

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of Two Types of Shoe Insole and Exercise Program on the Dynamics of Lower Extremities Joints in the Disabled with Leg Limb Length Discrepancy during Stance Phase of Walking

Protocol summary

Study aim

Effect of Two Types of Shoe Insole and Exercise Program on the Dynamics of Lower Extremities Joints in the Disabled with Leg Limb Length Discrepancy during Stance Phase of Walking

Design

This study is a clinical trial with a control group, parallel groups, non-blinded, randomized groups by number assignment to participants and a draw and 30 samples (10 individuals in each group).

Settings and conduct

The place of this study is the University of Mazandaran. The test is recorded in three conditions: with shoes, Internal insole and external insole for all subjects. They begin their movement from four meters of the force plate and by getting a controlled rhythm, the average of three successful attempts is recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Difference in the length of lower limb is between one to two and a half centimeters Full ability to walk age range between 45 and 65 years No balance problems Exit criteria: Having a history of a lower limb rehab program six months before the test Having a history of using the therapeutic shoe insoles six months before the test Having a history of lower limb joints fracture or surgery six months before the test Systemic diseases such as rheumatism and diabetes

Intervention groups

1. Internal insoles. They used an Internal insole for 12 weeks. This insole is equal to the difference in the length of the limb of each subject and is sloped in the heel area. 2. External insoles. They used an external insole in the under-shoe area for 12 weeks. This insole is equal to the difference in the length of the limb of each subject in the heel to toe section and is not sloping. 3. Exercise Group. Strengthening and Stretching exercises of the Lumbar and pelvis were performed for 12 weeks.

Main outcome variables

Dynamics of Lower Extremities Joints

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190718044261N1**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **retrospective**

Last update: **2019-10-11, 1398/07/19**

Update count: **0**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

Mansour Eslami

Name of organization / entity

The University of Mazandaran

Country

Iran (Islamic Republic of)

Phone

+98 11 3530 2210

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

2018-11-21, 1397/08/30

Actual recruitment end date

2019-03-11, 1397/12/20

Trial completion date

2019-03-16, 1397/12/25

Scientific title

Effect of Two Types of Shoe Insole and Exercise Program on the Dynamics of Lower Extremities Joints in the Disabled with Leg Limb Length Discrepancy during Stance Phase of Walking

Public title

Effect of foot insoles and exercise program on subjects with Leg Length Discrepancy (LLD)

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

The difference in length of the lower limb is between one to two and a half centimeters Full ability to walk Age range between 45 and 65 years No balance problems

Exclusion criteria:

Having a history of lower limb rehab program six months before the test Having a history of using the therapeutic shoe insoles six months before the test Having a history of lower limb joints fracture or surgery six months before the test Systemic diseases such as rheumatism and diabetes

Age

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

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Actual sample size reached: **29**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, all participants in the study were assigned a number, and then they were selected using the lottery for each group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of University of Mazandaran

Street address

Shahid Beheshti Ave, University of Mazandaran, Faculty of Physical Education and Sport Sciences

City

Babolsar

Province

Mazandaran

Postal code

4741613534

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.UMZ.REC.1397.050

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

Leg Limb Length Discrepancy

ICD-10 code

M21.7

ICD-10 code description

Unequal limb length (acquired)

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

Dynamics of Lower Extremities Joints

Timepoint

At the beginning of the study (before the intervention) and three months after the intervention

Method of measurement

General Health Questionnaire of Subjects, meter, and Scale to measure anthropocentric characteristics, Force plate, Camera and Marker to Record Motion and Calculate Dynamics of Lower Extremities Joints

Secondary outcomes

empty

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

First Intervention group: The intervention in this group involves the use of internal insole for Shortness of leg compensation for twelve weeks. The height of the insole in the heel area is equal to the length difference of two legs and does not have a high in the toe area and made of a semi-rigid material.

Category

Prevention

2

Description

Second Intervention group: The intervention in this group involves the use of external insole for shortness of leg compensation for twelve weeks. The height of the insole in the heel to toe area is equal to the length difference of two legs and made of a semi-rigid material.

Category

Prevention

3

Description

Third intervention group: The intervention in this group involves the use of exercise for twelve weeks. In subjects with short leg limbs due to lateral pelvic tilt, weakness hip abductors, shortness of iliopsoas muscle, muscle weakness lumbar muscles and the shorten of Plantar flexor muscles in short leg, exercise program with an emphasis on weakened muscle strength and stretch the muscles shortened.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Health Assessment and Monitoring, Faculty of Physical Education and Sports Sciences, Univ

Full name of responsible person

Mansour Eslami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fund for the Protection of Researchers and

Technologists of the Country

Full name of responsible person

Nasrallah Zargham

Street address

No. 3, 5th Alley, above the intersection of Jalal Al-Ahmad, Kargarshomali Ave.,

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Email

social@insf.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Fund for the Protection of Researchers and Technologists of the Country

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

The University of mazandaran

Full name of responsible person

Mansour Eslami

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Biomechanic

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data will only be presented in general and in the results of the report of the study.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Data Dictionary

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