

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of blended education on dialysis adequacy and nutritional status in patients with hemodialysis

Protocol summary

Summary

This study will be conducted to determine the effect of blended education on dialysis adequacy and nutritional status of hemodialysis patients. In this study, 60 patients referred to a dialysis center are divided into two groups: intervention group (30) and control group (30), according to going to the center on odd or even days and by throwing a coin. Dialysis patients with at least six months and at least two dialysis sessions per week, aged 18-65 years, and stable clinical status will be enrolled, and those with a lack of adherence to treatment regimens anticipated or those who participate in other courses, will be excluded. Patients in the intervention group will be conducted a needs assessment during the first meeting. Then, educational materials in the field of protection for vascular access, nutrition education, physical activity and medications will be provided in two group sessions and two individual sessions. Individual sessions will focus on the educational needs of the patient. At the end of the meeting, booklets will be provided. Group sessions will take 30 minutes and individual sessions 10 minutes. Then, every two weeks to the end of study, a telephone conversation with patient for answers to questions and emphasis on educational materials will be done. In this study, dialysis adequacy based on the Urea Kinetic Modeling and Urea Reduction Rate and nutritional status based on subjective global assessment questionnaire at baseline, one month and two months after the start of the study will be discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121025457N1**

Registration date: **2016-01-25, 1394/11/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Mojtaba Rayati

Name of organization / entity

Shahed University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Shahed University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-03-17, 1394/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of blended education on dialysis adequacy and nutritional status in patients with hemodialysis

Public title

The effect of blended education on dialysis adequacy and nutritional status

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: At least 6 months Dialysis; at least two dialysis sessions per week; Age 18-65 years; stable clinical situation. Exclusion criteria: Lack of adherence to treatment regimens anticipated; Participation in other training course

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study, patients referred to the center on odd or even days, are divided into two groups by throwing a coin.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahed University of Medical Sciences

Street address

Shahed University of Medical Sciences, Infront of the Shrin of Imam Khomeini, Tehran - Qom Freeway

City

Tehran

Postal code

Approval date

2015-09-11, 1394/06/20

Ethics committee reference number

Shahed.REC.1394.27

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

n18.5

ICD-10 code description

End stage kidney disease on dialysis

Primary outcomes

1

Description

Dialysis adequacy

Timepoint

Before intervention one month after the intervention and two months after the intervention

Method of measurement

DaugirddasII

2

Description

Dialysis adequacy

Timepoint

Before intervention one month after the intervention and two months after the intervention

Method of measurement

Urea Reduction Rate (URR)

Secondary outcomes

1

Description

Nutritional status

Timepoint

Before intervention, one month after intervention and two months after the intervention

Method of measurement

Subjective Global Assessment Questionnaire

Intervention groups

1

Description

Intervention group: In addition to routine dialysis training in the intervention group, patients also will receive integrated training. In the first session of this group, individual interviews are done to determine the educational needs of patients. During dialysis the next day and a 3-2 persons group sessions during 20-30 minutes will be held on hemodialysis Diet. The more an individual session will be based on patient needs. The next day a group meeting will be done on the protection of vascular access, physical activity and medicines. And then an individual session will be done In this context based on patient needs. At the end of the sessions will be presented the pamphlet. Then, a telephone conversation with patient and answers to questions and emphasis on educational materials will be done every two weeks to the end of study. Within one month after intervention and two months after intervention dialysis, adequacy and nutritional status will be reviewed.

Category
Lifestyle

2

Description

Control Group: At the beginning of the study, the adequacy of dialysis and nutritional status will be reviewed in the control group. During the study, patients will receive only training routine dialysis. Then, one month after intervention and two months after the start of the study, the adequacy of dialysis and nutritional status will be reviewed.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Maryam Pakfetrat
Street address
Zand Street, Shahid Faghihi Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research Shahed University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Shahed 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
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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