

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect of an Educational Package Related to a Diet on Quality of Life Among nondialysis Patients

Protocol summary

Summary

Study objective is to determine the effect of diet training package on quality of life in pre-dialysis patients . Design of study is Non-randomized, single blind with control group with the usual care. Dietary components of training packages that will be presented to the patient group, the dominant service in the second training session Hour of personal training and group training to be the same, the contents of the manual training, the quality of life questionnaire Live, in person at monthly follow-up clinic and monthly tests and questions and answers between patient and researcher Based on patient needs and retraining will be necessary The study population are all non-dialysis patients with glomerular filtration rate 15 to 60. Main inclusion criteria is having a GFR between 15 to 60 and main exclusion criteria is the disease progresses as the patient may require dialysis. Sample size is 63 people. intervention study is diet training package. intervention is 3 months. The primary outcome of the study is the diet of training packages after 12 weeks improves , general and specific aspects of quality of life in non-dialysis patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203139289N1**

Registration date: **2012-04-16, 1391/01/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-16, 1391/01/28

Registrant information

Name

Mahsa Pourshaban Oushibi

Name of organization / entity

Faculty of Nursing and Midwifery of Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 4447 4535

Email address

m-pourshaban@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-06, 1391/01/18

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of an Educational Package Related to a Diet on Quality of Life Among nondialysis Patients

Public title

Effect of diet on quality of life

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age higher than 18 years old ,the ability for conversation and understanding persian language, glomerular filtration rate=15-60 and ability for reading and Writing . exclusion criteria: patient's death,The disease progresses to dialysis, Mental illness or functional impairment of skeletal muscle, acute disease

with the need for hospitalization and kidney transplant

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Faculty of Nursing and Midwifery, Tohid sq.

City

Tehran

Postal code

Approval date

2012-03-14, 1390/12/24

Ethics committee reference number

90/130/2520/3

Health conditions studied

1

Description of health condition studied

chronic kidney disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

quality of life

Timepoint

Before and 3 months after intervention

Method of measurement

kidney disease quality of life questionnaire

Secondary outcomes

1

Description

blood exam include: Na,k,CBC,Pr,BUN,Cr

Timepoint

First, second and third months of intervention

Method of measurement

Exposure levels, hemoglobin and urea, and sodium and potassium and protein in the normal range

Intervention groups

1

Description

Intervention group: 4-hour training manual training in patients with pre-dialysis diet, and individual 2-hour first session and second sessions of 2 hours and 5-person group

Category

Lifestyle

2

Description

Control group: usual care, including routine doctor visit

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hasheminejad Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences. Faculty of Nursing and Midwifery

Full name of responsible person

Dr. Mehrdad

Street address

School of Nursing and Midwifery, Tohid Sq

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran University of Medical Sciences. Faculty of Nursing and Midwifery
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
 Faculty of Nursing and Midwifery
Full name of responsible person
 Mahsa Pourshaban Oushibi
Position
 MSc Of Nursing
Other areas of specialty/work
Street address
 Faculty of Nursing and Midwifery. Tohid sq.
City
 Tehran
Postal code
Phone
 +98 21 4447 4535
Fax
Email
 m-pourshaban@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Tehran University of Medical Sciences
Full name of responsible person
 Parsa Yekta Zohreh

Position
 Phd of nursing
Other areas of specialty/work
Street address
 Faculty of Nursing and Midwifery. Tohid Sq.
City
 Tehran
Postal code
Phone
 +98 21 6692 7171
Fax
Email
 zparsa@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
 Pourshaban Oushibi Mahsa
Position
 MSc of nursing
Other areas of specialty/work
Street address
City
Postal code
Phone
 00
Fax
Email
 m-pourshaban@razi.tums.ac.ir
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