

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of diet enriched with whole grains and grains with bran on severity of premenstrual syndrome symptoms in nurses

Protocol summary

Summary

The aim of this study was to investigate the effect of diet enriched with whole grains and grains with bran on the severity of symptoms of premenstrual syndrome in nurses as a randomized controlled clinical trial on 100 nurses with premenstrual syndrome. Inclusion criteria include ages 18 to 45, regular menstruation cycles of 21 to 35 days, bleeding times of 3 to 8 days, and exclusion criteria, including diseases and interventions that affect PMS symptoms, use Of hormones and antidepressant drugs, regular exercise, BMI of over 39, alcoholics and smokers, the death of close relatives over the past six months. According to these criteria, nurses will be assigned to two groups of intervention and control groups. Individuals in the intervention group will change their daily cereals to whole grains and grains with bran for a period of three months, and in order to provide at least four serving of whole grains daily, one loaf of 120 volumes of lavax bread will be provided free of charge, And individual in the control group will continue to have regular cereals in their diet. Finally, by comparing the mean scores obtained before and after the intervention, the effectiveness of this method will be determined by the number of servings eaten.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031132417N3**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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alizadeh.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Science

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of diet enriched with whole grains and grains with bran on severity of premenstrual syndrome symptoms in nurses

Public title

The effect of diet enriched with whole grains and grains with bran on severity of premenstrual syndrome symptoms in nurses

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 18 to 30 years old, having regular menstrual cycles of 21-35 days, bleeding for 3 to 8 days,

having a depression score of 0 to 16 based on beck depression inventory. Exclusion criteria: Having diseases and interventions that affect PMS symptoms, using hormones, using antidepressants and contraceptives drugs, treated with acupuncture, homeopathy and other complementary therapies, following a weight loss diet, exercising regularly, BMI over the 39, drinking alcohol, smoking, death of close relatives and having stressful events in the last month, undergoing surgical operation in the last 6 months, breast feeding and pregnancy.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Urmia University of Medical Science

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

Postal code

5714783734

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

ir.umsu.rec.1395.256

Health conditions studied

1

Description of health condition studied

Pre Menstrual Syndrome

ICD-10 code

F99

ICD-10 code description

not otherwise specified

Primary outcomes

1

Description

Severity of behavioral symptoms

Timepoint

Before intervention and at intervals of 1,2 and 3 months after intervention

Method of measurement

Evaluation of the questionnaire

2

Description

Severity of emotional symptoms

Timepoint

Before intervention and at intervals of 1,2 and 3 months after intervention

Method of measurement

Evaluation of the questionnaire

3

Description

Severity of physical symptoms

Timepoint

Before intervention and at intervals of 1,2 and 3 months after intervention

Method of measurement

Evaluation of the questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this study, people in the intervention group after become aware of foods that are considered as whole grains,for 3 months will change their daily intake of cereals from refined grain to whole grains or grains with bran. in order to provide at least four serving of whole grains, one loaf of 120 volumes of lavax bread is given free of charge to them daily And they will be asked to not change their physical activity during this time

Category

Other

2

Description

In this study, individuals in the control group were asked to take their usual daily intake of cereals for 3 months and not to change their physical activity.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Prof

Street address

Ershad Blvd,Ayatollah Modarres Blvd, Urmia

City

Urmia

2

Recruitment center

Name of recruitment center

Motahari Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

opposite the 15th Street, Kashani Street, Urmia

City

Urmia

3

Recruitment center

Name of recruitment center

Taleghani Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

opposite Takht-e Sport Complex, Kashani Street,
Urmia

City

Urmia

4

Recruitment center

Name of recruitment center

Urmia Seyyed Al-Shohada Hospital

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

Opposite Samadzadeh Street, 17 Shahrivar Blvd,
Urmia

City

Urmia

5

Recruitment center

Name of recruitment center

Razi Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

Junction of Agriculture Jihad, Salmas Road, Urmia

City

Urmia

6

Recruitment center

Name of recruitment center

Azarbaijan Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

Above Azad University, Shahid Beheshti Street, Urmia

City

Urmia

7

Recruitment center

Name of recruitment center

Imam Reza Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

Imam Reza Street, Molavi Street, Urmia

City

Urmia

8

Recruitment center

Name of recruitment center

Shafa Hospital, Urmia

Full name of responsible person

Specialty Doctorte Degree in Nutritioal Science/ Urmia
University of Medical Sciences Associate Pr

Street address

Imam Street, Urmia

City

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9

Recruitment center

Name of recruitment center

Dr Solatii Hospital, Urmia

Full name of responsible person

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Street address

Plaque 602, Imam Street, Urmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Urmia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Orjhans Street, Resalat Blvd, Urmia

City

Urmia

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 Urmia 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

Urmia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Alizadeh

Position

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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MS Student of nutrition

Other areas of specialty/work

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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