

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Telenursing Training on Adherence to Treatment Regimen in Hemodialysis Patients

Protocol summary

Study aim

Determination of adherence to treatment regimen in hemodialysis patients using telenursing training in case group before, during and after intervention
Determination of adherence to treatment regimen in hemodialysis patients using telenursing training in the control group before, during and after the intervention
Comparison of adherence to treatment regimen in hemodialysis patients in two groups before and after intervention

Design

A randomized controlled trial will be conducted on 56 patients

Settings and conduct

After splitting the patients, the intervention group will receive training via mobile phone line twice a week for 3 months and each time for 20 minutes. Once again, the questionnaire of adherence to treatment is completed every month and the patient's tests and weight gain are recorded.

Participants/Inclusion and exclusion criteria

Diagnosis of ESRD by a specialist physician and recorded in the relevant file
No history of kidney transplantation in the past 6 months
Passing at least three months after the first hemodialysis
Hemodialysis twice a week or more and each session 3 to 4 hours
Age 18 to 65 years
Ability to understand questions and literacy of reading and writing
Not having mental disorders
No vision or hearing problems

Intervention groups

The method of the study is that before the intervention, the patients' compliance with the standard questionnaire of treatment adherence in hemodialysis patients will be measured and the results of laboratory tests will be recorded on the basis of the patient's records in the relevant form and the patient's weight gain will be recorded. All research units will receive three training sessions with the same content individually and three times a week.

Main outcome variables

Score of treatment adherence questionnaire; monthly tests; weight gain between dialysis sessions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230531058349N1**

Registration date: **2023-06-14, 1402/03/24**

Registration timing: **prospective**

Last update: **2023-06-14, 1402/03/24**

Update count: **0**

Registration date

2023-06-14, 1402/03/24

Registrant information

Name

Sadegh Moslehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5524 0793

Email address

moslehiali93@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-07-01, 1402/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Telenursing Training on Adherence to Treatment Regimen in Hemodialysis Patients

Public title
The Effect of Telenursing Training on Adherence to Treatment Regimen in Hemodialysis Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of ESRD by a Specialist Physician and Recorded in the Relevant File Fill out a Consent Form At least 3 Months after the First round of Hemodialysis Hemodialysis twice a week or more and each session 3 to 4 hours Age 18 to 65 Ability to Understand questions and Literacy of Reading and Writing Having a fixed line or Mobile phone and the Ability to make Phone calls
Exclusion criteria:
 No History of Kidney Transplantation in the past 6 months Lack of Experience of a Stressful event within the last 6 months (Such as the death of a Family member or relative) No Mental disorder No vision or Hearing problems

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: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by simple and purposeful method according to the inclusion and exclusion criteria. Then, they will be randomly assigned to intervention and control groups by permutation block method. Six possible cases (BABA, ABBA, BAAB, AAB, ABAB, BBAA) will be listed, and by throwing dice of block numbers randomly up to the number of samples will be selected and the subjects will be divided into two groups of intervention (A) and control (B).

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, participants and their families are fully aware of the study and its complications and benefits and after obtaining informed consent, they are kept blind to random allocation in the experimental 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 Gonabad University of Medical Sciences
Street address
 Imam Khomeini St., Ghadir Sq., Gonabad Medical Sciences Headquarters
City
 Gonabad
Province
 Razavi Khorasan
Postal code
 9671668618
Approval date
 2023-05-30, 1402/03/09
Ethics committee reference number
 IR.GMU.REC.1402.047

Health conditions studied

1

Description of health condition studied
Adherence to Treatment Regimen in Hemodialysis Patients

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Adherence to the treatment regimen

Timepoint
Before the start of the study, after the training, after the intervention, for four months

Method of measurement
Dietary Adherence Questionnaire (ESRD-AQ)

2

Description
Monthly Tests

Timepoint
After intervention, monthly for up to four months

Method of measurement
Tests recorded in the patient's record

3

Description

Weight gain between dialysis sessions

Timepoint

After intervention, monthly for up to four months

Method of measurement

Patient records

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this stage, training will be given to the research units via mobile phone line twice a week for 3 months and each time for 20 minutes. The content of the conversations includes self-introduction, questions about the patient's general health status, encouraging the patient to follow the recommendations and aspects of general and dedicated self-care, follow-up of educational needs that will be based on the patient's educational needs checklist, and the patient will be provided with the necessary training and recommendations and answers to patients' questions. Phone calls and their content for each participant are recorded in certain sheets and at the end of the phone call with the patient's agreement the time of the next call is determined. The recorded file of the call will be sent to the patient by iGap or Soroush. Also, a text containing educational outline will be sent to the patient once a week.

Category

Rehabilitation

2

Description

Control group: Lack of follow-up and telephone training

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashmar Shahid Modares Hospital

Full name of responsible person

Mohammad Hashemi

Street address

Second Razi St., Razi St., Fayazbakhsh St., Kashmar

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Kashmar

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Razavi Khorasan

Postal code

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Email

moslehiali93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Moosa Sajjadi

Street address

Imam Khomeini St., Ghadir Sq., Gonabad Medical Sciences Headquarters

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Email

sajjadi1975@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Sadegh Moslehi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 15 Imam Khomeini St.

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about adherence to the treatment regimen of participants after undetectable

When the data will become available and for how long

Beginning of access period 3 months after printing

To whom data/document is available

Students and Professors of Medical Sciences

Under which criteria data/document could be used

After obtaining permission from the investigator

From where data/document is obtainable

moslehiali93@gmail.com

What processes are involved for a request to access data/document

One week after receiving the email.

Comments