

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of the effect of tensile connective tissue massage and sports with the control group on primary dysmenorrhea

#### Protocol summary

##### Study aim

The purpose of a stretching exercises and massage effects of connective tissues in patients with primary dysmenorrhea will perform

##### Design

Clinical trial has a control group

##### Settings and conduct

Coordination with the accommodation of Shiraz University of medical sciences will do the study. Exercise and stretching to both oral and written by a researcher to volunteers will be trained and each time are controlled by the researcher.

##### Participants/Inclusion and exclusion criteria

1-The desire to participate in the study 2- single 3-Being a student 4-Age between 18to 25 5-The lack of regular sport activity 6-The intensity of menstrual pain more than 5 VAS criteria 7-Lack of limits exercise and massage 8-Failure to use the OCP and pharmaceutical treatments and complementary therapies to treat dysmenorrhea during the study

##### Intervention groups

In the first group to people for 8 weeks stretching exercises 3 times a week and each time for 10 minutes. In the second group, people in the study for 8 weeks and each week the connective tissue massage 2 times a given program. This massage is not performed during the menstrual period. In the third group stretching exercises or any connective tissue massage. This group serves as the control group are considered.

##### Main outcome variables

By comparison, the average score for severity of pain; pain in two groups for the duration of the test and control group

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181212041948N1**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

##### Registration date

2019-01-10, 1397/10/20

##### Registrant information

###### Name

somaieh rahimy

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3647 4251

###### Email address

s\_rahimy@ymail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-05, 1397/10/15

##### Expected recruitment end date

2019-06-05, 1398/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of tensile connective tissue massage and sports with the control group on primary dysmenorrhea

##### Public title

Comparison of the effect of stretching exercises and massaging of connective tissue with the control group on dysmenorrhea

97-01-08-16839

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The desire to participate in the study single Being a student Lack of systemic disease or disease in reproductive organs Age between 18 to 25 Regular inactivity The intensity of menstrual pain more than 5 VAS criteria Lack of limits exercise and massage Non-use of OCPs and drug therapies and complementary therapies for the treatment of dysmenorrhea during the study

### Exclusion criteria:

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **165**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomizatin block

## 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

Shiraz University of medical sciences Ethics Committee

##### Street address

Namazi square

##### City

Shiraz

##### Province

Fars

##### Postal code

7439179333

#### Approval date

2018-11-27, 1397/09/06

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

primery Dysmenorrhea

#### ICD-10 code

N94.4

#### ICD-10 code description

Primary dysmenorrhea

## Primary outcomes

### 1

#### Description

The severity of the pain can be measured.

#### Timepoint

Eight weeks

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Anxiety

#### Timepoint

The first month of the third month

#### Method of measurement

Questionnaire spielberger

## Intervention groups

### 1

#### Description

Intervention group: The first group: stretching For 8 weeks stretching exercises 3 times a week and each time for 10 minutes, During the period of menstruation is not done.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Connective tissue massage, Connective tissue massage every week for 8 weeks and 2 times the given program, During the period of menstruation is not done.

#### Category

Treatment - Other

### 3

#### Description

Control group: there is no intervention

**Category**

N/A

**Type of organization providing the funding**

Academic

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Shiraz University of Medical Sciences for girls ' hostel

**Full name of responsible person**

somaieh rahimy

**Street address**

Namazi square, Faculty of nursing and midwifery

**City**

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**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

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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**

Shiraz University of Medical Sciences

**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****Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

somaieh rahimy

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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student

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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**

empty

**When the data will become available and for how long**

empty

**To whom data/document is available**

empty

**Under which criteria data/document could be used**

empty

**From where data/document is obtainable**

empty

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

empty

**Comments**