

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the effect of face-to-face and visual education on the quality of life of patients undergoing hemodialysis

#### Protocol summary

##### Study aim

Comparison of the effect of facial-facial and visual education on the quality of life of hemodialysis patients undergoing hemodialysis center in 17th Shahrivar Hospital and Waaham Hospital in Shahr-e-Mashhad

##### Design

In this study, 180 patients undergoing hemodialysis and studying conditions who were referred to dialysis centers of Ghaem Hospital and Wahefzah Shahrivar, Mashhad, were selected. The participants were randomly assigned to two groups of intervention and control and assigned to each participant a given code.

##### Settings and conduct

After determining the educational needs of hemodialysis patients in the field of diet, a self-care curriculum was developed by studying books and consulting with nutritionists in this area. The researchers developed and developed a booklet. The training was identical in both groups and was provided by the researcher. A video was used in various media. In the face-to-face training group, a 30- to 45-minute training session was conducted in person and weekly during dialysis, and was presented to the video training group within a week of dialysis. A questionnaire This interview was completed again at the end of the intervention. This study is a blind one-way study, in which the subjects of the company, the clinical caregiver, the data analyst, the safety committee of data monitoring, were not informed about the method of blindness.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: ages 65-18; minimum reading and writing literacy; kidney disease; end stage; permanently undergo hemodialysis; cognitive impairment; hearing loss; weekly two or three times each time Three to four hours undergoing dialysis; not seeing formal education about food during the intervention; at least 3 months and maximum 2 years being treated with dialysis; willing to participate in this study. Exclusion criteria: Cancellation of the study at any stage; Any event that prevents

further intervention.

##### Intervention groups

Intervention group: Pre-test, by completing the demographic information journals, in face-to-face education group, 30-45 minute training sessions, performed individually and intervals of one week during dialysis, and were prepared in the video training group of the film. , Was displayed within one week during dialysis. The questionnaire was completed again at the end of the intervention by interview. Control group: The pre-test was completed through the completion of demographic information, diet, and knowledge on disease in this department. Did not take place and received the usual care.

##### Main outcome variables

Evaluation of patients' quality of life before and after intervention in intervention and control groups

#### General information

##### Reason for update

##### Acronym

H.E

##### IRCT registration information

IRCT registration number: **IRCT20171013036747N2**

Registration date: **2018-01-17, 1396/10/27**

Registration timing: **retrospective**

Last update: **2018-01-17, 1396/10/27**

Update count: **0**

##### Registration date

2018-01-17, 1396/10/27

##### Registrant information

##### Name

Rasool Solaimani Moghadam

##### Name of organization / entity

Birjand University of Medical Sciences

##### Country

Iran (Islamic Republic of)

**Phone**

+98 51 5722 3028

**Email address**

rasool.solaimani@yahoo.com

**Recruitment status**

Recruitment complete

**Funding source****Expected recruitment start date**

2015-10-23, 1394/08/01

**Expected recruitment end date**

2016-01-21, 1394/11/01

**Actual recruitment start date**

2016-01-21, 1394/11/01

**Actual recruitment end date**

2016-04-08, 1395/01/20

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of face-to-face and visual education on the quality of life of patients undergoing hemodialysis

**Public title**

The effect of dietary education on the quality of life of hemodialysis patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

At least reading and writing skills End-stage renal disease, which is consistently under hemodialysis treatment Not having cognitive impairment, hearing loss or hearing loss Two weeks three or three times a week for dialysis Not seeing formal education about food during the intervention At least 3 months and maximum 2 years treated with dialysis Would like to participate in this research.

**Exclusion criteria:**

Cancellation of the study at any stage Any incident that prevents further intervention. Patient death

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **147**

Actual sample size reached: **180**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients; Clinical Clinical; Data Analyzer; Safety Data Supervisor; No data were available on how to blast the company.

**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**

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad Gonabad

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691954865

**Approval date**

2014-06-25, 1393/04/04

**Ethics committee reference number**

GMU.REC.1393.34

**Health conditions studied****1****Description of health condition studied**

Hemodialysis

**ICD-10 code**

Z49.31

**ICD-10 code description**

Encounter for adequacy testing for hemodialysis

**Primary outcomes****1****Description**

Quality of Life

**Timepoint**

Before the intervention, one week after the intervention, face to face training

**Method of measurement**

SF36 quality of life questionnaire

## Secondary outcomes

### 1

**Description****Timepoint****Method of measurement**

## Intervention groups

### 1

**Description**

Intervention group 1: Face-to-face training group, 30- to 45-minute training sessions of dietetics, per person per week and weekly during dialysis. Intervention group 2: A video training group produced diet films, at intervals of one week Displayed during dialysis.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Qa'im Hospital

**Full name of responsible person**

Abolfazl Ghadimifar

**Street address**

Ghaem Hospital - Taghi Abad Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3840 0000

**Email**

Quaem.Medical.Center@mums.ac.ir

### 2

**Recruitment center****Name of recruitment center**

Seventeen Shahrivar Hospital

**Full name of responsible person**

Abolfazl Ghadimifar

**Street address**

Couchesangi street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91109V3AAE

**Phone**

+98 51 5845 2271

**Email**

razavi@tamin.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Dr. Ali Mohammadpour

**Street address**

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad Gonabad

**City**

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**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 5722 3028

**Email**

Dr.Mohammadpour@gmu.ac.ir

**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**

Rasool Solaimani Moghadam

**Position**

Nursing non-faculty

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Rasool Solaimani Moghadam

**Position**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Rasool Solaimani Moghadam

**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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

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

Only part of the information, such as information on the main outcome or the like, can be shared.

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

10 months after printing results

**To whom data/document is available**

Researchers working in academia and academia

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

Just statistical tests

**From where data/document is obtainable**

To receive the data, they can only send their application to the email address of the person responsible for the study E-mail:rasool.solaimani@yahoo.com

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

After reviewing the ethics code of the respective research committee and the approval date and the university identification certificate of the applicant

**Comments**