

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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 assigned in to the intervention 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 assigned in to the intervention 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 goals and explaining sleep physiology Session2: Explaining effective factors on sleep and types of sleep disorders Session3: overview of the sleep hygiene education instructions Session 4 and 5: Training behavioral intervention such as relaxation 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)

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+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 of Cognitive_Behavioral intervention on Sleep quality in Hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having undergone hemodialysis for at least 6 months
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 psychotherapy

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

lr.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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj mohebbi

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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

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 Bagaie

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Phone

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