Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone

+98 21 5514 0585

Email address

naderabaazari@gmail.com

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
Full name of responsible person
Leila Heidarinasab
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Sponsors / Funding sources

1

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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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Position
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.
Comments