Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 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)

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+98 28 3333 6003

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z.alimoradi@qums.ac.ir

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

Age
From **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
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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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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
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