Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial Comparing the effect of relaxation and vitamin B6 on pre-menstrual syndrome in dormitories

Protocol summary

Summary

Comparing the effects of relaxation and vitamin B6 on premenstrual syndrome, this clinical trial study will conduct that aim to compare the effect of relaxation and vitamin B6 on premenstrual syndrome on girls living in dormitory of Rafsanjun University of Medical Sciences. According to the inclusion criteria aged 18 to 25 years; normal menstruation (3 to 8 days of bleeding, and interval between two cycles of 26 to 31 days); no history of use of antidepressants, tranquilizers or hormones, and no crises (loss of dear ones, divorce, ...), 250 girls will select and randomly assign to three groups (vitamin B6 recipients, relaxation trainee and control groups). Relaxation trainee group participate in two training sessions and will ask to do relaxation techniques every day a week before their menstruation. Also, the group receiving vitamin B6 will be asked to start 80 mg vitamin B6 pill three times per week from one week prior to the start of their menstruation. In the control group, there will not be any interference.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070518357N1**
Registration date: **2014-11-24, 1393/09/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-24, 1393/09/03

Registrant information

Name

Nahid Hassani

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial Comparing the effect of relaxation and vitamin B6 on pre-menstrual syndrome in dormitories

Public title

Comparing the effect of relaxation and vitamin B6 on pre-menstrual syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 25 to 18 years; Normal menstruation (bleeding interval: 3 to 8 days and during cycle: 26 to 31 days); Single; no history of mental illness and depression; No history of use antidepressants and hormones drug; Did not have any event in past two months

Age

From **18 years** old to **25 years** old

Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **250**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this study, subjects were assigned randomly to one of three groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rafsanjan University of Medical Sciences
Street address
Nursing faculty, Jomhori street, Rafsanjan, Iran
City
Rafsanjan
Postal code
7718796755
Approval date
2014-09-23, 1393/07/01
Ethics committee reference number
938

Health conditions studied

1

Description of health condition studied
Premenstrual Syndrome
ICD-10 code
N.94.3
ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Premenstrual Syndrome Symptoms
Timepoint
Before the intervention and 3 months after intervention with monthly
Method of measurement
DSM-IV Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group (Relaxation trainee group): received relaxation training in two sessions over one month.These techniques were printed and made available to this group to practice every day, a week before their next menstruation
Category
Treatment - Drugs

2

Description
Second Intervention group (vitamin B6 recipients): A week before their menstruation, were asked to take 80 mg tablets of vitamin B6 (Iran Hormone Company) 3 times per week, for one month
Category
Treatment - Drugs

3

Description
The control group: received no intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Amin's Residences
Full name of responsible person
Nahid Hassani
Street address
Nursing faculty, Jomhori street, Rafsanjan, Iran
City
Rafsanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Rafsanjan University of Medical Sciences

Full name of responsible person
Majid Kazemi
Street address
Nursing faculty, Jomhori street, Rafsanjan, Iran
City
rafsanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Rafsanjan 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
Name of organization / entity
Rafsanjan University of Medical Sciences
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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