

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Effect of Legs Strength Exercises on Activities of Daily Living, Physical Fitness, and Fatigue Level in Patients undergoing Hemodialysis

Protocol summary

Improved ADLs, physical fitness, and reducing fatigue level

Study aim

To assess level of activities of daily living, physical fitness, and fatigue in patients undergoing hemodialysis.

Design

The present study employed a quasi-experimental design to assess the effect of legs strengthening exercises on activities of daily living, physical fitness, and fatigue levels in patients undergoing HD.

Settings and conduct

The study was conducted Imam AL-Hussein Medical city and Imam AL-Hassan AL-Mujtaba teaching hospital Karbala, Iraq

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have three and two undergoing hemodialysis sessions. All patients male and female. Patient have stable cardiac profiles. Patients who are regular for HD sessions. patients age from 18 to 60 years old. and the Exclusion criteria: Patients who having femoral access to HD. Patients who refuse participant in the study. participants in the pilot study. Patients have physical disability and orthopedic problems

Intervention groups

A total of 90 samples were chosen through purposive sampling technique, including 45 samples for both control and experimental groups that met specified criteria. Before conducting the intradialytic legs strength exercises to the participants, socio-demographic data, clinical data, ADLs, physical fitness, and fatigue level were assessed on day 0 as a pre-test. Then, the intervention began for the experimental group on the initial day of the 4th week. The exercises last for 25 minutes, allocated as follows: patients' feet are positioned on pedals and rotated in cycles as though riding a bike for about 10 minutes and take 5 minutes rest, then another 10 minutes began. This occurs during the first 2 hours of HD for the 4th week of each session. Post-test evaluations were obtained after completion of exercises program.

Main outcome variables

General information

Reason for update

Acronym

HD, ADLs

IRCT registration information

IRCT registration number: **IRCT20241125063851N1**

Registration date: **2025-05-04, 1404/02/14**

Registration timing: **prospective**

Last update: **2025-05-04, 1404/02/14**

Update count: **0**

Registration date

2025-05-04, 1404/02/14

Registrant information

Name

Ilham Ghanam Jabbar

Name of organization / entity

University of Karbala

Country

Iraq

Phone

+964 773 070 1025

Email address

ilham.g@s.uokerbala.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-25, 1404/03/04

Expected recruitment end date

2025-07-20, 1404/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Legs Strength Exercises on Activities of Daily Living, Physical Fitness, and Fatigue Level in Patients undergoing Hemodialysis

Public title

Effect Legs Strength Exercises on Activities of Daily Living, Physical Fitness and Fatigue Level in Patients undergoing Hemodialysis: Clinical Trial

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Patients who have three and two undergoing hemodialysis sessions. 2. All patients male and female. 3. Patient have stable cardiac profiles. 4. Patients who are regular for HD sessions. 5. patients age from 18 to 60 years old.

Exclusion criteria:

1. Patients who having femoral access to HD. 2. Patients who refuse participant in the study. 3. participants in the pilot study. 4. Patients have physical disability and orthopedic problems

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Not randomized

Randomization description**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 in College of Nursing at University of Kerbala

Street address

Al-Baladia district street

City

Karbala

Postal code

56001

Approval date

2024-10-27, 1403/08/06

Ethics committee reference number

uok.coN.24.045

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**

The primary outcome variable is the level of activities of daily living that can be changed based legs strength exercises.

Timepoint

Before intervention and four weeks after intervention

Method of measurement

The Bristol of activities daily living well be used to assess the activities of daily living

Secondary outcomes**1****Description**

The secondary outcome variable is the level of physical fitness that can be changed based on legs strength exercises

Timepoint

Before intervention and four weeks after intervention

Method of measurement

The International Fitness Scale will be used to assess the level of physical fitness

2**Description**

The secondary outcome variable is the level of fatigue that can be changed based on legs strength exercises

Timepoint

Before intervention and four weeks after intervention

Method of measurement

The Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Scale (Version 4) will be used to assess the level of fatigue

Intervention groups

1

Description

Intervention group: the exercises began on the first day of the 4th week of hemodialysis therapy, each exercise session lasted for 25 minutes and was conducted during the first 2 hours of the dialysis sessions.

Category

Treatment - Other

2

Description

Control group: these patients take the routine nursing care just without intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam AL-Hussein Habib Bin Muzahir Al-Asadi Center

Full name of responsible person

Ilham Ghanam Jabbar

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2

Recruitment center

Name of recruitment center

Imam AL-Hassan AL-Mujtaba teaching hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Kerbala

Full name of responsible person

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Grant name

no

Grant code / Reference number

No

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

No

Title of funding source

The author of the trial is the funding source

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

University of Kerbala

Full name of responsible person

Ilham Ghanam Jabbar

Position

Master student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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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

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

Title and more details about the data/document

The data will be the results of the Bristol Activities of Daily living Scale, International Fitness Scale, and Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue Scale (Version 4) that measures activities daily living, physical fitness, and fatigue levels in both the control and intervention groups

When the data will become available and for how long

God Willing, once the article is published, the data will be available after 6 months of publication. If the article will be published in a subscribed journal, the data will be available after one year because of the policy of the subscribed journals.

To whom data/document is available

with academic nurses and any researcher who is interested in the data.

Under which criteria data/document could be used

The data could be used after getting permission via email. Also, users need to acknowledge the owner.

From where data/document is obtainable

Users can ask for the data and permission via email. Ilham Ghanam is the corresponding author. He will contact whoever he requests the information from. His email is ilham.g@s.uokerbala.edu.iq Users can ask for the data and permission via email. What processes are involved for a request to access data/document What processes are involved for a request to access data/document

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Comments