Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

evaluate the effectiveness of Emotion-Focused therapy on outcome treatment in premenstrual dysphoric disorder

Protocol summary

Study aim
Determining the effectiveness of Emotion-Focused therapy (EFT) on the outcome of treatment of women with Premenstrual dysphoric disorder (PMDD)

Design
A clinical trial with a control group, one-sided blind, block randomized. It is done with 48 samples, 24 of whom are the experimental group and 24 are the control group.The rand function of Excel software was used for randomization.

Settings and conduct
Sampling was done in the form of online research notices. The implementation took place in a private clinic. The evaluator and statistical analyst are blind to the research process, but the researcher and the participants are not blind to the research.

Participants/Inclusion and exclusion criteria
Inclusion criteria: woman with PMDD based on SCID-5; age range of 18 to 44 years old; regular menstrual cycle; at least diploma education. Exclusion criteria: pregnancy; breastfeeding (within the last 6 months); menopause; having certain medical diseases; having any psychiatric disorder that the person is prescribed for she uses medicine; use of hormonal birth control methods; use of drugs.

Intervention groups
The implementation of the treatment is individual and was done during 16 weekly treatment sessions. After taking the pre-test, the treatment begins. The treatment consists of three stages.1-therapeutic bond and promoting client awareness2-evocation and exploration 3- focused on emotion transformation.Then the post-test is performed. The waiting list method was used in the control group. After completing the treatment, follow-up will be done after three months.Then, treatment will be done individually by the researcher for the subjects of the control group who are willing to participate in the treatment.

Main outcome variables
Difficulties in Emotion Regulation; severity of symptoms of PMDD; severity of depression symptoms; severity of anxiety symptoms; severity of stress symptoms

General information

Reason for update

Acronym
PMDD

IRCT registration information
IRCT registration number: **IRCT20220920055998N1**
Registration date: **2023-02-12, 1401/11/23**
Registration timing: **retrospective**

Last update: **2023-02-12, 1401/11/23**
Update count: **0**

Registration date
2023-02-12, 1401/11/23

Registrant information

Name
Saeideh Izadi Dehnavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5566 5516

Email address
izadidehnavi.f@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
2022-04-21, 1401/02/01

Actual recruitment end date
2022-06-22, 1401/04/01
Trial completion date
2022-12-26, 1401/10/05

Scientific title
evaluate the effectiveness of Emotion-Focused therapy on outcome treatment in premenstrual dysphoric disorder

Public title
evaluate the effectiveness of Emotion-Focused therapy in PMDD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of PMDD disorder based on SCID-5 Regular menstrual cycle (25 to 32 days) Minimum education is diploma
Exclusion criteria:
Pregnancy (within the last 6 months) Breastfeeding (during the last 6 months) Menopause Having certain medical diseases (cardiac, respiratory, neurological diseases, high blood pressure, migraine, hormonal problems) according to the subject's self-report. Having any psychiatric disorder for which a person takes medicine Use of hormonal contraceptive methods Drug abuse
Age
From **18 years** old to **44 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
People are assigned to the Emotion-Focused therapy group and the control group by block randomization method. For this purpose, 4 blocks will be used, which will be designed using a random number table, and the allocation of people to the control and intervention groups will be done based on the sequence of the randomization table, which the statistical consultant and the interventionist are aware of.
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluator and statistical analyst are blind to the research process, but the researcher and the participants are not blind to the research.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences ,fifth floor
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-01-26, 1400/11/06
Ethics committee reference number
IR.IUMS.REC.1400.964

Health conditions studied

1

Description of health condition studied
Premenstrual Dysphoric Disorder
ICD-10 code
F38.8
ICD-10 code description
Other specified mood [affective] disorders

Primary outcomes

1

Description
Severity of symptoms in Premenstrual Dysphoric Disorder
Timepoint
Before the intervention, the last session, 3 months after the intervention
Method of measurement
Premenstrual Symptoms Screening Tool-PSST

Secondary outcomes

1

Description
Difficulties in Emotion Regulation
Timepoint
Before the intervention, the last session, 3 months after the intervention
Method of measurement

Difficulties in Emotion Regulation Scale (DERS)

2

Description
Severity of symptoms of anxiety, depression, stress
Timepoint
Before the intervention, the last session, 3 months after the intervention
Method of measurement
Depression, Anxiety, Stress Scale-21 (DASS-21)

Intervention groups

1

Description
Intervention group: In this research, Emotion-Focused Therapy was done individually. To start the Emotion-Focused Therapy, first in a meeting, we talked about the objectives of the research, the principles of secrecy and confidentiality of the participants' information, possible side effects, and the rules of participation in the research. Then, explanations were provided about Pre Menstrual Dysphoric Disorder, available treatments for it and their differences, types of interventions for this disorder, Emotion-Focused Therapy and its effectiveness, duration of sessions, number of sessions, and how to end them. Before the first session, the participants completed the research questionnaires as a pre-test and then entered the treatment.16 treatment sessions, each session 45 minutes, were held weekly. The treatment had three main stages.The first phase refers to an initial stage of treatment, which is focused onestablishing a therapeutic bond and promoting client awareness. This is centered onbuilding a safe and empathic therapeutic alliance and relationship, as well as setting ashared focus for the process, which allows clients to shift their attention inwards andbecome more aware of their experiences.In the second phase, focused on theevocation and exploration of core difficulties of emotional processing, the main goalis to help clients experience their core vulnerabilities by attending, arousing and exploring their maladaptive schemes. Gradual exploration of these experiences allowsreaching to the core experiences of vulnerability. In this phase, therapist and clientwork together in order to access and process the “core pain”.The third and final phase, focused on emotion transformation, involves theconstruction of alternatives by producing new emotions and building new alternativesand meanings.
Category
Treatment - Other

2

Description
Control group: In the control group, the waiting list method was used to comply with ethical principles. After completing the treatment, the questionnaires were given again to the people of both groups, and the follow-up will be done after three months. Then, Emotion-Focused Therapy will be done individually by the researcher for the subjects of the control group who are willing to participate in the treatment.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran institue of psychiatry
Full name of responsible person
Saeideh Izadi Dehnavi
Street address
shahid Mansouri Sreet, Niyayesh Sreet, Satarkhan Avenue
City
Tehran
Province
Alborz
Postal code
1445613111
Phone
+98 21 6655 1655
Email
tip@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Asistance of resarch and technology, Iran University of Medical Sciences
Street address
shahid Mansouri Sreet, Niyayesh Sreet, Satarkhan Avenue
City
Tehran
Province
Tehran
Postal code
1445613111
Phone
+98 21 6655 1655
Email
Ertebat .tip@iums.ac.ir
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

Saeideh Izadi Dehnavi

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

shahid Mansouri Sreet, Niyayesh Sreet, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1145613111

Phone

+98 21 6655 5516

Email

s.izadipsy@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Saeideh Izadi Dehnavi

Position

student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Shahid Mansouri Sreet, Niyayesh Sreet, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

0982166555516

Email

S.izadipsy@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Saeideh Izadi Dehnavi

Position

Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Shahid Mansouri Sreet, Niyayesh Sreet, Satarkhan Avenue

City

Tehran

Province

Tehran

Postal code

1445613111

Phone

+98 21 6655 5516

Email

s.izadipsy@gmail.com

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

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable