Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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 accessor 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
Pain, Balance, Daily functioning

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 foreward(5 repetition) for first two weeks, intermediate level with the single leg stretch(10 repetitions), saw(4 repitition) 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 5200051
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
Faisalabad
Postal code
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 Shahzad Colony, Satyana Road, Faisalabad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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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