

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of hypnosis and muscle relaxation exercises in symptom relief of premenstrual syndrome

Protocol summary

Summary

This study is aimed to assess the effectiveness of hypnosis in symptom relief of premenstrual syndrome and comparison with muscle relaxation exercises. Study population are 30 females referred to the two hospitals affiliated to Babol University of Medical Sciences who have premenstrual syndrome according to premenstrual syndrome screening scale and not to have exclusion criteria in baseline psychiatric visit. These 30 patients will be allocated randomly in two case (intervention) and control groups. 15 patients in case group will be under a standardized course of hypnotherapy included 6 weekly sessions of hypnosis (duration of each session: almost 30 minutes). In 15 patients of control group, six sessions of muscle relaxation exercises will be educated weekly. Hypnosis and muscle relaxation exercises will be carried out by a psychiatrist, faculty member, who has passed training course of hypnosis and has certificate of participation in this course. The status of the patients in both two groups will be evaluated in the first and third months after treatment with premenstrual symptoms screening and severity tool.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092822991N7**

Registration date: **2016-10-12, 1395/07/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-12, 1395/07/21

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Babol University of Medical Sciences

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2016-09-10, 1395/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of hypnosis and muscle relaxation exercises in symptom relief of premenstrual syndrome

Public title

Effectiveness of hypnosis in symptom relief of premenstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having premenstrual syndrome criteria; signing informed consent form Exclusion criteria: to have other organic diseases (based on the patient statement); serious psychiatric disorders (in baseline psychiatric

visit); continuous use of special drugs, contraceptives or alcohol, narcotics and psychotropic drugs; not filling out and signing informed consent form; previous experience of hypnosis; pregnancy or breast feeding

Age

From **10 years** old to **60 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random numbers table is used for randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

University of Medical Sciences, Babol

City

Babol

Postal code

Approval date

2015-12-06, 1394/09/15

Ethics committee reference number

Mubabol.Rec.1394.185

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

Primary outcomes

1

Description

premenstrual symptoms

Timepoint

first and third months of treatment

Method of measurement

premenstrual symptoms screening tool

Secondary outcomes

1

Description

mental status of the patients

Timepoint

weekly

Method of measurement

psychiatric visit

Intervention groups

1

Description

Intervention group: a standardized course of hypnotherapy included 6 weekly sessions of hypnosis (duration of each session: almost 30 minutes)

Category

Treatment - Other

2

Description

Control group: six sessions of weekly muscle relaxation exercises

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Sussan Moudi, MD

Street address

Ayatollah Rouhani Hospital, Ganjafrooz avenue, Babol

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2

Recruitment center

Name of recruitment center

Shahid Yahyanejad Hospital

Full name of responsible person

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Babol University of Medical Sciences

Full name of responsible person

Ali Akbar Moghadamnia, PhD

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Grant name**Grant code / Reference number**

2762

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

Yes

Title of funding source

Vice Chancellor for research of Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

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Assistant Professor

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty*

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty