

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of Relaxation Effectiveness by Hypnotherapy and Virtual Reality Technology on Depression, Anxiety and stress in Female Students with Premenstrual Syndrome

Protocol summary

Study aim

Comparison of Relaxation Effectiveness by Hypnotherapy and Virtual Reality Technology on Depression, Anxiety and stress in Female Students with Premenstrual Syndrome

Design

In this research , 90 female students with premenstrual syndrome who are eligible to enter the study are selected. Participants are randomly assigned to three intervention and control groups and each participant is assigned a code.

Settings and conduct

In this research, after obtaining the necessary permissions, using qualitative sampling, referring to the Kermanshah University of Medical Sciences dormitories, after obtaining informed consent, eligible samples are selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having an age range of 27-18 years; having regular menstruation (interval between two cycles of 35-22 days); having normal menstrual bleeding of 3 to 8 days; earning a score of 18 up from the screening tool for premenstrual syndrome (cases Moderate and severe). Exclusion criteria: history of drug use or cigarette, history of ovarian cysts or women's surgery, history of underlying diseases affecting premenstrual syndrome (including cardiovascular, respiratory, renal, hypertension, asthma, diabetes, epilepsy, migraine, thyroid , Anemia and psychiatric illnesses) having a history of mental illness and depression; history of taking antidepressants, sedation and hormones, adverse events or deaths of loved ones and divorce in the last three months.

Intervention groups

Intervention group 1: Relaxation with virtual reality
Intervention group 2: Relaxation with hypnosis

Main outcome variables

anxiety, depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151208025433N4**

Registration date: **2017-11-29, 1396/09/08**

Registration timing: **prospective**

Last update: **2017-11-29, 1396/09/08**

Update count: **0**

Registration date

2017-11-29, 1396/09/08

Registrant information

Name

Fatemeh Dehghan

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3432 1439

Email address

srghasemi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of Relaxation Effectiveness by Hypnotherapy and Virtual Reality Technology on Depression, Anxiety and stress in Female Students with Premenstrual Syndrome

Public title
Comparison of Relaxation Effectiveness by Hypnotherapy and Virtual Reality Technology 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) Having normal menstrual bleeding 3 to 8 days Earning a score of 18 up by the screening tool for premenstrual syndrome (moderate and severe)

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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation based on the lottery will be allocated to the control group and the intervention teams.

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

2017-10-25, 1396/08/03

Ethics committee reference number

IR.KUMS.REC.1396.390

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F39

ICD-10 code description

Unspecified mood [affective] disorder

Primary outcomes

1

Description

Depression

Timepoint

Before treatment

Method of measurement

DASS - 21 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Relaxation

Category

Behavior

2

Description

Intervention group: Hypnosis

Category
Behavior

3

Description

Control group: Failure to do extra work

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kermanshah University of Medical Sciences

Full name of responsible person
Fatemeh Dehghan

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

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3432 1439

Email
fateme.dehghan1368@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Korosh Hamzai

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

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Phone
+98 83 3836 0014

Email
k.hamzei@yahoo.com

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

Street address
Faculty of Nursing and Midwifery, Dolatabad,
Kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
6717698563

Phone
+98 83 3827 9394

Email
s.heydarpour1394@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Fatemeh Dehghan

Position
Department of Midwifery, School of Nursing and
Midwifery, Kermanshah University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

Street address
Faculty of Nursing and Midwifery, Dolatabad,
Kermanshah

City
Kermanshah

Province

Kermanshah

Postal code

6717698563

Phone

+98 83 3432 1439

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fateme.dehghan1368@gmail.com

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is 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**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Fateme Dehghan

Position

PhD

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street addressPart 18, Block 2, alleys action 21, Tang Knsh streets,
Zfr- Town, Kermanshah**City**

Kermanshah

Province

Kermanshah

Postal code

6717698563

Phone

+98 83 3432 1439