Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
mojtaba yusefi zoshk
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Tehran-West Fatemi St.-End of Etemadzadeh St.
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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
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
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Person responsible for updating data

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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