Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of face-to-face and distance training (Telenursing) versus control group on Self-efficacy of hemodialysis patients: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of face-to-face and distance training (Telenursing) versus control group on Self-efficacy of hemodialysis patients

Design
This is a randomized clinical trial, in which 180 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible hemodialysis patients referring to the Imam Reza Hospital in Kermanshah city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 65 years; Chronic renal failure; Under hemodialysis for at least 6 months; Literate; Access to phone call or cell phone; Exclusion criteria: Speech or hearing impairment; Hospitalization during stud period; Failure to answer the phone for 3 times

Intervention groups
Intervention group 1: Routine treatment plus face-to-face training (including encouraging the patient to study and exercise, energy conservation methods, side effects and symptoms of fluid accumulation in the body, nutritional management, restriction of taking sodium, potassium and fluids, signs and symptoms of hypertension, definition of fistula and how it works, how to control infection, and how to take medications) two 45-minute sessions weekly for 4 weeks Intervention group 2: Routine treatment plus distance training (Telenursing) (including encouraging the patient to study and exercise, energy conservation methods, side effects and symptoms of fluid accumulation in the body, nutritional management, restriction of taking sodium, potassium and fluids, signs and symptoms of hypertension, definition of fistula and how it works, how to control infection, and how to take medications) two 45-minute sessions weekly for 4 weeks Control group: Just routine treatment

Main outcome variables
Primary outcome: Self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N411**
Registration date: **2021-12-09, 1400/09/18**
Registration timing: **prospective**

Last update: **2021-12-09, 1400/09/18**
Update count: **0**

Registration date
2021-12-09, 1400/09/18

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-02-09, 1400/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of face-to-face and distance training (Telenursing) versus control group on Self-efficacy of hemodialysis patients: a randomized clinical trial

Public title

Effect of face-to-face and distance training (Telenursing) versus control group on Self-efficacy of hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years; Chronic renal failure; Under hemodialysis for at least 6 months; Literate; Access to phone call or cell phone;

Exclusion criteria:

Speech or hearing impairment; Hospitalization during stud period; Failure to answer the phone for 3 times

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

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

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-11-27, 1400/09/06

Ethics committee reference number

IR.UMSHA.REC.1400.682

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes

1

Description

Self-efficacy

Timepoint

Before the intervention and 4 weeks after that

Method of measurement

Using Shere General Self-efficacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Routine treatment plus face-to-face training (including encouraging the patient to study and exercise, energy conservation methods, side effects and symptoms of fluid accumulation in the body, nutritional management, restriction of taking sodium, potassium and fluids, signs and symptoms of hypertension, definition of fistula and how it works, how to control infection, and how to take medications) two 45-minute

sessions weekly for 4 weeks

Category

Other

2

Description

Intervention group 2: Routine treatment plus distance training (Telenursing) (including encouraging the patient to study and exercise, energy conservation methods, side effects and symptoms of fluid accumulation in the body, nutritional management, restriction of taking sodium, potassium and fluids, signs and symptoms of hypertension, definition of fistula and how it works, how to control infection, and how to take medications) two 45-minute sessions weekly for 4 weeks

Category

Other

3

Description

Control group: Just routine treatment

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Kermanshah city

Full name of responsible person

Forouzan Ahmadi

Street address

Imam Reza Hospital, Zakaria Razi Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Forouzan Ahmadi

Position

Bachlor of Nursery

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Takarli

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Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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