Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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 paitents 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 univercity 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
questionaire

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 expermental group.

Category
Behavior

2

Description
The control group received the conventional information avilableat 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 Univercity of Medical Sciences
Full name of responsible person
Dr. Dabaghmanesh
Street address
Vice Chancellor for Research, 7th floor, Shiraz Univercity 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 Univercity 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
Shiraz Univercity of Medical Sciences
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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