

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 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, Jacopsen'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

##### Postal code

91778-99191

#### Phone

+98 51 3229 1963

#### Fax

+98 51 3229 1960

#### Email

mh.manager@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

17 Shahrivar Hospital

##### Full name of responsible person

Dr. Hossein Hosseinpour

##### Street address

Koohsangi 14, Koohsangi Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9175973884

##### Phone

+98 51 3840 3015

##### Email

1\shahrivar\_razavi.hos@tamin.ir

## 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 Hoveyzeh Cinema, University Street, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Fax

+98 51 3843 0249

##### Email

vcresraech@mums.ac.ir

#### 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.  
Intersection, University St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

051 38591511-3

**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

**Street address**

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

PourghazneinT@mums.ac.ir

**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**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

051 38591511-3

**Email**

HasanzadehMR981@mums.ac.ir

**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