

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effect of Self-Efficacy Plan on Self-Management Behaviors in Hemodialysis Patients

#### Protocol summary

##### Study aim

determining The Effect of Self-Efficacy Plan on Self-Management Behaviors in Hemodialysis Patients Referring to Dialysis Centers in Selected Hospitals of Shahid Beheshti University of Medical Sciences in 2019

##### Design

A randomized, double-blind, placebo-controlled clinical trial with a sample size of 35 in each group

##### Settings and conduct

In this study, after determining the sample size, sampling will be done by available method and patients will be randomly assigned to two groups. In the experimental group, self-efficacy program with usual care is offered to hemodialysis patients and in the control group routine care is performed. The program will be run through six sessions, with the creation of a WhatsApp or Telegram group, which will include a self-efficacy training program.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: ages 18-65 years old having the verbal communication ability having the ability of self-care activities having the history of dialysis at least for past one year having dialysis 3-4 times per week having the skill of using of Virtual messenger exclusion criteria:  
1. psychological disorders like psychosis and acute depression which needed to be hospitalized  
2. Unwillingness to continuing participate in research  
3. Any emergency event that may lead the patient to the intensive care unit.

##### Intervention groups

The intervention consisted of providing a self-efficacy training program that included aspects of participation in treatment, problem solving, self-care, and emotion control, and runs over 6-12 weeks. The intervention group will receive a self-efficacy training program in addition to routine nursing care in the ward. The control group will receive only routine care in the ward.

##### Main outcome variables

self managemet

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191215045747N1**

Registration date: **2020-02-09, 1398/11/20**

Registration timing: **retrospective**

Last update: **2020-02-09, 1398/11/20**

Update count: **0**

##### Registration date

2020-02-09, 1398/11/20

##### Registrant information

##### Name

armin azizikia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3633 8120

##### Email address

arminazizikya@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-21, 1397/11/01

##### Expected recruitment end date

2019-03-21, 1398/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Self-Efficacy Plan on Self-Management Behaviors in Hemodialysis Patients

## Public title

The Effect of Self-Efficacy Plan on Self-Management Behaviors in Hemodialysis Patients

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

ages 18-65 years old having the verbal communication ability having the ability of self-care activities having the history of dialysis at least for past one year having dialysis 3-4 times per week having the skill of using of Virtual messenger

### Exclusion criteria:

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

We drop a coin and one side is the control group and the other is the intervention group. We assign the first patient to the group based on the result and the next sample is assigned to the opposite group.

## 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 Shahid Beheshti University of Medical Sciences

##### Street address

Ferdos Dormitory., Sought Ramin St., East Ferdos Blvd., Sadeghieh District., Tehran Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1481999586

## Approval date

2019-12-02, 1398/09/11

## Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.244

## Health conditions studied

### 1

#### Description of health condition studied

Chronic kidney Disease and Hemodialysis

#### ICD-10 code

Z99.2

#### ICD-10 code description

Applicable To Chronic kidney disease requiring chronic dialysisUse Additional code to identify dialysis status (Z99.2 )The following code(s) above N18.6 contain annotation back-referencethat may be applicable to N18.6: N00-N99 Diseases of

## Primary outcomes

### 1

#### Description

self-management score

#### Timepoint

determining Effect of Self-Efficacy Plan on Self-Management Behaviors in Hemodialysis Patients before and after intervention

#### Method of measurement

The hemodialysis self-management instrument (HDSMI) questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Once the validity of the educational content has been confirmed, the intervention group will form a virtual group at telegram or whatsapp and the training program will be delivered to them through the virtual program within 6-12 weeks. In addition, the intervention group will receive routine care.

#### Category

Other

### 2

#### Description

Control group: The control group is similar to the intervention group but will not receive any training or intervention except routine care.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Labbafi Nejad Hospital

**Full name of responsible person**

Armin Azizikia

**Street address**

Ferdos Dormitory., Sought Ramin St., East Ferdos Blvd., Sadeghieh District., Tehran Town

**City**

Tehran

**Province**

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**Postal code**

1481999586

**Phone**

+98 44 3633 8120

**Email**

Arminazizikya@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Mahrokh Dolatian

**Street address**

Vali Asr Ave., Niayesh Cross Road, Niayesh Complex, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

mhdolatian@gmail.com

**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**

Armin Azizikia

**Position**

Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The result of the research is whether self-efficacy can improve self-management or not.

**When the data will become available and for how long**

Start of access period 6 months after printing results

**To whom data/document is available**

researcher

**Under which criteria data/document could be used**

Raising awareness and guiding research for other people

**From where data/document is obtainable**

researcher

**What processes are involved for a request to access data/document**

Send academic email requesting results

**Comments**