Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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.rafiei@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

City

Jiroft

Province

Kerman

Postal code

78611764787

Phone

+98 34 4331 6313

Email

rafiei.2001@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Kazemipour

Street address

Azad University of Kerman, Valiasr Blv., Kerman town

City

kerman

Province

Kerman

Postal code

۷۶۳۵۱۳۱۱۶۷

Phone

+98 34 3321 0043

Fax

+98 34 3321 0051

Email

ertebat@iauk.ac.ir

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

Street address

Shafa St., Imam Khomeini Hospital

City

Jiroft

Province

Kerman

Postal code

78611764787

Phone

+98 34 4331 6313

Email

rafiei.2001@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Khandan

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Islamic Azad University of Kerman , Valiasr Blvd.

City

Kerman

Province

Kerman

Postal code

7635131167

Phone

+98 34 4331 1686

Email

mkhandan@iauk.ac.ir

Person responsible for updating data

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

Street address

Resalat St., No. 114

City

Jiroft

Province

Kerman

Postal code

7861765119

Phone

+98 34 4331 1686

Email

rafiei.2001@yahoo.com

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