

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of two methods of group cognitive- behavioral therapy and group cognitive hypnosis on Degree of depression in girl students with premenstrual syndrome.

Protocol summary

Study aim

1-comparison of depression score before and after intervention in cognitive-behavioral group therapy in female students with premenstrual syndrome 2-comparison of depression scores before and after cognitive hypnosis intervention in female students with premenstrual syndrome 3- comparison of depression score in two cognitive-behavioral therapy groups and cognitive hypnosis in female students with premenstrual syndrome

Design

community-based and pragmatic control group, with parallel groups, blinded and randomized.

Settings and conduct

The aim of this study was to compare the effects of two methods of cognitive-behavioral group therapy and group cognitive hypnosis on depression in female students in 2018 in Islamic Azad University. The type of research is experimental . The study groups consisted of two experimental groups and one control group, who were not aware of the inclusion of one-way blind in intervention groups and only participated in a study to study the premenstrual syndrome.

Participants/Inclusion and exclusion criteria

Entering the study include being a student in one of the psychology courses, ages 18 to 50, the absence of mental disorders, including depression and PMS in the family, and the lack of drug use, and the exit criterion is the existence of a negative Spigel test for hypnosis.

Intervention groups

The first test group (cognitive-behavioral group therapy)
The second test group (group of cognitive hypnosis treatment)
The control group(non intervention)

Main outcome variables

Comparison of the Effect of Two Psychological Therapies on depression; The Effect of Two Psychological Therapies on depression in Students

General information

Reason for update

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT2016090228931N1**

Registration date: **2016-09-02, 1395/06/12**

Registration timing: **prospective**

Last update: **2018-04-29, 1397/02/09**

Update count: **1**

Registration date

2016-09-02, 1395/06/12

Registrant information

Name

Leila Moghtader

Name of organization / entity

Azad University

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Rasht Azad University of Medical Sciences

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two methods of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students with premenstrual syndrome.

Public title

Comparison of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being a student in one of the psychology courses aged 18 to 50 years lack of medication

Exclusion criteria:

negative spiegel test for hypnosis

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, simple randomization method will be used. In this way, people in the test and control groups or lottery will be selected and will be replaced by lottery in these groups. Accident Unit: Individual Randomization Tool: Draw a random numbered table Participants will not be aware of the status of the target group until the completion of the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will not be aware of the status of the target group until the completion of the study.

Placebo

Not used

Assignment

Parallel

Other design features

After sampling, two experimental groups and one control group will be separat by lottery

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Rasht University of Medical Sciences

Street address

Rasht, Pole Taleshan, Azad University

City

Rasht

Province

Guilan

Postal code

4154974416

Approval date

2016-08-10, 1395/05/20

Ethics committee reference number

IR.GUMS.REC.1396.534

Health conditions studied**1****Description of health condition studied**

Premenstrual Syndrome

ICD-10 code

F99

ICD-10 code description

Mental disorder, not otherwise specified

Primary outcomes**1****Description**

Depression

Timepoint

Before and after the intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

The first experimental group: eight 2-hour sessions of cognitive behavior therapy

Category

Behavior

2**Description**

The first experimental group: eight 2-hour sessions of Cognitive Hypnotherapy

Category
Behavior

3

Description
No action

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Holistic Nursing Research Center

Full name of responsible person
Sedigheh Pakseresht

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Rasht, belt martyr Beheshti, Faculty of Nursing and Midwifery

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moghtaderleila@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Gilan University of Medical Sciences

Full name of responsible person
Sedigheh Pakseresht

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Grant name
Guilan University of Medical Science

Grant code / Reference number

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

Title of funding source
Vice Chancellor for research of Gilan 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
Azad University

Full name of responsible person
Leila Moghtader

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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

Azad University

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Psychology

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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