

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### The Effect of Rehabilitation Program on Fatigue and Quality of Sleep in hemodialysis Patients

#### Protocol summary

##### Study aim

The purpose of this study was to determine the effect of Rehabilitation program on fatigue and quality of sleep in Hemodialysis patients

##### Design

In this research, 50 eligible patients referring to Imam sajjad Hospital were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups

##### Settings and conduct

Due to easy access to samples, this study will be carried out at Imam Sajjad hospital of shahriar. Samples were selected by available method and randomly divided into two groups of intervention and control. Before and one month after the intervention, the multidimensional fatigue questionnaire MF1-20 and Pittsburgh quality of sleep will be completed in both groups. Data collected by SPSS software and statistical tests will be analyzed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Consent to participate in research and having cooperation; not participated in previous rehabilitation program in Last three months; Ability to communicate effectively with researcher; ability to handle meetings and prepared to respond to questions physically and mentally; Minimum 18 and maximum 80 years old; having the ability to read and write; Have a history of hemodialysis for at least 6 months. Exclusion criteria: withdrawal to continue cooperation; being in the recurrence of the disease and inability to attend in the meetings; Patient death.

##### Intervention groups

Control group: : The control group receive routine care. For the intervention group, Rehabilitation program is implement including: 1. Daily Activity Training 2. Walk 3. Perform foot massage during hemodialysis. In intervention group, Rehabilitation sessions will be performed in 12 sessions of 10 Minutes, two session a week.

#### Main outcome variables

fatigue

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171213037863N1**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **retrospective**

Last update: **2017-12-29, 1396/10/08**

Update count: **0**

##### Registration date

2017-12-29, 1396/10/08

##### Registrant information

##### Name

marzieh shayani momtaz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2218 0036

##### Email address

ma.shayani@uswr.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-08-01, 1396/05/10

##### Expected recruitment end date

2017-12-06, 1396/09/15

##### Actual recruitment start date

2017-08-01, 1396/05/10

##### Actual recruitment end date

2017-12-06, 1396/09/15

**Trial completion date**

empty

**Scientific title**

The Effect of Rehabilitation Program on Fatigue and Quality of Sleep in hemodialysis Patients

**Public title**

The Effect of Rehabilitation Program on Fatigue and Quality of Sleep

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Consent to participate in research and having cooperation not participated in previous rehabilitation program in Last three months Ability to communicate effectively with researcher; ability to handle meetings and prepared to respond to questions physically and mentally Minimum 18 and maximum 80 years old having the ability to read and write Have a history of hemodialysis for at least 6 months

**Exclusion criteria:**

withdrawal to continue cooperation being in the recurrence of the disease and inability to attend in the meetings Patient death

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

Actual sample size reached: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Table of random numbers was used For randomization

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Table of random numbers will be used For randomization

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of University of Social welfare and

Rehabilitation Sciences

**Street address**

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Approval date**

2017-10-18, 1396/07/26

**Ethics committee reference number**

IR.USWR.REC.1396.173

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

Patients who are treated with hemodialysis

**ICD-10 code**

Renal Fail

**ICD-10 code description**

N18.5

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

Fatigue

**Timepoint**

Before and one month after the intervention

**Method of measurement**

multidimensional fatigue inventory

**2****Description**

quality of Sleep

**Timepoint**

Before and one month after the intervention

**Method of measurement**

Pittsburgh Sleep Quality Questionnaire

**Secondary outcomes**

empty

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

Intervention group: For the intervention group, Rehabilitation program is implement including: 1. Daily Activity Training 2. Walk 3. Perform foot massage during hemodialysis. In intervention group, Rehabilitation sessions will be performed in 12 sessions of 10 Minutes, two session a week. Control group: : The control group receive routine care.

**Category**

Rehabilitation

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Imam Sajjad Hospital

**Full name of responsible person**

Marzieh Shayani Momtaz

**Street address**

Tehran Province, Shahriar, Nabovvat Alley, Vali-e Asr St

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۹۸۵۷۱۳۸۳۴

**Phone**

+98 21 6522 6041

**Email**

ma.shayani@uswr.ac.ir

**Web page address**

http://hospes.iums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Dr. Hamidreza Khankeh

**Street address**

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 2218 0036

**Email**

ma.shayani@uswr.ac.ir

**Web page address**

http://www.uswr.ac.ir/

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Marzieh Shayani Momtaz

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

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Tehran

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1985713834

**Phone**

+98 21 2218 0036

**Email**

ma.shayani@uswr.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Dr. narges Arsalani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Koodakyar Avenue, Daneshjoo Blvd, Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985713834

**Phone**

+98 21 2218 0036

**Email**

nargesarsalani@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Marzieh Shayani momtaz

**Position**

Nurse

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available