

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 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)

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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
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Person responsible for updating data

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Msc. of Surgical Internal Nursing

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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