

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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City

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Province

Tehran

Postal code

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

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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