Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of mindfulness training with “mindfulness coach ”mobile app on increasing the quality of life and reducing the symptoms of people with premenstrual syndrome

Protocol summary

Study aim

Evaluate the effectiveness of mindfulness training with Persian version of “mindfulness coach ” mobile App on increasing the quality of life and reducing the symptoms of people with premenstrual syndrome.

Design

A clinical trial with experimental and control groups, with parallel, randomized groups, on 80 patients.Excel software rand function was used for randomization.

Settings and conduct

All steps are done through cyberspace. Each of the 80 samples is randomly assigned to one of the groups using the rand function of Excel software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Minimum age 25 years and maximum 45 years; Higher education than diploma; Moderate to severe premenstrual syndrome (based on PSST questionnaire); Having regular menstruation (intervals between two menstrual periods 33-28 days and bleeding duration between 2 to 7 days); Access to the internet and smartphone Exclusion criteria: Any menstrual disorders in 3 months before the study; Simultaneous participation in other studies; Undergoing any medication to alleviate the symptoms of premenstrual syndrome; Physical or mental illness using self-report questionnaire and general health questionnaire;

Intervention groups

For the experimental group, 2 training sessions will be held via Skype, in which the mindfulness and how to use it by mobile App will be taught, then they will perform the exercises specified in the App for at least 15 minutes a day for 8 weeks. The control group is told that they are on the waiting list for training for 2 months.

Main outcome variables

Physical, emotional and behavioral symptoms of premenstrual syndrome; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180607040000N2**
Registration date: **2021-11-28, 1400/09/07**
Registration timing: **retrospective**

Last update: **2021-11-28, 1400/09/07**
Update count: **0**

Registration date

2021-11-28, 1400/09/07

Registrant information

Name

Komeil Zahedi Tajrishi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 1657

Email address

zahedi.komeil@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-20, 1400/07/28

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of mindfulness training with “mindfulness coach ”mobile app on increasing the quality of life and reducing the symptoms of people with premenstrual syndrome

Public title
The effectiveness of mindfulness training on premenstrual syndrome

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum age 25 years and maximum 45 years Higher education than diploma Moderate to severe premenstrual syndrome (based on PSST questionnaire) Having regular menstruation (intervals between two menstrual periods 33-28 days and bleeding duration between 2 to 7 days) Achieving a score less than or equal to 23 in the general health questionnaire (based on the GHQ-28 questionnaire, a score of 23 or lower is a sign of health) Access to the internet and smartphone

Exclusion criteria:
Suffering any menstrual disorders in the 3 months before the study Participating in other studies Undergoing any type of medication to alleviate the symptoms of PMS Suffering physical and Mental Illness Using Self-Reporting Questionnaire and General Health Questionnaire (GHQ-28)

Age
From **25 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample members are selected by simple randomization method through the rand function of Excel software. In this way, with using the analysis ToolPak plugin, which is responsible for analyzing data using statistical techniques, using the Random Number Generation option and then placing the required parameters related to the production of a random number such as (number of variables, number of random numbers, statistical distribution, parameters The desired distribution random seed) and the selection of the discrete distribution (uniform distribution) will produce random or natural random numbers. Based on this, Excel software automatically assigns the sample members to the two groups of the research in a completely random way.

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 Iran University of Medical Sciences

Street address
Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1333813444

Approval date
2021-10-18, 1400/07/26

Ethics committee reference number
IR.IUMS.REC.1400.659

Health conditions studied

1

Description of health condition studied
premenstrual syndrome/Premenstrual tension syndrome

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Physical symptoms of premenstrual syndrome

Timepoint
Before intervention, After intervention

Method of measurement
The Iranian version of the premenstrual symptoms screening tool (PSST); by answering question 14

2

Description
Emotional symptoms of premenstrual syndrome

Timepoint
Before intervention, After intervention

Method of measurement
The Iranian version of the premenstrual symptoms screening tool (PSST); by answering questions 1,2,3,4,13

3

Description
Behavioral symptoms of premenstrual syndrome
Timepoint
Before intervention, After intervention
Method of measurement
The Iranian version of the premenstrual symptoms screening tool (PSST); by answering questions 5-12

4

Description
Quality of life
Timepoint
Before intervention, After intervention
Method of measurement
12-Item short form survey health-related quality of life questionnaire(SF-12).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group receives mindfulness training. Initially, 2 training sessions will be held via Skype, in which the concepts related to mindfulness and how to use it by the software will be taught, then the participants will be asked to do at least 15 minutes of exercises specified in the software for 8 weeks a day. The content of 8 software sessions is: Week 1: mindful eating exercise (Audio); your experience of mindful eating; body scan exercise (audio); your experience of body scanning; first week lesson; homework. Week 2: breathing with mindfulness; meditation situations (video); acoustic breathing awareness training; remembering and forgetting; four important skills; second week lesson; homework. Week 3: mindfulness of body movement; practice to the point of endurance; conscious mind stretching movements (audio and video); audio breathing practice in three steps; physical barometer; approach and avoidance; homework. Week 4: managing reactions; learn the answer instead of the reaction; conscious mind walking (audio); what is anxiety? mindfulness of breathing and body (audio); mindfulness of sounds and thoughts (audio); inevitable consciousness (audio); attention with valve activity; homework. Week 5: accept all experiences; resilience; practicing companionship with unpleasant emotions (audio); be kind to yourself; practice breathing in three steps; homework. Week 6: give meaning; mindfulness and mental production; the conscious connection of the mind with thoughts; mindfulness with thoughts (audio); three ways to deal with distress; useless thought pattern; using breathing exercises to counteract thoughts; homework. Week 7: take good care of yourself; apply breathing exercises and choose a practical step; act mindfully; anxiety indicators and practical strategies; energizing and debilitating activities; homework. Week 8: living with the mindfulness, stay mindful, 21 keep mindfulness exercises to mindfulness in the workplace.
Category
Treatment - Other

2

Description
Control group: did not receive any treatment interventions and were merely put on the waiting list.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Behavioral Sciences and Mental Health Clinic
Full name of responsible person
Dr. Komeil Zahedi Tajrishi
Street address
School of Behavioral Sciences and Mental Health, Mansou of Behavioral Sciences and Mental Health, Mansouri St, Niyayesh St, Sattarkhan St, Tehran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Hossein Keyvani
Street address
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Komeil Zahedi Tajrishi

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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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)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable