Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Self Care Empowerment Program on Quality of Life and Functional Independence of the Older Adult Undergoing Hemodialysis

Protocol summary

Study aim
Determining the effect of the self-care empowerment program on the quality of life and functional independence of the older adult undergoing hemodialysis

Design
Semi-experimental with a control group, with parallel groups, without blinding, with available sampling, with the participation of 70 older adult undergoing hemodialysis.

Settings and conduct
This study is carried out in hospitals affiliated with Shahid Beheshti University of Medical Sciences.The intervention group will be trained in the self-care empowerment program, which will include training on diet, exercise, ways to prevent and control the complications of hemodialysis, control anxiety, and manage stress and self-care.

Participants/Inclusion and exclusion criteria
Be 60 years old or older;Six months have passed since the start of hemodialysis; Not suffering from cognitive disorders (based on the AMTS criteria and scoring at least 7 out of 10); To have the ability to communicate and to be able to complete questionnaires; Have the ability to participate in the self-care empowerment program

Intervention groups
Intervention group:The self-care empowerment program will have 6-8 sessions and each session will be about 60-70 minutes, which will include diet training, exercise, ways to prevent and control complications of hemodialysis, anxiety control and stress management, and self-care. At the end of each session, assignments are given to the patients and at the beginning of the next session, the assignments will be reviewed and feedback will be given. The researcher calls the patient during the week to ensure the correct implementation of the trained behaviors and also to answer the patient's questions. Control group: During the implementation of the research, they will only receive the usual treatment and follow-up of the center

Main outcome variables
Quality of Life; Functional Independence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230208057363N1**
Registration date: **2023-03-05, 1401/12/14**
Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**
Update count: **0**

Registration date
2023-03-05, 1401/12/14

Registrant information

Name
Marzieh Sotoudeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8865 5366

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2023-07-06, 1402/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Self Care Empowerment Program on Quality of Life and Functional Independence of the Older Adult Undergoing Hemodialysis

Public title
Effect of Self Care Empowerment Program on Quality of Life and Functional Independence of the Older Adult Undergoing Hemodialysis
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Be 60 years old or older Six months have passed since the start of hemodialysis Not suffering from cognitive disorders (based on the AMTS criteria and scoring at least 7 out of 10) To have the ability to communicate and to be able to complete questionnaires Have the ability to participate in the self-care empowerment program
Exclusion criteria:
The elderly do not want to continue participating in the research for any reason Do not participate in 2 sessions of the self-care empowerment program Any disturbance in the mental state or consciousness of the elderly
Age
From **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran.
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-05-24, 1401/03/03
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.047

Health conditions studied

1

Description of health condition studied
End–Stage Renal Disease; ESRD
ICD-10 code
I12.0
ICD-10 code description
Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease

Primary outcomes

1

Description
Quality of life score in SF-36 questionnaire
Timepoint
Completing the SF-36 quality of life questionnaire at the beginning of the study (before the start of the intervention) and one month after the end of the intervention
Method of measurement
Quality of life questionnaire SF-36 (36 Item Health Survey SF-36)

2

Description
Functional Independence score in Barthel index (Basic Activities Daily of Living) and Lawton index (Instrumental Activities Daily of Living)
Timepoint
Completing the Barthel index and the Lawton index at the beginning of the study (before the start of the intervention) and one month after the end of the intervention
Method of measurement
Barthel index (Basic Activities Daily of Living) and Lawton index (Instrumental Activities Daily of Living)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:First, quality of life questionnaire, Barthel index and Lawton index will be provided to the patients, then people with low scores will be selected as samples. The program is supposed to be presented in groups of 3-4 people. The grouping of the participants will be adjusted based on their opinion to participate in empowerment missions (from Saturday to Wednesday every week). Self-care empowerment program by holding 6-8 sessions for the intervention group, each session will be around 60-70 minutes. In this study, the content of the program will be compiled from a combination of two components, for the empowerment component, the BASNEF model will be used, and for the self-care component, the self-care questionnaire of patients with chronic kidney failure will be used for needs assessment. The empowerment program for these patients will include diet training, exercise, ways to prevent and control hemodialysis complications, anxiety control, stress management, and self-care.The training will be held face-to-face, discussion and exchange of ideas and using educational media such as video projector and PowerPoint.In the first to third sessions, the importance of changing wrong behaviors and its effects on health and improving the quality of life (belief structures, attitudes, mental norms) will be mentioned.The second session will be held with the presence of a doctor and nurse, and in the third session, a member of the patient's family who lives with him and plays an essential role in the patient's care will also participate.In addition, for the better effectiveness of the empowerment program, a booklet will be given to the family members of the patients. At the end of each session, homework is given to the patients, which includes the materials taught in the sessions, recording the patient's daily problems, complications of hemodialysis.At the beginning of the next session, homework will be reviewed and feedback will be given. In addition to following up the patient during the sessions, the researcher calls the patient during the week to ensure the correct implementation of the trained behaviors and also to answer the patient's questions. Finally, the questionnaires are completed again by the participants one month after the end of the intervention and the data are reviewed and compared.

Category

Behavior

2

Description

Control group: First, quality of life questionnaire, Barthel index and Lawton index will be provided to the patients, then people with low scores will be selected as samples. During the implementation of the research, the control group will not participate in any kind of educational program and will only receive the usual treatment and follow-ups of the center. Finally, the questionnaires are completed again by the participants one month after the end of the intervention and the data are reviewed and compared.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated to Shahid Beheshti University of Medical Sciences

Full name of responsible person

Marzieh Sotoudeh

Street address

Next to Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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
Shahid Beheshti University of Medical Sciences
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Marzieh Sotoudeh
Position
Master's student in nursing, majoring in geriatric nursing
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Position
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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