# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effect of exercise during hemodialysis on self-efficacy and fatigue in pationts: 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**

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Tahereh Zarei
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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 pationts: 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 Siences

**Street address**

Tabriz University of Medical Siences, 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 Diseas

**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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*