Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of appropriate nutrition education in small groups on the laboratory values in the hemodialysis patients

Protocol summary

Summary

(1) Objectives: The effects of appropriate nutrition education in small groups on the laboratory values in the hemodialysis patients; To determination and compare two month the average laboratory values before and after training between the intervention and control groups with each other and within both intervention and control group (2) Design: 32 control Person and 32 intervention Person, the total sample size of 64 people; Hemodialysis patients with sealed envelope draw in both intervention and control groups and parallel then in two days the pair (intervention) and oven (control) were randomly assigned. (3) Setting and Conduct: 2 times in 2 months laboratory values before the training were inserted and then Training diet intervention groups (5 members) was carried out. values alternately in the two months after the intervention were inserted. Existence significant difference between before and after training, and the average difference between the intervention group and the control group as the effect of education was considered. (4) Participants including major eliglibity criteria: age 18 to 70 years, without psychiatric disorder; Exclusion criteria: severity of illness, lack of willingness to cooperate and kidney transplant (5) Intervention: 1. The intervention; Goals and how diet training that include the reduction of body wastes, regulate body water and electrolytes, allowance food and complications increase the authorized laboratory values in three one-hour sessions for a month were performed. 2. The control; did not receive training. (6) main outcome measure: two month the average laboratory values before and after training between the intervention and control groups with each other and within both intervention and control group were compared.

General information

Acronym

nutrition education and laboratory values in the hemodialysis patients

IRCT registration information

IRCT registration number: **IRCT2016082229481N1**
Registration date: **2016-12-28, 1395/10/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-12-28, 1395/10/08

Registrant information

Name
Seyede Leila Hoseini
Name of organization / entity
Zanjan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-07-23, 1395/05/02

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of appropriate nutrition education in small

groups on the laboratory values in the hemodialysis patients

Public title
The effects of appropriate nutrition education in small groups on the laboratory values in the hemodialysis patients

Purpose
Health service research

Inclusion/Exclusion criteria
Criteria for study: 1. age 18 to 70 years 2. No known psychiatric disorders and psychiatric treatment, according to a Psychiatrist Specializing 3. The absence of any cognitive impairment, speech or hearing 4. The lack of pain during training 5. dialysis in Zanjan 6. phone access 7. having full consent to participate in the study 8. The End-Stage Renal Disease that is constantly undergoing Hemodialysis program 9. two to three times a week for three to four hours is treated with dialysis 10. Having read and write at least 11. sick or disabled family members are able to understand and speak the Persian orTurkish or Azari language 12. caregivers of patients who have the greatest participation in the treatment of disease, and he spent the most time with and least education (literacy), respectively. Exclusion criteria: 1. Used to treat kidney transplant during the study 2. migration from dialysis during the study 3. patient died during the study 4. who frequently ill during hemodialysis and hemodialysis have not been able to afford full-time 5. The incidence of severe deterioration and the development of critical situations for each of the samples during the study 6. Not wanting to take part in a training session or a follow-up sessions during the study

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
none

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
West Azerbaijan University of Medical Sciences

Street address
West Azerbaijan University of Medical Sciences, next to the Emergency, the end of Gahad Street, Resalat Boulvar, Urmia,Iran

City
Urmia

Postal code
5714783734

Approval date
2016-07-20, 1395/04/30

Ethics committee reference number
IR. umsu. rec. 1395. 138

Health conditions studied

1

Description of health condition studied
Chronic Renal Failuer Patients who need hemodialysis

ICD-10 code
XIV

ICD-10 code description
N18, N19

Primary outcomes

1

Description
the laboratory values BUN,Cr, Na, K, Ca, P

Timepoint
wo months before and two months after intervention

Method of measurement
five ml blood samples from patients and Biochemical reagents Company Bayvrks England

Secondary outcomes

empty

Intervention groups

1

Description
intervention group: Diet training program that includes three lecture one hour in unit hemodialysis Vali asr zanjan withe use educational tools 1. educational pamphlet proper diet supervised by a nutritionist 2. The CD contains a short educational videos for patients was conducted using computer 3. In the section with questions and answers from the patient and his entourage, the learning content taught was measured and, if necessary, further explanation was given All content included: 1. kidney function 2.failure and its

complications 3. diet goals: reducing waste in the body, providing enough food for growth and repair of body, regulate body water and electrolytes (sodium, potassium, calcium and phosphorus), the prevention of anemia, and balance blood urea and creatinine 4. The list of allowed and restricted food and fluid intake body 5. how to observe proper diet and fluid intake and Complications increase urea, creatinine, sodium, potassium, calcium, phosphorus 6. finally, non-compliance by the patient's diet: the accumulation of toxins and fluids in the body, increasing the workload of the kidneys, increase the risk of disease progression, impaired physical ability, depression, malnutrition, high blood pressure and death was and else. In three one-hour sessions in four weeks (August) in the even-numbered days in small groups 5 members was performed. that in to six groups of five person and one groups of two person was divided Control group: received no training and routine care

Category

Lifestyle

2

Description

Control group: received no diet training and routine care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr educational and treatment center, Zanjan, Iran

Full name of responsible person

Seyede Leila Hoseini

Street address

Zanjan University of Medical Sciences

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

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Street address

Ayatollah Mousavi educational and treatment center, Gavazng road, Zanjan, Iran

City

Zanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Seyede Leila Hoseini

Position

Critical Care Nursing graduate student

Other areas of specialty/work

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Person responsible for scientific inquiries

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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