Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, Volkerswill, 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

City

Kerman

Province

Kerman

Postal code

3555 691 761

Phone

+98 913 979 3857

Email

amirib1392@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Reza Malek Pourafshar

Street address

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

City

Kerman

Province

Kerman

Postal code

3555 691 761

Phone

+98 34 3226 3719

Email

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

Person responsible for general 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
No. 8, Komeyl Ave., Jomhoori Blvd., Kerman,
City
Kerman
Province
Kerman
Postal code
4133 889 761
Phone
+98 34 3212 5469
Email
amirib1392@gmail.com

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
No. 8, Komeyl Ave., Jomhoori Blvd., Kerman
City
Kerman
Province
Kerman
Postal code
4133 889 761
Phone
+98 34 3212 5469
Email
amirib1392@gmail.com

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
Street address
No. 8, Komeyl Ave., Jomhoori Blvd., Kerman,
City
Kerman
Province
Kerman
Postal code
4133 889 761
Phone
+98 34 3212 5469
Email
amirib1392@gmail.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
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

Banafsheh Amiri amirib1392@gnail.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