

# 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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**City**

Zanjan

**Postal code**

Iran

**Phone**

+98 24 3314 8318

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**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*