# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Jun 2026

## Efficacy of hypnotherapy on pain intensity and psychological distress among women with premenstrual dysphoric disorder: a clinical randomized trial

## Protocol summary

**Study aim**

1- Efficacy of hypnotherapy protocol on perceived pain intensity in women with premenstrual dysphoric disorder 2- Efficacy of hypnotherapy protocol on reducing psychological distress in women with premenstrual dysphoric disorder 3- Determining the permanence of hypnotherapy results on reducing the intensity of perceived pain after 3 months of follow-up in women with premenstrual dysphoric disorder 4- Determining the permanence of hypnotherapy treatment results on reducing the level of psychological distress after 3 months in women with premenstrual dysphoric disorder

**Design**

Clinical trial of control group, single intervention group, double-blind, randomized, use of random numbers Phone number

**Settings and conduct**

The study population is all female students of Shahed University in 1999. The research is conducted at Shahed University. evaluation and treatment and random allocation are done by different people without knowing each other. The hypnotherapy protocol is also held in 8 sessions

**Participants/Inclusion and exclusion criteria**

Entry: 1. Conscious satisfaction 2. At least a diploma 3. Diagnosis of premenstrual disorder 4. Being in the age range of 18 to 35 years No entry: 1. A gynecological disease that has led to the cessation of menstruation 2. Menopause 3. Pregnancy or breastfeeding 4. Consumption of drugs, alcohol or cigarettes 5. Taking drugs that affect the immune system in any clinical situation 6. Use of antidepressant and anti-anxiety psychiatric drugs from any class of drugs 7. Receive a diagnosis of any other psychiatric disorder

**Intervention groups**

The Intervention group: the treatment program is performed via using classical hypnosis. The control group: includes a group of patients who have been diagnosed with premenstrual dysphoric disorder but are in untreated conditions.

**Main outcome variables**

Change in pain intensity; Change in the level of psychological distress

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201110049332N1**
Registration date: **2020-11-16, 1399/08/26**
Registration timing: **prospective**

Last update: **2020-11-16, 1399/08/26**
Update count: **0**

**Registration date**

2020-11-16, 1399/08/26

**Registrant information**

**Name**

Nader Abazari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-11-28, 1399/09/08

**Expected recruitment end date**

2021-02-18, 1399/11/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Efficacy of hypnotherapy on pain intensity and psychological distress among women with premenstrual dysphoric disorder: a clinical randomized trial

**Public title**

Efficacy of hypnotherapy on pain intensity and psychological distress

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Conscious consent to participate in research At least diploma degree Receiving diagnosis of premenstrual disorder based on the PSST premenstrual symptoms screening questionnaire and receiving higher score than28 up to 57 Existence of at least 5 criteria of criteria B and C of DSM-5 according to the clinical interview Being in the age range of 20 to 35 years

**Exclusion criteria:**

Existence of a gynecological disease that has led to the cessation of menstruation and menopause Pregnancy or breastfeeding Abuse of drugs, alcohol or cigarettes Taking drugs that affect the immune system in any clinical condition Use of antidepressant and anti-anxiety psychiatric drugs from any class of drugs Receiving the diagnosis of any other psychiatric disorder with respect to receiving a score higher than 3 in any of the dimensions of SCL-90 clinical symptoms Viewing the threshold criteria for each disorder via clinical interview

**Age**

From **20 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This controlled clinical trial study is going to be performed in Shahed University in 1390 among female students. Initial screening will be performed by a female employee to detect premenstrual symptoms. After screening, 60 participants are contacted via simple random sampling and shuffling. Upon arrival at the clinic, each invited person receives a sealed envelope with A or B code written on each envelope. This sequence is determined by someone other than the researchers using the site www.randomizer.org. Code A means the control group and code B means the intervention group. Fisher and chi-square tests are also used to homogenize the underlying features.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

First of all, in order to blind the trial, a PhD student of psychology from out of research group, encode participants information. In this project, blinding means more than just keeping the name of the participants are allocated in treatment or control group hidden. The patients will be blinded in the sense that they do not know whether they are receiving the psychotherapy or not. In this double-blind trial, it is implicit that the assessment of patient outcome is done in ignorance of the treatment received. All study participants and main clinical researchers are prevented from knowing certain information that may somehow influence them.

**Placebo**

Not used

**Assignment**

Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahed University

**Street address**

persian gulf

**City**

Tehran

**Province**

Tehran

**Postal code**

3319118651

**Approval date**

2020-10-27, 1399/08/06

**Ethics committee reference number**

IR.SHAHED.REC.1399.118

## Health conditions studied

### 1

**Description of health condition studied**

Premenstrual dysphoric disorder

**ICD-10 code**

F32.81

**ICD-10 code description**

Premenstrual dysphoric disorder

## Primary outcomes

### 1

**Description**
pain intensity
**Timepoint**
Session 1, Session 5, Final Session, two months after the last session
**Method of measurement**
The Numerical Rating Scale

### 2

**Description**
psychological distress
**Timepoint**
Session 1, Session 5, Final Session, two months after the last session
**Method of measurement**
The Depression Anxiety and Stress Scales-42

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The use of hypnosis to treat or relieve clinical symptoms and improve the quality of life of people is called hypnotherapy. Hypnotherapy is performed in two main ways: classical hypnotherapy and implicit or Ericksonian hypnotherapy. In both types of hypnotherapy, the patient's mental abilities are used to alleviate, control, or treat the clinical symptoms of the disorder. In this study, hypnotherapy is performed as classical hypnotherapy by using progressive relaxation induction, inductions related to self-confidence and change of attitude, as well as repeated conditionings using condition betting. The treatment program is performed by using classical hypnosis. Using this form of session setting using classical hypnosis, induction of trance using progressive relaxation, conditioning using the key condition agreed between the patient and the therapist and instincts related to self-confidence and changing attitudes derived from Hammond's activities (2015). Thus, the induction of trance begins with the progressive relaxation method, and the end of the trance is performed using abdominal breathing and conditioning to the key of the countdown condition from 5 to 1. The number of sessions is predicted to be 8 based on clinical evidence. The duration of each session is 90 minutes
**Category**
Treatment - Other

### 2

**Description**
Control group: The control group is a group in which individuals are defined as a waiting group and no treatment is used to control experimental error.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahed University
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## Sponsors / Funding sources

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Vice Chancellor for Research, Shahed University
**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**
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Shahed University
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Assistant professor
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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**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable
**Title and more details about the data/document**
Data obtained from patients are published unrecognizably in the primary information table in the article. The collected data will be published simultaneously with the publication of the main article.
**When the data will become available and for how long**
The data will be published at the same time as the main article
**To whom data/document is available**
Due to the nature of the information, this data will only be available to academic researchers and clinicians
**Under which criteria data/document could be used**
Simultaneously with the publication of the main article, a way of requesting data is introduced. Also, individuals can analyze the data only if the researchers agree.
**From where data/document is obtainable**
Simultaneously with the publication of the main article, a way of requesting data is introduced
**What processes are involved for a request to access data/document**
Initially, the request is sent to the responsible author, after reviewing the group in order to prevent any kind of abuse, the information is sent in the form of a zip file.
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