

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis

Design

This is a randomized clinical trial with a control group with parallel groups without blinding, in which 40 eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct

This study will be conducted at the Beheshti Hospital in Hamadan city, involving 40 eligible patients undergoing hemodialysis. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Patients undergoing hemodialysis, Exclusion criteria: Movement disorders

Intervention groups

Intervention group: Treatment and routine care for hemodialysis patients, along with aerobic exercises including pedaling on a stationary mini electric bike for 30 minutes, and resistance exercises including leg raises (two sets of 10 repetitions), heel raises (three sets of 15 repetitions), and knee flexion and extension (two sets of 10 repetitions), performed three days per week for three months. Control group: Treatment and routine care for hemodialysis patients

Main outcome variables

Primary outcome: Blood calcium level; Blood phosphorus level; Blood sodium level; Blood potassium level; Blood hemoglobin level; Blood hematocrit level; Blood platelet level; Blood creatinine level; Blood urea level; Blood albumin level; Blood triglyceride level; Blood alkaline phosphatase level; Blood SGOT level; Blood SGPT level; Blood parathyroid hormone level; Psychological

symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N608**

Registration date: **2026-05-14, 1405/02/24**

Registration timing: **prospective**

Last update: **2026-05-14, 1405/02/24**

Update count: **0**

Registration date

2026-05-14, 1405/02/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-31, 1405/03/10

Expected recruitment end date

2026-09-01, 1405/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis: a randomized clinical trial

Public title

Effect of a course of aerobic training versus control group on blood factors and psychological symptoms in patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 65 years, Patients undergoing hemodialysis,

Exclusion criteria:

Movement disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Islamic Azad University - Boroujerd Branch

Street address

Islamic Azad University, Boroujerd Branch, Navab Square

City

Boroujerd

Province

Lorestan

Postal code

6915136111

Approval date

2026-04-22, 1405/02/02

Ethics committee reference number

IR.IAU.B.REC.1405.018

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

Hemodialysis

ICD-10 code

Z49.31

ICD-10 code description

Encounter for adequacy testing for hemodialysis

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

Blood calcium level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

2**Description**

Blood phosphorus level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

3**Description**

Blood sodium level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

4**Description**

Blood potassium level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

5

Description

Blood hemoglobin level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

6

Description

Blood hematocrit level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

7

Description

Blood platelet level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

8

Description

Blood creatinine level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

9

Description

Blood urea level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

10

Description

Blood albumin level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

11

Description

Blood triglyceride level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

12

Description

Blood cholesterol level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

13

Description

Blood alkaline phosphatase level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

14

Description

Blood SGOT level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

15

Description

Blood SGPT level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

16

Description

Blood parathyroid hormone level

Timepoint

Before the intervention and three months later

Method of measurement

By taking and testing a blood sample

17

Description

Psychological symptoms

Timepoint

Before the intervention and three months later

Method of measurement

Using the Garnefski standard questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment and routine care for

hemodialysis patients, along with aerobic exercises including pedaling on a stationary mini electric bike for 30 minutes, and resistance exercises including leg raises (two sets of 10 repetitions), heel raises (three sets of 15 repetitions), and knee flexion and extension (two sets of 10 repetitions), performed three days per week for three months.

Category

Other

2**Description**

Control group: Treatment and routine care for hemodialysis patients

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Beheshti Hospital in Hamadan city

Full name of responsible person

Fahimeh Ghodrati

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Beheshti Hospital, Eram Ave.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

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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

Islamic Azad 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**

Islamic Azad University

Full name of responsible person

Fahimeh Ghodrati

Position

Student of Exercise Physiology

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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