

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of exercise during hemodialysis on self-efficacy and fatigue in patients: Single-Blind Randomized Clinical Trial.

Protocol summary

Summary

Purpose of the study: The effect of exercise during hemodialysis on self-efficacy and fatigue of patients: Single-blind randomized clinical trial. The sample of the study involves HD patients undergoing hemodialysis referring to Shahid Madani hospital. The sample size is 46 patients with available sampling conducted, will be selected based on inclusion criteria and will be divided into two groups; Will be randomized layout blocks type. First, fatigue and efficacy of all patients will be measured by demographic questionnaires, Sherer General Self-Efficacy Scale (SGSES) and Fatigue Severity Scale (FSS). Then, the experimental group for 8 weeks and three days in every week will do the exercise with a stationary bike and control group will receive usual interventions. Efficacy and fatigue will be measured and compared using a questionnaire after 8 weeks. After collecting data from all subjects, the results will be analyzed using SPSS 20. Inclusion criteria: Over 18; at least 6 months of hemodialysis history. Exclusion criteria: physical limitations in self-care, orthopedic problems preventing exercise, a Plan for Sport since 6 months ago.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016063028715N1**

Registration date: **2016-09-08, 1395/06/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-08, 1395/06/18

Registrant information

Name

Tahereh Zarei

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-08-31, 1395/06/10

Expected recruitment end date

2016-11-30, 1395/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise during hemodialysis on self-efficacy and fatigue in patients: Single-Blind Randomized Clinical Trial.

Public title

The effect of exercise during hemodialysis on self-efficacy and fatigue.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Over 18; at least 6 months of hemodialysis history; to be literate; Willingness to participate in a sports program by obtaining informed consent. Exclusion criteria: physical limitations in self-care, orthopedic problems preventing exercise, a Plan for

Sport since 6 months ago; having cardiovascular disease, asthma and severe heart failure according to the specialist and patient records preventing exercise.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street, Azadi street, Tabriz.

City

Tabriz

Postal code

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.TBZMED.REC.1395.484

Health conditions studied

1

Description of health condition studied

Chronic Kidney Diseases

ICD-10 code

N18.5

ICD-10 code description

Chronic Kidney Disease, stage 5

Primary outcomes

1

Description

Self Efficacy

Timepoint

Before Sampling and after the 8-week exercise program

Method of measurement

Sherer General Self-Efficacy Scale questionnaire

2

Description

Fatigue

Timepoint

Before sampling and after the 8-week exercise program

Method of measurement

Fatigue Severity Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention patients group will do eight-week exercise program including a pedal bike during hemodialysis in a dialysis center, under the supervision of a physician and specialist in exercise physiology. Before starting a workout, vital signs (blood pressure, pulse and respiration) of all patients will be controlled. Exercise program includes a bicycle pedal. All of them are according to the recommendations in the context of the exercise of ESRD patients which involves three days a week and each session lasts about 30 to 60 minutes in the first two hours of dialysis.

Category

Other

2

Description

Patients in the control group do not participate in the exercise program and receive regular treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Zarei Tahereh

Street address

Shahid Madani Hospital, Next to Tabriz University,

Golbad street, Azadi street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Doctor Mohammad Reza Rashidi

Street address

3rd floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street.

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parvan Kobra

Position

Faculty member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty