

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of an educational program based on the teach back method on physical function and quality of life in hemodialysis patients

Protocol summary

Physical function; Quality of life

Study aim

The effect of an educational program based on the teach back method on physical function and quality of life in hemodialysis patients referred to Hamadan hospitals.

Design

This is a Randomised clinical trial study that patients will be randomly assigned to control and intervention based on block randomization. 90 patients will participate in this study.

Settings and conduct

The research community are the patients with kidney failure under the hemodialysis in the Beheshti and Besat hospitals in Hamedan city. At the pre - test stage, both groups will complete the demographic questionnaire, the questionnaire related to the quality of life of patients with renal disease (KDQOL SF) will be filled. It will also be recorded by the researcher for the length of a period of 6 minutes walking. The training of sports is given orally to the patient, and then we ask the patient to repeat the content of exercise to us if a wrong understanding is noticed, the patient will be trained again. The physical activity and quality of life in patients, lives in both groups will be measured at the end of the first week, 2nd, 4th, 6th, 8th, 10th and 12th.

Participants/Inclusion and exclusion criteria

Having satisfaction to participate in the study, performing a hemodialysis treatment for at least 6 months, having no cardiovascular disease that prevents the exercise program; not participating in the exercise program for 4 times during the entire test program, leaving the dialysis due to the transplant Kidney or any other action, dissatisfaction to continue cooperation.

Intervention groups

The intervention group will perform in 3 sessions of lower limb booster exercises with isotonic and isometric exercises designed by a sports medicine specialist within a week, and no action was taken in the control group and received routine care.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170130032303N5**

Registration date: **2019-02-14, 1397/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-14, 1397/11/25**

Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Morteza Shamsizadeh

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0535

Email address

shamsizadeh@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational program based on the teach back method on physical function and quality of life in hemodialysis patients

Public title

The effect of an educational program on physical function and quality of life in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to read and write Have satisfaction for the company in the study Under hemodialysis at least 6 months Lack of hospital history in the last six months Do not do regular exercise programme in the last six months Do not have a special orthopaedic problem preventing a walk Do not have Cardiovascular disease, asthma, acute heart failure to prevent a sports programme

Exclusion criteria:

Non - participating in the sport program for 4 times during the entire test program Dispensing the continuation of the exercise program Leave dialysis due to kidney transplant or any other action Patients death Lack of satisfaction with continuing co - operation

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Random allocation with block Randomization

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**

Hamedan University of Medical Sciences

Street address

Mahdiah street

City

hamedan

Province

Hamadan

Postal code

65178

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.UMSHA.REC.1397.734

Health conditions studied**1****Description of health condition studied**

Chronic Kidney Disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

Physical Function

Timepoint

Before the intervention begins, the end of the first week, the second, the fourth, the eighth, the tenth, the tenth and the twelfth.

Method of measurement

Six-Minute Walk Test

2**Description**

Quality Of Life

Timepoint

Before the intervention begins, the end of the first week, the second, the fourth, the eighth, the tenth, the tenth and the twelfth.

Method of measurement

Kidney Disease Quality of Life Short Form (KDQOL-SF™)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group will perform during the following week, along with isotonic and isometric exercise, which are designed by a sports expert

Category

Other

2**Description**

Control group: no action was carried out and routine health care was received.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Faezeh Ranjbaran

Street address

Shahidbeheshti Blvd

City

Hamedan

Province

Hamadan

Postal code

65178

Phone

+98 81 3264 0020

Fax

+98 81 3262 1515

Email

besat@umsha.ac.ir

Web page address<http://besat.umsha.ac.ir/>**2****Recruitment center****Name of recruitment center**

Shahid Beheshti Medical Educational Center

Full name of responsible person

Faezeh Ranjbaran

Street address

Eram Blvd

City

Hamedan

Province

Hamadan

Postal code

3371-5-65179

Phone

+98 81 3838 0283

Fax

+98 81 3838 1035

Email

Shahidbeheshti@umsha.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Manochehr karamy

Street address

Shahidfahmideh Avn

City

Hamedan

Province

Hamadan

Postal code

65178

Phone

+98 81 3252 0683

Email

ICT@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

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**

Hamedan University of Medical Sciences

Full name of responsible person

Faezeh Ranjbaran

Position

Nursing Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

No.300, Reyhani Allay, Jafari Avn, Mahdieh Str

City

Hamedan

Province

Hamadan

Postal code

6518011111

Phone

+98 81 3838 9902

Email

fa.ranjbaran.ezeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Faezeh Ranjbaran

Position

Nursing Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Faezeh Ranjbaran

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Currently, the university does not allow it.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available