

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison the effect of group counseling stress management skills with vitamin B6 on premenstrual syndrome

Protocol summary

Summary

Concerning relatively high prevalence of premenstrual syndrome and its negative effects on women with this syndrome, current study aims to compare the impact of group consultation about stress management skills with that of vitamin B6 on premenstrual syndrome symptoms. The study population included students living in three dormitories of Zanjan University of Medical Sciences who suffered from moderate to acute premenstrual syndrome and were studied using a simple method. Subjects with psychiatric and mental problems were excluded using general health questionnaire (GHQ). Finally, 66 subjects with premenstrual syndrome entered the study and were randomly divided into two control and intervention groups. Interventions included four two-hour sessions for stress management skills for one group and prescribing 80 mg of vitaminB6 daily for two menstrual cycles for another intervention group. After two months, PSST questionnaire was completed by participants in order to investigate the results of interventions and the decreasing frequency of moderate and acute premenstrual syndrome and it was compared using statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052127994N1**

Registration date: **2016-12-06, 1395/09/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-06, 1395/09/16

Registrant information

Name

Taraneh Emamgholi khooshehchin

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8318

Email address

khoosheh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of group counseling stress management skills with vitamin B6 on premenstrual syndrome

Public title

Effect of group counseling on premenstrual syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: written informed consent; suffering from moderate to acute premenstrual syndrome; having regular periods within 21-35 days intervals with 2-7 days of bleeding; obtaining a score lower than 23 in general health questionnaire; lack of known physical or

psychiatric diseases according to the general health questionnaire; failure to use premenstrual syndrome treatment procedures in order to alleviate its symptoms; absence of stressful occasions such as parents' divorce-severe financial failure- accident- death of a close relative- any surgical operations 3 months before the onset of this study; being at least 18 years old- lack of treatment of endocrine and metabolic disorders, epilepsy or any menstrual disorder from 3 months before the onset of this study; not following a special diet. Exclusion criteria: A terrible accident like intense family disputes-separation from parents- severe financial problems-death of a close relative during research period; being absent more than once from consultation sessions; establishment of side-effects during use of medication and being forced to withdraw it; leaving the study for any reason.

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azad Square, Zanjan

City

Zanjan

Postal code

4515613191

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

ZUMS.REC.1394.198

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**

Mood symptoms of premenstrual syndrome

Timepoint

Before and two months after intervention

Method of measurement

questionnaire

2**Description**

Physical symptoms of premenstrual syndrome

Timepoint

Before and two months after intervention

Method of measurement

questionnaire.

3**Description**

Behavioral symptoms of premenstrual syndrome

Timepoint

Before and two months after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

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

The stress management' group received four sessions of group consultation on stress management.

Category

Other

2**Description**

Vitamin B6 group received 80 mg Vitamin B6 pill daily for two menstrual cycles, one week before their menstruation get started

Category

Treatment - Drugs

3

Description

No interference seen in the Control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan University of Medical Sciences

Full name of responsible person

Marzeh Eshaghi

Street address

Zanjan University of Medical Sciences, Azadi Square, Zanjan

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Doctor Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi Square, Zanjan

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Emamgoli Khooshehchin

Position

PhD

Other areas of specialty/work

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Fax

Email

t_khooshehchin@yahoo.com

Web page address

Person responsible for updating data

Contact

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