

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The effect of empowerment on quality of life, self efficacy and clinical and lab indicators of patients under hemodialysis treatment

Protocol summary

Summary

Patients undergoing haemodialysis experience many changes in their quality of life. Despite of these changes they should actively manage their clinical problems for which they are not prepared. The aim of this quasi-experimental study was to determine the impact of empowerment on the quality of life, self efficacy, clinical and laboratory indicators of patients under hemodialysis. Subjects participated in this interventional study were 48 patients treated with haemodialysis at least for 3months who referred to Boo Ali Sina dialysis center located at Shiraz-in the south of Iran .Quality of life, self efficacy, clinical and laboratory indicators of all patients were measured by questionnaire ,interview and lab tests. Then they were randomly divided into two equal groups as control & experimental groups. In the next stage the experimental group participated in a 6 week empowerment program in which self management was enhanced by individual & group counselling. Quality of life, self efficacy, clinical and laboratory indicators in both groups were assessed 6 weeks after the implementation of intervention as post-test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901172621N4**

Registration date: **2011-05-19, 1390/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-19, 1390/02/29

Registrant information

Name

Marzieh Moattari

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4250

Email address

moattarm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2009-09-29, 1388/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empowerment on quality of life, self efficacy and clinical and lab indicators of patients under hemodialysis treatment

Public title

The effect of empowerment on quality of life of patients under hemodialyse

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:1-18-60 year old 2-abilityto read and write 3- three times dialysis in a week 4-giving permission to participate in the study 5-living in Shiraz 6- living along with family members7-able to walk & eat

without help 9-being under haemodialysis at least for three months. Exclusion criteria: lack of interest to continue hospitalization due to acute illness during the study diagnosed as having mental disorder being in waiting list for transplantation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

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

Shiraz university of medical sciences

Street address

Zand blvd

City

Shiraz

Postal code

Approval date

2009-11-01, 1388/08/10

Ethics committee reference number

ct-88-4785

Health conditions studied

1

Description of health condition studied

End stage renal disease treat with hemodialysis

ICD-10 code

Z49

ICD-10 code description

Care involving dialysis

Primary outcomes

1

Description

quality of life

Timepoint

before and 6 weeks after intervention

Method of measurement

Questionnaire

2

Description

clinical indicators

Timepoint

before and 6 weeks after intervention

Method of measurement

paitent chart

3

Description

lab indicators

Timepoint

before and 6 weeks after intervention

Method of measurement

paitent chart

4

Description

self efficacy

Timepoint

6 weeks after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention program consisted of two parts including individual and group counselling for 6 weeks. Individual counselling focused on educating, supporting and helping patients develop skills and self-awareness in problem identification, exploration of emotions associated with these problems, goal setting, problem solving and self-management through strategies to overcome the identified problems and achieving the goals, and making behavioural change.. In group counselling, the patients, attended in two small group sessions of 1.5-2 hours conducted by a psychiatric nurse for stress management, coping strategies, social support and motivation.this program offered just to the experimental group.

Category

Behavior

2

Description

The control group received the conventional information available at the center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo Ali sina hospital

Full name of responsible person

Mr Rasti

Street address

Sadra city

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Dabaghmanesh

Street address

Vice Chancellor for Research, 7th floor, Shiraz University of Medical Sciences, Zand st

City

Shiraz

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, Shiraz 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

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Full name of responsible person

Marzieh Moattari

Position

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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