

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effect of corrective exercise with massage on balance, motor function, gait and quality of life of the elderly male with hyperkyphosis

Protocol summary

Study aim

The aim of this study is the effect of corrective exercises with massage on balance, motor performance, walking and quality of life of elderly men with hyperkyphosis

Design

A randomized clinical trial study, a single-blind, factorial strain, 30 elderly people have been divided into an intervention group and a control group, through web randomization

Settings and conduct

The participants were equally divided into two groups of corrective exercises with massage and the control group. This study was conducted in Sabzevar city and Khoshab district. The importance of the sports program will be explained to the participants. The exercises are for 8 weeks and three sessions a week

Participants/Inclusion and exclusion criteria

Entry conditions: hyperkyphosis above 40 degrees, age between 65 and 74 years, not consuming Tranquilizers or any special medicine affecting balance, not having any neurological, severe respiratory, vascular, metabolic and uncontrollable musculoskeletal diseases, not having any severe and serious visual or hearing disorders. Conditions of non-entry: major psychiatric illness, cognitive impairment, alcohol or drug abuse, the presence of any physical defects affecting balance activities, the presence of joint sprains, the presence of hip, knee and ankle joint surgery, the presence of heart diseases. - acute respiratory, presence of chronic diseases of the motor system (joint rheumatism, chronic arthritis and osteoporosis) (confirmed by a specialist doctor)

Intervention groups

Intervention group: Corrective exercises and massage therapy were considered for each subject and three sessions were held for 8 weeks. the duration of each session was 6 min, including 10 minutes of warming up and cooling down. Control group: no activity during 8 weeks of the training program.

Main outcome variables

Kyphosis degree, balance, movement performance, walking kinematics and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220919055988N1**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **retrospective**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

Registration date

2022-11-28, 1401/09/07

Registrant information

Name

Abolfazl Tarkhasi

Name of organization / entity

The University of Kharazmi

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-22, 1401/04/31

Expected recruitment end date

2022-08-05, 1401/05/14

Actual recruitment start date

2022-07-31, 1401/05/09

Actual recruitment end date

2022-08-20, 1401/05/29

Trial completion date

empty

Scientific title

The effect of corrective exercise with massage on balance, motor function, gait and quality of life of the elderly male with hyperkyphosis

Public title

The effect of corrective exercise with massage on balance, motor function, gait and quality of life of the elderly male with hyperkyphosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hyperkyphosis above 40 degrees Age range from 65 to 74 years The ability to stand for at least 1 minute and walk 10 meters or more independently or with a regular cane. The doctor's permission to participate in this study and the ability to perform corrective movements. Not taking sedatives or any special medicine affecting balance Not having any uncontrollable neurological, severe respiratory, vascular, metabolic and musculoskeletal diseases Not having any severe and serious visual or hearing impairment

Exclusion criteria:

Major psychiatric disease, cognitive disorder Alcohol or drug abuse The presence of any physical defect affecting balance activities Having a history of sprained joints, having a history of hip, knee and ankle joint surgery Presence of acute cardio-respiratory diseases Existence of chronic diseases of the motor system (joint rheumatism, chronic arthritis and osteoporosis) (confirmed by a specialist doctor)

Age

From **65 years** old to **74 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomized into two groups (one intervention and one control) using an online randomization system (randomizer.org). A member of the research team who is not involved in the selection of samples will determine the randomization sequence using a computer program. Participants will be notified of their group allocation with a sealed envelope

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. In this way, during the evaluation before and after the intervention protocol, they do not make mistakes in their judgments in favor of a specific therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Sport Sciences Research Institute (SSRI)

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No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran

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Approval date

2022-07-20, 1401/04/29

Ethics committee reference number

IR.SSRC.REC.1401.042

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

Hypokyphosis

ICD-10 code

M40

ICD-10 code description

Kyphosis and lordosis

2**Description of health condition studied**

strengthening exercises

ICD-10 code

Y93.B9

ICD-10 code description

Activity, other involving muscle strengthening exercises

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

kyphosis status: In this study, the outcome of the first variable is the reduction of the kyphosis angle

Timepoint

Measurement of thoracic kyphosis at the beginning of the study (pre-test), measurement again at the end of the study (post-test)

Method of measurement

Flexible ruler

Secondary outcomes

1

Description

dynamic balance

Timepoint

At the beginning of the study (before the start of the intervention), (pre-test), and at the end of the intervention, (post-test)

Method of measurement

In this research, dynamic balance during movement will be measured by TUG.

2

Description

Motor performance factor

Timepoint

At the beginning of the study, before the intervention (pre-test), at the end of the intervention (post-test)

Method of measurement

6-minute walking test to measure motor performance

3

Description

walking item

Timepoint

At the beginning of the study, before the intervention (pre-test), at the end of the intervention (post-test)

Method of measurement

2D imaging for gait assessment

4

Description

Quality of life factor

Timepoint

At the beginning of the study, before the intervention (pre-test), at the end of the intervention (post-test)

Method of measurement

The SF_36 questionnaire was used to evaluate the quality of life.

5

Description

Static balance

Timepoint

At the beginning of the study, before the intervention (pre-test), at the end of the intervention (post-test)

Method of measurement

Sharpendermberg test to measure static balance.

Intervention groups

1

Description

Intervention group: Corrective exercises and massage therapy were considered for each subject and three sessions were held for 8 weeks. the duration of each session was 6 min, including 10 minutes of warming up and cooling down.

Category

Rehabilitation

2

Description

Control group: without any intervention. During this period, the control group asked to perform routine daily activities and not participate in specific exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farazmehr physiotherapy and hydrotherapy

Full name of responsible person

Samane Farazmehr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Dr Mohammad Delnavaz

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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

Kharazmi University

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

Kharazmi University

Full name of responsible person

Hassan Sadeghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to

make this available