Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Street address
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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