Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of smart wearable insoles on improvement of Gait Training in children with idiopathic Toe Walking, compared to the control group including physiotherapy and occupational therapy and the placebo group including the use of simple medical insoles , A clinical trial study

Protocol summary

Study aim

The effect of smart insoles based on Gait Training in improving the walking of children with idiopathic toe walking compared to the control group including physiotherapy and occupational therapy and the placebo group including the use of simple medical insoles

Design

This study is a randomized and double-blind clinical trial.This study is divided into 3 treatment groups. The first group: the intervention group, which includes the use of smart medical insoles, the second group: the control group, which includes physiotherapy and occupational therapy, and the third group: the placebo group, which includes the use of simple medical insoles.Patients in the intervention group receive insoles containing pressure sensors to analyze walking patterns. These people undergo the gait retraining program using the feedback of these insoles for 8 weeks

Settings and conduct

In physical medicine and orthopedic clinics of Bahrami and Shariati hospitals in Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 2 to 14 years old with a definite diagnosis of Idiopathic toe walking exclusion criteria 1. Having any background disease including orthopedic, neurological, psychological and other diseases. 2. Cases that use insoles for more than a week and for less than 6 hours a day will be excluded from the study. 3. In the last 6 months, he has not received any treatment, including physiotherapy, occupational therapy, etc.

Intervention groups

Children 2 to 14 years old with a definite diagnosis of Idiopathic toe walking

Main outcome variables

The amount of ankle dorsiflexion in both passive and active states Gate analysis or walking check Distance-time or spatiotemporal parameters The percentage of parents' satisfaction with your children's walking

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241223064140N1**
Registration date: **2025-04-10, 1404/01/21**
Registration timing: **prospective**

Last update: **2025-04-10, 1404/01/21**
Update count: **0**

Registration date

2025-04-10, 1404/01/21

Registrant information

Name

Mohammad Sadegh Dehghan Nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3355 3700

Email address

sadegh.nasiri73@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-21, 1404/06/30

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of smart wearable insoles on improvement of Gait Training in children with idiopathic Toe Walking, compared to the control group including physiotherapy and occupational therapy and the placebo group including the use of simple medical insoles , A clinical trial study

Public title
The effect of smart wearable insoles on the improvement of Gait Training in improving the gait of children with idiopathic Toe Walking
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 2 to 14 years definite diagnosis of idiopathic Toe Walking.
Exclusion criteria:
Age
From **2 years** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients and the data analyst will be unaware of the type of intervention applied to the patients. The attending physician and the people involved in providing the intervention will be aware of the grouping of the patients.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No.23, 16 Azar Ave., Keshavarz Blvd.Tehran wn
City
Tehran
Province
Tehran
Postal code
1417863181
Approval date
2024-07-13, 1403/04/23
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.177

Health conditions studied

1

Description of health condition studied
Idiopathic toe walking
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Analysis of ankle dorsiflexion range in both passive and active states
Timepoint
At the beginning and 8 weeks and 3 months later
Method of measurement
by goniometer

Secondary outcomes

1

Description
Satisfaction level of parents and doctor
Timepoint
At the beginning and 8 weeks and 3 months later
Method of measurement
Questions from parents and doctors

Intervention groups

1

Description
Intervention group: Using smart medical insoles
Category
Treatment - Devices

2

Description
Control group: Physiotherapy and occupational therapy
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital
Full name of responsible person
Mohammad Sadegh Dehghan Nasiri
Street address
Jalale ale ahmad Ave, North karegar Blvd., Tehran Town
City
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Postal code
1411713135
Phone
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Email
shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
6th floor of Research and Technology Vice Chancellor, Central Organization of the University, corner of Quds St.Keshavarz Blvd.
City
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Postal code
141765383761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Sadegh Dehghan Nasiri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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Person responsible for updating data

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Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Email
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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All study data and their analysis can be shared after the end of the study and after making it nonidentifiable

When the data will become available and for how long
The access period starts 1 year after the results are published

To whom data/document is available
It is accessible to all people

Under which criteria data/document could be used
It is accessible to all people

From where data/document is obtainable
sadegh.nasiri73@gmail.com

What processes are involved for a request to access data/document
sadegh.nasiri73@gmail.com

Comments