

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

##### Street address

Al-Baladia district street

##### City

Kerbala

##### Postal code

56001

##### Phone

+964 773 070 1025

##### Email

nursing@uokerbala.edu.iq

##### Web page address

<https://nursing.uokerbala.edu.iq/wp/en/>

### 2

#### Recruitment center

##### Name of recruitment center

Imam AL-Hassan AL-Mujtaba teaching hospital

##### Full name of responsible person

Ilham Ghanam Jabbar

##### Street address

Al-Baladia district street

##### City

Karbala

##### Postal code

56001

##### Phone

+964 773 070 1025

##### Email

ilham.g@s.uokerbala.edu.iq

##### Web page address

<https://nursing.uokerbala.edu.iq/wp/en/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

University of Kerbala

##### Full name of responsible person

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##### City

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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

##### Street address

Al-Baladia district street

##### City

Kerbala

##### Province

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##### Postal code

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Ilham Ghanam Jabbar

**Position**

Master student

**Latest degree**

Master

**Other areas of specialty/work**

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**Street address**

Al-Baladia district street

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## Person responsible for updating data

**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

**Street address**

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**Province**

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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**