

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Design and evaluation of nutrition education program based on health belief model (HBM) and its effect on the promotion of nutritional intake, quality of life and some nutritional and clinical outcomes in patients undergoing hemodialysis

Protocol summary

Summary

The purpose of this study is design and determine the effects of nutrition education based on health belief model (HBM) and its effect on the promotion of nutritional intake, quality of life and some nutritional and clinical outcomes in patients undergoing hemodialysis. This study is a randomized clinical trial with a control group design. The main inclusion criteria include : chronic kidney disease, hemodialysis for at least 6 months, age range 60-20 years. 100 patients were randomly divided into intervention and control groups that 50 people are in each group. The experimental group trained nutrition education to patients treated with hemodialysis in 8 one-hour sessions in 4 weeks. The outcomes of this study are: feeding behavior (particularly food), quality of life and nutritional consequences (particularly of nutrients, weight and body mass index) and clinical consequences (CRP, FBS, creatinine, BUN, hemoglobin, hematocrit, P, calcium, sodium, potassium, systolic and diastolic blood pressure).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081811763N29**
Registration date: **2017-09-27, 1396/07/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design and evaluation of nutrition education program based on health belief model (HBM) and its effect on the promotion of nutritional intake, quality of life and some nutritional and clinical outcomes in patients undergoing hemodialysis

Public title

Effect of nutrition education on patients undergoing hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: chronic kidney disease; hemodialysis for at least 6 months; age range 60-20 years; having stable conditions; lack of malignancies; absence on the waiting list for a kidney transplant in the next 6 months; the ability to collaborate on a single project and participate in meetings and training group; no pregnancy and breastfeeding. Exclusion criteria: lack of desire to continue cooperation; the displacement of dialysis centers to other centers for any reason; history of acute diseases and malignancies; the need to link the project for any reason.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjarib Street

City

Isfahan

Postal code

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.MUI.REC.1394.3.962

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Quality of life

Timepoint

Before, after and 3 months after intervention

Method of measurement

Questionnaire

2

Description

Nutritional intake

Timepoint

Before, after and 3 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Nutrient intake

Timepoint

Before, after and three months after intervention

Method of measurement

Questionnaire

2

Description

weight

Timepoint

Before, after and three months after intervention

Method of measurement

Questionnaire

3

Description

Body Mass Index

Timepoint

Before, after and three months after intervention

Method of measurement

Using the formula weight (kg) / height (m) ²

4

Description

CRP

Timepoint

Before, after and three months after intervention

Method of measurement

ELISA

5

Description

FBS

Timepoint

Before, after and three months after intervention

Method of measurement

The enzyme glucose oxidase method

6

Description

Creatinine

Timepoint

Before, after and three months after intervention

Method of measurement

Jaffe method

7

Description

BUN

Timepoint

Before, after and three months after intervention

Method of measurement

Chemical diacetyl Mvrvaksym

8

Description

Serum sodium

Timepoint

Before, after and three months after intervention

Method of measurement

Spectrophotometry

9

Description

Serum potassium

Timepoint

Before, after and three months after intervention

Method of measurement

Spectrophotometry

10

Description

Serum calcium

Timepoint

Before, after and three months after intervention

Method of measurement

Colorimetric

11

Description

Serum phosphorus

Timepoint

Before, after and three months after intervention

Method of measurement

Spectrophotometry

12

Description

Hemoglobin

Timepoint

Before, after and three months after intervention

Method of measurement

Photometry

13

Description

Hematocrit

Timepoint

Before, after and three months after intervention

Method of measurement

Calculated (HCT = RBC x MCV)

14

Description

Systolic blood pressure

Timepoint

Before, after and three months after intervention

Method of measurement

Mercury manometers

15

Description

Diastolic blood pressure

Timepoint

Before, after and three months after intervention

Method of measurement

Mercury manometers

Intervention groups

1

Description

For intervention group nutrition education appropriate to patients treated with hemodialysis, based on the latest scientific literature on such Krause's food & nutrition therapy, Modern nutrition in health and disease and Nutritional education National kidney foundation, 8 sessions in 4 weeks (each session an hour, individual training and in groups of 5-6 people, using educational pamphlets and manuals)

Category

Lifestyle

2

Description

The control group receive only the traditional training center offered.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis centers affiliated with the University

Full name of responsible person

Narjes Nooriani

Street address

Razi Hospital, Razi Square, Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Askari

Street address

Hezarjarib street, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences-Nutrition College

Full name of responsible person

Narjes Nooriani

Position

Masters student of nutrition

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty