

Wearing textured insoles in shoes to help selfmanagement for people with MS: an exploratory study of the effects on balance

Submission date
12/05/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
12/05/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
30/09/2013

Condition category
Nervous System Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7926

Study information

Scientific Title

Acronym

Textured Insoles & Balance in MS Version 3

Study objectives

To explore if wearing textured insoles in footwear can affect balance for people with multiple sclerosis (MS). The overall context of the study is about the use of footwear as an aid to improving balance in people with multiple sclerosis (MS). The results from this study on the effects of wearing insoles will serve to inform further work into the use of textured insoles to improve balance in people with MS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved on the 3rd June 2009 (ref: 09/H0903/35)

Study design

Single centre randomised interventional process of care trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Neurological; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions

The project will see if wearing insoles with a rough texture in shoes can help people affected by multiple sclerosis. We will investigate two different textured insoles (using a smooth insole as a control) to see if either or both can change people's ability to maintain their balance when standing and when walking. We will study what happens the first time they wear the textured insoles and also after two weeks of wearing them.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Balance

Secondary outcome measures

1. Muscle activation
2. The effects on balance of wearing textured insoles for two weeks

Overall study start date

01/07/2009

Completion date

31/03/2010

Eligibility**Key inclusion criteria**

1. Men and women aged between 18 - 65 years
2. Clinical diagnosis of MS
3. Can walk about 100 m with or without resting with the use of one stick or crutch

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 50; UK sample size: 50

Key exclusion criteria

Any potential participant will be excluded from the study for any of the following reasons:

1. Diagnosis of other central nervous system condition
2. Musculoskeletal injury within last 6 weeks
3. Relapse of symptoms in the last three months
4. Reduced sensation in either or both feet of a degree that would preclude them perceiving the textures
5. Known allergy to or subsequent allergic reaction to hypoallergenic tape
6. Inability to understand instructions
7. Unable to walk 10 metres (11 yards) without resting, either unassisted or with one stick or crutch
8. Previous use of these or similar textured insoles

Date of first enrolment

01/07/2009

Date of final enrolment

31/03/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Health and Social Care Institute

Middlesbrough

United Kingdom

TS1 3BA

Sponsor information

Organisation

Multiple Sclerosis Society (UK)

Sponsor details

Research and Development

372 Edgware Road

London

United Kingdom

NW2 6ND

Sponsor type

Charity

Website

<http://www.mssociety.org.uk/>

ROR

<https://ror.org/043fwdk81>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society (UK)

Alternative Name(s)

Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2014		Yes	No