Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of stretching exercises and Tai Chi exercise on fatigue in hemodialysis patiens

Protocol summary

Study aim
The aim of this study was to compare the effect of stretching exercises and Tai Chi exercise on fatigue of hemodialysis patients.

Design
Clinical trial with control group, randomized, three groups, double blind, single center.

Settings and conduct
This study is a clinical trial with three groups that will be performed in Hami Dialysis Center in Arak city and on hemodialysis patients. Samples are randomly assigned to three groups and then the intervention begins. At the beginning of the study, the fatigue questionnaire was completed by samples of three groups and then the study begins. The questionnaire will be completed again 6 weeks later. Clinical care giver and data analyzer will not know how to assign of samples to groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Verbal communication skills, The desire to participate in the study, At least 3 months of dialysis history, 18 to 65 years old, Exclusion criteria: Hearing and vision problems

Intervention groups
First intervention group: The first intervention group will perform stretching exercise after the training by the researcher for 6 weeks and 18 sessions (40-60 minutes). Second intervention group: The second intervention group will also perform the Ti-Chi exercise after training by a researcher and physiotherapist for 6 weeks and 18 sessions (40 to 60 minutes). Control group: During this period, no intervention will perform for control group samples.

Main outcome variables
Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161223031522N10**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **retrospective**

Last update: **2019-04-06, 1398/01/17**
Update count: **0**

Registration date
2019-04-06, 1398/01/17

Registrant information

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Vahid Naseri Salahshour
Name of organization / entity
Arak University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-14, 1397/07/22

Expected recruitment end date
2019-02-10, 1397/11/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of stretching exercises and Tai Chi exercise on fatigue in hemodialysis patiens

Public title
Comparison of the effect of stretching exercises and Tai Chi exercise on fatigue in hemodialysis patiens
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Verbal communication skills The desire to participate in the study At least 3 months of dialysis history 18 to 65 years old
Exclusion criteria:
Hearing and vision problems
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
The samples were individually divided into three groups of first intervention, second intervention and control group using simple randomization method. In this study, dice will be considered as a randomization tool. For making sequences, numbers 1 and 2 will be assigned to the first group, numbers 3 and 4 will be assigned to the second group, and the numbers 5 and 6 will be assigned to the third group. Clinical care giver and data analyzer will not know allocation of samples to interventions and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Clinical care giver and data analyzer will not know how to allocation of samples to interventions and control groups. The questionnaires will be distributed by the researcher in the pre-test phase and after completion of the intervention and in the post-test phase by clinical care giver .
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences.
Street address
Daneshgah St., Basij Sq., Sardasht Region
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2018-06-10, 1397/03/20
Ethics committee reference number
IR.ARAKMU.REC.1397.081

Health conditions studied

1

Description of health condition studied
Fatigue
ICD-10 code
R53
ICD-10 code description
Malaise and fatigue

Primary outcomes

1

Description
The fatigue score of the Smith's Fatigue Multi-Dimensional Questionnaire
Timepoint
Before and 6 weeks after intervention
Method of measurement
Smith's Fatigue Multi-Dimensional Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: The first intervention group will perform tensile training after the training by the researcher for 6 weeks and 18 sessions (40-60 minutes).
Category
Rehabilitation

2

Description
Second intervention group: The second intervention group will also perform the Tai Chi exercise after training by a researcher and physiotherapist for 6 weeks and 18 sessions (40 to 60 minutes).
Category

Rehabilitation

3

Description
Control group: During this period, no intervention will perform for control group samples.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hami Dialysis Center
Full name of responsible person
Seyed Mohammad Jamalian
Street address
Hami Dialysis Center, Gerdoo Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Mohammad Arjomandzadegan
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Vahid Naseri Salahshour
Position
MSc of Nursing
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Person responsible for updating data

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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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Part of the data, such as information on the main outcome and the demographic information, will be shared.

When the data will become available and for how long
The beginning of the access period is 36 months after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions.

Under which criteria data/document could be used
In order to utilize scientific purposes and mention the source used.

From where data/document is obtainable
Dr Mahboubeh Sajjadi, Ph.D. of Nursing, Faculty of Nursing and Midwifery, Arak University of Medical Sciences, Arak, Iran. E-mail address: sajadimahbobeh@yahoo.com

What processes are involved for a request to access data/document
After receiving the email, the information will be sent within 2 to 3 working days.

Comments