Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effectiveness of quality of life training on self-efficacy of patients under hemodialysis treatment

Protocol summary

Summary

Objective: This study was conducted aimed at determining the effect of quality of life training on self-efficacy of patients under hemodialysis treatment. Procedure: This research is a clinical trial. The Sample consists of 90 subjects (two groups, 45 subjects each), who were selected at random from among patients referring to dialysis centers of the city of Kerman. Participants' inclusion and exclusion major eligibility criteria: Inclusion criteria were: At least 6 months ought to be passed from the start of their dialysis; have no history of mental health diseases and problems; have no physical problem other than chronic kidney disease; do not have a history of kidney transplantation. Exclusion criteria were: The subject's intention to undergo a kidney transplant and intention to emigrate and his/her suffering from acute physical and psychological problems during the intervention and implementation of the study plan Intervention: Both groups took the first round test. In the study group, quality of Life training program was implemented in the forms of speech, question and answer and giving educational pamphlets in sessions, 45 min each, while the time interval between two consecutive sessions was 10 min. Two months after the first test, the second test was conducted for both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013061513677N1**
Registration date: **2013-11-22, 1392/09/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-11-22, 1392/09/01

Registrant information

Name

Somayeh Soltani Nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 5500

Email address

s.soltaninejad@iauba.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University Bandar abbas Branch

Expected recruitment start date

2011-10-16, 1390/07/24

Expected recruitment end date

2012-03-14, 1390/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effectiveness of quality of life training on self-efficacy of patients under hemodialysis treatment

Public title

Effect of quality of life training on self-efficacy hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The subjects ought to be older than 18 years; at least 6 months have been passed from their start of dialysis; have a minimum level of literacy (reading and writing); be willing to participate in the investigation; have no history of mental health problems,

suffer from no physical problem other than chronic kidney disease; do not have a history of kidney transplantation; have not participated in other similar studies. Exclusion criteria: Intending to undergo a kidney transplant and emigration during the intervention and implementation of the study plan; suffering from acute physical and psychological problems during the study plan.

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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Taking note of the criteria of the study, 90 subjects were selected and were divided into two groups after casting lots, each consisting of 45 subjects.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Bandar Abbas University of Medical Sciences

Street address
Islamic Azad University Campus, Universities Blvd, Bandar abbas

City
Bandar abbas

Postal code
7915893144

Approval date
2011-10-02, 1390/07/10

Ethics committee reference number
518660/11/15

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
Self-efficacy

Timepoint
Before and 2 months after intervention

Method of measurement
Strategies used by people to promot health questionnaire

Secondary outcomes

1

Description
Quality of Life

Timepoint
Before and 2 months after intervention

Method of measurement
The world health organization quality of life (WHOQOL) - BREF questionnaire

Intervention groups

1

Description
A Pamphlet in (physical, mental, social, and family) dimensions was prepared and was approved by 10 authoritative instructors from various departments of nursing, medicine and the nephrologist. During three 45-minute sessions with an interval of 10 days between any two of them, training was given individually in the form of speech, and questions and answers were given individually, too.

Category
Behavior

2

Description
The control group received no intervention.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Specific Diseases Center
Full name of responsible person
Mrs. Fatemeh Hosseini
Street address
Shahid Rajai St ,Kerman
City
Kerman

2

Recruitment center
Name of recruitment center
Shafa hospital
Full name of responsible person
Mrs. Ashraf Haghdoost
Street address
Shafa Blvd, Kerman
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Islamic Azad University Bandar abbas Branch
Full name of responsible person
Dr. Mohsen Dehghani
Street address
Islamic Azad University Campus, University Blvd, Bandar abbas
City
Bandar abbas
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, Islamic Azad University Bandar abbas Branch
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
Islamic Azad University Bandar abbas Branch
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Person responsible for updating data

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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