

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

Phone

+98 21 8865 5366

Email address

msotoudeh@sbmu.ac.ir

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

AgeFrom **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 Zarafshan & South Falamak, Qods Town, Tehran.

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Postal code

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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

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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

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Master's student in nursing, majoring in geriatric nursing

Latest degree

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Other areas of specialty/work

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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