

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparing the effects of vision, balance and combined exercises on motor function and quality of life of hemodialysis patients

Protocol summary

Study aim

The effect of visual and balance exercises on motor function and quality of life of hemodialysis patients.

Design

The clinical trial has a control group and three intervention groups that include vision exercises, balance exercises and combined exercises. The randomization method of this intervention is simple, which will be performed on 110 patients, which will be blinded on one side, and the randomization will be used by Statacrop software .

Settings and conduct

The clinical trial has a control group and three intervention groups of vision exercises, exercises and combined exercises. Simple on 110 patients is blinded on one side and randomized program will be used by Statacrop computer.

Participants/Inclusion and exclusion criteria

Inclusion criteria:undergoing HD for at least 1 year and agreeing to participate, Exclusion criteria: having medical contraindications for exercise .

Intervention groups

Vision training group, balance training group, combined training group, all groups will attend three sessions a week for 12 weeks for one hour each session, and the control group will be without intervention and only pre-test and post-test will be taken from them.

Main outcome variables

Motor Function; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220809055648N1**

Registration date: **2023-05-08, 1402/02/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-08, 1402/02/18**

Update count: **0**

Registration date

2023-05-08, 1402/02/18

Registrant information

Name

Mahboobeh Hosini sarbazu

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 0506

Email address

m.h.sarbazi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of vision, balance and combined exercises on motor function and quality of life of hemodialysis patients

Public title

The effect of vision, balance and combined exercises on motor function and quality of life of hemodialysis patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 80 years
More than 1 year of dialysis experience
Having a three-time hemodialysis program
No heart attack and stroke in the past three months
Having the ability to communicate with others
The permission of the attending physician to practice

Exclusion criteria:

unstable heart condition (angina, congestive heart failure, severe arterial stenosis) during exercise
Active infection or acute medical illness during intervention
Hemodynamic instability during intervention
Unstable blood sugar during intervention
Unable to do exercises, after a few sessions of participating
Having severe musculoskeletal pain during exercises

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, individual with random number generation program
Randomization was performed by a biostatistician using a computer-generated randomization program [using Stata 16, StataCrop, College Station, Tx] (regarding number of groups) with an allocation ratio of 1:1:1:1. For allocation concealment, allocation information will be protected in opaque sealed envelopes by an identified individual not participating in the study. Only after participant registration and baseline measurements are completed will envelopes be opened.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, it is not plausible to blind participants and study staff who enroll participants and monitor the intervention delivery. Research project collaborator who is blinded to study arm assignments will obtain outcome measurements of the functional test and abnormalities. Outcome adjudicators, and data analysts will be kept blinded to the allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Azad University of Khorasgan Branch

Street address

University Blvd, Arghavanieh Ave, Estern Jey Str, Esfahan Town

City

Esfahan

Province

Isfahan

Postal code

8155139998

Approval date

2022-09-14, 1401/06/23

Ethics committee reference number

IR.IAU.KHUISF.REC.1401.204

Health conditions studied

1

Description of health condition studied

End stage renal disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

motor performance

Timepoint

Before starting exercise and three months later

Method of measurement

6-minute walk test, Berg balance test, Timed up and Go test

Secondary outcomes

1

Description

Quality of life

Timepoint

Before starting exercise and three months later

Method of measurement

The standard questionnaire of the quality of life for kidney patients

Intervention groups

1

Description

Intervention group: The group of balance exercises, three sessions per week for 12 weeks (each for 1 hour) includes stretching exercises (neck stretching, arm and hand stretching, shoulder rotation and vertical movement, lateral stretching, single knee stretching, leg stretching) which Taken from Pinter's studies at the Medical Education Institute, it is an empowering resource. and balance exercises taken from the studies of Bennett, Lingard and Maxwell (2015), which include (chest press, shoulder press, triceps strengthening, straight arm stretch, horizontal shoulder stretch, back grip, palmar grip, biceps rotation, rotation leg press, calf press, leg press in a straight position, leg press in bent knee position, hip pull, straight leg lift, drawing letters with feet in the air, pulling knees in the stomach).

Category

Rehabilitation

2

Description

The vision training group, which has three sessions (each for 1 hour) per week for 12 weeks, will do vision exercise which includes saccadic eye movements and tracking.

Category

Rehabilitation

3

Description

Intervention group: Combined exercises for 12 weeks, three sessions per week (each for 1 hour). The participants will do balance and vision exercises (each one for half an hour).

Category

Rehabilitation

4

Description

Control group: without exercising

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Isfahan Hospital Hemodialysis Center

Full name of responsible person

Majid Hosseinzadeh

Street address

Sonbolestan Ave, Ebn Sian Str, Esfahan Town

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2

Recruitment center

Name of recruitment center

Farabi Hospital Hemodialysis Center, Isfahan

Full name of responsible person

Hamid Mohamad Beigi

Street address

Arghavanie Blvd, Mushtaq third Str, Esfahan Town

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8166176141

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Toghyani

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info@khuisf.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University of Khorasgan, Isfahan

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

Mahbobeh Hosseini Sarbazi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Rokhsare Badami

Position

Academic Staff, Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

zohre Meshkati

Position

Academic Staff, Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study group are made available

When the data will become available and for how long

After November 2023

To whom data/document is available

Only academics are allowed.

Under which criteria data/document could be used

If the data is used for the purpose of research in the field of variables and providing new solutions, it can be used by mentioning the source.

From where data/document is obtainable

by email m.h.sarbazi@gmail.com
rokhsareh.badami@gmail.com zmeshkati@gmail.com be referred.

What processes are involved for a request to access data/document

It will be answered within one month after receiving the email.

Comments