

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effectiveness Relaxation by Hypnotherapy on Depression, Anxiety and stress in Female Students with Premenstrual Syndrome

Protocol summary

Study aim

the effectiveness of relaxation by Hypnotherapy on depression, anxiety and stress in female Students with premenstrual syndrome

Design

A clinical trial with a control group, with parallel groups, blinded, randomized, lottery was used for randomization.

Settings and conduct

The intervention study was conducted in the dormitories of girls in Kermanshah University of Medical Sciences. First, students were screened for premenstrual syndrome, then those who were eligible for the study were included in the study and pre-test from both intervention and Control was taken and then for the intervention group, relaxation technique was performed using hypnosis. After the sessions, participants from both groups were retested and the results were compared.

Participants/Inclusion and exclusion criteria

Entry requirements: Having ages 27-18 years, Having regular menstruation (interval between two cycles of 35-22 days), Having normal menstrual bleeding 3 to 8 days, Earning a score of 18 up by the screening tool for premenstrual syndrome (moderate and severe) No entry conditions: History of drug use or cigarette, History of ovarian cyst or female surgeries, History of underlying diseases affecting premenstrual syndrome (including cardiovascular, respiratory, renal, hypertension, asthma, diabetes, epilepsy, migraine, thyroid, anemia and diseases Nervous and psychological), Having a history of depression history of taking antidepressants, sedation and hormones, adverse events or deaths of loved ones and divorce in the last three months

Intervention groups

Experimental group: received 3 sessions of relaxation using Hinutism. Control group: It was their turn to relax after the post-test.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151208025433N5**

Registration date: **2020-09-27, 1399/07/06**

Registration timing: **retrospective**

Last update: **2020-09-27, 1399/07/06**

Update count: **0**

Registration date

2020-09-27, 1399/07/06

Registrant information

Name

Fatemeh Dehghan

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

2019-11-01, 1398/08/10

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2020-02-19, 1398/11/30

Scientific title

Effectiveness Relaxation by Hypnotherapy on Depression, Anxiety and stress in Female Students with Premenstrual Syndrome

Public title

Effectiveness Relaxation by Hypnotherapy on Depression, Anxiety and stress

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having ages 27-18 years Having regular menstruation (interval between two cycles of 35-22 days) Earning a score of 18 up by the screening tool for premenstrual syndrome (moderate and severe) Having normal menstrual bleeding 3 to 8 days

Exclusion criteria:

History of drug use or cigarette History of ovarian cyst or female surgeries History of underlying diseases affecting premenstrual syndrome (including cardiovascular, respiratory, renal, hypertension, asthma, diabetes, epilepsy, migraine, thyroid, anemia and diseases Nervous and psychological) Having a history of depression history of taking antidepressants sedation and hormones, adverse events or deaths of loved ones and divorce in the last three months

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation based on lottery in that individuals were given numbers from one to thirty and even numbers were assigned to the control group and odd numbers to the intervention group.

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 of Kermanshah University of Medical Sciences

Street address

Vice Chancellor of Research, No 2 Building , Kermanshah University of Medical Sciences, Martyr Shahid Beheshti, Kermanshahi

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-08-18, 1399/05/28

Ethics committee reference number

IR.KUMS.REC.1399.520

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F34.9

ICD-10 code description

Persistent mood [affective] disorder, unspecified

Primary outcomes

1

Description

Depression

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

DASS - 21 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Three sessions of hypnosis treatment were provided for the intervention group Outline of the issues raised during the hypnosis intervention includes the following: In the first session for the experimental group (relaxation with hypnotherapy), premenstrual syndrome and the physical and psychological consequences of this disorder are explained and the purpose of relaxation With the method of hypnosis and virtual reality technology for each experimental group is

expressed separately and the number of sessions and its duration are discussed. For the group (hypnotherapy), a number of hypnosis techniques are performed and the confidentiality of information is emphasized and informed informed consent is obtained and permission to publish the results is obtained from the research units in the form of a research report. The second session is devoted to explaining hypnotherapy and correcting misconceptions about hypnosis, relaxation practice guided by mental imagery, and hypnosis induction. In the last session, they are taught self-hypnosis techniques to use when they feel the need.

Category

Behavior

2

Description

Control group: In order to observe justice, after conducting the research, hypnosis sessions were also performed for the control group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Dehghan

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Vice President of Research, Building 2, Kermanshah University of Medical Sciences, Martyr Shahed Behesht, Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fariad Najafi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Sosan Heydarpour

Position

Associate professor Department of Midwifery, School of Nursing and Midwifery, Kermanshah University

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Department of Midwifery, School of Nursing and
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Latest degree

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Other areas of specialty/work

Psychology

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Person responsible for updating data**Contact****Name of organization / entity**

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Information about the research included results

When the data will become available and for how long

12 months

To whom data/document is available

Researchers working in Academia

Under which criteria data/document could be used

Meta-analysis

From where data/document is obtainable

fateme.dehghan1368@gmail.com

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

Maximum one week

Comments