Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Iran (Islamic Republic of)

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+98 83 3432 1439

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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

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Kermanshah

Province
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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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