Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 unawear 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
Peshawar
Province
Khyber Pukhtunkhwa
Postal code
25001
Phone
+92 345 2231141
Email
salmankmu@gmail.com

Person responsible for scientific inquiries

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
Postal code
25001
Phone
+92 91 5823496
Fax
Email
salman.farooqi@kmu.edu.pk

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
Postal code
25001
Phone
+92 91 5823496
Fax
Email
salman.farooqi@kmu.edu.pk

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