

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of health-promotion behaviors education versus no education on the quality of life in hemodialysis patients: a before after randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of health-promotion behaviors education versus no education on the quality of life in hemodialysis patients. Design: a before after randomized clinical trial. Setting and conduct: The eligible hemodialysis patients who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. Inclusion criteria: (a) being dialyzed for at least 6 months; (b) not having any chronic diseases including high blood pressure, diabetes, and malignancy; (c) age of 18 to 60 years.; (d) ability of verbal communication and not having any psychological disorder or fictional disability; (e) literate; (f) being dialyzed for two or three times a week. Exclusion criteria: (a) moving to another center and not returning due to death or medical reasons; (b) participating in a similar research concurrently. Intervention: Receiving an educational booklet plus face to face health-promotion behaviors education, 6 sessions for 30 minutes during 3 consecutive weeks Control: Receiving an educational booklet only. Primary outcome: Measuring the quality of life before and 3 months later using Ferrans & Powers standard questionnaire. Secondary outcome: Nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201505109014N62**
Registration date: **2015-05-17, 1394/02/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-17, 1394/02/27

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2015-03-03, 1393/12/12

Expected recruitment end date

2016-03-02, 1394/12/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of health-promotion behaviors education versus no education on the quality of life in hemodialysis patients: a before after randomized clinical trial

Public title

Effect of health-promotion behaviors education versus no education on the quality of life in hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: (a) being dialyzed for at least 6 months; (b) not having any chronic diseases including high blood pressure, diabetes, and malignancy; (c) age of 18 to 60 years.; (d) ability of verbal communication and not having any psychological disorder or fictional disability; (e) literate; (f) being dialyzed for two or three times a week. Exclusion criteria: (a) moving to another center and not returning due to death or medical reasons; (b) participating in a similar research concurrently.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: One of the two hospitals will be randomly selected as intervention group and the other one as the control group. Therefore, the trial will be run as single blind trial. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-02-09, 1393/11/20

Ethics committee reference number

D/P/16/35/9/5862

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes

1

Description

Measuring the quality of life

Timepoint

before and 3 months later

Method of measurement

using Ferrans & Powers standard questionnaire

Secondary outcomes

1

Description

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups

1

Description

Receiving an educational booklet plus face to face health-promotion behaviors education, 6 sessions for 30 minutes during 3 consecutive weeks

Category

Lifestyle

2

Description

Receiving an educational booklet only

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Sahar Zonoori

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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Hamadan

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 the Technology, Hamadan
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

Shahid Beheshti Hospital

Full name of responsible person

Sahar Zonoori

Position

Nursing Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Hospital

Full name of responsible person

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Position

PhD in Nuring Education

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

School of Public Health, Hamadan University of
Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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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

