

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

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

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

Name

Vahid Naseri Salahshour

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

v.naserisalahshour@arakmu.ac.ir

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 patients

Public title

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

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

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

info@arakmu.ac.ir

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

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

vahidnaseri1994@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Vahid Naseri Salahshour

Position

MSc of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

vahidnaseri1994@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Vahid Naseri Salahshour

Position

MSc of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Arak University of Medical Sciences, Basij Sq.,
Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3505

Email

vahidnaseri1994@yahoo.com

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