■ CHILDREN'S ORTHOPAEDICS

Supportive bandage, removable splint, or walking casts for low-risk ankle fractures in children: a feasibility randomized controlled trial

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Aims

It is unclear if a supportive bandage, removable splint, or walking cast offers the best outcome following low-risk ankle fractures in children. The aim of this study was to evaluate the feasibility of a randomized controlled trial to compare these treatments.

Methods

Children aged five to 15 years with low-risk ankle fractures were recruited to this feasibility trial from 1 February 2020 to 30 March 2023. Children were randomized to supportive bandage, removable splint, or walking cast for two weeks. Follow-up at two, six, and 12 weeks was undertaken to determine feasibility for a definitive trial. Outcomes collected included complications, the Patient-Reported Outcomes Measurement Information System (PROMIS) mobility score, Paediatric Quality of Life Inventory, youth version of the EuroQol five-dimension health questionnaire, and Activities Scale for Kids - Performance.

Results

A total of 87 children from six hospitals were randomized at a rate of 0.9 participants per site per month. Two children in the supportive bandage group crossed over to an alternative device. Complications were reported in six children. One child in the cast group developed skin blisters. One child in cast and one in bandage sustained a reinjury during the 12-week follow-up, and two children (one splint and one cast) required additional immobilization after the two-week treatment for persistent pain. Of the 84 participants who remained in the study at six weeks, 43 (51.2%) returned follow-up questionnaires at six weeks. Of the patient-reported outcome measures (PROMs), proxy-reported PROMIS mobility showed good responsiveness, low ceiling effects, and low missing item rates. In an exploratory analysis, small differences were observed between groups, with no evidence that any of the treatments were superior.

Conclusion

This feasibility study showed acceptable recruitment and retention rates. There remains equipoise regarding the best treatment of these injuries. All three treatments appear well tolerated with similar complication rates. A primary outcome of complications or treatment failure would provide the highest study retention with secondary PROMs and economic analysis.

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Introduction

Paediatric ankle fractures are common, with a reported annual incidence of one in 1,000 children.[1,2] They contribute 5% of all childhood fractures and are typically sustained after a twisting injury.[3] Ankle fractures in children can be classified based on the fracture configuration into high-risk and low-risk fractures.[4] Ankles at high risk of displacement require robust immobilization or surgery to prevent malunion. In contrast, low-risk

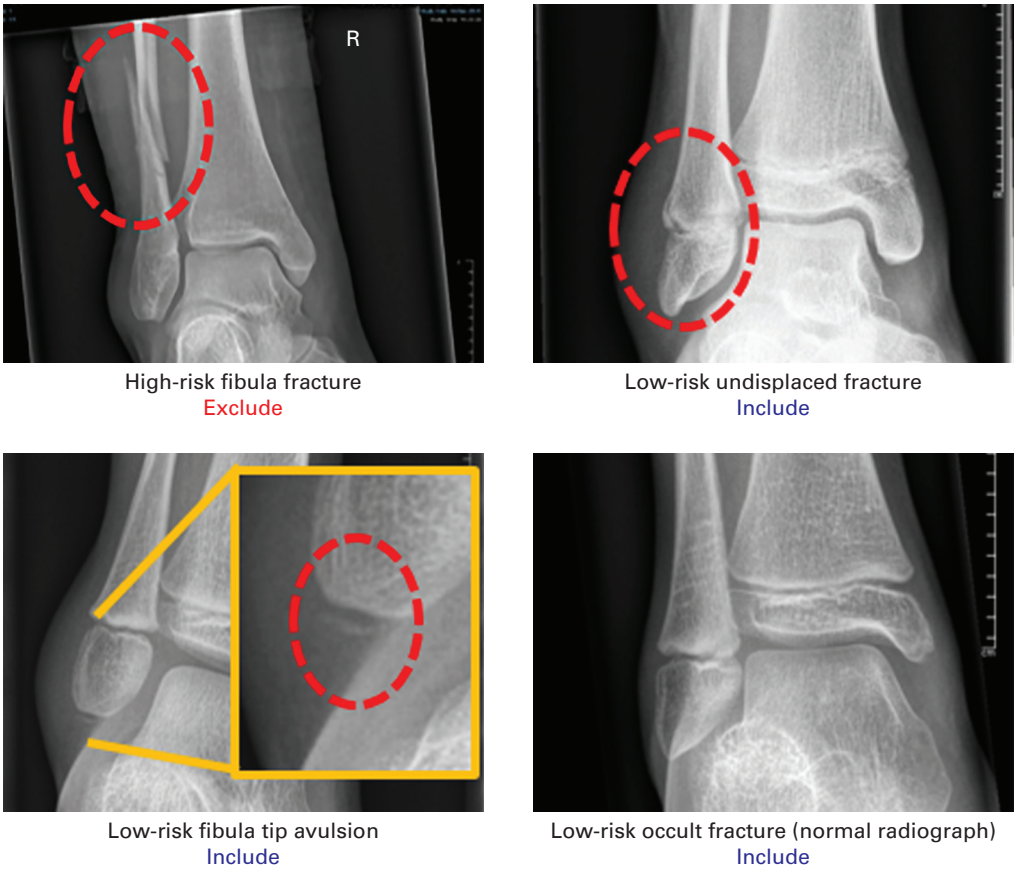

Fig. 1

Radiograph examples of eligible fracture patterns.

fractures maintain inherent stability, typically through an intact periosteum. These include minimally displaced Salter-Harris 1 and 2 fractures of the distal fibula, avulsion fractures from the distal fibula, and clinical fractures that are occult on initial radiographs.[4–6] The ideal management of children with low-risk ankle fractures has not been established. A range of treatments are commonly used. These all offer support and immobilization in varying degrees. Common treatments include rigid cast, brace, or supportive bandage.[7–10]

Below-knee immobilization with plaster or fibreglass has been used to immobilize the ankle for two to four weeks in several series.[11,12] Removable devices such as walking boots or splints have also been considered. In a 2016 Cochrane review, Yeung et al[13] found two randomized controlled trials (RCTs) that compared interventions for these injuries, finding low-quality evidence for an improvement in functional outcome when a removable brace was used in preference of rigid casting. Elastic bandaging and tubigrip support have been studied in small-scale RCTs,[7,14] and it remains unclear how much immobilization is required to achieve the best outcome.

Given the frequency of the diagnoses, there is a need to deliver a RCT to identify the best treatment for these children. The implications of a child with a fracture are substantial, including direct healthcare costs, societal costs, and in missed opportunities including sport, education, play, and time with their family.[15–17] However, there are several key parameters that need to be established before a definitive RCT is attempted.

The purpose of this current study is to assess the feasibility of undertaking a definitive trial to compare walking cast, removable brace, and supportive bandage therapy for low-risk ankle fractures. To do this, recruitment and retention, patient, and outcome factors were collected and evaluated using a feasibility trial.

Methods

Design. A parallel-group feasability RCT was undertaken to evaluate if a definitive trial could be delivered. The trial was multicentre, and was prospectively registered on the ISRCTN database (ISRCTN29688616). The trial protocol was approved by East Midlands - Derby Research Ethics Committee (IRAS277534). The study has been reported using the CONSORT 2010 extended guideline for pilot and feasibility studies.[18]

Inclusion and exclusion criteria. Children aged five to 15 years were considered eligible for the study if they had either a proven low-risk ankle fracture on radiograph (defined as a minimally or undisplaced distal fibula fracture) or a clinical undisplaced ankle fracture (Figure 1). Children with clinical fractures required a history of trauma, tenderness at the posterior edge of the lateral malleolus, an inability to weightbear for more than four steps,

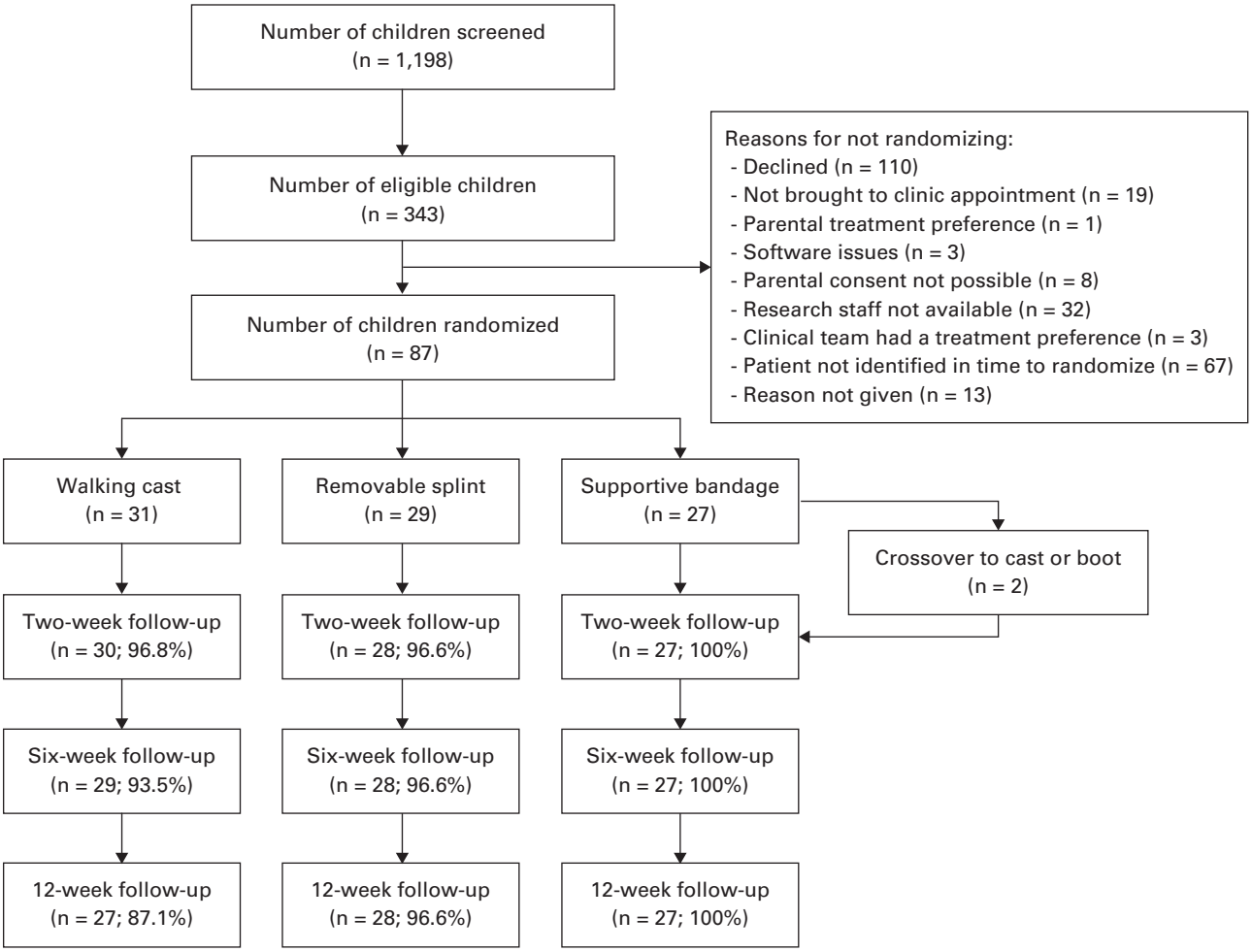

Fig. 2

CONSORT flow diagram.

and no alternative cause of pain identified on radiograph based on the Ottawa criteria.[19]

Children were excluded if the injury was more than seven days old, if they would be unable to complete the outcome measures in English, if the child were on the Child Protection Register, or where there was any concern about the cause of the injury.

Children were screened and recruited from six UK hospitals. Participants were typically recruited in the emergency department (ED) or first fracture clinic visit, depending on local protocols. Electronic 'virtual' recruitment was not possible due to the need of provision of a treatment device. Clinical follow-up was at the discretion of the local clinicians, with research follow-up delivered electronically.

Consent. Eligible children completed a written consent form completed by a person with parental responsibility. Children who wished to confirm assent were also able to sign the consent form. Where any disagreement between child and parent was detected, the child was not recruited.

Treatment groups. Participants were randomized to one of three treatments. A pragmatic approach was taken to permit local centres to accommodate local skill sets and device availability. The following definitions were applied to the three treatments: "supportive bandage" was an elastic bandage (e.g. Tubigrip; Mölnlycke Health Care, Sweden) to be worn for two weeks; "semi-rigid, removable brace" was a removable ankle brace (e.g. removable weightbearing backslab or walker boot) prescribed at the discretion of the local treating physician; and "below-knee walking cast" was a non-removable synthetic or resin-based below-knee walking cast applied according to local protocols.

Allocation and blinding. Eligible consenting patients were individually allocated to one of the three treatment groups using a computerized, web-based randomization system in a 1:1:1 ratio. The randomization was stratified by fracture type (occult and visible fracture line) and child age (five to ten years and 11 to 15 years) with randomly varying block sizes of size three, six, and nine. The allocation sequence was fully concealed from researchers involved in patient recruitment.

Due to the nature of the treatments, it was not possible to blind participants to treatment allocation. Assessor blinding was planned by removal of the treatment device by nursing staff independent from the trial on arrival to follow-up clinic for those children who required an appointment to remove a

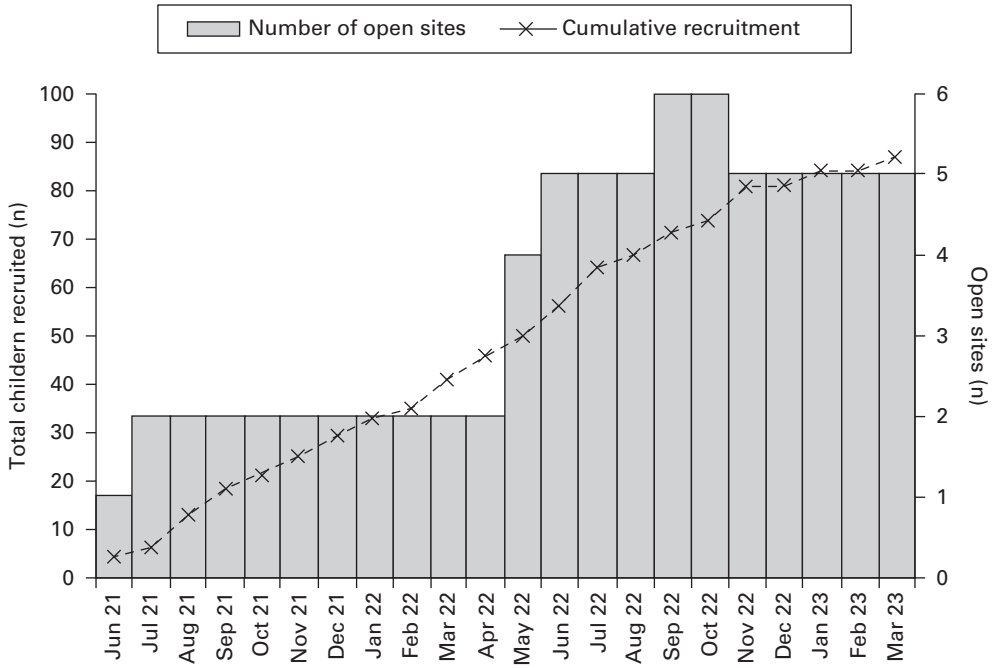

Fig. 3

Cumulative recruitment to study and number of open sites.

cast. Assessor bias was minimized by undertaking electronic follow-up of participants with self-reported scores.

Outcomes. The key objectives of this study were to understand the patient, recruitment, and outcome factors that determine the feasibility of a full trial. Patient factors included compliance with treatment and complications with treatment to confirm the safety profile of the prescribed devices. Recruitment and retention factors included determining the recruitment rate to the study and estimation of the study retention rates. Outcome factors included usefulness of outcome measures and confirmation that there remains equipoise in the trial interventions through an exploratory analysis.

To measure these outcomes, screening logs were maintained at each site. Patient eligibility and trial recruitment was monitored with issues documented prospectively. At enrolment, retrospective pre-injury patient-reported outcome measures (PROMs) were collected with demographic information and fracture configuration. Study follow-up occurred two, six, and 12 weeks following the injury with collection of PROMs.

All participants who did not withdraw consent were monitored for expected and unexpected adverse events. Participants who did not report any adverse events were deemed to have a complication-free recovery. Economic data including use of additional devices, visits to healthcare professionals, and medication prescriptions was recorded. A primary outcome measure was not set a priori as there is no defined standard outcome for this patient group. The PROMs during this study were the Activity Scale for Kids performance version,[20] PROMIS mobility computer adaptive test,[21,22] youth version of the EuroQol five-dimension health questionnaire (EQ-5D-Y),[23] and Paediatric Quality of Life Inventory 4.0 core set (PedsQL).[24] Where possible, age-appropriate scores were collected from children and proxy-reported score from carers. EQ-5D-Y profiles were converted into a numerical index using the UK time trade-off (TTO) set.[25]

In addition to the established outcome scores, families were asked at each timepoint if their child had returned to normal activities and school. A seven-point global rating of change score was also collected to act as an anchor for minimal important differences. Scores were collected electronically in a REDCap CloudCap data capture tool (Vanderbilt University, USA) hosted at the University of Nottingham.[26,27]

Sample size. The objectives of this study are to evaluate trial feasibility rather than compare interventions. As such, formal sample size calculation for between-group comparison is not appropriate. Equally, a primary outcome measure could not be set a priori as no PROMs with minimal clinically important differences have been validated in this patient group.[28] We therefore aimed to approach and recruit 90 children to assess the feasibility parameters.

Changes in protocol during study. Two amendments to improve trial recruitment and retention were implemented during the study. The first was the introduction of text message reminders to the follow-up system, and the second was a reduction in questionnaire burden. This was achieved by removing the self-reported scores from follow-up timepoints.

Statistical analysis. Statistical analysis was performed in Stata v. 18 (StataCorp, USA). Recruitment rates were collected during the study and presented in a CONSORT flow diagram. Reasons for exclusion were tabulated. Monthly recruitment rates were reported both for the whole study and for individual sites. To extrapolate the recruitment figures into a potential

Table I. Responsiveness of candidate outcome measures.

Variable	Mean change (SD)						Correlation with global score	p-value† at six weeks
	Baseline to two weeks	p-value*	Two to six weeks	p-value*	Baseline to 12 weeks	p-value*		
PROMIS mobility								
Proxy	-15.6 (13.9)	< 0.001	12.6 (11.6)	< 0.001	1.2 13.8)	0.675	0.410	0.007
Self	-14.7 (11.7)	0.002	7.4 (14.6)	0.168	1.4 (16.1)	0.861	0.342	0.374
ASK-P	-13.0 (20.1)	0.031	6.2 (24.6)	0.403	7.2 (21.8)	0.324	0.391	0.209
Total PedsQL								
Proxy	-16.5 (18.9)	< 0.001	12.7 (13.7)	< 0.001	1.7 (18.4)	0.671	0.340	0.050
Self	-8.5 (17.9)	0.112	7.0 (17.1)	0.231	2.3 (22.3)	0.753	0.195	0.598
EQ-5D-Y index								
Proxy	-28.2 (27.7)	< 0.001	22.0 (31.8)	0.002	-6.5 (10.1)	0.003	0.306	0.070
Self	-10.1 (32.6)	0.250	14.5 (35.7)	0.207	-20.0 (41.7)	0.142	0.145	0.669
EQ-5D-Y VAS								
Proxy	-4.6 (18.0)	0.100	8.1 (12.9)	0.001	-0.6 (14.3)	0.836	0.476	0.003
Self	-2.6 (25.6)	0.713	8.8 (17.2)	0.140	2.1 (8.8)	0.449	0.180	0.615

*Paired *t*-test.
†Spearman rank correlation coefficient.
ASK-P, Activities Scale for Kids - Performance; EQ-5D-Y, youth version of the EuroQol five-dimension health questionnaire; PedsQL, Paediatric Quality of Life Inventory; PROMIS, Patient-Reported Outcomes Measurement Information System; VAS, visual analogue scale.

Table II. Ceiling effects for candidate outcome scores.

Candidate score	Scores clustered at top 15%				Maximum score			
	Baseline	2 wks	6 wks	12 wks	Baseline	2 wks	6 wks	12 wks
PROMIS mobility, n (%)								
Proxy	41 (66.1)	3 (6.3)	13 (30.2)	18 (60.0)	41 (66.1)	3 (6.3)	13 (30.2)	18 (60.0)
Self	12 (60.0)	1 (7.1)	5 (45.5)	7 (70.0)	9 (52.9)	2 (14.3)	3 (27.3)	3 (30.0)
ASK-P, n (%)	23 (82.1)	6 (37.5)	7 (53.9)	10 (90.9)	8 (28.6)	1 (6.3)	3 (23.1)	5 (45.5)
Total PedsQL, n (%)								
Proxy	42 (63.6)	11 (21.6)	22 (56.4)	17 (58.6)	16 (24.2)	4 (7.8)	9 (23.1)	8 (27.6)
Self	14 (63.6)	5 (35.7)	6 (54.6)	8 (66.7)	3 (13.6)	0 (0)	2 (18.2)	4 (33.3)
EQ-5D-Y index, n (%)								
Proxy	58 (85.3)	11 (21.6)	21 (50.0)	17 (58.6)	57 (83.8)	7 (13.7)	18 (42.9)	17 (58.6)
Self	11 (47.8)	4 (25.0)	6 (54.6)	7 (58.3)	11 (47.8)	2 (12.5)	5 (45.5)	7 (58.3)
EQ-5D-Y VAS, n (%)								
Proxy	47 (70.2)	33 (64.7)	38 (90.5)	22 (75.9)	30 (44.8)	5 (9.8)	13 (31.0)	8 (27.6)
Self	14 (63.6)	8 (53.3)	9 (81.8)	12 (75.0)	8 (36.4)	2 (13.3)	1 (9.1)	3 (25.0)

ASK-P, Activities Scale for Kids - Performance; EQ-5D-Y, youth version of the EuroQol five-dimension health questionnaire; PedsQL, Paediatric Quality of Life Inventory; PROMIS, Patient-Reported Outcomes Measurement Information System; VAS, visual analogue scale.

definitive study, an estimate of the local population each recruiting site was made. For this, the population of children aged five to 15 years was extracted from the Office for National Statistics 2021 census.[29] The overall retention rate was evaluated by monitoring participant withdrawal from the study, which was collected by local teams and displayed in the CONSORT study flow diagram.

Compliance with treatment was defined as patients maintaining the allocated treatment as intended during the two-week treatment period. Complications with treatment, with expected complications including skin damage or pressure complications and unexpected complications, were monitored to confirm the safety profile of the prescribed devices.

The usefulness of PROMs to guide selection of a primary outcome was evaluated by assessing the responsiveness of measures, ceiling effects, and missing data rates. Responsiveness was evaluated using two hypothesis tests. The first was that there should be a significant difference in mean scores between baseline and two-week scores, two- and six-week scores, and minimal change between baseline and 12-week scores tested with a paired *t*-test. The second was that there should be a significant Spearman rank correlation coefficient between the six-week global rating of change score and the change in outcome score between two and six weeks. Ceiling effects were measured by calculating the proportion of scores clustered within the top 15% of the possible scores and by the proportion of responses at the maximum score.[30,31]

Questionnaire return rates were calculated using the number of participants who returned at least one questionnaire at the six-week follow-up point. Impact of study amendments on retention rates were analyzed as the study progressed. The outcome completion rates were collected for each measure. Missing data were evaluated by the return rate of each score for participants who returned any of the scores at six weeks.

An exploratory analysis of outcomes was performed to confirm equipoise in the trial interventions. Six-week outcome

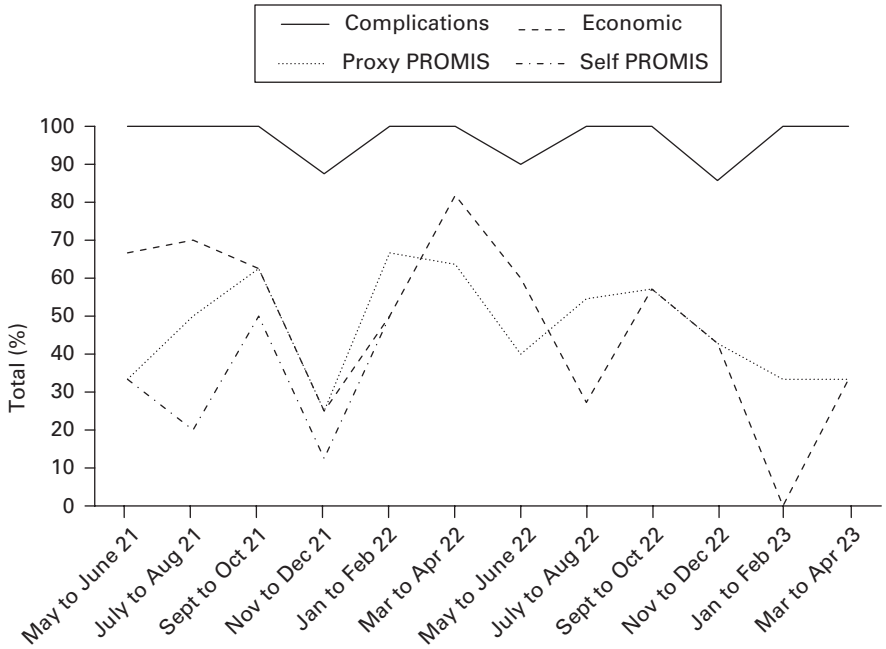

Fig. 4

Study retention for complication-free, economic, proxy, and self-reported Patient-Reported Outcomes Measurement Information System (PROMIS) outcomes by time of recruitment.

scores were compared for overall differences between groups using a regression analysis (linear for continuous and logistic for binary outcomes) adjusted for the stratification variables of age > ten years and presence of an occult fracture. Regression coefficients and odds ratios were calculated with 95% CIs with the plaster cast group as the reference group. Statistical significance was set at a p-value < 0.05.

Results

The study recruitment window ran from 1 February 2020 to 30 March 2023. The CONSORT participant flow diagram is shown in Figure 2. A total of 87 participants were randomized to the three interventions. Key reasons for exclusion were potential participants declining (n = 11), patients being identified too late to randomize (n = 67), and patients presenting to ED or clinic when the research teams were unavailable (n = 32). Clinical or parental treatment preference was reported as a barrier to recruitment for only four children.

The monthly recruitment to the study is shown in Figure 3. The overall mean number of recruits per month was 4.0 (SD 2.1). Two sites did not recruit any participants, while the other sites recruited at a rate of 1.4, 2.5, 1.4, and 0.1 participants per month. Based on census estimates for the local populations of the six recruiting centres, this equates to a mean of 0.2 recruits per 10,000 children aged five to 15 years per month. The baseline characteristics of the recruited participants are shown in Supplementary Table i.

Consent to participate in the study was withdrawn by five participants. Two participants withdrew before the two-week follow-up; one in the plaster group withdrew due to treatment preference and rescinded consent to participate. Another participant in the boot group felt better at nine days, so withdrew from the study. One participant withdrew before the six-week follow-up and two withdrew before the 12-week follow-up at the parents' request.

Compliance with treatment. Following randomization, two children were unable to comply with the allocated treatment. These were both in the supportive bandage group. These children reattended the ED: one was converted to a cast, and one provided with a removable splint. No children in the removable splint or walking cast group crossed over to a different intervention.

Complications with treatment. Complications were reported by six patients (6.9%). No children reported more than one complication. The greatest number of complications occurred in the walking cast group (n = 3; 9.7%): one child was re-injured at six weeks, which was treated with immobilization in a removable splint; one child required a longer period of immobilization; and one child developed blisters. The supportive bandage group had two complications (7.4%): one child experienced a reinjury five weeks after randomization, and one child reported persistent pain at four weeks and was subsequently reviewed in an orthopaedic clinic and resolved with further non-surgical management. In the removable splint group, one child required further immobilization after the device was removed (3.4%).

Responsiveness of outcome measures. The responsiveness of the candidate outcome measures is shown in Table I. The proxy-reported PROMIS mobility, total PedsQL, and EQ-5D-Y scores demonstrated significant changes between baseline and two weeks and two and six weeks ($p < 0.001$, < 0.001, and 0.002, all paired *t*-test). The proxy-reported EQ-5D-Y index score differed from other scores in that a significant mean decrease of 6.5 (SD 10.1) was observed between baseline and

Table III. Estimates of effect of different interventions on outcome at six weeks. The reference outcome for each outcome is the plaster cast group.

Variable	Unadjusted mean difference (95% CI)		Adjusted mean difference (95% CI)	
	Supportive bandage	Removable brace	Supportive bandage	Removable brace
PROMIS mobility				
Proxy	5.2 (-1.8 to 12.2)	2.1 (-4.8 to 9.1)	5.2 (-2.0 to 12.3)	1.6 (-5.8 to 9.1)
Self	19.2 (4.0 to 34.3)	15.8 (1.2 to 29.8)	20.8 (-0.3 to 41.8)	17.0 (-6.2 to 40.2)
ASK-P	2.4 (-31.6 to 36.2)	4.1 (-28.0 to 36.3)	-3.6 (-40.0 to 32.8)	-3.4 (-50.1 to 43.2)
EQ-5D-Y TTO				
Proxy	0.1 (-0.0 to 0.2)	0.0 (-0.1 to 0.2)	0.1 (-0.1 to 0.2)	0.0 (-0.2 to 0.1)
Self	0.3 (-2.0 to 0.8)	0.2 (-0.3 to 0.8)	0.3 (-0.3 to 0.9)	0.1 (-0.6 to 0.8)
EQ-5D-Y VAS				
Proxy	1.2 (-8.3 to 10.6)	4.1 (-5.6 to 13.8)	0.9 (-8.8 to 10.5)	2.5 (-8.0 to 13.0)
Self	19.5 (-0.5 to 21.5)	8.1 (-2.9 to 19.1)	8.8 (-4.6 to 22.1)	5.0 (-9.6 to 19.6)
PedsQL				
Proxy	-3.6 (-15.0 to 7.8)	-0.1 (-11.5 to 11.3)	-3.9 (-15.7 to 7.9)	-1.4 (-13.9 to 11.1)
Self	6.2 (-24.4 to 36.9)	-1.0 (-31.8 to 29.6)	3.3 (-25.9 to 32.4)	-17.7 (-49.6 to 14.2)
Days off school	-0.8 (-3.8 to 2.4)	-1.4 (-4.5 to 1.8)	-0.6 (-3.7 to 2.5)	-0.8 (-4.0 to 2.5)
Return to normal activities, OR (95% CI)	4.8 (0.8 to 28.0)	4.4 (0.7 to 25.8)	4.8 (0.8 to 28.5)	5.0 (0.8 to 31.5)

*Regression adjusted for age > ten years and presence of occult fracture.
ASK-P, Activities Scale for Kids - Performance; EQ-5D-Y, youth version of the EuroQol five-dimension health questionnaire; OR, odds ratio; PedsQL, Paediatric Quality of Life Inventory 4.0 core set; PROMIS, Patient-Reported Outcomes Measurement Information System; TTO, time trade-off; VAS, visual analogue scale.

12 weeks (p = 0.003, paired *t*-test). None of the self-reported measures detected a change between two and six weeks. Proxy PROMIS mobility and proxy EQ-5D-Y visual analogue scale (VAS) scores demonstrated moderate but significant correlation with the global rating of change scores, with correlation coefficients of 0.410 and 0.476, respectively.

Ceiling effects of outcome measures. Significant clustering of scores in the top 15% was observed at baseline for all measures with 47.8% (n = 11) to 85.3% (n = 58) of scores in the top 15% of possible scores. This is shown in Table II. At two- and six-week follow-up, the lowest proportion of scores at the top 15% was found in the proxy-reported PROMIS mobility with three (6.3%) and 13 (30.2%) respondents in the top cluster.

Missing data. Missing items from each outcome score was minimized by using an electronic data capture system which required participants to complete all items to proceed. Of the participants who completed six-week follow-up scores, 93.5% completed the proxy PROMIS mobility (n = 43), 84.8% completed the proxy PedsQL (n = 39), and 91.3% completed the proxy EQ-5D-Y (n = 42). The ASK-P score was completed by the highest proportion of eligible children, with 68.4% returning valid scores (n = 13). EQ-5D-Y was returned by 11 (61.1%, age > eight years), PedsQL by 11 (52.3%), and PROMIS by ten (55.6%, age > eight years).

Estimated retention rates. The retention rates for each outcome are presented in Supplementary Table ii. The retention rates at six weeks for PROMIS, complications, and economic outcomes are shown in Figure 4. Retention for complication-free recovery was good, with 7/8 (85.7%) to 11/11 (100%) follow-up across all timepoints. Completion of electronic questionnaires had lower retention of 41.9% for walking cast (n = 13), 44.8% for removable splint (n = 13), and 51.9% for supportive bandage (n = 14). Completion of proxy-reported PROMIS mobility improved from 45.9% (n = 28) to 57.7% (n = 15) for participants who received SMS text reminders. Simplification of the follow-up questionnaires marginally improved response rates for at least one completed patient-reported questionnaire at six weeks, with 48.6% return before simplification (n = 17) and 50.0% after (n = 26).

Exploratory analysis of between-group effects. Mean follow-up scores for each outcome are reported for each timepoint in Supplementary Table i. Children made a good recovery, with all children returning to school by 12 weeks.

The estimated between group effect sizes between different treatment groups is shown in are shown in Table III. As a feasibility study, the sample size was inadequate to undertake hypothesis tests to compare treatment effectiveness. Minimal differences in treatments were observed between supportive bandage and removable splints. Small differences were identified from proxy-reported scores between supportive bandage or removable splints and walking cast. Self-reported outcome scores had larger mean differences and wider CIs.

Discussion

This feasibility study has shown that it is possible to recruit children with low-risk ankle fractures into a three-way trial to evaluate different treatments. This study has shown that there remained equipoise between these three interventions and a full trial is required to define the best intervention for these children.

There is a need to be critical in the interventions that are provided to children with these fractures. As low-risk fractures are inherently stable, there may be an economic advantage to treating with simple devices than costly single-use devices or casts that require a clinic visit to remove. The recent FORCE trial has demonstrated equivalence between rigid immobilization or bandage in the wrist, it may be that a similar strategy can be applied to these ankle fractures.[32]

We noticed two significant consequences from the COVID-19 pandemic when running this feasibility study. The first issue encountered was a difficulty in undertaking study start-up in early 2020, with competing pressures from other studies and staff redeployed for the duration of the pandemic. The second

was an unexpected shift in routine practice away from circumferential walking casts as first aid to removable splints. This was advocated by the British Orthopaedic Association Casting Committee in their 2020 guidelines to remove the need for reattendance for removal of cast by plaster saw.[33] Our experience was that older children who had been treated with a boot were reluctant to be randomized to any other device when they were approached in the clinic.

The low completion rates of PROMs suggests that this type of outcome may not be the best primary outcome for this trial. There remains no validated PROM for low-risk ankle fractures in children with high ceiling effects and attrition during the study window. It seems that the loss to follow-up was not at random, with parents and children who have made a full recovery potentially more likely to fail to return questionnaires. In this small-scale feasibility trial, we did not have the full resources of a trial unit. Our loss to follow-up was similar to some previous reports and the use of text message and simplified questionnaires improved questionnaire responses, but response rates would need to be significantly improved to permit reliable comparison in a full trial. We did not have the resources to provide a financial incentive to participants, which may also improve retention rates for a definitive trial.[34]

Of the PROMs tested, the proxy-reported PROMIS mobility seemed to be the most valid. This tool demonstrated responsiveness throughout the study, minimal ceiling effects, and was easy to administer with the computer-adaptive design. Proxy scores can be administered as a single tool for children of all ages, and for children with additional disabilities who might otherwise struggle with completion of questionnaires. The experience of the child is a valid and important outcome, and should be included in a definitive trial as a secondary outcome or through embedded quantitative analysis. Equally, a definitive trial should include measurement of the health economic consequences of the interventions.

This attrition of PROMs could be mitigated by using an outcome such as complication-free recovery. This could be augmented using routinely collected healthcare data (e.g. Hospital Episode Statistics) to reliably extend the follow-up monitoring for additional ED or hospital admissions. Similar numbers of children experiencing complications were observed in each group. The use of casts led to skin issues which had previously been described in removable splints.[9] No evidence was found to suggest that rigid immobilization prevented delayed reinjury, with this complication occurring in both bandage and cast groups.

Our experience of recruitment at the two mains sites identified two main challenges, depending on the site of approach. For participants approached in the ED, common feedback was that the inclusion of the bandage concerned parents as it might not be supportive enough. For those approached in the fracture clinic at 48 to 72 hours post-injury, potential participants reported an unwillingness to be randomized as they may receive a cast, particularly if they had been provided with a boot at initial presentation. While a third arm improves research efficiency as multiple interventions can be compared simultaneously, we recognize that a pairwise comparison may be beneficial for local research teams. The removable splint and supportive bandage may be the most relevant comparison, as reducing the prescription of single-use plastic boots may have a notable economic and environmental impact.

This feasibility study had some limitations. The number of eligible fractures was lower than anticipated from previous internal audits. We suspect this is due to the tighter inclusion criteria for this trial. We did not permit inclusion of avulsions or any other fracture from any bone other than the fibula, in order to ensure randomized ankle fractures were low-risk. This could be reconsidered for a definitive trial, as several low-risk fracture patterns including flakes from medial malleolus may have a similar prognosis to the included fractures. A further potential criticism is the inclusion of occult fractures in this cohort.

There is debate around the precise pathology of these injuries, particularly if they are physeal injuries, ligamentous sprains, or osseus fractures.[35,36] Our preparatory audit for this study showed that many of these injuries are being treated in casts. We limited the inclusion criteria to include only severe soft-tissue injuries with the Ottawa criteria.[19] However, given this ongoing uncertainty, we would advocate maintaining occult fractures as this as an important sub-group and stratification variable in the definitive analysis.

The 51.2% follow-up at six weeks is lower than some of the previous trials for children with this injury. We are currently analyzing interview transcripts from children who were part of this study or who declined to participate, in order to further understand and improve our trial recruitment and retention strategies. Boutis et al[10] reported 93.7% follow-up, but used a physiotherapist who attended the children's homes to collect outcome scores at four weeks post-injury. Gleeson et al[7] reported 88% follow-up at four weeks, but only 66.7% had complete data. Launay et al[8] had difficulty in reviewing children one week following treatment, with a follow-up rate at one week of 54.4%. For a definitive trial, additional resources would be required to encourage return of follow-up scores and make the trial more engaging for participants. Text message reminders have been helpful in other studies, and we have some evidence that they may be helpful for this definitive study.[37]

Within the limitations of this feasibility study, we have found that it is possible to recruit to this study. All interventions have acceptable and comparable complications, and the three treatments seem to be well tolerated. A primary outcome of complications or treatment failure would provide highest study retention with secondary PROMs and economic analysis.

Take home message

- There remains equipoise for management of low-risk ankle fractures in children.
- Rates of complications may be a superior outcome for a definitive trial.
- A definitive trial can be achieved and may be most relevant as a two-arm comparative trial.

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Supplementary material

Raw outcomes at baseline and follow-up, and outcome completion rates at different follow-up intervals.

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