

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of telenursing on self-care, readmission and psychological reactions of hemodialysis patients

#### Protocol summary

Self-Care, Readmission, Psychological problems

#### Study aim

Determination effect of telenursing on self-care, readmission and psychological reactions of hemodialysis patients of Ali ibn Abitaleb hospital in Zahedan city, in 2018

#### Design

This clinical trial is community-based, pragmatic, non-blind with control group and 80 hemodialysis patients will be randomly assigned into two groups.

#### Settings and conduct

In the intervention group, telephone training will be conducted twice a week and the duration of the telephone training will be on average 15 minutes per training. In the control group, routine care has been performed and there will be no intervention in this group. In both groups, self-care questionnaires and DASS21 will be filled in before and after the study

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Beginning hemodialysis in the past year 2- Having a history of at least one hospitalization due to hemodialysis complications during the past three months 3- Have a cell phone to call Telenursing 4- Having ages 18 to 65 years Exclusion criteria: 1-Not having at least reading and writing literacy 2- Inability to establish verbal communication 3- Presence of psychological disorders and treatment with antidepressants in the last 3 months 4- Reject to enter the study or non-cooperation at each stage of the research 5- Failure to respond to cell phone for 2 weeks in the first month and for 3 weeks in the second month. 6- Immigration or travel for more than 3 months. 7- The occurrence of new stressors (psychological and disease) 8- Kidney transplant

#### Intervention groups

In the intervention group, the telephone training will be conducted by the researcher for 12 weeks (3 months). In the control group, routine care has been performed and there will be no intervention in this group.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171105037236N5**

Registration date: **2019-03-06, 1397/12/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-06, 1397/12/15**

Update count: **0**

##### Registration date

2019-03-06, 1397/12/15

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 33442481

##### Email address

askarihas77@zaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-28, 1397/11/08

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of telenursing on self-care, readmission and psychological reactions of hemodialysis patients

## Public title

Training through telenursing for hemodialysis patients

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

Beginning hemodialysis in the past year Having a history of at least one hospitalization due to hemodialysis complications during the past three months Having a cell phone to call Telenursing Having ages 18 to 65 years

### Exclusion criteria:

Not having at least reading and writing literacy Inability to establish verbal communication Presence of psychological disorders and treatment with antidepressants in the last 3 months Reject to enter the study or non-cooperation at each stage of the research Failure to respond to cell phone for 2 weeks in the first month and for 3 weeks in the second month Immigration or travel for more than 3 months The occurrence of new stressors (psychological and disease) Kidney transplant

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

80 individuals will be randomly assigned to two groups. Block randomization based on permutation. Accordingly, 20 blocks will be allocated to patients, in each block 2 from study group and 2 from the control group will be placed.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

### Placebo

Not used

### Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical

Sciences

#### Street address

School Of Health, Zahedan University Of Medical Sciences, Jannat Blvd, Prof. Hesabi Sq, Zahedan, Iran. Zahedan

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9816913396

#### Approval date

2019-01-08, 1397/10/18

#### Ethics committee reference number

IR.ZAUMS.REC.1397.374

## Health conditions studied

### 1

#### Description of health condition studied

Telephone follow up telenursing training

#### ICD-10 code

Z49.1

#### ICD-10 code description

Encounter for fitting and adjustment of extracorporeal dialysis catheter

## Primary outcomes

### 1

#### Description

Self care: The score will be accounted of hemodialysis patients self care scale by participant and its scope is 0-72

#### Timepoint

Self-care measurements before and 12 weeks after study

#### Method of measurement

Self care questionnaire

### 2

#### Description

Readmission: Reception of patients until 30 days after discharge

#### Timepoint

Measurement of re-admission before and 12 weeks after the study

#### Method of measurement

the number of readmission using hospital HIS system.

### 3

#### Description

Stress:The score of stress in DASS21 questionnaire

#### Timepoint

Measurement of stress score before and 12 weeks after the study

#### Method of measurement

DASS21 questionnaire

#### 4

##### **Description**

Depression: The score of depression in DASS21 questionnaire

##### **Timepoint**

Measurement of depression score before and 12 weeks after the study

##### **Method of measurement**

DASS21 questionnaire

#### 5

##### **Description**

Anxiety: Anxiety Score in the DASS21 questionnaire

##### **Timepoint**

Measurement of anxiety score before and 12 weeks after the study

##### **Method of measurement**

DASS21 questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group: in this group, the telephone training will be conducted by the researcher for 12 weeks (3 months). The telephone training will be conducted twice a week, and the duration of the telephone training will be 15 minutes per training on average. Patients will be trained in telephone conversations with diet, fluid intake, fistula care, skin care, exercise and rest, treatment follow-up, infection prevention, digestive problems, anxiety, stress and self-care education. Before and after the study, patients with self-care and DASS21 questionnaires will be examined

##### **Category**

Lifestyle

#### 2

##### **Description**

Control group: In the control group, routine care has been taken and there is no intervention. Before and after the study, patients with self-care and DASS21 questionnaires will be examined

##### **Category**

Lifestyle

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Ali ibn Abitaleb Hospital Zahedan

###### **Full name of responsible person**

Hasan Askari

##### **Street address**

School Of Health, Zahedan University Of Medical Sciences, Jannat Blvd, Prof. Hesabi Sq, Zahedan, Iran. Zahedan Sistan And Baluchestan Iran

##### **City**

Zahedan

##### **Province**

Sistan-va-Balouchestan

##### **Postal code**

9816913396

##### **Phone**

+98 54 3329 5572

##### **Fax**

+98 54 3329 5572

##### **Email**

askarihas77@yahoo.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Zahedan University of Medical Sciences

###### **Full name of responsible person**

Nor Muhammad Bakhsani

###### **Street address**

University of Medical Sciences and Health Services, Zahedan University of Medical Sciences, Dr. Hesabi - Persian Gulf Blvd

###### **City**

Zahedan

###### **Province**

Sistan-va-Balouchestan

###### **Postal code**

9816743463

###### **Phone**

+98 54 3329 5796

###### **Fax**

+98 54 3329 5796

###### **Email**

bakhsani@zaums.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

No

##### **Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hasan Askari

**Position**

Nursing Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Zahedan, Zahedan  
Nursing and Midwifery Faculty, Fellowship Square

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816913396

**Phone**

+98 54 3344 2481

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**Email**

Askarihas77@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Hasan Askari

**Position**

Nursing Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

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Zahedan University of Medical Sciences

**Full name of responsible person**

Hasan Askari

**Position**

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**Email**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The Main Outcomes of the Participants are Public.

**When the data will become available and for how long**

6 months after the results .

**To whom data/document is available**

Researchers at Academic and Academic Institutions .

**Under which criteria data/document could be used**

Statistical Result .

**From where data/document is obtainable**

Nursing and Midwifery Faculty of Zahedan Phone and  
Fax: 05433442481 Zip Code: 9816913396 Address:  
Faculty of Nursing and Midwifery, Zahedan, Zahedan  
Nursing and Midwifery Faculty, Fellowship Square

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

En Contact the Nursing Faculty Library section.

**Comments**

Does not have