Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of an educational program and tele-nursing on the adherence to treatment regimen in dialysis patients referred to Taleghani Hospital in urmia

Protocol summary

Study aim
Determining the effect of educational program and telephone follow-up by nurses on adherence to treatment regimen in dialysis patients

Design
Random generation sequence was used for randomization in 66 hemodialysis patients with control and intervention group, uncorrected, randomized, phase not applicable.

Settings and conduct
This clinical trial study was performed on 66 dialysis patients with end-stage renal disease in the dialysis ward of Taleghani Hospital in Urmia. The data collection tool was a questionnaire and its validity was measured in terms of content and reliability by retest method. Data were collected in four shifts (before the start of the study, immediately after the intervention, one month after the intervention and three months after the intervention). Then the prepared educational set was given to both groups. The intervention group was followed up by telephone conversation (twice a week for twenty minutes) and telephone message (one short message per day) for three months.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: Willingness to participate in the study, having no reading and writing problems, having acceptable level of consciousness, not having visual or hearing impairment Exclusion criteria include: Willingness to participate in the study

Intervention groups
Intervention group: Telephone intervention in the intervention group will be done for three months. Thus, for follow-up and training by the researcher, telephone calls will be established with the research units twice a week. The content of the telephone conversations will include a training program in the field of diet, medications and fluids, Control group: No follow-up or intervention was performed for the control group.

Main outcome variables
Adhere to diet

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190127042512N1**
Registration date: **2020-09-12, 1399/06/22**
Registration timing: **retrospective**

Last update: **2020-09-12, 1399/06/22**
Update count: **0**

Registration date
2020-09-12, 1399/06/22

Registrant information

Name
Rasoul Goli
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 4853 3530
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rasoulgoli94@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-09, 1398/01/20

Expected recruitment end date
2019-11-05, 1398/08/14

Actual recruitment start date
2019-04-09, 1398/01/20

Actual recruitment end date
2019-09-27, 1398/07/05
Trial completion date
2020-05-30, 1399/03/10

Scientific title
The effect of an educational program and tele-nursing on the adherence to treatment regimen in dialysis patients referred to Taleghani Hospital in urmia

Public title
The effect of an educational program and tele-nursing on the adherence to treatment regimen in dialysis patients: A randomized controlled trial
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
willing to participate in the study Ability to read No vision problems No cognitive impairment Having a cell phone having a medical file in hemodialysis ward having three hemodialysis sessions per week (3-4hrs each) age between 18 to 65 years.
Exclusion criteria:
Not willing to participate in the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **66**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomize using Random generation sequence The English letters A and B were typed on 66 cards (33 each) and then placed in an envelope. Patients who met the inclusion criteria took a T-card from the envelope and were placed in the intervention group if card A was selected and in control group if card B was selected.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was Single-blinded and the researcher analyzing the statistical data will be unaware of the control and intervention groups.
Placebo
Not used
Assignment
Parallel
Other design features
Unlike other studies conducted in one educational intervention group, this study provided an educational file for both groups and only guided the intervention group through telephone follow-up.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Unit 2, Floor 1, No 2, Emergency alley, after Jahad Sq, Resalat Ave
City
urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-03-17, 1397/12/26
Ethics committee reference number
IR.UMSU.REC.1397.490

Health conditions studied

1

Description of health condition studied
Chronic renal failure
ICD-10 code
I13.11
ICD-10 code description
Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease

Primary outcomes

1

Description
Adherence to the diet of hemodialysis patients
Timepoint
The effect of telephone follow-up (tele-nursing) on the diet of hemodialysis patients
Method of measurement
The effect of telephone follow-up (tele-nursing) on the diet of hemodialysis patients How to measure treatment adherence questionnaire in patients with chronic renal failure

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Telephone intervention in the intervention group will be done for three months. Thus, for follow-up and training by the researcher, telephone calls will be established with the research units twice a week. The time of making a telephone call is determined by asking the opinion of the research units. The average duration of each conversation is 20 minutes. The content of telephone conversations will include a training program in the field of diet, medications and fluids, and if a problem is found, a suggested solution will be offered to solve the problem and answer the patient's questions.

Category
Prevention

2

Description
Control group: No follow-up was performed for the control group.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani Hospital in Urmia

Full name of responsible person
mansour arad

Street address
No. 3, Shahr Ave, Ataee Blvd, farhangian Town

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5714783734

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m1372.arad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. iraj mohebi

Street address
Unit 4, Floor 1, No 2, Emergency alley, after Jahad Sq, Resalat Ave

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rasoulgoli94@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia University of Medical Sciences

Proportion provided by this source
60

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
Oroumia University of Medical Sciences

Full name of responsible person
mansour arad

Position
Masters

Latest degree
Master

Other areas of specialty/work
Nursery

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Unit 4, Floor 3, No. 56, Laleh alley, after moalem Sq, farhangian Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
mansour arad
Position
master nursing
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available