

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

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Phone

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Armin Azizikia

Position

Nursing Student

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Armin Azizikia

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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