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Foot orthoses for children with flat feet (the OSTRICH trial)

Submission date
27/03/2020

Recruitment status
No longer recruiting

Registration date
18/05/2020

Overall study status
Completed

Last Edited
04/06/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
As a child grows the shape of their foot changes, and most develop an arch in their foot. This doesn't always happen though, and sometimes the arch does not form, or it might be flat against the ground. When this happens, it is known as having flat feet. Unfortunately, some of these children get pain in their feet, legs or back because of their 'flat feet'. At the moment the researchers are not sure which is the best treatment for them, so the researchers are going to conduct a study to compare two of the most common treatments that are used today. The first is exercise and advice about things like which types of shoes might help. The second is a type of insole, which is put inside the shoe.

Who can participate?
Patients aged between 6 and 14 years and have one or both symptomatic pes planus.

What does the study involve?
If a young person and their parent, or guardian, decide that they want to take part in the study, they will receive their treatment as part of their normal NHS care. The researchers will ask 478 children aged between 6 and 14 years to take part in the study. 239 children will receive insoles that are the correct size but not custom made (i.e. off the shelf); and 239 will receive the exercise programme and advice without insoles. The researchers will ask for their help for 12 months. During this time, the researchers will track their progress by sending them three questionnaires in the post to fill in and the researchers will send them some text messages, to find out how painful their feet are in the first few months. The researchers also want to learn more about the problems that flat feet have caused, and children's experiences of the treatments delivered as part of the trial. The researchers will explore this through in-depth conversations with children and their parents or guardian. Once the researchers have finished the trial, the researchers will work with the people who took part in the trial and clinicians, to make sure that our results can be used by as many people as possible.

What are the possible benefits and risks of participating?
There may not be many direct benefits of participating in this trial as the treatments are provided in routine care. However, if enough people take part in the study, the results will provide valuable information about the best way to manage children with painful flat feet in the

future. Equally, we do not think that taking part in the trial poses any additional risks for participants as the treatments are used in routine care. Taking part in the study will involve some of your time to complete questionnaires, texts and possibly an extra visit to the clinic.

Where is the study run from?
York Trials Centre, University of York (UK)

When is the study starting and how long is it expected to run for?
September 2020 to August 2023

Who is funding the study?
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Who is the main contact?
Caroline Fairhurst, caroline.fairhurst@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/trials/research/trials/ostrich

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282832

ClinicalTrials.gov number
NCT04104555

Secondary identifying numbers
CPMS 44513, IRAS 282832

Study information

Scientific Title
Orthotics for Treatment of Symptomatic Flat Feet in Children - The OSTRICH study

Acronym
OSTRICH

Study objectives
Current study hypothesis as of 19/11/2021:
There is a difference in the clinical effectiveness of prefabricated orthoses in addition to advice and exercise alone on the physical functioning of children with symptomatic pes planus.

Previous study hypothesis:
There is a difference in the clinical effectiveness of custom-made and prefabricated orthoses in addition to advice and exercise alone on the physical functioning of children with symptomatic pes planus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/08/2020, North East York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 104 8091; york.rec@hra.nhs.uk), ref: 20/NE/0173

Study design
Interventional randomized controlled trial including a qualitative study within a trial and economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

Interventions
Current intervention as of 27/02/2023:
To mitigate the effect of the COVID-19 pandemic and as many sites have been unable to deliver the 3-arm trial design and struggled with the provision of custom insoles the funder and ethics approved a change in design to the study and agreed the custom insole arm of the trial could be dropped.

Participants will be allocated in a 1:1 ratio to one of two groups in the trial:
1. A package consisting of an exercise programme and advice covering topics such as typical arch development in children, coping strategies, and footwear advice
2. The exercise and advice package plus a pair of prefabricated, off-the-shelf orthoses (i.e., insoles which are mass-produced to a generic shape but can be adapted by a clinician)

The participant will be informed which group they have been allocated to at their first trial appointment. Participants will be asked to wear their orthoses every day in their shoes and to do their exercises. Participants in group 1 will, overall, need one clinic appointment, but those in group 2, may need a total of 2 or 3 appointments. Blinding participants to the treatment allocation is not possible.

Measures will be collected at baseline, weeks 1-12, and at three, six, and 12 months after a participant is enrolled on the study. The measures are all self-reported by either the participant or their parent/legal guardian.

Birthday card study
In the birthday card SWAT, the researchers will evaluate whether sending a participant a birthday card increases the number of questionnaires they return to the study team. Participants will be allocated to one of two groups: a birthday card, or no birthday card. The birthday card will be developed with the help of a patient and public involvement group.

Sites will have the option to undertake an embedded observational sub-study that explores the variation in foot shape using a 3D scanning approach. Foam impression boxes will be used to capture the 3D shape of the participant’s feet. These will be scanned using a 3D scanner to enable the construction of the computer model. Participants will complete a second impression 12 months later. This will allow us to explore i) variation in foot shape; ii) whether foot shape influences response to therapy within the main trial iii) how a child's foot changes over 12 months and whether orthoses influence this change.

Previous intervention as of 19/11/2021 to 27/02/2023:
In order to mitigate the effect of the COVID-19 pandemic and as many sites have been unable to deliver the 3 arm trial design and struggled with the provision of custom insoles the funder and ethics approved a change in design to the study and agreed the custom insole arm of the trial could be dropped.

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2. The exercise and advice package plus a pair of prefabricated, off-the-shelf orthoses (i.e. insoles which are mass-produced to a generic shape but can be adapted by a clinician)

The participant will be informed which group they have been allocated to at their first trial appointment. Participants will be asked to wear their orthoses every day in their shoes and to do their exercises. Participants in group 1 will, on the whole, need one clinic appointment, but those in group 2, may need a total of 2 or 3 appointments. Blinding of participants to the treatment allocation is not possible.

Measures will be collected at baseline, weeks 1-12, and at three, six, and 12 months after a participant is enrolled into the study. The measures are all self-reported by either the participant or their parent/legal guardian.

Birthday card study
In the birthday card SWAT, the researchers will evaluate whether sending a participant a birthday card increases the number of questionnaires they return to the study team. Participants will be allocated to one of three groups; birthday card, birthday card informed by nudge theory to encourage completion of questionnaires or no birthday card. The birthday card will be developed with the help of a patient and public involvement group.

Previous intervention:
Participants will be allocated to one of three groups:
1. A package consisting of an exercise programme and advice covering topics such as typical arch development in children, coping strategies, and footwear advice
2. The exercise and advice package plus a pair of prefabricated, off-the-shelf orthoses (i.e. insoles which are mass produced to a generic shape but can be adapted by a clinician)
3. The exercise and advice package plus a pair of custom-made foot orthoses, where the shape of the insole is made for a specific person based on a 3D impression or scan of the patient's foot

The participant will be informed which group they have been allocated to at their first trial appointment. Participants will be asked to wear their orthoses every day in their shoes and to do their exercises. Participants in group 1 and 2 will on the whole, need one clinic appointment, but those in group 3, may need a total of 2 or 3 appointments. Blinding of participants to the treatment allocation is not possible.

Measures will be collected at baseline, weeks 1-12, and at three, six and 12 months after a participant is enrolled into the study. The measures are all self-reported by either the participant or their parent/legal guardian.

Birthday card study
In the birthday card SWAT, the researchers will evaluate whether sending a participant a birthday card increases the number of questionnaires they return to the study team. Participants will be allocated to one of three groups; birthday card, birthday card informed by nudge theory to encourage completion of questionnaires or no birthday card. The birthday card will be developed with the help of a patient and public involvement group.

Intervention Type
Mixed

Primary outcome measure
Physical domain subscale of the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C); Timepoint(s): Over the 12-month follow up period

Secondary outcome measures

1. The well-being of children measured using the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C) other domains at 3, 6 and 12 months
2. Quality of life measured using the CHU9D at 3, 6 and 12 months
3. Mobility, ability to look after themselves, doing their usual activities, whether they have any pain or discomfort and if they feel worried, sad or unhappy measured using the EQ-5D-Y at 3, 6 and 12 months
4. Foot pain scores reported by parents once a week, for a total of 12 weeks on a scale of 0 to 9
4.1. Participants foot pain, over the past week, for both their left and right foot using the Wong-Baker FACES pain rating scale at 3, 6 and 12 months
5. Complications and adverse events. Information about any problems participants have had whilst either wearing the insoles or doing the exercises will be recorded as they happen. Expected complications such as aches and pains, blisters, ulcers, skin irritation and falling will be recorded in the follow-up questionnaires sent to participants at 3, 6 and 12 months
6. Health care use by self-report at 3, 6 and 12 months
7. Qualitative interview of children and parents to find out about their experiences of having flat feet, at the start and the end of the study
8. SWAT outcome: number of questionnaires returned throughout the study period

Overall study start date
01/06/2019

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. Are aged between 6 and 14 years, inclusive
2. Have one or both symptomatic pes planus*
3. The child and/or parent/legal guardian is able to speak, write and understand English
4. The parent/legal guardian is able to give informed consent

*Symptomatic pes planus is described as the manifestation of foot and lower limb symptoms, secondary to altered foot alignment (reduced medial longitudinal arch, everted rearfoot and abducted forefoot). The diagnosis will be made pragmatically, by treating clinicians in line with current practice.

Eligibility for the Birthday card SWAT
All participants recruited into the host trial will be eligible to take part in this SWAT.

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
14 Years

Sex
Both

Target number of participants
478

Total final enrolment
134

Key exclusion criteria
1. Have a history of major trauma or fracture to lower leg (below knee)
2. Have pes planus secondary to any systematic condition/syndrome**/malignancy
3. Have a history of foot and/or ankle surgery
4. Require an ankle-foot orthosis or other lower limb device
5. Have previously received treatment for pes planus

** This does not exclude children with hypermobility spectrum disorder (HSD) where the manifestation is non-syndromic and isolated (L-HSD), peripheral (P-HSD) or generalised hypermobility (G-HSD)

Eligibility for the Birthday card SWAT
Participants will be excluded from this study if they have asked to be withdrawn from the main OSTRICH study.

Date of first enrolment
21/04/2022

Date of final enrolment
26/07/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Birmingham Community Healthcare NHS Foundation Trust
3, Priestley Wharf
Holt Street
Birmingham Science Park
Aston
Birmingham
United Kingdom
B7 4BN

Study participating centre
The Royal Bolton Hospital
Bolton NHS Foundation Trust
Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre
Cardiff and Vale University Health Board
Cardiff and Vale UHB Headquarters
University Hospital of Wales (UHW)
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Macclesfield District General Hospital
East Cheshire NHS Trust
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Harrogate District Hospital
Harrogate and District NHS Foundation Trust
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust
Sceptre Point
Sceptre Way
Bamber Bridge
Preston

United Kingdom
PR5 6AW

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Diana Princess of Wales Hospital
Northern Lincolnshire and Goole Nhs Foundation Trust
Scartho Road
Grimsby
United Kingdom
DN33 2BA

Study participating centre
Leeds Community Healthcare Nhs Trust
Stockdale House
8 Victoria Road
Leeds
United Kingdom
LS6 1PF

Study participating centre
Walsgrave General Hospital
University Hospitals Coventry and Warwickshire Nhs Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road

Southampton
United Kingdom
SO16 6YD

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
United Kingdom
HA7 4LP

Study participating centre
Kent Community Health NHS Foundation Trust
Unit D
The Oast
Hermitage Lane
Maidstone
United Kingdom
ME16 9NT

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre
Walsall Healthcare NHS Trust
Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
South Tees Hospitals NHS Foundation Trust
James Cook University Hospital
Marton Road

Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Medway Community Healthcare
21 Bailey Drive
Gillingham Business Park
Gillingham
United Kingdom
ME8 0PZ

Study participating centre
Royal Cornwall Hospitals NHS Trust
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United Kingdom
TR1 3LJ

Study participating centre
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michael.barber@york.ac.uk

Sponsor type

University/education

Website
http://www.york.ac.uk/

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR127510

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings from this trial will be disseminated at appropriate professional and scientific conferences and published in appropriate journals. Findings will also be disseminated to patient groups and the wider public.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

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