

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of exercises with Therabands and core stability on back pain and quality of life in patients with chronic renal failure undergoing peritoneal dialysis

Protocol summary

Study aim

Determining the effect of eight weeks of central stability exercises with stretch band on back pain and quality of life of peritoneal dialysis patients

Design

A clinical trial work with a control group with parallel groups without blinding and randomized with a table of random numbers with 30 patients.

Settings and conduct

In this research, the subjects are selected from the patients undergoing peritoneal dialysis after being called and invited to participate in Khurshid peritoneal dialysis center located in Isfahan city, according to the criteria for entering the research and with the approval of expert doctors. In this plan, the candidates will get acquainted with the type of study and the purpose of the work, the possible benefits and risks, and they will be randomly assigned to one of the two intervention (exercise) or control groups. Each of the subjects signed a written informed consent before being assigned to the groups. For 8 weeks, the intervention group performs the training program at home with the simultaneous supervision of the trainer online, 3 sessions per week. Tests are taken from people before the start of the exercise period and two times after the start of the exercise

Participants/Inclusion and exclusion criteria

People undergoing peritoneal dialysis for at least 3 months who agree to participate in the study and have chronic back pain are included in the study, and patients who are medically prohibited from exercising are excluded.

Intervention groups

The intervention group performs the training program online for 8 weeks and 3 sessions at home with the same supervision as the trainer. These exercises are taught face-to-face in the first week. From the control group, participants wanted to continue their usual physical

activities as well as their usual treatment plans.

Main outcome variables

Low back pain and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200819048461N3**

Registration date: **2023-01-09, 1401/10/19**

Registration timing: **prospective**

Last update: **2023-01-09, 1401/10/19**

Update count: **0**

Registration date

2023-01-09, 1401/10/19

Registrant information

Name

Mohammad ali Tabibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3230 1795

Email address

m.tabibi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of exercises with Therabands and core stability on back pain and quality of life in patients with chronic renal failure undergoing peritoneal dialysis

Public title

Effect of exercise in Peritoneal dialysis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

More than 3 months of peritoneal dialysis experience
Having chronic back pain
The permission of the attending physician to practice
No history of heart attack or stroke in the last 3 months
Able to walk without assistance (assistive devices such as canes and walkers are allowed).

Exclusion criteria:

Unstable blood pressure
Changing the type of dialysis
Uncontrolled arrhythmias
Congestive heart failure
Having severe musculoskeletal pain at rest or minimal activity

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, individual with random number generation program
Randomization was performed by a biostatistician using a computer-generated randomization program [using Stata 16, StataCrop, College Station, Tx] with an allocation ratio of 1:1. For allocation concealment, allocation information will be protected in opaque sealed envelopes by an identified individual not participating in the study. Only after participant registration and baseline measurements are completed will envelopes be opened.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention, it is not plausible to blind participants and study staff who enroll participants and monitor the intervention delivery. Research project collaborator who is blinded to study arm assignments will obtain outcome measurements of the functional test and abnormalities. Outcome

adjudicators, and data analysts will be kept blinded to the allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of Arak University of Medical Sciences

Street address

Arak University, Karbala Boulevard, Basij Square, Arak

City

Arak

Province

Markazi

Postal code

3848177584

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.ARAKU.REC.1401.033

Health conditions studied**1****Description of health condition studied**

End stage renal disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

Back pain score

Timepoint

Before starting exercise and two months later

Method of measurement

Brief Pain Inventory Questionnaire

2**Description**

Quality of life score

Timepoint

Before starting exercise and two months later

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: The experimental group will do 3 sessions of 30-minute exercise program at home for 8 weeks with the simultaneous supervision of the trainer online. These exercises are taught face-to-face in the first week. The training program will include general body warm-up (5 minutes), central stability exercises and general body cooling (10 minutes). After each exercise, a 30 to 60 second rest is given to the patient. Resistance exercises will be done with body weight, special bands, dumbbells, ankle and wrist weights

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Shahrzad Shahidi

Street address

No. 105, Ostandari Street, Esfahan

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Isfahan

Postal code

8135673381

Phone

+98 31 3222 2127

Email

Shahidi_shahrzad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pardis Specialized Wellness Institute

Full name of responsible person

Dr Mohamad Ali Tabibi

Street address

71 Alley, Jey Street

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Esfahan

Province

Isfahan

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8156135414

Phone

+98 913 318 4624

Email

m.tabibi@ut.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pardis Specialized Wellness Institute

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Pardis Specialized Wellness Institute

Full name of responsible person

Dr Mohammad Ali Tabibi

Position

Assistant professor of exercise physiology

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Pardis Specialized Wellness Institute

Full name of responsible person

Dr Mohammad Ali Tabibi

Position

Assistant professor of exercise physiology

Latest degree

Ph.D.

Other areas of specialty/work

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of the study group are made available

When the data will become available and for how long

After October 2023

To whom data/document is available

Only academics are allowed

Under which criteria data/document could be used

If the data is used for the purpose of research in the field of variables and providing new solutions, it can be used by mentioning the source

From where data/document is obtainable

Dr. Mohammad Ali Tabibi via email address
m.tabibi@ut.ac.ir

What processes are involved for a request to access data/document

It will be answered within one month after receiving the email

Comments