

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 aeorbic 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rashid Latif Medical College

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

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

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Latest degree

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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