

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

Sakineh Mohammad-Alizadeh-Charandabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

alizades@tbzmed.ac.ir

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

Email

info@student-affairs.tbzmed.ac.ir

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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Tabriz

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5166616471

Phone

+98 41 3479 8870

Email

info@student-affairs.tbzmed.ac.ir

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

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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Phone

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5

Recruitment center

Name of recruitment center

Non-governmental dormitory of Tamaddon

Full name of responsible person

Farideh Vatankhah

Street address

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

Jafar Fazli

Street address

Gulgasht Street, not reaching Imam Reza Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

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No. 2, Central building of the university, Golgasht street, Azadi Ave., Tabriz

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research-vice@tbzmed.ac.ir

Web page address

<https://researchvice.tbzmed.ac.ir/>

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

Tabriz University of Medical Sciences

Full name of responsible person

Sanam Borji Navan

Position

MSc student in Counseling in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sakineh Mohammad-Alizadeh Charandabi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Professor

Latest degree

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Other areas of specialty/work

Reproductive Health

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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