

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6641 8590

###### Email address

m.rayati@shahed.ac.ir

##### 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  
**City**  
Shiraz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**  
Vice Chancellor for Research Shahed University of Medical Sciences  
**Full name of responsible person**  
Zahra kiasalari  
**Street address**  
Shahed University of Medical Sciences, Infront of Shrin of Imam Khomeini, Tehran - Qom Freeway  
**City**  
Tehran

**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**  
School of Nursing and Midwifery Shahed  
**Full name of responsible person**  
Mojtaba Rayati  
**Position**  
Msc of nursing Student  
**Other areas of specialty/work**  
**Street address**  
School of Nursing and Midwifery Shahed, Alley Rahimzadeh, Valiasr Intersection of Taleghani  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 6641 8590  
**Fax**  
**Email**  
m.rayati@shahed.ac.ir  
**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**  
School of Nursing and Midwifery Shahed  
**Full name of responsible person**  
Maryam Jadid Milani  
**Position**  
PHD Nursing  
**Other areas of specialty/work**  
**Street address**  
School of Nursing and Midwifery Shahed, Alley Rahimzadeh, Valieasr Intersection of Taleghani  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 6640 8590  
**Fax**  
**Email**  
milani2000ir@yahoo.com  
**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**  
School of Nursing and Midwifery Shahed  
**Full name of responsible person**  
Mojtaba Rayati  
**Position**  
Msc nursing student  
**Other areas of specialty/work**  
**Street address**  
School of Nursing and Midwifery Shahed, Alley

Rahimzadeh, Valieasr Intersection of Taleghani

**City**

Tehran

**Postal code**

**Phone**

+98 21 6641 8590

**Fax**

**Email**

m.rayati@shahed.ac.i

**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*