

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effectiveness of Cognitive Behavior Therapy (CBT) on sleep quality, depression, anxiety and general health in patients with hemodialysis

Protocol summary

Study aim

The effectiveness of Cognitive Behavior Therapy (CBT) on sleep quality, depression, anxiety and general health in patients with hemodialysis and Reducing the problems of these patients, improving their quality of life and increase their satisfaction

Design

Clinical trial with control group; with parallel groups; one-blind blind; sample size is 30 and no randomization

Settings and conduct

This research is done in the dialysis section Vasei Hospital of Sabzevar and one in the blind. Patients will be unaware of the purpose of the research and the difference in work. In order to blindness, the patients of the two groups enter the study on different days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have a history of dialysis lasting at least 6 months; age 20-60; having poor sleep quality based on the response to the PSQI questionnaire. Non-inclusion criteria: having chronic underlying disease; having severe anxiety and depression; having a history of admission to the mental unit.

Intervention groups

In this study, in the intervention group, cognitive-behavioral therapy is administered individually and after each hemodialysis session during the ten sessions, but in the control group, only dialysis care is provided and they receive no intervention and training.

Main outcome variables

Sleep quality, depression, anxiety, general health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171219037967N1**

Registration date: **2019-04-19, 1398/01/30**

Registration timing: **retrospective**

Last update: **2019-04-19, 1398/01/30**

Update count: **0**

Registration date

2019-04-19, 1398/01/30

Registrant information

Name

Mehdi Jamalnik

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4441 5745

Email address

mhd.niki67@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Cognitive Behavior Therapy (CBT) on sleep quality, depression, anxiety and general health in patients with hemodialysis

Public title

The effectiveness of Cognitive Behavior Therapy (CBT) on sleep quality, depression, anxiety and general health

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of diagnosis of chronic renal failure according to expert diagnosis and clinical criteria that lasts at least six months history of hemodialysis for at least six months willingness to participate in the study and signature consent form having at least 20 and maximum 60 years of age Having full vigilance and acceptable listening and speaking ability to answer questions and learn methodological cognitive behavioral learning having poor sleep quality based on responding to the PSQI questionnaire having Minimum level of depression and anxiety and mental health based on response to questionnaire The BDI2, BAI, GHQ28

Exclusion criteria:

Having a history of drug addiction Having a history of admission to mental health Having high levels of depression or anxiety Having a history of chronic cardiovascular disease mental disability having drug addiction admission to psychiatric wards and acute psychiatric disorders

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

In this study, the intervention group received cognitive-behavioral therapy after hemodialysis sessions, but the control group was participated in the recall sessions after hemodialysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Science and Research Branch, Islamic Azad University of Neyshabur

Street address

No 36, Hekmat 2 Alley, Hekmat Ave, Block 6, Sabzevar Town

City

Neyshabur

Province

Razavi Khorasan

Postal code

9617973577

Approval date

2018-12-13, 1397/09/22

Ethics committee reference number

IR.IAU.NEYSHABUR.REC.1397.020

Health conditions studied**1****Description of health condition studied**

Hemodialysis

ICD-10 code

Z49.0

ICD-10 code description

Preparatory care for renal dialysis

Primary outcomes**1****Description**

Sleep quality score in Pittsburgh questionnaire

Timepoint

After each hemodialysis session

Method of measurement

Pittsburgh sleep quality questionnaire

2**Description**

depression score in Beck's questionnaire

Timepoint

After each hemodialysis session

Method of measurement

Beck Depression Inventory

3**Description**

anxiety scores in Beck's questionnaire

Timepoint

After each hemodialysis session

Method of measurement

Beck anxiety Inventory

4**Description**

general health score in the Goldberg questionnaire.

Timepoint

After each hemodialysis session

Method of measurement

Goldberg General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition to routine dialysis care, individual sessions of cognitive-behavioral therapy will be conducted by a respected clinical psychologist in ten sessions of 45 to 60 minutes. Meetings will be held in a separate room that will be provided in coordination with the responsible department.

Category

Rehabilitation

2

Description

Control group: In the control group, patients receiving dialysis routine care only.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational, therapeutic and research center of Sabzevar Vasei Hospital

Full name of responsible person

Mehdi Jamalini

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No 36, Hakmat Ave

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mhd.niki67@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehdi Jamalini

Street address

No 36, Hekmat Ave

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Sabzevar University of Medical Sciences

Full name of responsible person

Mehdi Jamalini

Position

Consultant

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only information from the main research outcome will be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results.

To whom data/document is available

academic institutions

Under which criteria data/document could be used

For information on research results

From where data/document is obtainable

Via email

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

About a month.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

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