Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigation of effectiveness of progressive muscle relaxation technique on fatigue in hemodialysis patients

Protocol summary

Summary

This study will be done with aim to investigation of effectiveness and non-effectiveness of progressive muscle relaxation technique on fatigue in hemodialysis patients. The study population will be included all patients undergoing hemodialysis referring to Imam Reza Hospital of Kermanshah city. The number of 60 eligible patients will selected and randomly will assigned to two experimental and control groups. Beginning of the study, BFI fatigue checklist will be provided for both groups. Then a relaxation CD derived from Relax in depth book that is written by Bahadurani and Poornaseh, will be put to the experimental group. Each relaxation step lasts about 15 minutes. Relaxation technique is taught to the patient during two consecutive sessions and the patients will be asked to do relaxation exercises at home according to the set out schedule, 2 times a day for 30 days; That means a time of relaxation be before the main bedtime. No special intervention will be done in the control group and routine process will be carried out. At the end of the study BFI fatigue checklist will be provided for both groups and both groups are compared. Inclusion criteria: Hemodialysis for at least 6 months; Age above 15 years; Having full consciousness. Exclusion criteria: Failure to do trained relaxation program schedule.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092514333N59**
Registration date: **2016-10-31, 1395/08/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-10-31, 1395/08/10

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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-11-05, 1395/08/15

Expected recruitment end date

2017-05-05, 1396/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of effectiveness of progressive muscle relaxation technique on fatigue in hemodialysis patients

Public title

Effect of progressive muscle relaxation technique on fatigue in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hemodialysis for at least 6 months; Age above 15 years; Having full consciousness; Listening and speaking ability for learning relaxation technique; no

known mental illness. Exclusion criteria: Failure to do trained relaxation program schedule; Hospitalization from any cause during the study

Age
From **15 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of 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
2016-04-27, 1395/02/08

Ethics committee reference number
kums.rec.1395.53

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
Fatigue

Timepoint
Baseline, the end of the study (a month later)

Method of measurement
BFI fatigue checklist

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will do the relaxation exercises at home according to the set out schedule, 2 times a day for 30 days

Category
Behavior

2

Description
No special intervention will be done in the control group and routine process will be carried out

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza Hospital

Full name of responsible person
Fereshteh Jalalvandi

Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, 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
Vice chancellor for research, 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
Fatemeh Hadaddin
Position
Master of Nursing, Internal Surgical trends
Other areas of specialty/work
Street address
School of Paramedical Sciences, Dolatabad Boulvard, Eisar Square
City
Kermanshah
Postal code
Phone
+98 83 3828 0642
Fax
Email
F.Hadadian@kums.ac.ir
Web page address

Person responsible for updating data

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
Street address
School of Paramedical Sciences, Dolatabad Boulvard, Eisar Square
City
Kermanshah
Postal code
Phone
+98 83 3828 0642
Fax
Email
fjalalvandi@kums.ac.ir
Web page address

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