

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of cognitive-behavioral intervention on adherence to therapeutic regimen and remove of related barriers in hemodialysis patients

Protocol summary

Summary

The purpose of the study is to determine the effect of cognitive - behavioral therapy on adherence and remove of related barriers in hemodialysis patients. This study is a clinical trial and will be done on 70 hemodialysis patients who will be admitted in hemodialysis wards of Lar and Lamerd hospitals. Inclusion criteria: Having writing and reading abilities and scoring less than 50 on adherence to treatment with patient consent. Exclusion criteria: Not willing to continue the study. The patients randomly are allocated in intervention and control groups. In the intervention group: cognitive - behavioral therapy will be carried out in six stages consist of: identifying patient's problem, creating self confidence and commitment to patient, improving awareness of the behavior; making a good plan, evaluating of training plan and maintaining behavioral changes. In the control group without any intervention adherence and barriers questionnaires will be completed again 3 months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211101599N21**

Registration date: **2013-05-12, 1392/02/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-12, 1392/02/22

Registrant information

Name

Mitra Zolfaghari

Name of organization / entity

Tehran University of Medical Sciences and Health Services

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Science

Expected recruitment start date

2013-05-30, 1392/03/09

Expected recruitment end date

2013-09-19, 1392/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive-behavioral intervention on adherence to therapeutic regimen and remove of related barriers in hemodialysis patients

Public title

Improving adherence to therapeutic regimen in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20-60 years old hemodialysis patients who are on hemodialysis for at least one year 2 or 3 times a week, each session lasting 4-3 hours.

Hemodialysis should be able to read and write in research subjects and Score less than 50 on adherence to treatment. Exclusion criteria: Not willing to continue participating in the study .Not attending any of the educational intervention

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Two hospitals in Lar and Lamerd will be randomly assigned to the cognitive - behavioral intervention and control groups. These hospitals have equal aspects for hemodialysis and have similar nursing performance. 70 hemodialysis patients who will be admitted in hemodialysis wards of Lar and Lamerd hospitals will be participated in this study by convenience sampling.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee-Tehran University of Medical Sciences

Street address

Ghods St. Keshavarz Blv. Central building of Tehran University of Medical Sciences, 6th floor

City

Tehran

Postal code**Approval date**

2013-01-07, 1391/10/18

Ethics committee reference number

2527/130/1

Health conditions studied**1****Description of health condition studied**

Chronic renal disease

ICD-10 code

N18.5

ICD-10 code description

Chronic uremia

Primary outcomes**1****Description**

Adherence to therapeutic regimen

Timepoint

Before the intervention, and three months after intervention

Method of measurement

A researcher-made questionnaire with likert scale

Secondary outcomes**1****Description**

Barriers of adherence to therapeutic regimen

Timepoint

Before the intervention, and three months after intervention

Method of measurement

A researcher-made questionnaire with likert scale

Intervention groups**1****Description**

Cognitive-behavioral intervention consist of six steps: Step 1: Identifying the problem. In This step, Knowledge, belief, and the barrier to self-care will be determined by person-to-person interviews. Step 2: Creating confidence and commitment. In This step, the patient and the researcher will be signed a contract to begin working on a particular behavior change after face-to-face counseling. Step 3: Increasing awareness of behavior. This step leads to increase in the patient's awareness of his or her behavior patterns through self-monitoring. The subjects were asked to keep a diary of adherence every day until the next consultation. Step 4: Developing and implementing the action plan. Based on the subject's behavior, statements in the diary of adherence, a short-term action plan (On an individual basis), will be designed by researcher. Step 5: Evaluating the plan is designed. Impact on behavior change plan will be evaluated. If the subject failed, a new plan that can be achieved will be designed. Step 6: Maintain the desired behavior change to prevent undesirable behavior. The purpose of this step is to maintain and reinforce desired behaviors through motivational phrases.

Category

Treatment - Other

2

Description

Control group with no intervention adherence rates and barriers to adherence to treatment is evaluated before and 3 months after

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Street address

Doctor Dadman High Way. Lar. New Town.

City

Larestan

2

Recruitment center

Name of recruitment center

Hospital Lamerd

Full name of responsible person

Street address

Lamerd City. Hospital Lamerd

City

Lamerd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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

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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

Nursing and Midwifery College

Full name of responsible person

Sookhak Fatemeh

Position

Master of Science Critical Care Nursing

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