Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Efficacy of Unified Trans diagnostic Treatment on Cognitive Mechanisms of Emotion Regulation, Sleep Disorder and Symptoms Remission of Premenstrual Syndrome (PMS)

Protocol summary

Study aim

The aim of present study is the Efficacy of Unified Trans diagnostic Treatment on Cognitive Mechanisms of Emotion Regulation, Sleep Disorder and Symptoms Remission of Premenstrual Syndrome (PMS).

Design

A randomized, double -blind, with parallel groups clinical trial. 40 patients with Premenstrual symptoms in two groups (20 people) of experimental and control are assigned randomly.

Settings and conduct

Location is Taleghani hospital.40 patients are selected. 20 patients in experimental group and 20 patients in control group are assigned randomly. In this double-blind study, the psychiatrist and data analyzer were kept blind to the treatment. In fact, participants pick up envelopes inside the box randomly which are in an unspecified wrapper.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of premenstrual syndrome based on diagnostic and Statistical Manual of Mental Disorders (DSM), Lack of mental retardation, No use of psychiatric drugs before the study. Exclusion criteria:Dissatisfaction to participate in study, Psychiatric comorbidity, Drug allergy.

Intervention groups

Intervention group:The first group was treated with Unified Trans diagnostic Treatment: The first group participates in Unified Trans diagnostic Treatment session for 8 weeks (One session per week). Control group: The control group does not receive any treatment.

Main outcome variables

Symptoms of Premenstrual, Quality of sleep, Cognitive emotion regulation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201128049518N1**
Registration date: **2020-12-05, 1399/09/15**
Registration timing: **prospective**

Last update: **2020-12-05, 1399/09/15**
Update count: **0**

Registration date

2020-12-05, 1399/09/15

Registrant information

Name

Nazanin Ahangari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7717 4767

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drahangari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-04, 1399/10/15

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Efficacy of Unified Trans diagnostic Treatment on Cognitive Mechanisms of Emotion Regulation, Sleep Disorder and Symptoms Remission of Premenstrual Syndrome (PMS)

Public title
Unified Trans diagnostic Treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of premenstrual syndrome based on diagnostic and Statistical Manual of Mental Disorders (DSM) Lack of mental retardation No use of psychiatric drugs before the study
Exclusion criteria:
Dissatisfaction to participate in study Psychiatric comorbidity Drug allergy
Age
From **17 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is a simple randomization method. The unit of randomization is individual. Using the table of random numbers, patients are randomly divided into two groups: experimental and control. Even numbers are considered for the experimental group and odd numbers are for the control group. Random allocation is done by the researcher and the clinical caregiver and data analyzer are not aware of the allocation of patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
Treatment allocation was concealed from the psychiatrist and the data analyzer who rated patients by using successively numbered, opaque, and sealed envelopes. In fact, participants pick up envelopes inside the box randomly which are in an unspecified wrapper. They are aware which experimental group they were assigned to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی شهید بهشتی
Street address
Taleghani hospital, Yemen street, Shahid Chamran road, Shahid Beheshti University of Medical Science, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-09-24, 1398/07/02
Ethics committee reference number
IR.SBMU.MSP.REC.1398.668

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
Timepoint
At the first of study (before the intervention), 4 and 8 week after starting psychotherapy sessions in experimental and control group premenstrual symptoms are evaluated.
Method of measurement
Premenstrual Syndrome Screening (PSST)

2

Description
Quality of sleep
Timepoint
At the first of study (before the intervention), 4 and 8 week after starting psychotherapy sessions in experimental and control group quality of sleep is evaluated.
Method of measurement
Iowa Sleep Disturbances Inventory (ISDI)

3

Description

تنظیم شناختی هیجان

Timepoint

At the first of study (before the intervention), 4 and 8 week after starting psychotherapy sessions in experimental and control group cognitive emotion regulation is evaluated.

Method of measurement

Cognitive Emotion Regulation Questionnaire (CERQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The first group was treated with Unified Trans diagnostic Treatment: The first group participates in Unified Trans diagnostic Treatment session for 8 weeks (One session per week).

Category

Treatment - Other

2

Description

Control group: The control group does not receive any treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Nazanin Ahangari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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ایران، تهران، دانشگاه علوم پزشکی شهید بهشتی، بزرگراه شهید چمران، خیابان یمن، بیمارستان طالقانی

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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

Shahid Beheshti 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Saba Hasanvandi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to main outcome or like that , can be share.

When the data will become available and for how long

Start of access, 6 months after publishing the results

To whom data/document is available

Only people working in academic institutions could apply.

Under which criteria data/document could be used

People who are conducting clinical trials in this field could apply.

From where data/document is obtainable

By referring to the electronic address: drahangari@sbmu.ac.ir

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

The applicant can receive information by registering the exact personal details.

Comments