Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The effect of home visit program on quality of life and adherence to treatment of hemodialysis patients

Protocol summary

Study aim
Determining the effect of home visit program on quality of life and adherence to treatment in patients undergoing hemodialysis in Ardabil, 1400

Design
Clinical trial with control group, with parallel groups, single-blind, randomized. Blocking method with placement was used for randomization.

Settings and conduct
72 patients undergoing hemodialysis are divided into two groups. For 36 patients, training is provided in patients' homes and for 36 patients, training is given by telephone. In each intervention, evaluation is done before and one month after the training.

Participants/Inclusion and exclusion criteria
Conditions Admission to the study: 1. All hemodialysis patients who have been on hemodialysis for more than 6 months 2. Patients live in Ardabil 3. The age of the participants is between 18 and 65 years Conditions for not entering the study: 1. Have hearing problems 2. Have a mental disorder

Intervention groups
Intervention group: Intervention process during 3 months Home visit: Each month a session of 45-60 minutes will be performed for each patient. After coordination with the patient and their family, in the first month, the educational needs of patients about of quality of life and treatment adherence items discussed and the patient and family questions are answered. And is planned for the next session. In the second and third sessions, the educational needs of patients are answered. A contact number is also given to contact the researcher if necessary. In each session, questionnaires are filled in before the communication begins. Control group: In the control group, the patient or The main caregiver of the patient is contacted every month for three months and full explanations are given about of quality of life and adherence to treatment. Also, the contact number is given to communicate if necessary.

Main outcome variables
Quality of life, adherence to treatment

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210614051575N1**
Registration date: **2021-09-30, 1400/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-30, 1400/07/08**
Update count: **0**

Registration date
2021-09-30, 1400/07/08

Registrant information
Name
Mina pooresmaeil
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 45 3353 4381
Email address
m.pooresmaeil@aums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-16, 1400/06/25
Expected recruitment end date
2021-12-16, 1400/09/25
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of home visit program on quality of life and adherence to treatment of hemodialysis patients

Public title
The effect of home visit program on quality of life and adherence to treatment of hemodialysis patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
All hemodialysis patients that More than 6 months have passed of the beginning of hemodialysis Patients living in Ardabil Participants should be between 18 and 65 years old

Exclusion criteria:
Have hearing problems Have a mental disorder

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the block randomization method will be used to allocate participants in two groups with equal ratio (1: 1) with a fixed block size of 4. 6 different modes of 4-member blocks with two groups (A and B) are numbered from 1 to 6, and with 18 rounds of dice, 18 random numbers from 1 to 6 are identified, and the corresponding blocks of those numbers are placed in a row. The random chain will consist of A and B. Group A is considered as the intervention group and group B as the control group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In patient blinding, the researcher will explain the purpose of the study to both groups equally Before random Assign of samples. testimonial to participate in the study will be obtained from each participant And a questionnaire of quality of life and adherence to treatment and demographics will be filled out for all participants Patients. Then, patients will be randomly placed in the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences

Street address
2nd Floor, No. 9, Pardisan 2، Dadgostari Town

City
Ardabil

Province
Ardabil

Postal code
5618983655

Approval date
2021-05-23, 1400/03/02

Ethics committee reference number
IR.ARUMS.REC.1400.065

Health conditions studied

1

Description of health condition studied
Quality of life and adherence to treatment of hemodialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of life

Timepoint
before the intervention, end of the first, second and third months of the intervention

Method of measurement
Quality of life questionnaire for hemodialysis patients

2

Description
Adherence to treatment

Timepoint
before the intervention, end of the first, second and third months of the intervention

Method of measurement
Questionnaire of adherence to treatment of hemodialysis patients

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention process during 3 months Home visit: Each month a session of 45 minutes to one hour will be performed for each patient. The patient or family is contacted first and an agreement is reached on when to visit the home. In the first month, patients are given an educational booklet and for 45 minutes to an hour, the educational needs of patients in the areas of quality of life items and treatment adherence are discussed and patient and family questions are answered. The next session is planned. In the second and third sessions, patients' questions and educational and care needs are answered. A contact number is also given so that they can contact the researcher in case of any problem or specific question. In each previous session From the beginning of the communication, the questionnaires are filled in to identify the needs of the patients

Category
Behavior

2

Description
Control group: In the control group, after obtaining written and informed consent and sharing the purpose of the study with the patient and family, contact numbers are obtained from patients. Then, the patients' files are studied and the patient or his main caregiver is contacted every month, and based on the patients' educational needs, the required explanations are given and the contact number is given so that communication can be established if needed.

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Buali Hospital
Full name of responsible person
Minapooresmaeil
Street address
Ardabil, sports field
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۳۶۴۳۱۹۷
Phone
+98 45 3325 2251
Email
minapooresmaeil@yahoo.com

2

Recruitment center
Name of recruitment center
Helal ahmar Center
Full name of responsible person
Mina pooresmaeil
Street address
Between Shariati Square and Sarein Station
City
Ardabil
Province
Ardabil
Postal code
0000000000
Phone
+98 45 3323 2001
Email
minapooresmail@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Minapooresmaeil
Street address
2nd Floor,No. 9, Pardisan 2, DadgostariTown
City
Ardabil
Province
Ardabil
Postal code
5618983655
Phone
+98 45 3353 4381
Email
minapooresmail@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
Ardabil University of Medical Sciences

Full name of responsible person
Mina pooresmaeil

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
2nd Floor،No. 9،Pardisan 2،Dadgostari Town

City
Ardabil

Province
Ardabil

Postal code
5618983655

Phone
+98 45 3353 4381

Email
minapooresmail@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Minapooresmaeil

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
2nd Floor, No. 9, Pardisan 2, Dadgostari Town

City
Ardabil

Province
Ardabil

Postal code
5618983655

Phone
+98 45 3353 4381

Email
minapooresmail@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Minapooresmaeil

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
2nd Floor, No. 9, Pardisan 2, Dadgostari Town

City
Ardabil

Province
Ardabil

Postal code
5618983655

Phone
+98 45 3353 4381

Email
minapooresmail@yahoo.com

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