

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of home visit plan on the adherence to therapeutic regimen of patients undergoing hemodialysis in selected hospitals of Isfahan University of Medical Sciences in 2018

Protocol summary

Study aim

Effect of home visit plan on the adherence to treatment regimen of patients undergoing hemodialysis in selected hospitals of Isfahan University of Medical Sciences in 2018

Design

A clinical trial with a community-based control group, Pragmatic, Randomized, parallel groups

Settings and conduct

In this study, need assessment and sampling were performed in Khorshid and Alzahra hospitals in Isfahan and then 3-5 home visits were held in patients' home.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who had had at least 3 months of onset of hemodialysis, Patients treated with hemodialysis three times a week and 3-4 hours each, Patients who approved their initial consent and one of their family members to participate in the study, Patients who were able to speak and understand fully the Persian language, and at least to read and write literacy, Patients in the age range of 18-65 years, Patients who had not already received the home visit plan
Exclusion criteria: Patients with acute and chronic infections, inflammatory diseases, malignancy, and cognitive and psychological problems.

Intervention groups

In the intervention group, Training diet therapy, adherence behaviors to patient and families as 3-5 sessions of home education and in the routine control of hospital education.

Main outcome variables

Adherence to Therapeutic Regimen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130801014242N2**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **retrospective**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Maryam Shirazi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2018-10-23, 1397/08/01

Trial completion date

2019-02-20, 1397/12/01

Scientific title

The effect of home visit plan on the adherence to

therapeutic regimen of patients undergoing hemodialysis in selected hospitals of Isfahan University of Medical Sciences in 2018	
Public title	The effect of home visit plan on the adherence to therapeutic regimen of patients undergoing hemodialysis
Purpose	Education/Guidance
Inclusion/Exclusion criteria	Inclusion criteria: Patients who had had at least 3 months of onset of hemodialysis and had had an acute illness Patients treated with hemodialysis three times a week and 3-4 hours each Patients who approved their initial consent and one of their family members to participate in the study Patients who were able to speak and understand fully the Persian language, and at least to read and write literacy. Patients in the age range of 18-65 years Patients who had not already received the home visit plan Exclusion criteria: Patients with acute and chronic infections. Patients with malignancy. Patients with cognitive and psychological problems.
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: 66 Actual sample size reached: 60
Randomization (investigator's opinion)	Randomized
Randomization description	In order to randomly assign samples to the intervention and control groups, the researcher will write the names of the samples on small sheets after the completion of the sampling and place them in the box and begin to remove the sheets without inserting them from the box. Individuals (first, third, ...) will be assigned to the control group to the intervention group and the couple (second, fourth, and ...).
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 Isfahan University Of Medical Sciences Street address Hezarjirib Ave, Isfahan, Iran City Isfahan Province Isfahan Postal code 8174673461 Approval date 2018-02-26, 1396/12/07 Ethics committee reference number IR.MUI.REC.1396.3.870 Health conditions studied 1 Description of health condition studied Dialysis ICD-10 code T81.502 ICD-10 code description Unspecified complication of foreign body accidentally left in body following kidney dialysis Primary outcomes 1 Description Adherence to therapeutic regimen Timepoint Before, After and 1 month After The Prevention Method of measurement Renal adherence behavior Questionnaire (RABQ) Secondary outcomes 1 Description Patient weight Timepoint Before, After and 1 month After The Prevention Method of measurement Weighing the patient and blood tests Intervention groups 1 Description "Intervention group:" Training on dietary behaviors including diet, medication and water and electrolyte restraint behaviors were given to the patient and their family during 3-5 sessions of at least 40-minute home

visits and identified as existing It provides families with the opportunity to address it and improve adherence to their diet and improve community health and reduce medical costs.

Category

Lifestyle

2**Description**

Control group: Questionnaires are filled in at intervals before, immediately and one month later and given to them after evaluation of educational booklets.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Selected Hospitals Of Isfahan University Of Medical Sciences

Full name of responsible person

Maryam Shirazi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mahnaz Norouzi

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Shirazi

Position

Academic Member, Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

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