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The long-term effects of textured shoe insoles on balance, walking ability and function in people with multiple sclerosis

Submission date
20/03/2014

Recruitment status
No longer recruiting

Registration date
07/04/2014

Overall study status
Completed

Last Edited
17/02/2017

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a disease affecting nerves in the brain and spinal cord. Impairments of gait and balance are common symptoms of MS and cause significant reduction of independence and quality of life. Gait and balance are impaired as a result of several of the primary symptoms of MS, one of which is peripheral sensory loss. MS patients can develop reduced sensation in the soles of their feet as a result. Sensation in the soles of the feet has been shown to be important in the control of gait and balance so its loss contributes to the development of gait and balance impairments. Wearing textured insoles in shoes is a method of increasing stimulation of the soles of the feet. Textured insoles have been found to improve the gait and balance of elderly people who also have reduced sensation in their feet. initial studies over short periods of time have shown that MS patients may also benefit from wearing textured insoles. A larger study is now needed to give more evidence and show how insoles can help. The aim of this study is to investigate whether textured insoles improve the walking ability of people with MS when they are worn for a period of three months and to find out how acceptable textured insoles are to them.

Who can participate?
People aged between 18 and 65 with a clinical diagnosis of MS and the ability to walk independently for 100 metres with or without a unilateral walking aid.

What does the study involve?
Participants are invited to attend sessions at the Teesside Centre for Rehabilitation Science in James Cook University Hospital (UK). Their gait characteristics and balance control are tested. They are asked to complete some questionnaires about how they regard their health and how their symptoms impact on their lives. Before taking part in the study, the sensitivity of each participants foot sole is tested - if this is too low they are not able to take part. Participants are randomly allocated to one of three groups: textured insole group, smooth insole group or control group (no insole). They are asked to wear the insole during their normal daily activities

for three months, after which the testing procedure is repeated in all three groups. At the end of the study, participants are invited to take part in focus groups to share their experience of wearing the insoles. Focus groups are not compulsory.

What are the possible benefits and risks of participating?
Taking part is necessarily beneficial, but textured insoles of this type have been shown to help people with MS in an initial study so there may be some benefit to gait and balance. There is a small risk of falls during the gait and balance testing. To prevent falls, bars and handles are present for support should participants require it and the chief investigator, a qualified physiotherapist, is beside participants all of the time. Participants are able to rest between tests. There is also a possibility that some participants may find the insoles uncomfortable. Participants are advised to contact the chief investigator if this is the case and to stop wearing the insoles if they find them too uncomfortable. The team supervising the study and the clinicians responsible for participants care feel that the risks are minimal.

Where is the study run from?
Teesside Centre for Rehabilitation Science, Teesside University in James Cook University Hospital, Middlesborough (UK)

When is the study starting and how long is it expected to run?
April 2014 to May 2016

Who is funding the study?
Multiple Sclerosis Society (UK)

Who is the main contact?
Dr Yael Jenny Baron
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
972/12

Study information

Scientific Title
The long-term effects of textured shoe insoles on balance, walking ability and function in people with multiple sclerosis: an exploratory randomised controlled trial

Study objectives
It is hypothesised that wearing textured insoles will improve the gait and balance of people with MS due to the increase in sensory stimulation to the soles of their feet. The null hypothesis is that textured insoles will make no difference to gait and balance ability compared to baseline measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Teesside University School of Health & Social Care Research Governance and Ethics Committee, 17/03/2014, ref: 181/13
2. North EastNewcastle and North Tyneside 2 National Research Ethics Service Research Ethics Committee, 20/03/2014, ref: 14/NE/0043

Primary study design
Interventional

Study design
Single-blinded exploratory randomised controlled trial with three arms

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Patients are randomised to three arms:
1. Intervention - textured insoles (Evalite Pyramid EVA 3mm thickness, Algeos Ltd.)
2. Control - smooth insole (medium density EVA, 3mm thickness, Algeos Ltd.)
3. Control - no insole

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Spatio--temporal parameters of gait, recorded by an electronic GAITRite mat
2. Standing balance during quiet bipedal stance, recorded by a Kistler (TM) force plate

3. Functional mobility, measured by the timed--up--and--go test
4. Qualitative information regarding acceptability and comfort of the insole interventions, gathered in semi-structured interviews and focus groups at the end of the study

Key secondary outcome(s)
1. Self-reported health, measured using the EQ-5D-5L
2. Self-reported fatigue, measured using the modified fatigue impact scale
3. Self-reported pain level, measured using the Medical Outcomes Study (MOS) pain effects scale
4. Self-reported cognitive deficits, measured using the perceived deficits questionnaire
5. Self-reported fear of falling, measured using the falls efficacy scale International
6. Self-reported walking ability, measured using the MS Walking Scale (MSWS-12)

Completion date
06/05/2016

Eligibility

Key inclusion criteria
1. Be aged between 18 and 65
2. Have a clinical diagnosis of MS
3. Be able to walk 100m independently, with or without a unilateral walking aid

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Current acute exacerbation and/or relapse of symptoms within the last three months
2. Diagnoses of any other condition affecting the central nervous system, for example Parkinson s Disease
3. Any musculoskeletal injury or condition for which a health professional has advised the person to refrain from undertaking moderate physical activity
4. Inability to give informed consent
5. Inability to read or speak English
6. Inability to feel the textured insoles (foot sole sensitivity tested using Semmes-Weinstein monofilaments to exclude people with peripheral neuropathy)
7. Current use of textured insoles or shoes with textured insoles

Date of first enrolment

01/04/2014

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Teesside University
Middlesbrough
United Kingdom
TS1 3BA

Sponsor information

Organisation
Teesside University (UK)

ROR
https://ror.org/03z28gk75

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society - grant reference 972/12

Alternative Name(s)
mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Yael Jennifer Baron (yael.baron@nuth.nhs.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No