

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 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

#### City

Peshawar

#### Postal code

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

#### Street address

Hayatabad Phase 5 Peshawar Pakistan

#### City

Peshawar

#### Postal code

25001

#### Phone

+92 321 6710675

#### Email

ifrah.masood@yahoo.com

#### 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

#### Street address

K5/47 Phase 3 hayatabad Peshawar

#### City

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#### Province

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25001

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#### Email

salmankmu@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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#### Position

Lecturer

#### Latest degree

Ph.D.

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

Khyber Medical University Peshawar Pakistan

**Full name of responsible person**

Salman Farooqi

**Position**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Phase 5 hayatabad

**City**

Peshawar

**Province**

Khyber Pukhtoonkhwa

**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