

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of sleep hygiene teaching program on sleep quality of hemodialysis patients

Protocol summary

Summary

Introduction: Sleep disorders are common in hemodialysis patients. High prevalence of sleep disorders should be addressed. Present study has conducted to determine the effect of sleep hygiene training program on sleep quality of hemodialysis patients. Methods: This study is a clinical trial study. 82 hemodialysis patients of Arak Valiasr hospital are randomly selected and randomly allocated in intervention(n=41) and control(n=41) groups. Sleep quality is assessed by Pittsburgh Sleep Quality Index. Sleep hygiene program is trained to Intervention group and after a month sleep quality will be assessed in two groups again and are compared with before.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062010076N1**

Registration date: **2012-08-09, 1391/05/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

Maryam Saeedi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

m.saeedi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2011-09-21, 1390/06/30

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sleep hygiene teaching program on sleep quality of hemodialysis patients

Public title

Effect of sleep hygiene on sleep quality

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: intent for participating in the study, having 18 years old to 65; experience of at least 6 months of hemodialysis; Having full consciousness, acceptable ability to learn sleep hygiene programme; No history of mental disabilities such as severe depression and anxiety; literacy as ability to read and write. Exclusion criteria: If the patients didn't want to continue participating in the study; If occur a crisis or an unforeseen event for patients during the intervention period; If the patient didn't complete two weeks sleep diary;

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 82

Randomization (investigator's opinion)

Randomized

Randomization description

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

arak medical sciences university

Street address

arak, sardasht, basij square

City

arak

Postal code

Approval date

2011-09-05, 1390/06/14

Ethics committee reference number

90-112-7

Health conditions studied

1

Description of health condition studied

Chronic renal disease

ICD-10 code

N18.9

ICD-10 code description

Chronic renal disease, unspecified

Primary outcomes

1

Description

sleep quality

Timepoint

before intervention and one month after intervention

Method of measurement

Pittsburg sleep quality index

Secondary outcomes

empty

Intervention groups

1

Description

The intervention is sleep hygiene teaching programme that only were taught to intervention group during 5 session and includes introduction of study, sleep physiology and effective factors on sleep and also the instructions such as avoid disturbance agents of Sleep, appropriate sleep environment and teaching behavioral intervention such as relaxation and imagery guiding to promote sleep quality of patients.

Category

Behavior

2

Description

in control group, no intervention is done and control group receive routine care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis center of vali-asr arak hospital

Full name of responsible person

Maryam Saeedi

Street address

Hemodialysis center, Vali-asr hospital, Vali-asr square, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy, arak university of medical sciences

Full name of responsible person

Maryam Saeedi

Street address

Research deputy, arak medical sciences university, basij square, sardasht, Arak

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source
Research deputy, arak university of medical sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin
empty

Type of organization providing the funding
empty

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Lecturer, Faculty member

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty