Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of the effectiveness of metacognitive therapy, acceptance and commitment therapy and Pilates exercises on emotional self-regulation, loneliness feeling, dysfunctional attitudes, and distress tolerance in the women with premenstrual syndrome

Protocol summary

Study aim

Comparing the effectiveness of metacognitive therapy, acceptance and commitment therapy and Pilates exercise on emotional self-regulation, loneliness, dysfunctional attitudes and distress tolerance of women with premenstrual syndrome.

Design

Experimental research method, 80 people with premenstrual syndrome, available sampling method 4 groups in simple randomization with sealed envelopes, with unblinded parallel groups The experimental groups included metacognition, acceptance-commitment therapy and Pilates exercise Follow-up phase is two months later

Settings and conduct

In the Islamic Azad University in Doroud city in the form of group training of students to improve premenstrual syndrome. First, the subjects were pre-tested, then the interventions were performed on three groups, and the control group did not receive any intervention, then the post-test was performed by filling in the questionnaires, and a follow-up was performed after two months. Blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of the syndrome of the sample based on the screening questionnaire (cut point 28 and above) Lack of medication for menstrual problems before the research Exclusion criteria: Taking psychiatric and psychoactive drugs and other therapies Suffering from psychiatric disorders based on the person's own report

Intervention groups

Acceptance and Commitment Therapy Metacognitive Therapy Pilates exercises control group

Main outcome variables

The most important outcome of this research is comparing the effectiveness of therapeutic interventions of acceptance and commitment, metacognition and Pilates exercises on dysfunctional attitudes, loneliness feelings, psychological distress and emotional self-regulation in women with premenstrual syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230123057194N1**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **retrospective**

Last update: **2023-06-13, 1402/03/23**
Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Azadeh Niroomand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4251 8000

Email address

az.niroomand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-08, 1401/11/19

Expected recruitment end date
2023-02-14, 1401/11/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the effectiveness of metacognitive therapy, acceptance and commitment therapy and Pilates exercises on emotional self-regulation, loneliness feeling, dysfunctional attitudes, and distress tolerance in the women with premenstrual syndrome

Public title
The comparison of the effectiveness of metacognitive therapy, acceptance and commitment therapy and Pilates exercises in the women with premenstrual syndrome
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of the syndrome of the subjects based on the screening questionnaire (cut point 28 and above) Informed consent to participate in research Lack of medication for menstrual problems before the study No abuse of tobacco, drugs and cigarettes
Exclusion criteria:
Taking psychiatric and psychoactive drugs Absence of more than 2 sessions in treatment sessions Simultaneous participation in other courses and therapeutic interventions at the same time as research Drug abuse and smoking Having psychiatric disorders based on the person's self-report
Age
From **18 years** old to **50 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
Available sampling method, simple randomization: each person was presented with 4 sealed envelopes in the number of groups (three experimental groups and one control), based on the choice of an envelope by the subject himself, his placement in a group is done. Individual unit
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 in Research of Islamic Azad University, Borujerd Branch
Street address
No 26, Moazami Alley, Golstan Blvd. Takhti St.
City
Borujerd
Province
Lorestan
Postal code
6915973863
Approval date
2022-04-20, 1401/01/31
Ethics committee reference number
IR.IAU.B.REC.1401.009

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
Premenstrual syndrome cut point score is 28
Timepoint
pre-test (before the intervention), post-test (after the last intervention session), follow-up (two months after the last intervention session)
Method of measurement
Premenstrual Screening Questionnaire (PSST) Steiner et al. (2003)

Secondary outcomes

1

Description
the intervention should increase self-emotional regulation
Timepoint

pre-test (before the intervention), post-test (after the last intervention session), follow-up (two months after the last intervention session)

Method of measurement

Emotional self-regulation questionnaire (ERQ) Gross and John (2003)

2

Description

the intervention should decrease the loneliness feeling

Timepoint

pre-test (before the intervention), post-test (after the last intervention session), follow-up (two months after the last intervention session)

Method of measurement

Loneliness Scale-Third Edition (UCLA LS3) Russell (1996)

3

Description

the intervention should decrease the dysfunctional attitudes

Timepoint

pre-test (before the intervention), post-test (after the last intervention session), follow-up (two months after the last intervention session)

Method of measurement

Dysfunctional Attitudes Questionnaire (DAS) by Beck and Wiseman (1978)

4

Description

the intervention should increase the distress tolerance

Timepoint

pre-test (before the intervention), post-test (after the last intervention session), follow-up (two months after the last intervention session)

Method of measurement

Distress Tolerance Scale (DTS) Simmons and Gaher (2005)

Intervention groups

1

Description

The structure of the acceptance and commitment treatment protocol sessions, which is taken from the article by Hayes et al. (2016), is implemented in a group for eight weeks and a two-hour session every week for women with PMS.

Category

Other

2

Description

The structure of the sessions of metacognitive therapy protocol, which is taken from the article of Wells (2009), is implemented for ten weeks and a two-hour session every week for women with premenstrual syndrome.

Category

Other

3

Description

The structure of the Pilates exercise protocol session, which is taken from the research of Taghizadeh et al. (2020) and Ghorbanian and Mahmoodpoor (2019), is performed for eight weeks and three one-hour sessions every week for women with premenstrual syndrome as a group.

Category

Other

4

Description

Control group: without intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Doroud Branch

Full name of responsible person

Azadeh Niroomand

Street address

No. 26, Moazami Alley, Golstan Blvd, Takhti St.

City

Borujerd

Province

Lorestan

Postal code

6915973863

Phone

+98 66 4253 0877

Email

az.niroomand@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Personal

Full name of responsible person

Azadeh Niroomand

Street address

Takhti St.

City

Borujerd

Province

Lorestan

Postal code

6915973863

Phone

+98 66 4253 0877

Email

az.niroomand@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University. Borujerd Branch

Full name of responsible person

Azadeh Niroomand

Position

Ph. D Student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Nawab Square - Yadgar Imam St.

City

Borujerd

Province

Lorestan

Postal code

6915136111

Phone

+98 66 4251 8000

Fax

+98 66 4251 8013

Email

az.niroomand@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Azadeh Niroomand

Position

PhD. student

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Navab Sq. Yadegare Emam Street

City

Borujerd

Province

Lorestan

Postal code

6915973863

Phone

+98 66 4251 8000

Fax

Email

az.niroomand@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Azadeh Niroomand

Position

PhD. student

Latest degree

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Other areas of specialty/work

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Street address

Navab Sq. Yadegare Emam Street

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Fax

Email

az.niroomand@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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