Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-weak 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
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Name of organization / entity
Tarbiat Modares University

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Iran (Islamic Republic of)

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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 ± 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□ and Valgus angel > 15□) 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

Tehran

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 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
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Recruitment center
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Sponsors / Funding sources

1

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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

Person responsible for general inquiries

Contact
Name of organization / entity
Tarbiat modares university
Full name of responsible person
Giti Torkaman
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
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

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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