# A qualitative study of clinicians' experience of a clinical trial for displaced distal radius fractures

## Overcoming obstacles: tension, time, and territories

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### Aims
The aim of this study was to explore clinicians' experience of a paediatric randomized controlled trial (RCT) comparing surgical reduction with non-surgical casting for displaced distal radius fractures.

### Methods
Overall, 22 staff from 15 hospitals who participated in the RCT took part in an interview. Interviews were informed by phenomenology and analyzed using thematic analysis.

### Results
Analysis of the findings identified the overarching theme of "overcoming obstacles", which described the challenge of alleviating staff concerns about the use of non-surgical casting and recruiting families where there was treatment uncertainty. In order to embed and recruit to the Children's Radius Acute Fracture Fixation Trial (CRAFFT), staff needed to fit the study within clinical practice, work together, negotiate treatment decisions, and support families.

### Conclusion
Recruiting families to this RCT was challenging because staff were uncertain about longer-term patient outcomes, and the difficulties were exacerbated by interdisciplinary tensions. Strong family and clinician beliefs, coupled with the complex nature of emergency departments and patient pathways that differed site-by-site, served as barriers to recruitment. Cementing a strong research culture, and exploring families' treatment preferences, helped to overcome recruitment obstacles.

### Take home message
- Randomized controlled trials for paediatric injuries are challenging for clinicians and parents. The complex nature of emergency departments, interdisciplinary tensions, and strong clinician and parent beliefs about treatments can hinder recruitment.
- Surgeons can overcome barriers to recruitment by working together, fitting trials within current practices and pathways and providing support and reassurance to their colleagues, and to families where there is concern about one of the trial treatments.

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## Introduction

The Children's Radius Acute Fracture Fixation Trial (CRAFFT) is a multicentre, randomized non-inferiority trial of surgical reduction (surgery) versus non-surgical casting with approximate alignment for displaced distal radius fractures in children aged four to ten years.[1] Prior to the CRAFFT study, surgery was the most common treatment for these fractures in the UK. However, there is historic evidence to show that the wrist has significant potential for remodelling in children.[2] Non-surgical casting with approximate alignment is a standard treatment in other parts of the world.[3] Nevertheless, clinicians have been concerned about outcomes of non-surgical casting as there is little high-quality evidence to support this practice, coupled with a degree of apprehension about not correcting the appearance of a fracture with obvious initial deformity.

We have already demonstrated that the families of children invited to take part in the CRAFFT study worried about their child's recovery, and found the uncertainty while waiting for fractures to remodel challenging.[4] They sometimes experienced feelings of regret or responsibility if healing took longer than they anticipated.

In order to recruit children to randomized controlled trials (RCTs), clinicians need to effectively communicate the trial, present equipoise, and overcome parents' concerns. Staff need to meet the needs of the trial while also addressing the burden that the trial brings, such as meeting recruitment targets, maintaining the trial visibility and the enthusiasm among staff, coping with high staff turnover, managing heavy clinical workloads and staff who are uninterested in research.[5,6] In RCTs comparing treatments for adult fractures, clinicians' beliefs about treatments and interpretation of the inclusion criteria can hinder recruitment.[7,8] Therefore, understanding the experience of staff involved in trials and their views of the treatments is valuable. Data regarding staff experience of RCTs for paediatric trauma, particularly where there is uncertainty about the treatment outcome, is limited. This qualitative study explored staff experience of the CRAFFT study.

## Methods

The CRAFFT study is registered with the International Standard Randomized Controlled Trials Number Registry (ISRCTN10931294: 27/02/2020). The Black Country Research Ethics Committee approved the CRAFFT study including this qualitative study (REC reference 20/WM/0054). Recruitment is ongoing in 49 NHS sites. As of October 2023, 688 families have consented.

### Sample

A purposive sample of 22 members of staff took part in 19 interviews (18 individual and one group interview). Staff included 12 research nurses (RNs) and ten clinicians (eight paediatric orthopaedic surgeons and two emergency department (ED) paediatricians) from 15 NHS sites recruiting to the CRAFFT study. In 11 of the 15 sites that contributed to the qualitative study, the principal investigator (PI) responsible for the study at the site was a surgeon; in three sites, the PI was a paediatrician specializing in emergency medicine and in one site, the responsibility for the study was shared.

Overall, 39 staff were invited to take part, five declined due to workload, and 12 did not respond to the invitation. All participants received an information sheet and had at least 24 hours to consider their participation. Verbal informed consent was recorded and witnessed by an administrator trained in good clinical practice.

### Interviews

The methodology for the interviews drew upon Heideggerian phenomenology,[9] which seeks to understand individuals' lived experience. We were interested in understanding their thoughts and feelings about the CRAFFT study. In this study, individual experience was collated to create an overview of the experience of the group. A qualitative researcher (EEP) experienced in health research conducted the interviews between July and October 2021, by telephone or video conference, with interviews lasting up to 45 minutes.

The interviews explored each participant's experience of being involved in the CRAFFT study and factors that helped or hindered recruitment. Interviews were semi-structured to cover key topics, such as study set-up, screening and recruitment, equipoise, and communication (see Supplementary material).

### Patient and public involvement

Parents have been involved throughout the CRAFFT study, including throughout this qualitative study, by contributing to the study design, developing study materials, and being part of the CRAFFT management and steering committees. Moreover, a parent co-investigator (PG) has contributed to the interpretation of the qualitative findings, and has co-authored and contributed to the development of this article.

### Analysis

Interviews were audio recorded, transcribed, and data were managed using NVIVO 12 (QRS, UK). Analysis was inductive and used a reflexive approach to thematic analysis,[10] This method involved: 1) familiarization with the data by listening to the recordings, reading transcripts and writing field notes; 2) coding data into groups based upon meaning; and 3) developing categories and themes by grouping similar codes and then categories together. Analysis was iterative, with new codes added and existing codes revised as more data were analyzed.

To achieve rigour and trustworthiness,[11] EEP was immersed in the data, and regularly discussed the data and framework with ET. Further discussions took place with the parent co-investigator, an experienced research nurse, and all the co-authors. Descriptions of the participants, context and methods, and illustrative quotations enable readers to consider our interpretation of the data and the transferability of these findings to other contexts. Data saturation, when no new categories or themes arise from subsequent data collection, was achieved. The consolidated criteria for reporting qualitative research (COREQ) guidelines informed this article.[12]

## Findings

This study identified the overarching theme of "overcoming obstacles – tension, time, and territories" which describes the work staff undertake to embed and recruit to paediatric studies of injury in emergency settings. This was conveyed through four themes: 1) fitting in with clinical practice; 2)

working together; 3) negotiating treatment decisions; and 4) supporting families, as presented in Figure 1.

Each theme is presented, followed by a table highlighting barriers and facilitators to recruitment and a table of illustrative quotations.

**Theme 1: Fitting in with clinical practice**

Staff identified the challenge of fitting the study into clinical practice and the time required to make the study work in each site. They achieved this by navigating the busy ED and making sense of the study's eligibility criteria and interventions. (See Table I for barriers and facilitators to recruitment and Table II for illustrative quotations).

Navigating ED*:* The fast pace and volume of work meant recruiting in an ED was challenging and was of secondary importance to delivering clinical care. Some staff described a clear pathway from which they would approach patients, recruiting either in the ED or fracture clinic, whereas staff from other sites used a more ad-hoc approach, which could feel rushed, last minute, and potential patients could be missed. By the time some participants were screened in fracture clinic, the injury was too old for inclusion or the family had already decided upon a treatment. In sites where there was insufficient physical space, insufficient staff numbers, or insufficient time to adequately deliver the trial in the ED, staff felt the study did not fit the current pathway.

*I recognize the challenges for the consultants are that they've got other priorities, haven't they, and for them they can be in a busy place and the research can be secondary. (RN8*)

Making sense of the study: Clinicians took into account how they would usually treat these fractures when making sense of the study. Beliefs about whether a patient met the criterion "may benefit from surgical reduction with or without fixation" varied, enabling some clinicians to include more patients than others.

*Some doctors have a very high threshold for what they will operate on, on distal radiuses, and some surgeons have lower ones. It can be the same injury - but two different doctors - and they're treated differently. (RN1*)

Clinicians needed to work out how the local policy for manipulating wrists in the ED fitted with the study at their site. Non-surgical casting could include some degree of manipulation, to restore approximate alignment of the fracture in ED, but did not include manipulation with the intent of restoring the normal anatomical position of the broken bone. However, in some EDs, manipulation under general anaesthesia or sedation altering the conscious state of the child was possible and, if this was performed with the intent of fully restoring the normal anatomy, such a manipulation would meet the study's definition of surgery. This could lead to confusion about how the study protocol fit with local processes. Sometimes staff had three treatments in their mind (surgery, manipulation in the ED, and remodelling). Some staff felt strongly that manipulation in the ED, where possible, was the best option, and chose to exclude patients from the trial where this could be achieved.

**Theme 2: Working together**

Staff identified the challenge of recruiting to an interdisciplinary study, where everyone needs to be on-board, and the ED and orthopaedic surgery teams need to reach agreement and overcome territorial barriers. (See Table III for barriers and facilitators to recruitment and Table IV for illustrative quotations).

Getting everyone on board: Staff endeavoured to get all healthcare professionals (HCPs) across the patient pathway on-board with the study, taking time and energy. This helped ensure potential participants were identified and reduced unhelpful 'early treatment recommendations' from well-meaning clinicians. Early treatment recommendations influenced parent treatment preferences, and were difficult to unpick without undermining parent's trust in clinicians. Staff sometimes found that, despite their efforts, some HCPs did not know about the study. Clinicians and RNs could feel anxious or alone when they had little support with recruitment. They needed to approach the patient in the right place at the right time with a clinician who was enthusiastic about the study - but the optimal environment for recruitment was difficult to orchestrate. Staff found it helpful to support colleagues within their site and across the study using a secure instant messaging service.

*When the patient comes in with the injury, they have to line up with the correct doctor on-call and the correct doctor doing the surgery the next day to get full agreement - so it's taken a little bit of time to get all of that in place. (RN1*)

Reaching an agreement: ED and orthopaedic trauma teams negotiated how to run the study in their site, for example who would lead the study, approach and randomize patients, and which fractures were acceptable to include. Some sites shared ownership of the study helping staff work together, while in other sites, either the trauma or ED team led the study. Both teams were vital to the study's success as the EDs were the first 'line of defence' and in several sites introduced the study, but the orthopaedic trauma teams were considered to have more knowledge of patients' treatment and recovery.

Staff described tension between the ED and the orthopaedic trauma teams when they disagreed which patients to include. In some sites, this led orthopaedic trauma registrars to be wary of recruiting to avoid disapproval from senior colleagues. Strategies, such as using multidisciplinary team (MDT) meetings, where senior colleagues explained and endorsed the study and interested senior clinicians offering to follow-up study patients, increased support.

*It's been quite territorial, they all have their different opinions and it's very difficult to navigate. I can see why some of the orthopaedic registrars are not wanting to be involved because they don't want to burn their bridges. It reinforces the fact that we're doing the right thing doing this study because you've got everyone bickering about it and you know it's going okay. This is topical, this is the right thing to do and so you take it on the chin. In the beginning, some of the abuse was a little bit hurtful because this is a national study but now you harden up a bit and you just go okay. (Clinician10*)

**Theme 3: Negotiating treatment decisions**

Staff identified enthusiasm for the study and the belief that practice should change while recognizing tensions among their colleagues due to concerns about non-surgical casting. (See Table V for barriers and facilitators to recruitment and Table VI for illustrative quotations).

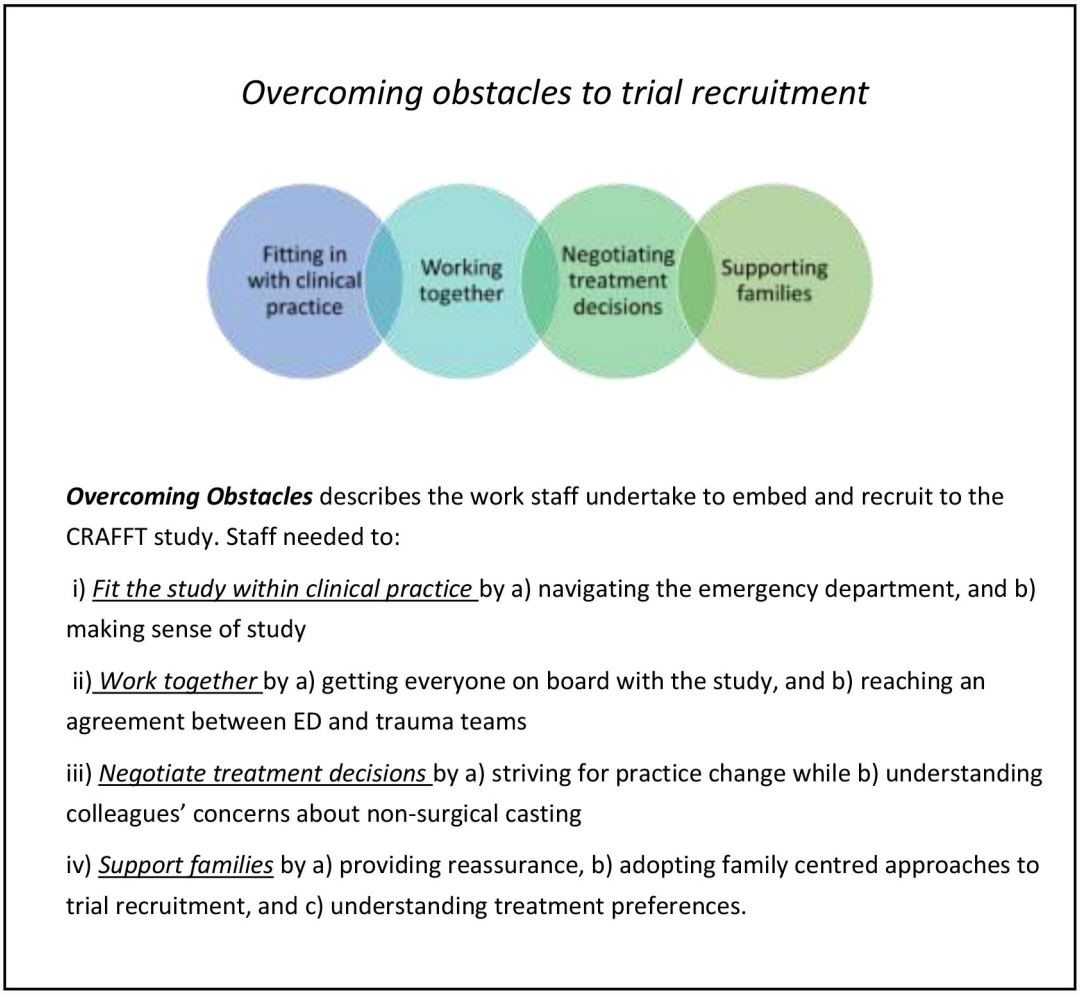


**Fig. 1**
Overcoming obstacles: themes and categories.

**Table I.** Fitting in with clinical practice: barriers and facilitators to recruitment.

| |
|---|
| **Barriers to recruitment** |
| Heavy workload and clinical priorities. |
| Emergency department environment can be challenging for families. |
| Change in practice might be required. |
| Clinical pathways can impede recruitment. |
| Beliefs about whether a fracture requires surgery can influence whether patients are deemed eligible. |
| **Facilitators to recruitment** |
| Giving families time and space to discuss the study. |
| Clear pathway for potential trial patients (e.g. who will approach families and when). |
| Sufficient facilities in emergency department to recruit to the study. |

Striving for practice change: Staff were enthusiastic about the study and eager to recruit. They believed the CRAFFT study would lead to practice change, particularly for less severe fractures or to a choice of treatment for parents. While some staff already used non-surgical casting, others planned to adopt a more conservative approach in the future, by allowing the bones to remodel with a cast, manipulating in the ED, or avoiding Kirschner (K)-wires. They referred to surgery as "over-treating", "aggressive" or "old ideas" and some questioned whether treating these fractures aggressively could cause harm.

**Table II.** Fitting in with clinical practice: illustrative quotations.

| Theme 1: Fitting in with clinical practice | |
|---|---|
| **Category** | **Illustrative quotes** |
| Navigating ED involves understanding: 1) the challenge of identifying all potential participants in the fast-paced ED; 2) the impact of patient pathways on recruitment; and 3) the impact of the environment on families. | 1) The challenge of identifying all potential participants:<br>They (clinical staff) can't even think about doing research because their brain doesn't have the capacity. Even though they're trained it's just not feasible and I suppose you're always going to get that a bit. *(RN20)* |
| | 2) The impact of patient pathways on recruitment:<br>At the trauma meetings, we pick up any patients that have been admitted overnight to the hospital that are a potential (recruit) for the study. Otherwise, our patients are coming in via the emergency department and then they are potentially getting picked up at what we call a virtual fracture clinic. So, they may have a telephone call or attend an actual clinic where they are reviewed by an orthopaedic clinician. Obviously at that point it may be that they're too far down the line to be eligible for the study. Or it may be that they've already had quite a lot of information to say that they may be getting a manipulation or they may just be staying in a cast, there's a lack of equipoise at that point. *(RN2)* |
| | 3) The impact of the environment on families:<br>I think parents needed time and information. Sometimes in the rush of the emergency department, the noise in the background and the concern and the fear about their child, especially if their child is crying and in pain, sometimes bringing up the topic of participating in a study might sound a bit academic. It is not the time for it. *(Clinician12)* |
| Making sense of the study involves: 1) interpreting the study's eligibility criteria; 2) understanding the impact of current patient pathways on eligibility; and 3) making sense of the treatments within the trial. | 1) Interpreting the study's eligibility criteria:<br>I think we had an idea that we see a lot of distal radiuses (fractures) in kids, but we don't actually operate on a lot here. So, I think we had in our heads that we had loads and loads but actually when it comes down to it, and to fit the criteria, they're quite rare and we don't get them very often. *(RN1)* |
| | 2) Understanding the impact of current patient pathways on eligibility:<br>Our emergency department are very good if it's a fracture, which they can manipulate well and give pain relief. They can just do it there and then and send them on their way and they won't think "Oh, this could actually go into the CRAFFT study". *(RN5)* |
| | 3) Making sense of the treatments within the trial:<br>Initially there were a couple of areas we were not sure about, particularly about the inclusion criteria - for example, if a child was given morphine would that be considered sedation…or would that be considered a non-surgical option and just a simple analgesia. *(Clinician12)* |

**Table III.** Working together: barriers and facilitators to recruitment.

| |
|---|
| **Barriers to recruitment** |
| Challenge in engaging multiple healthcare professionals throughout the patient pathway. |
| Early unhelpful treatment recommendations were frequently made by clinical staff not involved in the trial. |
| Lack of enthusiasm for research from some clinical staff. |
| Differences in clinical decision making between emergency department and orthopaedic trauma teams. |
| Apprehension among medical/surgical trainees regarding disagreement with senior colleagues. |
| **Facilitators to recruitment** |
| Early involvement from all teams to agree roles and which patients the site will include in the study. |
| Engaging and involving clinical colleagues who are not involved in research. |
| Local support from colleagues so the burden does not fall on one person. |
| Support from the wider study team (e.g. use of instant messaging to support recruitment and prompt debate and resolve questions). |
| Emergency department and orthopaedic trauma teams sharing responsibility for the study. |
| Multidisciplinary team and support for the study from senior colleagues. |
| Interested senior clinicians supporting follow-up for study patients, if required. |

**Table IV.** Working together: illustrative quotations.

| Theme 2: Working together | |
|---|---|
| **Category** | **Illustrative quotes** |
| Getting everyone on board involves engaging HCPs across the patient pathway in the study to help: 1) identify patients; 2) prevent early treatment recommendations; and 3) enable staff to support one another. | 1) Identify patients:<br>If everyone was thinking the same thing about CRAFFT we wouldn't be so anxious that we're going to miss a patient. I feel if everyone was a bit more up with the research, and on the delegation log, and knew about it, it would be less easy for them to slip through the net and less pressure on us – we can't miss them. *(RN19)* |
| | 2) Prevent early treatment recommendations:<br>If the orthopaedic team have seen patients before we have spoken to them about CRAFFT, then they're already on that path to "I need surgery". Then, you've got to try and pull them back from the abyss knowing that actually they're an orthopaedic surgeon - but they're misinformed. You're trying to not undermine that clinical relationship and that trust, because you are basically coming in and going "yes, I know what the surgeon said, but they are kind of wrong". That's tricky to navigate. *(Clincian10)*<br>Often what's happening is that the emergency department doctors are seeing the patients and referring them through to us (orthopaedic surgeon). It would be the emergency department junior doctors on-call, the Senior House Office grade, seeing the patient and parents; … If they say "Oh crikey, that's a very bent wrist - they need an operation, so we'd better call the orthopaedic surgeons", there's difficulty in trying to unpick that expectation made by a very junior doctor, who's the first person they see. *(Clinician13)* |
| | 3) Enable staff to support one another:<br>I do feel a bit alone in recruitment because these children always come 'out of hours' - so it's me doing the approach, consent and all the work…because we have to decide whether they're going to go through an operation or not. *(Clincian14)*<br>Recruitment has been difficult because we're all over the place and there's multiple people involved. Because it's difficult to recruit, it takes effort. Trying to get people on board and doing the actual work has been hard, but it has been helped immensely by the support from instant messaging and the Chief Investigator and so that's been a useful tool. *(Clinician10)* |
| Reaching an agreement involves: 1) ED and orthopaedic trauma teams negotiating how the study will work in their site; 2) sharing their expertise; and i3) managing tension and disagreements between the teams. | 1) ED and orthopaedic trauma teams negotiating how the study will work in their site:<br>We've spent a lot of time in the multidisciplinary teams really pushing it and having some top-down discussions about how and what we're happy to randomize. I think now the orthopaedic registrars are coming on board a bit more with the studies. *(RN3)* |
| | ii) Sharing their expertise:<br>I think it has to be a mix between emergency department and orthopaedics. Emergency department have good experience, but they don't have the same background. I think it should be a mix and so definitely emergency department are really important to be involved. They are the first to see the patient but sometimes it's really hard for them and it's unfair to put all the load on them to sell it to the patients. For example, last week I was on call and there was a child who was eligible, and emergency department spoke to the parents and apparently, they declined it but when I went again to speak to the parents I answered more questions, I've elaborated more and they have agreed to go for it. *(Clincian18)* |
| | 3) Managing tension and disagreements between the teams:<br>It's taken a really long time to get buy in from the orthopaedic teams. Our Principal Investigator (PI) is emergency department and our co-PI is orthopaedic - as opposed to it being an orthopaedic lead with a co-PI in the emergency department. We feel like we have 'butted heads' a bit trying to get orthopaedic teams on board because of the idea of not manipulating … it's taken a lot of time and energy but I think that we've feel we've got on top of that now. *(RN3)* |

**Table V.** Negotiating treatment decisions: barriers and facilitators.

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| **Barriers to recruitment** |
| Clinicians' treatment preferences (belief that study treatment was unethical, concerns about including severe fractures and older children). |
| Practice change over the course of the study. |
| **Facilitators to recruitment** |
| Enthusiasm for the study. |
| Sharing radiograph images of wrists that have healed with a cast with colleagues. |

**Table VI.** Negotiating treatment decisions: illustrative quotations.

| Theme 3: Negotiating treatment decisions | |
|---|---|
| **Category** | **Illustrative quotes** |
| Striving for practice change involves: 1) believing in the study and non-surgical casting; 2) supporting parent choice; 3) encouraging practice change; and 4) anticipating reluctance | 1) Believing in the study and nonoperative treatment:<br>What it's also raised with me personally is the fact that we have been very aggressive with these fractures. We've probably been operating and putting kids at risk of complications with surgery that we didn't need to, in a number of cases. *(Clinician9)*<br>I think this will be strong evidence to show that we don't need to take every single child with just a bendy arm or just a little bit of displacement to theatre or do manipulation. So, I think this will make a massive difference in practice. *(Clinician18)* |
| | 2) Supporting parent choice*:*<br>I think that (after the study) the different treatment measures should be offered to the parents…. I think it's a different journey that the patient takes and the parents need to be aware of that and there are still hurdles whichever treatment path you take. But the vast majority of patients do really well whichever treatment arm they take, it's just a different way of doing it really. *(Clinician15)* |
| | 3) Encouraging practice change:<br>I think within our department attitudes to what can be managed nonoperatively has changed already which has affected the recruitment to the trial. Fractures that would always have been taken (*for surgery*) are now less likely to be so by the individuals who wanted to operate on it, which is amazing. *(Clinician9)*<br>You see some of the really horrible ones and they're doing okay and that is quite reassuring. I've used one or two of the pictures – "you're worried about it, come and look at these" and you send it round to your colleagues and they say they think it's a bit much and I'll say "well, have a look at these pictures six weeks down the line, this is what happens". *(Clinician17)*<br>I think we've stopped operating on these fractures. Compared to other orthopaedic surgeons I am very conservative in the sense that I think it remodels pretty well and we over treat many of them. We look for perfection, we don't let 'Mother Nature' do her job. My feeling is that once we have the outcomes most likely we will stop operating on them, especially for the very young so I would say less than eight (years old) for definite. *(Clinician11)* |
| | 4) Anticipating reluctance:<br>I know there are some of my colleagues that, no matter what you put in print, will not change their practice and that's the difficult bit: "I've always done it this way" or "I know it says that, but it's a bit (displaced/ angulated/ worse) beyond what they looked at". Just publishing the paper isn't going to be enough. If you find that nonoperative treatment is appropriate for all of them, or a sub-set or whatever it happens to be, you're going to have to do more than just publish the paper to get the message out and get people to change their practice. Because finding the evidence and changing the practice are two totally different things. *(Clincian17)* |
| Concerns about nonoperative treatment involves understanding: 1) colleague's concerns about nonoperative treatment; and 2) factors that influence surgeon's preference for surgery | 1) Colleague's concerns about nonoperative treatment:<br>Seeing a very bent forearm in a child, it is sometimes difficult to believe that remodelling will occur. I have concerns that children will end up with deformities or functional problems where the fractures are quite severe and they're a bit older. So, I worry about the kids who are between ten (years old) and say ten and 364 days and so for me that's the only clinical concern, about causing harm. *(Clinician9)*<br>I suppose my only residual concern is around the very grossly deformed off-ended fractures and what happens with the distal radio-ulna joint (DRUJ) as the patient gets older. If they have any residual problems with the DRUJ when they've reached skeletal maturity - which won't really be answered by the study for many, many years and it hasn't really been addressed in the literature yet. That's my only hesitancy. *(Clinician13)* |
| | 2) Factors that influence surgeon's preference for surgery:<br>It has to be agreed by the parents and the consultant. The consultants are the ones who are carrying the responsibility and the ones to make the final decision, which I totally understand. It's part of defensive medicine? *(Clinician18)*<br>When you look at the classic paper from Hawaii, about the nonoperative treatment of overriding distal radial fractures, in that age group they were very particular in reducing the angulation. Although (*the fractures*) were still off-ended, and short, they were still ensuring the angulation was correct and the bones were roughly in the same direction. *(Clinician15)* |

*I would certainly avoid K-wires more than I would have done previously so would potentially undertake a manipulation alone rather than pinning it. (Clinician13*)

Staff encouraged their colleagues to recruit to the study by showing them radiographs of children's wrists that had straightened without surgery. This helped to get more staff on-board, but also led to more patients being treated with non-surgical casting and consequently less patients meeting the eligibility criteria "may benefit from surgical treatment".

**Table VII.** Supporting families: barriers and facilitators to recruitment.

| **Barriers to recruitment** |
|---|
| Injury causes a challenging time for families who may experience anxiety and distress to see their child injured and face decisions about clinical trial participation. |
| Challenging to communicate the study and answer questions in a simple way. |
| Only one parent allowed in hospital with the child, owing to COVID-19 restrictions. |
| Families' prior experience of fractures and surgery may influence views of the treatments. |
| Beliefs about treatments and clinical trials. |
| Research hesitancy. |
| **Facilitators to recruitment** |
| Giving families time to discuss and reach a decision about participation together. |
| Exploring and alleviating parent concerns about treatment. |
| Tailoring information to the needs of the family. |
| Experienced clinicians discussing the study and treatments with confidence. |
| Exploring reasons for treatment preferences to ensure they are informed. |
| Reassuring parents both treatments are good and used within the NHS to alleviate concerns about testing the treatment. |
| Use of explainer videos to explain key concepts and treatments. |

Concerns about non-surgical casting: Staff understood why their colleagues might be reluctant to recruit to the study. Some shared their colleagues' concerns, particularly for off-ended fractures or older girls, as there is less time for their bones to remodel; girls growth plates generally closing before boys of a similar age. Leaving a child with a grossly deformed wrist was unacceptable, especially as surgery was considered "relatively simple, unobtrusive, with a good result, and able to fix the fracture straight away" (Clinician13). Some staff had concerns about the long-term impact of non-surgical casting, while others worried the study would not show which subset of children require surgery. Clinicians' preference for surgery was influenced by their clinical experience, their thoughts about which treatment that they would prefer for their own child, clinical guidelines, and previous studies in which the bones were aligned before being put in a cast.

*The general rule or idea is that you cannot leave a child like this (with an off-ended fracture) and you need to do something. It was reflecting on personal experience as a parent yourself or as a treating surgeon who has seen and treated many children over the years, and the idea or principles are that certain angles or certain degrees of deformity and beyond that there is no way we would accept that kind of deformity. (Clinician12*)

Some staff felt frustrated by their colleagues' lack of engagement with research as it could prevent learning which treatments are better.

**Theme 4: Supporting families**

Staff identified the importance of reassuring parents and alleviating their concerns about the trial and treatments, recognizing the importance of family centred approaches to recruitment and understanding parents' treatment preferences. (See Table VII for barriers and facilitators to recruitment and Table VIII for illustrative quotations).

Reassuring families: Staff recognized the decision was daunting for parents. They sought to reassure parents that their child would be cared for and that both treatments work. Staff demonstrated confidence in remodelling and explained the risk of surgery was low. They reassured families by showing parents images of wrists that have straightened without surgery and explaining they would include their own child in the trial. However, staff could feel constrained by the study, finding it difficult to answer questions in an honest, simple way without putting parents off participating. Staff felt frustrated or disappointed when, despite their efforts, parents declined to include their child.

*There have been parents, where I think I've done the best possible explanation I can possibly do and they just haven't gone with it. Then, I do feel very frustrated, and not cross with myself but very disappointed that I haven't managed to get it across to them and I still don't know why that is. (Clinician15*)

Adopting family-centred approaches: COVID-19 restrictions often prevented both parents from accompanying children in hospital. To facilitate family discussion, staff included the parent who was not present by telephone and gave families the opportunity to discuss the study at home. Tensions and different opinions within the family could hinder recruitment as they often resulted in families declining to take part or withdrawing after randomization.

*The vast majority of parents work out decisions together and so not having a parent there has been difficult. There are certain situations where dad is in the car park or mum is in the car park because they can't come in with the child where we've phoned and spoken. (Clinician9*)

Staff shared the study's "explainer videos" (carefully scripted animations explaining clinical trials and CRAFFT) with families, which helped explain key concepts, such as randomization, overcame language barriers, and give families the opportunity to watch the information again as required. Staff tailored the amount of information they provided depending

**Table VIII.** Supporting families: illustrative quotations.

| Theme 4: Supporting families | |
|---|---|
| **Category** | **Illustrative quotes** |
| Reassuring families involves: 1) providing parents reassurance that their child will be cared for; 2i) trying to communicate the study; and 3) using resources such as images and videos | 1) Providing parents reassurance that their child will be cared for:<br>I would like to be able to sell the faith I have in the trial. Some people are not assertive enough to say this works and no matter what the computer chooses, you will be fine. *(Clinician14)*<br>Both ways are very good ways of treating this injury, but all treatments carry risks. In case something happens in the future, we're always around to look into it and how can we make it better. So, we are not sending them away with nothing, we're sending them away with a plan and a message of reassurance and usually they're happy with this. *(Clincian12)* |
| | 2) Trying to communicate the study:<br>I still find it really difficult to recruit patients because everyone is different in the way people respond. The art is selling it to the patient so that you get them to go with what you want as the doctor, because you think that's what's best for the patient. I thought I was quite good at that, but because you're confined by the study and what you can say, it actually becomes more tricky than I thought. *(Clincian10)* |
| | 3) Using resources such as images and videos:<br>I find the actual website, the CRAFFT website is a fantastic resource for families and it does help them a lot in understanding the study. I think the video is a great thing. It explains things a lot more clearly than reading a sheet, especially when you're already stressed and feeling a bit exposed and vulnerable in hospital. Having a video there that's able to explain it a lot more clearly is such a benefit. *(RN1)* |
| Adopting a family centred approach involves: 1) facilitating opportunities for families to discuss the study together; 2) tailoring information to the needs of the family; 3) managing different opinions within families; and 4) involving children in the discussion where appropriate. | 1) Facilitating opportunities for families to discuss the study together:<br>At the moment (due to COVID-19) there's only one relative with the child. I think sometimes if there's a lot going on they might not want to take the decision by themselves. They don't know what decision to make and sometimes I find that they can be preoccupied with lots of things going on. *(RN19)* |
| | 2) Tailoring information to the needs of the family:<br>So, they (parents with more education) tend to ask a lot more questions and they repeat questions again and again, "which is best?, What would you do if it was your child?" are the common ones. "I want this because to me this seems better" but they don't have any knowledge or experience to understand the basic principles of fracture union and fracture remodelling. So, they can sometimes be slightly difficult consultations, but it's important really that you just spend a bit more time because sometimes people do need a bit more information. *(Clinician9)* |
| | 3) Managing different opinions within families:<br>I had a kid the other day, whose mother was keen on non-surgical, the father was *laissez faire* 'whichever way kind of thing'. They randomized and went to non-surgical. She then called the husband, they talked further, and the husband decided that he wanted surgery. So, we had to do a protocol deviation and so the kid's still in the study, but with all that time and effort and at the point of randomization you think there's equipoise and then obviously afterwards the parent changes their views. *(Clinician10)* |
| | 4) Involving children in the discussion where appropriate:<br>Yes, I always get the children involved, by explaining to them and showing them the videos. I find that sometimes the children convince their parents to go into the study and they say "I like this, I want to be involved with this study, I'm convinced with the videos". Yes, I'm always getting the children involved and even some of them like to counter sign the consent - there's a different form for children where they counter sign (assent form). *(Clincian18)* |
| Understanding parent preferences involves: 1) understanding how preferences are influenced; 2) exploring preferences to see if they can be overcome; and 3) acknowledging research hesitancy. | 1) Understanding how preferences are influenced:<br>Round here we've got two very different demographics - we've got the complete extreme. So, we've got one set who have read all the literature before they've turned up with their child to casualty and don't want an operation, and we've got the other end of the social deprivation index where it's "I don't know what to do, you tell me doc" – actually they're the ones (the lower socioeconomic deprivation participants) more likely to go into the trial, because we can say we don't know either and the trial will answer that question. *(Clincian17)*<br>My experience tends to be the slightly less educated parents see a bent arm and just know it needs fixing, it needs straightening out and they couldn't possibly have a child with a bent arm versus the better educated parents who might be willing to have a discussion with you about how bone remodelling works and what they could expect over the coming years. *(Clinician13)* |
| | 2) Exploring preferences to see if they can be overcome<br>I think what we tend to do here is to ask them why they've got that preference - a lot of the time it's because they're worried about the risks of surgery. So, we explain to them that we're a children's hospital and we operate on very, very sick children every day and your child is very fit and healthy and the risks are very, very low. So, I think just reassuring the parents that it's not really going to cause them anymore issues by being involved in the study. *(RN7)*<br>There was one particular patient that our PI spoke to concerning CRAFFT and actually I don't think it was too little information - I think she had too much information. It actually started swaying them the other way. They would prefer an operation for a fractured wrist, but he actually started swaying them away from this, asking why they actually need an operation if it's going to heal and there is evidence of that. *(RN5)* |
| | 3) Acknowledging research hesitancy:<br>I think it's that they're scared about the concept of a study or a trial and being like a guinea pig. There's a lot of stuff obviously with the (COVID-19) vaccinations and everything going around in the news…and false information out there on social media. I think that's possibly had an impact on peoples' decision making. *(Clinician15)* |

on the families' needs and included children in discussions where appropriate. Some families asked questions or did their own research, while others were comfortable to accept the study as clinicians endorsed it.

Understanding parent preferences: Parents' treatment preferences were challenging to overcome. Staff believed preferences were influenced by treatment recommendations from the ED, the families' prior experiences of fractures, existing health conditions, or family backgrounds, such as socio-economic status, geographical location, or cultural beliefs. Staff tried to overcome parent preferences by alleviating concerns or identifying misconceptions, such as the belief that surgery is a "quick fix". Exploring preferences gave staff confidence that parents understood both treatments and had given informed consent. However, it could lead parents to change their preference and did not always aid recruitment. Some staff described 'research hesitant' families, those that were unlikely to participate in any research due to concerns of being a 'guinea pig'.

*We always try and make sure that the patient, no matter what their decision is truly informed. I think when they have a very strong preference for a treatment arm you want to make sure that that's an informed decision, rather than doctor google has given them that information. (RN6)*

## Discussion

This study identified obstacles to recruitment that staff overcame through four themes: fitting in with clinical practice, working together, negotiating treatment decisions, and supporting families. Key challenges for staff were the difficulty of reassuring families about the study in the busy time-pressured ED, getting clinicians on-board with the study and overcoming territorial barriers, fitting the study in with local pathways, tension arising from disagreements about inclusion, concerns about non-surgical casting, and parent treatment preferences.

This study demonstrates the challenge of recruiting to a paediatric orthopaedic RCT in an ED where it is difficult to have the study as a top priority, keep everyone up-to-date, and fit with local practices. The high-pressured environment, requirement for rapid decisions, and concerns about including acute patients in research have contributed to the lack of research tradition within emergency care.[13] In trauma, strong visible research teams who are integrated and support clinical teams, engagement with multiple studies to build momentum, and clinicians recruiting to their colleagues' studies, as well as their own have helped to develop research cultures.[14] Further research to understand how to develop research cultures within an ED, and particularly paediatrics, is needed.

Prior to this study, displaced or angulated fractures of the distal radius were predominantly treated with surgery in the UK. While there is evidence to suggest that practice has changed during the study alongside participation in the CRAFFT study and during the COVID-19 pandemic, concerns about non-surgical casting persist. These concerns hindered recruitment and led to tension between teams when they disagreed which fractures to include in the trial. This was difficult for staff who felt hurt and frustrated that their colleagues believed they were not acting in their patients' best interests. Staff in this study adopted strategies to overcome disagreements and concerns about non-surgical casting. These included sharing radiographs of wrists that had healed without surgery with colleagues, MDTs to address concerns about the CRAFFT study and provide reassurance, early discussion to agree how the study will work in each site, and sharing responsibility for the study. These strategies demonstrate that resistance to change in practice can be overcome and may be valuable for future studies.

This study highlights the challenge of recruiting families to paediatric RCTs after injury. Treatment uncertainty is difficult for families who need reassurance that their child will be okay.[15] In this study, staff reported that when parents were recommended a treatment before hearing about the trial, this became their preference, reinforcing the need to get all staff involved in the study. Parent preferences were also shaped by family backgrounds, prior experience of fractures, beliefs about treatments, and research hesitancy where parents wanted standard treatment. Engaging with families from a broad range of backgrounds when designing trials may enable researchers to uncover unexpected beliefs. Understanding beliefs about treatments and reasons for research hesitancy may help improve trial information, ensure families make informed decisions, and may enable staff to overcome concerns.

### Strengths and limitations

This is the first study to explore staff experiences of a paediatric trauma trial. Our purposeful sample included surgeons, paediatricians specializing in emergency medicine, and RNs from 15 sites involved in the CRAFFT study. These sites were geographically distributed across the UK, allowing us to gain multiple perspectives into how the study works in different sites. Interviewees were actively involved in the study; interviewing staff who are not involved may provide additional insight.

In conclusion, obstacles were overcome by staff's enthusiasm for the research question forming the basis of this study, using strategies to promote team working and overcome territorial barriers, and reassuring clinicians and families about the treatments within the trial. Staff required time to overcome tensions regarding inclusion and to fit the study within the patient pathway. Organizational ways of supporting staff in their endeavours to enhance research cultures within an ED, and understanding the beliefs that underpin parent's treatment preferences, may facilitate recruitment to future studies.

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## Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

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