Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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

City
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2

Recruitment center

Name of recruitment center
Shahid Yahyanejad Hospital

Full name of responsible person
Sussan Moudi, MD

Street address
Shahid Yahyanejad Hospital, Modarres Avenue, Babol
City
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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
Street address
Babol University of Medical Sciences, Ganjafrooz Avenue, Babol
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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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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