-report Occurrence of a very stressful event in the past six months, such as: separation of parents, death of first degree family members, self-report History of major psychiatric disorders (psychosis, bipolar disorder, suicide attempt) Having some gynecological problems (hysterectomy, Ooforectomy, female cancer, polycystic ovary syndrome, endometriosis, infertility)

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: **92**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated in a 1:1 ratio to counselling or control groups. A computerized program will be used for stratified block randomization with randomly varied block sizes of four and six, stratify for severity of the syndrome (with or without PMDD). Consecutively numbered opaque sealed envelopes will be used to conceal the allocation sequence. The sequence generation and the envelop preparation will be done by a person not involved in the participant recruitment, intervention implementation, or collection or analysis of data.

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 Tabriz University of Medical Sciences

Street address
No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Ave., Tabriz, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2019-04-08, 1398/01/19

Ethics committee reference number
IR.TBZMED.REC.1398.014

Health conditions studied

1

Description of health condition studied
Premenstrual Syndrome

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Symptoms of premenstrual syndrome

Timepoint
Daily record of severity of symptoms for two menstrual cycle at two stages, first at the baseline (before

randomization) and just after completion of the intervention

Method of measurement

Daily Record of Severity of Problems chart (DRSP)

2

Description

Quality of life at luteal phase of menstruation

Timepoint

At the first or second day of menstrual cycle at two stages (at the cycle prior to the randomization and at the cycle just after completion of intervention)

Method of measurement

Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q-SF)

3

Description

Quality of life follicular phase of the menstrual

Timepoint

At the 11th-13th day of menstrual cycle at two stages (at the cycle prior to the randomization and at the cycle just after completion of intervention)

Method of measurement

Q-LES-Q-SF

Secondary outcomes

1

Description

Menstrual Attitude

Timepoint

At the first or second day of menstrual cycle at two stages (at the cycle prior to the randomization and at the cycle just after completion of intervention)

Method of measurement

Menstrual Attitude Questionnaire

2

Description

Patient satisfaction

Timepoint

At the first or second day of the first menstrual cycle just after completion of intervention

Method of measurement

Patient Satisfaction Questionnaire

3

Description

Disability

Timepoint

At the first or second day of menstrual cycle at two stages (at the cycle prior to the randomization and at the cycle just after completion of intervention)

Method of measurement

Sheehan Disability Scale (SDS)

Intervention groups

1

Description

Intervention group: Web-based cognitive-behavior counselling (through the Learning Management System (MOODLE) of Tabriz University of Medical Sciences) including 14 modules over 8 consecutive weeks, one module for the first (introduction session about premenstrual syndrome (PMS) and its etiology) and the eighth (review of the previous sessions and prevention of relapse) sessions and two parallel (concurrent) modules (modules C1 to C6 about cognitive strategies and B1 to B6 regarding suggestions about behavior changes in lifestyle) for the other sessions. For modules designed for the second to seventh weeks, an approximate working time will be 5 hours per week. Contents of the modules have been approved by the study team including specialists in reproductive health and in psychology and cognitive-behavior therapy. The sessions will be guided by a MSc student in counselling in midwifery trained on cognitive-behavior counselling and will regularly be supervised by the psychologist. Before the sessions, participants will receive detailed instructions on how to use the information, importance of exercises and how to deal with any technical obstacles. Every week at the time of publishing new content in the e-learning management system, an email and a SMS will be sent to the individuals as reminders. There will be also the possibility of online commentary so users can submit their questions and problems online on the site. Participants will give weekly feedback. If a participant does not send her feedback, she will receive an email reminder, and if she does not respond to this reminder, they will be reminded by telephone. Contents of the modules for the second to seventh weeks will be C1: the role of thoughts and its relationship with emotions and behavior (cognitive triangle), and B1: the relationship between stress and PMS and learning of relaxation techniques for the second week, C2: moving to a specific field of PMS and B2: interdependence between nutrition, exercise and PMS for the third week, C3: the restructuring of dysfunctional perceptions and B3: integrating sport into daily life by motivational plans and strategies for the fourth week , C4: PMS specific myths and the use of cognitive strategies learned and B4: a balanced diet and an implementation in routine life for the fifth week, C5: effective thoughts and the development of new evaluations and B5: the effects of stress-related errors in reasoning for the sixth week, C6: PMS-specific behavior (the use of health care, support, communication) and B6: implementation of positive activities in routine daily life for the seventh week.

Category

Behavior

2

Description

Control group: nothing

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar dormitory

Full name of responsible person
Haniyeh Naghizadeh

Street address
End of Shariati South - next to Nursing Faculty

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Email
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Web page address

2

Recruitment center

Name of recruitment center
Fajr dormitory

Full name of responsible person
Farzaneh Shiri

Street address
Rah Ahan Street - next to the former Babak hospital

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3

Recruitment center

Name of recruitment center
Quds dormitory

Full name of responsible person
Fariba Pourhassan

Street address
University Road inside the University of Tabriz - next to the kindergarten of the university

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4

Recruitment center

Name of recruitment center
Azadi dormitory

Full name of responsible person
Roghayeh Ghanbari

Street address
Azadi Street - In front of the Gulgasht - Baharan Deadend

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5

Recruitment center

Name of recruitment center
Non-governmental dormitory of Tamaddon

Full name of responsible person
Farideh Vatankhah

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Taleghani Street, above the intersection of Pasteur, not reaching Taleghani Crossing

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6

Recruitment center

Name of recruitment center
Non-governmental dormitory of Ferdows

Full name of responsible person
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Gulgasht Street, not reaching Imam Reza Hospital

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Sponsors / Funding sources

1

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Name of organization / entity
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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
Tabriz 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
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Full name of responsible person
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All deidentified IPD can be shared.
When the data will become available and for how long
Starting soon after publication of the study results for ten years
To whom data/document is available
Data will be available for researchers working in academic institutions, as well as to chief editor and reviewers of the submitted manuscript.
Under which criteria data/document could be used
The data will be available to researchers upon request and submission of the proposal to perform meta-analysis using IPD. Also, in exceptional cases, data will be made available to chief-editor of the journals for checking.
From where data/document is obtainable
Refer to the email addresses (borjisanam@gmail.com, alizades@tbzmed.ac.ir).
What processes are involved for a request to access data/document
The requests should be sent by email and data will be available within two week.
Comments