Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Recruitment status
Recruitment complete
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, Borujerd 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

Street address
Beheshti Hospital, Eram Ave.

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6517838695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Ali Aryapoor

Street address
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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

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Person responsible for updating data

Contact

Name of organization / entity
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Professor of Epidemiology

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Ph.D.

Other areas of specialty/work
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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