Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

Improved ADLs, physical fitness, and reducing fatigue level

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

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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
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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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Street address
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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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Web page address
https://nursing.uokerbala.edu.iq/
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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Person responsible for updating data

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Web page address
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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