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Patient and parent perspectives on being invited to join a trial of night-time only versus full-time bracing for adolescent idiopathic scoliosis

a qualitative study

From University of Liverpool, Liverpool, UK

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Aims

The Bracing Adolescent Idiopathic Scoliosis (BASIS) study is a randomized controlled non-inferiority pragmatic trial of 'full-time bracing' (FTB) compared to 'night-time bracing' (NTB) for the treatment of adolescent idiopathic scoliosis (AIS). We anticipated that recruiting patients to BASIS would be challenging, as it is a paediatric trial comparing two markedly different bracing pathways. No previous studies have compared the experiences of AIS patients treated with FTB to those treated with NTB. This qualitative study was embedded in BASIS to explore families' perspectives of BASIS, to inform trial communication, and to identify strategies to support patients treated in a brace.

Methods

Semi-structured interviews were conducted with parents (n = 26) and young people (n = 21) who had been invited to participate in BASIS at ten of the 22 UK paediatric spine services in hospitals recruiting to BASIS. Audio-recorded interviews were transcribed and analyzed thematically.

Results

Families viewed their interactions with BASIS recruiters positively, but were often confused about core aspects of BASIS, such as the aims, expectations of bracing, and the process of randomization. Participants typically expressed a preference for NTB, but recruiters may have framed NTB more favourably. Patients and parents reported challenges wearing a brace, such as physical discomfort, feelings of self-consciousness, difficulty participating in physical activities, and strain on financial resources to support brace use. Patients in FTB reported more pronounced challenges. While families valued health professional support, they felt there was a lack of social, emotional, and school support, and relied on online resources, as well private counselling services to address this need.

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Conclusion

The findings informed the development of resources and strategies, including guidance for schools and the recommendations in this paper, to support patients to wear NTB and FTB as prescribed. The results indicated opportunities for recruiters to enhance trial communication in ways that could improve informed consent and recruitment to BASIS, and inform future trials of bracing.

Take home message

- This study has identified strategies that trial recruiters can use to enhance communication with families and support their understanding of trials.
- The study also provides resources and guidance that health professionals and schools can use to support patients who find it difficult to wear a brace as recommended.

Introduction

Adolescent idiopathic scoliosis (AIS) is characterized by a lateral curvature of the spine with associated vertebral rotation.[1] It affects 2% to 3% of children and young people aged under 16 years, most commonly females.[2] Scoliosis can cause significant spinal deformity, with the magnitude of the deformity often becoming worse as the child grows, particularly during puberty. The condition can affect the young person's appearance and psychological wellbeing,[3] and lead to reduced health-related quality of life and capacity to work in middle age.[4,5] There is strong evidence to support the use of a plastic brace worn around the torso, to reduce the risk of the curve progression among patients during growth. A rigid brace worn full-time (FTB) has the most robust evidence,[6] which works by holding the spine to prevent the curve worsening. While the benefit of bracing in reducing the progression of deformity is established, young people who undergo bracing face psychosocial challenges and difficulties with body image, which affect brace compliance and effect.[7]

A brace worn only at night (NTB) is an alternative to FTB. The NTB works in a slightly different way to a FTB, by pushing the curve further in the opposite direction, and it is only worn at night while the young person is lying down. As the brace is not worn during the day, NTB could significantly minimize the negative impact of bracing on quality of life and psychological outcomes. This may also mean that children and young people are more compliant with NTB; a recent study found that the NTB was worn for an average of 90% of the prescribed time,[8] while FTBs were worn for an average of 46% of the prescribed time (19% to 90%).[9] However, evidence for the effectiveness of NTB is of low quality. The Bracing Adolescent Idiopathic Scoliosis (BASIS) study is arandomized controlled non-inferiority pragmatic trial exploring whether NTB is similarly effective to FTB in preventing curve progression, with benefits in terms of minimizing negative impacts on daily life.[10]

There were several anticipated challenges for BASIS. Recruiting participants to randomized controlled trials (RCTs) is frequently challenging,[11] particularly in children and young people.[12-14] Consequently, recruitment delays can incur increased costs, compromise statistical power, and delay treatments becoming available.[15] Patients, parents, and health professionals often have strong treatment preferences, which can further impede recruitment.[16,17] Qualitative studies have been embedded in RCTs to identify and address recruitment challenges.[18,19] Such studies explore how recruiters communicate about RCTs, before providing tailored feedback to support them in enhancing RCT communication and recruitment.

We describe a qualitative study that was embedded in the pilot phase of BASIS. The aims were to explore patients' and parents' views and experiences of recruitment, and establish their perspectives on the two treatments. The objectives were to enhance BASIS communication and recruitment, assist interpretation of BASIS quantitative findings, and inform ways to support patients in wearing braces as prescribed.

Methods

The qualitative study was embedded within BASIS during the internal pilot phase of recruitment. Qualitative research methods provide rich descriptions of complex phenomena and illuminate participants' experiences and interpretation of events.[20] Semi-structured interviews were conducted with young people and parents. These interviews are conversational, with an emphasis on open-ended questions. Typically, questions central to the study aims are asked of all participants,[21] with further probing tailored to each participant. The aim is to enable exploration of previously unanticipated topics and generate data that are more in-depth compared to structured interviews or surveys.[22]

Patient contributors with experience of AIS and some of their parents provided input into the study design and conduct, including proposing changes to patient-facing materials and suggesting ways to apply the findings in real-world contexts. A research ethics committee (North of Scotland - Research Ethics Committee 1) approved the study (21/NS/0038). The findings informed a recruiter hints and tips document, orthotist results summary, a webinar to which all stakeholders were invited, and advice for schools.

Setting and procedure

BASIS is registered with International Standard Randomized Controlled Trial Number (ISRCTN) as ISRCTN63247077. The trial opened in November 2021 and, at the time of writing, recruitment is ongoing in 22 NHS paediatric spine services at hospitals in the UK. The qualitative study was conducted at all BASIS hospital sites that were open from March 2022 to March 2023. All young people who were eligible for BASIS were also eligible for the qualitative study. Health professionals (typically orthopaedic surgeons) requested informed consent from parents for their contact details to be shared with the qualitative researcher (FCS). FCS contacted families to invite them to participate in an interview approximately three to nine months into bracing (or sooner for those who declined BASIS). We monitored sampling characteristics to ensure the sample was inclusive in terms of participant age, sex, hospital, ethnicity, and socioeconomic status, and aimed to include families who both declined or participated in BASIS.

Interviews

A qualitative researcher with a background in health research (FCS) conducted and audio-recorded semi-structured, topic-guided interviews (see Supplementary Material) with participants, after obtaining informed consent from parents and assent/consent from young people. We developed interview topic guides for both young people and parents/caregivers, which we refined throughout the study in response to findings from the ongoing analysis. Table I summarizes the topics explored. Interviews were by telephone or video call, depending on the family's preference.

Table I. Summary of topics explored during the patient and parent interviews.

Topics
Symptoms, diagnosis, and treatment(s)
Initial thoughts about BASIS
Experience of being approached about BASIS
Views on how BASIS and bracing was explained
Perceptions of recruiter's views on BASIS and bracing preferences
Resonant messages about BASIS
Views and understanding of randomization
Reasons for consent or decline
Perceptions and experiences of full-time and night-time bracing
Hopes or worries about the future

Analysis

Audio-recorded interviews were transcribed and pseudonymized. Data collection continued until achieving an adequate sample size, as informed by the concept of 'information power', which involved ongoing consideration of the data collected to decide when they were sufficient to address the study questions.[23] Data analysis was interpretative, aiming to go beyond simply describing what participants said and consider how and why participants narrated their experiences as they did. We predominantly worked inductively, grounding the analysis in the data rather than using predefined categories, although we also referred to the research aims when analyzing data.[24]

In terms of procedures, the analysis drew flexibly on both thematic[25] and constant comparison[26] approaches to identify and interpret patterns in the qualitative data.[27] FCS listened to audio-recordings of interviews to familiarize with the data, and then read and re-read transcripts, with BY also reading a sub-set of transcripts and meeting periodically to develop the coding framework, and thereby enhance the rigour of the analysis.[28] FCS further elaborated the coding framework, which involved developing, combining, naming, and renaming categories and themes. Throughout the analysis, FS compared new categories to previous categories in an iterative process to refine the analysis. QSR Nvivo 12 (USA) was used to organize the data and facilitate the analysis. Quotes are illustrative of FCS's interpretation of the findings and are referenced in-text, but shown in Tables II–IV.

Results

Table V summarizes family characteristics. Data were collected from 24 families, including 21 young people and 26 parents across ten UK hospitals. One interview could not be transcribed due to the parent having a strong accent; FCS also had difficulties understanding the participant during the interview. FCS and BY agreed to create notes from the parts of the interview that FCS could understand, to integrate data into the analysis. Excluding this interview (Family 12), interviews lasted from 32 to 97 minutes (median 60 minutes).

Young people's ages ranged from ten to 15 years. In line with the normal pattern of scoliosis, and eligibility criteria for BASIS, most young people were female (n = 20/24; 83%). Most parents described their child's ethnicity as 'English/Welsh/Scottish/Northern Irish/British' (n = 20/24; 83%), with the remaining families describing their ethnicity as 'Arab', 'African', 'any other white background', and 'prefer not to say'. We used the 2019 English Index of Multiple Deprivation (IMD) deciles as a measure of socioeconomic status:[29] five families lived in the most deprived areas of England (IMD deciles 1 to 3), five lived in areas of average deprivation (IMD deciles 4 to 7), and 13 lived in the least deprived areas (IMD deciles 8 to 10). IMD deciles are not available for one family who had a Welsh postcode. Most families chose to participate in BASIS (n = 21/24; 88%) and of those, most were randomized to FTB (n = 13/21; 62%). At interview, the median time in brace for those treated was four months.

Qualitative results

Views and understanding of BASIS

Participants largely described positive experiences of being approached about BASIS. They described recruiters as approachable (Q1) and child-centred (Q2). Participants were aware that BASIS was voluntary (Q3), felt comfortable asking questions, and were given adequate time to decide whether to participate (Q4). While most families tended to understand that they would be offered FTB outside of BASIS if they decided not to participate, roughly one-third of families thought that the alternative to BASIS would be either monitoring (Q5), a different type of FTB (Q6), or said they were unsure (Q7). See Table II for linked illustrative quotes.

Aims of BASIS and bracing

Parents tended to describe the aim of BASIS as comparing whether NTB is as effective as FTB. Young people also described this aim, but some conflated trial aims with bracing aims (Q8). However, some families misinterpreted the trial design. At least two parents suggested that BASIS was a "trial of NTB" with all patients allocated to NTB (Q9). Families had different expectations of what the brace was designed to do. Some thought that the brace was designed to maintain the curve and avoid it from worsening (Q10), while others described with uncertainty how the brace might correct the curve (Q11).

Randomization

Almost all families understood that BASIS braces would be allocated at random (Q12). Families were largely accepting of this, as it meant there was a chance of randomization to NTB,

Table II. Illustrative quotes focused on views and understanding of BASIS.

Quote no.	Views and understanding of BASIS
1	*“[Recruiter] was really friendly, approachable, [recruiter] directed all [their] questions mainly to [Child] actually and really good eye contact towards her rather than to me.”* (Parent 02, Consent, Full-time).
2	*“He was interested in our opinions. I like the way he talked to [Child]. He didn’t just talk to me; he asked [Child]’s opinion and was talking her through things. It’s her condition, isn’t it, it’s her body.”* (Parent 21, Consent, Full-time).
3	*“I couldn’t see any downsides to it. It’s not like I was being forced to do it or I was locked into keeping doing it.”* (Child 08, Consent, Night-time)
4	*“I’ve never felt rushed or anything they’ve always given loads of time and to ask questions and no matter how many questions we’ve had they’re always really good.”* (Parent 20, Consent, Full-time)
5	Interviewer: *“Did they say what the sort of option would be if you weren't to take part in the BASIS study and what you might get outside of the BASIS study?”*
	Child 07: *“They just said that I just wouldn't wear a brace -laughs- really; they would just monitor and then see if my curve did get worse.”* (Consent, Full-time)
6	Interviewer: *“If you decided not to take part in the BASIS study, did they talk about what treatment might entail outside of the, the trial?”*
	Child 05: *“Well, that would have still been a brace… I think it would be 6 to 8 hours without your brace off… I wear the brace more than I would have but I think it’s slightly different the actual brace.”* (Consent, Full-time)
7	Parent 18: *“I think so, yeah, yeah. What if I don’t go in the study? What will I [be] offered… I suppose is maybe… I don’t remember seeing that specifically.”*
	Child 18: *“No, I don’t remember seeing that specifically.”* (Consent, Full-time)
	Aims of BASIS and bracing
8	*“I think [recruiter] just said to try and help people like with scoliosis and stuff to prevent curves from getting worse and stuff.”* (Child 06, Consent, Night-time)
9	*“They gave me the choice of the night-time one (offered BASIS), but I said ‘oh actually [I] like the full-time one cos there’s more like research… The aim (of BASIS) was that they’re trying to do this trial on the night thing to see if that does work.”* (Parent 24, Decline, Full-time)
10	*“It stops the curve from developing and then I won’t need surgery on my back in the future.”* (Child 04, Consent, Full-time)
11	*“I don’t think it’s very clear about the results and what is does actually do other than maybe prevents I guess the, there’s some results that show it can correct a curve that you do have results with correction of a curve… That’s maybe vague in both cases.”* (Parent 17, Consent, Night-time)
	Randomization
12	*“We could do the trial, which would be a choice between the night-time and the full time, but we don't know which one we we’re gonna get.”* (Child 03, Consent, Full-time)
13	*“[Child] might as well go for it and see if we could get the night brace which was [child’s] thing you know, but [Child] was fully aware that there was a 50/50 chance.”* (Parent 02, Consent, Full-time)
14	*“I didn’t get [randomization], they were very much like it is not our decision but we take into account, they wrote on the notes that we wanted the night-time brace in the hope it might sway it a little bit, I don’t know.”* (Parent 14, Consent, Night-time)
15	*“Basically, [recruiter] put it in (the computer) … did [recruiter] have to tick something? And [recruiter] said it would generate any, everyone’s brace … Someone said, that whatever one I ask for they got, it just seemed to be a bit weird…”* (Parent 09, Consent, Full-time)
	Managing family treatment preferences
16	*“[Recruiter] said… well there’s an opportunity to wear the night-time one… it’s a… shorter time period of wearing it and it would… be like beneficial to her in the long run.”* (Parent 01, Consent, Night-time)
17	*“[Child] was really upset about the back brace and [recruiter] said ‘what if I told you that you might, you might, not have to wear it through the day; there is a chance that you could wear one through the night.’ So she was like you know, ‘tell me a bit more’ .”* (Parent 06, Consent, Night-time)
18	Interviewer: *“So what sort of times of the day you think, if you had the full time one, what times of the day do you think would have worn it, [Child]?”*
	Child 14: *“Probably wouldn’t have really.”*
	Parent 14: *“Or maybe the same as what we’re doing with the night-time brace essentially.”* (Consent, Night-time)
19	*“[Child] preferred [night-time bracing] … He was worried about school, bullying and people talking about it and how the bulge from his clothes and … then worried about the [physical] restrictions.”* (Parent 08, Consent, Night-time)
20	*“They kind of just said that the day time one was more well-known on and it had a lot more research on… they did tell me that they don't have much research on the night-time one and then after [randomization] they did say that the day time one has got more record of working.”* (Child 07, Consent, Full-time)

(*Continued*)

(*Continued*)

Quote no.	Views and understanding of BASIS
21	*"Expectations were set… but when the disappointment [of being randomized to full-time brace] occurred, the reassurance was that we know where we are with [full-time bracing], so we know it's got positive results… they span it that way then."* (Parent 02, Consent, Full-time).
	Views on BASIS follow-up
22	*"A lot of [the questionnaire items] were to do with like mental health. So talking about how she was day to day. [Child] thought some… questions were a bit strange because it didn't have anything to do with spine… a lot about mental health."* (Parent 13, Consent, Night-time)
23	*"It surprised me when [the questionnaire] talks about mental health and things like that. It was a nice, a pleasant surprise. It wasn't like: 'Hm, they shouldn't be asking that'. It was nice that it was thought about."* (Parent 21, Consent, Full-time)
24	*"I was surprised that it would be like… will be under four years? But… because obviously you know I didn't know how long it were going to be for or whatever else or when an operation could be thought about."* (Parent 01, Consent, Night-time)

Quote identifiers include family member (parent or child), family number (e.g. 01), BASIS participation status (consent or decline), and bracing (full-time, night-time, or none).

which was not available outside of BASIS (Q13). At least three families indicated that they thought allocation was informed by their personal needs or preferences (Q14), while some believed that the information they inputted into the computer immediately prior to randomization (i.e. BASIS study questionnaire), or discussions with recruiters about their preferences, may have influenced which arm they were allocated to (Q15).

Managing families' treatment preferences

The prospect of bracing was worrying for both parents and young people. Families indicated that, pre-randomization, recruiters framed NTB as an exciting opportunity to avoid FTB (Q16), and this appealed to families with young people who were worried about wearing a brace during the day (Q17). Roughly three-quarters of families said they would have preferred to have been randomized to NTB. Three young people and three parents from four families randomized to NTB indicated that they would have refused FTB if they had been randomized to it, or they would have worn it at night only (Q18). None of the families randomized to NTB queried whether they could change to FTB, whereas one family who was randomized to FTB wondered whether they could change to NTB.

Parents and young people preferred NTB because they felt that FTB would limit physical activity. They also felt that wearing a brace would make them feel more self-conscious and attract negative attention from friends or peers, which could lead to bullying (Q19). Those who preferred FTB did so because they viewed it as an effective and well-established treatment (Q20). They also anticipated sleep difficulties with NTB and that it could be more uncomfortable than FTB, due to the perception that NTB was "stiffer", "more rigid", or "over-compensated".

Families who said they would have preferred NTB but were randomized to FTB were largely accepting of this. They said that, following randomization, recruiters emphasized that a FTB was effective and sometimes indicated it was superior, perhaps because most families expressed a preference for NTB pre-randomization (Q21).

Views on BASIS follow-up

Largely, families were happy to be followed up as part of BASIS. Some commented that questionnaires were too frequent and broached subjects they did not anticipate (e.g. mental health) (Q22, Q23), although they typically viewed the questionnaires as straightforward, and young people liked the idea of being entered into a prize draw for completing study questionnaires. Families were unclear about how long they would be followed up as part of BASIS (Q24).

Expectations and experiences of bracing

How braces look and feel

Almost all young people who went on to have a brace were surprised to see what their brace ultimately looked like. They emphasized how important it was to see a brace in advance of receiving it, to manage expectations and help to allay their worries about bracing. They suggested that ideally, this would entail seeing both NTB and FTB, and especially seeing a brace that is similar in shape to one that they might have to wear (Q25, Q26). See Table III for linked illustrative quotes.

Day-to-day life wearing a brace

Families explained that an orthopaedic surgeon would usually present information on bracing pros and cons and current evidence, and orthotists would provide families with information about day-to-day life wearing a brace when they were being fitted. Despite this information from orthotists, parents and young people felt that their expectations of what life would be like with a brace did not always match up to the reality. In particular, they would have liked to have known more about daily life challenges of wearing a brace prior to bracing (Q27, Q28).

Irrespective of FTB or NTB, almost all families reported challenges wearing the brace. Nearly all found that bracing caused discomfort. Although the severity of discomfort varied, it was often described in terms such as "rubbing", "itching", or "pain". Three parents referred to NTB as an "over-correction brace", suggesting that it was holding the curve more firmly.

While hardly any patients in FTB commented on the difficulties they had endured sleeping in the brace, almost all patients randomized to NTB described sleeping in NTB as

Table III. Illustrative quotes focused on ‘expectations and experiences of bracing’.

Quote no.	Expectations and experiences of bracing	
How braces look and feel		
25	*“If they let us more into like what it would actually look like, it wouldn't be such a shock when you have to wear it just there and then… And seeing like the shaping, seeing how it would affect everything… I didn't realise they're, the brace is a full body cast of my torso, like I didn't expect that at all, I expected one that had a lot of gaps in it because they were the only ones that I had seen.”* (Child 07, Consent, Full-time)	
26	*“If I do get a brace, like a full-time brace, and I don’t get [a night-time brace], I think that I’d like to know before, actually know what mine would look like or similar to, because [recruiter] did show us a brace but it was for like a three year old, so it was a bit different to the one that I would obviously get, so I’d like to maybe see one that like.”* (Child 23, Decline, N/A)	
Day-to-day life wearing a brace		
27	Interviewer:	*“And is there anything at all that you think that you would’ve liked to have known about the study at the beginning that you know now as well? …”*
	Child 09:	*“What it’s like to wear it.”*
	Parent 09:	*“Just what it’s like to wear it I suppose, ‘cos you’re not really told that. You’re not told you’re restricted sort of thing… You’re not going to realise that you’re going to have trouble going to the toilet or… like bending your knees that way you can’t still look to see if you’re picking something up.”* (Consent, Full-time)
28	*“Maybe it would just be nice to know, to be able to expect a bit more, because I know like as soon as you get [the brace] you understand, you’re like, ok I’m going to be limited in my mobility and I’m going to need to just think about these things before I go into PE, or you know just like sit down and can’t stand up- … that kind of, it’s very difficult to [sit down and stand up] myself, and then it gets all awful and sweaty and disgusting.”* (Child 18, Consent, Full-time)	
29	*“I’ve been wearing it regularly. It’s like sometimes I don’t feel like wearing it but I need to because sometimes I’m just too tired and want to have a good sleep.”* (Child 08, Consent, Night-time)	
30	*“In the book it says ‘Oh yeah, within a week you should be wearing it all night and be sleeping’, it’s like, no. Still not. Still not doing that… [Child] felt quite bad about it. She was like ‘I’m letting everybody down’. So I mean [Child’s] still not able to wear it all night.”* (Parent 14, Consent, NTB)	
31	*“Like some things like that I used to wear are a bit too tight with my brace so… I’ve got like a couple of new outfits that like go over my brace.”* (Child 05, Consent, Full-time)	
32	*“I think we got given one [seamless vest] … and I bought two more, they were quite expensive… 20 or 30 quid to get them but like sometimes they don’t come through the washing quick enough and [child] wears a t-shirt… so I don’t know if that’s left a mark on you?”* (Parent 19, Consent, Night-time)	
Anticipated outcomes of wearing a brace		
33	*“[By having the brace] hopefully [child will] not need the operation. The next radiograph without the brace on, if it’s a lower degree then you know it’s working or you know it’s doing something.”* (Parent 01, Consent, Night-time)	
34	*“I would kind of just want to see a bit of a change in the way my body looks because my scoliosis is slightly noticeable to the eye, if you know what you're looking for.”* (Child 07, Consent, Full-time)	

Quote identifiers include family member (parent or child), family number (e.g. 01), BASIS participation status (consent or decline), and bracing (full-time, night-time, or none).

particularly challenging (Q29). When they experienced these challenges, young people were disappointed that they had not been able to wear the brace as advised. The parent of a child who had been using the brace for over two months explained how their child still found it difficult to wear NTB as instructed (Q30). Although some challenges were frequent and persistent, others were occasional events or circumstances that made wearing the brace difficult for short time periods. Challenges experienced by both groups included short-term illness (e.g. bracing exacerbating chest infection symptoms, such as cough), exam periods (i.e. discomfort sitting for several hours), and hot weather (i.e. feeling very sweaty and uncomfortable wearing the brace in heat).

Families also spoke about the financial burden of bracing, as they had to purchase new clothes, seamless vests to go under the brace, pillows, and expensive moisturizers to treat areas on the body where the brace rubbed. This was pertinent for all families, but the impact was more pronounced for those randomized to FTB, especially girls, because the brace restricted their choice of clothing. Young people described how their clothes no longer fitted well with the brace underneath, or that they could no longer wear tight-fitting clothes that they were used to, as the brace was visible when wearing them. These families had the additional expense of purchasing new clothes to fit with the brace (Q31, Q32).

Anticipated outcomes of wearing a brace

Parents and young people most frequently described avoiding surgery and no curve progression on radiographs as outcomes that showed the brace had worked (Q33). Participants also said that they would look for a visible reduction in the curve, reduced back pain, better posture, and being able to pursue careers that they might not otherwise be able to if they have surgery (Q34).

Table IV. Illustrative quotes focused on support needs for young people wearing a brace and their parents.

Quote no.	Support needs for young people wearing a brace and their parents
35	*"[Orthotist] said that I need to tell him if there's like anything wrong and then he knows where to like help me out and stuff and see where the issues are and get it sorted out."* (Child 06, Consent, Night-time)
Social and emotional support	
36	*"There's been no offer of, sort of access to any sort of mental health support in terms of people understanding, like support groups or anything. I've had a word with the school nurse locally as well, there's nothing in our area. You think, being somewhere like [hospital site], a Children's hospital, that you'd get that kind of support available. And like resources and opportunities for her to meet other people in her position, and there isn't."* (Parent 21, Consent, Full-time)
37	*"I did some research on Facebook and found a support group for people with scoliosis and I actually asked the question in the group whether anybody else was taking part in [BASIS], and we connected with another family and they're like, sort of 'how far in front of you was she?' 'About a month.' So she was braced about a month before [child]. So they sort of, formed a friendship, you know, they Whatsapp each other, and [child] was waiting to get a brace fitted, or the first few nights that she were wearing and she text this girl and said, 'this is happening', and then she could say, 'oh yeah, that happened to me', so she had a bit of support from somebody else, that were going through it and me, the same as well with mum. Like saying, 'oh my God, this is horrendous', somebody else that were going through the same."* (Parent 13, Consent, Night-time)
38	*"The doctor said it was to be under your clothes, but [P13 Child] said [FTB] will make her fat."* (Parent 13, Consent, Night-time)
39	Interviewer: *"What support is available to help with any issues that children and young people might experience with bracing?"*
	Parent: *"I've put [child] in private therapy because she's got a lot going on bless her, so there was no chance I would have got any help on the NHS with the timescales and everything, I felt it needed to be done now so I done it myself… It will be nice for her to talk to other kids with scoliosis but there isn't really, well not that I've come across apart from Facebook, there isn't really any groups or anything that I've come across that she could join… I don't know anybody else with scoliosis."* (Parent 07, Consent, Full-time)
40	*"[Having a brace has] probably exacerbated her mental health a little bit, but [child has experienced mental health issues] prior to getting the brace… she actually has counselling… I'm hoping it's going to help, in the whole balance of it all to be honest. It's not just to do with her back… but obviously, the back creates another issue."* (Parent 21, Consent, Full-time)
School support	
41	*"They get a medical pass… so she can leave when she needs if she gets uncomfortable, if it itches or she's just not in a good place or you know need to walk round, she can use her medical pass to excuse herself from any situation."* (Parent 02, Consent, Full-time)
42	*"She's had one incident where a teacher touched her back saying 'What is this?', well I thought that was disgusting, because they've all had the information from me as a parent, I've provided all the information."* (Parent 20, Consent, Full-time)

Quote identifiers include family member (parent or child), family number (e.g. 01), BASIS participation status (consent or decline), and bracing (full-time, night-time, or none).

Support needs for young people wearing a brace and their parents

All families spoke about the adaptions the child had made and the strategies the family had adopted to support their child in wearing the brace as advised. For young people, this involved strategies such as going for short walks to adjust it, completing tasks using different positions, using moisturizer on sore patches, and adjusting sleeping positions. For parents, this involved empathizing with their child, incentivizing brace use with rewards, and bargaining. All families were aware and confident that if they encountered difficulties in wearing the brace as advised, they could contact health professionals at the hospital where the brace was issued (Q35). See Table IV for linked illustrative quotes.

Social and emotional support

Parents and older young people wanted more social, emotional, and practical support to learn new strategies to help with wearing the brace, and to know that others are going through a similar experience (Q36). They sought such support via online social media platforms, such as TikTok or Facebook (Q37). Parents spoke about the negative impact of scoliosis and bracing on their child's mental health, particularly how scoliosis and bracing can exacerbate issues that many teenage girls may already experience with body image (Q38). Two parents of young people with FTB reported that bracing had exacerbated their child's pre-existing mental health difficulties. Both had paid for private counselling for their children, noting that emotional support for patients with scoliosis was otherwise limited (Q39, Q40).

School support

Families' experiences of support from schools varied widely. Excellent support included school staff meeting with families before and after bracing to discuss individual needs, use of a medical pass to allow young people to discreetly leave class to adjust their brace when needed, allowing young people to wear more comfortable clothing, and staff support if a student needed help to remove and replace the brace (Q41). While some families described school support as excellent, others noted that their school had not always been supportive. For example, parents mentioned that while they informed schools that their child was wearing a brace, schools did not always pass this information on to staff. This often led to poor handling of the young person's needs, or situations that drew attention to their brace (Q42).

Table V. Participant characteristics.

Family no.	Family member interviewed	Child's age, yrs	Child's sex	Hospital site	BASIS participation status	Brace allocated/used (if applicable)	Months in brace (if applicable)	Interview mode
1	Father	10	Female	1	Participant	Night-time	4	Telephone
2	Mother, Father, Child	11	Female	1	Participant	Full-time	3	Telephone
3	Father, Child	11	Female	1	Participant	Full-time	3	Telephone
4	Mother, Child	12	Female	1	Participant	Full-time	3	Telephone
5	Mother, Father, Child	12	Female	2	Participant	Full-time	2	Telephone
6	Mother, Child	13	Female	1	Participant	Night-time	3	Telephone
7	Mother, Child	14	Female	3	Participant	Full-time	2	Telephone
8	Mother, Child	12	Male	4	Participant	Night-time	5	Telephone
9	Mother, Child	15	Female	5	Participant	Full-time	4	Telephone
10	Mother, Child	13	Male	1	Participant	Night-time	5	Telephone
11	Mother, Child	13	Female	6	Participant	Full-time	2	Telephone
12	Mother	12	Female	7	Participant	Full-time	6	Telephone
13	Mother, Child	11	Female	1	Participant	Night-time	6	Telephone
14	Mother, Child	14	Female	5	Participant	Night-time	2	Telephone
15	Mother, Child	11	Female	2	Participant	Full-time	3	Telephone
16	Mother, Child	15	Male	1	Participant	Full-time	5	Telephone
17	Mother, Child	14	Female	8	Participant	Night-time	4	Video call
18	Mother, Child	13	Female	9	Participant	Full-time	4	Telephone
19	Mother, Child	13	Male	2	Participant	Night-time	8	Telephone
20	Mother, Child	11	Female	6	Participant	Full-time	9	Telephone and video call
21	Mother	13	Female	1	Participant	Full-time	5	Telephone
22	Mother, Father, Child	12	Female	10	Declined	Full-time	4	Video call
23	Mother, Child	12	Female	1	Declined	N/A	N/A	Video call
24	Mother, Child	14	Male	1	Declined	Full-time	11	Telephone

N/A, not applicable.

Discussion

This qualitative study was the first to explore young people and their parents' views and experiences of FTB compared with NTB. Patients with NTB experienced a less profound impact of bracing on their lives compared to those with FTB, but they were more likely to describe sleep difficulties, and indicated feeling unprepared for the upheaval of bracing or disappointed when they were unable to wear the NTB as prescribed. Although more prominent among families with FTB, both groups described the need for better social and emotional support. Overall, young people and parents reported that bracing had a profound impact on their lives.

Few studies have explored patients' and parents' experiences of bracing and no such research has been conducted in the UK. In line with previous studies conducted elsewhere,[30–34] we found that FTB was perceived and experienced as limiting physical activity. It also led young people to feel self-conscious and fear negative attention from peers/friends, and exacerbated pre-existing mental health difficulties. The findings have informed spinal bracing advice for schools produced by the British Scoliosis Society[35] and Scoliosis Support and Research.[36] Recommendations in Table VI are informed by the findings, offering health professionals pointers to support patients to wear their FTB or NTB brace as prescribed.

This was also the first qualitative study to examine families' experiences of communication in a paediatric orthopaedic trial, and the findings indicate possible opportunities for recruiters to enhance how such trials are communicated. We provided hospital sites with written feedback and hosted a webinar based on the findings, highlighting families' experiences of communication about BASIS and identifying strategies to enhance informed consent and recruitment.

Table VI. Considerations to support patients in wearing their full-time or night-time brace.

1. Families are keen to know what braces look and feel like before deciding whether to use a brace. Showing a sample brace (or photos if not possible) that looks similar to the one they might be prescribed, or explaining that their brace might look different as designs vary by the individual patient's curve, could allay misconceptions and help patients begin to process what having a brace might be like.
2. Avoid presenting night-time bracing as an easier option than full-time bracing. Some young people may experience difficulties wearing a night-time brace and with expectations that a night-time brace is an "easy" option, this can leave young people feeling disappointed that they have not been able to wear the brace as prescribed despite their best efforts.
3. Some families would like advance information about what day-to-day life with a brace might be like, so briefly mentioning this prior to fitting could help to manage expectations (e.g. brace might itch or rub but if sore, help is available to adapt brace; braces can make some activities difficult like picking something up from the floor, but often young people will start to do things in a different way). Some families might like a health professional to call them a few days into bracing to check in with them and, if needed, offer support or advice.
4. Many parents/carers will need to purchase new clothes, vests, pillows etc. to support their child in wearing a brace especially among those with a full-time brace. This can create financial hardship and may create a barrier to bracing. Where possible, providing additional support and resources to such families (e.g. providing additional vests) may facilitate adherence to bracing.
5. Providing families with information on the scope of support that is available from health services and charities/local support, offering a point of contact, and arranging to adjust the brace in a timely manner will avoid long periods of time out of the brace and help to maintain patient motivation.
6. Patients and parents frequently feel that they could benefit from additional social, emotional, and practical support to learn new strategies to help with wearing the brace and to know others are going through a similar experience. Where possible, signpost families to additional resources or networks, ideally local, that are available to support families.
7. Families' experiences of school support varies widely. Signposting families to online resources designed for schools[35,36] may help avoid the difficulties some young people experienced at school and support them to wear the brace as advised during school hours.

While families' understanding of BASIS is not simply a product of how it is explained, their suboptimal or incomplete comprehension of core trial concepts point to possible opportunities for recruiters to enhance trial communication and improve consent and recruitment. These include providing information that is more balanced and consistent with clinical equipoise (i.e. uncertainty regarding the relative merits of trial interventions)[37,38] and clearer descriptions of randomization.[39,40] Families' interpretations of BASIS as a single-arm trial of NTB, and recall of NTB framing as an exciting opportunity to avoid FTB, indicate that recruiters may have lacked equipoise in consultations.

Difficulties in conveying equipoise are typically linked to recruiters' beliefs that one treatment arm is superior to another.[37] Families' comments indicated that recruiters empathized with the predicament of young people, knowing that FTB is often unpopular with patients,[31] and wanted to offer a more acceptable alternative to FTB. Additionally, in the current study, recruiters may have framed NTB favourably as a strategy to increase BASIS recruitment. Our suggestion that the favourable framing of NTB was a strategy to increase BASIS recruitment is further supported by families' reports of receiving information from recruiters to balance their preference for NTB after randomization, as opposed to before. Gently exploring families' anxieties about treatment following randomization may help to allay their concerns, although exploring and balancing treatment preferences before allocation could help to prevent such difficulties[41] and optimize informed consent.[42,43]

It is widely established that randomization is a challenging concept for recruiters to communicate and for families to understand.[44,45] Referring to treatment allocation by a computer can lead to patient and parent misunderstandings, whereby they believe that they will receive a treatment designed for them.[46] This study demonstrated that further misunderstandings might be introduced by the timing of randomization in relation to when patients and parents complete electronic questionnaires. In BASIS, some families who were asked to input data into a study e-questionnaire immediately before randomization believed that the information they inputted may have informed treatment allocation. Patients may prefer descriptions of randomization that reference a computer,[39] but in future trials, care should be taken to avoid randomizing immediately following electronic data collection, and/or clarify that the data inputted does not inform trial arm allocation.

Strengths and weaknesses

Qualitative studies are characterized by smaller sample sizes to support the in-depth case-oriented analysis that is crucial to this mode of investigation.[47] Research partners with lived experience of scoliosis were involved in the design and conduct of the study, which is a key strength, improving the study for participants and bringing a patient perspective to the outputs produced. The study sample was diverse in terms of age, sex, ethnicity, hospital site, and bracing allocation (i.e. NTB/FTB). However, we only interviewed three families who declined BASIS, reflecting the high recruitment rate for BASIS (90% at the time of writing). Although we monitored socioeconomic status, most interviewed families lived in the least socioeconomically disadvantaged areas. This pattern aligns with well-documented challenges of recruiting those experiencing socioeconomic disadvantage to clinical trials,[48] but further highlights the need to develop strategies to improve inclusion of such groups.[49]

Our study focused on UK-based families and research is needed in other countries to explore the wider transferability of our findings. This is the first study we know of that has explored experiences of NTB with FTB, and since previous research which focused on FTB in other countries aligns with our results, we anticipate that, overall, our findings will be widely transferable.

In conclusion, we found that bracing can have a significant adverse impact on young people's and parents' lives, although young people with NTB experienced a less profound impact compared to those with FTB. More social, emotional, and practical support is required for these young people and their families. The findings informed resources to support the wearing of FTB and NTB, including the recommendations presented in this paper. By exploring the views and experiences of families approached about BASIS, we were also able to identify strategies to enhance trial communication and recruitment. The findings also informed written feedback and a webinar to support recruiters to enhance how they communicate with families about BASIS, particularly in ensuring discussions are more balanced regarding how NTB and FTB are presented. Overall, the findings have wider implications for improving informed consent and recruitment in future paediatric trials.

Supplementary material

BASIS study topic guide for parents/guardians.

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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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