

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessing the effect of aerobic exercises on cardiorespiratory and cardiometabolic fitness in post menopausal females in Multan

Protocol summary

Study aim

Exploring the effect of stress inducers aerobic exercises (stair climbing, 6MWT, step up) between BP, HR, oxygen saturation, glucose level, lipid profile, temperature, and RR estrogen and progesterone level of post-menopausal females of Multan with body mass index and cardiorespiratory and cardiometabolic health.

Design

Randomized control trial, three parallel groups design, triple blinded study with a sample size of 45

Settings and conduct

Shahbaz Sharif Hospital, Muhammad Rehabilitation center, Faiz hospital

Participants/Inclusion and exclusion criteria

Including Criteria: Females; Aged 40-60 years; Postmenopausal females; Good mental and physical health; Naturally menopausal females; Negative screening mammogram. Exclusion criteria: Young females; Perimenopausal females; Any type of physical disability; Any type of major surgery; Females with osteoporosis and osteoarthritis; History of melanoma or breast cancer; Females who have any type of hormone replacement therapy.

Intervention groups

3 groups of intervention are included in this study. group 1 with 6 minute walk test, group 2 with stair climbing exercise and group 3 with step up exercise

Main outcome variables

cardiorespiratory and cardiometabolic parameters improvement

General information

Reason for update

Acronym

cross sectional experimental study

IRCT registration information

IRCT registration number: **IRCT20230718058826N3**

Registration date: **2023-09-01, 1402/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-01, 1402/06/10**

Update count: **0**

Registration date

2023-09-01, 1402/06/10

Registrant information

Name

Perwasha Perwasha

Name of organization / entity

Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan.

Country

Pakistan

Phone

+92 310 6562039

Email address

perwashaanaseer123@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-29, 1402/05/07

Expected recruitment end date

2023-09-14, 1402/06/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the effect of aerobic exercises on cardiorespiratory and cardiometabolic fitness in post menopausal females in Multan

Public title

Assessing the effect of aerobic exercises on cardiorespiratory and cardiometabolic fitness in post menopausal females in Multan

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Females 40-60 post menopausal females good mental and physical health natural menopausal negative screening mammogram
Exclusion criteria:
young females perimenopausal any type of physical and mental disability, major surgery females with OP OA history of melanoma or breast cancer hormone replacement therapy patient

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation is done by the lottery method in which the names of the participants are written on pieces of paper and randomly chosen the paper by an individual and then people are allocated randomly to different groups without knowing which participant is added to which intervention group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
in this study, triple blinding method involved in which the participants, investigator and data analyzer will be blinded. Participants randomly allocate in different intervention group and they do not know about exercise in any intervention group ,investigator randomly allocate the patient or participant and data analyzer will be independent for results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Muhammad Institute of Medical and Allied Sciences
Street address
HBL street near sabzazar metro station bosan road Multan
City
Multan
Postal code
66000
Approval date
2023-07-10, 1402/04/19
Ethics committee reference number
2023/ MIMAS/Anosha/07/19

Health conditions studied

1

Description of health condition studied
cardiorespiratory and cardiometabolic health in post menopausal females age 40-60

ICD-10 code
ICD-10

ICD-10 code description
post menopausal females, cardiorespiratory fitness

Primary outcomes

1

Description
Improve Cardiorespiratory and cardiometabollic health

Timepoint
time duration of study will be six weeks. 5 days in a week for 6 weeks

Method of measurement
BP, RR, HR, Temperature, Oxygen saturation, glucose level, cholestrol level

Secondary outcomes

1

Description
Quality of life

Timepoint
time duration of study will be 6 weeks. 5 days in a week for 6 weeks

Method of measurement
vo2max,cardiorespiratory parameters

Intervention groups

1

Description
"Intervention Group 1": with 6 Minute Walk Test (6MWT)A 30m walking pace will be decided. Subjects will be

instructed to walk from end to end, while attempting to cover as much distance as possible in the 6 minutes. The time and distance covered will be recorded. The Borg scales for dyspnea and leg fatigue, as well as heart rate were recorded before and immediately after completion of the walk test(24). BP, HR, RR, temperature and oxygen saturation will be measured before and after the exercise.

Category

Lifestyle

2

Description

"Intervention Group 2": with Stair climbing 3 bouts of stair climbing will be separated. In this, protocol will be included 3 daily bouts of ascending a 3-flight stairwell (10 steps) for 4 minutes gently without break. The height of step will be 35cm. This activity will be performed 5 days/week for 6 weeks. BP, HR, RR, temperature and oxygen saturation will be measured before and after the exercise.

Category

Lifestyle

3

Description

'Intervention group 3': with Step up exercise 3 sets with 10 repetitions in each set will be performed for 6 weeks. BP, HR, RR, temperature and oxygen saturation will be measured before and after the exercise.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Faiz hospital

Full name of responsible person

Nimra Arif

Street address

BCG chock

City

Multan

Postal code

66000

Phone

+92 321 6563479

Email

nimraarif@gmail.com

2

Recruitment center

Name of recruitment center

Shahbaz Sharif hospital

Full name of responsible person

Ali Abbas

Street address

Fawara chock

City

Multan

Postal code

66000

Phone

+92 321 5654897

Email

shahbaz@gmail.com

Web page address

3

Recruitment center

Name of recruitment center

MIMAS, Multan

Full name of responsible person

Imran Ahmad Khan

Street address

HBL street near sabzazar metro station bosan road
Multan

City

Multan

Postal code

66000

Phone

+92 333 6120602

Email

imtanahmadkhandurrani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CUVAS

Full name of responsible person

Zahid Manzoor

Street address

Bahawalpur, Punjab, Pakistan

City

Bahawalpur

Postal code

63100

Phone

+92 312 6678543

Email

zahidmanzoor@cuvas.edu.pk

Grant name

scholarship for research

Grant code / Reference number

4531

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

No

Title of funding source

scholarship for research

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**Type of organization providing the funding**

Academic

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

CUVAS

Full name of responsible person

Zahid Manzoor

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

Street address

bahawalpur , punjab, Pakistan

City

Bahawalpur

Province

punjab

Postal code

63100

Phone

+92 312 6678543

Email

zahidmanzoor@cuvas.edu.pk

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

MIMAS

Full name of responsible person

Perwasha

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Service Management

Street address

HBL street near sabzazar metro station bosan road

Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 310 6562039

Email

perwashaanaseer123@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

MIMAS

Full name of responsible person

Perwasha

Position

Assistasnt Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Service Management

Street address

HBL street near sabzazar metro station bosan road

Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 310 6562039

Email

perwashaanaseer123@gmail.com

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

Aim of this study is to explore the correlates (BP, HR, oxygen saturation, glucose level, lipid profile, temperature, RR) of post menopausal females of Multan that are associated with body mass index and cardiorespiratory and cardiometabolic health. Aim of this study is to improve the quality of life. 1.4. Expected Outcomes This study will investigate the correlation of cardiorespiratory fitness and cardiometabolic with body mass index in post menopausal females of Multan and also investigate the respiratory improvements.

When the data will become available and for how long

After the protocol completion data will be available for long time

To whom data/document is available

Supervisor provided the all documents

Under which criteria data/document could be used

Under strict ethical consideration

From where data/document is obtainable

from secretary BASR

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

IRB form, informed consent for and reports

Comments

Kindly approve it