

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

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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

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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

minapooresmail@yahoo.com

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
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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
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Email

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
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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