Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Effectiveness of stress inoculation training (SIT) counseling approach on anxiety, and depression of students with premenstrual syndrome

Protocol summary

Study aim
Determining the effectiveness of stress inoculation training approach on anxiety and depression of students with premenstrual syndrome
Design
Randomized controlled clinical trial
Settings and conduct
Dormitory students of Babol University of Medical Sciences are selected as available, then they are given a 14-question anxiety/depression questionnaire. Any person who has a score of 8 or higher in one of the following components, i.e. depression or anxiety, will enter the study with the diagnosis of depression/anxiety symptoms. Students who meet the study entry criteria are randomly assigned to two intervention and control groups. Then, all of them are given questionnaires 5 days before menstruation and maximum in the first 2 days of menstruation, and students with moderate and high PMS are included in the study based on the PSST questionnaire.
Participants/Inclusion and exclusion criteria
Inclusion criteria: students with premenstrual syndrome. Exclusion criteria: students without premenstrual syndrome.
Intervention groups
Recipient of six training sessions on the stress inoculation approach
Main outcome variables
Change in anxiety and depression scores

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230130057274N2**
Registration date: **2023-12-31, 1402/10/10**
Registration timing: **retrospective**
Last update: **2023-12-31, 1402/10/10**
Update count: **0**
Registration date
2023-12-31, 1402/10/10

Registrant information
Name
Hajar Adib-Rad
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-30, 1401/08/08
Expected recruitment end date
2023-06-21, 1402/03/31
Actual recruitment start date
2022-10-30, 1401/08/08
Actual recruitment end date
2023-06-21, 1402/03/31
Trial completion date
2023-06-21, 1402/03/31

Scientific title
Effectiveness of stress inoculation training (SIT) counseling approach on anxiety, and depression of students with premenstrual syndrome

Public title
Effectiveness of stress inoculation training approach on premenstrual syndrome
Purpose
Supportive
Inclusion/Exclusion criteria

Inclusion criteria:
Being Iranian Students living in the student dormitory of Babol University of Medical Sciences Declaration of consent to participate in the study Having premenstrual syndrome Having regular menstrual cycles with intervals of 21 to 35 days and a duration of 3 to 7 days at least during the last six months Having 5 symptoms of premenstrual syndrome for two consecutive months Having symptoms of depression or anxiety with a score of 8 or higher Access to the smartphone Age range from 18 to 38 years

Exclusion criteria:
Use of antidepressants and anxiety medications during the study Participation in other psychological interventions such as psychotherapy, meditation, yoga Occurrence of stressful events at least six months before the start of the study Suffering from genital diseases and known and chronic underlying diseases Taking birth control pills Hormonal disorders and irregular menstruation Current or history of severe mental illness such as severe depression, bipolar disorder, and suicidal thoughts Drug addiction and consumption of psychoactive substances or alcohol

Age
From **18 years** old to **38 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**
Actual sample size reached: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects are randomly divided into two groups after applying the inclusion and exclusion criteria in the form of random allocation using the alternative block method. The size of the blocks is 4 and using the statistical software, 4 blocks will be produced 25 times. Considering that the sampling is done in one center, a sample list of 100 items will be produced. Using this randomly generated list, the participants are assigned to two groups of 50 people. The random sequence of people in the intervention or control groups is done through block building with a ratio of 1:1, and the researcher cannot predict the placement of the next person in any of the two groups.

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
Health Research Institute - Babol University of Medical Sciences (Research Ethics Committee)

Street address
Ganj Afrooz St., Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
47176-47745

Approval date
2022-10-30, 1401/08/08

Ethics committee reference number
IR.MUBABOL.HRI.REC.1401.156

Health conditions studied

1

Description of health condition studied
Anxiety and depression

ICD-10 code
F41.2

ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Anxiety

Timepoint
Before the intervention, immediately after the end of the intervention in the luteal phase, the first and second menstrual cycle after the intervention

Method of measurement
Hospital anxiety and depression questionnaire

2

Description
Depression

Timepoint
Before the intervention, immediately after the end of the intervention in the luteal phase, the first and second menstrual cycle after the intervention

Method of measurement
Hospital anxiety and depression questionnaire

Secondary outcomes

1

Description

Stress

Timepoint

Before the intervention, immediately after the end of the intervention in the luteal phase, the first and second menstrual cycle after the intervention

Method of measurement

Perceived Stress Questionnaire 14

2

Description

Performance

Timepoint

Before the intervention, immediately after the end of the intervention in the luteal phase, the first and second menstrual cycle after the intervention

Method of measurement

Sheehan's Disability Questionnaire

3

Description

Psychological well-being

Timepoint

Before the intervention, immediately after the end of the intervention in the luteal phase, the first and second menstrual cycle after the intervention

Method of measurement

Riff's Psychological Well-Being Questionnaire

4

Description

Symptoms of premenstrual syndrome

Timepoint

Before the intervention, immediately after the end of the intervention in the luteal phase, the first and second menstrual cycle after the intervention

Method of measurement

Premenstrual Symptoms Screening Questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, SIT therapy method is performed individually, which includes 6 consecutive sessions (one session per week) and the duration of each session is 30-45 minutes. The content of the meetings includes:The first session: Conceptualization of the therapeutic model, gaining awareness about the relationship between premenstrual syndrome and negative emotions, acquiring the skills to identify and evaluate thoughts and feelings, relaxation techniquesThe second session: acquiring the ability to identify negative automatic thoughts and begin to change them, relaxation techniquesThe third session: acquiring the ability to recognize cognitive errors, relaxation techniquesThe fourth session: acquiring the skill of correcting auto-negative thoughts, calming techniques The fifth session: acquiring the ability to evaluate daily activities, stress coping techniques, relaxation techniquesThe sixth session: developing effective coping plans for stress, challenges of ending treatment, complete relaxation techniques

Category

Treatment - Other

2

Description

Control group: This group of students does not receive SIT treatment.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences dormitories

Full name of responsible person

Mahbobeh Faramarzi

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School of Medicine, Babol University of Medical Sciences, Ganj Afrooz St., Babol, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajab Nia

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ramazan69@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Hajar Adib-Rad

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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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