

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The Effect of an Education Program Based on Illness Perception on Self-Management among Hemodialysis Patients: A Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of an educational program based on the understanding of illness on the self-management of hemodialysis patients: a randomized trial study.

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized on 62 patients with hypertension in the elderly with a one-month follow-up.

Settings and conduct

The present study will be conducted on hemodialysis patients referred to the hemodialysis center of Imam Reza Medical Education Center (AS) in Larestan.

Participants/Inclusion and exclusion criteria

Patients must be 18 years old or older. be treated with hemodialysis for at least 3 months. Have at least two hemodialysis sessions per week. Having independence in daily activities (walking, eating, etc.) Able to cooperate to complete the questionnaire and carry out the intervention
Exclusion criteria: Patients with kidney transplant experience Unwillingness to participate in the study Occurrence of serious physical and mental illnesses during the intervention Participation in similar educational and research projects during the course of study

Intervention groups

The intervention framework in this study is based on Loenthal's self-regulation model(37), which educational content will be based on 5 dimensions of disease perception and also the effect that disease perception can have on patients' self-management behaviors. These dimensions are: the nature (label and symptoms related to the disease such as fatigue and weakness), the belief or reason of the person about the causes of the onset of the disease, the duration or the person's perception of the duration of the disease, the expected consequences of the person or the findings of the disease and the effectiveness of control. And improve

Main outcome variables

Self-management scale of hemodialysis patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240122060771N1**

Registration date: **2024-02-29, 1402/12/10**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-29, 1402/12/10**

Update count: **0**

Registration date

2024-02-29, 1402/12/10

Registrant information

Name

Ali Mohammad Parviniannasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5224 7110

Email address

ali_parviniyan@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-19, 1402/11/30

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of an Education Program Based on Illness Perception on Self-Management among Hemodialysis Patients: A Randomized Controlled Trial

Public title
The Effect of an Education Program Based on Illness Perception on Self-Management among Hemodialysis Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients must be 18 years old or older. be treated with hemodialysis for at least 3 months Have at least two hemodialysis sessions per week. Having independence in daily activities (walking, eating, etc.) Able to cooperate to complete the questionnaire and carry out the intervention
Exclusion criteria:
Patients with kidney transplant experience Unwillingness to participate in the study occurrence of serious physical and mental illnesses during the intervention Participation in similar educational and research projects during the course of study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
It should be noted that this blinding study will be done in such a way that after the participants are placed in two groups of test and control, the patients will be identified with the code A for test and B for control. Blinding will be done in such a way that the study questionnaires will be completed by an informed nurse with the items of the questionnaire who is not aware of the allocation of the patients, and then the patients of the test group will be trained and at the end of the study, the questionnaire will be divided into two test and control groups. will be completed by patients and through the same nurse. In addition, the information of the patients is also specified in the statistical software with A and B code, and the statistician does not know about the patient code. It will be used blindly in some way

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the nature of the intervention, which is

educational, it is not possible to blind the participants, but the researcher who collects the data and the person who performs the statistical analysis will not know which of the intervention and control groups the patients are in.

had

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Larestan University of Medical Sciences

Street address

Dadman Blvd

City

لارستان

Province

Fars

Postal code

74319-75566

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

IR.LARUMS.REC.1402.033

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Self-management scale in hemodialysis patients

Timepoint

Before the intervention, immediately after the intervention and one month later

Method of measurement

Self-management questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 5 sessions based on Levantal's self-regulation model for one hour per session, one session per week

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز آموزشی درمانی امام رضا (ع) لارستان

Full name of responsible person

Ali Mohammad Parviniannasab

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Phone

+98 917 149 2744

Email

ali_parviniyan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Mohsen Salmanpor

Street address

میدان امام خمینی ، بلوار ولایت

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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

Larestan 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

Larestan University of Medical Sciences

Full name of responsible person

علی محمد پروینیان نسب

Position

Assistant Professor of nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Imam Khomeini Square, Velayat Blvd

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

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علی محمد پروینیان نسب

Position

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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

It can be shared after de-identifying people

When the data will become available and for how long

Access starts one year after results are published

To whom data/document is available

People working in academic and scientific institutions

Under which criteria data/document could be used

Subject to the agreement of Larestan Faculty of Medical Sciences

From where data/document is obtainable

Dr. Ali Mohammad Parviniyan Nesab, assistant professor of Larestan Faculty of Medical Sciences, email address: ali_parviniyan@yahoo.com, phone number: 07152255278, mobile number: 09171492744

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

A written and official request to the Research Vice-Chancellor of Larestan Faculty of Medical Sciences

Comments