

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of education on the quality of nutrition of patients undergoing hemodialysis in the prevalence of COVID-19

Protocol summary

Study aim

Determining the effect of education on the quality of nutrition of hemodialysis patients in the prevalence of COVID-19.

Design

Clinical trial with intervention and control groups, with parallel groups, one-way blind, randomized, because the drug was not used in this study, the trial phase is not applicable in this study. About 60 patients. A random number table was used for randomization.

Settings and conduct

Field of study of Jiroft city of Kerman province. Study place Jiroft University of Medical Sciences. One-way blind patients are unaware of the division into intervention and control groups.

Participants/Inclusion and exclusion criteria

1- Willingness to participate in research 2. Have a minimum literacy 3. Access to the smartphone

Intervention groups

Participants are divided into two groups of 30 control and intervention. All of them will be encouraged to fast for 10 hours a day with a family member who has the necessary knowledge about using the Internet to attend the initial meeting and take a blood sample of albumin and TIBC serum in the hemodialysis ward of the hospital. Imam Khomeini (RA) to participate in Jiroft. In the intervention group, before and after the intervention, blood samples will be taken free of charge and according to laboratory standards, and their height and weight will be measured and body mass index will be calculated and recorded. The questionnaires are then completed by interview. Educational materials will be presented through cyberspace in the form of educational materials in the form of films, images, scientific texts, etc. in 10 sessions, as well as times for questions and answers and discussions. 3 months after the intervention, the data will be collected again by the same questionnaires. The control group will receive routine training and interventions as scheduled.

Main outcome variables

Quality of nutrition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210424051067N1**

Registration date: **2021-05-11, 1400/02/21**

Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**

Update count: **0**

Registration date

2021-05-11, 1400/02/21

Registrant information

Name

Mahdiyeh Rafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4331 1686

Email address

m.rafaei@iauk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education on the quality of nutrition of patients undergoing hemodialysis in the prevalence of COVID-19

Public title

The effect of education on the quality of nutrition of patients undergoing hemodialysis

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in research Have a minimum literacy rate Smartphone access

Exclusion criteria:

Creating unexpected conditions for the patient
Reluctance to continue participating in the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 patients with random entry blocking criteria with 4 blocks will be identified using a random number table of Random Allocation Software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research. The sample allocation ratio will be 1: 1 and will be divided into intervention and control groups. Patients will then be instructed based on the blocks obtained and in the order of allocation sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a one-way blind randomized clinical trial. In this way, patients are divided into two groups by one of the researchers who do not interfere in the intervention and evaluation of results. The intervention group is labeled A and the control group is labeled B. Using a table of random numbers, participants are randomly divided into groups A and B in blocks of four [ABAB, BAAB, etc.]. The data analyst does not know in which group each participant was divided. Before dividing, all participants are told that dividing them into groups will not harm them, and they will be informed in order to be divided into groups. The experimental group receives educational intervention and the control group receives routine care and training.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Azad University of Kerman

Street address

Azad University of Kerman, Valiasr Blv., Kerman

City

Kerman

Province

Kerman

Postal code

۷۶۳۵۱۳۱۱۶۷

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.IAU.KERMAN.REC.1399.012

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

Chronic renal failure

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

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

Quality of nutrition

Timepoint

Before the intervention and three months after

Method of measurement

questionnaire - Blood test (TIBC-Alb)

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group in this study is a group of 30 people, all of whom will be emphasized to participate in the initial session with 10 hours of fasting per day with a

family member who has the necessary knowledge about using the Internet. And take a blood sample of albumin and serum TIBC in the hemodialysis ward of Imam Khomeini Hospital in Jiroft. Before and after the intervention, blood samples will be taken for free and according to laboratory standards and their height and weight will be measured and body mass index will be calculated and recorded. The questionnaires are then completed by interview. Educational materials will be presented through cyberspace in the form of educational materials in the form of films, images, scientific texts, etc. in 10 sessions, as well as times for questions and answers and discussions. 3 months after the intervention, the data will be collected again by the same questionnaires.

Category

N/A

2

Description

Control group: The control group in this study is a group of 30 people who receive routine training and interventions according to the previous schedule.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mahdiyeh Rafiei

Street address

Shafa St., Imam Khomeini Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Kazemipour

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Jeeroft University of Medical Sciences

Full name of responsible person

Mahdiyeh Rafiei

Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some data, such as main outcome information and demographic information, can be shared after making individuals unrecognizable.

When the data will become available and for how long

The start of access to information is 36 months after the results are published.

To whom data/document is available

Researchers working in academic, scientific and industrial institutions.

Under which criteria data/document could be used

In order to be used for scientific purposes and by mentioning the source used.

From where data/document is obtainable

Dr Maryam Khandan, PHD in Nursing, Islamic Azad University Kerman Branch, Iran Email address: M_khandan49@yahoo.com

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

After receiving the email from the applicant, the information will be sent within 3 to 5 working days.

Comments