Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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1969714713
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Email
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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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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
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Nursery
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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