

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

the effect of subject specific Foot progression angle retraining on the kinetics, kinematic, muscle activation and functional ability during walking in patients with knee osteoarthritis.

Protocol summary

Study aim

the effect of subject specific Foot progression angle retraining on the kinetics, kinematic, muscle activation and functional ability during walking in patients with knee osteoarthritis

Design

Two arm parallel group, a single blinded randomised control trial

Settings and conduct

place to do: tarbiat modares university way to do: 6-week gait retraining and assessment of parameters before and after training

Participants/Inclusion and exclusion criteria

osteoarthritis patients with grade II & III according to Kellgren-Lawrence scale in one knee or, if bilateral, being mild in one side

Intervention groups

intervention group: gait retraining as subject specific Toe out or Toe in control group: normal walking

Main outcome variables

knee joint moment, muscle activation, pain, functional activity, quality of life

General information

Reason for update

Acronym

FPA, TO, TI

IRCT registration information

IRCT registration number: **IRCT20101017004952N8**

Registration date: **2019-10-09, 1398/07/17**

Registration timing: **prospective**

Last update: **2019-10-31, 1398/08/09**

Update count: **1**

Registration date

2019-10-09, 1398/07/17

Registrant information

Name

Giti Torkaman

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of subject specific Foot progression angle retraining on the kinetics, kinematic, muscle activation and functional ability during walking in patients with knee osteoarthritis.

Public title

the effect of subject specific Foot progression angle retraining in knee osteoarthritis.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Definite OA Grade II & III as defined by the Kellgren-Lawrence scale in one knee or, if bilateral, being mild in one side BMI: Between 25 and 30 Ability to walk independently on an even surface without any assistive devices Minimum age 45 and maximum 65 years old

Exclusion criteria:
History of intra-articular injections over the past 6 months (such as hyaluronic acid, hydrocortisone and PRP) History of regular physical activity in the past 3 months (at least 2 or 3 times per week and at least half an hour each time History of musculoskeletal disorders and lower extremity joint injuries affecting balance Severe TI or TO ($57/7 \pm 5/7$) Pes Planus (Flat foot) (rigid and flexible), Pes cavus (High arch) Any malalignment of lower extremity which is evident by observation (Varus angel $> 5^\circ$ and Valgus angel $> 15^\circ$) History of knee and lower extremity surgery, severe muscle weakness in lower extremity, MMT lower than 3/5 History of neurological, vestibular, neuromuscular diseases (Diabetes and Neurapathy), chronic orthopedic disorders of the trunk and lower extremities (Rheumatoid Arthritis), visual impairments, inability to comprehend commands Osteoporosis Taking medications not prescribed by a Rheumatologist. Unwillingness to participate in the study for any reason

Age
From **45 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
blocking randomization using the sealed, opaque, and stapled envelopes by an independent person

Blinding (investigator's opinion)
Single blinded

Blinding description
Assessment and data acquisition will be performed by an expert in the Movement Disorders Laboratory that is blinded about grouping and kind of intervention

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat modares university

Street address

Jalale ale ahmad., nasr bridge., chamran highway

City

Tehran

Province

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Postal code

14115-111

Approval date

2019-03-17, 1397/12/26

Ethics committee reference number

IR.MODARES.REC.1398.004

Health conditions studied

1

Description of health condition studied

knee osteoarthritis disease

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthritis

Primary outcomes

1

Description

knee adduction moment

Timepoint

before and after six-week retraining

Method of measurement

motion analysis system, nexus software

2

Description

knee flexion moment

Timepoint

before and after six-week retraining

Method of measurement

motion analysis system, nexus software

3

Description

Muscle activation

Timepoint

before and after six-week retraining

Method of measurement

Electromyography

Secondary outcomes

1

Description

pain

Timepoint

before and after six-week retraining

Method of measurement

visual analog scale

2

Description

Quality of life

Timepoint

before and after six-week retraining

Method of measurement

SF-36 questionnaire and WOMAC

3

Description

functional activity

Timepoint

before and after six-week retraining

Method of measurement

8-walking test and Timed up and go test

Intervention groups

1

Description

Intervention group: gait retraining

Category

Rehabilitation

2

Description

Intervention group: change the walking pattern (Toe in or Toe out) on the basis of the first session assessment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Therapeutic and research center of movement disorder

Full name of responsible person

Giti Torkaman

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2

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Noushin Bayat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Yaghoob Fathollahi

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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

Tarbiat Modares 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

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Web page address<http://www.modares.ac.ir>**Person responsible for general inquiries****Contact****Name of organization / entity**

Tarbiat modares university

Full name of responsible person

Giti Torkaman

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Samaneh gholami

Position

دانشجوی دکتری تخصصی

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Full name of responsible person

Dr Giti Torkaman

Position

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Latest degree

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Other areas of specialty/work

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Tehran

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

demographic data, main variable and its consequences

When the data will become available and for how long

6 month after publication results

To whom data/document is available

only for researchers

Under which criteria data/document could be used

they do not have permission to process the data

From where data/document is obtainable

Samaneh gholami 09125343099

samaneh_gh_65@yahoo.com

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

he or she must by email indicate the title of the research proposal and the reason for the request

Comments