

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effect of progressive muscle relaxation and physical exercises on subjective well-being and Fatigue of patients undergoing hemodialysis

Protocol summary

Study aim

Comparison of the effect of progressive muscle relaxation and physical exercises on subjective well-being and Fatigue of patients undergoing hemodialysis

Design

This study will be a two-group randomized clinical trial with a pre-test and post-test design. Using SPSS software, the sequence of allocations will be determined and will be randomly assigned to two intervention groups by even and odd time blocking

Settings and conduct

Performing progressive muscle relaxation and physical exercises in hemodialysis centers of Montaserieh and Shahrivar hospitals in Mashhad In both groups, the intervention will be performed for 4 weeks and then the post-test with the same pre-test tools will be taken one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 6 months history of hemodialysis • Age 18- 65 years • Literacy for reading and writing • Willingness to participate in the study No visual, auditory or speech impairments • No mental illness • Do not have a physical disability or neuromuscular diseases or debilitating and chronic diseases • Serious accident or bad experience in the last 6 months • Ability to use the training file • Not participating in a regular exercise program in the last 6 months Do not take antidepressants and sedatives Exclusion criteria: • Lack of cooperation in the study • Do not do more than 2 sessions a week • Death of a patient or travel • Change the dialysis center • Kidney transplantation or the use of peritoneal dialysis

Intervention groups

First group: the Jacopsen progressive muscle relaxation technique will be taught individually in 2 face-to-face sessions for 50 to 60 minutes. Second group: Stretching and balance exercises will be taught to the patient in one

session. Then, patients will do 4 times a week (at home) using video training for 1 month

Main outcome variables

Subjective well-being - fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201227049856N1**

Registration date: **2021-02-15, 1399/11/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-15, 1399/11/27**

Update count: **0**

Registration date

2021-02-15, 1399/11/27

Registrant information

Name

Mohammadreza Hasanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3282 9783

Email address

hasanzadehmr981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-07-21, 1400/04/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of progressive muscle relaxation and physical exercises on subjective well-being and Fatigue of patients undergoing hemodialysis

Public title
Comparison of the effect of progressive muscle relaxation and physical exercises on subjective well-being and Fatigue

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
6 months history of hemodialysis Age 18 to 65 years
Literacy for reading and writing Willingness to participate in the study No vision, hearing or speech impairments
Ability to participate in interventions Lack of mental illness Lack of physical disability or neuromuscular diseases or debilitating and chronic diseases No serious accidents or bad experiences in the last 6 months Ability to use the training file Not participating in a regular exercise program in the last 6 months Do not take antidepressants and sedatives
Exclusion criteria:
Lack of cooperation in the study Do not do more than 2 sessions a week Death of a patient or travel Change the dialysis center Kidney transplantation or the use of peritoneal dialysis

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

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized clinical trial of time-pair and single-group block with pre- and post-test design Randomization unit: individually Randomization tool: Sealed Envelopes
Random sequence construction: SPSS software After random allocation, the allocations will be placed in sealed envelopes in order, and after selecting the research sample, it will come out of the sealed envelope and the person will be included in the intervention group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The statistical analyst will not be aware of the presence of patients in the intervention groups

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad School of Nursing and Midwifery, Doctoral Crossroads, University Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199

Approval date
2021-01-12, 1399/10/23

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.078

Health conditions studied

1

Description of health condition studied
Chronic kidney disease, stage 5(End stage kidney disease)

ICD-10 code
N18.5

ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
subjective well-being of patients undergoing hemodialysis

Timepoint
Before and one month after the intervention

Method of measurement
Keyes and Magyar-moe subjective well-being questionnaire

2

Description
Fatigue

Timepoint
Before and one month after the intervention

Method of measurement

Multidimensional fatigue inventory questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group, Jacobsen's progressive muscle relaxation technique will be taught individually for 2 to 50 minutes in 2 face-to-face sessions, and a video file of relaxation movements will be provided to patients with the approval of the relevant respected consultant. People in this group will be asked to do relaxation exercises twice a day for 4 weeks, according to a set schedule during hemodialysis and at home. The researcher will examine patients each week by making a phone call or attending hemodialysis sessions.

Category

Lifestyle

2

Description

Intervention group: In the physical exercises group, first suitable stretching and balance exercises are designed under the supervision of a specialized consultant, then these exercises will be taught to the patient in one session for 50 to 60 minutes, and the video file of how to perform the exercises will be provided to patients with the approval of the relevant consultant. Will be placed. 4 sessions of 45 minutes each week (on non-hemodialysis days and on Fridays) and for 4 weeks these exercises will be performed by patients and at home. The researcher will then examine the patients each week by making a phone call or attending hemodialysis sessions.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Montaserieh Hospital

Full name of responsible person

Dr. Mahin Ghorban Sabbagh

Street address

in front of the Radio and Television Conference Hall, Golestan St. , Imam Khomeini 25, Imam Khomeini St.

City

Mashhad

Province

Razavi Khorasan

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2

Recruitment center

Name of recruitment center

17 Shahrivar Hospital

Full name of responsible person

Dr. Hossein Hosseinpour

Street address

Koohsangi 14, Koohsangi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Khalil Abnos

Street address

Deputy of Research and Technology, Gharashi Building, next to Hoveyze Cinema, University Street, Mashhad

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadreza Hasanzadeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Ibn Sina St., Ph.D.
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Email

HasanzadehMR981@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tayebe PourGhaznein

Position

Assistant Professor, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadreza Hasanzadeh

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

After printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Permission from the person in charge

From where data/document is obtainable

To Mr. Mohammad Reza Hassanzadeh
HasanzadehMR981@mums.ac.ir

What processes are involved for a request to access data/document

By requesting the email of the person in charge

Comments