

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the Effectiveness of Patient-Caregiver Cognitive-Behavioral Intervention on Promoting Adherence to Treatment Behaviors in Hemodialysis Patients in Isfahan

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral educational intervention of caregiver on promoting adherence to treatment behaviors in hemodialysis patients in Isfahan

Design

A Randomized experimental intervention (clinical trial) of pre-test-post-test type with control group

Settings and conduct

First, two centers were selected from hemodialysis centers under the auspices of Isfahan University of Medical Sciences by cluster sampling method and then randomly divided into two groups of intervention and comparison. Then, the participants were selected using a random number table. Patients enter the study after describing the objectives of the study and obtaining consent. The control group receives routine care and advice from hemodialysis patients at the center. In addition to receiving routine hemodialysis care, the intervention team will receive the "Training Program for Chronic Renal Failure and Hemodialysis" application. The researchers then explain to the intervention group how to receive training programs through the application. Evaluation in two stages, 1 month and 3 months after the end of the educational intervention, will be done by a questionnaire (in person, online) and then the data will be collected and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who undergo hemodialysis twice a week or more. Patients who have been on dialysis for at least three months. Exclusion criteria: 1. Patients who are hospitalized due to acute diseases. Patients with mental illness. 3. Patients on the kidney transplant list for the next six months.

Intervention groups

The intervention group will receive routine hospital training and the "Chronic Kidney Failure and

Hemodialysis Training Program" application

Main outcome variables

Adherence to treatment behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220504054737N1**

Registration date: **2022-07-12, 1401/04/21**

Registration timing: **prospective**

Last update: **2022-07-12, 1401/04/21**

Update count: **0**

Registration date

2022-07-12, 1401/04/21

Registrant information

Name

Mahin Nematollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3633 0177

Email address

nematollahimahin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Patient-Caregiver Cognitive-Behavioral Intervention on Promoting Adherence to Treatment Behaviors in Hemodialysis Patients in Isfahan

Public title

Investigating the Effect of Educational Program using Mobile Phone on the hHealth of hHemodialysis Patients

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients receiving Hemodialysis twice a Week or more
Patients who have been on Dialysis for at least three Months

Exclusion criteria:

Patients who are hospitalized due to acute Illness
Patients with Mental Illness Patients on the Kidney Transplant list for the next six Months

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

The current research is a randomized experimental intervention (clinical trial) of pre-test-post-test type with a control group. The sampling method in this research is multi-stage random cluster sampling: The first stage: Isfahan hemodialysis centers are identified, which includes 4 government hemodialysis centers: Al-Zahra, Farabi, Amin, Ali Asghar and 3 private hemodialysis centers: Zahra Marzieh, Hojjatiyeh and Abolfazl. These centers are almost similar to each other in terms of socio-economic characteristics, and each of them includes heterogeneous groups, and these centers can be considered as clusters. The number of 80 samples is required for the study. Then, the number of hemodialysis patients in each center is specified and the number of patients participating in the study will be determined based on the probability proportional to size (PPS) approach. The second step: simple random method with replacement is used to select patients participating in the study. The list of hemodialysis patients of each center is specified and a code is given to each patient. Each code is written on a sheet and placed inside the box, and then we take the papers one by one and write down the names of the patients and put the sheets back

into the box, and this process continues until the desired sample volume is complete. This selection is done by lottery, which shows that it is a random sampling. This method will be implemented for all 7 centers to obtain 80 samples. The third step: 80 samples will be allocated in two control groups (40 samples) and intervention (samples) by simple random sampling method. Each sample is given a code and each code is written on a sheet and placed inside the box and the samples are selected by simple random sampling method and the first 40 samples will be placed in the intervention group and the second 40 samples will be placed in the comparison group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blindness is one-way and the subjects do not know which intervention or control groups they are in.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan

Street address

Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences and Health Services, Hezar Jerib St., Shiraz Gate, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2022-04-30, 1401/02/10

Ethics committee reference number

IR.MUI.RESEARCH.REC.1401.048

Health conditions studied**1****Description of health condition studied**

Hemodialysis

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Adherence to diet

Timepoint

Outcome variable is measured in three stages: before the intervention, one month and three months after the end of the educational intervention.

Method of measurement

End-Stage Renal Disease - Adherence Questionnaire (ESRD-AQ)

2

Description

Compliance with fluid restrictions

Timepoint

Outcome variable is measured in three stages: before the intervention, one month and three months after the end of the educational intervention

Method of measurement

End-Stage Renal Disease - Adherence Questionnaire (ESRD-AQ)

3

Description

Adherence to prescription drugs

Timepoint

Outcome variable is measured in three stages: before the intervention, one month and three months after the end of the educational intervention

Method of measurement

End-Stage Renal Disease - Adherence Questionnaire (ESRD-AQ)

4

Description

Regular attendance at hemodialysis sessions

Timepoint

Outcome variable is measured in three stages: before the intervention, one month and three months after the end of the educational intervention

Method of measurement

End-Stage Renal Disease - Adherence Questionnaire (ESRD-AQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Hemodialysis patients enter the study after describing the study objectives and obtaining consent. In addition to receiving routine hemodialysis care, the intervention team will

receive the "Training Program for Chronic Renal Failure and Hemodialysis" application. The researchers then explain to the intervention group how to receive training programs through the application. Also, how to use the application in the form of text and videos will be included in the application. Then the application will be installed on the mobile phone or tablet of the intervention group and how to use it will be explained. The duration of sending training programs is one month and the programs are in 4 sessions (one session every 7 days).) Is sent to the intervention group through the application. The training programs of each session are divided and sent to the intervention group within seven days (one or more programs per day). Necessary trainings are given to the intervention group before the start of the program and at the beginning of each session through the application. At the end of each session, a simple and short test will be sent to users to measure their learning. Also, reminders for taking medicine and participating in dialysis sessions are embedded in this software that will help patients in managing the disease.

Category

Other

2

Description

Control group: Hemodialysis patients enter the study after describing the study objectives and obtaining consent. The control group will receive routine hospital training on chronic renal failure and hemodialysis, and no educational intervention will be performed for the control group by the researchers. The control group will receive the application "Educational program related to chronic kidney failure and hemodialysis" after the end of the educational intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis centers under the auspices of Isfahan University of Medical Sciences

Full name of responsible person

Mahin Nematollahi

Street address

Department of Health Education, School of Health, Isfahan University of Medical Sciences, Shiraz Gate, Isfahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3239

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmadali Eslami

Street address

Department of Health Education, School of Health,
Isfahan University of Medical Sciences, Shiraz Gate,
Isfahan,

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3239

Email

eeslami@hlth.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

50

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**

Esfahan University of Medical Sciences

Full name of responsible person

Ahmadali Eslami

Position

Assistant Professor of Health Education and Health
Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education, School of Health,
Isfahan University of Medical Sciences, Shiraz Gate,
Isfahan,

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

(+98)-31-3723239

Email

eeslami@hlth.mui.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ahmadali Eslami

Position

Assistant Professor of Health Education and Health
Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education, School of Health,
Isfahan University of Medical Sciences, Shiraz Gate,
Isfahan,

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

(+98)-31-3793239

Email

eeslami@hlth.mui.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahin Nematollahi

Position

PhD student in health education

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Department of Health Education, School of Health,
Isfahan University of Medical Sciences, Shiraz Gate,
Isfahan,

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3792 3242

Email

nematollahimahin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of information is one of the important ethical principles of our study

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