Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of wheat Germ Extrat and Flexible Traning on primary Dysmenorrhea of Non- athlete Girls

Protocol summary

Study aim

The aim of this study was to compare the effect of wheat germ and flexural exercises on severity of primary dysmenorrheal in non-athlete female students of Shahrood University of Technology.

Design

This study was a randomized controlled clinical trial with pre-test and post-test design with control group. A total of 88 students residing in dormitories will be selected based on entry criteria. In the case of having the criteria for entering the students, they will be grouped into blocks of 8 by randomization software and will be grouped into four groups (wheat germ, training group, practice + wheat germ and control group

Settings and conduct

It is a three-button type, and participant, researcher and analyst have blinded the information. At the beginning of the study, students went to the dormitory and selected 88 eligible students.

Participants/Inclusion and exclusion criteria

Inclusion criteria: regular menstruation; non-athletic status; non-use of any type of housing during menstruation; history of severe primary to primary dysmenorrheal pain. Exclusion criteria: absence from more than two sessions; irregular menstruation; history of certain diseases.

Intervention groups

Includes 4 groups: 1- Group germination at day 16 of the menstrual cycle until 5 menstruation daily consumes two tablets of 500 mg capsules of wheat germ; 2- Training group for 8 weeks, 4 days a week, 8 moves with 3 repetitions of 10 seconds They did. 3- Training group + Wheat germ. 4- The control group filled in only the relevant questionnaires

Main outcome variables

Primary dysmenorrhea (severity of pain, systemic symptoms and mood and mood symptoms)

General information

Reason for update

Acronym

primary dysmenorrheal

IRCT registration information

IRCT registration number: **IRCT20180929041175N1**
Registration date: **2019-03-06, 1397/12/15**
Registration timing: **retrospective**

Last update: **2019-03-06, 1397/12/15**
Update count: **0**

Registration date

2019-03-06, 1397/12/15

Registrant information

Name

Fatemeh Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-20, 1397/01/31

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

2018-04-20, 1397/01/31

Actual recruitment end date

2018-06-21, 1397/03/31

Trial completion date

2018-06-21, 1397/03/31

Scientific title
Comparison of wheat Germ Extrat and Flexible Traning on primary Dysmenorrhea of Non- athlete Girls

Public title
Comparison of wheat Germ Extrat and Flexible Traning on primary Dysmenorrhea of Non- athlete Girls

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Female students residing in dormitories aged between 18 and 30 years Regular menstruation Not athlete No history of alcoholic beverages Not having a history of surgery, especially in the abdomen and pelvis Healthy and physically and psychologically History of moderate to severe dysmenorrheal Not having pelvic diseases

Exclusion criteria:
Absence of more than two sessions during the review period The history of certain diseases Gastric ulcer and taking anticoagulants Irregular menstruation

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **88**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Sequencing was done using software and by methodologist based on a block size of 8 volumes. Considering the fact that in the present study, four groups were examined (three groups of intervention and one control group) to equalize the sample size In all of the studied groups, 8 blocks were used. So that in each block 8 people were placed. Regarding the sample size, 11 blocks were considered. The random allocation of individuals to the study groups was carried out in such a way that at first 11 envelopes containing 8 cards, labeled with Latin letters AA, BB, CC, DD, of the letters of the letter Wax was used and each random sequence created on a card was recorded and the cards were inserted into the envelope respectively. In order to preserve the random sequence, the envelopes were also numbered on the outer surface and finally the envelopes are pasted.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Due to the study nature of the study, there is no possibility for participants to blindness to practice intervention, but the information analyst will not know about how the participants will be present in the groups and they will be educated. The collector does not know the information before the intervention. To fill in the questionnaire after the intervention, another person who is not aware of the group will be used to complete the questionnaire.

Placebo
Used

Assignment
Factorial

Other design features
This is a randomized trial with pre-test and post-test design with a study group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrood University of Medical Sciences

Street address
Seventh Tir Square, Shahrood University of Medical Sciences and health services

City
shahrood

Province
Semnan

Postal code
36147-73947

Approval date
2018-07-22, 1397/04/31

Ethics committee reference number
IR.SHMU.REC.1397.083

Health conditions studied

1

Description of health condition studied
Primary Dysmenorrhea

ICD-10 code
N80.0

ICD-10 code description
Endometriosis of uterus

Primary outcomes

1

Description
Primary dysmenorrhea

Timepoint
8 Weeks

Method of measurement
Before and after 8 weeks, the questionnaire for systemic symptoms, the mental and emotional symptoms questionnaire, and the visual assessment questionnaire filled the pain or pain intensity.

Secondary outcomes

1

Description
Motion range (flexibility)
Timepoint
8 Weeks
Method of measurement
Before and after exercises, measure the flexibility of the muscles of the waist and the waist using (ruler), hamstring muscles using (board and brush or flexure board) and thigh closers with (goniometer), height and weight with

Intervention groups

1

Description
Intervention group Widow: Wheat germ group: From day 16 of menstrual cycle to five menstruation daily, two capsules of 500 mg capsules consume wheat germ in two consecutive cycles. Capsule, extracts with ethanol 70% in three steps and each stage for 24 hours Done. The resulting extract is then powdered after drying and poured into a 500 mg capsule and each day should consume two capsules several different directions.
Category
Prevention

2

Description
Second intervention group (training group): In this study, the subjects performed 8 moves with 3 replicates of 10 seconds for 8 weeks, 4 days a week. Some moves take place in several different directions. Taking these directions in total, 18 moves were performed and each 1 second was added to the stretch. Before and after the training period, all subjects were submucosal flexion (flexion), lumbar (humorous), hamstring (test Sit and brush) and thigh closers (goniometers) are measured and recorded
Category
Prevention

3

Description
Intervention group: Third intervention group: A training group with wheat germ was also operated according to the protocol of the training group and wheat germ.
Category
Prevention

4

Description
Control group: During the two-course practice protocol, 500 mg capsules consume the placebo in two consecutive cycles and do not participate in any training program, and only use the relevant questionnaires before and after the training period.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Students of Shahrood University of Tecnology
Full name of responsible person
Fatemeh Mirzaei Karizaki
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrood University of Technology
Proportion provided by this source
60
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Nahid Bolbol haghighi
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available