Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Jamalinik

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 Jamalinik
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No 36, Hakmat Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mehdi Jamalinik
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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 Jamalinik
Position
Consultant
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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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