

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The effect of self- management Training on the self-efficacy and quality of life in elderly patients undergoing hemodialysis

Protocol summary

Study aim

The aim of this study is to assess the effect of self-management Training on the self-efficacy and quality of life in elderly patients undergoing hemodialysis

Design

Samples will be chosen from the patients admitted to hasheminejad hospital affiliated with Iran University of Medical Sciences. In this randomized controlled clinical trial, 96 patients will be randomly assigned to the experiment and control groups. The Samplers will be blinded to the study.

Settings and conduct

This study will be done in hemodialysis unit of hasheminejad hospital affiliated with Iran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The desire to participate in the study; Age over 60 years old; A history of at least 6 months of dialysis; Be on the weekly dialysis list; Having cognitive function; No history of mental illness with doctor approval; No history of mental illness with doctor approval; Listening and speaking ability acceptable for relationship; There are no any crisis during the past three months. Exclusion criteria: Unwillingness to continue to participate in the study; absence of more than 2 sessions of our session; participating in a similar research concurrently; acute stress, such as the death of relatives and family members, change location during this study.

Intervention groups

In the test group, the test group samples, a self-management program is performed for each patient during 6 weeks.

Main outcome variables

In two group, self-efficacy and quality of life are measured before intervention, immediately after intervention, and 4 weeks after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N20**

Registration date: **2018-10-25, 1397/08/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-25, 1397/08/03**

Update count: **0**

Registration date

2018-10-25, 1397/08/03

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self- management Training on the self- efficacy and quality of life in elderly patients undergoing hemodialysis

Public title

The effect of self- management Training on elderly patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The desire to participate in the study; Age over 60 years old; A history of at least 6 months of dialysis; Be on the weekly dialysis list; Having cognitive function; No history of mental illness with doctor approval; Listening and speaking ability acceptable for relationship; There are no any crisis during the past three months; Ability to do daily activities;

Exclusion criteria:

Unwillingness to continue to participate in the scheme; Absence of more than 2 sessions of our session; Participating in a similar research concurrently; Acute stress, such as the death of relatives and family members, change location during this study;

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned into two groups using permuted block randomization, Random numbers table will be used, Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 96 will be used for allocation concealment

Blinding (investigator's opinion)

Single blinded

Blinding description

Samplers and the statistical analyzer will be blind to patients 'allocation of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Eligible patients will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 2:2. Random allocation sequence will be determined using a computerized program. Opaque sealed

sequentially numbered envelopes from number 1 to 96 will be used for allocation concealment.

Secondary Ids

empty

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

Ethics committee of Shahed University

Street address

Opposite to Holy Shrine of Imam Khomeini, Tehran- Qom Freeway,

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-06-25, 1397/04/04

Ethics committee reference number

IR.SHAHED.REC.1397.029

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

End Stage Renal Disease

ICD-10 code

End stage

ICD-10 code description

N18.5 Chronic kidney disease, stage 5

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

Self-efficacy

Timepoint

Before intervention, after intervention, and 4 weeks after intervention

Method of measurement

Self-efficacy questionnaire

2**Description**

Quality of life

Timepoint

Before intervention, after intervention, and 4 weeks after intervention

Method of measurement

SF™ 3.1 - KDQOL questionnaire

3

Description

Self-efficacy for managing chronic disease

Timepoint

Before intervention, after intervention, and 4 weeks after intervention

Method of measurement

Self-efficacy for managing chronic disease questionnaire

4

Description

Mental statues

Timepoint

before intervention

Method of measurement

Abbreviated Mental Test Score

5

Description

Activity Daily Living

Timepoint

Before intervention, after intervention, and 4 weeks after intervention

Method of measurement

Activity Daily Living Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Educational sessions will be held in elderly people undergoing hemodialysis during 6 weeks and each session will be 45-60 minutes. Based on the training, the problems solving program will be taught with the help of family members for possible and actual problems.

Category

Lifestyle

2

Description

in control group no intervention required

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Hasheminejad hospital

Full name of responsible person

Marziyeh Mahdi Farani

Street address

Hasheminejad hospital, Valinezhad St, Vanak Sq.,
Tehran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahed University

Full name of responsible person

Vice chancellor for research, Shahed University, Dr.
Zahra Kiasalari

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Shahed University, Opposite to Holy Shrine of Imam
Khomeini, Tehran-Qom Freeway, Tehran.

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Kiasalari@shahed.ac.ir

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

Yes

Title of funding source

Shahed University

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**

Shahed University

Full name of responsible person

Nahid Rejeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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