Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of education based on Trans Theoiretical Model on hemodialysis patients self-care behaviours for gaining weight adjustment between dialysis sessions.

Protocol summary

Summary

The purpose of this study is evaluating the effect of education based on Trans Theoretical Model on hemodialysis patient's self-care behaviors for gaining weight adjustment between dialysis sessions.Inclusion criteria: Willing to participate in the study; Patients who have hemodialysis three sessions in a week;Having at least literacy.Exclusion criteria: Participating in another similar interventional study at the same time; Unwilling to participate in the study. This study is a semi-experimental study.The study population consist of hemodialysis patients who are 12-90 years old that referred to Tehran University's hospitals. 228 patients were selected and allocated randomly two groups: Intervention group(n=114) and control group(n=114). Intervention is education by using the CD and booklet for intervention group.The information content in CD and booklets are based on Trans Theoretical Model. Control group won't receive education.Data collected by questionnaire before education and will be collected12 weeks after education. Primary outcome of this study is gaining weight adjustment between dialysis sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102012382N4**
Registration date: **2013-12-28, 1392/10/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-28, 1392/10/07

Registrant information

Name

Zahra Rahnavard

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

zrahnavard@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Scienses

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of education based on Trans Theoiretical Model on hemodialysis patients self-care behaviours for gaining weight adjustment between dialysis sessions.

Public title

The effect of education based on Trans Theoretical Model on gaining weight between hemodialysis sessions.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate in the study;

Patients who have hemodialysis three sessions in a week; Having at least literacy. Exclusion criteria: Participating in another similar interventional study at the same time; Unwilling to participate in the study.

Age
From **12 years** old to **90 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **228**

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
Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences - Poursina St

City
Tehran

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
1758/130/91/د

Health conditions studied

1

Description of health condition studied
dialysis

ICD-10 code
z49.0

ICD-10 code description
preparatory care for dialysis

Primary outcomes

1

Description
gaining weight between dialysis sessions

Timepoint
before and 12 weeks after intervention

Method of measurement
weighing by scale (kgr)

Secondary outcomes

1

Description
Hemodialysis self- care behaviours for adjusting the weight

Timepoint
before and 12 weeks after intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention is education based on Trans Theoretical Model to intervention group using the CD and booklet

Category
Prevention

2

Description
The control group didn't recieve any intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hasheminegad Hospital

Full name of responsible person
Zahra Rahnavard

Street address
Hasheminegad Hospital, Valinegad alley, Vanak SQ, Valiasr St

City
Tehran

2

Recruitment center

Name of recruitment center
Amiralam Hospital

Full name of responsible person
Zahra Rahnavard

Street address
Amiralam Hospital,North Saadi Street, Enghelab

Avenue

City

Tehran

3

Recruitment center

Name of recruitment center

Hazrate Rasool Hospital

Full name of responsible person

Zahra Rahnavard

Street address

Rasool Hospital, Niyayesh Street, Sattar Khan Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciencesl

Full name of responsible person

Ziba Taghizadeh

Street address

Tehran University of Medical Sciences, Nursing School

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciencesl

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, Nursing School

Full name of responsible person

Zahra Rahnavard

Position

Associated Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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