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Off-the-shelf versus customised foot orthoses for people with rheumatoid arthritis (RA).

Submission date
25/01/2016

Recruitment status
No longer recruiting

Registration date
09/02/2016

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Rheumatoid arthritis (RA) is the commonest form of inflammatory polyarthritis (arthritis that involves 5 or more joints at the same time) affecting an estimated 645,000 people in the UK. Most sufferers will develop foot and ankle problems over the course of their disease that will affect their quality of life. Foot orthoses (FOs) are specially designed braces that fit inside the shoe to help support the foot and ankle. It is a recognised non-pharmacological adjunct therapy (that is a non-drug treatment given in addition to other treatments) to standard medical care of people with RA who suffer with foot and ankle problems. FOs are designed to redistribute the weight from one part of the foot to another. Research suggests that FOs may be able to reduce the pain and increased pressure bearing on the front of the foot (forefoot) resulting from RA. However, although guidelines for foot care for people with RA typically recommend the use of FOs in the management of those with relevant foot problems, there isn't enough evidence that is it beneficial and more research in this area is still needed. In addition, the term "foot orthoses" describes a highly variable range of devices designed to change how the foot works that may differ in terms of materials used to male the device, material properties, dimensions, additional design features, and degree of customisation. There are currently no treatment guidelines regarding what the specific types of FOs provide the greatest therapeutic benefits for people with RA. FOs can be either customised, made from a mould or scan of an individual patients foot or "off-the-shelf" (prefabricated). The customised FO is considered the "gold standard" (despite no strong evidence that proves this is the case), but take longer to make than fabricated FOs and are more expensive. The prefabricated FOs approach is considered to be less expensive, are usually fitted in one sitting (unlike the customised FOs) and can be fitted at the initial consultation. Another issue yet to be explored is when to use an FO to treat RA. Many people with RA suffer from foot joint arthritis within two years of diagnosis. Some research has demonstrated that earlier treatment with FOs for patients with RA reduces foot pain and disability. This study looks at comparing the performance and cost-effectiveness of customised against prefabricated FOs fir the treatment of patients with early RA foot pain.

Who can participate?
Adults aged 18-65 diagnosed with RA within the last two years.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given prefabricated FOs. These are off-the-shelf insoles that can be adapted to fit and have a cushioning for the front of the foot. Those in group 2 are given customized FOs, based on the individuals foot shape. All participants are then followed up six months later and again after a year to see if their FO is of benefit.

What are the possible benefits and risks of participating?
By taking part in the study, participants will undergo a detailed examination of their feet by a Podiatrist which might not normally be undertaken. If as a result of these examinations any problems are detected, the Podiatrist will discuss this with them and organise treatment if required. Adverse effects of wearing FOs are rare and relatively minor, ranging from mild discomfort to minor abrasions from friction against the skin. In order to minimise these , podiatrists will review comfort and fit of the FOs at an initial fitting appointment, and at a further review appointment following at least 6 weeks of wearing time (as would be done in normal clinical practice). Should participants experience any discomfort in the meantime, they will be able to self-refer for an additional review appointment for adjustment of the FO.

Where is the study run from?
Four NHS trusts in the UK

When is the study starting and how long is it expected to run for?
June 2015 to June 2019

Who is funding the study?
Dr William M. Scholl Podiatric Research and Development Fund

Who is the main contact?
Dr Kellie Gibson

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.2

Study information

Scientific Title
A randomised controlled trial (RCT) of prefabricated versus customised foot orthoses for people with rheumatoid arthritis (RA): the FOCOS RA trial [Foot Orthoses – Custom v Off-the-Shelf in RA].

Acronym
FOCOS-RA

Study objectives
H0 There will be no difference between the experimental and control groups in terms of pain (measured using the primary outcome measure – the FFI pain subscale) following exposure to intervention (at 6 and 12 months from baseline).
H1 There will be a significant difference between the experimental and control groups in terms of pain (measured using the primary outcome measure – the FFI pain subscale) following exposure to intervention (at 6 and 12 months from baseline).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England- Essex Research Ethics Committee, 24/12/2015, ref: 15/EE/0410
Amendment:14/12/2016, ref:15/EE/0410

Study design
Multicentre, two arm parallel superiority randomised controlled trial design.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Early rheumatoid arthritis

Interventions
For the purposes of this study, participants will be randomised to receive prefabricated (experimental) or customised (control) foot orthoses. Prefabricated orthoses are off-the-shelf insoles with adaptable elements such as clip on wedges, the addition of a cushioning forefoot cover which come in a range of sizes. Customised orthoses are based on the individuals foot shape, in this case collected using a foam box impression. This is manufactured based on the Podiatrists prescription from a biomechanical assessment and manufactured in a commercial lab. For this study, we have developed a protocol-driven intervention prescription plan for both arms of the study to ensure fair comparison between the two devices.

For both intervention arms, each participant will receive a minimum of 2 one-to-one sessions with the podiatrist pertaining to the foot orthoses interventions:-

Session 1. All participants will be assessed in order to inform their foot orthoses prescription. During this session participants will receive standard podiatry co-interventions. In the prefab foot orthoses arm only, participants will receive their foot orthoses at this session following the assessment by the podiatrist (this is in line with routine clinical practice for prefab foot orthoses – which can be provided ‘off-the-shelf’ on the same day). The podiatrist will check fit-to-feet, and fit-to-shoe or the orthotic, and will seek subjective information from the participant concerning initial comfort and fit. This appointment will take approximately 45 minutes.

Session 2 [custom arm only]. Participants in the custom foot orthoses arm a will return for the fitting of either their customised foot orthoses within 2-3 weeks of their session 1 appointment (this is in line with routine clinical practice where there is a gap between initial assessment and fitting to allow for manufacture of the custom device). At fitting stage, the podiatrist will check fit-to-feet, and fit-to-shoe or the orthotic, and will seek subjective information from the participant concerning initial comfort and fit. This will take approximately 20 minutes.

Session 3. All participants will return for a review of their orthotic device 6-8 weeks after initial fitting of the respective orthotic device at either session 1 (prefab) or session 2 (custom). At this appointment the podiatrist will repeat the initial assessments that led to the prescription to ensure the orthotic device is still appropriate for each participant. The podiatrist will review

subjective information from the participant concerning comfort, fit, and self-reported efficacy, including whether or not there has been any change in symptoms and/or short-term benefit over the previous 6-8 weeks. This will take approximately 20 minutes.

Unscheduled foot orthoses review sessions. From initial fitting of foot orthoses to the end of the trial period at 12 months from baseline, self-referral for review of foot orthoses will be permitted for participants in either treatment arm where there are adverse reactions, and/or loss of or damage to foot orthoses. To facilitate this, participants will be provided with a number to contact in order to book unscheduled foot orthoses review sessions. This will take approximately 20 minutes.

The participants will attend 3 appointments with the outcome assessor to collect primary and secondary outcome measures. These will occur at baseline, 6 months and 12 months.

Intervention Type
Device

Primary outcome measure
Foot function. It will be calculated at 12 months using the Foot Function Index pain subscale (FFIpain), which is a composite score for foot pain. The FFI is a widely used, valid and reliable self-administered questionnaire consisting of 23 items grouped into 3 domains: foot pain (9 items), disability (9 items), and activity limitation (5 items). For each subscale, items are rated using a 100mm visual analogue scale (VAS), and a composite score is calculated by summing item and dividing by the total number of items in that subscale. A higher score is indicative of more severe foot pain and disability.

Secondary outcome measures
1. Foot related disability (Foot Functional Index- FFI and Leeds Foot Impact Scale- LFIS subscales)
2. Localised foot disease activity (RADAIF5)
3. Global disability (Health Assessment questionnaire- HAQ)
4. Health related quality of life (HRQoL) (EQ5D 5L)

All measured at baseline, 6 and 12 months following intervention with either custom or prefabricated FOs.

5. A satisfaction questionnaire used to measure orthotic device comfort, fit, and self-reported efficacy symptoms and activity levels, at baseline, 6 and 12 months
6. A small random sample of participants will be invited to take part in an interview to explore experiences of the interventions and perceptions of improved/deteriorated outcomes
7. Global disability will be measured using the Stanford Health Assessment questionnaire, collected at baseline, 6 and 12 months
8. Global disease activity will be measured using the Disease activity Score using 28 joints (DAS28), collected at baseline, 6 and 12 months
9. Disease duration will be recorded as the time in months from onset of symptoms and time in months from disease diagnosis as self-reported by the patient. Collected at baseline, 6 and 12 months.
10. Reproducibility of the Rheumatoid Arthritis Foot Disease Activity Index (RADAI-F5), collected at baseline and 1 week later

Overall study start date
01/06/2015

Completion date
30/06/2019

Eligibility

Key inclusion criteria
Current Inclusion Criteria (06/03/2018):
1. Are aged over 18 years old, male/female
2. Have been diagnosed with RA <2 years previously based on the 2010 ACR/EULAR classification criteria 3. Meet the minimum threshold score of ≥20mm on a visual analogue scale for foot pain which is localised to any one of the following: MTP joints, midfoot, rearfoot, and/or periarticular tendons surrounding the ankle/subtalar joints.
4. If any rearfoot or forefoot bony deformity or malalignment is present, this must be passively correctable as tested through a range of motion assessment.
5. Must not have worn foot orthoses in the previous 6 weeks if provided prior to RA diagnosis or anytime post diagnoses.

Previous Inclusion criteria:
1. Are aged 18-65 , male/ female
2. Have been diagnosed with RA <2 years previously based on the 2010 ACR/EULAR classification criteria.
3. Meet the minimum threshold score of ≥20mm on a visual analogue scale for foot pain which is localised to any one of the following: MTP joints, midfoot, rearfoot, and/or periarticular tendons surrounding the ankle/subtalar joints
4. Have any rearfoot or forefoot bony deformity or malalignment is present, this must be passively correctable as tested through a range of motion assessment
5. Are foot orthotic treatment naïve

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
216 (108 in each arm)

Key exclusion criteria
1. They have been diagnosed with any neurological or endocrine diseases such as diabetes which could potentially affect peripheral nerves, foot structure, function and pain perception
2. They have any trauma or injury affecting the musculoskeletal systems of the lower limb of foot.

3. They do not have early RA
4. They do not meet the minimum threshold for foot pain
5. They are not orthotic-treatment naïve

Date of first enrolment
01/03/2016

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Homerton University Hospital
London
United Kingdom
E9 6SR

Study participating centre
NHS Ayrshire and Arran
United Kingdom
KA6

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/057jrqr44

Funder(s)

Funder type
Charity

Funder Name
Dr William M. Scholl Podiatric Research and Development Fund

Results and Publications

Publication and dissemination plan
We intend to publish at least 3 articles. One will outline the clinical outcomes of the study, the second will concentrate on the embedded cost effectiveness study and the third, the qualitative aspect discussing participant's opinions of the interventions in relation to their joint pain. We anticipate these publications will take place between June and September 2017.

From January 2017 will disseminate results at various relevant conferences either via poster or oral presentations.

Intention to publish date
30/09/2017

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/05/2018		Yes	No
Other publications		13/08/2021	27/10/2022	Yes	No
HRA research summary			28/06/2023	No	No