

Immobilisation of torus fractures of the wrist in children (FORCE): a randomised controlled equivalence trial in the UK



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Summary

Background The most common fractures in children are torus (buckle) fractures of the wrist. Controversy exists over treatment, which ranges from splint immobilisation and discharge to cast immobilisation, follow-up, and repeat imaging. This study compared pain and function in affected children offered a soft bandage and immediate discharge with those receiving rigid immobilisation and follow-up as per treating centre protocol.

Methods In this randomised controlled equivalence trial we included 965 children (aged 4–15 years) with a distal radius torus fracture from 23 hospitals in the UK. Children were randomly allocated in a 1:1 ratio to the offer of bandage group or rigid immobilisation group using bespoke web-based randomisation software. Treating clinicians, participants, and their families could not be masked to treatment allocation. Exclusion criteria included multiple injuries, diagnosis at more than 36 h after injury, and inability to complete follow-up. The primary outcome was pain at 3-days post-randomisation measured using Wong-Baker FACES Pain Rating Scale. We performed a modified intention-to-treat and per protocol analysis. The trial was registered with ISRCTN registry, ISRCTN13955395.

Findings Between Jan 16, 2019, and July 13, 2020, 965 children were randomly allocated to a group, 489 to the offer of a bandage group and 476 to the rigid immobilisation group, 379 (39%) were girls and 586 (61%) were boys. Primary outcome data was collected for 908 (94%) of participants, all of whom were included in the modified intention-to-treat analysis. Pain was equivalent at 3 days with 3·21 points (SD 2·08) in the offer of bandage group versus 3·14 points (2·11) in the rigid immobilisation group. With reference to a prespecified equivalence margin of 1·0, the adjusted difference in the intention-to-treat population was $-0·10$ (95% CI $-0·37$ to $0·17$) and $-0·06$ (95% CI $-0·34$ to $0·21$) in the per-protocol population.

Interpretation This trial found equivalence in pain at 3 days in children with a torus fracture of the distal radius assigned to the offer of a bandage group or the rigid immobilisation group, with no between-group differences in pain or function during the 6 weeks of follow-up.

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Introduction

A third of individuals sustain a fracture during childhood.^{1,2} Although adult fractures typically result in a complete disruption of the cortex of the bone, children's bones can crush or buckle, resulting in mild deformation with no break in the cortex, such injuries are called torus or buckle fractures. Torus fractures of the distal radius are the most common fractures in children,^{3,4} causing 60 000 emergency department attendances per year in the UK. Torus fractures are considered minor injuries, with pain being the principal clinical feature. Despite the frequency of the injury there is national and international variation in practice and guidelines about whether the wrist of children with torus fractures of the distal radius needs to be immobilised and whether or not they need clinical follow-up.⁵

There is a common belief among families and clinicians that a fracture needs plaster cast immobilisation to ensure adequate healing. However, torus fractures heal very quickly, and it has been suggested simple splints that can

be removed at home could be safe and effective alternatives to casts.⁶ A Cochrane review identified ten randomised controlled trials (including a total of 695 children) investigating the treatment of torus fractures. The review concluded that the recovery appeared similar regardless of treatment given (ie, plaster cast, removable splint, or bandage). In addition, the location of immobilisation removal (ie, clinic visit or home) had no effect on recovery; however, the quality of the evidence was deemed low or very low.⁷ The review generated uncertainty as to whether torus fractures of the distal radius required rigid immobilisation or if recovery would be equivalent with a bandage or no treatment. The review highlighted uncertainty concerning the safety and acceptability of immediate discharge at diagnosis; however, if safe and acceptable, these interventions could demedicalise this injury and prevent the overuse of health-care resources for this common fracture.

We sought to undertake a trial of no treatment and discharge versus current care, which was a research

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Research in context

Evidence before this study

There is national and international variation in practice and guidelines about whether children with torus fractures of the distal radius need to have their wrist immobilised and whether they need clinical follow-up. The variation is in part due to the absence of quality evidence, as shown in a 2018 Cochrane review. At the outset of the study we considered ten randomised controlled trials comprising 695 patients summarised in a 2018 Cochrane review of interventions for treating wrist fractures in children. Early in recruitment we also updated the search using PubMed using the terms “buckle” OR “torus” AND “fracture*” to identify papers between January 2017 and 28 May 2020 (overlapping the period of the Cochrane search). The newer search identified 59 new papers, of which none were randomised controlled trials.

Added value of this study

This is a large, multicentre randomised controlled trial that provides high quality evidence to guide clinicians and patients

on the most appropriate treatment for torus fractures of the distal radius. This trial supports the strategy to de-escalate the treatment of children with a torus fracture of the distal radius by offering a bandage and immediate discharge from the emergency department rather than rigid immobilisation.

Implications of all the available evidence

The study addresses a research recommendation posed by a UK National Institute for Health and Care Excellence guideline, and it will be incorporated into the next guideline update. The findings will also contribute to guidelines rationalising the overuse of health-care resources. Future research should seek to develop and validate clinical decision tools to identify children who would not benefit from radiography (ie, differentiating torus fractures and soft tissue injuries from more severe fractures requiring treatment).

recommendation made by the UK National Institute for Health and Clinical Excellence (NICE).⁸ However, families advising our study group indicated that this approach was not acceptable to them. These families expressed that they were only prepared to consent for inclusion in the trial if children were offered a bandage, even though it might not always be applied. The aim of this randomised clinical trial was to establish whether treating children with a torus fracture of the distal radius with the offer of a soft bandage and immediate discharge (offer of bandage group) provides the same pain relief and recovery as treating them with rigid immobilisation and follow-up as per the standard practice of the treating centre (rigid immobilisation group).

Methods

Study design and participants

The Forearm Fracture Recovery in Children Evaluation (FORCE) trial was a multicentre, randomised, controlled, equivalence trial conducted in 23 emergency departments within the UK, which included children’s major trauma centres, mixed adult and children’s trauma centres, and district hospitals. An equivalence design was chosen as both interventions have been suggested to be acceptable, although there is no evidence for either to be the standard of care. Each intervention is compared against the other as a possible replacement since they are similarly good clinically, but one is potentially better in terms of safety, acceptability, or cost. The National Research Ethics Committee approved this study on Nov 16, 2018 (18/WM/0324). The protocol and statistical analysis plan have been published.^{9,10}

Children aged 4–15 years with a radiologically confirmed torus fracture of the distal radius were eligible to enter the study. The diagnosis was made by the treating clinician with a poster detailing the fracture pattern used to assist

recruitment. Any type of concomitant ipsilateral fracture to the ulna was permitted. Patients were excluded if the injury was more than 36 h old, the treating clinician judged that there was a cortical disruption of the radius on radiographs (eg, a greenstick fracture), there were additional fractures outside the affected wrist, or if the patient or parent would be unable to adhere to trial procedures (eg, insufficient English language comprehension, developmental delay, or no internet access). A radiologist reviewed all images in the days following discharge and any radiographs requiring additional consideration were highlighted to the clinical team. Eligible children and their families were approached by a local researcher and were provided with verbal and multimedia or printed information about the trial before being asked to provide written informed consent (parents) and assent (children older than 7 years).

Randomisation and masking

Once consented, participants were randomly assigned in a 1:1 ratio to the offer of bandage group or rigid immobilisation group using bespoke web-based randomisation software provided by the Oxford Clinical Research Trials Unit. The randomisation sequence, generated by the trial statistician, was stratified by recruitment centre and age (4–7 years vs 8–15 years) and used variable block sizes of 2, 4, and 6. Treating clinicians, participants, and their families could not be masked to treatment allocation; however, the treating clinical team did not take part in the follow-up assessment of participants. The outcome data was collected directly from the participant or their parent. Those involved in the data cleaning and analysis were not blinded to participant treatment allocation.

Procedures

In the offer of a bandage group, a simple bandage such as a gauze roller bandage was offered to participants. The decision to use and discontinue use of the bandage was at the discretion of the families. For those immediately choosing to use a bandage it was applied in the emergency department. For those initially choosing not to use the bandage, it was provided should they choose to use it at home. Participants were discharged from the emergency department with no planned clinic follow-up. Participants were advised to return to activities as comfort allowed and that the bandage should not be worn for more than 3 weeks.

In the rigid immobilisation group, a rigid wrist splint that was either manufactured to conform to the wrist (eg, a futura-type splint) or was moulded by clinicians to conform to the wrist (eg, backslab or plaster cast) was applied in the emergency department. The type of splint was left to the discretion of the clinicians, but a record was made of the splint used. Treatment advice and clinic follow-up was as per the standard practice of the treating centre.

Physiotherapy did not typically form a part in the management of these injuries in either group, and no specific guidelines were offered to clinicians or patients. Prescriptions for analgesia were at the discretion of the treating clinician following hospital guidelines or those of the UK Royal College of Emergency Medicine.¹¹ Families were prompted by email or SMS to complete follow-up questionnaires at 1, 3, and 7 days and at 3 and 6 weeks after randomisation for the primary outcome, with additional questionnaires for the secondary outcomes at several of these timepoints. The primary contact was the parent. With parental agreement, children older than 12 years with a mobile telephone could be contacted directly to complete questionnaires. If there was no response to the initial and reminder messages, an attempt was made to speak to families by telephone.

Outcomes

Outcome data were collected using REDCap electronic data capture tools.^{12,13} The primary endpoint was pain at 3-days post-randomisation measured using Wong-Baker FACES Pain Rating Scale (Wong-Baker scale).¹⁴ The primary outcome, primary outcome timepoint, and primary outcome measurement tool was decided in association with a parent and carers forum, along with children and young people from the GenerationR Young Persons Advisory Group.¹⁵ The Wong-Baker scale is an ordinal assessment of pain using a series of six facial expressions to illustrate the degree of pain intensity. A numerical rating is assigned to each face (from 0 meaning not hurting to 10 meaning hurts worst). It has been validated for use among children older than 3 years, including in the paediatric emergency department.¹⁶

Most secondary outcomes were proxy reported for participants younger than 8 years old, and self-reported by participants 8 years and older. Secondary outcomes that

were proxy reported for participants younger than 8 years and self-reported by participants aged 8 years and older were: functional recovery—Patient Report Outcomes Measurement System (PROMIS Bank version 2.0) Upper Extremity Score for Children Computer Adaptive Test,¹⁷ which was collected at baseline, 3, and 7 days, and 3 and 6 weeks and health-related quality of life using the EuroQol 3-level EQ-5DY (EQ-5DY-3L), which is a child-friendly version of the EQ-5D-3L.^{18,19} Responses were converted to a utility score (range -0.594 to 1 [where 0 corresponds to a health state equivalent to death and 1 to best health state. Negative values are judged to be health states worse than death]). These data were collected at baseline, 3, and 7 days, and 3 and 6 weeks; analgesia use and type over the last 24 h was collected as a binary outcome at 1, 3, and 7 days. Secondary outcomes that were proxy reported for all participants during the 6 weeks after randomisation were: days of school or childcare absence collected at 3 and 6 weeks; health-care resource use collected at 3 and 6 weeks (not reported in this Article); complications collected at 1, 3, and 7 days and 3 and 6 weeks, specifically return to hospital, which prompted corroboration with treating hospital; and satisfaction with treatment received using a 7-item Likert scale collected at 1 day and 6 weeks (range $1-7$ [extremely satisfied to extremely unsatisfied]). Serious adverse events were to be collected on an ad-hoc basis using a bespoke form; however, none occurred during the trial.

After 250 participants had been recruited, sites were invited to take part in an audit to verify the diagnosis of torus fracture. Diagnoses of patients enrolled were compared to the formal radiological report produced in the days following diagnosis.

Statistical analysis

The Wong-Baker scale has a minimally clinical important difference of one face (2 points), determined in the setting of the paediatric emergency department.¹⁶ This trial was designed to investigate the equivalence of the offer of bandage compared with rigid immobilisation, assessing the difference in means on the Wong-Baker scale 3 days after randomisation. The equivalence margin was chosen as half the minimally clinical important difference, which is standard practice in equivalence trials. We discussed this with clinical and non-clinical stakeholders to confirm that this approach would be acceptable to families and sufficient to change clinical practice. Assuming an equivalence margin of one point, 90% power, conducting two one-sided tests at 2.5% significance, and assuming that the SD was 2.3 (based on results from a feasibility study²⁰), 278 patients (139 per group) with primary outcome data were required to show equivalence.

The trial was separately powered to assess equivalence between treatments in two age groups (4–7 years and 8–15 years). This took into account differences in outcome response characteristics by age,²¹ accommodated a discontinuity within reporting of the secondary outcome

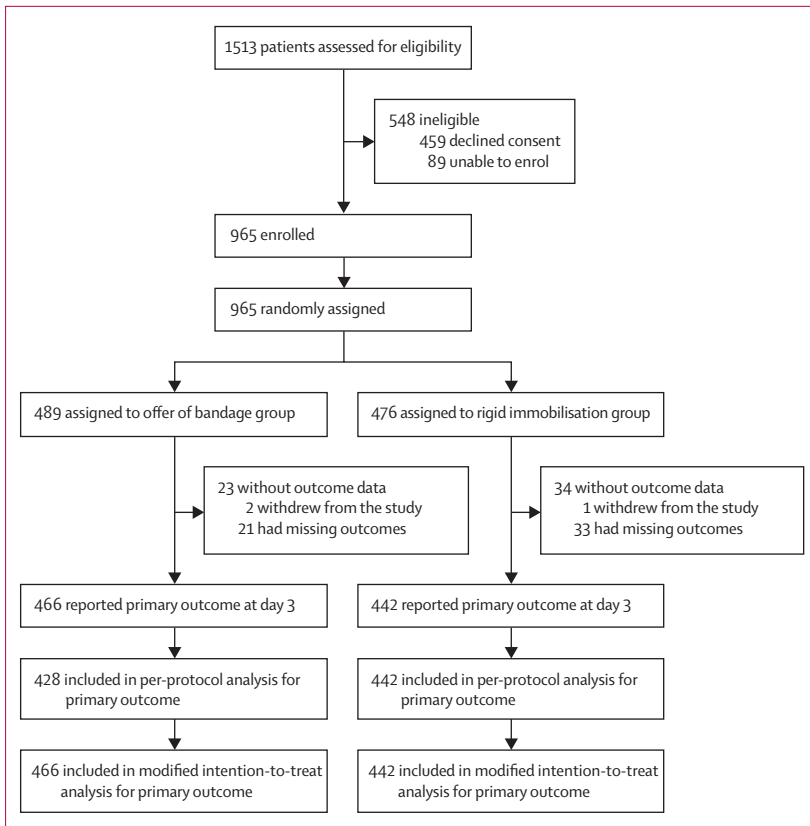


Figure 1: Trial-flow diagram

instruments (ie, self-reported for the older group and proxy-reported the younger group), and increased the power to examine rare secondary outcomes (ie, complications).

As per the prespecified analysis plan,¹⁰ two analysis populations were considered: the intention-to-treat population and the per-protocol population. The intention-to-treat analysis is referred to as modified as it only includes the intention-to-treat population with available primary outcome data. The per-protocol population included all participants who received their allocated treatment, did not change from this treatment before the primary outcome timepoint, provided sufficient follow-up data for analysis, and were eligible for the study. Analyses of outcomes were performed for the intention-to-treat population and repeated for the per-protocol population, with equivalence required in both populations for equivalence to be claimed.^{22,23}

Wong-Baker scores at 3 days after randomisation were summarised by treatment group using means and SDs. A multivariable linear regression model adjusting for stratification factors and participant gender was used to compare the two groups with the adjusted difference and 95% CI reported. The assumption of approximate normality of the residuals was assessed graphically and confirmed to be appropriate. An unadjusted *t*-test was also performed. These analyses were repeated separately

	Offer of bandage group (n=489)	Rigid immobilisation group (n=476)
Age, years	9.61 (2.99)	9.69 (2.85)
Age range, years		
4-7	153 (31%)	147 (31%)
8-15	336 (69%)	329 (69%)
Sex		
Female	179 (37%)	200 (42%)
Male	310 (63%)	276 (58%)

Data are n (%) or mean (SD) unless indicated otherwise.

Table 1: Baseline characteristics by treatment group

for the two age groups, with results reported in a similar manner. A sensitivity analysis was performed using repeated measures linear regression models, including treatment-by-time interactions to compare Wong-Baker scores from 1 day to 6 weeks after randomisation.

Similar methods were used to analyse the continuous secondary outcomes (PROMIS and EQ5DY) and analogous logistic regression models were used to analyse binary secondary outcomes (analgesia use and school absence). Satisfaction scores were summarised using medians and IQRs and compared using a Mann-Whitney U-test. The number of complications observed was very low; therefore, formal comparison was not performed. A significance level of 0.05 was used throughout, with 95% CIs reported. All secondary analyses were considered as supporting the primary outcome analysis. All analyses were conducted using STATA (version 15.1). A steering and Data and Safety Monitoring Committee oversaw progress, conduct, and participant safety. The trial was registered with ISRCTN registry, ISRCTN13955395.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Jan 16, 2019, and July 13, 2020, we screened 1513 patients, of which 965 were eligible for inclusion and randomised to a group. 489 (51%) patients were randomly allocated to the offer of a bandage group and 476 (49%) patients to the rigid immobilisation group (figure 1) and 379 (39%) were girls and 586 (61%) were boys. Study follow-up was continued until Aug 27, 2020. All 965 participants were included in the intention-to-treat population, and 870 (90%) participants were included in the per protocol population. 908 (94%) participants provided data for the primary endpoint (466 in the offer of a bandage group and 442 in the rigid immobilisation group).

Baseline demographics of recruited participants were similar in both treatment groups (table 1) and between

those eligible and randomised and those not eligible and not randomised (ie, declined consent; appendix p 2). Over the recruitment period, approximately twice as many children who were aged 8–15 years presented to hospital with a torus fracture and were screened for inclusion than did children aged 4–7 years. Recruitment continued until at least 278 primary outcomes were collected for each age subgroup. Consequently, 665 participants were recruited who were aged 8–15 years and 300 were aged 4–7 years. The injury involved the dominant hand in 426 (44%) participants and the non-dominant hand in 524 (54%) participants; 15 (2%) participants were reported to be ambidextrous or were unsure about their dominant hand. 20 protocol deviations were reported during the trial (appendix p 2).

Of those patients assigned to the offer of bandage group, 458 (94%) chose to have the bandage applied in the emergency department. In the rigid immobilisation group, 451 (95%) patients were treated with a removable wrist splint, with the remainder treated with a more traditional cast (ie, backslab or circumferential cast) or a soft cast. The median days of bandage usage was 7 days (IQR 4–16) in the offer of bandage group and the median days of splint usage was 18 days (14–21) in the rigid immobilisation group. At 3 weeks, 177 (37%) of patients in the rigid immobilisation group indicated that they continued to wear the immobilisation device, while only 50 (10%) in the offer of bandage group continued to wear the bandage.

By the primary outcome timepoint of 3 days, 36 (7%) patients in the offer of bandage group had changed treatment to rigid immobilisation, while one (0.2%) patient in the rigid immobilisation group declined the intervention (table 2). After day 3, a further 21 (4%) patients in the offer of bandage group changed treatment to rigid immobilisation. Overall, 53 (11%) participants in the offer of bandage group and 22 (5%) participants in the rigid immobilisation group returned to hospital during follow-up for at least one change of immobilisation (ie, participants changing from bandage to bandage, bandage to splint or splint to splint).

The study demonstrated equivalence of the interventions using the primary outcome of pain at 3 days (figure 2). Average pain scores at 3 days were 3.21 points (SD 2.08) in the offer of bandage group and 3.14 points (2.11) in the rigid immobilisation group using a modified intention-to-treat analysis. With reference to the prespecified equivalence margin of 1.0, the adjusted difference in the intention-to-treat population was -0.10 (95% CI -0.37 to 0.17) and the per protocol population was -0.06 (95% CI -0.34 to 0.21; table 3). The trial was separately powered to assess equivalence in the two age subgroups and there was equivalence in both subgroups at the primary timepoint (figure 2). Similarly, there was evidence of equivalence in the Wong-Baker Scale at all other follow-up timepoints throughout the trial (figure 3; table 3). Sensitivity analyses

of the primary outcome also demonstrated equivalence between the offer of a bandage and rigid immobilisation group. The PROMIS upper extremity scores from

See Online for appendix

	Offer of bandage group (n=489)	Rigid immobilisation group (n=476)
Total participants changed from allocated treatment by day 3	36 (7%)	1 (0.2%)
Aged 4–7 years	15/153 (10%)	0/147
Aged 8–15 years	21/336 (6%)	1/329 (0.3%)
Reason for crossover		
Child or parent decision	6 (1%)	1 (0.2%)
Clinical decision	1 (0.2%)	0
Pain	18 (4%)	0
Alternative fracture identified	1 (0.2%)	0
Other	10 (2%)	0
Changed from allocated treatment after day 3	21 (4%)	0
Aged 4–7 years	6/153 (4%)	..
Aged 8–15 years	15/336 (4%)	..
Reason for change after day 3		
Pain	11 (2%)	0
Alternative fracture identified	1 (0.2%)	0
Other*	9 (2%)	0
Number of patients returning to hospital for hospital-initiated immobilisation changes by follow-up timepoint		
Day 1	10 (2%)	5 (1%)
Day 3	22 (4%)	8 (2%)
Day 7	20 (4%)	3 (0.6%)
Day 21	9 (2%)	6 (1%)
Total number of immobilisation changes	61	22
Total number of participants with at least one immobilisation change	53 (11%)	22 (5%)

Data are n (%) or n/N (%) unless indicated otherwise. *Splint to bandage, splint to splint, bandage to bandage or bandage to splint

Table 2: Details of treatment received by allocated group

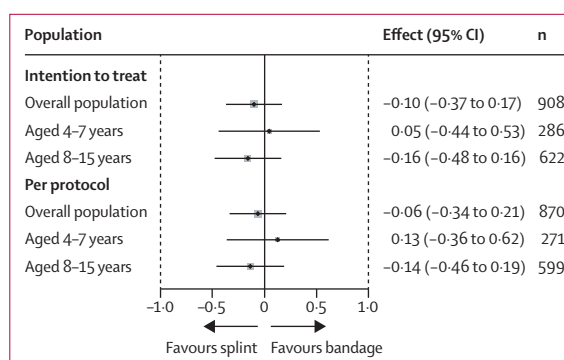


Figure 2: Day 3 Wong-Baker Scale score treatment effects compared with equivalence margin

	Offer of bandage group (n=489)	Rigid immobilisation group (n=476)	Effect size (95% CI)*	p value
Primary outcome				
Modified intention-to-treat analysis	3.21 (2.08); n=466	3.14 (2.11); n=442	-0.10 (-0.37 to 0.17)	
Per-protocol analysis	3.17 (2.04); n=428	3.14 (2.11); n=442	-0.06 (-0.34 to 0.21)	..
Other timepoints for the primary outcome				
Day 0	5.21 (2.32)	4.91 (2.10)
Day 1	4.29 (2.25); n=408	3.94 (2.13); n=382	-0.36 (-0.61 to -0.12)	..
Day 3	3.21 (2.08); n=466	3.14 (2.11); n=442	-0.09 (-0.32 to 0.14)	..
Day 7	2.32 (1.81); n=459	2.12 (1.68); n=439	-0.21 (-0.44 to 0.02)	..
Day 21	0.81 (1.32); n=432	0.87 (1.39); n=429	0.04 (-0.20 to 0.27)	..
Day 42	0.27 (0.81); n=436	0.24 (0.77); n=431	-0.05 (-0.28 to 0.19)	..
Secondary outcomes				
PROMIS				
Baseline	25.0 (6.3); n=489	25.6 (7.7); n=476
Day 3	28.4 (7.8); n=462	27.8 (7.9); n=441	-0.50 (-1.58 to 0.57)	0.36
Day 7	34.7 (9.9); n=456	34.5 (9.2); n=437	-0.12 (-1.20 to 0.96)	0.82
Day 21	46.6 (10.1); n=431	46.3 (10.1); n=426	-0.26 (-1.36 to 0.83)	0.64
Day 42	52.8 (7.3); n=434	52.6 (7.5); n=428	-0.20 (-1.29 to 0.90)	0.72
EQ5DY-3L				
Baseline	0.53 (0.34); n= 489	0.56 (0.34); n=476
Day 3	0.56 (0.27); n=459	0.55 (0.27); n=441	-0.01 (-0.04 to 0.02)	0.43
Day 7	0.71 (0.23); n=456	0.69 (0.24); n=435	-0.01 (-0.04 to 0.02)	0.53
Day 21	0.89 (0.16); n=430	0.89 (0.16); n=426	-0.01 (-0.04 to 0.02)	0.65
Day 42	0.97 (0.10); n=434	0.96 (0.10); n=428	-0.00 (-0.04 to 0.03)	0.82
Satisfaction				
Day 1	2 (1, 2), 406	1 (1, 2), 380	..	<0.0001
Day 42	1 (1, 2), 433	1 (1, 2), 425	..	0.12
Use of any analgesia within the previous 24h				
Day 1	337/408 (83%)	297/382 (78%)	OR 0.53 (0.28 to 0.98)	0.04
Day 3	264/465 (57%)	227/442 (51%)	OR 0.60 (0.36 to 0.99)	0.05
Day 7	116/459 (25%)	100/439 (23%)	OR 0.70 (0.40 to 1.22)	0.21
School absence				
Participants who missed school	112/430 (26%)	93/425 (22%)	OR 0.79 (0.57 to 1.08)	0.14
Number of days of school missed	1.5 (1-2); n=112	1.5 (1-2); n=93	..	0.37
Any complication				
Alternative fracture: greenstick	1 (0.2%)	1 (0.2%)
Alternative fracture: complete but remains undisplaced	3 (0.6%)	2 (0.4%)
Other	1 (0.2%)	0

Data are mean (SD), n/N (%), or median (IQR) unless otherwise indicated. Analyses are by intention to treat unless otherwise stated. PROMIS=Patient Report Outcomes Measurement System. EQ5DY-3L=child friendly EuroQol 3-level. OR=odds ratio. *Effect sizes are adjusted difference, unless otherwise stated as OR.

Table 3: Primary and secondary outcomes by treatment group

baseline to week 6 for the intention-to-treat population are summarised by treatment group and separately for each age subgroup (table 3; appendix p 3). There was no significant difference between the offer of bandage group and rigid immobilisation group at any timepoint. There was an increase in function over time with a marked increase between day 7 and week 3. PROMIS scores were higher in the older age subgroup than in the younger age subgroup.

EQ-5DY-3L utility scores from baseline to week 6 increased over time, and the mean score at 6 weeks was

0.97 (SD 0.10) in the offer of bandage group and 0.96 (0.10) in the rigid immobilisation group (table 3); however, there were no significant differences between the two groups. Scores were consistently higher in the younger age subgroup than in the older age subgroup. Overall parental satisfaction was high at days 1 and 42; at day 1 parents in the rigid immobilisation group were more satisfied than parents in the offer of bandage group; however, this difference was not present at 6 weeks (table 3).

There was no difference in the rate of complications, with five complications (1%) in the offer of bandage

group and three (1%) in the rigid immobilisation group (table 3). Seven complications were treatment changes owing to a change in the fracture diagnosis after randomisation, and one was a re-fracture. No complications required any intervention beyond the application of a plaster cast, and there was no need for surgery or fracture manipulation for any patient. The rates of school absence were similar in both groups (table 3), and among those who reported missing school the median school absence was 1.5 days (IQR 1–2), which was the same for each intervention group. There was a small, yet significant increase in the use of analgesia in the offer of bandage group compared with the rigid immobilisation group (83% vs 78%) at day 1, although this did not occur at any other timepoints (table 3). The analgesia used was either paracetamol or ibuprofen on all but two occasions, and a post-hoc analysis of pain scores adjusted by contemporaneous analgesia use demonstrate treatment effect estimates are all within the prespecified equivalence margin (appendix p 3).

12 centres agreed to participate in the diagnostic confirmation audit, which included 218 (87%) of the first 250 participants enrolled. The radiological report confirmed the diagnosis of torus fracture in 84% of participants (95% CI 80–89). There was diagnostic variance in 16% of participants. No fracture was reported in 15 (7%; 95% CI 4–10) patients, a greenstick fracture in 15 (7%; 4–10) patients, a Salter-Harris II fracture in three (1%; 0–3) patients, and an unspecified fracture in one (0.5%; 0–1) patient.

Discussion

This multicentre trial of torus fractures of the distal radius, with or without an ulna fracture, found equivalence in pain scores at 3 days post-randomisation among children treated with an offer of a bandage and immediate discharge, and those treated with rigid immobilisation and routine follow-up. There was no significant difference in the pain scores at any timepoint during the 6 weeks of follow-up and no evidence of any significant differences in patient self-reported function.

The FORCE Study was a large pragmatic study in 23 hospitals with diverse catchment areas and a range of health professionals engaged in participant recruitment (ie, physicians, surgeons, physiotherapists, and nurse practitioners). As such, the findings are likely to be generalisable broadly in the UK and across different health-care settings. This study contributes to the evidence in this field by improving the methodological quality and recruiting more participants than the total of the ten studies that contributed to the current Cochrane review in this area.⁷ The results were aligned with those from the Cochrane review, confirming that pain and recovery were equivalent regardless of treatment. Furthermore, the size of this study allowed particular consideration to patient safety.

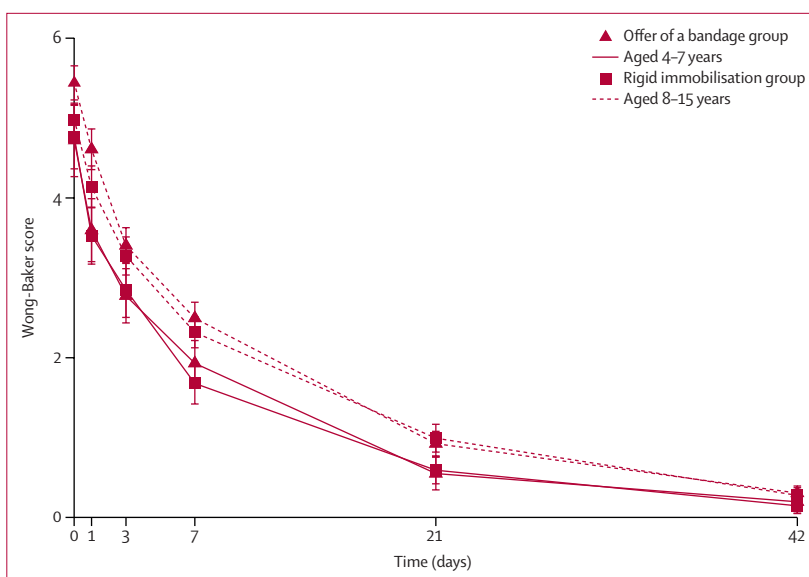


Figure 3: Wong-Baker Scale score by treatment group and age group from baseline to 6 weeks after randomisation for the intention-to-treat population

Re-fracture or progressive deformity are key safety concerns that are commonly perceived by clinicians and families, which have slowed the de-escalation of treatment for torus fractures. Of the 965 children in this study, none were found to have a worsened deformity. In total, only eight complications were reported, seven of which were treatment changes owing to a change in the fracture diagnosis after randomisation (four originally allocated to bandage and three originally allocated to rigid immobilisation), all of whom were treated with cast immobilisation without any manipulation. Although a change of treatment was only necessary in seven participants (<1%), the diagnostic confirmation audit demonstrated diagnostic disagreements in approximately 15% of participants. As with many radiological diagnoses, it is often difficult to establish whose diagnosis is correct among emergency department clinicians and radiologists. Although reporting radiologists are experts in image interpretation, they cannot correlate clinical and radiological findings and infrequently use standardised terms when reporting fracture films of distal radius fractures in children.²⁴ An independent radiological report from an expert is therefore helpful, although disagreements should prompt further diagnostic verification with minor disagreements rarely being of clinical significance.

Despite the range of different types of rigid immobilisation available, the majority of participants were treated with a removable wrist splint. A study of UK practice from 2017 illustrated that 40% of hospitals primarily used casts for this injury,²⁰ which differs to the widespread use of removable wrist splints within this study. This difference either reflects a widespread adoption across the UK of the 2016 NICE guideline,

which advocates removable splints for torus fractures,⁸ or reflects the progressive nature of hospitals involved in research who were early adopters of this practice. Nevertheless, the results of this study support the continued de-escalation of treatments in these injuries.

Recruiting patients to clinical trials in the context of emergencies is difficult, which is magnified when the patient group involves children. A concern before this trial started was that families or clinicians would not be willing to take part. This concern was unfounded among clinicians, who were broadly in equipoise, with only 14 patients not enrolled owing to clinician preference. However, families had strong pre-existing preferences, with more than half of those who declined to participate in the study citing a preference for rigid immobilisation, while only 1% indicated a preference for the offer of a bandage.

There remained a preference among parents or carers after randomisation for rigid immobilisation, with 57 children changing treatment. Crossovers might have been due to the pre-existing belief among parents or carers that rigid immobilisation is the gold standard, coupled with the clinician's desire to escalate care among those returning to hospital following the first visit. The desire of clinicians to escalate care should be framed in the context that both intervention groups had participants who returned to hospital. In the offer of bandage group this resulted in a crossover from bandage to a splint or cast. Participants in the rigid immobilisation group were treated with a different rigid immobilisation device, which was not reported as a crossover. As such there was an imbalance in crossovers reported between the intervention groups, which could compromise the integrity of the trial; however, as the total number of such crossovers was small (6%) in the context of a trial of 965 participants it is unlikely to have affected the results. Furthermore, the analysis undertaken considered the results according to analysis of both the per protocol and intention-to-treat populations.

The inability to mask families to the treatment allocation is likely to have introduced some bias in patient-reported outcomes. Given the strong preference for rigid immobilisation, this bias seems likely to have overstated the outcome severity in the offer of bandage group. This bias could be indicative of the marginally increased use of analgesia, the higher pain scores, and lower satisfaction scores on day 1 in the offer of bandage group. The finding of equivalence, despite this potential for bias, adds further weight to strengthen the study findings.

To maximise the generalisability of the findings, no exclusion was made for comorbid diseases (ie, neuromuscular or metabolic disease). There could be specific comorbid groups for whom clinicians believe the results are not applicable.

Implementing the offer of a bandage as the primary treatment for patients with a torus fracture should consider the strong preference among patients and their families for rigid immobilisation; and it should involve clinician and

patient or family education and policy change, such as updates to guidelines produced by NICE.⁸ The approach of immediate discharge appears safe and is easily implementable worldwide. Normalising the process of offering a bandage among clinicians and better education among patients and families could help to overcome preconceived preferences, enabling better adoption of this intervention. Additional reassurance to families could come from the knowledge that immediate discharge is safe, and the need for analgesia is not significantly different between the offer of a bandage and rigid immobilisation, with only simple analgesia (ie, paracetamol or ibuprofen) necessary. To facilitate the implementation into clinical practice and optimise external validity we have developed an online dissemination tool. This tool has been co-designed by clinicians and families, and it includes educational materials and a diagnostic aid or treatment pathway developed from the original recruitment materials. A clinical decision tool to determine which wrist injuries require radiography (ie, to differentiate clinically significant fractures from torus fractures or soft tissue injuries) could be used to further de-escalate care by preventing unnecessary radiation and over-diagnosis. Similar tools have been successful for ankle injuries with the development of the Ottawa ankle rules.²⁵ There have been clinical decision tools developed in paediatric wrist injuries, although these only differentiate between fracture and no fracture, and their implementation needs greater uptake.²⁶

There was equivalence in reported pain at 3 days post-randomisation and throughout the 6-week follow-up period between children with a torus fracture of the distal radius treated with the offer of a bandage and immediate discharge and those treated with rigid immobilisation and follow-up. There were no safety concerns in either group. This trial supports the strategy of the offer of a bandage and immediate discharge from the emergency department for children with torus fractures of the distal radius.

Contributors

DCP conceptualised the study. JA oversaw project administration. DA developed software. MLC provided overall supervision to the project. RK and MD were responsible for formal analysis with direct access to the data. SJD oversaw the statistical analysis and independent verification of the result. DCP and JA wrote the original draft. DTR, SM, and JW were responsible for coordinating the investigation at sites. JMM oversaw the resource use analysis. All authors contributed to funding acquisition, methodology and data curation, and were responsible for reviewing and editing the manuscript. All authors had full access to all of the available data in the study and accept responsibility to submit for publication.

Declaration of interests

All authors received a grant from National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (17/23/02) during the conduct of the trial. DCP is a NIHR Research Professor and a member of the Commissioning Board for the NIHR HTA funding stream. DTR was chair of Paediatric Emergency Research United Kingdom and Ireland (PERUKI), which was a partner organisation for the study. SM receives financial support from the NIHR Research Scholar North West Coast and is the secretary of PERUKI. MLC is a NIHR Senior Investigator and a member of the General Board for the NIHR HTA funding stream. The views expressed in this report are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Data sharing

Data request proposals can be made to the corresponding author. Proposals can be made for access to deidentified participant data up to 3 years after the publication of these results. Additional related documents (ie, the study protocol and statistical analysis plan) have been published elsewhere, although the formal study documents are available on request.

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References

- Naranje SM, Erali RA, Warner WC Jr, Sawyer JR, Kelly DM. Epidemiology of pediatric fractures presenting to emergency departments in the United States. *J Pediatr Orthop* 2016; **36**: e45–48.
- Cooper C, Dennison EM, Leufkens HGM, Bishop N, Van Staa TP. Epidemiology of childhood fractures in Britain: a study using the general practice research database. *J Bone Miner Res* 2004; **19**: 1976–81.
- Baig M. A review of epidemiological distribution of different types of fractures in paediatric age. *Cureus* 2017; **9**: e1624.
- Chung KC, Spilson SV. The frequency and epidemiology of hand and forearm fractures in the United States. *J Hand Surg Am* 2001; **26**: 908–15.
- Perry DC, Gibson P, Roland D, Messahel S. What level of immobilisation is necessary for treatment of torus (buckle) fractures of the distal radius in children? *BMJ* 2021; **372**: m4862.
- Davison J, Brown D, Barnes S, Bruce C. Simple treatment for torus fractures of the distal radius. *J Bone Joint Surg Br* 2001; **83**: 1173–1175.
- Handoll HHG, Elliott J, Iheozor-Ejiofor Z, Hunter J, Karantana A. Interventions for treating wrist fractures in children. *Cochrane Database of Syst Rev* 2019; **12**: CD012470
- National Institute Clinical Excellence. Fractures (non-complex): assessment and management. 2016. <https://www.nice.org.uk/guidance/ng38> (accessed June 7, 2022).
- Achten J, Knight R, Dutton SJ, et al. A multicentre prospective randomized equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilization for torus fractures of the distal radius in children. *Bone Jt Open* 2020; **1**: 214–21.
- Knight R, Dritsaki M, Mason J, Perry DC, Dutton SJ. The Forearm Fracture Recovery in Children Evaluation (FORCE) trial: statistical and health economic analysis plan for an equivalence randomized controlled trial of treatment for torus fractures of the distal radius in children. *Bone Jt Open* 2020; **1**: 205–13.
- The Royal College of Emergency Medicine. Management of pain in children. 2017. https://rcem.ac.uk/wp-content/uploads/2021/11/Pain_in_Children_2017_18_National_Report_Oct_2018.pdf (accessed June 7, 2022).
- Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009; **42**: 377–81.
- Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform* 2019; **95**: 103208.
- Wong DL, Baker CM. Pain in children: comparison of assessment scales. *Pediatr Nurs* 1988; **14**: 9–17.
- Achten J, Knight R, Dutton SJ, et al. A multicentre prospective randomized equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilization for torus fractures of the distal radius in children: protocol for the Forearm Fracture Recovery in Children Evaluation (FORCE) trial. *Bone Jt Open* 2020; **1**: 214–21.
- Garra G, Singer AJ, Taira BR, et al. Validation of the Wong-Baker FACES pain rating scale in pediatric emergency department patients. *Acad Emerg Med* 2010; **17**: 50–54.
- HealthMeasures. PROMIS (Patient-Reported Outcomes Measurement Information System). <https://www.healthmeasures.net/explore-measurement-systems/promis> (accessed June 15, 2020).
- Eidt-Koch D, Mittendorf T, Greiner W. Cross-sectional validity of the EQ-5D-Y as a generic health outcome instrument in children and adolescents with cystic fibrosis in Germany. *BMC Pediatr* 2009; **9**: 55.
- Wille N, Badia X, Bonsel G, et al. Development of the EQ-5D-Y: a child-friendly version of the EQ-5D. *Qual Life Res* 2010; **19**: 875–86.
- Widnall J, Capstick T, Wijesekera M, Messahel S, Perry DC. Pain scores in torus fractures. *Bone Jt Open* 2020; **1**: 3–7.
- Oliveira AM, Batalha LM, Fernandes AM, Goncalves JC, Viegas RG. A functional analysis of the Wong-Baker Faces Pain Rating Scale: linearity, discriminability and amplitude. *Rev Enferm Ref* 2014; **4**: 121–30.
- Chow SC, Wang H. On sample size calculation in bioequivalence trials. *J Pharmacokinetic Pharmacodyn* 2001; **28**: 155–69.
- Christensen E. Methodology of superiority versus equivalence trials and non-inferiority trials. *J Hepatol* 2007; **46**: 947–54.
- Ruess L, Chmil M, Singh S, Samora JB. Improving diagnostic accuracy for distinguishing buckle fractures from other distal radius fractures in children. *Pediatr Qual Saf* 2022; **7**: e547. 24
- Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Worthington JR. A study to develop clinical decision rules for the use of radiography in acute ankle injuries. *Ann Emerg Med* 1992; **21**: 384–90. 25
- Slaar A, Walenkamp MMJ, Bentohami A, et al. A clinical decision rule for the use of plain radiography in children after acute wrist injury: development and external validation of the Amsterdam Pediatric Wrist Rules. *Pediatr Radiol* 2016; **46**: 50–60. 26