Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Randomized clinical trial effect of diet therapy and nutrition education on clinical indicators, malnutrition, depression and quality of life in chronic kidney disease patients referred to Motahari clinic and Faghihi Hospital of Shiraz in 1398

Protocol summary

Study aim

Effects of diet and nutrition training on clinical indicators, malnutrition, depression and quality of life in chronic kidney patients

Design

Randomized parallel clinical trial with two groups of control and intervention with a sample size of 120

Settings and conduct

Chronic kidney disease patients in Shahid Motahari and Shahid Faghihi clinic at shiraz. with satisfaction of patients and under the supervision of the doctor, the intervention begins for six months. Patients do the blood test for the examination considerable biomarkers and also do the needful questionnaire before and Patients in the intervention group will be given diet and nutrition education for dialysis patients. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Drugs used during the past six months did not change during the study, adults between 18-65 years old, willing to participate in the study , GFR of 15 to 60, and Exclusion criteria: with malignancy , AIDS, acute or inflammatory infection, diabetes patient, cancer patients, decompensated HF patient, renal transplant patients, dialysis , Alzheimer's , patients with problems Cognitive, Mental Illness, Pregnant Patients or those who intend to die during pregnancy, Mar during the study, the patient's unwillingness to cooperate and participate in training sessions, participants developing movement disorders (weakness of the skeletal - muscle), the treatment regimen during the past month, losing inclusion criteria, acute decline in GFR

Intervention groups

Control group: we have routine advice in nutrition without without diet regimens and nutrition education. Intervention group: diet regimens and nutrition training for 6 months in addition to conventional medical treatment of Chronic kidney disease patients.

Main outcome variables

Evaluation of nutritional indicators, depression, malnutrition status and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100223003408N6**
Registration date: **2020-02-09, 1398/11/20**
Registration timing: **retrospective**

Last update: **2020-02-09, 1398/11/20**
Update count: **0**

Registration date

2020-02-09, 1398/11/20

Registrant information

Name

Maryam Ekramzadeh

Name of organization / entity

Shiraz University of Medical Sciences, Nutrition Department

Country

Iran (Islamic Republic of)

Phone

+98 917 317 3891

Email address

ekramzadeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01
Expected recruitment end date
2019-07-21, 1398/04/30
Actual recruitment start date
2019-06-22, 1398/04/01
Actual recruitment end date
2019-08-05, 1398/05/14
Trial completion date
2020-02-04, 1398/11/15

Scientific title
Randomized clinical trial effect of diet therapy and nutrition education on clinical indicators, malnutrition, depression and quality of life in chronic kidney disease patients referred to Motahari clinic and Faghihi Hospital of Shiraz in 1398

Public title
Randomized clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The dosage of medications taken during the past six months did not change during the study Willing to participate in the study and have written consent GFR between 15 and 60 Adults between 18-65 years
Exclusion criteria:
Has malignancy AIDS , acute or inflammatory infection , diabetes patient , cancer patients , decompensated HF patient, renal transplant recipients , dialysis patients , Alzheimer's patients , patients Cognitive problems, patients with mental illness , pregnant patients or those who plan to be pregnant during the study period , the patient's death during the study , the patient's unwillingness to participate and participate in training sessions , the participant with motor impairment (weakness) Musculoskeletal), treatment regimen over the past month , loss of inclusion criteria decline GFR
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization, Individual, Random allocation software, 11 randomization sequence in permuted blocks of size 4 In this study, the allocation of people to the two groups was done using permutational block method. In this method, T represents the person who receives the intervention, and C represents the person who is in the control group. Considering the quadruple block; we achieved TTCC , TCCT , CTTC , TCCT , CCTT , TCCT , TCTC , TCCT , CCTT , TCTC and TTCC . Then, using the randomization software and sealed envelopes we allocate each one to a patient respectively.
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
Ethics committee of Shiraz University of Medical Sciences
Street address
Zand street Shiraz University of Medical Sciences
City
shiraz
Province
Fars
Postal code
71348-14336
Approval date
2019-06-22, 1398/04/01
Ethics committee reference number
IR.SUMS.REC.1398.531

Health conditions studied

1

Description of health condition studied
chronic kidney disease
ICD-10 code
N18.3
ICD-10 code description
Chronic kidney disease, stage 3 (moderate)

Primary outcomes

1

Description
eGFR
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
formula

Secondary outcomes

1

Description
BUN
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

2

Description
Cratinine
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

3

Description
Albumin
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

4

Description
Calcium
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

5

Description
Sodium
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

6

Description
Phosphor
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

7

Description
Potasium
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

8

Description
hemoglobin
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

9

Description
uric acid
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

10

Description
hematocrit
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
Autoanalyser

11

Description
weight
Timepoint
At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training
Method of measurement
scale

12

Description

BMI

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training

Method of measurement

Formula

13

Description

Subjective global assessment

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training

Method of measurement

questionnaire

14

Description

Quality of Life

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training

Method of measurement

questionnaire

15

Description

Depression

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training

Method of measurement

questionnaire

16

Description

Parathyroid hormone

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training

Method of measurement

autoanalyser

17

Description

feritin

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition training

Method of measurement

ELISA

18

Description

vitamin D

Timepoint

At the beginning of the study (before the intervention) and six months after the start of treatment and nutrition

Method of measurement

ELISA

Intervention groups

1

Description

Intervention group:direct education based on chronpoic kidney disease diet .the intervention is carried through education aid such as powerpoint(and CKD diet,nutrition counseling,diet tip s,exchange list) through 1-2hours sessions twice in 6 month.indirect education has been done by booklet. and also especial type of diet according to pre dialysis based on blood sample ,weight and hight and patients followed.educational and diet therapy in case done during 24-week

Category

Lifestyle

2

Description

Control group: this group are educated about routin nutrition and diet during 24_ week by nephrologist

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid faghihi hospital of Shiraz

Full name of responsible person

Maryam Ekramzade

Street address

Zand street

City

shiraz

Province

Fars

Postal code

71876-56895

Phone

+98 71 3612 1000

Email

m_ekramzade@yahoo.com

2

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Maryam Ekramzade
Street address
Namazi square
City
shiraz
Province
Fars
Postal code
71876-56895
Phone
+98 71 3612 1000
Email
m_ekramzade@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Gholam Reza Hatam
Street address
zand sreet
City
shiraz
Province
Fars
Postal code
71876-56895
Phone
+98 71 3235 2559
Email
m_ekramzade@yahoo.com
Grant name
Shiraz University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Ekramzade
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Nutrition
Street address
Razi Blvd.
City
shiraz
Province
Fars
Postal code
71536-75541
Phone
+98 71 3725 1001
Email
m_ekramzade@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Ekramzade
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Razi Blvd.
City
Shiraz
Province
Fars
Postal code
71536-75541
Phone
+98 71 3725 1001
Email
m_ekramzade@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Hamidianshirazi
Position
Master Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Razi Blvd.
City

Shiraz
Province
Fars
Postal code
71536-75541
Phone
+98 71 3725 1001
Email
mhamidian@sums.ac.ir

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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available