

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of exercise training on self-efficacy and functional ability of hemodialysis patients

Protocol summary

Summary

The aim of this study is to evaluate the effects of home walking exercise on self-efficacy and functional ability of hemodialysis patients. The sample of the study includes 60 HD patients undergoing hemodialysis in Fatemeh Zahra and Emam Khomeini hospital in Mazandaran, Iran. This study is a randomized clinical trial in which hemodialysis patients randomly allocated to 2 groups of exercise and control group. Inclusion criteria: age 18 to 65 years, at least six months hemodialysis history, the ability to walk independently, no history of unstable angina and heart attack in the past month, shortness of breath and severe heart failure which prevents the exercise program, physician allow to walk at home . Exclusion criteria included not participating in sports programs as much as four times in total and The patient withdrew the study. First, functional ability and self-efficacy of all patients will be measured by, Six minute walk test, Exercise Self-Efficacy Scale (ESES) and chronic disease self-efficacy scale (CDSSES) and demographic questionnaires. The experimental group for 2 weeks will do the core stability exercise then after two weeks they will do the home walking exercise for 6 weeks (three days in every week and 30 minutes each day). Patient in control group will receive usual care. Self-Efficacy and functional ability will be measured and compared after 2 and 8 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111824342N4**
Registration date: **2017-01-02, 1395/10/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-02, 1395/10/13

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research and Technology,
Mazandaran University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercise training on self-efficacy and functional ability of hemodialysis patients

Public title

The effect of exercise training on self-efficacy and functional ability

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 years, at least six months hemodialysis history, the ability to walk independently, no history of unstable angina and heart attack in the past month, shortness of breath and severe heart failure which prevents the exercise program, physician allow to walk at home, tend inclusion, no history of hospitalization within the past 6 months, not participate in a regular exercise program in 6 months ago, lack of orthopedic problems in the lower extremities such as hips, knees and ankles that prevents walking. Exclusion criteria included not participating in sports programs as much as four times in total and The patient withdrew the study.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

All patients randomly allocated to 2 groups with the aid of computer software by professor of statistics .

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee Mazandaran University of Medical Sciences

Street address

Moalem Square.

City

sari

Postal code**Approval date**

2010-10-25, 1389/08/03

Ethics committee reference number

IR.MAZUMS.AC.IR.95.2428

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

hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

hemodialysis

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

functional ability

Timepoint

Before the intervention, 2weeks after started the intervention and 2 months after started the intervention

Method of measurement

6MWt (six minute walk test)

2**Description**

exercise self efficacy

Timepoint

Before the intervention, 2weeks afterstarted the intervention and 2 months after started the intervention

Method of measurement

exercise self efficacy questionnaire(ESES)

3**Description**

Chronic diseases self efficacy

Timepoint

Before the intervention, 2weeks afterstarted the intervention and 2 months after started the intervention

Method of measurement

Chronic diseases self efficacy scale questionnaire(CDSES)

Secondary outcomes**1****Description**

Dialysis adequacy

Timepoint

befor intervention-2 months after intervention

Method of measurement

adequacy of dialysis formula

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

intervention1 (intervention group) First,before the study, functional ability will be measured by Six minute walk test and self-efficacy of patients measured by Exercise Self-Efficacy Scale (ESES) and chronic disease self-

efficacy scale (CDESES) and demographic questionnaires. The experimental group for 2 weeks will do the core stability exercise then after two weeks functional ability and self efficacy in patients will measured again. after that, they will do the home walking exercise for 6 weeks (three days in every week and 30 minutes each day). after six weeks Self-Efficacy and functional ability will be measured again.

Category

Behavior

2**Description**

intervention2 (control group) The control group received routine medical care. before started the study and after 2weeks and after 8 weeks, functional ability will be measured by Six minute walk test and self-efficacy of patients will be measured by Exercise Self-Efficacy Scale (ESES) and chronic disease self-efficacy scale (CDESES) and demographic questionnaires.

Category

Rehabilitation

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

Fatemeh Zahra Hospital

Full name of responsible person

Maryam Alizadeh

Street address

Artesh Boulevard,shahrdari square

City

sari

2**Recruitment center****Name of recruitment center**

EmamKhomeiny Hospital

Full name of responsible person

habibollah deilamy

Street address

EmamKhomeiny street-Namaz Boulevard

City

fereydoonkenar

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

Vice-Chancellor of Research and Technology,
Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Esmaeili

Street address

Moalem Square

City

sari

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

Yes

Title of funding source

Vice-Chancellor of Research and Technology,
Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Marzieh Hatef

Position

Master Critical Care Nursing Student

Other areas of specialty/work**Street address**

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4989726391

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Phd.Educational Nursing-faculty member

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Position

Master Critical Care Nursing Student

Other areas of specialty/work

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City

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Postal code

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