

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigating the effect of self-care training program on self-efficacy and quality of life of hemodialysis patients

Protocol summary

Study aim

Determining the effect of self-care training program on self-efficacy and quality of life of hemodialysis patients

Design

A two-group clinical trial with a control group, with parallel groups, randomized, with the participation of 100 patients.

Settings and conduct

The present study will be conducted as a two-group randomized clinical trial with the participation of 68 patients undergoing hemodialysis referred to Shahid Beheshti hospital in Hamedan in 2023. Patients will be randomly assigned to intervention and control groups. In the intervention group, the self-care training program will be carried out. The sessions of the self-care training program will be held during 6 sessions during two weeks for 10-15 minutes exclusively for each person, on each patient's bed. Evaluation of self-efficacy and quality of life after self-care training intervention will be done one and two months after the last care session. In order to achieve more patients' participation and to minimize sample loss, an electronic questionnaire will be used to complete the questionnaire (one and two months after the intervention) in both groups. Patients in the control group will receive only the routine care of the department and no special action will be taken for them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Access to smart phones, Ability to communicate verbally, Having at least reading and writing literacy Exclusion criteria: Not completing the questionnaire completely, Unwillingness to continue cooperation

Intervention groups

Intervention group: The self-care training program will be conducted for the intervention group. The sessions of the self-care training program will be held during 6 sessions for 10-15 minutes specifically for each person, on each patient's bed. Control group: The control group will receive only routine care.

Main outcome variables

Self-efficacy and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N42**

Registration date: **2023-01-05, 1401/10/15**

Registration timing: **prospective**

Last update: **2023-01-05, 1401/10/15**

Update count: **0**

Registration date

2023-01-05, 1401/10/15

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-09, 1401/11/20

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of self-care training program on self-efficacy and quality of life of hemodialysis patients

Public title
Effect of self-care training program on self-efficacy and quality of life

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having at least reading and writing literacy Ability to communicate verbally Access to smart phones
Exclusion criteria:
Unwillingness to continue cooperation Not completing the questionnaire completely

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, four random blocks method is used. For this purpose, four sheets of paper are prepared. The letter A (intervention) is written on two sheets and the letter B (witness) is written on the other two sheets. The sheets are mixed together and removed by the researcher consecutively without placing them. This process is repeated for the number of qualified patients and whether each patient is group A or B is recorded.

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.UMSHA.REC.1401.629

Health conditions studied

1

Description of health condition studied

Renal failure

ICD-10 code

I13.2

ICD-10 code description

Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1

Description

Self-efficacy

Timepoint

Before and two months after the intervention

Method of measurement

Sherer general self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the self-care training program will be carried out. The sessions of the self-care training program will be held during 6 sessions during two weeks for 10-15 minutes exclusively for each person, on each patient's bed. Educational content will include infection prevention education, proper nutrition, how to take medications, explanations about exercise, sleep, and sexual activities. These trainings will be face-to-face training.

Category

N/A

2

Description

Control group: Control group: Patients in the control

group will receive only limited and routine care and education, such as vascular access site care and nutrition, and no special action will be taken for them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Firouzeh Beiranvand

Street address

Hamedan - the beginning of Eram Boulevard - Shahid Beheshti Hospital

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

firoozebeiranvand@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Email

R.shokouhi@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Firoozeh Beiranvand

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Hamadan University of Medical Sciences, Shahid Fahmideh Street

City

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Province

Hamadan

Postal code

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Phone

+98 81 3838 0535

Email

firoozebeiranvand@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Firoozeh Beiranvand

Position

Instructor

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Phone

+98 81 3838 0535

Email

firoozebeiranvand@yahoo.com

Person responsible for updating data

m.molavi@umsha.ac.ir

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mehdi Molavi

Position

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Other areas of specialty/work

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Postal code

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Phone

+98 81 3838 0535

Email

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