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An assessment by measurement (measuring arm) on the effects of a Footjacks flat orthotic compared to a flat insole and a standard orthotic on the lower limb, pelvis and spine together with the wearing effects (wearing arm) over a seven month period on adults with chronic low back pain compared to a flat control insole

Submission date
21/08/2017

Recruitment status
No longer recruiting

Registration date
23/08/2017

Overall study status
Completed

Last Edited
14/06/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Collapsing feet (flat feet) are a common problem. Orthotics for supporting the arch of the foot are often uncomfortable and difficult to fit in certain types of shoes. Testing has shown that these devices do not level the pelvis due to their not properly correcting foot function. Collapsed arches are only generally considered a problem if they cause pain. This approach overlooks the supporting function of the feet for the rest of the body and the effect of collapse on stability. Through its effects on joint position the consequences of foot collapse on the body can over time be considerable. The aim of this study is to test the effects of wearing a new flat orthotic relative to a standard flat insole over a 7-month period in adults with chronic low back pain. The length of the study should be enough to allow participants' backs to adapt to the new device. In addition, the effects of the new device on pelvic levelness and various aspects of the body will be assessed and compared with a flat control and a standard arch support. This part of the study will seek to prove the theories on the correct functioning of the foot and what goes wrong with it together with the effects of collapsed arches on certain aspects of the body.

Who can participate?
Adults aged 18 to 75 with chronic low back pain and unlevelness at the pelvis due to one foot collapsing medially more than the other foot

What does the study involve?
The wearing part of the study involves participants being randomly allocated to receive the new flat orthotic or a flat insole. Participants wear the insoles as much as possible, including around the house in evening footwear such as slippers. Questionnaires and assessments are completed after 1, 2, 3, 5 and 7 months to assess pain and physical functioning. The measuring part of the study involves measuring other parameters including rotation at the ankle and the heel, rotation of head, arm and thorax and of the pelvis. Measurements are also performed to try and find out where correct weight bearing should be borne in general standing and walking.

What are the possible benefits and risks of participating?
It is hoped that once adapted to the flat orthotic wearers will have reduced low back pain together with improvements in pain and motion throughout the lower limbs and spine. Further, it is hoped the device will lead to increased stability in high heels in particular and flat shoes in general. The device may offer superior support to the lower limbs and spine compared to conventional orthotics and may also be much more comfortable to wear due to it being flat and thin. It is hoped that participants wearing the device will be able to undertake more exercise once adjusted to the device thereby improving health. Physical risks to the participants are extremely small. Some short-term tenderness in the upper femur (thigh bone) may be experienced within the first 3 months due to changes in support imposed by the device. Due to the probable increased stabilisation experienced with its use, the main risk may be from not wearing it and especially in those who may have any balance issues.

Where is the study run from?
Footjacks Limited (UK)

When is the study starting and how long is it expected to run for?
April 2016 to April 2018

Who is funding the study?
Footjacks Limited (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3/210217

Study information

Scientific Title
An assessment of the effects Footjack flat orthotic on (1) the foot, lower limbs, pelvis, and spine compared to a control and a standard arch support and (2) on pain and function in subjects with pes planus and chronic low back pain over a 7 month period compared to a control with random allocation

Study objectives
Primary hypothesis for the wearing arm:
That there is a significant difference between the device and the control with regards the effects on pain and function in the low back in subjects with chronic low back using the Oswestry Low Back Disability Index

Secondary hypothesis for the wearing arm:
1. That the device is safe and does not give rise to serious adverse events
2. That the device is comfortable relative to the control
3. That the device does subjectively improve the stability of walking in high heeled shoes
4. That the device does significantly give rise to global improvement
5. That the device improves pain and function in the lower limb

Primary hypothesis for the measuring arm is:
That the device does prevent or substantially prevent medial calcaneal roll in the transverse plane compared to a control insole or a standard arch support and therefore does improve or substantially improve support of the calcaneus/calcanei, malloli, pelvis and HAT in bilateral and unilateral stance whilst the foot is flat on the ground and is equivalent or substantially equivalent to the support of these structures when standing on the lateral calcaneus/calcanei

Secondary hypotheses for the measurement arm are:
1. That the device does prevent elongation of the abutments of the medial longitudinal arch and increases the height of the arch under load compared to a control insole and standard arch support
2. That the device does stabilise the foot in high heeled shoes and does therefore prevent or substantially prevent excursion of the knee beyond the boundary of the footprint medially and laterally compared to a control insole or a standard arch support.
The hypothesis applies to easy normal movements without forcing the lower limb to pivot at the heel of the shoe and tip forcing the knee beyond the foot boundary.
3. That medial calcaneal roll in the transverse plane starts at V1
4. That medial roll through the mid foot does starts in the lateral heel

5. That lateralising the foot to 25 degrees does reduce but not eliminate unlevelness in the pelvis at the iliac crests whether in bilateral standing with or without translation of the pelvis
6. That the heads of the 1st and 5th MTP's do contact the ground together on the device if the calcaneus was resting on its lateral aspect before the abutments contact the ground

Ethics approval required
Old ethics approval format

Ethics approval(s)
London-Dulwich Research Ethics Committee, 01/03/2017, ref: 17/LO/0053

Study design
1. Wearing arm: Randomised controlled interventional single-site study
2. Measuring arm: Within-subject single-site double-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Pes planus

Interventions
Wearing arm
Participants will be selected from the Chief Investigator's osteopathic patients. A trial case history will be taken to determine that they are eligible for the trial. Written consent will be sought from eligible participants who will be between the ages of 18 and 75. After a obtaining consent, subjects will complete some questionnaires and VAS assessments as base measurements. Subjects will then be randomised to receive either the device or a flat control insole. Randomisation will be performed by an independent statistician. The Chief Investigator and the subjects will be blinded as to which insole the subjects receive. 40 participants will receive the device, 20 will receive the control insole. Participants will then be fitted with two pairs of the insoles allocated to them. They will wear the insole allocated in their footwear throughout the day whilst standing on their feet. Subjects will wear the insoles as much as possible, including around the house in evening footwear such as slippers. The questionnaires and VAS assessments will be completed at the end of 1, 2, 3, 5 and 7 months.

Measuring arm
The measuring arm of the trial will involve 21 subjects all being non level at the pelvis. The

participants will be chosen to be as large out of true at the pelvis as can be found in bilateral standing, and if possible 1.5 cm or more. This will increase the chance of showing differences between the 3 different footbeds being tested. The measuring arm will measure other parameters including rotation at the ankle and the heel, rotation of HAT (Head, Arm, Thorax) and of the pelvis in unilateral stance. Measurements will also be performed to try and ascertain where correct weight bearing should be borne in general standing and walking.

Intervention Type
Device

Primary outcome measure
Wearing arm:
Level of pain and physical functioning as determined by the Oswestry Low Back Disability Questionnaire at baseline and at the end of 1, 2, 3, 5 and 7 months

Measuring arm:
Levelness or substantial levelness of the iliac crests with or without pelvic translation. Measurements will be taken on the three footbeds in easy normal standing with the feet pointing straight where the iliac crests are not otherwise level in bare feet in the same stance. The measurements will be compared to the position of the iliac crests when standing in the same stance with the centre of pressure on the lateral aspect of the calcanei.

Secondary outcome measures
Wearing arm:
1. Safety and adverse events. Subjects will be asked to report adverse events that are not expected at baseline and at the end of the 1, 2, 3, 5 and 7 months. Subjects will be asked to advise of unusual, unexpected or persistent adverse events as they occur so that appropriate action can be taken.
2. Usual pain in the last week, measured using a VAS assessment at inception and at the end of 1st, 2nd, 3rd, 5th and 7th months
3. Stability in high heel shoes (women only), measured using VAS assessment at inception, and at the end of 1st, 2nd, 3rd, 5th and 7th months
4. Comfort, measured using a VAS assessment at inception, and at the end of 1st, 2nd, 3rd, 5th and 7th months
5. Significant global improvement, measured using a VAS assessment at the end of 1st, 2nd, 3rd, 5th and 7th months
6. Function in the lower limb, measured using the Lower Extremity Functional Scale at the end of the 1st, 2nd, 3rd 5th and 7th months

Measuring arm:
1. Levelness or substantial levelness of the ASIS's in the coronal plane in the same stance as in 1. above with or without pelvic translation testing the three footbeds in easy normal bilateral standing and comparing the same to their levelness when standing in the same stance with the centre of pressure on the lateral calcanei
2. The rotational attitude of HAT (Head, Arms and Thorso) in the coronal plane as measured just below the xiphoid process standing on the most collapsing calcaneus in the transverse/coronal planes in unilateral stance and the foot placed straight at mid stance. The degree of rotation, whether left or right, should substantially approximate that as measured when standing on the same calcaneus at mid stance on a bare foot and standing with the foot on the ground and standing on the lateral aspect of the calcaneus, on a straight placed foot
3. Prevention or substantial prevention of medial roll of the calcaneus in the transverse plane in

easy normal standing with the feet straight
4. The primary outcome measure above, in the same stance on the device and a control with both feet lateralised to 25 degrees
5. Prevention or substantial prevention of elongation of the abutments to the medial longitudinal arch under load
6. Position of the centre of pressure at the contact of the anterior abutments of the medial longitudinal arch at the heads of the 1st and 5th MTP's and contact and order of contact of the heads of the 1st and 5th MTP's
7. With the foot in a high heeled shoe position the excursion of the knee in internal and external rotation does not exceed or substantially exceed the lateral and medial borders of the foot
8. The position of the Malleoli in the transverse plane when standing and walking with the feet straight on the 3 footbeds as compared to their position when standing on the lateral calaneus /calcanei
9. Medial calcaneal roll starting at V1
10. Medial roll starting in the lateral heel

Overall study start date
01/04/2016

Completion date
30/04/2018

Eligibility

Key inclusion criteria
Wearing arm:
1. Age 18-75
2. Iliac crests not level with easy normal standing with feet straight and iliac crests level or substantially level when standing on lateral calcanei
3. Chronic low back pain (three episodes of back pain in the last 24 months with pain at the time consent taken) below T12, including lumbar spine and pelvic joints with or without radiating pain

Measuring arm:
1. Age 18 to 75
2. Iliac crests not level by at least 1.5 degrees with easy normal standing with feet straight and iliac crests level or substantially level when standing on the lateral calcanei

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex

Both

Target number of participants
Total number of participants: 81; Wearing arm: 60; Measuring arm: 21

Total final enrolment
59

Key exclusion criteria
Wearing arm:
1. Under 18 and over 75
2. No history of chronic low back pain
3. Lack of suitability for whatever clinical reason to be randomised (any condition in the opinion of the Investigator would make it unsafe or unsuitable for the patient to participate in the study)
4. Person unable to give consent
5. Vulnerable people
6. Patient with any musculoskeletal condition making it difficult for the spine to adapt to a change, e.g. spinal fusion in the neck, disc herniation threatening the cord, severe spinal stenosis etc. Subject will complete a case history at the assessment stage of the trial and excluded if unsuitable for the trial due to such a condition
7. Severe sciatica with neurological signs
8. Cancer
9. Pregnancy or planned pregnancy
10. Severe osteoarthritis of lower limb joints
11. Inflammatory arthritis
12. Recent or complicated fractures
13. Congenital lower limb deformity
14. Undertaking a course of medical treatment or physical therapy of more than 1 a month that could interfere with the validity of the trial data
15. Foot pathology which interferes with levelling of the pelvis
16. Already wearing standard arch supports
17. Progressive and/ or severe multiple sclerosis

Measuring arm:
1. Musculoskeletal system is unable to adjust to changes in movement through the lower limb, pelvis and spine
2. Subjects being unlevel at the iliac crests of less than 1.5 degrees using the Palm Inclinometer
3. A congenital lower limb deformity
4. Any balance problem making difficult to stand on one leg
5. Anyone who is unable to follow the necessary instructions. They will not be excluded if they have a family member who can explain/translate

Date of first enrolment
24/08/2017

Date of final enrolment
30/09/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Footjacks Registered Office
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Sponsor information

Organisation
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Footjacks Limited

Results and Publications

Publication and dissemination plan
The protocol and statistical analysis plan will be made available at a later date. Planned publication of the results in a peer-reviewed journal.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The de-identified datasets generated during and/or analysed during the current study are/will be made available on request at the end of the trial to the MHRA and other bona fide academic investigators via data sharing agreements.

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