

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Aerobic Exercises as an Adjunctive Therapy In Depression: A Randomized Controlled Trial

Protocol summary

Study aim

this study aim is to compare the effectiveness of aerobic exercises as an adjunctive therapy along with antidepressants on depression.

Design

In this observer blinded Randomised Controlled Trial, total 32 patients with depression were recruited via consecutive sampling. Both groups were having equal number of patients that is 16 in each.

Settings and conduct

I-fitness Gym of Iqra National Univeristy Peshawar Pakistan

Participants/Inclusion and exclusion criteria

This study will include patients (both male and females) with mild to severe depression of age 18-35. Patients who resided in Peshawar Pakistan and had an easy access to the aforementioned clinic or the i-fitness gym of Iqra National University, Peshawar Pakistan will be included. Patients who had participated in any other clinical study/trial at the time the present study will be excluded patients who is involved in any sporting or exercise activity at the time of this study conduction or anyone who could not participate in any physical activity or had any other psychiatric or physical disorder will be excluded from this study. Patients who had been taking any antipsychotic drugs or psychotherapy within last 3 months before the commencement of the present study will also be excluded.

Intervention groups

The experimental group received aerobic exercises and antidepressants while the controls received only antidepressants for 8 weeks.

Main outcome variables

The primary outcome measures were Hamilton Depression rating scale (HDRS) and Beck Depression Inventory-II (BDI-II).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211011052727N1**

Registration date: **2022-05-19, 1401/02/29**

Registration timing: **prospective**

Last update: **2022-05-19, 1401/02/29**

Update count: **0**

Registration date

2022-05-19, 1401/02/29

Registrant information

Name

Salman farooqi

Name of organization / entity

Khyber Medical University Peshawar Pakistan

Country

Pakistan

Phone

+92 91 5823496

Email address

salman.farooqi@kmu.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-31, 1401/03/10

Expected recruitment end date

2022-09-01, 1401/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Aerobic Exercises as an Adjunctive Therapy In Depression: A Randomized Controlled Trial

Public title

Effectiveness of Aerobic Exercises as an Adjunctive Therapy In Depression: A Randomized Controlled Trial

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

This study included both male and females patients patients with mild to severe depression will be included in the study Patients who resided in Peshawar Pakistan and had an easy access to the aforementioned clinic or the i-fitness gym of Iqra National University, Peshawar will be included. patients with the age between 18-35 will be included

Exclusion criteria:

Patients who are currently enrolled in any other clinical study/trial Patients who are involved in any sporting or exercise activity at the time of this study conduction Anyone who could not participate in any physical activity Patients having other psychiatric or physical disorder will be excluded from this study Patients who are taking any antipsychotic drugs or psychotherapy within last 3 months before the commencement of the present study will be excluded

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

After meeting the inclusion criteria and filling a written informed consent, a total of 32 patients will be enrolled in this study. These participants will be randomly allocated into two groups namely; the Experimental group (aerobic exercises and antidepressants) and the Control group (antidepressants only). The random allocation will be performed using sealed envelope (opaque). Total 32 envelopes will be prepare, 16 will have a paper with group A (control group: antidepressants) written on it and 16 will have group B (experimental group: aerobic exercises and antidepressants). This will be for equal distribution of subjects in the two groups. Each participant will be asked to pick an envelope and he/she will hand over the envelop to the researcher. Participants were not blinded about their allocation as it was not possible. All the participants were well informed about the goals and intervention of the study by providing detailed

Blinding (investigator's opinion)

Single blinded

Blinding description

the investigator was unaware of the patient level of depression and of the detail of weather the patient is in the control group or experimental group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethical review committee of Khyber Medical University

Street address

Phase 5 Hayatabad Peshawar

City

Peshawar

Postal code

25001

Approval date

2022-03-25, 1401/01/05

Ethics committee reference number

KMU/ERC- 15011

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

Primary outcomes**1****Description**

the primary outcome is the level of depression

Timepoint

8 weeks

Method of measurement

Hamilton Depression rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aerobic Exercises and Antidepressants (n=16) Exercises: three days for 8 weeks • 5 mins warm up, 30 mins treadmill walk, 5 mins cool down (1st 4 weeks) • 5 mins warm up, 30 mins cycling on cycle ergometer, 5 mins cool (next 4 weeks)

Category

Rehabilitation

2

Description

Control group: Antidepressant drugs (n=16) for 16 weeks types and dosage as per the condition of the patient (prescribe by a Psychiatrist)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

The Iqra National University

Full name of responsible person

Dr. Eiman Summaya

Street address

Hayatabad Phase 2 Peshawar Pakistan

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25000

Phone

+92 315 9710104

Email

eimaanktk@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khyber Medical University

Full name of responsible person

Dr Masood Ifrah

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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

Khyber Medical University

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

Khyber Medical University

Full name of responsible person

Farooqi Salman

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Ph.D.

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

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Full name of responsible person

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Position

Lecturer

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

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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

there is no further information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

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