

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Study the effectiveness and ineffectiveness of progressive muscle relaxation techniques on sleep quality and sleepiness of hemodialysis patients

#### Protocol summary

##### Summary

The presents study aims to investigate the effects of progressive muscle relaxation techniques on sleep quality and sleepiness of hemodialysis patients. It is a clinical study and is not blinded. 74 hemodialysis patients in Imam Reza hospital were selected randomly and divided to control and experiment groups. To assess sleep quality and pattern, PSQI questionnaire was delivered to both groups. Then, the experiment group was asked to do relaxation practices twice a day for 6 weeks at home based on a schedule. One try must be accomplished before night sleep. Finally, patients who followed over %70 of their schedule went under final investigation and the rest were omitted from the study. There was no special treatment passed to control group. After 6 weeks, PSQI questionnaire was offered to the patients in both groups to study their total quality of sleeping, delayed sleep, practical sleep duration, enough sleep, sleeping disorders, taking sleeping pills and daily dysfunction. Inclusion: being hemodialysis for at least two months; willingness to participate in the study; patients in experiment group included patients at evening and night shifts; patients in control group were the morning shift. Exclusion: being younger than 15

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015052114333N33**

Registration date: **2015-06-11, 1394/03/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-06-11, 1394/03/21

#### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

kermanshah University of Medical Sciences

#### Expected recruitment start date

2015-05-15, 1394/02/25

#### Expected recruitment end date

2015-07-06, 1394/04/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Study the effectiveness and ineffectiveness of progressive muscle relaxation techniques on sleep quality and sleepiness of hemodialysis patients

#### Public title

Effectiveness of progressive muscle relaxation techniques on sleep quality and sleepiness of hemodialysis patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion: being hemodialysis for at least two months; willingness to participate in the study; patients in experiment group included patients at evening and night shifts; patients in control group were the morning shift.  
Exclusion: being younger than 15

**Age**

From **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **74**

**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**

Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Postal code****Approval date**

2015-04-28, 1394/02/08

**Ethics committee reference number**

kums.rec.1394.6

**Health conditions studied****1****Description of health condition studied**

Hemodialysis

**ICD-10 code**

N18

**ICD-10 code description**

Chronic renal failure

**Primary outcomes****1****Description**

Delay sleep

**Timepoint**

At the beginning of the study and 6 weeks later

**Method of measurement**

PSQI questionnaire

**2****Description**

Practical sleep duration

**Timepoint**

At the beginning of the study and 6 weeks later

**Method of measurement**

PSQI questionnaire

**3****Description**

Enough sleeping

**Timepoint**

At the beginning of the study and 6 weeks later

**Method of measurement**

PSQI questionnaire

**4****Description**

Sleeping disorders

**Timepoint**

At the beginning of the study and 6 weeks later

**Method of measurement**

PSQI questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

To assess sleep quality and pattern in experiment group, PSQI questionnaire was delivered to them. They were asked to do relaxation practices twice a day for 6 weeks at home based on a schedule. One try must be accomplished before their night sleep. Finally, patients who followed over %70 of their schedule went under final investigation and the rest were omitted from the study. After 6 weeks, PSQI questionnaire was offered to the patients in experiment group to study their total quality of sleeping, delayed sleep, practical sleep duration, enough sleep, sleeping disorders, taking sleeping pills and daily dysfunction.

**Category**

Behavior

**2**

**Description**

There was no special treatment delivered to control group

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam reza Hospital

**Full name of responsible person**

Fatemeh Hadadian

**Street address**

Emamreza hospital, Parastar boulevard

**City**

Kermanshah

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Koroush Hamzehee

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**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**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Fereshteh Jalalvandi

**Position**

Msc. of Surgical Internal Nursing

**Other areas of specialty/work**

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**Postal code**

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**Web page address**

**Person responsible for updating data**

**Contact**

**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*