

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the effect of social network-based cognitive-behavioral therapy intervention on the severity of PMS symptoms

Protocol summary

Study aim

The aim of this study was to investigate the effect of social network-based cognitive-behavioral therapy intervention on the severity of PMS symptoms.

Design

Clinical trial with control group, with randomized parallel groups, without blinding, phase 3 on 140 patients

Settings and conduct

This randomized controlled trial study will be performed in comprehensive health centers affiliated to Guilan University of Medical Sciences, Rudbar city. The social media -based CBT program will be provided in 8 consecutive weeks within 14 separate sections of introductory, cognitive strategies, suggestions for behavioral lifestyle changes, and ends with relapse prevention. The Cognitive Strategies provides information and strategies for identifying and correcting dysfunctional cognitions, especially specific PMS cognitions and specific PMS behaviors and misconceptions. The other sections include suggestions for lifestyle changes such as stress reduction, exercise, and diet Cover a balanced diet. In the last section, a summary and a plan to protect the benefits and prevent returns is provided. All sections include practical exercises for applying and practicing theoretical content. Blinding will be done according to the nature of the study. Control group will receive no intervention.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study; Age 45-20 years; Moderate to severe premenstrual syndrome; Internet access; Having a smartphone

Intervention groups

The intervention group will receive social network-based cognitive-behavioral therapy for 8 consecutive weeks consisting of 14 separate sections including introductions, cognitive strategies, and suggestions for behavioral lifestyle changes and relapse prevention.

Control group will receive no intervention.

Main outcome variables

Severity of premenstrual syndrome symptoms

General information

Reason for update

Enter the actual date of start and end of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20180218038789N4**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**

Update count: **1**

Registration date

2020-10-28, 1399/08/07

Registrant information

Name

Zainab Alimoradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6003

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-30, 1399/08/09

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

2021-01-20, 1399/11/01

Actual recruitment end date

2021-08-30, 1400/06/08

Trial completion date

2021-08-30, 1400/06/08

Scientific title

Investigating the effect of social network-based cognitive-behavioral therapy intervention on the severity of PMS symptoms

Public title

Social network-based CBT for PMS

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Moderate to severe premenstrual syndrome Internet access having smart phone Willingness to participate in the study

Exclusion criteria:

Diagnosis of psychosis or bipolar disorder Diagnosis of eating disorder Diagnosis of moderate to severe depression Participate in psychotherapy for premenstrual symptoms now or in the past Acute suicidal tendencies Childbirth or breastfeeding during the last three months Pregnancy Gynecological diseases (hysterectomy, oophorectomy, cervical cancer, polycystic ovary syndrome, endometriosis, infertility) Initiation or change in the use of antidepressants, benzodiazepines, antipsychotics, oral contraceptives or hormones over the past three months

AgeFrom **20 years** old to **45 years** old**Gender**

Female

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **140**Actual sample size reached: **140****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be done by balanced blocking method with a block size of 4. The block randomization method is such that the allocation sequence is written before the start of the research. Given that the two groups will be studied, 4 blocks are used and each letter is assigned to a group (A: intervention group: B control group). All possible modes are written and numbered for a block of 4. Then, in a simple random method (using a table of random numbers), a number of numbers are selected from the block numbers and by writing the contents of the blocks related to those numbers (until the specified sample size is reached), The random assignment sequence is specified.

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 affiliated to Qazvin University of Medical Sciences

Street address

Bahonar Boulevard

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2020-09-30, 1399/07/09

Ethics committee reference number

IR.QUMS.REC.1399.252

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**

Severity of PMS symptoms

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

Daily record of premenstrual syndrome symptoms

Secondary outcomes**1****Description**

General self-efficacy

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

General self-efficacy questionnaire

2

Description

Professional QoL

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

Professional QoL questionnaire

3

Description

The impact of premenstrual syndrome on daily life

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

PMS-Impact Questionnaire

4

Description

Coping with premenstrual symptoms

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

Coping with premenstrual symptoms Scale

5

Description

Anxiety and Depression

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

Hospital Anxiety and Depression Scale

6

Description

Fear of covid

Timepoint

Before the intervention, immediately and two months after the intervention

Method of measurement

Fear of Covid-19 scale

Intervention groups

1

Description

Intervention group: Cognitive-behavioral therapy based on social networks

Category

Behavior

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers affiliated to Guilan University of Medical Sciences, Rudbar city

Full name of responsible person

Zainab Alimoradi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Mohammad Mahdi Emam Jomeh

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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

Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Zainab Alimoradi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Full name of responsible person

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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

Not applicable

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

The study-related files will be shared as supplementary articles after the end of the studies and at the time of publication of the results

When the data will become available and for how long

after the end of the studies and at the time of publication of the results

To whom data/document is available

All individuals

Under which criteria data/document could be used

In order to use the data for secondary data analysis or meta-analysis and by e-mail request to the responsible author

From where data/document is obtainable

Email to the person in charge

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

Email to the person in charge

Comments