Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Cognitive_Behavioral intervention on Sleep quality in hemodialysis patients

Protocol summary

Study aim
Determining the effect of cognitive-behavioral intervention on the quality of sleep in hemodialysis patients

Design
Participants were randomly selected from among the hemodialysis patients in the dialysis unit and randomly assinged in to the internention and control groups.

Settings and conduct
This randomized controlled trial was conducted on patients undergoing maintenance hemodialysis in hemodialysis centers of UrmiaThalegani Hospital. Eighty patients with sleep problem were randomly selected..

Participants/Inclusion and exclusion criteria
Having undergone hemodialysis for at least 6 months،Who can read and write Persian،willing to participate

Intervention groups
Participants were randomly selected from among the hemodialysis patients in the dialysis unit and randomly assinged in to the internention and control groups. patients in the intervention group participated in 6 weekly sessions of half _ hour sleep hygiene training program. The content of training sessions was developed according to standard scientific methods.Direct teaching methods a combination of face_ to_face methods/lectures/ and group discussion were used. Training in each session was as follows:session1:Introduction/statement of research gools and explaining sleep physiology Session2: Explaining effective factors on sleep and types of sleep disorders Session3: overview of the sleep hygine education instructions Session 4 and 5: Training behavioral intervention such as relaxtion and imagery practice Session6: Review sessions/getting feed back from the sample/ and providing an educational pamphlet The intervention group received cognitive behavioral therapy whereas the subjects in the control group received non-directive counseling while both the groups were receiving routine care.

Main outcome variables
Sleep quality؛Hemodialysis patients؛ Cognitive Behavioral intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180224038848N1**
Registration date: **2018-09-01, 1397/06/10**
Registration timing: **retrospective**

Last update: **2018-09-01, 1397/06/10**
Update count: **0**

Registration date
2018-09-01, 1397/06/10

Registrant information

Name
Hajar Razavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 44 3367 0503

Email address
razavi.ha@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-22, 1396/05/31

Expected recruitment end date
2017-12-20, 1396/09/29

Actual recruitment start date
2017-08-22, 1396/05/31

Actual recruitment end date
2018-01-09, 1396/10/19
Trial completion date
empty

Scientific title
The effect of Cognitive_Behavioral intervention on Sleep quality in hemodialysis patients

Public title
The effect ofCognitive_Behavioral intervention on Sleep quality inHemodialisis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having undergone hemodialysis for at least 6months Scores above 5 in Pittsburgh sleep quality index willing to participate Who can read and write Persian
Exclusion criteria:
Suffering from known mental diseases including deep anxiety and depression(according to patient answer and his/her medical history) Unwilling to participate Waiting for transplant Received any form of psychohterapy
Age
From **25 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Further the entire samples were randomly allocated into experimental and control groups by using computer generated random order
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia university of Medical sciences
Street address
headquarters of the university of medical science, Jahad ave, Resalat blvd.
City
Urmia
Province
West Azarbaijan
Postal code
57147-83734
Approval date
2017-06-06, 1396/03/16
Ethics committee reference number
Ir.umsu.rec.1396-100

Health conditions studied

1

Description of health condition studied
sleep disorders
ICD-10 code
F51
ICD-10 code description
Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description
The percentage of people whose quality Score in the sleep quality questionnaire above 5
Timepoint
measure of quality of sleep quality in starting of study and after 70 days cognitive behavioral intervention
Method of measurement
Data were collected by petersburg sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In this study, 6 sessions of cognitive-behavioral intervention were performed. Interaction was done by agreement of patients, morning shift patients after hemodialysis and patients in the evening shift before hemodialysis sessions. At the beginning of each session, muscle relaxation and breathing exercises were performed for patients. The description of the intervention was based on scientific standards
Category
Behavior

2

Description
Control group: In this study, there was no intervention other than hemodialysis routine for the control group. After the end of the intervention, a manual of sleep hygiene education and pamphlet, a muscle relaxation technique was given to patients in the control group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Talegani hospital

Full name of responsible person
Rahim Bagaie

Street address
Kashani Ave,Talegani hospital

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3344 4591

Email
hajar65.razavi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Iraj mohebbi

Street address
Headquarters of the univercity of medical science, Jahad ave, Resalat blvd

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Phone
+98 44 3193 7224

Fax
+98 44 3224 0642

Email
mohebbi_iraj@yahoo.co.uk

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Rahim Bagai

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Nursing and midwifery faculty,Nazloo road,Urmia Town

City
Urmia

Province
West Azarbaijan

Postal code
57147-83734

Phone
+98 44 3275 4918

Email
rbagaie@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Hajar Razavi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Kashani Ave, Motahhari hospital

City
Urmia

Province
West Azarbaijan

Postal code

5714783734

Phone

+98 44 3367 0503

Email

hajar65.razavi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

HajarRazavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Kashani Ave, Motahhari hospital, Urmia Town

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Phone

+98 44 3367 0503

Email

hajar65.razavi@gmail.com

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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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