

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of yoga on women's premenstrual syndrome

Protocol summary

Study aim

1. The effect of yoga on premenstrual syndrome
2. The effect of yoga on sleep quality in women with premenstrual syndrome
3. Yoga effect on anxiety in women with premenstrual syndrome
4. Yoga effect on depression and Blood Pressure in women with premenstrual syndrome
5. The effect of yoga on quality of life in women with premenstrual syndrome

Design

This is a double-blind, randomized controlled trial. Allotment in the yoga and control group will be done randomly in blocks 4 and 6 with an assignment ratio of 1 to 1. The sample size will be 62, which will be selected in each group of 31

Settings and conduct

In this double-blind randomized clinical trial, among women referring At the private clinics of Tabriz women and delivery, those who were admitted to study with their desire to ask for a PSN PSK screening questionnaire for one month, and asked those who were diagnosed with PSAs with premenstrual syndrome, after obtaining informed consent, 61 Persons selected in a class and randomly assigned 4 and 6 blocked blocks to 31 yoga groups and 31 control group. Yoga moves for 10 weeks and each week in 3 60-minute sessions. Finally, the data on the variables of mood, behavior, physical and pms effects on the life of the questionnaires were analyzed using covariance analysis.

Participants/Inclusion and exclusion criteria

1. Women aged 18 to 45
2. Having a regular menstrual period
3. Catching PMS

Intervention groups

Yoga exercises are conducted by a yoga instructor for a period of 10 weeks and each week for 3 sessions of 60 minutes. The samples will be applied and no intervention will be performed for the control group.

Main outcome variables

Yoga affects mood, behavior and physical symptoms in women with premenstrual syndrome.

General information

Reason for update

Acronym

PMS

IRCT registration information

IRCT registration number: **IRCT201501216582N9**

Registration date: **2015-03-15, 1393/12/24**

Registration timing: **prospective**

Last update: **2019-01-26, 1397/11/06**

Update count: **1**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 414796770

Email address

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences branch aras

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-04-09, 1394/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of yoga on women's premenstrual syndrome

Public title
The effect of yoga on premenstrual syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Inclusion criteria: age range of 20 till 45 years old Having regular history of menstruation Suffering from PMS according to the results of PSST questionnaire in two periods before intervention No consumption of effective medication on premenstrual syndrome and anti-pregnancy drugs three months before entering the study No history of depression based on the patients' self representation No history of diseases related to genital organs based on the patients' own representation No consumption of herbal drugs effective for premenstrual syndrome during last three months No consumption of alcohol, cigars and other impermissible materials based on the patients' own representation No history of joints diseases and arthritis based on the patients' own representation No history of surgery in body organs preventing individual from doing yoga practices No athletes; No consumption of caffeine; Tendency to participate in the research
Exclusion criteria:
 No tendency to remain in the study Having a history of yoga practices Occurrence of any influential incidence to the study trend, occurrence of stressful incidents like the death of close relatives during last 6 months

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocations in yoga and control groups will be done randomly in blocks 4 and 6 with a 5: 5 assignment ratio. In order to hide the allocation of opaque envelopes, which will be numbered sequentially. These packs are already prepared by the non-involved researcher in the data collection and the first envelope will be given to the first person with the inclusion criteria and will continue to complete the sample volume.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study was an interventional study of double-blind randomized controlled clinical trial, in which the data

collector and analyzer were blind.

Placebo
Not used

Assignment
Parallel

Other design features
no

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tabriz University of Medical Sciences
Street address
 Golgasht Ave
City
 Tabriz
Province
 East Azarbaijan
Postal code
 51767-63663
Approval date
 2015-02-20, 1393/12/01
Ethics committee reference number
 IRCT201501216582N9

Health conditions studied

1

Description of health condition studied
Depression

ICD-10 code
N94.3

ICD-10 code description
Premenstrual tension syndrome

Primary outcomes

1

Description
Symptoms of premenstrual syndrome

Timepoint
Before intervention and 10 weeks after intervention

Method of measurement
PSST Questionnaire

Secondary outcomes

1

Description
The Effect of Yoga on Quality of Sleep of Women with

Premenstrual Syndrome
Timepoint
Before intervention and 10 weeks after intervention
Method of measurement
PSST Questionnaire

2

Description
Added at 2016-10-11: quality of sleep
Timepoint
Added at 2016-10-11: 2015/4/29 to 2015/7/11
Method of measurement
Added at 2016-10-11: Quality of Sleep Questionnaire

3

Description
The Effect of Yoga on Depression and Blood Pressure of Women with Premenstrual Syndrome
Timepoint
Before intervention and 10 weeks after intervention
Method of measurement
Beck Depression Questionnaire

4

Description
The Effect of Yoga on Anxiety and Vital Signs of Women with Premenstrual Syndrome
Timepoint
Before Intervention and 10 Weeks After Intervention
Method of measurement
Hamilton Anxiety Rating Scale

5

Description
The Effect of Yoga on Quality of Life of Women with Premenstrual Syndrome
Timepoint
Before Intervention and 10 Weeks After Intervention
Method of measurement
Quality of Life SF36 Questionnaire

Intervention groups

1

Description
The yoga group will exercise the designed movements under supervision of the yoga coach for 10 weeks in three sessions and each session for 60-minute every week.
Category
Treatment - Other

2

Description
The control group will not receive intervention.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Science
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Deputy of Scientific and Research of Nursing and Midwifery Faculty
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tabriz University of Medical Science
Proportion provided by this source

100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Kamalifard
Position
Professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

2016

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

To check the results and the relationship of data

From where data/document is obtainable

00989144058245 Ghafoureh ghaffarilaleh

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What processes are involved for a request to access data/document

Email or mobile will be sent within two weeks.

Comments

I would share my scientific information.