

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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

+98 51 5229 4107

##### Email address

f.mirzai@shahroodut.ac.ir

##### 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

##### Street address

Shahrood University of Technology, Faculty of Physical Education

##### City

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##### Province

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##### Postal code

3619995161

##### Phone

+98 23 3932 0422

##### Email

Fatemeh\_mir\_95@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahrood University of Technology

##### Full name of responsible person

Ali Younesian

##### Street address

Haft Tir Square - Shahrood University of Technology

##### City

Shahrood

##### Province

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3619995161

##### Phone

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##### Email

Ayonesian@Shahrod.ac.ir

#### 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 haghghi

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahroud University of Medical Sciences

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**Province**

Semnan

**Postal code****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