

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Otago Exercise on Sleep Quality, Fatigue and dialysis adequacy in Hemodialysis Patients

Protocol summary

Study aim

Determining the effect of Otago home exercise on sleep quality score, fatigue and dialysis adequacy of hemodialysis clients in selected AJA hospitals in Tehran

Design

A control trial with a control group used the variable block method in two groups for randomization.

Settings and conduct

The required number of patients will be included in the study according to the inclusion criteria. Then exercise is taught to patients and companions. Before the intervention and after 8 weeks of Otago home exercise by patients, Pittsburgh Sleep Quality Questionnaire and fatigue measurement are completed. Dialysis adequacy is also calculated.

Participants/Inclusion and exclusion criteria

*Inclusion criteria: Age over 18 years and under 75 years
At least 6 months of hemodialysis treatment
Do dialysis twice or more a week
Absence of acute infection

*Exclusion criteria: Identification of any of the problems and diseases mentioned in the inclusion criteria during the study
Reluctance to continue cooperation
Failure to perform the desired exercise program for three sessions

Intervention groups

In the intervention group, first the Otago home exercise movements will be taught face to face by the researcher once or twice to the patient and his companion in the hemodialysis ward to ensure complete learning. The film, the Otago Sports Training Booklet, and the researcher's mobile number will then be provided to clients for possible questions. The clients of the intervention group and their companions will be explained that this exercise should be performed by the clients undergoing hemodialysis according to the schedule, including 8 weeks and three sessions per week and one hour each day on non-hemodialysis days under the supervision of a family member.

Main outcome variables

Sleep Quality; Fatigue; Adequacy of Hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210911052440N1**

Registration date: **2022-02-25, 1400/12/06**

Registration timing: **retrospective**

Last update: **2022-02-25, 1400/12/06**

Update count: **0**

Registration date

2022-02-25, 1400/12/06

Registrant information

Name

Hamid Beig Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7750 0404

Email address

hamid.f4b@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-04, 1400/08/13

Expected recruitment end date

2022-01-03, 1400/10/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Otago Exercise on Sleep Quality, Fatigue and dialysis adequacy in Hemodialysis Patients

Public title

Effect of Otago Exercise in Sleep Quality, Fatigue and dialysis adequacy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years and under 75 years At least 6 months of hemodialysis treatment Do dialysis twice or more a week Absence of acute infection Lack of musculoskeletal disorders such as multiple sclerosis, heart failure and severe respiratory Absence of chronic inflammatory disease of unknown origin Ability to perform sports movements based on the patient's own statements Do not take sleeping pills, sedatives

Exclusion criteria:

Identification of any of the problems and diseases mentioned in the inclusion criteria during the study Reluctance to continue cooperation Failure to perform the desired exercise program for three sessions

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients based on inclusion criteria in the random allocation method using variable block method (if A: intervention group, B: control group, there will be six different modes for 4 blocks: 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB (blocks that can be written on paper and removed from the bag) will be distributed in two groups. In this way, after explaining the method and objectives of the study to patients and, if necessary, their families and obtaining their informed consent, they are randomly assigned to two groups of intervention and control. Thus, the first patient will be in the intervention group and the second patient in the control group and will be observed in the same way until the last patient.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Army University of Medical Sciences

Street address

Tehran-West Fatemi St.-End of Etemadzadeh St.

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-06-26, 1400/04/05

Ethics committee reference number

97001793

Health conditions studied

1

Description of health condition studied

Adequacy of dialysis

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Sleep quality of dialysis patients

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Fatigue of dialysis patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Adequacy of dialysis

Timepoint

Measurement of dialysis adequacy at the beginning of the study (before the intervention) and 8 weeks after the start

Method of measurement

According to the patient's tests and the use of two formulas Kt / V and URR

2

Description

Sleep quality of dialysis patients

Timepoint

Measurement of sleep quality at the beginning of the study (before the intervention) and 8 weeks after the start

Method of measurement

Pittsburgh Sleep Quality Inventory (PSQI)

3

Description

Fatigue of dialysis patients

Timepoint

Measurement of fatigue at the beginning of the study (before the intervention) and 8 weeks after the start

Method of measurement

Multidimensional Fatigue Questionnaire MFI-20

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, first home exercise movements Otago will be taught face-to-face once or twice by the researcher to the patient and his / her companion in the hemodialysis ward to ensure complete learning (performing flawless exercise in front of the researcher). The film, the Otago Sports Training Booklet, and the researcher's mobile number will then be provided to clients for possible questions. The clients of the intervention group and their companions will be explained that this exercise should be performed by the clients undergoing hemodialysis according to the schedule, including 8 weeks and three sessions per week and one hour each day on non-hemodialysis days under the supervision of a family member. In addition, the researcher will follow the exercise through face-to-face, mobile phone, SMS and cyberspace.

Category

Rehabilitation

2

Description

Control group: The control group does not receive any intervention. Only at the beginning and end of the research, they are asked about demographic information and questionnaire questions. At the end of the intervention, the questionnaires in both groups will be completed and analyzed again. In addition, after the intervention, educational booklets and videos will be provided to the clients of the control group.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Nahaja Hospital

Full name of responsible person

Hamid Beig Mohammadi

Street address

Basij Highway. Hijrat Street

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 3995 5555

Email

hamid.f4b@gmail.com

2

Recruitment center

Name of recruitment center

Khanevade Hospital

Full name of responsible person

Hamid Beig Mohammadi

Street address

Dr. Shariati St.

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 7750 7512

Email

hamid.f4b@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

mojtaba yusefi zoshk

Street address

Tehran-West Fatemi St.-End of Etemadzadeh St.

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

hamid.f4b@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Hamid Beig Mohammadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Tehran. West Fatemi Street. End of Etemadzadeh Street.

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8802 8350

Email

hamid.f4b@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Affat Afaqi

Position

teacher

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Tehran. West Fatemi Street. End of Etemadzadeh

Street

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8820 8350

Email

afaghi8181@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Hamid Beig Mohammadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

West Fatemi Street - the end of Etemadzadeh Street

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8820 8350

Email

hamid.f4b@gmail.com

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