

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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

Full name of responsible person

Somayeh Soltani Nejad

Position

MSc in nursing - Faculty member

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

Data Dictionary

empty