

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Fatigue and Recovery-related Changes in Postural and Core Stability, Back and Hamstring Muscle Strength, and Spine Mobility in Sedentary Adults

Protocol summary

Study aim

To investigate (1) the effect of trunk muscles fatigue on postural and core stability, back and hamstring muscle strength, and spine mobility in sedentary adults, and (2) their changes after recovery modalities including the trunk stabilization exercises, foam rolling exercises, and diaphragmatic breathing exercises.

Design

A clinical trial with a control group, with 3 parallel groups, randomized (simple method), will be conducted on 160 subjects.

Settings and conduct

Each participant will take part in two phases including familiarization and data collection. In the first phase, all participants will undergo a familiarization session and become familiar with the standard test and techniques. In the second phase, data will be collected under three conditions: No fatigue, Fatigue, Recovery. The present study will be performed at the Medical University of Kerman, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria Sedentary middle-aged adults at risk of developing non-specific low back pain. Exclusion criteria Pregnancy; history of spinal, femoral, or intra-abdominal surgery in the previous 12 months; receiving physiotherapy services 1 month before the beginning of the study; having suffered any kind of mental health disorder during the past 3 years.

Intervention groups

A: Trunk Stabilization Exercises, B: Foam Rolling Exercises, C: Breathing Exercises, D: Passive Recovery.

Main outcome variables

Help to restore postural and core stability; core, and hamstring muscle strength, and spine mobility in sedentary adults; Help to reduce trunk muscles fatigue and consequently lessen any potential of subsequent injuries in sedentary adults.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056606N1**

Registration date: **2022-12-25, 1401/10/04**

Registration timing: **retrospective**

Last update: **2022-12-25, 1401/10/04**

Update count: **0**

Registration date

2022-12-25, 1401/10/04

Registrant information

Name

Banafsheh Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 279 3857

Email address

amirib1392@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-01, 1401/09/10

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Fatigue and Recovery-related Changes in Postural and Core Stability, Back and Hamstring Muscle Strength, and Spine Mobility in Sedentary Adults

Public title

The effect of 3 different recovery modalities on fatigue induced by prolonged sitting in sedentary adults

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The sedentary middle-aged adults (aged 25 to 44 years), At risk of developing non-specific low back pain, Self-reporting sitting for at least two hours on any working day.

Exclusion criteria:

Pregnancy; History of spinal, femoral, or intra-abdominal surgery in the previous 12 months; Participants having been diagnosed with a congenital anomaly of the spine, arthritis, rheumatoid, infection of the spine and discs, spondylolisthesis, ankylosing spondylitis, spondylosis, tumor, systemic lupus erythematosus, or osteoporosis; Receiving physiotherapy services 1 month before the beginning of the study; Having suffered any kind of mental health disorder, including anxiety and depression, during the past 3 years.

Age

From **25 years** old to **44 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Restricted randomization, Permuted block randomization: For randomization, the 'proc plan' procedure in the SAS software (ver. 9.1; SAS Institute, Cary, NC, USA) will be used. Using a block randomization method, 160 subjects will be divided randomly into 4 groups in a 1:1:1:1 ratio (block size, 4).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This is a cross-sectional study to model the process of fatigue and recovery-related changes in postural and core stability, back and hamstring muscle strength, and spine mobility in sedentary middle-age adults at risk of low back pain.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of medical sciences

Street address

Deputy of Research, Kerman University of medical sciences, Somayeh Cross way, Kerman

City

Kerman

Province

Kerman

Postal code

7618751151

Approval date

2022-11-07, 1401/08/16

Ethics committee reference number

IR.KMU.REC.1401.386

Health conditions studied

1

Description of health condition studied

Low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Postural stability

Timepoint

Pre-fatigue, post-fatigue, post-recovery modalities, and follow-up.

Method of measurement

FiTRO Sway Check (FiTRONiC, Bratislava, Slovakia)

2

Description

Core stability

Timepoint

Pre-fatigue, post-fatigue, post-recovery modalities, and follow-up.

Method of measurement

Gyko inertial sensor system (Microgate, Bolzano, Italy)

3

Description

Maximal isometric back extensor muscle strength

Timepoint
Pre-fatigue, post-fatigue, post-recovery modalities, and follow-up.

Method of measurement
FiTRO Back Dynamometer (FiTRONiC, Bratislava, Slovakia)

4

Description
Maximal isometric hamstring muscles strength

Timepoint
Pre-fatigue, post-fatigue, post-recovery modalities, and follow-up.

Method of measurement
FiTRO Back Dynamometer (FiTRONiC, Bratislava, Slovakia)

5

Description
Spine mobility

Timepoint
Pre-fatigue, post-fatigue, post-recovery modalities, and follow-up.

Method of measurement
Spinal Mouse device (Idiag, Volkswill, Switzerland)

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Trunk Stability Exercises will be applied as an active recovery after the fatigue protocol in order to investigate its effect on the recovery of the studied factors.

Category
Prevention

2

Description
Second intervention group: Foam Rolling Exercises will be applied as an active recovery after the fatigue protocol in order to investigate its effect on the recovery of the studied factors.

Category
Prevention

3

Description
Third Intervention group: Diaphragmatic Breathing Exercises will be applied as an active recovery after the fatigue protocol in order to investigate its effect on the recovery of the studied factors.

Category

Prevention

4

Description
Control group: Lying on the bed will be applied as a passive recovery after the fatigue protocol in order to investigate its effect on the recovery of the studied factors.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman University of Medical Science

Full name of responsible person
Banafsheh Amiri

Street address
The beginning of Haft Bagh Alavi axis, University of Medical Sciences campus

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr. Reza Malek Pourafshar

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src@kmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

SK

Type of organization providing the funding

Academic

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Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Banafsheh Amiri

Position

Ph.D. student

Latest degree

Master

Other areas of specialty/work

Rehabilitation management

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Person responsible for general inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Banafsheh Amiri

Position

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Latest degree

Master

Other areas of specialty/work

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Just that part of the data that includes the main results of the work can be shared, which means that the data related to the personal characteristics of the participants will not be shared.

When the data will become available and for how long

April 2024 onward

To whom data/document is available

Scientific researcher

Under which criteria data/document could be used

In case of request for cooperation to perform comparative analysis or validation.

From where data/document is obtainable**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Banafsheh Amiri

Position

Ph.D student

Latest degree

Master

Other areas of specialty/work

Rehabilitation management

Street address

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Banafsheh Amiri amirib1392@gmail.com
What processes are involved for a request to access data/document

I will send data after receiving a request email as soon as possible.
Comments