

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 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)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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.

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

8518465816

**Phone**

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**Email**

fr.ahmadi267@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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**

Bachelor of Nursery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fatemeh Takarli

**Position**

Master of Nursery

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

poorolajal@umsha.ac.ir

**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