Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Family-centered and patient-centered teaching on adherence to therapeutic regimen and hemodialysis complications

Protocol summary

Summary

The aim of this randomized clinical trial with pre-test-post-test design is to investigate effect of two educational methods (Family-centered and patient-centered) on adherence to therapeutic regimen and some of complications during hemodialysis. Sixty hemodialysis patients 18 - 65 years old randomly will be assigned in two groups: patient -centered (N=30 on even days) and family-centered (N=30 on odd days). Some of inclusion criteria would be the patients with positive history of muscle cramps or hypotension two weeks before the intervention. The patient had neither history of cardiovascular problems nor consuming any anti-hypertensive drugs or history of musculoskeletal problems. The patients should not be in uremic phase. Patient's primary care taker will have the highest participation in the treatment and should be able to read and write at least. Hypotension and muscle cramp will be assessed by use of check list in three stages (pre-test, 2 weeks and 4 weeks after intervention).peri-dialysis Hypotension would be checked (pre dialysis, first, second, third, four and final hour) and muscle cramps (mid and final half hour) as well. The adherence to therapeutic regimen will be evaluated by using researcher-made questionnaires once in before intervention and once in the fourth week after intervention. The results would be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204161599N17**
Registration date: **2014-04-16, 1393/01/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-16, 1393/01/27

Registrant information

Name
Mitra Zolfaghari
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Country
Iran (Islamic Republic of)
Phone
+98 21 6692 7171
Email address
zolfaghm@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Nursing & Midwifery Care Research Center

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-07-19, 1391/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Family-centered and patient-centered teaching on adherence to therapeutic regimen and hemodialysis complications

Public title

Family-centered teaching vs patient-centered teaching on hemodialysis patient adherence of therapeutic regimen

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: 18 to 65 years old patients on hemodialysis three times a week and each time 3 to 4 hours of dialysis. The patients with positive history of muscle cramps or hypotension two weeks before the intervention. The patient had neither history of cardiovascular problems nor consuming any anti-hypertensive drugs or history of musculoskeletal problems. The patients should not be in uremic phase. Patient's primary care taker will have the highest participation in the treatment and should be able to read and write at least. Exclusion criteria: 1- patients who are candidates for transplantation during the study. 2- patients who change nutrition or drug programs by physicians
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: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Ghods St. Tehran , Tehran, IR,Iran
City
Tehran
Postal code
1416614741
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
2454/130/90/د

Health conditions studied

1

Description of health condition studied
End stage renal disease
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
Hypotension
Timepoint
before dialysis, first, second, third, fourth and final hour of dialysis
Method of measurement
checklist

2

Description
muscle cramps
Timepoint
in middle and final half-an-hour of dialysis
Method of measurement
checklist

3

Description
adherence to therapeutic regimen
Timepoint
once before intervention and once in the fourth week after intervention
Method of measurement
researcher-made questionnaires

Secondary outcomes

empty

Intervention groups

1

Description
Intervention patient-centered education: The researcher trains the patient's four meetings, 30-45 minutes of training as face to face training. The end of each meeting will be relevant educational pamphlet.
Category
Prevention

2

Description
Intervention family-centered education: The researcher

trains the patient along with patient's primary care taker four meetings, 30-45 minutes of training as face to face training. The end of each meeting will be relevant educational pamphlet

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Parvaneh Asgari

Street address

Nosrat St., Tohid Sq.,Imam Khomeini Hospital, Tehran, IR Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Ghods St., Keshavarz BLVD, Tehran. Iran.

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, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Asgari

Position

Ms Degree

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Nosrat St., Tohid Sq.,Tehran University of Medical Science, Tehran, Iran

City

Tehran

Postal code

1416614741

Phone

+98 21 8896 8862

Fax

Email

p_marjan@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Science

Full name of responsible person

Mitra Zolfaghari

Position

Assistant professor of Virtual School.

Other areas of specialty/work

Street address

Virtual School, Tehran University of Medical Sciences, Dolatshahi All., Naderi St., Keshavarz BLVD, Tehran. Iran.

City

Tehran

Postal code

1416614741

Phone

+98 21 8897 8088

Fax

Email

zolfaghm@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Parvaneh Asgari

Position

Ms Degree

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Nosrat St., Tohid Sq.,Tehran University of Medical Science, Tehran, IR Iran

City

Tehran

Postal code
982347654524
Phone
+98 21667198
Fax
Email
P_Marjan@ymail.com
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