

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Study of the effect of educational supportive group therapy on hemodialysis patients' quality of life

Protocol summary

Study aim

Study of the effect of educational supportive group therapy on quality of life among hemodialysis' patients

Design

The present interventional study was a semi-experimental one which was performed on pre-test and post-test in intervention and control groups. The study population was all hemodialysis patients of Shohada Ashayer Hospital (Khoramabad, Iran). 60 patients were selected by convenient method of sampling and divided into two groups of control and intervention based on the weekly days (patients undergoing dialysis on Saturdays, Mondays and Wednesdays in the intervention group and dialysis patients on Sundays, Tuesdays and Thursdays in the control group).

Settings and conduct

The experiment group received eight 50-70 min sessions including two sessions per week. The control group received the normal interventions. The participants were assessed using a demographics form and Kidney Disease Quality of Life Short Form before, immediately after, and one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Have a history of hemodialysis for more than 6 months 2. Have a desire to participate in study 3. Be able to read and write 4. Age 18 to 65 years
Non-entry criteria: 1. History of kidney transplantation 2. History of attending similar classes 3. Existence of physical disabilities such as deafness, blindness

Intervention groups

Group therapy was performed for 8 sessions twice a week. In each session, 15 members of the intervention group participated. The control group received only the usual interventions in the department.

Main outcome variables

Hemodialysis patients' quality of life in intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216041997N1**

Registration date: **2020-05-25, 1399/03/05**

Registration timing: **retrospective**

Last update: **2020-05-25, 1399/03/05**

Update count: **0**

Registration date

2020-05-25, 1399/03/05

Registrant information

Name

Sajad Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3365 2345

Email address

sjdmansouri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title

Study of the effect of educational supportive group therapy on hemodialysis patients' quality of life

2018-05-08, 1397/02/18

Ethics committee reference number
IR.KUMS.REC.1397.043

Public title

The effect of educational supportive group therapy on quality of life

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Have a history of hemodialysis for more than 6 months.
Have a desire to participate in research. Be able to read and write. Age 18 to 65 years.

Exclusion criteria:

History of attending similar classes
History of kidney transplantation
Existence of physical disabilities such as deafness, blindness

Age

From **32 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Beheshti ave. Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

657889909

Approval date

Health conditions studied

1

Description of health condition studied

Quality of Life

ICD-10 code

N18.4

ICD-10 code description

Chronic kidney disease, stage 4 (severe)

Primary outcomes

1

Description

Quality of life

Timepoint

Before; Immediately after ; A month later

Method of measurement

Kidney disease quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: Group therapy with supportive-educative approach was performed in 8 sessions(70-80 min) twice a week for intervention group(15 members groups).The sessions content was based on credible papers and sources on the assessment of quality of life in hemodialysis patients. Cognitive counseling techniques including emotional venting, interpersonal learning, self-awareness, clarification, restatement, reflection, self-awareness, role playing, and rotational and purposeful questions were used.Session 1: pretest, introduction and familiarization, clarifying the objectives of the sessions and the general structure, discussing the expectations, discussing the role of self-care and self-awareness in recovery process, and listening to the participants problems. Session 2: giving lecture and group discussion about chronic renal failure, hemodialysis, life with hemodialysis, giving time to the patients to express their feelings, viewpoints, and concerns, and answering the patients' questions through group discussion. Home assignment: each patient was needed to report their experience with general health problems. Session 3: group discussion about the physical and mental side-effects of dialysis, prevention, and treatment, coping and attenuating the side-effects to preserve one's social role and giving feedback to patients. Home assignment: To record one's concerns and problems about everyday activities and interactions with others. Session 4: Group

discussion about the third session home assignment and emotional and sensory intervention. This session was aimed at educating the participants about relaxation methods along with positive mental image to decrease probable tensions of the day. Sessions 5 and 6: emotional and mental intervention; the main theme was to educate the participants about identifying their emotions and feelings and how to express them. In addition, the participants were encouraged to vent their suppressed emotions and feelings and in return the instructor and group members showed they sympathy and gave feedback. In addition, the importance of being independent, self-care, quality of social interactions, having a positive and good feeling, spiritual beliefs, and the role of pain and agony in life and the constructive effect of spiritual beliefs in alleviation of pains were reminded to the participants. Session 7: Spiritual interventions; the main theme of this session was care from spiritual viewpoint. The role of pain and agony in life and its constructive effect and development and expansion of ethical merits were examined. The relationships of man and nature, man and God, and man and the environment were also discussed. Session 8: Summarizing, concluding, answering the participants' questions, and giving a general review of the previous session. Before concluding the course, the authors showed their gratitude to the participants.

Category

Lifestyle

2**Description**

Control group: The patients of control group received only the usual interventions in the ward and no intervention was made by the researcher.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shohada-ye Ashayer's hospital, Khoramabad

Full name of responsible person

Farah Piriaee

Street address

Enghelab

City

Khoramabad

Province

Lorestan

Postal code

6576543

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+98 66 3323 6402

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Shohadahospital@lums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Amir Jalali

Street address

Dolatabad

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Fac_n.m@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Amirjalali

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data are available in the general form of study results

When the data will become available and for how long

from Jan. 2020

To whom data/document is available

researchers and university centers

Under which criteria data/document could be used

All results are available in the form of a study report a without any conditions

From where data/document is obtainable

Sajad Mansouri Email: sjdmansouri@gmail.com

What processes are involved for a request to access data/document

Request project report via email address

Comments