

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of Aerobic and Kegel exercises on menstruation related pain and fatigue in females with primary dysmenorrhea

#### Protocol summary

##### Study aim

To Compare the effectiveness of aerobic and kegal exercises on menstruation related pain and fatigue in primary dysmenorrhea

##### Design

The design of this study is Randomized, parallel Clinical Trial. Randomization is done by lottery method. In this method, the researcher gives each participant of the trial a number. Researchers draw numbers from the box randomly to allocate participants in two groups.

##### Settings and conduct

This study is conducted at Rashid latif medical college.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria • 18-25 years old, young female • Bleeding time 3-10 days • Primary dysmenorrhea [patient are previously diagnosed] • Not taking any vitamin or mineral supplementation during one menstrual cycle before trial • Not practicing physical exercise [ more than 3 times a week ,for >30 min ]  
Exclusion Criteria • chronic disease[ heart disease ,respiratory disease ,asthma, nervous disorder etc ] • history of irregular cycles • history of gynecological surgery • women who use oral contraceptives

##### Intervention groups

Patient of group A received aerobic exercise Patient of group B received Kegel exercises

##### Main outcome variables

The intensity of pain is measured by the numeric pain rating scale which is an accurate and reliable tool for measuring pain intensity symptoms of primary dysmenorrhea. Fatigue is assessed by an accurate and reliable scale i.e: fatigue severity scale.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220626055280N1**

Registration date: **2023-01-13, 1401/10/23**

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

Last update: **2023-01-13, 1401/10/23**

Update count: **0**

##### Registration date

2023-01-13, 1401/10/23

##### Registrant information

###### Name

Nazeer Ahmad

###### Name of organization / entity

Rashid Latif medical college

###### Country

Pakistan

###### Phone

+92 333 8054247

###### Email address

nazeer.ahmad@rlmc.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-28, 1401/10/07

##### Expected recruitment end date

2023-05-28, 1402/03/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of Aerobic and Kegel exercises on menstruation related pain and fatigue in females with primary dysmenorrhea

##### Public title

Effect of Aerobic and Kegel exercises on primary dysmenorrhea

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

18-25 years old, young female Menstrual Bleeding time 3-10 days Previously diagnosed with primary dysmenorrhea Not practicing physical exercise for more than 3 times a week ,for more than 30 min

#### **Exclusion criteria:**

taking any vitamin or mineral supplementation during menstrual cycle history of irregular cycles history of gynecological surgery women who use oral contraceptives chronic disease e.g.: heart disease ,respiratory disease ,asthma, nervous disorder

### **Age**

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

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

- Participant

### **Sample size**

Target sample size: **38**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Patients were allocated into two groups i.e.; Group A and Group B, by lottery method. Lottery method is a type of simple random sampling. In this method, each participant of the trial is assigned a unique number. In the next step these numbers are written on separate cards which are physically similar in shape, size, color etc. 45 cards were used. Then they are placed in a basket and thoroughly mixed. In the last step the slips are taken out randomly without looking at them and are placed into two sets randomly. Total of 38 cards were taken out, 19 participants in each group.

### **Blinding (investigator's opinion)**

Single blinded

### **Blinding description**

The blinding of patients means that the patients did not know which treatment group are they allocated. This blinding is achieved by concealment. The allocation sequence is concealed in envelopes which were numbered serially, and letter envelopes are opened only after all pre-intervention assessments of the participants have been completed. This is done to avoid biasness.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Institutional Review Board of Rashid Latif Medical College

##### **Street address**

35-Km Ferozepur road Lahore

##### **City**

Lahore

##### **Postal code**

54600

##### **Approval date**

2022-10-05, 1401/07/13

##### **Ethics committee reference number**

IRB/2022/058

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Primary dysmenorrhea

#### **ICD-10 code**

N94.4

#### **ICD-10 code description**

Primary dysmenorrhea

## **Primary outcomes**

### 1

#### **Description**

Pain

#### **Timepoint**

Pre and 1 Month Post

#### **Method of measurement**

The intensity of pain is measured by the numeric pain rating scale which is an accurate and reliable tool for measuring pain intensity symptoms of primary dysmenorrhea.

### 2

#### **Description**

Fatigue

#### **Timepoint**

Pre and 1 Month Post

#### **Method of measurement**

Fatigue is assessed by an accurate and reliable fatigue severity scale.

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### Description

Intervention group: Patient of group A aerobic exercises: The protocols for exercise training in the study include, Frequency: 3 days per week for one menstrual cycle. Time: 20-30 minutes per session (5-10minutes warm-up, 15-20 minutes aerobics, 5 minutes cool-down)Type: Stationary cycling and treadmill Speed: 4-6 mph

### Category

Prevention

## 2

### Description

Intervention group: Patient of group B received Kegel exercises in form of pelvic floor exercises [ 10 min] , and warm up and cool down [both for 5 min].Pelvic Tilt Patient is in crook lying position. Ask them to lift the pelvis off the plinth with hands placed by the side. Hold this position for 10 seconds Repeat for 25 times. Kegel Exercise: Squeeze the pelvic muscle for 10 seconds and relax it for 10 seconds stop after 3 repetitions. Repeat this exercise three times in a day. Flutter Exercise: Squeeze the pelvic muscles and relax it as quickly as possible for 10 contractions. It is recommended 3times a day. Subtle Exercise: First exercise, except that with the imagination that the person is sucking and holding tampon in the vagina for 10 seconds and release the contraction. Relax for 10 seconds.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rashid Latif Medical College

##### Full name of responsible person

Maryam Sarfraz

##### Street address

25-Km Ferozepur road Lahore

##### City

Lahore

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54900

##### Phone

+92 333 4435278

##### Email

maryamsarfraz33@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rashid Latif Medical College

##### Full name of responsible person

Nazeer Ahmad

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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

Rashid Latif Medical College

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Rashid Latif Medical College

##### Full name of responsible person

Maryam Sarfraz

##### Position

Physiotherapist

##### Latest degree

Bachelor

##### Other areas of specialty/work

Physiotherapy

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rashid Latif Medical College

##### Full name of responsible person

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Assistant Professor  
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## Person responsible for updating data

### Contact

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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