Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 prospective, randomized, open-label, routine care–controlled 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, a self-efficacy program in addition to usual care is offered to hemodialysis patients, and in the control group only routine care is provided. The program will be run through 12 sessions, delivered over a period of 6 to 12 weeks, through 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
This update includes: 1. Completion of the previously empty "Actual recruitment start/end date" and "Trial completion date" fields, based on the actual study timeline. 2. Addition of contact information for six additional recruitment centers (beyond the originally registered center) that participated in the actual conduct of the study. 3. Correction of the study design description in the protocol summary from "double-blind/placebo-controlled" to "open-label/routine care-controlled," consistent with the actual methodology. 4. Correction of the number of intervention sessions from 6 to 12, consistent with the approved proposal and protocol. 5. Correction of the number of intervention sessions from 6 to 12 in the "Intervention Groups" section (consistent with the approved proposal and protocol), and reclassification of the intervention type for both groups from "other" to "behavioral."

Acronym

IRCT registration information
IRCT registration number: **IRCT20191215045747N1**
Registration date: **2020-02-09, 1398/11/20**
Registration timing: **prospective**

Last update: **2026-10-02, 1405/07/10**
Update count: **1**

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
2020-02-20, 1398/12/01
Actual recruitment end date
2020-04-19, 1399/01/31
Trial completion date
2020-07-21, 1399/04/31

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**
Actual sample size reached: **61**
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-referencesthat 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 in 12 sessions within 6-12 weeks. In addition, the intervention group will receive routine care.
Category
Behavior

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
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafi Nejad Hospital
Full name of responsible person
Armin Azizikia
Street address
Labbafinejad Hospital, 9th Boustan St., Pasdaran Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 23601
Email
Arminazizikya@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Armin Azizikia
Street address
Tajrish Sq., Shahrdari St., Shohadaye Tajrish Hospital
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1989934148
Phone
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3

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Armin Azizikia
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Niavaran, Darabad, Masih Daneshvari Hospital
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1956944413
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Arminazizikya@sbmu.ac.ir

4

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Armin Azizikia
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Imam Hossein Sq., Shahid Madani St., Imam Hossein Hospital
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1617763141
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Arminazizikya@sbmu.ac.ir

5

Recruitment center
Name of recruitment center
Shahid Modarres Hospital
Full name of responsible person
Armin Azizikia
Street address
Saadat Abad, Yadegar-e-Imam Hwy., Shahid Modarres Hospital
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Phone
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Email
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6

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Armin Azizikia
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Velenjak, Tabnak St., Taleghani Hospital
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Arminazizikya@sbmu.ac.ir

7

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Armin Azizikia
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South Kargar St., Makhsous St., Loghman Hospital
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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
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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
Ferdos Dormitory., Sought Ramin St., East Ferdos Blvd., Sadeghieh District., Tehran Town
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Position
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Latest degree
Bachelor
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Nursery

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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
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Nursing Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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

City
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Email
Arminazizikya@sbmu.ac.ir

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