Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of lifestyle educational interventions on quality of life of patients undergoing hemodialysis

Protocol summary

Study aim
The effect of lifestyle education on the quality of life of dialysis patients
Design
Clinical trial with control group, double-blind, randomized by random number table on 60 patients
Settings and conduct
This study is a double-blind clinical trial that will be performed in the dialysis ward of Hojjat Koohkamari Hospital in Marand. After selecting the individuals according to the entry and exit criteria, random and blind allocation will be done in the intervention and test groups. The study is blind will be completed. Then, the members of the intervention group will receive lifestyle trainings twice a week for 6 sessions of 30 minutes in a face-to-face method with 6 questions. Then, both groups will be followed up for 12 weeks. After 12 weeks, the quality of life questionnaire for dialysis patients will be completed for both groups. It should be noted that the intervention will be performed by the researcher but, the completion of the questionnaires will be done by another person who will be blind to the intervention and control groups
Participants/Inclusion and exclusion criteria
Age 18 to 65 years History of dialysis for more than one year No mental illness Physical-motor disability
Intervention groups
Lifestyle training intervention that will be done in 6 sessions of 30 minutes face to face with questions and answers during dialysis.
Main outcome variables
Change in quality of life score Change in life style score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220504054733N1**
Registration date: **2022-05-09, 1401/02/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-09, 1401/02/19**
Update count: **0**
Registration date
2022-05-09, 1401/02/19

Registrant information
Name
Soraya Soheili
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 41 4225 8854
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-07, 1401/02/17
Expected recruitment end date
2022-06-07, 1401/03/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of lifestyle educational interventions on quality of life of patients undergoing hemodialysis

Public title
The effect of lifestyle education on the quality of life of dialysis patients

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Dialysis history of at least one year
Exclusion criteria:
No mental illness Physical-motor disability Unwillingness
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
First, according to the medical record, from all patients, people who are eligible to enter the study will be selected. Then, according to the phone number listed in the patient's file, they will be contacted gradually to provide them with the necessary explanations about the study plan and confirm the desire of people to participate in the project. Contact people until completion. The number of samples will continue. After completing the number of samples, by simple randomization method by random number table, people will be placed in intervention or control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
After fully explaining the plan, how to do it and its purpose to the participants and obtaining informed consent will be randomly placed in the intervention and control groups. Also, data collection by a trained person who will be blind to the intervention and control groups Was to be accepted.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Islamic Azad University-Tabriz Branch (Research Ethics Committee)
Street address
No 31,narmak 1,kashani Ave
City
Marand
Province
East Azarbaijan
Postal code
5413633536
Approval date
2021-12-07, 1400/09/16
Ethics committee reference number
IR.IAU.TABRIZ.REC.1400.171 شماره طرح در سامانه دانشگاه (کد پژوهشی):1400916

Health conditions studied

1

Description of health condition studied
renal failure, hemodialysis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
سطح کیفیت زندگی بیماران تحت همودیالیز بر اساس پرسشنامه کیفیت زندگی بیماران دیالیزی
Timepoint
Measurement of quality of life before and 12 weeks after the intervention in the intervention and control groups
Method of measurement
Quality of life questionnaire for dialysis patients

Secondary outcomes

1

Description
lifestyle score
Timepoint
Before intervention and 12 weeks after intervention
Method of measurement
Walker Health Promoting Lifestyle Questionnaire

Intervention groups

1

Description
The intervention is in the form of exercises related to a healthy lifestyle for the intervention group, which will be done in 6 sessions of 30 minutes face to face with questions and answers in the patient's bed and during hemodialysis twice a week. The content of the sessions will be on topics such as diet, physical activity, a sense of responsibility for personal health, attention to spiritual growth and self-sufficiency, interpersonal relationships and stress management. The content of the meetings will be as follows. Session 1: Communicating between

people, the importance and necessity of a healthy lifestyle in everyday life Session 2: Lifestyle education and its components, review of factors affecting lifestyle and self-management education Session 3: Training on the effect of nutrition on health with the cooperation of a nutritionist, familiarity with the food pyramid, training on food calories and their impact on health and explaining meals and snacks Session 4: Review and training of exercises that affect health with the cooperation of a physical education expert and explain the importance of exercise in the prevention of various diseases and even in the treatment of some diseases Session 5: Familiarity with the role of sleep and adequate rest in health and the introduction of correct patterns of sleep hygiene, relaxation training, concentration and positive mental imagery to affect the improvement of disease Time management training, stress management Session 6: Summarizing and reviewing the contents. At the end of the sessions, individuals in both groups will be followed for 12 weeks to ensure the application of the training given by the intervention group and no specific changes in the lifestyle of the control group. Follow-up will be done in the form of a phone call.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis ward, Hojjat Koohkamari Marand Hospital

Full name of responsible person

Soraya Soheili

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No31,narmak1,kashani Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Email

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Islamic Azad University, Marand Branch

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Soraya Soheili

Position

member of faculty

Latest degree

Master

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

There is no more information

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable