

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of adaptive sustainability care model on sleep quality in hemodialysis patients

Protocol summary

Study aim

Determining the Impact of Compliance Sustainability Care Model on Sleep Quality in Hemodialysis Patients

Design

The present study is a controlled clinical trial with 40 patients undergoing hemodialysis. After sampling in the available method, they are divided into two groups of intervention and control by random allocation method.

Settings and conduct

Participants in two groups of 20 people in each group will receive counseling and training based on a sustainability model during their 8 45-minute sessions. The training environment is located at the Imam Khomeini Hospital in Sonqor. The sessions are organized on a regular basis twice a week, with prior notice to the patients.

Participants/Inclusion and exclusion criteria

Participants include the family of hemodialysis patients. Inclusion criteria for this study: 1- Willingness to cooperate. 2- A history of 6 months of renal disease. Exclusion criteria: 1- Mental illness 2- Drug Addiction

Intervention groups

The type of intervention is in fact counseling and education. In the intervention group, the adaptive sustainability model helps helping the family of hemodialysis patients to cope with their patient's problem and their attitude towards the rationalization of the disease and vaginal pain is somewhat different. It is subsequently assumed that this adaptation leads to an increase in the quality of sleep in hemodialysis patients. In the control group, only routine training is given

Main outcome variables

Sleep quality of hemodialysis patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170606034353N2**

Registration date: **2019-05-19, 1398/02/29**

Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**

Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Soroush Maazinezhad

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 4612 6767

Email address

soroush.maazi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-10, 1397/10/20

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adaptive sustainability care model on sleep quality in hemodialysis patients

Public title

The effect of adaptive sustainability care model on sleep

quality

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate in the study No drug addiction and psychotropic substance History of at least 6 months of kidney disease
Exclusion criteria:
Having mental illness Drug addiction

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
After completion of the sampling, 40 sealed envelopes containing the codes 1 (intervention group) and 2 (Control group) control is available to all patients and each person is placed in the selected group according to the selected code.

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 Kermanshah University of Medical Sciences

Street address

Building No. 1, Kermanshah University of Medical Sciences(KUMS), Shahid Beheshti Boulevard, Kermanshah,Iran

City

Kermanshah

Province

Kermanshah

Postal code

6714415153

Approval date

2018-12-05, 1397/09/14

Ethics committee reference number

ir.kums.rec.1397.665

Health conditions studied

1

Description of health condition studied

sleep quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality of hemodialysis patient

Timepoint

1 - Before the intervention 2 - Immediately after the end of the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Implementation of Compliance Model Before the intervention, the quality of sleep in hemodialysis diaphragm is recorded with Pittsburgh sleep quality questionnaire. After completing the intervention, patients' sleep quality is recorded again. Intervention in dialysis treatment center classes is held. The purpose of this intervention is to change the attitude of patients towards the concept of renal disease, hemodialysis, pain and sleep hygiene.

Category

Lifestyle

2

Description

Control group: simple and routine training is done in the field of hygiene

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Kermanshah

Full name of responsible person

Hiva Mohammadi

Street address

Building No.Imam Reza Hospital , Parastar Boulevard,
Kermanshah,Iran

City

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Email

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Latest degree

Master

Other areas of specialty/work

Nursery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Soroush Maazinezhad

Position

Academic Staff

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Soroush Maazinezhad

Position

Academic Staff

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Academic Staff

Latest degree

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available