

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Clinical trial of Evaluation of effectiveness comprehensive protocol spinal muscle training with and without functional electrical stimulation on angle of kyphosis and quality of life in elderly with functional of kyphosis

Protocol summary

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Summary

Objectives: the aim of this study was randomized controlled trial of effectiveness comprehensive protocol spinal muscle training with and without functional electrical stimulation in elderly with functional of kyphosis. Design: pre- post intervention. Setting and conduct: participants evaluated before and after 8 weeks of intervention. Single blind is related to participants. Participants including major: 45 women with functional hyperkyphosis age above the 60 years. Interventions: 8 weeks corrective exercises and functional electrical stimulation. Main outcome measure: degree of thoracic kyphosis; function; gait speed; quality of life.

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-04-20, 1396/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060634351N1**

Registration date: **2017-06-29, 1396/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-29, 1396/04/08

Registrant information

Name

Neda Shariatinia

Name of organization / entity

Kharazmi university

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Iran (Islamic Republic of)

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Email address

Scientific title

Clinical trial of Evaluation of effectiveness comprehensive protocol spinal muscle training with and without functional electrical stimulation on angle of kyphosis and quality of life in elderly with functional of kyphosis

Public title

Comprehension of exercises and electrical stimulation on elderly hyperkyphosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: elderly women equal to and above 60 years old with functional Hyperkyphosis angle equal to or greater than 40 degrees; the participants do not took part in any other treatment. Exclusion criteria: No advanced disease and acute neuromuscular; orthopedic and neurologic; limb fractures; structural defects and cardiovascular diseases; No more than three falling in the past year (self-report); Do not use narcotic drugs (self-report); Lack of total knee replacement or hip

(reported via physician); lack of hip fracture in the last six months (reported via physician); Not taking glucocorticoid medications for at least 3 months in the previous year (reported by the physician); surgery on the trunk and lower extremities; lasting damage in the lower limbs; and influence the research process; such as degenerative changes in the knee and lower limb visible malalignment included (Geneva Valgvm, genu varum, Geneva Rkvrvtvm, pes cavus and planus).

Age

From **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Simple randomization-random numbers

Secondary Ids

empty

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

Ethics committee of Kharazmi university

Street address

Faculty of physical education; south razan;
mirdamad;tehran

City

Tehran

Postal code

Iran

Approval date

2016-10-22, 1395/08/01

Ethics committee reference number

14442

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

Hyperkyphosis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Angle of kyphosis; gait speed; quality of life

Timepoint

Before and after eight weeks intervention

Method of measurement

Angle of kyphosis(cobb angle); function(7 item test); gait speed(six meter walk test); quality of life(questionnaire)

Secondary outcomes**1****Description**

Quality of life; Gait of speed

Timepoint

Before and after eight weeks

Method of measurement

Questionaries

Intervention groups**1****Description**

1st intervention group: corrective exercises training 2nd
intervention group: Functional Electrical Stimulation
along with training Control group: without intervention

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shariati physiotherapy clinic

Full name of responsible person

Neda shariatinia

Street address

No 1;perofessor hesabi blvd;safaeieh;yazd

City

Yazd

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Investigator

Full name of responsible person

Neda shariatinia

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Faculty of physical education;kharazmi
university;Tehran

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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

Investigator

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Phd

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty