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Synopsis

OrthoticS for TReatment of symptomatic flat feet In CHildren (OSTRICH): a randomised controlled trial

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Abstract

Background: Children and young people with symptomatic pes planus (flat feet) often seek treatment from healthcare professionals. There are various treatment options, but there is a lack of high-quality evidence about which is most effective.

Objectives: To assess the clinical and cost-effectiveness of prefabricated orthoses, plus exercise and advice, compared with exercise and advice alone on physical function, measured using the physical domain of the Oxford Ankle Foot Questionnaire for Children, among children with symptomatic pes planus.

Design and methods: A pragmatic, multicentre, two-armed individually randomised controlled trial with an internal pilot, economic evaluation and qualitative study.

Setting and participants: Children and young people aged 6–14 years with symptomatic flat feet were recruited from hospital or community healthcare facilities in England and Wales. Participants were randomised 1 : 1 using a secure web-based randomisation system and followed up for up to 12 months.

Interventions: We planned to provide all participants with advice and exercises, with the intervention group also receiving a prefabricated orthosis. Due to the nature of the study treatments, blinding of participants or the research team was not possible.

Main outcome measures: The primary outcome was the physical domain subscale of the Oxford Ankle Foot Questionnaire for Children over the 12-month follow-up. Secondary outcomes included the physical domain subscale at 3, 6 and 12 months, and the 'School and Play' and 'Emotional' domains of the Oxford Ankle Foot Questionnaire, pain scores, healthcare resource use, EQ-5D-Y and Child Health Utility 9D at all time points. The qualitative study

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drew on health literacy and health belief perspectives and examined fidelity and explored the experiences of being in the trial for those receiving and delivering the study treatments.
Results: COVID-19 severely delayed trial set-up and recruitment and the study closed before meeting its recruitment target. Of 549 participants assessed for eligibility, 134 were randomised (intervention *n* = 70, control *n* = 64). The mean age of participants was 10.6 years (range 6.3–14.8) and 55.2% were male. No adverse events were reported. The planned statistical and health economic analyses could not be fully conducted due to the limited data. The qualitative study identified pain, posture and gait as the most common concerns by participants with pain relief as the primary motivator for seeking health care. Participants generally reported little understanding of their condition with barriers including misattribution (e.g. growing pains). Misinformation was common emphasising a need for accessible accurate education materials and structured follow-up care. There was a common belief that orthoses were superior to exercises leading to high levels of adherence, satisfaction and outcomes with orthoses compared with poor adherence, and low perceived efficacy with exercises linked to challenges incorporating these into daily routines.
Limitations: We could not deliver the study objectives as planned. Due to the limited data available, we were unable to undertake the planned analysis.
Conclusions: The COVID-19 pandemic significantly impacted trial set-up and recruitment. Extending the study was not feasible due to cost and time constraints.
Future work: The evidence for the clinical and cost-effectiveness of orthotics for the treatment of symptomatic flat feet in children remains inconclusive and an area for further research.
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Introduction

This report details the Orthotics for Treatment of Symptomatic Flat Feet in Children (OSTRICH) trial, the aim of which was to compare the clinical and cost-effectiveness of two widely used treatments for flat feet: exercise and advice alone; and exercise, advice and prefabricated insoles. It arose from a call commissioned by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme. However, ultimately, we could not deliver the study objectives as planned within a reasonable time frame and cost, due to the problems with setting up sites and recruiting participants during and after the COVID-19 pandemic.

Background

In most children, pes planus (flat feet) are physiologically normal, asymptomatic and part of the typical developmental trajectory of the feet.[1,2] However, it has been estimated that around 1% of children develop symptoms associated with their foot posture[3] including foot and ankle pain, which can lead to reduced engagement with physical and childhood activities.[4] Effectively managing the burden of foot and ankle issues in children with symptomatic pes planus is crucial for maintaining their activity levels and supporting their healthy physical, and their social and psychological development.[5] Pes planus has been described as one of the most common conditions seen in paediatric practice[6,7] and the most common reason for attending paediatric orthopaedic clinics.[8] However, management options for symptomatic pes planus vary considerably across the country and there is a lack of high-quality evidence to inform clinical practice. A systematic review for paediatric pes planus[9] reiterated the need for 'robust, adequately powered randomised trials to inform current evidence'. The OSTRICH study was commissioned in response to a call from the NIHR HTA programme, asking 'What is the clinical and cost-effectiveness of using foot orthoses (insoles) for children with symptomatic flat feet? And, if orthoses are effective, is there added benefit of customised foot orthoses?'.

Aims and objectives

The primary aim of this study was to compare the clinical effectiveness of prefabricated orthoses in addition to exercise, and education and advice about footwear, and exercise and advice alone on the physical functioning of children with symptomatic pes planus, as measured by the physical domain of the Oxford Ankle Foot Questionnaire for Children (OxAFQ-C). The main objectives were to:

1. Compile a menu of acceptable orthoses, exercises, and education and advice to be used in the trial.
2. Conduct an internal pilot trial to review recruitment and retention to the study.

3. Compare the clinical effectiveness of prefabricated orthoses in addition to exercise and advice with exercise and advice alone on the physical functioning of children and young people with symptomatic pes planus in a randomised controlled trial (RCT).
4. Estimate the cost-effectiveness of the prefabricated orthoses in addition to exercises and advice compared with exercise and advice alone.
5. Use qualitative approaches to (1) understand the experiences of young people and their families with symptomatic pes planus and explore common strategies used to manage the condition, (2) explore their experience of using the interventions in the trial and (3) explore with clinicians the barriers and facilitators to delivering the trial.
6. Undertake an assessment of fidelity of the intervention.
7. Undertake a recruitment Study within a Trial (SWAT) to evaluate the effectiveness of providing multimedia information (MMI), consisting of a graphical web page and an animation, to convey the study information to potential participants to improve trial recruitment.
8. Undertake a retention SWAT to evaluate the effectiveness of sending a birthday card to participants on questionnaire response rates.

Methods

Consensus meetings

The first aim of the study was to produce a list of acceptable exercises and orthoses to be used in the trial. These lists were developed during the two consensus meetings which were held in the set-up phase of the study. This process has been reported elsewhere[10] and so will not be covered in this report.

Regulatory approval

Research ethics approval for the study was obtained from the Health Research Authority – North East – York Research Ethics Committee (REC) (20/NE/0173) and the Health Research Authority and Health and Care Research Wales on the 6 August 2020. Local NHS trusts confirmed capacity and capability to run the study within their organisation. Protocol amendments submitted to the REC are detailed in *Appendix 1*, *Table 6*.

The OSTRICH design was to be a pragmatic, multicentre, two-arm, open RCT with an internal pilot and embedded qualitative and economic evaluations. Full details of the study are published as a protocol[11] with key information summarised in *Table 1*.

TABLE 1 Summary of study protocol

Recruitment	Participants were recruited from NHS providers in primary or secondary care and other independent businesses that provide health care (i.e. Social Enterprises or Community Interest Companies) in England and Wales.
Eligibility	Inclusion criteria All the following criteria needed to be met for patient inclusion in the OSTRICH trial: • Aged between 6 and 14 years inclusive, with symptomatic pes planus of one or both feet[a] • The young person and/or parent/legal guardian was able to speak, write and understand English • The parent/legal guardian was able to give informed consent Exclusion criteria Potential participants were excluded from the study if any of the following applied: • Had previously received treatment for pes planus (i.e. any treatment in the last 3 months, had taken part in an exercise intervention or used health professional prescribed insoles) • Had a history of major trauma or fracture of the lower leg (below knee) • Had pes planus secondary to any systemic condition/syndrome[b]/malignancy • Required an ankle–foot orthoses or other lower limb device • Had a history of foot and/or ankle surgery

continued

TABLE 1 Summary of study protocol (*continued*)

Sample size	We planned to recruit and randomise 478 participants to the OSTRICH study in a 1 : 1 ratio, allowing for 20% attrition at 12 months to provide 90% power (two-sided alpha of 0.05) to detect a difference of eight points on the physical domain subscale of the OxAFQ-C over a 12-month follow-up period, between the two groups, assuming a standard deviation of 24 (StataCorp. 2013, Stata Statistical Software: Release 15, College Station, TX: StataCorp LP).
Randomisation	Eligible consenting participants who had completed baseline data were randomised using the York Trials Unit's remote, secure, web-based randomisation system. The allocation sequence was generated by an independent statistician who was not involved in the recruitment of participants. Block randomisation stratified by hospital trust with randomly varying block sizes was used.
Intervention and control groups	Participants were randomly assigned 1 : 1 to either the intervention (prefabricated insole, foot strengthening and stretching exercises and advice) or control (exercises and advice only) group. Education and advice covered areas such as suitable footwear and how to maintain participation/activity.[10] All participants were offered an exercise programme and advice regarding footwear and foot health. Exercises were selected from a menu compiled during the consensus meetings.[10] Sites had free access to the Physiotec exercise app.[12] Participants allocated to the intervention group were also offered one pair of CE/UKCA marked prefabricated orthosis from a list compiled during the consensus meetings.
Data collection	We planned to follow up participants with postal questionnaires at 3, 6 and 12 months post randomisation to collect data on patient self-reported outcomes. Weekly texts collecting pain scores were sent to the parent/legal guardian for 12 weeks from the point of randomisation, and then at 6 and 12 months post randomisation. Adverse events were reported by participants or members of the research team at sites.
Primary outcome	The planned primary outcome was the physical domain subscale (six items) of the child-reported OxAFQ over the 12-month follow-up.
Secondary outcomes	Planned secondary outcomes included: foot pain scores over the past week, proxy (parent/guardian)-completed OxAFQ-C physical domain, 'School and Play' and 'Emotional' subscales and the 'Footwear' item, quality of life using Child Health Utility 9D, EQ-5D-Y, adherence to wearing insoles and undertaking exercises, all at 3, 6 and 12 months; and qualitative interviews.
Recruitment SWAT	Cluster randomised (at site level) trial of multimedia information vs. standard written information given to potential participants before enrolment to increase recruitment to the study.
Retention SWAT	Individually randomised trial of sending a birthday card vs. no birthday card on retention to the study as measured by return of follow-up questionnaires.

a Symptomatic pes planus was 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 was made pragmatically by treating clinicians in line with their current practice.
b This did not exclude children/young people with hypermobility spectrum disorder (HSD) where the manifestation was non-syndromic and isolated (L-HSD), peripheral (P-HSD) or generalised hypermobility (G-HSD).[13]

Protocol changes

We initially designed a three-arm trial to evaluate both prefabricated and custom-made orthoses with exercises and advice compared to exercise and advice alone, with participants randomised in a 2 : 2 : 1 ratio. However, the COVID-19 pandemic transformed healthcare provision with a decreased access to healthcare services, a large reduction in the number of face-to-face appointments and prioritisation of patients with higher risk pathologies and higher medical need than pes planus.[14] In addition, many sites were struggling with the provision of custom-made orthoses which caused significant delays in setting up study sites. A decision was therefore made, prior to the start of recruitment, to drop the custom-made orthoses arm of the study and randomise participants in a 1 : 1 ratio to either exercise and advice alone or exercise and advice plus prefabricated orthoses. An additional advantage of removing this arm of the study was a reduction in the overall sample size from 1055 to 478 which we hoped would increase the chances of successful delivery and completion of the study.

Table 2 reports the timeline of the key study milestones, both as planned and as observed. The project commenced in June 2019, and we planned for a 6-month site set-up phase before starting recruitment in December 2019. However, significant delays were incurred, initially due to a protracted regulatory approval process and later the COVID-19 pandemic. In March 2021 we received a 10-month funded extension which allowed us to extend

TABLE 2 Timelines of key planned and actual milestones on the OSTRICH study

Year	Month	Original planned milestones	Planned milestones given 10-month extension	Issues	Actual milestones
2019	June	Start of grant.			Start of grant.
2019	September	Submit application for regulatory approval.		Reduced capacity by Sponsor to review the Integrated Research Application System application delayed submission.	
2019	November	Regulatory approval received.			
2019	December	Start recruitment to pilot phase.		Regulatory approval delayed: REC reviewed the application but gave an unfavourable opinion and did not allow the study team to respond to the issues raised. Application had to be resubmitted.	Submit application for regulatory approval
2020	February–March	End of recruitment to pilot phase.			
2020	May				
2020	June	Start recruitment to main trial.		Regulatory approval not in place.	Submitted application for regulatory approval.
2020	August			COVID-19 delayed opening sites.	Regulatory approval received.
2021	May	End recruitment to main trial.	Recruitment begins	COVID-19 delayed opening sites.	
2022	March	–	Recruitment ends	Extension to recruitment period needed to achieve recruitment target.	First site opened 1 March 2022. Start recruitment to pilot phase.
2022	April	–	–		
2022	May	End of follow-up.			
2022	September				End recruitment to pilot phase.
2022	October				Start recruitment to main trial.
2022	December	Analysis completed and final report submitted.			
2023	March	–	End of follow-up.	Knock-on effect of delayed recruitment impacted the end of follow-up date.	
2023	May		–		End recruitment to main trial. Decision made to close the study after completion of 3-month follow-up.
2023	August				Final follow-up of participants.
2023	October	–	Analysis completed and final report submitted.		Analysis completed and final report submitted.
2024	January				

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the end of the study from 30 November 2022 to 30 September 2023. Recruitment finally began in March 2022. An application for a further funded extension was submitted to the HTA in March 2023. In May 2023 the funder informed the study team that the extension request could not be supported due to concerns with the study's progress, in particular the poor recruitment and low retention rates at the 3-month time point. Following discussion with the study team and with the support of the independent members of the Trial Steering Committee (TSC), it was felt that the study was not feasible, and it was suggested that the study be closed. The funder agreed with the decision, and the trial was closed on the 31 August 2023.

Statistical methods

While a comprehensive analysis to investigate the clinical and cost-effectiveness of the OSTRICH intervention was planned as detailed in the trial protocol, due to the trial closing prior to attaining the required recruitment target, the limited data are only summarised descriptively [Stata v18 (StataCorp LP, College Station, TX, USA)]. No formal hypothesis testing was undertaken.

Qualitative work/intervention fidelity

To fulfil objective five, qualitative interviews were conducted with trial participants and staff from sites involved in local delivery to explore acceptability of, and adherence to, the trial treatments. Semistructured interviews were conducted via Microsoft Teams (Microsoft Corporation, Redmond, WA, USA) or telephone. Topic guides were used to facilitate the interviews which included a focus on interviewee experiences within the trial and acceptability of the treatment, to identify barriers and facilitators to delivery and acceptability of, and adherence to treatments. Following transcription, participants were provided with a copy of the transcripts to confirm that they were happy with the transcription. The interviews were subjected to reflexive thematic analysis.

Results

Challenges in study set-up and recruitment

Following project commencement in June 2019, we faced significant unexpected challenges resulting in long delays in setting up OSTRICH and starting recruitment. We originally allowed 6 months to set up the study and had 30 sites interested in recruiting to the study at the grant application stage. However, delayed regulatory approval and the COVID-19 pandemic had a significant impact on the study. *Figures 1* and *2* report a summary of the challenges we experienced in set-up and recruitment.

The impact of COVID-19 on set-up and recruitment

The set-up and planned recruitment to OSTRICH took place against the backdrop of the COVID-19 pandemic, which severely impacted the study. The grant commenced 10 months prior to the first UK COVID-19 lockdown (March 2020), therefore was attempting to set up and recruit in a period of unprecedented demand on research study sponsors, approval committees and NHS Trusts. Despite gaining ethical approval in August 2020, recruitment did not commence until March 2022. The reasons for the delay included: (1) recruitment to OSTRICH, like many other trials at this time, was put on hold by the NIHR from March 2020 to February 2021 to facilitate the running of COVID-19 trials within the NHS during the pandemic; (2) due to the accumulated backlog of applications for capacity and capability approval, many research and development (R&D) departments at potential trial sites were unable to review the OSTRICH application in a timely manner; this impacted study momentum at sites which had initially expressed an interest in taking part in the study; (3) once non-COVID-19 trials were reopened, some R&D departments only restarted studies that were open pre-pandemic, which did not include OSTRICH; (4) some R&D departments focused on opening studies which had larger sample sizes than OSTRICH, as there was the potential to recruit more participants; (5) some clinical site staff were redeployed to support front-line staff dealing with COVID-19 admissions, so they were unavailable to work on OSTRICH; (6) capacity within the clinics to see patients with flat feet was negatively affected, with clinicians initially prioritising more time-critical or severe pathologies and subsequently encountering challenges related to social distancing, which limited the number of patients seen in clinics and the ability to recruit to OSTRICH; and (7) while the study team considered remote clinic appointments, it was not possible to deliver the custom-made orthoses arm of the trial as the participant had to be seen in clinic. Overall, we were required to make reactive adaptations to our research plans in response to an uncertain service landscape. We streamlined the set-up and delivery of the trial by removing the custom-made orthoses intervention arm. We did reconsider delivering the trial using remote appointments; however, overall, the clinical members of the team considered this would not be feasible, and would affect the generalisability of the study's findings, once the pandemic was over.

Clinic capacity and delivery of the intervention

Waiting lists for appointments increased considerably post COVID and patients seeking treatment for flat feet were not prioritised.[14] Some sites experienced up to 8-week delays in starting recruitment once their site was

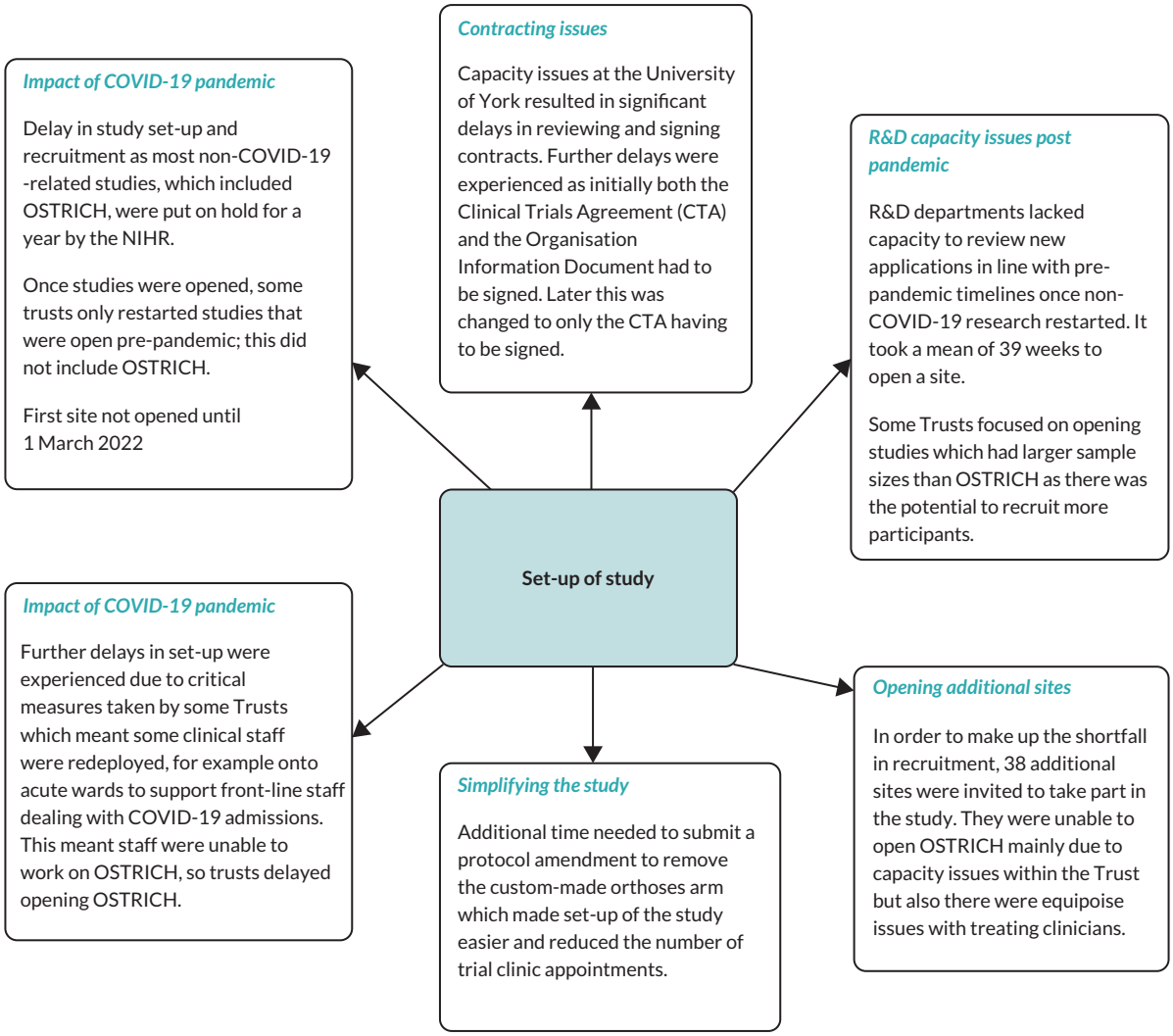

FIGURE 1 Summary of set-up challenges in the OSTRICH study.

given approval to open, due to lack of capacity within their clinics to see new patients. This was despite sites being asked to protect the delivery of some OSTRICH clinics in advance. Some sites were research naive, so were unfamiliar with the tasks required to enrol participants into the trial. Sites found it challenging to complete the additional tasks needed to recruit a patient in a routine appointment. In addition, it was not always feasible for research nurses to support the study as they were based in a different location within the Trust to where OSTRICH participants were being recruited. This meant some participants were not approached to take part in the study. Some sites ran OSTRICH-specific clinics, which had research nurse support and additional time to undertake trial tasks. However, some potential participants were not directed to these clinics as their referral letters, often from the general practitioner (GP), were unclear that the patient had flat feet, or they were unable to attend the OSTRICH-specific appointments, or some Trusts offered patients a 'choose and book' system, which could not accommodate OSTRICH trial appointments. This meant potentially eligible patients were not always invited to take part in the study or assessed for eligibility.

Patient preferences

Sites reported that some patients were reluctant to take part in the trial as patients believed that orthotics were the better treatment than exercise and advice alone. They were not willing to take a chance on being assigned to a treatment which did not include orthotics; instead, they opted for routine care in which they were likely to receive orthotics. This belief generally came either from research they had personally undertaken on the internet or from conversations with family and friends. This opinion was sometimes endorsed by their referring healthcare professional, who informed them that they were being referred for orthotics and may have had an opinion of the potential efficacy of orthoses as a treatment.

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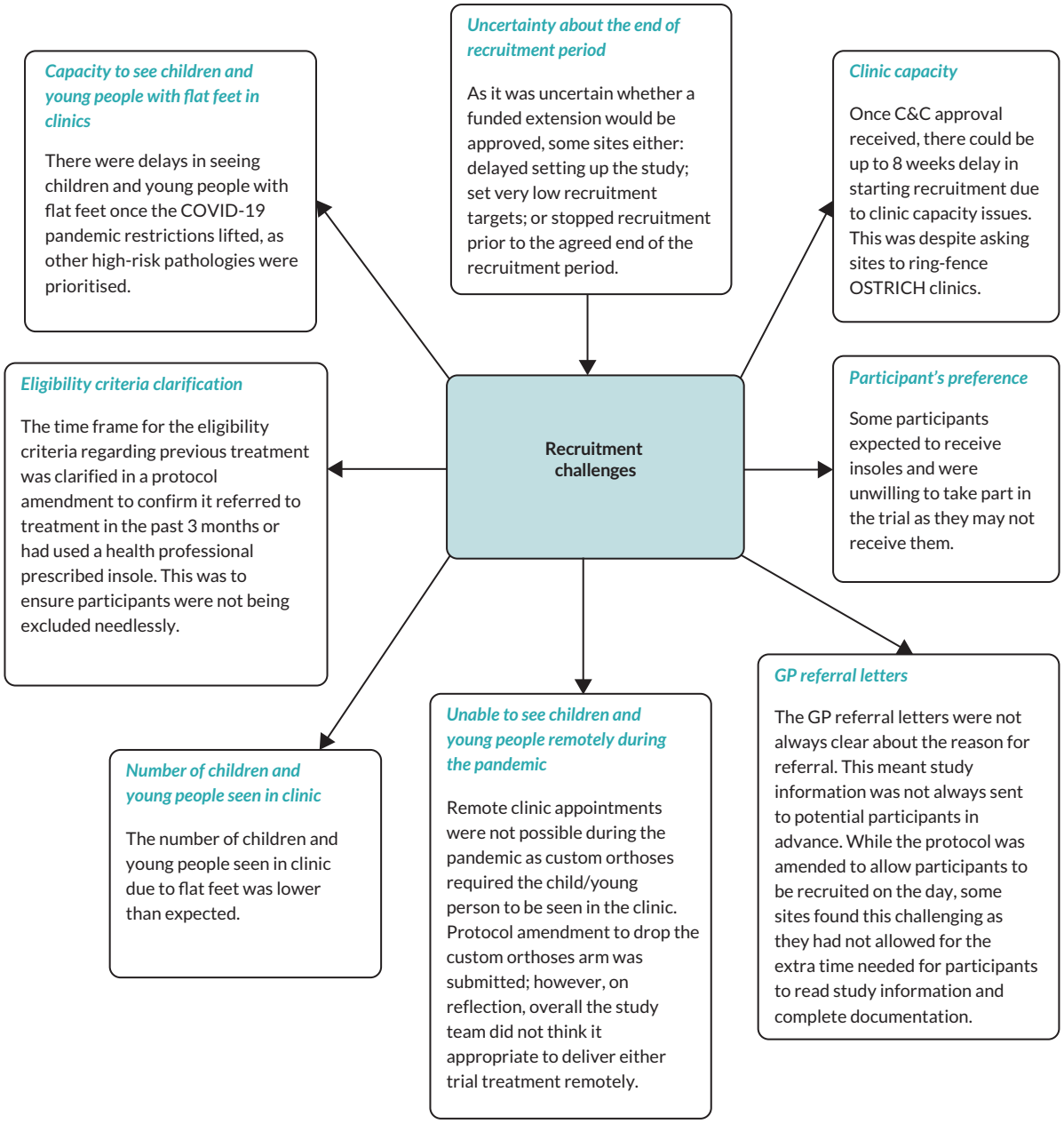

FIGURE 2 Summary of recruitment challenges in the OSTRICH study.C&C, capacity and capability.

Documentation

Study case report forms for the participant (see *Report Supplementary Materials 1–4*), their parent (see *Report Supplementary Materials 5–8*) and the clinician (see *Report Supplementary Materials 9* and *10*) were provided in paper format, as this was the standard method of collecting participant data used by the York Trials Unit (YTU) at the point of trial set-up. However, the study's screening logs were completed electronically. Some sites reported the burden imposed by the study documentation was too great and would have preferred exclusively online data collection. Some patients were not recruited as they did not read or speak English and study documentation or interpreters/translators were not available.

Uncertainty around the end date of the study

In March 2021, we received a 10-month funded extension which meant the grant would close on 30 September 2023. Recruitment finally began in March 2022 and the first 6 months of recruitment constituted the internal pilot phase. The progress made during the pilot phase was reviewed by the funder in September 2022 who confirmed that recruitment should continue and that six

new sites, including three podiatry schools, should be opened. Another contract variation was submitted at the end of March 2023. Study sites were notified that the HTA had requested recruitment to the study to continue while a decision was made about the request for a funded extension. However, the uncertainty around whether the study would receive an extension had a negative impact on some sites and study momentum. Two open sites were unwilling to recruit participants to the study only to potentially find out the next week that the study was closing due to recruitment issues. Trusts were unwilling to disappoint potential participants, and so recruitment at sites that were initially recruiting well started to stall.

Due to poor recruitment, the HTA was unable to support a further extension and the research team, with the support of the independent TSC, made the recommendation to the funder in May 2023 to close the study. The funder supported this suggestion. The last participant was randomised at the end of May 2023 and data collection stopped on 31 August 2023, when all participants had been in the study for at least 3 months.

Findings from the trial

Internal pilot phase

The trial protocol outlined that the study's progress after 6 months of recruitment (assuming recruitment started on 1 March 2022) would be based on the following progression criteria:

- number of sites open to recruitment: red ≤ 8; amber = 8–11; green ≥ 12
- number of participants randomised: red ≤ 75; amber = 75–119; green ≥ 120
- child questionnaire return rates at 3 months: red ≤ 50%; amber = 50–79%; green ≥ 80%

At the start of September 2022, we had 16 sites open to recruitment, had randomised 45 participants and had a return rate for the 3-month child follow-up of 50%. Therefore, we were in the 'green', 'red' and 'amber' thresholds, respectively, for the progression criteria. The funder and TSC supported continuation of the study.

Recruitment to the trial

In total, recruitment took place within 18 sites based in primary and secondary care and Social Enterprises and Community Interest Companies in England and Wales. Potential participants were sent or given a recruitment pack including a consent form, an information sheet for the parent (see *Report Supplementary Material 11*) and an age-appropriate version for the young person and a baseline questionnaire. The treating clinician assessed eligibility, obtained informed consent and assent if appropriate, completed baseline data and randomised the participant using a secure web-based application.

Recruitment rates

Between 1 March 2022 and 31 May 2023, 549 patients were screened for eligibility across 17 sites (1 of the 18 sites did not screen any potential participants). Sites were asked to screen any child aged 6–14 years of age, attending their clinic, for treatment of flat feet. Sites screened an average of 31 participants (median 31, range 1–114). Of these 549 potential participants, 246 (44.8%) were eligible to take part in the study, 186 (33.9%) were ineligible and 117 (21.3%) had an unconfirmed eligibility status. The main reason for ineligibility was the patient not having symptomatic pes planus (76/186, 40.9%), which was the main criterion for participant inclusion. Five sites reported that referral letters from healthcare professionals were not always clear on the reason for referral, which may account for the high level of patients not having symptomatic pes planus. The other reasons for ineligibility and non-consent are reported in *Appendix 2*, *Table 7*.

Of the 246 eligible participants, 25 (10.2%) were not approached for consent and 84 (34.1%) declined participation in the study. Of the remaining 137 participants, 134 were recruited and randomised into the OSTRICH study (3 were not randomised despite providing consent; 1 due to a clinician's decision to provide insoles, and 2 who did not provide a reason for non-recruitment). There was variable follow-up in the study depending on when participants were recruited; 44 (32.8%) participants were eligible for all follow-up time points (3, 6 and 12 months), 75 (56.0%) who were eligible for 3- and 6-month follow-up and 15 (11.2%) who were only eligible for 3-month follow-up.

One hundred and thirty-four participants were randomised into the OSTRICH trial from 17 sites between 21 April 2022 and 26 May 2023, of which 70 (52.2%) were allocated to receive exercise and advice plus insoles (intervention) and 64 (47.8%) to receive exercises and advice alone (control). Of these, 132 (98.5%) remained full participants; 2 (1.5%) participants withdrew from the trial. The withdrawals both happened in the control group and were at the request of the parent. The flow of participants is illustrated in the Consolidated Standards of Reporting Trials (CONSORT) diagram in *Figure 3*.

Baseline data

Participants were on average 10.6 years old [standard deviation (SD) 2.3], 55.2% were male and nearly two-thirds

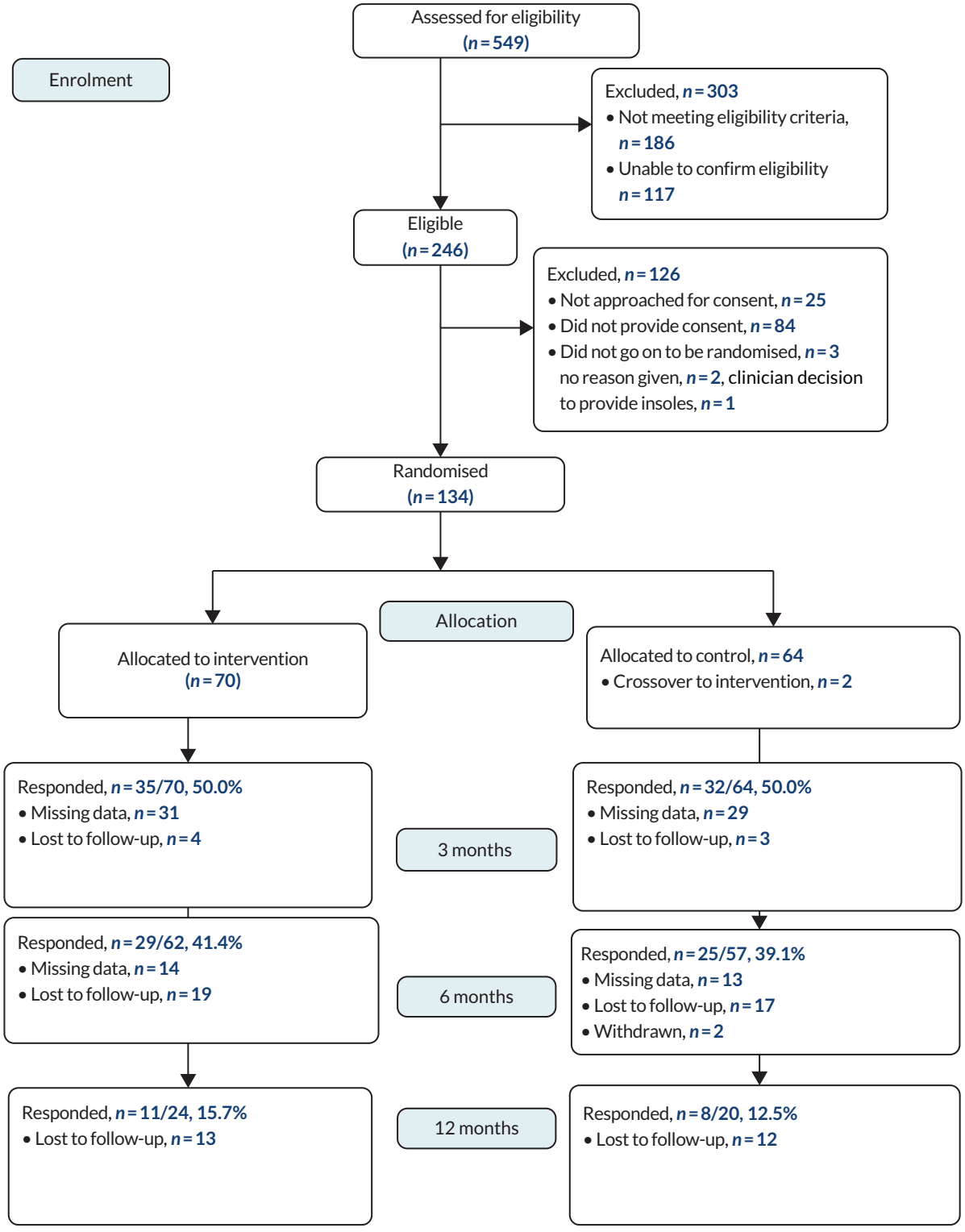

FIGURE 3 Consolidated Standards of Reporting Trials diagram of OSTRICH participants through the trial.

(63.4%) were White British. There was a slightly higher proportion of males in the control arm of the study (59.4%) than in the intervention arm (51.4%) (see *Appendix 2*, *Table 8*).

Child-reported baseline data of the outcome measures for the randomised participants are presented in *Table 3*. These data are mostly balanced across both study arms, although the mean OxAFQ emotional score was higher in the intervention arm.

Data collected at baseline by investigators at site relating to the child's foot posture index, leg balance and insoles and exercise provided are detailed in *Appendix 2*, *Table 9*. A form

TABLE 3 Child-reported baseline data, by trial arm

Outcome measure[a]	Control (*N* = 64)	Intervention (*N* = 70)	Total (*N* = 134)
OxAFQ (physical)[b]			
Mean (SD)	53.0 (21.3)	50.5 (19.4)	51.7 (20.3)
Median (IQR)	54.2 (37.5–66.7)	50.0 (37.5–62.5)	54.2 (37.5–62.5)
Minimum–maximum	4.2–91.7	4.2–100.0	4.2–100.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
OxAFQ (school and play)[b]			
Mean (SD)	75.9 (22.3)	75.7 (23.3)	75.8 (22.8)
Median (IQR)	81.3 (56.3–100)	75.0 (56.3–100)	78.1 (56.3–100)
Minimum–maximum	31.3–100.0	18.8–100.0	18.8–100.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
OxAFQ (emotional)[b]			
Mean (SD)	82.0 (19.5)	87.0 (15.2)	84.7 (17.5)
Median (IQR)	87.5 (68.8–100.0)	93.8 (81.3–100.0)	87.5 (75.0–100.0)
Minimum–maximum	18.8–100.0	37.5–100.0	18.8–100.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
OxAFQ (footwear)[b]			
Mean (SD)	70.2 (31.7)	66.7 (34.2)	68.4 (33.0)
Median (IQR)	75.0 (50.0–100.0)	75.0 (50.0–100.0)	75.0 (50.0–100.0)
Minimum–maximum	0.0–100.0	0.0–100.0	0.0–100.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
Wong Baker Faces (Left)[c]			
Mean (SD)	3.7 (2.9)	4.0 (2.6)	3.9 (2.8)
Median (IQR)	4.0 (2.0–6.0)	4.0 (2.0–6.0)	4.0 (2.0–6.0)
Minimum–maximum	0.0–10.0	0.0–8.0	0.0–10.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
Wong Baker Faces (Right)[c]			
Mean (SD)	4.3 (2.8)	4.1 (2.5)	4.2 (2.6)
Median (IQR)	4.0 (2.0–6.0)	4.0 (2.0–6.0)	4.0 (2.0–6.0)
Minimum–maximum	0.0–10.0	0.0–10.0	0.0–10.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
Child Health Utility 9D[d]			
Mean (SD)	0.85 (0.13)	0.85 (0.12)	0.85 (0.12)
Median (IQR)	0.88 (0.79–0.93)	0.88 (0.79–0.94)	0.88 (0.79–0.94)
Minimum–maximum	0.41–1.0	0.51–1.0	0.40–1.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)

IQR, interquartile range.
a IQR reported as (lower quartile limit–upper quartile limit).
b A higher score represents better functioning.
c A higher score indicates worse pain.
d A higher score indicates better health-related quality of life.

was not received for one participant in the intervention group. For the other 69 intervention participants, the investigator confirmed that they had fitted the child with an insole at the appointment. There were two reported instances of insoles being fitted for control participants at the baseline appointment.

Intervention delivery

One hundred and twenty-nine treatment confirmation forms were completed for 128 participants. Treatment confirmation forms were completed by investigators at site at the first routine clinic appointment (or a phone call with the patient) between 12 weeks and 6 months after the participant's baseline visit, or at 12 weeks if the patients were not routinely contacted during this time frame. The results are reported in *Appendix 3*, *Table 10*. Six of the 62 (9.7%) control participants for whom a form was received were recorded as having had insoles fitted following the baseline appointment.

In addition to the proxy-reported outcome measures, parents/guardians were asked to complete multiple questions regarding their child's experience of using the prefabricated insoles and/or undertaking the prescribed exercises, at each follow-up time point. Responses are summarised descriptively, by trial arm, in *Appendix 3*, *Table 11*. Of those who acknowledged receipt of insoles at their baseline study appointment, the majority reported using the insoles 'all of the time over the past week' at 3 and 6 months post randomisation (23/34, 67.6% and 17/28, 60.7%, respectively). However, < 10% of participants in each group reported undertaking the prescribed exercises 'all of the time' during the past week, at each follow-up time point.

Withdrawals

Two participants withdrew from follow-up, both from the control arm. Both took place shortly after the participant was sent their 6-month follow-up questionnaire, neither of which were returned; neither participant had reached the 12-month time point before follow-up ceased.

Follow-up and retention

Participants were followed up by postal questionnaire at 3, 6 and 12 months post randomisation until 31 August 2023 when all 134 randomised participants had reached the 3-month time point, 119 (88.8%) had reached 6 months and 44 (32.8%) had reached 12 months. In addition, participants were sent weekly text messages for 12 weeks, and again at 6 and 12 months post randomisation to collect pain score data. Postal questionnaire and text message response rates are reported in *Appendix 3*, *Table 12* and text message reported pain scores are summarised in *Appendix 3*, *Table 13*. Response rates to postal questionnaires, of those sent, were low (50% at 3 months, 45% at 6 months, and 43% at 12 months), and were similar across trial arms. Responses to the weekly text messages varied from week to week as to which treatment arm provided a higher response.

Primary outcome

The child-reported OxAFQ domain scores are summarised in *Table 4*. Scores of the physical domain were higher in the control group at all follow-up time points, indicating better functioning. Parent-reported OxAFQ domains are summarised in *Table 5*. Pain scores (using Wong Baker Faces) and Child Health Utility 9D (CHU9D) at each time point are summarised descriptively in *Appendix 3*, *Table 14*. Pain scores were similar across groups at all follow-up time points.

Parent/guardian-completed OxAFQ are reported in *Appendix 3*, *Table 15*. Scores of the OxAFQ (physical) domain were higher in the control group at 6 and 12 months post randomisation but not at 3 months.

Adverse events

Over the course of the OSTRICH trial, there were no serious or non-serious adverse events reported to YTU.

Health economic data

The EQ-5D-Y and EQ-5D-Y proxy version were collected at baseline, 3, 6 and 12 months post randomisation. Utility index values cannot currently be calculated for the EQ-5D-Y or ED-5D-Y proxy and so these are summarised by reporting the number and percentage choosing each response for the five domains at each time point. Child- and parent-reported data are summarised in *Appendix 3*, *Tables 16* and *17* with resource use reported in *Appendix 3*, *Table 18*.

Recruitment Study within a Trial

Fifteen (88.2%) of 17 sites that recruited at least 1 participant took part in the MMI SWAT. The aim of this SWAT was to determine if providing information to potential participants online and including a short animation about the trial would increase recruitment to the study.

Of the 15 sites, 8 (53.3%) were allocated to the intervention and 7 (46.7%) to control. Sites in the SWAT intervention group recruited 83 participants, compared to 40 participants recruited across sites in the SWAT control group. When considering response to postal questionnaires, at 3 months' post randomisation 38 (45.8%) participants in the SWAT intervention group

TABLE 4 Child-reported primary outcome measure

	Control (*n* = 64)		Intervention (*n* = 70)		Total (*n* = 134)	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
OxAFQ (physical)						
3 months	32	60.0 (25.6)	34	58.9 (19.8)	66	59.5 (22.6)
6 months	25	65.3 (27.4)	29	57.3 (22.4)	54	61.0 (24.9)
12 months	8	62.5 (23.7)	10	58.3 (29.6)	18	60.2 (26.4)
OxAFQ (school and play)						
3 months	32	84.4 (20.7)	34	80.9 (23.1)	66	82.6 (21.9)
6 months	25	79.3 (23.8)	29	79.1 (23.0)	54	79.2 (23.2)
12 months	8	78.9 (20.3)	10	86.9 (18.0)	18	83.3 (18.9)
OxAFQ (emotional)						
3 months	32	82.2 (23.7)	33	82.2 (22.0)	65	82.2 (22.7)
6 months	25	86.0 (21.0)	29	78.4 (25.4)	54	81.9 (23.6)
12 months	8	89.1 (13.7)	10	88.1 (13.6)	18	88.5 (13.3)
OxAFQ (footwear)						
3 months	32	59.4 (33.5)	33	65.2 (38.0)	65	62.3 (35.7)
6 months	25	64.0 (34.7)	29	60.3 (39.8)	54	62.0 (37.2)
12 months	8	65.6 (32.6)	10	60.0 (39.4)	18	62.5 (35.6)

This synopsis should be referenced as follows: Cockayne S, Baird K, Gates S, Fairhurst C, Adamson J, Bottomley-Wise RM, *et al.* OrthoticS for TReatment of symptomatic flat feet In CHildren (OSTRICH): a randomised controlled trial [published online ahead of print August 6 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/PLKJ4541

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TABLE 5 Parent-reported OxAFQ domains

	Control (*n* = 64)		Intervention (*n* = 70)		Total (*n* = 134)	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
OxAFQ (physical)						
3 months	32	56.3 (21.8)	34	61.3 (22.6)	66	58.8 (22.2)
6 months	25	63.3 (27.5)	28	55.7 (21.6)	53	59.3 (24.6)
12 months	8	67.2 (26.6)	10	60.8 (23.4)	18	63.7 (24.3)
OxAFQ (school and play)						
3 months	32	79.9 (24.8)	34	81.8 (23.9)	66	80.9 (24.2)
6 months	25	83.3 (21.8)	28	83.3 (21.4)	53	83.3 (21.4)
12 months	8	79.7 (18.5)	10	88.8 (14.7)	18	84.7 (16.6)
OxAFQ (emotional)						
3 months	32	85.4 (18.1)	34	81.3 (22.5)	66	83.2 (20.4)
6 months	25	87.0 (18.7)	28	81.5 (24.0)	53	84.1 (21.6)
12 months	8	88.3 (16.8)	10	86.3 (15.5)	18	87.2 (15.7)
OxAFQ (footwear)						
3 months	32	57.0 (33.1)	34	60.3 (38.0)	66	58.7 (35.5)
6 months	25	69.0 (35.6)	28	54.5 (37.9)	53	61.3 (37.2)
12 months	8	68.8 (32.0)	10	55.0 (36.9)	18	61.1 (34.5)

returned a postal questionnaire compared to 17 (42.5%) participants in the SWAT control group. At 6 months, 15 (37.5%) participants in the SWAT control group returned a postal questionnaire, compared to 29 (34.9%) participants in the SWAT intervention group. Response rates were 12.0% and 10.0% for the SWAT intervention and control groups respectively, at 12 months post randomisation.

Qualitative study

Recruitment to the qualitative study

Sixteen semistructured interviews were conducted via Microsoft Teams with participants of the OSTRICH study and their parents. Participants were recruited across social–demographic characteristics including ages (6–14 years, mean = 9.5) and gender (male = 10, female = 6), as well as intervention arm, (orthoses and exercise = 9, exercise alone = 6, crossover from exercise to exercise and orthoses = 1) and treatment site (see *Appendix 4*, *Table 19*).

Seventeen semistructured interviews were conducted with NHS employees involved in local delivery of the OSTRICH study. Participants were recruited across 10 NHS Trusts and held roles including podiatrists = 7, research role = 7 and administrative = 1 (see *Appendix 4*, *Table 20*).

Findings from qualitative interviews with parents and children

Thematic analysis was conducted; the themes developed are presented below.

Experience of flat feet and accessing health care

Pain from flat feet was a universal symptom described by the participants, often impacting the participants' ability to undertake normal activity, resulting in lifestyle changes including giving up sport.

> *Child: It just started to cause a lot of pain after a long day, or after I did PE or something.*
> *Parent: . . . At the weekend, we usually go up the woods or somewhere and it got to the point where it was like, right, where can we go? Because if we're walking that far, [my child] won't be able to do it.*
>
> *P21, female aged 12*

Other symptoms included experiencing trips and falls and concerns around posture or gait. Some of the anxiety around the latter stemmed from a family history of posture/gait issues and the belief that they had the potential to lead to future problems (e.g. pes planus, genu valgus, in-toeing and pronation causing poor alignment at the ankle).

> *Parent: His granny . . . said when she was younger she got knock-kneed, and I think [my child] doesn't want that.*
>
> *P50, male aged 6*

Pain was a common factor in triggering participants to seek health care for their flat feet, although as symptoms could be attributed to other causes (e.g. growing pains), they could be normalised or dismissed by adults including parents or school teachers. For example, one mother mentioned a change in gait to the father who told her she was being paranoid. The lack of legitimacy of symptoms can delay seeking health care.

> *Parent: His teachers just didn't believe him initially until I had to go in and say, look, he's not lying. I thought it was the same thing a couple of years ago, but actually he is genuine. He's not trying to get out of PE; he enjoys PE. So just keep an eye on him and believe what he's saying.*
>
> *P55, male aged 7*

Some respondents mentioned experiencing barriers to accessing health care; for example, during the study period, the COVID-19 pandemic was the most commonly reported barrier, either because parents did not want or feel able to contact the GP at this time or because non-urgent services were unavailable. Given the referral pathway from GP to secondary care, fear of hospitals or fear of the unknown were also common barriers to accessing care, although all children reported that the experience was fine once they overcame the fear.

> *Parent: When we went in it wasn't very pleasant, the waiting room. There's a lot of people on trolleys and I suppose it was not the best kind of environment for a child to go into really so you were very nervous about the hospital bit but then when we got to the paediatrics part-*
> *Child: That was fine.*
>
> *P21, female aged 12*

Health literacy regarding flat feet

Knowledge of the condition varied across the sample of participants, in terms of the nature of the condition and the treatments available.

Interviewer: How much do you feel you know about your foot condition?
Child: I pretty much know roughly all of it. I'm pretty sure it's to do with muscles and stuff, like not having as many muscles or them being in a different position.
P49, male aged 11

However, some participants held on to misconceptions relating to flat feet, that in some cases appeared resistant to contrary information provided by clinicians. Some parents would also overrule the opinions of children in favour of incorrect information relating to the condition. For example, for some there was the belief that rigid, structured footwear over should be worn over softer footwear such as trainers, despite healthcare advice to the contrary and reports of increased pain from the child. Some parents maintained the belief that flat feet are a pathology in themselves and that the long-term effects can be catastrophic (e.g. leading to permanent damage and deformity), even when asymptomatic, leading to views that surgery to feet or hips would be required either immediately or in early- to mid-adulthood.

Parent: I would like to know what will be next? Because yeah, we had appointment, so he received insoles or something like that. But what is the next part of the appointment? So we will see another consultation with other doctors or about maybe surgery?
P19, male aged 9

Several participants reported being told by the GP that they were being referred to secondary care 'for insoles'. While for some, the idea of insoles as a treatment was new and unexpected.

Parent: He's never really spoken about foot pain. I have always concentrated on, I don't know, it must be his legs. So I didn't think that you might get insoles because I didn't know how it was linked.
P22, male aged 12

However, for others, they were already familiar with this treatment approach.

Child: I expected them to give me inserts because my dad has flat feet as well and he has some inserts for his feet, so I was hoping that I'd get them.
P35, male aged 14

Previous knowledge or the expectation set by the GP at referral seemed to influence the belief expressed by several participants that insoles were the superior treatment for flat feet.

Parent: I think if I'd had a choice I would have asked for him to have exercises and an insole, so I suppose in that respect maybe a bit disappointed.
P50, male aged 6

There was a limited awareness among participants that exercises were a possible treatment for flat feet.

The number of clinical questions posed by participants during the qualitative interviews was an indication that information was either lacking or not being retained from clinic appointments. In particular, children were keen to understand how long the treatment process would take, how long they could expect to experience symptoms.

Child: How long do you think it will last? The pain?
P19, male aged 9

Trial interventions

While several participants indicated an expectation and or preference for insoles, this was not universal, less commonly, there was a preference for exercise treatment; for example one parent believed her child would lose insoles.

Self-reported insole adherence was high, and the device well tolerated. Most participants who had received insoles reported improvement in symptoms, particularly in relation to pain relief, improved gait and improved mood.

Parent: Basically he's wearing them all the time now. So in school shoes, normal shoes, when he's playing football . . . in each pair of shoes he has an insole. We're trying to keep them all the time for him because I think if they help him, why not?
P19, male aged 9

Some participants described an expectation that attending their secondary care appointment would be more like visiting a shoe shop, where they could try on several pairs of insoles rather than being assessed and having insoles prescribed. While most understood the role of specialism in secondary care, there was a small minority who demonstrated a lack of understanding of the process and described the GP as the specialist who created the prescription and the prescribing clinician more like a technician who filled the prescription.

Parent: I'm not sure if she could have been given a choice, or maybe try different ones. It was just a case of OK, pop the insole in and that's it.

P3, female aged 8

Self-reported exercise adherence was universally poor; this was the case across both arms of the trial. Barriers to adherence were varied, with the most common being failure to assimilate into the daily routine, pain during exercises and problems with equipment (e.g. therapy balls) provided by the clinician. Facilitators to adherence were less commonly reported, and focused on assimilation into the daily routine, having a printed sheet of exercises which served as a reminder, making exercises fun or social and incentives provided by parents. Participants reported no change in symptoms following exercises but acknowledged that poor adherence may be a factor in this.

Parent: I'll be quite honest, with the exercises it comes across as yes, this is fantastic, this will work really well, but to do something like that on a daily basis for a 7-year-old, he doesn't do it . . . I have to make him do it and then he half-heartedly does it and I'm not sure how much of an effect it's going to have on his feet.

P55, male aged 7

Experience of the OSTRICH study

Participants reported that they liked the text message capture of pain scores and found these easy to complete. Regular text messages meant that they became part of the weekly routine, and quick responses meant that they could be returned quickly without hassle.

Parent: He likes the text messages that we get once a week asking about the pain. That's good, isn't it? Keeping an eye on you.

P27, male aged 7

Participants who were asked about the quantity of materials provided and amount of participation expected reported they were happy and did not feel overloaded, but it must be noted that those who did feel that the amount of participation expected was excessive would have been less likely to engage with the qualitative interviews.

Some participants commented on the child-friendly materials, such as the separate participant information sheet (PIS) and assent form for the child, although one reported that she would have benefited from a more age mediated set of questionnaires as her 7-year-old child required her support to complete those provided. Additionally, some terms, for example 'randomiser', were difficult for younger children to comprehend.

Child: I thought it was going to be like a 'random eyes' kind of person.

P27, male aged 7

Motivations for taking part in research were varied, with the most common responses including desire to help others, desire to help themselves and desire to grow the knowledge base around the condition.

Parent: We did say to him that this is going to help other children and he loves that. That's a real carrot. You know that you're helping other children.

P75, male aged 6

Findings from qualitative interviews with clinicians

Thematic reflective analysis of the qualitative interviews with clinicians, and comparison with the findings from the qualitative interviews with participants, is ongoing and due for completion in the first quarter of 2024.

Discussion/interpretation

Principal findings and achievements

The OSTRICH trial was designed to robustly evaluate the research question regarding the clinical and cost-effectiveness of orthoses in addition to exercise and advice relative to exercise and advice alone on the physical functioning of children with symptomatic pes planus. OSTRICH aimed to address the paucity of high-quality evidence available to answer this question. However, as described in this report, the study faced many challenges, the most significant being the COVID-19 pandemic which impacted on set-up and recruitment. One hundred and thirty-four participants were recruited to the study, and while limited data prohibited a useful formal comparison of outcome data between the groups from being undertaken, data collected during the study will be available to future researchers for secondary analysis including use in systematic reviews and meta-analyses.

We interviewed 16 trial participants and 17 staff at sites involved with delivering the intervention to explore the experiences of those who took part in the study. Participant interviews aimed to explore access to services for paediatric symptomatic pes planus, views on the treatment options and their experience within the trial to identify barriers and facilitators to receiving effective treatment. Staff interviews aimed to explore a combination of clinical and non-clinical perspectives on

treatment options, patient response and clinical capacity for the treatment of paediatric pes planus.

The mean age of the participants interviewed in the qualitative study was 9.5 years, which was slightly lower than the mean age of the overall trial population (10.6 years) but covered the same range (6–14 years). More boys than girls were interviewed (10 vs. 6) which reflects the overall trial sample in which there was a higher proportion of males (55.2%) than females.

Pain, posture and gait were the most commonly identified concerns by participants, with pain frequently being sufficient to alter or reduce activity. Reducing pain was a strong motivator in seeking health care, and an intervention that could reduce pain quickly to allow a return to normal activity was viewed as a priority. Participants described long delays in seeking or accessing health care, so by the time they reach assessment the need for an intervention that works quickly is more pressing. Some delays in accessing health care occurred due to the COVID-19 pandemic and might not be generalisable outside of this period, but some participants described long delays that predated the pandemic. Delays can also occur as a result of children's complaints not being believed or being downplayed by parents, teachers and primary care practitioners. Lack of credibility combined with delays in treatment resulted in participants describing pain normalisation and lifestyle changes to accommodate chronic pain among children.

Participants reported that this was often the child's first experience of health care beyond the GP or occasional visits to the accident and emergency department, and this could be quite intimidating for the patient. Location of the department, while unavoidable, can affect the mood and confidence of the child, and they may need extra reassurance when they reach the clinic. Both parents and children reported a lack of understanding of the secondary care process and what to expect from a specialist assessment, compounding the feeling of entering the unknown.

Participants generally reported little understanding of flat feet and a lack of easily identifiable and reliable sources of information. Misinformation was common, including catastrophising due to fixed health beliefs surrounding the idea that a flat foot is inherently pathological. More readily available resources from reputable sources could help to reduce misinformation, provide reassurance to parents, support self-management and encourage earlier access to health care when appropriate by supporting parents in recognising the difference between normal development and symptoms that require further management. The prevalence of misinformation described by participants combined with the number of questions asked of the interviewer does, however, indicate the value of follow-up appointments to allow patients to ask any questions arising after the appointment or where information has not been retained. Several participants reported that they were not provided with a follow-up appointment, or were required to contact the clinic should they require a follow-up but were unsure whether this was appropriate. A clearer process, such as arranging a follow-up either in person or by telephone at the initial assessment, proved reassurance for participants and allowed the opportunity to ensure further questions were answered.

The interviews identified a common health belief among patients that insoles are superior to exercises, leading to high levels of adherence and satisfaction with insoles compared with poor adherence and satisfaction with exercises. Insole or exercise-only group allocation did not affect adherence and satisfaction with exercises. Participants reported expectations of ease of use and greater and faster success with insoles, and those allocated to the intervention group confirmed that this was what they experienced. Participants who were able to identify the origin of this belief reported that it came from friends and family or the GP, which is supported by the clinician interviews where it was frequently reported that GP referrals state patients are being referred 'for insoles'. Participants reported an expectation of insole provision encouraged by GPs; however, without an empirical evidence base, this highlights the ongoing need to address the objectives of the OSTRICH Study.

In comparison, participants reported little satisfaction with and poor adherence to exercises. Reasons for not engaging with exercises were diverse, indicating that there is no simple solution to facilitating adherence. Reported success was poor, and participants acknowledged that this is in part due to low adherence, but some were also able to identify that poor perceived effectiveness of exercises was a factor in poor adherence. Participants reported little confidence in the ability of exercises to affect significant or prolonged change, and without belief in the effectiveness of the intervention motivation and engagement tapered. Essentially in the context of OSTRICH, the exercise arm was generally considered a 'no-treatment' arm. It would be important in future trials to think carefully about how the comparison was presented and understood by eligible patients and trial participants.

When asked about their experience of taking part in the study, participants expressed a preference for digital

methods. Weekly pain scores captured by text message were considered quick and easy, and apps were described as preferable to printed sheets or exercises or questionnaires, especially when combined with gamification to engage children. The age ranges of the populations involved, both parents and children, are very technologically engaged, and replying to an online survey through a smartphone or tablet is more convenient than completing and posting a paper version. Future studies focused on these demographic groups may benefit from making contributions as digital as possible.

Strengths and weakness of the study

The main strength of this study was its methodological quality and rigour. It was a multicentre RCT – the 'gold standard' method of evaluating an intervention. Randomisation was conducted by a secure, remote, web-based system with concealed allocation. The trial was planned to be reported in line with CONSORT and other relevant guidelines. An independent (joint) TSC/Data Monitoring and Ethics Committee helped ensure the trial was conducted as per protocol and that participant safety issues were considered. However, despite all this, due to the issues previously detailed, the trial recruited well below target and too few participants returned follow-up data to be able to conduct the planned analyses and answer the research question.

Challenges faced and limitations

Site set-up during and post COVID-19 pandemic

Set-up of the 30 sites that had expressed an interest in taking part at the grant application stage and the additional sites we planned to open to help mitigate the delay in recruitment was severely hampered by the COVID-19 pandemic. It took a mean of 39 weeks to set up sites, based on the sites we were able to open. Mitigating the impact of the pandemic was not possible. While the study team were reactive and made changes to the research plan (e.g. dropping the custom-made orthosis arm of the study), frequently it was not possible to take any action. The study team had to rely on the research landscape improving. Once studies were being opened again, Trust's R&D capacity to review new applications was impeded by the backlog of applications. Some Trusts prioritised studies with larger sample sizes than OSTRICH as they had the potential to recruit more participants, resulting in greater accrual numbers for the Trust.

Recruitment issues

The NIHR paused recruitment to most non-COVID-19-related studies, including OSTRICH, so the study team had to wait for this pause to be lifted. Then, once studies opened, recruitment to OSTRICH was impeded by sites prioritising the clinical backlog of high-risk foot pathologies. Children with symptomatic flat feet were not considered as high risk, so again the study team had to wait for clinics to start seeing patients with flat feet before recruitment could start. Even when clinics were seeing patients with flat feet, their ability to recruit was hampered by social distancing requirements, which meant for some sites finding a treatment room large enough to accommodate the treating clinician, research nurse, the participant and their parent was challenging. The ability to recruit was also affected by clinics' capacity to see trial participants, patients' preference for orthotic devices, fewer participants presenting in clinic than expected and uncertainty around the end date of the study. Sites also found that many of their potential participants had previously received recent treatment for their flat feet and so were ineligible (this was a reason for non-participation for over a quarter of the ineligible screened participants). To mitigate this effect, a protocol amendment was submitted to clarify that the time frame for previous treatment was within the last 3 months: therefore, any child who had taken part in an exercise intervention or had used health professional prescribed insoles within the past 3 months would be excluded from the study. Adding a time frame to the previous treatment meant that patients would no longer be needlessly excluded.

Adherence to the exercise component

Participants had access to an OSTRICH-specific area of the Physiotec© app (https://physiotec.ca/ca/en/), where they could access their prescribed exercises and view videos of children (of a similar age to those in the trial) demonstrating them. The data-sharing agreement between Physiotec© a health and software company in Chapais, Quebec, Canada, and the University of York did not allow for sharing of data, so we are unable to tell whether the videos were viewed. Future studies may wish to ensure they have the capability to monitor App usage/intervention adherence. Participant-reported data backed up with interviews from trial participants indicated poor adherence to the exercise component of the trial treatments.

Engagement with partners and stakeholders

At the point of submitting the grant application, engagement with clinicians was high, with 30 sites expressing an interest in taking part in the study. However, set-up and recruitment to OSTRICH took place during the COVID-19 pandemic which severely impacted the ability of partners and stakeholders to engage with the study.

Set-up of sites took significantly longer than the 6 months we allowed for in the project management plan. While we were able to open 19 sites, we were unable to open all the sites that had initially expressed an interest in taking part or the additional sites we planned to open to make up the shortfall in recruitment. The challenges Trust R&D departments faced in processing applications, after the pandemic, can be seen in the time it took to set up OSTRICH sites. Based on the sites we were able to open, it took a mean of 28 weeks from the point of sending the local information pack to receiving 'Capacity and Capability' approval and 39 weeks to open a site. Some R&D departments prioritised studies other than OSTRICH, as they had the potential to recruit more participants. Some new sites were reluctant to commit the time required to review and approve a new study, only to find the study was closing; they preferred to prioritise studies that were not struggling. Staff at sites were sometimes redeployed to help support the vaccination programme during the pandemic or were dealing with the backlog of appointments that had built up. Throughout this period, the study team kept in contact with sites. They provided information to help inform decisions about clinical clarifications as to the treatment arms of our research plans such as exploring the feasibility of delivering the trial treatments remotely. Delay in seeking clinical clarification was compounded as queries would have to go back to the clinical members of the study team. However, once sites were open, the majority set very low recruitment targets, due to the uncertainty around research studies in the context of possible further lockdowns. The uncertainty around the recruitment end date, which was contingent upon the funder approving a further extension, negatively impacted engagement with sites. Sites wanted a firm date for the end of recruitment, but this could not be provided, affecting study morale which resulted in reduced confidence among staff at sites that the study would be completed. Some sites were unwilling to continue recruitment or recruited at a slow rate. They raised concerns that they may recruit participants only to have to inform them shortly afterwards that the trial was closing. This would not only disappoint participants but could also affect their willingness to take part in future research. They also considered it unethical to enrol a patient in the study only for it to close shortly afterwards. To reduce the burden on NHS Trusts and to open sites up in a shorter time frame, it was agreed to open three Podiatry Schools. However, delays due mainly to reduced staff capacity were experienced, which resulted in there being insufficient time to open these sites.

We originally planned to conduct an observation visit at each site to assess trial fidelity. However, following feedback from sites, the focus of these visits was changed from observation to that of supporting sites to deliver the intervention. Sites found this extremely useful and considered the momentum of the trial would have been maintained if further support could have been given. Sites were also offered the opportunity to join virtual coffee drop-in sessions with the trial co-ordinators and researchers undertaking the observation visits twice a month. Issues about the day-to-day management of the study were raised. This was better attended than the invitation to attend Trial Management Group meetings. A lesson for future studies is to include funding for members of the study team to support delivery at sites. Alternatively, the study team could include members who have a clinical background and are currently working within the NHS. They could support trial fidelity and help foster clinical engagement for the study.

Patients' treatment preferences reduced their willingness to take part in the study. Some patients had been on the waiting list for a long time and were often told they were being referred for orthotics. Some were reluctant to be in the study as they did not want to take the chance that they might be allocated to the exercise and advice only arm. Once in the trial, parent/guardian participants were willing to provide data via text messages about the amount of pain their child was experiencing. However, the response rates to paper postal questionnaires were lower than expected. A key finding of this study is that alternative methods of data collection with this patient population, for example online formats, should be explored. One limitation to the study was that study documentation was only provided in English and some potential participants were excluded as they were unable to read and write English. Future studies should consider whether funding to provide study documentation in languages other than English or to provide translators/interpreters is required.

Individual training and capacity-strengthening activities

Many of the clinicians taking part in the study were research naive, which was reflected by the fact that many sites involved research nurses to support the team at site. If it were possible to expose Allied Health Professionals (AHP) to research pre-registration, it would help develop a stronger research-ready AHP workforce.

One possible way to train future AHPs would be to consider opening recruitment sites within organisations such as Podiatry Schools based in universities. This would give the AHPs of the future first-hand experience in the day-to-day running of RCTs. Universities have an ethos of undertaking research and yet there are few opportunities for podiatrists to take part in large multicentre RCTs. Being

involved in a large trial such as OSTRICH would also develop an understanding of the need for relevant high-quality research and a culture of evidence-based practice.

Take-home messages

Conducting a RCT during and after the COVID-19 pandemic was very challenging and sufficient lead time should be allowed for the set-up of the study. Key learning points from this study include the need to:

- Address patient's treatment preferences around the efficacy of orthotics in absence of empirical evidence.
- Explore ways of improving exercise adherence within trials and how the intervention is understood by patients.
- Provision of resources for pes planus from reputable sources should be considered to reduce misinformation and improve engagement with services.
- Priority should be for use of digital methods for engagement/ follow-up routes for studies involving children/parents of this age range (e.g. outcome measures should be captured through online surveys or text messages).
- Include funding for members of the study team to support delivery at sites including a clinician to expediate clinical concerns.
- Include funding to provide study documentation in languages other than English or translators/ interpreters in grants to allow studies to be more population inclusive.

Patient and public involvement

We worked with patient and public involvement (PPI) representatives from the grant application stage through to dissemination of study findings. Our PPI work helped us understand the challenges that young people and their parents face when experiencing foot symptoms, as well as understanding the effects the symptoms have on a child's ability to play, engage with their friends, and on their wider quality of life. We wanted to ensure that the views of children and young people with flat feet were woven into the research such that the results would be of direct benefit to them.

Pre-funding preparation

Advice was sought from the Young Persons Advisory Group for Kent, Surrey and Sussex and patients at one of the co-applicant's clinics who were aged between 8 and 18 years of age, on the proposed grant application. They provided the following feedback:

1. They considered the aims of the study to be clear and the study burden acceptable to potential participants.
2. They thought children and their parents would be committed to take part in the study.
3. The randomisation ratio, which favoured the intervention groups, were seen as an element that could encourage trial participation

Post-funding preparatory work

The PPI lead was involved in frequent communications (e-mail, teleconferences, newsletters and face-to-face meetings) with the PPI group. We developed a guidance document to explain the roles and responsibilities of the group. We asked for feedback on the study to help develop the protocol and develop participant-facing documentation. We set up a virtual PPI group which was made up of five young people (and one parent per child), aged between 8 and 14 years of age (three females and two males). We also asked members of the Young Persons Advisory Group for Kent, Surrey and Sussex who are aged between 8 and 19 years of age for help. The group reviewed the participant-facing documents which included, but was not limited to, the PISs (one for adults and two for children aged 6–10 and 11–14 years), consent and assent forms, case report forms, topic guides, study logo, preferences of what should be included in the birthday card such as the design and colour, wording in the card, who the card should be signed by, and content and pictures used in the animation for the MMI SWAT and summary findings. Documentation was amended following their comments. For example, we included more ethnically diverse characters in the MMI animation and amended the wording on the information sheets and birthday card which aided the understanding of the aims of the study and tasks participants would need to undertake if they joined the study. On occasion, feedback from the PPI group conflicted. For example, feedback on the children's information sheet for those aged 11–14 ranged from the language used was too complicated to it was too simple, so the study team had to make a judgement call on the language used.

Two parents of young people with flat feet were independent members of the Trial Steering and Data Monitoring and Ethics Committee. Throughout the course of the study, they were involved in discussions about changes to the study design and in the close-down of the study. Overall, the input from our PPI members was extremely useful in ensuring patient documentation was suitable for participants and that the results of the study would be of direct benefit to patients with symptomatic flat feet.

Equality, diversity and inclusion

The OSTRICH study was conducted across England and Wales and participants were aged between 6 and 14 years of age. They were predominantly White British/White European (67.1%), with 11% being of mixed/multiple ethnic groups and 10% Asian/Asian British. It is difficult to infer whether the trial population reflects those widely seen in routine practice, as most clinics do not routinely collect ethnicity data. We did, however, receive data from four sites, which reported between 24% and 71% of patients of this age being white. The 2021 UK Census data[15] indicate that 75% of children aged 5–14 years are white, 12% are Asian, 6% are black and 9% mixed/other, so our sample was broadly representative of the UK population in terms of ethnicity for this age range.

We did not anticipate the intervention would affect groups of children in different ways. We adopted a broad approach to our eligibility criteria but did exclude children with a history of major trauma or fracture, and/or a history of foot/and or ankle surgery. This exclusion was applied as the study focused on interventions for symptomatic, idiopathic flat feet as different interventions would be needed for children post trauma and/or surgery. In addition, children who had received treatment (either exercises or worn a health professional prescribed insole) within the past 3 months were excluded as they had already recently received the trial treatments. We did not collect socioeconomic data for the trial participants but, to facilitate attendance to the trial appointment, a one-off travel payment of £10 was given to participants' parents to help cover the cost of attending the clinic. We also minimised the number of trial appointments required to take part in the study to one, thereby minimising participant burden.

To support an inclusive approach to the recruitment of participants, we worked with our PPI group to co-develop three PISs and two assent forms. One was designed for the parents and the other two for young people aged 6–10 years and 11–14 years. The design of the PIS and assent forms were predominantly image-based, and we worked with young people to ensure that the images and language were age appropriate and could be easily understood. The trial team acknowledged that the PIS needed to be more representative, and this was something that we factored into the development of the animation for our Multimedia Information SWAT. The aim of this SWAT was to determine if providing information online and including short animation about the trial would increase recruitment to the study. The short animation provided the key points of the study, so that those with reading difficulties would be able to access study information. The short animation included representation of minority ethnic groups, children with disabilities, and there was diverse representation of health professionals.

To participate in the trial, written, informed consent was required from the parental caregiver(s) and those who were unable to read, write and/or understand English were excluded from the study unless they had a family member to translate/interpret study materials for them. While using a family member to translate/interpret study materials may not be ideal, it may have reflected how they would usually communicate. Further, the outcome measures for the trial were written, child-reported and parent-report outcome scales, and not all were available in other languages (or could be translated). A key learning point for future trials is to request funding to provide information in other languages or translation/interpreter fees. Data were collected mainly via postal questionnaires, but response rates were lower than we expected (50% at 3 months, 45% at 6 months, and 43% at 12 months). However, a higher response rate was achieved when we used text messages to collect data. When designing future studies, researchers should know that while 93% of adults in the UK had access to a mobile phone between April 2020 and March 2021, 7% of the population were unable to access this technology.[16] If researchers plan to use this technology to collect data, they should also consider alternative data collection methods to ensure they are as inclusive as possible. During the study, it was not feasible to offer data collection via other methods, for example completion of online questionnaires. A key learning point would be to offer participants alternative methods of providing data, an option which is now being offered on other studies run by the study team.

The OSTRICH team drew upon a range of expertise and experience. Our research team included a diverse mix of researchers, academics and clinicians, with representation across England who were supported by a diverse mix of children and parents. Members of the study team based at YTU and the University of Salford included a trainee trial co-ordinator, trainee trial statistician and a trainee qualitative researcher. Supported by other members within the YTU and members of the study team, these staff received hands-on experience of day-to-day management/undertaking statistical tasks/undertaking qualitative research, required to undertake large pragmatic RCTs. Gaining such experience would help facilitate their career progression. It is acknowledged that the members of the public involved in the trial were predominantly from the South-East of England and did not represent the broader diversity of the UK.

Impact, learning and implications for decision-makers

Due to poor recruitment and insufficient data, we are unable to assess the clinical and cost-effectiveness of prefabricated orthoses in addition to exercise and advice with exercise and advice alone on the physical functioning of children aged 6–14 with symptomatic pes planus. It may be that prefabricated orthotics plus exercises and advice is insufficiently effective at improving the physical functioning of children to offer good value for money, in which case resources could be diverted elsewhere and the negative environmental impact of both disposing of the prescribed orthotics and reducing travel to clinics to attend appointments reduced.

This report details the main findings of the study, so that other researchers planning future research in this area can learn from our experiences. Participants have been sent a short summary of the findings of the study. We plan to report the findings of the MMI SWAT, in a peer-reviewed journal so others can learn about how we developed the multimedia information and tested its effectiveness. We also plan to publish a mixed-methods paper reporting the findings from the qualitative interviews with trial participants and quantitative data from participant self-reported questionnaires, about participant's treatment and adherence to a prescribed treatment plan.

The findings from the qualitative interviews exploring the factors affecting adherence to treatments for flat feet were presented at the Royal College of Podiatry Conference in November 2023. The role of orthoses in the treatment of symptomatic flat feet was presented at the CDT Prosthetics and Orthotics Society Conference in November 2023.

The key lessons learnt to date are:

- Future studies should include funding for NHS-based clinicians who can regularly support sites to deliver the trial while supporting trial fidelity and help foster clinical engagement for the study.
- Patient's preferences for insoles should be addressed and healthcare professionals given advice about what information should be included in referral letters to other healthcare professionals for the treatment of symptomatic flat feet.
- To improve adherence to exercise, alternative methods to delivering an exercise component of an intervention, for example gamification, should be considered.
- The reliance on study documentation in paper format should be reviewed and alternative data collection methods such as online questionnaires, SMS text messages and online animations and videos may be considered, although there is currently scarce evidence of effectiveness.
- Funding to provide study documentation in languages other than English or translation/interpreters fees should be included to be more population inclusive.
- Sufficient time should be allowed to set up study sites.
- Podiatry Schools, which have an ethos of undertaking research, should be considered as research sites at the outset.

Research recommendations

The research question of the clinical and cost-effectiveness of orthoses in addition to exercise and advice compared to exercise and advice alone on the physical functioning of children with symptomatic pes planus as measured by the physical domain of the OxAFQ-C remains unanswered. Therefore, there is still the need for robust, adequately powered randomised trials to inform current practice. Based on the lessons learnt from conducting this study, we would recommend future studies should:

- Include the evaluation of different treatment modalities, including custom orthotics, prefabricated insoles, physical therapy and placebo interventions.
- Consider gamification of the exercise component of the intervention in future trials, given the feedback from the qualitative interviews, and determine whether the provision of therapy balls is a help or hinderance and if their provision is cost-effective.
- Consider collecting data via digital delivery formats, for example text messages. At the point of setting up the study, paper questionnaires were routinely used to collect data, with pain scores being collected by SMS messages. Our response rates to paper questionnaires were significantly lower than anticipated, but response rates to text messages were high.
- Undertake research to (1) gain a better understanding of clinician's health beliefs around flat feet and the use of orthoses to help inform future health literacy campaigns; (2) make clinicians prescribing foot orthoses aware of the lack of high-quality evidence supporting their use; (3) undertake a health literacy campaign to educate the public about the lack of evidence and the need for quality research in this area; (4) determine the predictors of treatment

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success; (5) identify which patients need treating and which will resolve without any intervention (which could potentially lead to cost savings within the NHS); and (6) consider the skill set of future study teams and include members who have a clinical background who are currently working within the NHS. Funding should be included to allow these members to support sites to deliver the trial while supporting trial fidelity and help foster clinical engagement for the study.

Conclusions

The COVID-19 pandemic significantly impacted the set-up and recruitment to the study. Due to the cost and time involved, it was not feasible to extend the study. Due to the limited amount of data, we are unable to answer the research question. However, it is important that RCTs are conducted to evaluate the clinical and cost-effectiveness of interventions to ensure treatments offered to patients are evidence-based.

Additional information

CRediT contribution statement

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration in line with current YTU Standard Operating procedures. Access to available anonymised data may be granted following review.

Ethics statement

The study protocol (including subsequent amendments) and all associated study documents were approved by the Health Research Authority – North East – York Research Ethics Committee (Reference 20/N/0173) on 6 August 2020. Informed written consent from the participant's parent or legal guardian and assent from the child where appropriate was obtained prior to participation in the OSTRICH trial.

Information governance statement

The University of York and the University of Salford are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation [EU General Data Protection Regulation (GDPR) 2016/679]. Under the Data Protection legislation, The University of Salford is the Data Processor; The University of York is the Data Controller, and we process personal data in accordance with their instructions. You can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.york.ac.uk/healthsciences/research/trials/trials-gdpr/ and www.salford.ac.uk/privacy.

Disclosure of interests

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Publications

Gates S, Parker DJ, Cockayne S, Woodward A, Adamson JA. *Why Children Don't Do What You Tell Them: A Qualitative Study Exploring Factors Affecting Adherence to Treatment for Paediatric Flat Feet* [Conference Poster]. Royal College of Podiatry Annual Conference, Liverpool, UK, 23–25 November 2023.

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Trial registration

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Members of the OSTRICH team

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List of Supplementary material

Report Supplementary Material 1
OSTRICH Participant Baseline Questionnaire (Child/Young Person Version) version 2.0 22 April 2021

Report Supplementary Material 2
OSTRICH Participant 3-Month Questionnaire (Child/Young Person Version) version 1.0 27 May 2020

Report Supplementary Material 3
OSTRICH Participant 6-Month Questionnaire (Child/Young Person Version) version 1.0 27 May 2020

Report Supplementary Material 4
OSTRICH Participant 12-Month Questionnaire (Child/Young Person Version) version 1.0 27 May 2020

Report Supplementary Material 5
OSTRICH Participant Baseline Questionnaire (Parent/Legal Guardian Version) version 3.0 30 May 2022

Report Supplementary Material 6
OSTRICH Participant 3-Month Questionnaire (Parent/Legal Guardian Version) version 2.0 19 October 2020

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OSTRICH Participant 6-Month Questionnaire (Parent/Legal Guardian Version) version 2.0 19 October 2020

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OSTRICH Participant 12-Month

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Report Supplementary Material 9
OSTRICH Investigator Baseline Questionnaire version 4.0 10 January 2022

Report Supplementary Material 10
OSTRICH Treatment Confirmation Questionnaire version 4.0 21 February 2022

Report Supplementary Material 11
OSTRICH Main trial PIS for parents version 5 28 October 2021

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/PLKJ4541).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

AHP	Allied Health Professionals
CHU9D	Child Health Utility 9D
CONSORT	Consolidated Standards of Reporting Trials
COVID-19	coronavirus disease 2019
GDPR	General Data Protection Regulation
GP	general practitioner
HSD	Hypermobility Spectrum Disorder
HTA	Health Technology Assessment
MMI	multimedia information
NIHR	National Institute for Health and Care Research
OSTRICH	Orthotics for Treatment of Symptomatic Flat Feet in Children
OxAFQ-C	the Oxford Ankle Foot Questionnaire for Children
PIS	participant information sheets
PPI	patient and public involvement
RCT	randomised controlled trial
R&D	research and development
REC	Research Ethics Committee
SWAT	Study within a Trial SD standard deviation
TSC	Trial Steering Committee
YTU	York Trials Unit

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Appendix 1 Protocol amendments

TABLE 6: Protocol amendments

Amendment number	Description	Substantial/ non-substantial	Date HRA approved
1	Study documentation updated in light of additional PPI comments.	Substantial	20 November 2020
2	Adaptation to enable delivery during COVID-19. Removal of the custom orthoses arm and switch from a 3- to a 2-arm trial and an additional foot shape sub-study.	Substantial	Not approved
3	Re-submission of part of Amendment 2 to remove the custom orthoses arm to switch from a 3- to a 2-arm trial.	Substantial	19 July 2021
4	Update to the organisation information document and update to study end date.	Substantial	14 October 2021
5	Minor update to consent form and PIS regarding sharing information with Physiotec.	Non-substantial	1 November 2021
6	MultimediaSWAT. Clarification to birthday card SWAT. Recruitment permitted on the same day as given study information. Additional sites.	Substantial	10 March 2022
7	Foot shape substudy.	Substantial	10 June 2022
8	Minor clarification to exclusion criteria re definition of previous treatment.	Substantial	15 July 2022
9	Extension to the study end date and recruitment period. Additional site.	Non-substantial	23 August 2022
10	Additional study document regarding payment of travel expenses. Extension to end of recruitment period and study end date.	Substantial	5 September 2022
11	Exclusion criteria updated to exclude siblings due to cluster effect and logistical issues with the parent receiving two text messages per week and two questionnaires at each follow-up point. Additional sites.	Non-substantial	4 November 2022
12	Extension to study end date.	Non-substantial	15 March 2023
13	Addition of podiatry schools as recruiting sites and updated study documentation. Time frame of sending unconditional £5 changed from 12 to 3 months.	Substantial	5 April 2023

continued

TABLE 6 Protocol amendments (*continued*)

Amendment number	Description	Substantial/ non-substantial	Date HRA approved
14	Minor changes to consent form and PIS.	Non-substantial	13 June 2023
15	Notification letter of end of study and summary of findings for participants.	Substantial	2 October 2023

HRA, health research authority.

Appendix 2 Screening and baseline data

TABLE 7 Summary of reasons for ineligibility (reasons are not mutually exclusive)

	N	% of 186 who are ineligible
Inclusion criteria (not met)		
Has symptomatic pes planus affecting one or both limbs	76	40.9
Patient aged between 6 and 14 years	19	10.2
Child and/or parent/guardian is able to speak, write and understand English	10	5.4
Parent/guardian is able to give informed consent	3	1.6
Exclusion criteria (met)		
Has previously received treatment for pes planus in the last 3 months	52	28.0
Has pes planus secondary to any systemic condition/syndrome	33	17.7
Has a history of major trauma or fracture to either lower leg (below knee)	3	1.6
Requires an ankle–foot orthoses or other lower limb device	1	0.5
Has a history of foot/ankle surgery	0	0.0

Of the 246 eligible participants, 25 (10.2%) were not approached for consent and 84 (34.1%) did not provide consent to take part in the study. Reasons for non-approach include: did not attend an appointment, were unable to be contacted for an appointment, or have a history of non-attendance (*n* = 15); no reason provided (*n* = 2); moved out of the area (*n* = 1); not interested in taking part in research (*n* = 1); would be out of the eligible age range at the next appointment (*n* = 1); child not engaging (*n* = 1) or other reasons (*n* = 4).

Reasons for non-consent include: did not want to participate, not interested in taking part, (*n* = 27); did not want to change an existing appointment, did not attend an appointment or cancelled an appointment (*n* = 13); wanted to receive insoles (*n* = 9); no reason given (*n* = 6); other (*n* = 6); personal reasons or circumstances (*n* = 5); did not want to be randomised (*n* = 3); patient had read or received the information pack prior to the appointment (*n* = 3); felt they could not commit the time (*n* = 2); did not attend the appointment with a parent/guardian (*n* = 2); parent had limited English (*n* = 2); parent did not want to delay treatment or insoles (*n* = 2); unable to make further contact (*n* = 1); was not keen on exercises (*n* = 1); had to have an emergency appointment (*n* = 1); unable to complete questionnaires due to learning difficulties (*n* = 1).

TABLE 8 Parent/guardian-reported baseline data, by trial arm

Characteristic[a]	Control (*n* = 64)	Intervention (*n* = 70)	Total (*n* = 134)
Age (years)			
Mean (SD)	10.2 (2.3)	10.9 (2.2)	10.6 (2.3)
Median (IQR)	10.2 (7.8–11.7)	10.8 (9.4–12.7)	10.3 (9.1–12.3)
Minimum–maximum	6.5–14.8	6.3–14.3	6.3–14.8
Not reported, *n* (%)	0 (0.0)	0 (0.0)	0 (0.0)
Gender, n (%)			
Male	38 (59.4)	36 (51.4)	74 (55.2)
Female	26 (40.6)	32 (45.7)	58 (43.3)
Prefer not to say	0 (0.0)	1 (1.4)	1 (0.7)
Not reported, *n* (%)	0 (0.0)	1 (1.4)	1 (0.7)
Height (cm)			
Mean (SD)	143.5 (16.7)	149.5 (14.4)	146.6 (15.8)
Median (IQR)	144.0 (127.0–156.0)	150.0 (139.0–160.0)	147.5 (134.0–158.0)
Minimum–maximum	116.0–180.0	121.0–187.0	116.0–187.0
Not reported, *n* (%)	13 (20.3)	15 (21.4)	28 (20.9)
Weight (kg)			
Mean (SD)	41.3 (17.7)	44.7 (12.7)	43.1 (15.3)
Median (IQR)	35.0 (28.0–53.6)	45.0 (36.1–54.2)	43.5 (30.0–54.0)
Minimum–maximum	20.0–92.0	21.0–70.0	20.0–92.0
Not reported, *n* (%)	17 (26.6)	18 (25.7)	35 (26.1)
Ethnicity, n (%)			
White British	44 (68.8)	41 (58.6)	85 (63.4)
White European	4 (6.2)	1 (1.4)	5 (3.7)
Asian/Asian British	7 (10.9)	6 (8.6)	13 (9.7)
Black/African/Caribbean/Black British	2 (3.1)	7 (10.0)	9 (6.7)
Mixed/multiple ethnic group	5 (7.8)	10 (14.3)	15 (11.2)
Other	2 (3.1)	4 (5.7)	6 (4.5)
Not reported, *n* (%)	0 (0.0)	1 (1.4)	1 (0.7)
OxAFQ (physical)[b]			
Mean (SD)	50.9 (20.0)	46.9 (19.0)	48.8 (19.5)
Median (IQR)	50.0 (33.3–66.7)	50.0 (33.3–58.3)	50.0 (33.3–62.5)
Minimum–maximum	8.3–91.7	4.2–100.0	4.2–100.0
Not reported, *n* (%)	0 (0.0)	1 (1.4)	1 (0.7)

continued

TABLE 8 Parent/guardian-reported baseline data, by trial arm (*continued*)

Characteristic[a]	Control (*n* = 64)	Intervention (*n* = 70)	Total (*n* = 134)
OxAFQ (school and play)[b]			
Mean (SD)	73.3 (21.0)	72.2 (23.4)	72.7 (22.2)
Median (IQR)	75.0 (56.25–93.75)	75.0 (56.25–93.75)	75.0 (56.25–93.75)
Minimum–maximum	25.0–100.0	12.5–100.0	12.5–100.0
Not reported, *n* (%)	0 (0.0)	1 (1.4)	1 (0.7)
OxAFQ (emotional)[b]			
Mean (SD)	84.1 (22.2)	85.0 (17.9)	84.5 (20.0)
Median (IQR)	93.75 (75.0–100.0)	87.5 (75.0–100.0)	93.75 (75.0–100.0)
Minimum–maximum	18.8–100.0	31.3–100.0	18.8–100.0
Not reported, *n* (%)	0 (0.0)	1 (1.4)	1 (0.7)
OxAFQ (footwear)[b]			
Mean (SD)	66.0 (32.5)	64.5 (32.2)	65.2 (32.3)
Median (IQR)	75.0 (50.0–100.0)	75.0 (50.0–100.0)	75.0 (50.0–100.0)
Minimum–maximum	0.0–100.0	0.0–100.0	0.0–100.0
Not reported, *n* (%)	0 (0.0)	1 (1.4)	1 (0.7)
Pain score (left foot)[c]			
Mean (SD)	3.2 (2.6)	3.8 (2.4)	3.5 (2.6)
Median (IQR)	3.0 (0.0–6.0)	4.0 (2.0–6.0)	3.0 (1.0–6.0)
Minimum–maximum	0.0–8.0	0.0–9.0	0.0–9.0
Not reported, *n* (%)	1 (1.6)	2 (2.9)	3 (2.2)
Pain score (right foot)[c]			
Mean (SD)	3.7 (2.8)	4.0 (2.6)	3.9 (2.7)
Median (IQR)	4.0 (1.0–6.0)	4.5 (2.0–6.0)	4.0 (2.0–6.0)
Minimum–maximum	0.0–9.0	0.0–9.0	0.0–9.0
Not reported, *n* (%)	2 (3.1)	2 (2.9)	4 (3.0)
CHU9D[d]			
Mean (SD)	0.86 (0.14)	0.96 (0.11)	0.86 (0.12)
Median (IQR)	0.88 (0.82–0.97)	0.87 (0.80–0.95)	0.88 (0.80–0.95)
Minimum–maximum	0.48–1.00	0.51–1.00	0.48–1.00
Not reported, *n* (%)	2 (3.1)	1 (1.4)	3 (2.2)

IQR, interquartile range.
a IQR reported as (lower quartile limit–upper quartile limit).
b A higher score represents better functioning.
c A higher score indicates worse pain.
d A higher score indicates better health-related quality of life.

Note
Baseline data are available for 133 (99.3%) participants randomised into the OSTRICH study. Participants were on average 10.6 years old (SD 2.3), 55.2% were male and two-thirds were White British or White European (67.2%). There was a higher proportion of males in the control arm of the study (59.4%) than in the intervention arm (51.4%).

TABLE 9 Baseline data collected by the investigator, by trial arm

Outcome measure[a]	Control (*n* = 64)	Intervention (*n* = 70)	Total (*n* = 134)
Foot posture index (left)[b]			
Mean (SD)	8.1 (2.1)	7.8 (3.0)	8.0 (2.6)
Median (IQR)	8.0 (6.0–10.0)	8.0 (6.0–10.0)	8.0 (6.0–10.0)
Minimum–maximum	4.0–12.0	−5.0–12.0	−5.0–12.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
Foot posture index (right)[b]			
Mean (SD)	7.9 (2.1)	7.9 (3.1)	7.9 (2.6)
Median (IQR)	8.0 (6.0–9.0)	8.0 (7.0–10.0)	8.0 (6.0–10.0)
Minimum–maximum	4.0–12.0	−5.0–12.0	−5.0–12.0
Not reported, *n* (%)	1 (1.6)	1 (1.4)	2 (1.5)
Static single leg balance, eyes open (seconds)			
Mean (SD)	35.9 (34.0)	38.9 (38.9)	37.4 (36.4)
Median (IQR)	20.0 (16.0–40.0)	25.0 (11.0–54.0)	21.0 (13.0–48.0)
Minimum–maximum	3.0–120.0	1.0–120.0	1.0–120.0
Not reported, *n* (%)	6 (9.4)	10 (14.3)	16 (11.9)
Static single leg balance, eyes closed (seconds)			
Mean (SD)	12.9 (23.7)	15.0 (23.5)	13.9 (23.5)
Median (IQR)	6.0 (3.0–10.0)	7.0 (4.0–15.0)	6.0 (3.0–13.0)
Minimum–maximum	1.0–120.0	1.0–120.0	1.0–120.0
Not reported, *n* (%)	14 (21.9)	21 (30.0)	35 (26.1)
Consultation location, n (%)			
In person	62 (96.9)	68 (97.1)	130 (97.0)
Online/via telephone	0 (0.0)	0 (0.0)	0 (0.0)
Not reported	2 (3.1)	2 (2.9)	4 (3.0)
Prefabricated insoles fitted at the appointment, n (%)			
Yes	2 (3.0)	69 (98.6)	71 (53.0)
No	14 (21.2)	0 (0.0)	14 (10.5)
Not reported	48 (75.0)	1 (1.4)	49 (36.6)
Model of prefabricated insole,[c] n (%)			
First Line	0 (0.0)	1 (1.5)	1 (1.4)
4Kids	0 (0.0)	3 (4.4)	3 (4.2)
Biomex	0 (0.0)	4 (5.8)	4 (5.6)
Basis Pro	0 (0.0)	1 (1.5)	1 (1.4)
Haplabase	0 (0.0)	1 (1.5)	1 (1.4)
Interpod – Flex	0 (0.0)	3 (4.4)	3 (4.2)
Kids Feet in Motion	0 (0.0)	4 (5.8)	4 (5.6)
Peapods – Dinky	0 (0.0)	5 (7.3)	5 (7.0)
Peapods – Junior	0 (0.0)	2 (2.9)	2 (2.8)

continued

TABLE 9 Baseline data collected by the investigator, by trial arm (*continued*)

Outcome measure[a]	Control (*n* = 64)	Intervention (*n* = 70)	Total (*n* = 134)
Pedipod	0 (0.0)	5 (7.3)	5 (7.0)
Polypod	0 (0.0)	1 (1.5)	1 (1.4)
Prostep	0 (0.0)	2 (2.9)	2 (2.8)
Slimflex – Amber	0 (0.0)	3 (4.4)	3 (4.2)
Slimflex – Green	0 (0.0)	1 (1.5)	1 (1.4)
Slimflex – Simples	1 (50.0)	16 (23.2)	17 (23.9)
Xline – Standard	0 (0.0)	6 (8.7)	6 (8.5)
Other[d]	1 (50.0)	11 (15.9)	12 (16.9)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)
Modifications/additions made to prefabricated insole,[c,e] n (%)			
First Met Cutout	0 (0.0)	3 (4.4)	3 (4.2)
Heel Cup	0 (0.0)	2 (2.9)	2 (2.8)
Heel raise	0 (0.0)	6 (8.7)	6 (8.5)
Medial extrinsic rear	0 (0.0)	24 (34.8)	24 (33.8)
Medial heel kive	0 (0.0)	1 (1.5)	1 (1.4)
Not reported			
Structures targeted in prescribed stretches,[f] n (%)			
Calf (gastrocnemius, soleus, plantaris, Achilles)	43 (67.2)	40 (57.1)	83 (61.9)
Gluteals	5 (7.8)	5 (7.1)	10 (7.5)
Intrinsic foot muscles	10 (15.6)	14 (20.0)	24 (17.9)
Long flexors (Flexor Hallucis Longus, Flexor Digitorum Longus, tibialis posterior)	5 (7.8)	2 (2.9)	7 (5.2)
Peroneals	0 (0.0)	1 (1.4)	1 (0.8)
Quadriceps	5 (7.8)	4 (5.7)	9 (6.7)
Tibialis posterior	1 (1.6)	3 (4.3)	4 (3.0)
Hamstrings	30 (46.9)	29 (41.4)	59 (44.0)
Plantar fascia	17 (26.6)	17 (24.3)	34 (25.4)
None	3 (4.7)	5 (7.1)	8 (6.0)
Other	2 (3.1)	2 (2.9)	4 (3.0)
Not reported	13 (20.3)	14 (20.0)	27 (20.2)
Structures targeted in prescribed strengthening,[g] n (%)			
Calf (gastrocnemius, soleus, plantaris, Achilles)	30 (46.9)	31 (44.3)	61 (45.5)
Gluteals	10 (15.6)	11 (15.7)	21 (15.7)
Core muscles	9 (14.1)	11 (15.7)	20 (14.9)
Intrinsic foot muscles	31 (48.4)	31 (44.3)	62 (46.3)
Long flexors (FHL, FDL, tibialis posterior)	24 (37.5)	15 (21.4)	39 (29.1)
Peroneals	3 (4.7)	3 (4.3)	6 (4.5)
Quadriceps	7 (10.9)	4 (4.3)	10 (7.5)
Tibialis posterior	19 (29.7)	24 (34.3)	43 (32.1)

TABLE 9 Baseline data collected by the investigator, by trial arm (*continued*)

Outcome measure[a]	Control (*n* = 64)	Intervention (*n* = 70)	Total (*n* = 134)
Hamstrings	8 (12.5)	9 (12.9)	17 (12.7)
None	1 (1.6)	7 (10.0)	8 (6.0)
Other	4 (6.3)	3 (4.3)	7 (5.2)
Not reported	5 (7.8)	10 (14.3)	15 (11.2)
Approaches recommended for the exercise programme,[h] n (%)			
Activity prescription	11 (17.2)	12 (17.1)	23 (17.2)
Balance exercises	30 (46.9)	22 (31.4)	52 (38.8)
Games and play	11 (17.2)	8 (11.4)	19 (14.2)
None	9 (14.1)	16 (22.9)	25 (18.7)
Other	5 (7.8)	1 (1.4)	6 (4.5)
Not reported	14 (21.9)	16 (22.9)	30 (22.4)
Exercise programme explained/demonstrated, n (%)			
Yes	45 (70.3)	54 (77.1)	99 (73.9)
No	0 (0.0)	2 (2.9)	2 (1.5)
Not reported	19 (29.7)	14 (20.0)	33 (24.6)
Participant provided with,[i] n (%)			
Link to personalised programme on the Physiotec app	20 (31.3)	21 (30.0)	41 (30.6)
Printed exercise leaflet	46 (71.9)	52 (74.3)	98 (73.1)
Neither	0 (0.0)	3 (4.3)	3 (2.2)
Other	5 (7.8)	4 (5.7)	9 (6.7)
Not reported	2 (3.1)	2 (2.9)	4 (3.0)
Participant provided with the advice leaflet, n (%)			
Yes	51 (79.7)	53 (75.7)	104 (77.6)
No	2 (3.1)	9 (12.9)	11 (8.2)
Not reported	11 (17.2)	8 (11.4)	19 (14.2)
Time taken for assessment (minutes)			
Mean (SD)	45.9 (13.6)	54.4 (19.3)	50.4 (19.3)
Not reported, *n* (%)	2 (3.1)	1 (1.4)	3 (2.2)

IQR, interquartile range.
a IQR reported as (lower quartile limit–upper quartile limit).
b Reference values: normal = 0 to +5; pronated = +6 to +9; highly pronated 10+; supinated = −1 to −4; highly supinated −5 to −12.
c Of those who answered 'yes' to the question 'were prefabricated insoles fitted at the appointment'.
d Other insole types included Slimflex Blue ¾ (*n* = 3); Peak (*n* = 2); Talar made and Extrinsic addition (*n* = 1); Xline standard and Slimflex ¾ mdensity eva (*n* = 1); Bio advance ¾ low density (*n* = 1); Bio advanced LD FL (*n* = 1); Discovery eva (*n* = 1); gaitway classic 314 (*n* = 1); Xune TPD (*n* = 1).
e Participants may have had more than one modification or addition made to their prefabricated insole.
f Participants may have targeted multiple structures in prescribed stretches.
g Participants may have targeted multiple structures in prescribed strengthening exercises.
h Participants may have multiple approaches recommended as part of the exercise programme.
i Participants may have been provided with multiple items.

Note
Baseline investigator data are available for 133 (99.3%) participants randomised into the OSTRICH study (questionnaire not received for one participant in the intervention group).

Appendix 3 Follow-up, retention and results

TABLE 10 Treatment confirmation

	Control (*n* = 62)	Intervention (*n* = 67)	Total (*n* = 129)
Participant had additional appointments following their original baseline study appointment, n (%)			
Yes	22 (35.5)	27 (40.3)	49 (38.0)
No	40 (64.5)	40 (59.7)	80 (62.0)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)
Number of additional appointments[a]			
1	18 (81.8)	23 (85.2)	41 (83.7)
2	3 (13.6)	4 (14.8)	7 (14.3)
3	1 (4.6)	0 (0.0)	1 (2.0)
Further appointments booked in relation to pes planus, n (%)			
Yes	7 (11.3)	7 (10.5)	14 (10.9)
No	44 (71.0)	45 (67.2)	89 (69.0)
Not reported	11 (17.7)	15 (22.4)	26 (20.2)
Number of further appointments,[b] ***n (%)***			
1	5 (71.4)	7 (100.0)	12 (85.7)
2	1 (14.3)	0 (0.0)	1 (7.1)
Not reported	1 (14.3)	0 (0.0)	1 (7.1)
Participant provided with prefabricated insoles following their baseline appointment, n (%)			
Yes	6 (9.7)	8 (11.9)	14 (10.9)
No	*53 (85.5)*	*57 (85.1)*	*110 (85.3)*
Not reported	3 (4.8)	2 (3.0)	5 (3.9)
Model of prefabricated insole was fitted,[c] ***n (%)***			
Interpod Flex	1 (16.7)	1 (12.5)	2 (14.3)
Slimflex – Amber	0 (0.0)	1 (12.5)	1 (7.1)
Slimflex – Simples	1 (16.7)	3 (37.5)	4 (28.6)
Xline – Standard	1 (16.7)	3 (37.5)	4 (28.6)
Other	1 (16.7)	0 (0.0)	1 (7.1)
Not reported	2 (33.3)	0 (0.0)	2 (14.3)
Modifications and additions made to the insole,[c] ***n (%)***			
Heel raise	0 (0.0)	2 (25.0)	2 (14.3)
Medial extrinsic rear	2 (33.3)	2 (25.0)	4 (28.6)
Not reported	4 (66.7)	4 (50.0)	8 (57.1)
Reason for providing insoles after the baseline appointment,[c] ***n (%)***			
Insole required assembly after baseline appointment	1 (16.7)	0 (0.0)	1 (7.1)
Insole needed further adjustment/customisation	0 (0.0)	2 (25.0)	2 (14.3)

TABLE 10 Treatment confirmation (*continued*)

	Control (*n* = 62)	Intervention (*n* = 67)	Total (*n* = 129)
Additional insoles provided	0 (0.0)	2 (25.0)	2 (14.3)
Different insoles	0 (0.0)	1 (12.5)	1 (7.1)
Other	2 (33.3)	2 (25.0)	4 (28.6)
Not reported	3 (50.0)	1 (12.5)	4 (28.6)
Participant's insoles modified since they were issued, n (%)			
Yes	0 (0.0)	4 (6.0)	4 (3.10)
No	57 (91.9)	59 (88.1)	116 (89.9)
Not reported	5 (8.1)	4 (6.0)	9 (7.0)
Modifications/changes to the insoles originally supplied,[d] n (%)			
Heel extrinsic post – lateral flare	0 (0.0)	1 (25.0)	1 (25.0)
Medial extrinsic rear	0 (0.0)	2 (50.0)	2 (50.0)
Other	0 (0.0)	1 (25.0)	1 (25.0)
Participant provided with exercises and advice following their baseline appointment, n (%)			
Yes	9 (14.5)	6 (9.0)	15 (11.6)
No	52 (83.9)	57 (85.1)	109 (84.5)
Not reported	1 (1.6)	4 (6.0)	5 (3.9)
Structures targeted in prescribed stretches,[e] n (%)			
Calf (gastrocnemius, soleus, plantaris, Achilles)	3 (33.3)	2 (33.3)	5 (33.3)
Iliotibial band/tensor fascia latae	1 (11.1)	0 (0.0)	1 (6.7)
Intrinsic foot muscle	0 (0.0)	2 (33.3)	2 (13.3)
Long flexors (FHL, FDL, tibialis posterior)	0 (0.0)	1 (16.7)	1 (6.7)
Peroneals	0 (0.0)	1 (16.7)	1 (6.7)
Hamstrings	0 (0.0)	2 (33.3)	2 (13.3)
Plantar fascia	1 (11.1)	0 (0.0)	1 (6.7)
Other	2 (22.2)	0 (0.0)	2 (13.3)
Not reported	4 (44.4)	2 (33.3)	6 (40.0)
Structures targeted in prescribed strengthening exercises,[e] n (%)			
Calf (gastrocnemius, soleus, plantaris, Achilles)	0 (0.0)	2 (33.3)	2 (13.3)
Gluteals	1 (11.1)	0 (0.0)	1 (6.7)
Core muscles	1 (11.1)	1 (16.7)	2 (13.3)
Intrinsic foot muscle	0 (0.0)	2 (33.3)	2 (13.3)
Tibialis posterior	1 (11.1)	0 (0.0)	1 (6.7)
Hamstrings	1 (11.1)	1 (16.7)	2 (13.3)
None	1 (11.1)	0 (0.0)	1 (6.7)

continued

TABLE 10 Treatment confirmation (*continued*)

	Control (*n* = 62)	Intervention (*n* = 67)	Total (*n* = 129)
Other	1 (11.1)	0 (0.0)	1 (6.7)
Not reported	6 (66.7)	2 (33.3)	8 (53.3)
Specific approaches recommended as part of the exercise programme,[e] n (%)			
Activity prescription	0 (0.0)	1 (16.7)	1 (6.7)
Balance exercises	1 (11.1)	1 (16.7)	2 (13.3)
None	3 (33.3)	1 (16.7)	4 (26.7)
Not reported	5 (55.6)	3 (50.0)	8 (53.3)
Exercise programme explained and demonstrated, n (%)			
Yes	5 (8.1)	7 (10.5)	12 (9.3)
No	2 (3.2)	0 (0.0)	2 (1.6)
Not reported	55 (88.7)	60 (89.6)	115 (89.2)
Participant provided with, n (%)			
Link to personalised programme on the Physiotec app	0 (0.0)	0 (0.0)	0 (0.0)
Printed exercise leaflet	3 (4.8)	3 (4.5)	6 (4.7)
Neither	1 (1.6)	1 (1.5)	2 (1.6)
Other	4 (6.5)	2 (3.0)	6 (4.7)
Not reported	55 (88.7)	61 (91.0)	116 (89.9)
Participant provided with the advice leaflet, n (%)			
Yes	4 (4.8)	3 (4.5)	6 (4.7)
No	5 (8.1)	2 (3.0)	7 (5.4)
Not reported	54 (87.1)	62 (92.5)	116 (89.9)
Participant experienced any issues with wearing their insoles or undertaking their exercises, n (%)			
Yes	9 (14.5)	13 (19.4)	22 (17.1)
No	48 (77.4)	53 (79.1)	101 (78.3)
Not reported	5 (8.1)	1 (1.5)	6 (4.7)

a Responses of those who answered 'yes' to 'Has the participant had any additional appointments since their original baseline study appointment?'.
b Responses of those who answered 'yes' to 'Are further appointments booked in relation to pes planus?'.
c Response of those who answered 'yes' to 'Has the participant been provided with prefabricated insoles following their baseline appointment?'.
d Responses of those who answered 'yes' to 'Have the participant's insoles been modified since they were issued?'.
e Responses of those who answered 'yes' to 'Has the participant been provided with any exercises and advice following their baseline appointment?'. Participants may have multiple prescribed stretches.

TABLE 11 Parent/guardian-completed experience with the intervention and/or exercises, by trial arm

	3 months		6 months		12 months	
	Control (*n* = 32)	Intervention (*n* = 35)	Control (*n* = 25)	Intervention (*n* = 28)	Control (*n* = 8)	Intervention (*n* = 11)
Did your child/young person receive a pair of insoles at the original study appointment/s?, n (%)						
Yes	3 (9.4)	34 (97.1)	4 (16.0)	28 (100.0)	3 (37.5)	9 (81.8)
No	29 (90.6)	0 (0.0)	20 (80.0)	0 (0.0)	5 (62.5)	0 (0.0)
Not reported	0 (0.0)	1 (2.9)	1 (4.0)	0 (0.0)	0 (0.0)	2 (18.2)
Did your child/young person need to change their usual footwear in order to fit the study insoles in?, n (%)[a]						
Yes	2 (66.7)	12 (35.3)	2 (50.0)	15 (53.6)	1 (33.3)	4 (44.4)
No	1 (33.3)	21 (61.8)	2 (50.0)	13 (46.4)	2 (66.7)	5 (55.6)
Not reported	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Over the past week, typically how often did your child/young person wear the insoles?, n (%)[a]						
All of the time	2 (66.7)	23 (67.7)	2 (50.0)	17 (60.7)	2 (66.7)	3 (33.3)
Most of the time	1 (33.3)	5 (14.7)	1 (25.0)	5 (17.9)	1 (33.3)	1 (11.1)
Some of the time	0 (0.0)	1 (2.9)	0 (0.0)	2 (7.1)	0 (0.0)	2 (22.2)
A little of the time	0 (0.0)	3 (8.8)	0 (0.0)	2 (7.1)	0 (0.0)	2 (22.2)
None of the time	0 (0.0)	1 (2.9)	1 (25.0)	2 (7.1)	0 (0.0)	1 (11.1)
Not reported	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Thinking about your child/young person's experiences of wearing the insoles that they were given for the study, please tell us if,[a] ***n (%)***						
They were a good fit						
Yes	3 (100.0)	32 (94.1)	4 (100.0)	26 (92.9)	3 (100.0)	6 (66.7)
No	0 (0.0)	2 (5.9)	0 (0.0)	2 (7.1)	0 (0.0)	3 (33.3)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
They were comfortable to wear						
Yes	3 (100.0)	28 (82.4)	2 (50.0)	24 (85.7)	3 (100.0)	5 (55.6)
No	0 (0.0)	6 (17.7)	2 (50.0)	4 (14.3)	0 (0.0)	3 (33.3)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)

continued

This synopsis should be referenced as follows: Cockayne S, Baird K, Gates S, Fairhurst C, Adamson J, Bottomley-Wise RM, *et al.* OrthoticS for TReatment of symptomatic flat feet In CHildren (OSTRICH): a randomised controlled trial [published online ahead of print August 6 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/PLKJ4541

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TABLE 11 Parent/guardian-completed experience with the intervention and/or exercises, by trial arm (*continued*)

	3 months		6 months		12 months	
	Control (*n* = 32)	Intervention (*n* = 35)	Control (*n* = 25)	Intervention (*n* = 28)	Control (*n* = 8)	Intervention (*n* = 11)
They improved or resolved any usual problems with your child's feet						
Yes	1 (33.3)	23 (67.7)	2 (50.0)	21 (75.0)	3 (100.0)	5 (55.6)
No	2 (66.7)	9 (26.5)	1 (25.0)	4 (14.3)	0 (0.0)	2 (22.2)
Not reported	0 (0.0)	2 (5.9)	1 (25.0)	3 (10.7)	0 (0.0)	2 (22.2)
They wore out quickly						
Yes	0 (0.0)	4 (11.8)	0 (0.0)	6 (21.4)	0 (0.0)	0 (0.0)
No	3 (100.0)	29 (85.3)	4 (100.0)	22 (78.6)	3 (100.0)	9 (100.0)
Not reported	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Your child outgrew them						
Yes	0 (0.0)	4 (11.8)	0 (0.0)	3 (10.7)	1 (33.3)	1 (11.1)
No	3 (100.0)	29 (85.3)	4 (100.0)	25 (89.3)	2 (66.7)	8 (88.9)
Not reported	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Over the past week, typically how often did your child undertake the exercises as prescribed at the study appointment?, n (%)						
All of the time	3 (9.4)	2 (5.7)	2 (8.0)	1 (3.6)	0 (0.0)	0 (0.0)
Most of the time	12 (37.5)	7 (20.0)	6 (24.0)	4 (14.3)	0 (0.0)	1 (9.1)
Some of the time	10 (31.3)	14 (40.0)	5 (20.0)	15 (53.6)	2 (25.0)	4 (36.4)
A little of the time	4 (12.5)	8 (22.9)	5 (20.0)	6 (21.4)	1 (12.5)	4 (36.4)
None of the time	2 (6.3)	2 (5.7)	6 (24.0)	1 (3.6)	5 (62.5)	0 (0.0)
Not reported	1 (3.1)	2 (5.7)	1 (4.0)	1 (3.6)	0 (0.0)	2 (18.2)
Did your child/young person have any problems (e.g. blisters or pain) as a result of wearing the insoles (if applicable), doing the exercises or taking part in the study?, n (%)						
Yes	2 (6.2)	8 (22.9)	1 (4.0)	6 (21.4)	0 (0.0)	5 (45.5)
No	9 (28.1)	26 (74.3)	11 (44.0)	22 (78.6)	7 (87.5)	4 (36.4)
Not reported	21 (65.6)	1 (2.9)	13 (52.0)	0 (0.0)	1 (12.5)	2 (18.2)

a Of those who responded 'yes' to the question 'Did your child/young person receive a pair of insoles at the original study appointment/s'.

TABLE 12 Response rates to postal questionnaires and text messages, by trial arm

Questionnaire	Control (*n* = 64)	Intervention (*n* = 70)	Total (*n* = 134)
Due[a]	64	70	134
3-month child, *n* (% due, % randomised)	32 (50.0, 50.0)	35 (50.0, 50.0)	67 (50.0, 50.0)
3-month parent, *n* (% due, % randomised)	32 (50.0, 50.0)	35 (50.0, 50.0)	67 (50.0, 50.0)
Due[a]	57	62	119
6-month child, *n* (% due, % randomised)	25 (43.9, 39.1)	29 (46.8, 41.4)	54 (45.4, 40.3)
6-month parent, *n* (% due, % randomised)	25 (43.9, 39.1)	28 (45.2, 40.0)	53 (44.5, 39.6)
Due[a]	20	24	44
12-month child, *n* (% due, % randomised)	8 (40.0, 12.5)	11 (45.8, 15.7)	19 (43.2, 14.2)
12-month parent, *n* (% due, % randomised)	8 (40.0, 12.5)	11 (45.8, 15.7)	19 (43.2, 14.2)
	***N* (% sent, % randomised)**	***N* (% sent, % randomised)**	***N* (% sent, % randomised)**
Sent[b]	54	60	114
SMS message week 1	48 (88.9, 75.0)	47 (78.3, 67.1)	95 (83.3, 70.9)
Sent[b]	54	60	114
SMS message week 2	45 (83.3, 70.3)	47 (78.3, 67.1)	92 (80.7, 68.7)
Sent[b]	54	61	114
SMS message week 3	42 (77.8, 65.6)	49 (80.3, 70.0)	91 (79.1, 67.9)
Sent[b]	53	62	115
SMS message week 4	45 (84.9, 70.3)	50 (80.7, 71.4)	95 (82.6, 70.9)
Sent[b]	53	61	114
SMS message week 5	41 (77.4, 64.1)	49 (80.3, 70.0)	90 (79.0, 67.2)
Sent[b]	54	62	116
SMS message week 6	41 (75.9, 64.1)	46 (74.2, 65.7)	87 (75.0, 64.9)
Sent[b]	54	62	116
SMS message week 7	45 (83.3, 70.3)	44 (71.0, 62.9)	89 (76.7, 66.4)
Sent[b]	53	60	113
SMS message week 8	38 (71.7, 59.4)	40 (66.7, 57.1)	78 (69.0, 58.2)
Sent[b]	53	60	113
SMS message week 9	41 (77.4, 64.1)	43 (71.7, 61.4)	84 (74.3, 62.7)
Sent[b]	51	60	111
SMS message week 10	33 (64.7, 51.6)	44 (73.3, 62.9)	77 (69.4, 57.5)
Sent[b]	52	60	112
SMS message week 11	32 (61.5, 50.0)	41 (68.3, 58.6)	73 (65.2, 54.5)
Sent[b]	52	61	113
SMS message week 12	31 (59.6, 48.4)	44 (72.1, 62.9)	75 (66.4, 56.0)
Sent[b]	47	46	93
SMS message month 6	26 (55.3, 40.6)	21 (45.7, 30.0)	47 (50.5, 35.1)
Sent[b]	19	21	40
SMS message month 12	13 (68.4, 20.3)	6 (28.6, 8.6)	19 (47.5, 14.2)

a Reflects the number of participants due and sent the questionnaire up to 31 August 2023 when follow-up was prematurely ceased due to the trial closure.
b Reflects the number of participants due and sent the SMS up to 31 August 2023; in addition, messages were not sent between 20 April and 13 June 2023 due to a technical error with the SMS software.

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TABLE 13 Pain scores collected from SMS messages, by trial arm

	Control (*n* = 64)		Intervention (*n* = 70)		Total (*n* = 134)	
Pain score[a]	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
Week 1	48	4.3 (2.5)	47	4.2 (2.2)	95	4.2 (2.4)
Week 2	45	5.1 (2.5)	47	4.0 (2.2)	92	4.5 (2.4)
Week 3	42	4.3 (2.8)	49	4.2 (2.2)	91	4.2 (2.5)
Week 4	45	4.4 (2.8)	50	4.0 (2.3)	95	4.2 (2.5)
Week 5	41	4.4 (3.0)	49	3.7 (2.5)	90	4.0 (2.8)
Week 6	41	4.0 (2.8)	46	3.4 (2.4)	87	3.7 (2.6)
Week 7	45	4.3 (2.9)	44	3.0 (2.4)	89	3.7 (2.7)
Week 8	38	3.8 (2.8)	40	3.3 (2.3)	78	3.5 (2.6)
Week 9	41	3.4 (2.5)	43	3.5 (2.2)	84	3.5 (2.4)
Week 10	33	4.0 (2.6)	44	3.5 (2.4)	77	3.7 (2.5)
Week 11	32	4.4 (2.8)	41	3.3 (2.2)	73	3.8 (2.5)
Week 12	31	3.5 (2.9)	44	3.1 (2.1)	75	3.3 (2.5)
Month 6	26	3.9 (3.2)	21	3.8 (2.5)	47	3.9 (2.8)
Month 12	13	2.9 (2.7)	6	4.3 (2.9)	19	3.4 (2.8)

a Higher score indicates worse pain.

TABLE 14 Participant-reported secondary outcome measures, by trial arm, at all follow-up time points

	Control (*n* = 64)		Intervention (*n* = 70)		Total (*n* = 134)	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
Wong Baker Faces (left)[a]						
3-month	31	3.0 (2.3)	34	2.8 (1.9)	65	2.9 (2.1)
6-month	25	2.4 (2.2)	29	3.2 (2.2)	54	2.9 (2.2)
12-month	8	2.3 (2.3)	10	3.2 (2.5)	18	2.8 (2.4)
Wong Baker Faces (right)[a]						
3-month	32	3.3 (3.0)	34	3.7 (2.6)	66	3.5 (2.8)
6-month	25	2.9 (2.8)	29	3.9 (2.4)	54	3.4 (2.6)
12-month	8	2.8 (3.0)	10	2.6 (2.8)	18	2.7 (2.8)
CHU9D[b]						
3-month	32	0.86 (0.13)	33	0.83 (0.12)	65	0.85 (0.12)
6-month	25	0.87 (0.13)	29	0.85 (0.14)	54	0.86 (0.13)
12-month	8	0.92 (0.11)	8	0.86 (0.09)	16	0.89 (0.11)

a A higher score indicates worse pain.
b A higher score indicates better health-related quality of life.

This synopsis should be referenced as follows: Cockayne S, Baird K, Gates S, Fairhurst C, Adamson J, Bottomley-Wise RM, *et al.* OrthoticS for TReatment of symptomatic flat feet In CHildren (OSTRICH): a randomised controlled trial [published online ahead of print August 6 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/PLKJ4541

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TABLE 15 Parent/guardian-reported outcome measures, by trial arm, at all follow-up time points

	Control (*n* = 64)		Intervention (*n* = 70)		Total (*n* = 134)	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
OxAFQ (physical)[a]						
3-month	32	56.3 (21.8)	34	61.3 (22.6)	66	58.8 (22.2)
6-month	25	63.3 (27.5)	28	55.7 (21.6)	53	59.3 (24.6)
12-month	8	67.2 (26.6)	10	60.8 (23.4)	18	63.7 (24.3)
OxAFQ (school and play)[a]						
3-month	32	79.9 (24.8)	34	81.8 (23.9)	66	80.9 (24.2)
6-month	25	83.3 (21.8)	28	83.3 (21.4)	53	83.3 (21.4)
12-month	8	79.7 (18.5)	10	88.8 (14.7)	18	84.7 (16.6)
OxAFQ (emotional)[a]						
3-month	32	85.4 (18.1)	34	81.3 (22.5)	66	83.2 (20.4)
6-month	25	87.0 (18.7)	28	81.5 (24.0)	53	84.1 (21.6)
12-month	8	88.3 (16.8)	10	86.3 (15.5)	18	87.2 (15.7)
OxAFQ (footwear)[a]						
3-month	32	57.0 (33.1)	34	60.3 (38.0)	66	58.7 (35.5)
6-month	25	69.0 (35.6)	28	54.5 (37.9)	53	61.3 (37.2)
12-month	8	68.8 (32.0)	10	55.0 (36.9)	18	61.1 (34.5)
Pain score (left)[b]						
3-month	31	3.2 (2.6)	34	2.9 (2.2)	65	3.0 (2.4)
6-month	25	2.9 (2.4)	27	3.4 (2.2)	52	3.1 (2.3)
12-month	8	2.1 (2.4)	10	3.0 (2.2)	18	2.6 (2.2)
Pain score (right)[b]						
3-month	31	3.1 (2.7)	33	3.8 (2.7)	64	3.5 (2.7)
6-month	25	3.2 (2.7)	27	3.4 (2.2)	52	3.3 (2.5)
12-month	8	2.5 (2.9)	10	2.8 (2.1)	18	2.7 (2.4)
CHU9D[c]						
3-month	32	0.88 (0.11)	33	0.85 (0.12)	65	0.86 (0.12)
6-month	25	0.88 (0.13)	28	0.89 (0.12)	53	0.89 (0.13)
12-month	8	0.91 (0.12)	9	0.88 (0.08)	17	0.90 (0.10)

a A higher score represents better functioning.
b A higher score indicates worse pain.
c A higher score indicates better health-related quality of life.

TABLE 16 EQ-5D-Y – child completed

	Baseline		3 months		6 months		12 months	
	Control (*n* = 63)	Intervention (*n* = 69)	Control (*n* = 32)	Intervention (*n* = 35)	Control (*n* = 25)	Intervention (*n* = 29)	Control (*n* = 8)	Intervention (*n* = 11)
Mobility, n (%)								
I have no problems walking about	30 (47.6)	31 (44.9)	19 (59.4)	18 (51.4)	15 (60.0)	16 (55.2)	6 (75.0)	6 (54.6)
I have some problems walking about	30 (47.6)	35 (50.7)	10 (31.3)	14 (40.0)	8 (32.0)	12 (41.4)	1 (12.5)	4 (36.4)
I have a lot of problems walking about	3 (4.8)	3 (4.4)	3 (9.4)	2 (5.7)	1 (4.0)	1 (3.5)	1 (12.5)	0 (0.0)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	1 (4.0)	0 (0.0)	0 (0.0)	1 (9.1)
Looking after myself, n (%)								
I have no problems washing or dressing myself	53 (84.1)	58 (84.1)	27 (84.4)	33 (94.3)	21 (84.0)	26 (89.7)	6 (75.0)	10 (90.9)
I have some problems washing or dressing myself	7 (11.1)	10 (14.5)	4 (12.5)	1 (2.9)	4 (16.0)	3 (10.3)	2 (25.0)	0 (0.0)
I have a lot of problems washing or dressing myself	3 (3.2)	1 (1.5)	1 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Not reported	1 (1.6)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
Doing usual activities, n (%)								
I have no problems doing my usual activities	31 (49.2)	36 (52.2)	21 (65.6)	20 (57.1)	18 (72.0)	17 (58.6)	7 (87.5)	8 (72.7)
I have some problems doing my usual activities	30 (47.6)	29 (42.0)	10 (31.3)	13 (37.1)	7 (28.0)	11 (37.9)	1 (12.5)	2 (18.2)
I have a lot of problems doing my usual activities	2 (3.2)	4 (5.8)	1 (3.1)	1 (2.9)	0 (0.0)	1 (3.5)	0 (0.0)	0 (0.0)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
Having pain or discomfort, n (%)								
I have no pain or discomfort	16 (25.4)	12 (17.4)	12 (37.5)	12 (34.3)	11 (44.0)	11 (37.9)	4 (50.0)	5 (45.5)
I have some pain or discomfort	38 (60.3)	47 (68.1)	16 (50.0)	18 (51.4)	12 (48.0)	14 (48.3)	3 (37.5)	3 (27.3)
I have a lot of pain or discomfort	8 (12.7)	10 (14.5)	4 (12.5)	3 (8.6)	2 (8.0)	3 (10.3)	1 (12.5)	2 (18.2)
Not reported	1 (1.6)	0 (0.0)	0 (0.0)	2 (5.7)	0 (0.0)	1 (3.5)	0 (0.0)	1 (9.1)
Feeling worried, sad or unhappy, n (%)								
I am not worried, sad or unhappy	40 (63.5)	40 (58.0)	22 (68.8)	24 (68.6)	19 (76.0)	19 (65.5)	6 (75.0)	7 (63.6)
I am a bit worried, sad or unhappy	19 (30.2)	26 (37.7)	7 (21.9)	8 (22.9)	4 (16.0)	7 (24.1)	2 (25.0)	3 (27.3)
I am very worried, sad, or unhappy	4 (6.4)	3 (4.4)	3 (9.4)	2 (5.7)	2 (8.0)	2 (6.9)	0 (0.0)	0 (0.0)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (3.5)	0 (0.0)	1 (9.1)
EQ-5D-Y VAS, mean (SD)	76.6 (20.7)	77.7 (19.6)	73.9 (23.2)	76.4 (19.3)	81.1 (21.6)	77.2 (22.5)	89.5 (13.9)	80.0 (19.0)
Not reported	3 (4.8)	1 (1.4)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)

VAS, visual analogue scale.

This synopsis should be referenced as follows: Cockayne S, Baird K, Gates S, Fairhurst C, Adamson J, Bottomley-Wise RM, *et al.* OrthoticS for TReatment of symptomatic flat feet In CHildren (OSTRICH): a randomised controlled trial [published online ahead of print August 6 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/PLKJ4541

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TABLE 17 EQ-5D-Y proxy – parent/guardian completed

	Baseline		3 months		6 months		12 months	
	Control (*n* = 64)	Intervention (*n* = 69)	Control (*n* = 32)	Intervention (*n* = 35)	Control (*n* = 25)	Intervention (*n* = 28)	Control (*n* = 8)	Intervention (*n* = 11)
Mobility, n (%)								
I have no problems walking about	35 (54.7)	30 (43.5)	19 (59.4)	24 (68.6)	20 (80.0)	16 (57.1)	6 (75.0)	8 (72.7)
I have some problems walking about	27 (42.2)	35 (50.7)	11 (34.4)	8 (22.9)	4 (16.0)	10 (35.7)	1 (12.5)	2 (18.2)
I have a lot of problems walking about	2 (3.1)	4 (5.8)	2 (6.3)	1 (2.9)	1 (4.0)	2 (7.1)	1 (12.5)	0 (0.0)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.7)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
Looking after myself, n (%)								
I have no problems washing or dressing myself	54 (84.4)	57 (82.6)	30 (93.8)	32 (91.4)	22 (88.0)	27 (96.4)	7 (87.5)	10 (90.9)
I have some problems washing or dressing myself	8 (12.5)	11 (15.9)	2 (6.3)	2 (5.7)	3 (12.0)	1 (3.6)	1 (12.5)	0 (0.0)
I have a lot of problems washing or dressing myself	2 (3.1)	1 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Not reported	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)
Doing usual activities, n (%)								
I have no problems doing my usual activities	33 (51.6)	42 (60.9)	22 (68.8)	22 (62.9)	18 (72.0)	17 (60.7)	7 (87.5)	7 (63.6)
I have some problems doing my usual activities	27 (42.2)	20 (29.0)	10 (31.3)	12 (34.3)	6 (24.0)	9 (32.1)	1 (12.5)	3 (27.3)
I have a lot of problems doing my usual activities	3 (4.7)	7 (10.1)	0 (0.0)	0 (0.0)	1 (4.0)	1 (3.6)	0 (0.0)	0 (0.0)
Not reported	1 (1.6)	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)	1 (3.6)	0 (0.0)	1 (9.1)
Having pain or discomfort, n (%)								
I have no pain or discomfort	15 (23.4)	12 (17.4)	14 (43.8)	10 (28.6)	10 (40.0)	7 (25.0)	4 (50.0)	5 (45.5)
I have some pain or discomfort	38 (59.4)	49 (71.0)	14 (43.8)	23 (65.7)	11 (44.0)	19 (67.9)	3 (37.5)	5 (45.5)
I have a lot of pain or discomfort	11 (17.2)	7 (10.1)	4 (12.5)	1 (2.9)	3 (12.0)	1 (3.6)	1 (12.5)	0 (0.0)
Not reported	0 (0.0)	1 (1.5)	0 (0.0)	1 (2.9)	1 (4.0)	1 (3.6)	0 (0.0)	1 (9.1)
Feeling worried, sad or unhappy, n (%)								
I am not worried, sad or unhappy	37 (57.8)	36 (52.2)	23 (71.9)	25 (71.4)	17 (68.0)	16 (57.1)	6 (75.0)	6 (54.6)
I am a bit worried, sad or unhappy	24 (37.5)	31 (44.9)	8 (25.0)	7 (20.0)	6 (24.0)	10 (35.7)	2 (25.0)	3 (27.3)
I am very worried, sad, or unhappy	3 (4.7)	1 (1.5)	1 (3.1)	2 (5.7)	2 (8.0)	1 (3.6)	0 (0.0)	0 (0.0)
Not reported	0 (0.0)	1 (1.5)	0 (0.0)	1 (2.9)	0 (0.0)	1 (3.6)	0 (0.0)	2 (18.2)
EQ-5D-Y Proxy VAS, mean (SD)	79.3 (21.8)	80.8 (20.4)	78.2 (20.3)	81.1 (20.2)	83.6 (17.0)	84.1 (17.2)	91.6 (12.1)	90.4 (12.3)
Not reported, *n* (%)	1 (1.6)	2 (2.9)	0 (0.0)	1 (2.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)

VAS, visual analogue scale.

TABLE 18 Resource use

	Baseline				3 months				6 months				12 months[a]			
	Control (*n* = 64)		Intervention (*n* = 69)		Control (*n* = 32)		Intervention (*n* = 35)		Control (*n* = 25)		Intervention (*n* = 28)		Control (*n* = 8)		Intervention (*n* = 11)	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
GP at GP practice																
In person	61	0.8 (0.83)	67	0.9 (0.76)	32	0.1 (0.30)	31	0.3 (0.77)	22	0.0 (0.21)	26	0.2 (0.69)	8	0.3 (0.46)	9	0.1 (0.33)
Phone/online	59	0.4 (0.71)	62	0.4 (0.88)	31	0.0 (0.18)	28	0.2 (1.13)	23	0.0 (0.0)	25	0.1 (0.40)	7	0.0 (0.0)	9	0.1 (0.33)
GP at home	62	0.0 (0.0)	64	0.0 (0.0)	32	0.0 (0.0)	30	0.0 (0.0)	22	0.0 (0.0)	26	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Nurse at GP practice																
In person	62	0.0 (0.28)	64	0.1 (0.27)	32	0.0 (0.0)	30	0.0 (0.0)	22	0.0 (0.0)	26	0.0 (0.20)	8	0.0 (0.0)	9	0.1 (0.33)
Phone/online	58	0.0 (0.0)	57	0.0 (0.13)	30	0.0 (0.0)	28	0.1 (0.26)	22	0.0 (0.0)	24	0.0 (0.20)	5	0.0 (0.0)	9	0.0 (0.0)
Nurse at home	62	0.0 (0.0)	64	0.0 (0.0)	32	0.0 (0.0)	30	0.0 (0.0)	22	0.0 (0.0)	26	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Occupational therapist																
In person	62	0.0 (0.22)	63	0.1 (0.25)	32	0.0 (0.18)	30	0.1 (0.25)	22	0.0 (0.0)	26	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Phone/online	57	0.0 (0.13)	55	0.0 (0.0)	30	0.0 (0.18)	28	0.0 (0.19)	22	0.0 (0.0)	25	0.0 (0.20)	7	0.0 (0.0)	9	0.0 (0.0)
Physiotherapist																
In person	62	0.1 (0.38)	63	0.2 (0.92)	32	0.0 (0.18)	31	0.2 (0.67)	22	0.0 (0.0)	25	0.0 (0.0)	8	0.4 (1.06)	9	0.0 (0.0)
Phone/online	55	0.0 (0.0)	54	0.0 (0.14)	30	0.0 (0.0)	28	0.0 (0.0)	22	0.0 (0.0)	25	0.0 (0.0)	7	0.0 (0.0)	9	0.0 (0.0)
Podiatrist																
In person	62	0.3 (1.32)	63	0.2 (0.41)	32	0.4 (0.76)	32	0.4 (0.67)	23	0.2 (0.39)	27	0.3 (0.62)	8	0.4 (0.74)	9	0.1 (0.33)
Phone/online	55	0.1 (0.26)	54	0.0 (0.19)	31	0.0 (0.18)	27	0.1 (0.27)	22	0.0 (0.21)	25	0.0 (0.20)	7	0.0 (0.0)	9	0.0 (0.0)
Orthotist																
In person	61	0.0 (0.18)	63	0.0 (0.13)	32	0.0 (0.0)	29	0.0 (0.19)	23	0.0 (0.21)	26	0.0 (0.0)	8	0.0 (0.0)	9	0.1 (0.33)
Phone/online	56	0.0 (0.0)	55	0.0 (0.0)	31	0.0 (0.0)	28	0.0 (0.0)	22	0.0 (0.0)	25	0.0 (0.0)	7	0.0 (0.0)	9	0.0 (0.0)
Podiatry outpatient clinic																
In person	62	0.1 (0.32)	66	0.1 (0.37)	32	0.4 (0.80)	32	0.4 (0.67)	22	0.2 (0.39)	28	0.3 (0.53)	8	0.4 (0.74)	9	0.2 (0.44)

continued

This synopsis should be referenced as follows: Cockayne S, Baird K, Gates S, Fairhurst C, Adamson J, Bottomley-Wise RM, *et al.* OrthoticS for TReatment of symptomatic flat feet In CHildren (OSTRICH): a randomised controlled trial [published online ahead of print August 6 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/PLKJ4541

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TABLE 18 Resource use (*continued*)

	Baseline				3 months				6 months				12 months[a]			
	Control (*n* = 64)		Intervention (*n* = 69)		Control (*n* = 32)		Intervention (*n* = 35)		Control (*n* = 25)		Intervention (*n* = 28)		Control (*n* = 8)		Intervention (*n* = 11)	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
Phone/online	57	0.0 (0.19)	57	0.0 (0.13)	30	0.1 (0.31)	27	0.0 (0.19)	22	0.1 (0.29)	25	0.0 (0.20)	7	0.0 (0.0)	9	0.0 (0.0)
Orthotics outpatient clinic																
In person	62	0.0 (0.18)	63	0.1 (0.33)	32	0.0 (0.0)	32	0.2 (0.45)	22	0.1 (0.29)	27	0.1 (0.36)	8	0.3 (0.46)	9	0.3 (0.71)
Phone/online	57	0.0 (0.0)	56	0.0 (0.0)	30	0.0 (0.0)	27	0.0 (0.0)	22	0.0 (0.0)	25	0.0 (0.20)	6	0.0 (0.0)	9	0.0 (0.0)
Orthopaedics outpatient clinic																
In person	61	0.0 (0.22)	63	0.0 (0.21)	31	0.0 (0.0)	32	0.0 (0.0)	21	0.0 (0.0)	27	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Phone/online	57	0.0 (0.0)	56	0.0 (0.0)	30	0.0 (0.0)	27	0.0 (0.0)	22	0.0 (0.0)	25	0.0 (0.0)	7	0.0 (0.0)	9	0.0 (0.0)
Blood taking	62	0.1 (0.35)	64	0.1 (0.29)	32	0.0 (0.18)	32	0.1 (0.42)	21	0.0 (0.0)	27	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Radiology																
In person	62	0.0 (0.18)	63	0.2 (0.40)	31	0.1 (0.25)	32	0.0 (0.0)	21	0.0 (0.22)	27	0.0 (0.19)	8	0.0 (0.0)	9	0.2 (0.7)
Phone/online	53	0.0 (0.0)	51	0.0 (0.0)	28	0.0 (0.0)	25	0.0 (0.0)	21	0.0 (0.0)	24	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Visit to A&E	60	0.1 (0.29)	64	0.1 (0.44)	29	0.0 (0.19)	29	0.0 (0.0)	23	0.0 (0.0)	25	0.0 (0.20)	8	0.1 (0.35)	9	0.0 (0.0)
Hospital visit as a day case	60	0.1 (0.22)	64	0.1 (0.34)	29	0.6 (3.16)	29	0.1 (0.26)	23	0.0 (0.0)	25	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Hospital as an inpatient	62	0.0 (0.0)	65	0.0 (0.0)	31	0.0 (0.0)	32	0.0 (0.0)	24	0.0 (0.0)	26	0.0 (0.0)	8	0.0 (0.0)	9	0.0 (0.0)
Number of days off school																
Due to appointment	63	0.2 (0.52)	67	1.3 (7.4)	32	0.3 (0.58)	33	0.4 (0.65)	24	0.0 (0.20)	27	0.4 (0.74)	8	0.3 (0.71)	9	0.4 (1.33)
Due to foot pain	61	0.3 (0.98)	67	0.6 (1.37)	32	0.3 (1.02)	31	0.5 (1.18)	24	0.4 (1.14)	26	0.3 (0.72)	8	0.0 (0.0)	9	0.2 (0.70)
Number of days off work	62	0.2 (0.59)	67	0.3 (1.02)	32	0.3 (0.76)	31	0.1 (0.40)	24	0.1 (0.41)	27	0.1 (0.36)	8	0.1 (0.35)	9	0.3 (1.00)

A&E, accident and emergency.
a At 12 months the recall period was 6 months.

Appendix 4 Qualitative interviews

TABLE 19 Participant interviews

Qualitative ID	Age	Sex	Parent present	CYP present	Treatment arm	Site
P3	8	Female	Yes	Yes	Intervention	A
P11	10	Female	Yes	Yes	Intervention	B
P16	10	Male	Yes	Yes	Crossover	C
P19	9	Male	Yes	Yes	Intervention	B
P21	12	Female	Yes	Yes	Intervention	D
P22	12	Male	Yes	Yes	Intervention	E
P25	11	Female	Yes	No	Control	F
P26	9	Female	Yes	Yes	Intervention	F
P27	7	Male	Yes	Yes	Control	F
P35	14	Male	Yes	Yes	Intervention	G
P40	9	Male	Yes	Yes	Intervention	C
P49	11	Male	Yes	Yes	Control	H
P50	6	Male	Yes	Yes	Control	H
P55	7	Male	Yes	Yes	Control	B
P63	11	Female	Yes	Yes	Intervention	H
P75	6	Male	Yes	Yes	Control	I

TABLE 20 Clinician interviews

Qualitative ID	Role	Site
C3	PI/podiatrist	B
C17	Clinical research therapist	C
C19	Research co-ordinator	I
C24	Research nurse	A
C27	Research nurse	J
C30	Clinical Trials Support Officer	J
C31	Research officer	J
C32	PI/podiatrist	K
C47	PI/podiatrist	G
C49	Podiatrist	G
C58	PI/podiatrist	L
C67	PI/podiatrist	H
C68	Podiatrist	H
C76	Podiatry Biomechanics Administrator	H
C79	Research nurse	M
C98	PI/podiatrist	B
C99	Podiatrist	K