

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Effects of Pilates exercises versus Aerobic Training on Menstrual Pain, Balance and Daily Functioning in University Students with Primary Dysmenorrhea

Protocol summary

Pain, Balance, Daily functioning

Study aim

To evaluate the effectiveness of Pilates exercises on Menstrual Pain, Balance and function in university students with Primary Dysmenorrhea.

Design

Parallel group randomized clinical trial and Randomization will be achieved through computer generated random number table.

Settings and conduct

Outpatient Physical Therapy Department of Safi Hospital, Faisalabad, Pakistan. It will be assessor blinded study Who will be unaware of the type of intervention patients have received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Students with Primary Dysmenorrhea, Age:18 to 25 years, having regular Menstrual cycles, Moderate-to-severe Primary Dysmenorrhea-associated pain, indicated by a score of ≥ 4 on a numerical rating scale, ranging from '0' (no pain) to '10' (unbearable pain) for at least two previous consecutive menstrual periods, The participants were not involved in other exercise programme Exclusion Criteria: Menstrual cycles > 35 days, Pregnant females, No pain relief with over the counter analgesic

Intervention groups

Group A: Intervention group 1: The training will be started with warm-up exercises including simple stretching of whole body for 10 minutes preceded by Pilates for 20 minutes, and followed by cool-down exercises comprising of simple breathing for 10 minutes. Group B: Intervention Group 2: The training will be started with warm-up exercises including simple stretching of whole body for 10 minutes preceded by Aerobic training for 20 minutes, and followed by cool-down exercises comprising of simple breathing for 10 minutes.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230216057434N6**

Registration date: **2023-04-05, 1402/01/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-05, 1402/01/16**

Update count: **0**

Registration date

2023-04-05, 1402/01/16

Registrant information

Name

Zainab Sheraz

Name of organization / entity

Riphah International University, Faisalabad

Country

Pakistan

Phone

+92 301 7070941

Email address

zainab.48@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative Effects of Pilates exercises versus Aerobic Training on Menstrual Pain, Balance and Daily Functioning in University Students with Primary Dysmenorrhea

Public title
Pilates exercises in Primary Dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Students with Primary Dysmenorrhea Age group 18 to 25 years Having regular Menstrual cycles Moderate-to-severe Primary Dysmenorrhea-associated pain, indicated by a score of ≥ 4 on a numerical rating scale Ranging from '0' (no pain) to '10' (unbearable pain) for at least two previous consecutive menstrual periods
Exclusion criteria:
Menstrual cycles > 35 days apart • Pregnant females No pain relief with over the counter analgesics

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done through a computer software "Random allocation software Version 2. The total sample size will be entered with required number of participants to be allocated in two groups. An automated randomization list will be achieved with attrition rate included. The program starts running with the default settings. Users may run the program with the default settings or set the number of groups, the name of participants in each group and the sample size. Clicking the 'Generate' button produces the random sequence. Before generating the random sequence, the option window will be displayed and different randomization settings can be entered.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding will be done on part of outcome assessor who will be an experienced therapist. Patients will be assessed by him at the end of treatment session. He will be blinded about the type of intervention patient will received

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Riphah International University Faisalabad

Street address
Riphah International University, Faisalabad

City
Faisalabad

Postal code
38000

Approval date
2022-05-12, 1401/02/22

Ethics committee reference number
RCRAHS/REC/23/09

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
Assessment will be performed at 0 week (baseline) at 4t week and at completion of 8 weeks treatment

Method of measurement
McGill pain Questionnaire

Secondary outcomes

1

Description
Static Balance

Timepoint
Assessment will be performed at 0 week (baseline) at 4th week and at completion of 8 weeks treatment

Method of measurement
one leg standing test with eyes open and closed

2

Description

Dynamic balance

Timepoint

Assessment will be performed at 0 week (baseline) at 4th week and at completion of 8 weeks treatment

Method of measurement

Berge Balance Scale

3

Description

Daily Functioning

Timepoint

Assessment will be performed at 0 week (baseline) at 4th week and at completion of 8 weeks treatment

Method of measurement

Brief Pain Inventory - Short form

Intervention groups

1

Description

Intervention group 1 (Pilates exercises): The training will be started with warm-up exercises including simple stretching of whole body for 10 minutes preceded by Pilates for 20 minutes, and followed by cool-down exercises comprising of simple breathing for 10 minutes. The session will be conducted three times per week, each session will be started with warm up exercise including simple stretching for 10 minutes preceded by pilates for 20 minutes, and followed by cool down exercises comprising of simple breathing for 10 minutes. Pilates exercises will be performed at basic level in the form of roll up(6 repetition), double leg stretch(5-10 repetition) and spine stretch forward(5 repetition) for first two weeks, intermediate level with the single leg stretch(10 repetitions), saw(4 repetition) and criss cross(5-10 repetitions) for third to fifth week and advance level in the form of shoulder bridge(3 repetitions) for sixth to eighth week.

Category

Treatment - Other

2

Description

Intervention group 2 (Aerobic Training)The training will be started with warm-up exercises including simple stretching of whole body for 10 minutes preceded by Aerobic training for 20 minutes, and followed by cool-down exercises comprising of simple breathing for 10 minutes. The aerobic training session will be conducted three times per week each session will be started with warm up exercise including simple stretching for 10 minutes preceded by running on treadmill (B1 motorized treadmill 3.0 HP, black) for 20 minutes, and followed by cool down exercises comprising of simple breathing for 10 minutes .During the session the distance covered by the participants on the treadmill and the heart rate will be recorded via pedometer and radial pulse with 70-85%

of their maximum heart rate (maximum heart rate= 206-88% of age in years) respectively

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Safi Hospital

Full name of responsible person

Mubashra Nouman

Street address

Safi Hospital, Near Fish Farm, Satyana Road , Faisalabad

City

Faisalabad

Postal code

38000

Phone

+92 320 520051

Email

mubasharanouman@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Self funded

Full name of responsible person

Zainab Sheraz

Street address

house no. 32, street no. 2, Rehman Town, adjacent Shahzad Colony, Satyana Road, Faisalabad

City

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38000

Phone

+92 335 6600141

Email

zainab.48@hotmail.com

Grant name

N/A

Grant code / Reference number

N/A

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

N/A

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Riphah International University

Full name of responsible person

Zainab Sheraz

Position

Senior Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

house no. 32, street no. 2, Rehman Town, adjacent
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City

Faisalabad

Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah International University, Faisalabad

Full name of responsible person

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Position

Senior Lecturer

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Real Patient involved

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available