

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effect of continuous nursing care based on Information, Knowledge, Attitude, and Practice (IKAP) theory on quality of life and lifestyle of hemodialysis patients

#### Protocol summary

##### Study aim

The effect of continuous nursing care based on Information, Knowledge, Attitude, and Practice (IKAP) theory on quality of life and lifestyle of hemodialysis patients

##### Design

A quasi-experimental study with control and intervention group, randomized, will be performed on 68 patients. Excel software will be used for randomization.

##### Settings and conduct

This quasi-experimental study with a control and intervention group will be performed randomly on 68 patients undergoing hemodialysis in the dialysis ward of Golestan Hospital in Ahvaz. In the intervention group, nursing care is performed by ICAP method during various training-care sessions and by establishing telephone communication and, if necessary, the Internet. But in the control group, nursing care will be done routinely.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Have the desire to participate in the present study, be literate, access to Smart phone.

Exclusion criteria: the patient dies during the study, history of mental illness or hospitalization in a psychiatric hospital, the patient develops new physical problems that make him lose the ability to take care of himself and continue the training process.

##### Intervention groups

Intervention group: The intervention group receives continuous nursing care based on IKAP theory every 2 weeks for 20 to 30 minutes (four sessions in total for 8 weeks) along with routine nursing care. Control group: Control group receive only routine nursing care.

##### Main outcome variables

Lifestyle of hemodialysis patients; Quality of life of hemodialysis patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220106053644N1**

Registration date: **2022-02-25, 1400/12/06**

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

Last update: **2022-02-25, 1400/12/06**

Update count: **0**

##### Registration date

2022-02-25, 1400/12/06

##### Registrant information

##### Name

Ziya Azizi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3373 8383

##### Email address

ziya.azizi64@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-04, 1400/11/15

##### Expected recruitment end date

2022-07-06, 1401/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effect of continuous nursing care based on Information, Knowledge, Attitude, and Practice (IKAP) theory on quality of life and lifestyle of hemodialysis patients

## Public title

The effect of IKAP-based continuing nursing care on quality and lifestyle of hemodialysis patients

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willingness to participate in research Ability to read and write Ability to make direct telephone calls to the patient and active family member Ability to complete a questionnaire and participate in interviews cognitively Smartphone access

### Exclusion criteria:

History of mental illness or hospitalization in a psychiatric hospital

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 68

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will be selected by Simple randomization from hemodialysis patients. Randomization is done based on number Random table with Excel software and then Participants are divided into two groups of intervention and control.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Factorial

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

##### Street address

No. 4; Ground Floor; Vice Chancellor for Research and

Technology Development; Ahvaz Jundishapur University of Medical Sciences; Ahvaz Town

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

61357-15794

#### Approval date

2021-12-25, 1400/10/04

#### Ethics committee reference number

IR.AJUMS.REC.1400.596

## Health conditions studied

### 1

#### Description of health condition studied

Hemodialysis

#### ICD-10 code

Z99.2

#### ICD-10 code description

Dependence on renal dialysis

## Primary outcomes

### 1

#### Description

Quality of life score of hemodialysis patients

#### Timepoint

before and three months after IKAP intervention

#### Method of measurement

Standard Quality of Life Questionnaire for Kidney Patients (KDQOL-SF)

### 2

#### Description

Lifestyle of hemodialysis patients

#### Timepoint

IKAP قبل و سه ماه بعد از مداخله

#### Method of measurement

Lifestyle Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group receives 20 to 30 minutes of continuous nursing based on IKAP theory every 2 weeks along with routine nursing care (4 sessions in total). When and how, while determining and agreeing on face-to-face / telephone appointments, mentioning goals and how communication is possible; They will take the course from this period and the two will be taken to the hospital. At the end, the patients will

be received and the date of the next session will be announced. The sessions will be in the form of questions and answers (at the beginning of the session) and The presentation is then led by the researcher. At the end of each session, an educational booklet is provided to patients and they are asked questions about the topics of the previous session. Data collection takes 15-15 minutes, knowledge acquisition takes 10-15 minutes, and changes in patients' attitudes and performance are assessed after the intervention.

**Category**

Lifestyle

**2****Description**

Control group: Patients in the control group are provided with routine care that includes a hemodialysis training session (20-30 minutes). This includes information about the factors that affect the disease and make the condition of hemodialysis patients worse.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ahvaz Golestan Hospital

**Full name of responsible person**

Neda Sayadi

**Street address**

Farvardin St., Golestan Blvd., Golestan Educational and Medical Center; Ahvaz Town

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6136835685

**Phone**

+98 61 3320 4501

**Email**

golestanhospital@ajums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohamad Sadegh Salahshoor

**Street address**

Vice Chancellor for Finance; Ahvaz Jundishapur University; Ahvaz Town

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

6135715794

**Phone**

+98 61 3333 7075

**Email**

info@ajums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ziya Azizi

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery; Jundishapur University of Medical Sciences; Ahvaz Town

**City**

آبادان

**Province**

Khouzestan

**Postal code**

6131579457

**Phone**

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ziya Azizi

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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University of Medical Sciences; Ahvaz Town

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

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Masters student

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**Email**

ziya.azizi64@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**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not 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**

No - There is not a plan to make this available