Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness comparison of two interventions emotion regulation skills training versus self-helper mood tracking software on female sexual modes, female sexual distress and husband’s sexual satisfaction in medical university students undergoing premenstrual dysphoric disorder

Protocol summary

Study aim

Effectiveness comparison of emotion regulation training intervention versus mood monitoring software on female sexual modes, female sexual distress and spouse sexual satisfaction in medical students with premenstrual dysphoric disorder

Design

In parallel clinical trial, recruitment is made Shahid Sadoughi University student groups . 68 eligible women are given number from 1 to 68. Using random allocation software, women are randomly assigned to group 1, emotion regulation or group 2, using mood monitoring software, based on software output table. Each group of 34 women is then randomly divided into two subgroups 17 women. Blinding is not possible.

Settings and conduct

Group 1 emotion regulation training group receives the intervention based on Skyroom and WhatsApp in one-hour sessions one day a week for eight weeks. Group 2 are asked to share mood monitoring software data with the therapist through WhatsApp once a week.

Participants/Inclusion and exclusion criteria

Married female students aged 19-49, have smartphone, history of diagnosis and treatment of dysphoric disorder based on diagnostic mental disorder 5 and premenstrual calendar for two cycles, symptoms are presence, having sex with spouse , having negative sexual modes, sexual distress and low spouse sexual satisfaction. Exclusion criteria: pregnancy, sexual dysfunction, having physical illnesses, severe mental illness , drug and alcohol addiction, co-participation in another study.

Intervention groups

Group 1 receives intervention emotion regulation skills in Skyroom and WhatsApp in the form of one-hour sessions one day a week for eight weeks. Group 2 are asked to the daily mood record. They are asked to share mood monitoring software data with the therapist through WhatsApp weekly.

Main outcome variables

Female's sexual modes; Female's sexual distress; woman's opinion about her husband's sexual satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220310054250N1**
Registration date: **2022-03-15, 1400/12/24**
Registration timing: **prospective**

Last update: **2022-03-15, 1400/12/24**
Update count: **0**

Registration date

2022-03-15, 1400/12/24

Registrant information

Name

Tahmineh Farajkhoda

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1754

Email address

farajkhoda_t@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-09, 1401/01/20

Expected recruitment end date
2022-05-10, 1401/02/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness comparison of two interventions emotion regulation skills training versus self-helper mood tracking software on female sexual modes, female sexual distress and husband’s sexual satisfaction in medical university students undergoing premenstrual dysphoric disorder

Public title
Emotion regulation skills training versus self-helper mood tracking software on female sexual modes, female sexual distress and husband’s sexual satisfaction in medical university students undergoing premenstrual dysphoric disorder
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Married female students of Shahid Sadoughi University of Medical Sciences aged 19-49 Desire to participate in the study Having an Android or iOS smartphone History of diagnosis and treatment of premenstrual dysphoric disorder based on the seven criteria of DSM5 and in at least two consecutive cycles according to the calendar of premenstrual syndrome and clinical interviews, symptoms are still presence. Having sex with spouse until the end of the study Negative sexual modes Having sexual distress Low spouse sexual satisfaction
Exclusion criteria:
Pregnancy Presence of sexual dysfunction disorder in first half of mensural cycle Having systemic illness Having sever mental disorder Being alcohol or drug abuser Simultaneously participation in other similar study
Age
From **19 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
In parallel Randomized Clinical Trial, recruitment is made Shahid Sadoughi University student groups. 68 eligible women are given number from 1 to 68. Using random allocation software, women are randomly assigned to group 1, emotion regulation or group 2, using mood monitoring software, based on software output table. Each group of 34 women is then randomly divided into two subgroups 17 women. Blinding is not possible.
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
Research Ethics committee of Shahid Sadoughi University of Medical Sciences
Street address
Bahonar
City
Yazd
Province
Yazd
Postal code
۸۹۱۶۸۷۷۴۴۳
Approval date
2022-03-02, 1400/12/11
Ethics committee reference number
IR.SSU.REC.1400.248

Health conditions studied

1

Description of health condition studied
Premenstural Dysphoric Disorder
ICD-10 code
F06.31
ICD-10 code description
Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description
Female sexual modes
Timepoint
Baseline, completion of intervention at week 8, follow-up at week 12 from baseline
Method of measurement
Female sexual modes questionnaire

2

Description

Female sexual distress

Timepoint

Baseline, completion of intervention at week 8, follow-up at week 12 from baseline.

Method of measurement

Female Sexual Distress Scale

3

Description

Woman's opinion about her husband's sexual satisfaction

Timepoint

Baseline, completion of the intervention in week 8, follow-up of study completion in week 12 from baseline.

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group 1 receives the intervention emotion regulation training in Skyroom and WhatsApp in one-hour sessions one day a week for eight weeks.

Category

Behavior

2

Description

Intervention group: group 2 users of mood monitoring software are given explanations related to software installation by the therapist and are asked to, in addition to daily recording of mood, other related factors such as sleep quality, nutritional status, meditation, compassion, relaxation, communication Record with spouse, family and friends as well as favorite pastimes. In addition, a diary of the explanations for these emotions, the cause of their occurrence, and the behavioral responses to these emotions are recorded. They are asked to share mood monitoring software data with the therapist via WhatsApp once a week.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dormitory of Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Ali Dehghani

Street address

Bahonar

City

Yazd

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Postal code

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Phone

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Adehghani42@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amir Hoshang Mehrparvar

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Yazd

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Phone

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Ah.mehrparvar@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Tahmineh Farajkhoda

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work
Clinical Psychologist
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available