

# 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)

##### Phone

+98 31 1792 2904

##### Email address

m\_shirazi@nm.mui.ac.ir

#### 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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Hezarjirib Ave, Isfahan, Iran

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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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Hezarjirib Ave, Isfahan, Iran

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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 scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Shirazi

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## Person responsible for updating data

### 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  
**Street address**  
Hezarjirib Ave, Isfahan, Iran  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**

## 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