

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

##### Email address

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, Ataei Blvd, farhangian Town

#### City

urmia

#### Province

West Azarbaijan

#### Postal code

5714783734

#### Phone

+98 21 4625 8538

#### Email

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

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

5714783734

#### Phone

+98 44 3913 4227

#### Fax

+98 44 4223 2460

#### Email

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

#### Street address

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

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Mahabad

#### Province

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#### Postal code

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#### Phone

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#### Email

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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****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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**Postal code**

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**Phone**

+98 21 4625 8538

**Email**

m1372.arad@gmail.com

**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