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Does digital, multimedia information increase recruitment and retention in a children's wrist fracture treatment trial, and what do people think of it? A randomised controlled Study Within A Trial (SWAT)

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ABSTRACT

Objectives To evaluate digital, multimedia information (MMI) for its effects on trial recruitment, retention, decisions about participation and acceptability by patients, compared with printed information.

Design Study Within A Trial using random cluster allocation within the Forearm Fracture Recovery in Children Evaluation (FORCE) study.

Setting Emergency departments in 23 UK hospitals.

Participants 1409 children aged 4–16 years attending with a torus (buckle) fracture, and their parents/guardian. Children's mean age was 9.2 years, 41.0% were female, 77.4% were ethnically White and 90.0% spoke English as a first language.

Interventions Participants and their parents/guardian received trial information either via multimedia, including animated videos, talking head videos and text (revised for readability and age appropriateness when needed) on tablet computer (MMI group; n=681), or printed participant information sheet (PIS group; n=728).

Outcome measures Primary outcome was recruitment rate to FORCE. Secondary outcomes were Decision-Making Questionnaire (nine Likert items, analysed summatively and individually), three 'free text' questions (deriving subjective evaluations) and trial retention.

Results MMI produced a small, not statistically significant increase in recruitment: 475 (69.8%) participants were recruited from the MMI group; 484 (66.5%) from the PIS group (OR=1.35; 95% CI 0.76 to 2.40, p=0.31). A total of 324 (23.0%) questionnaires were returned and analysed. There was no difference in total Decision-Making Questionnaire scores: adjusted mean difference 0.05 (95% CI −1.23 to 1.32, p=0.94). The MMI group was more likely to report the information 'very easy' to understand (89; 57.8% vs 67; 39.4%; Z=2.60, p=0.01) and identify information that was explained well (96; 62.3% vs 71; 41.8%). Almost all FORCE recruits were retained at the 6 weeks' timepoint and there was no difference in retention rate between the information groups: MMI (473; 99.6%); PIS (481; 99.4%).

Conclusions MMI did not increase recruitment or retention in the FORCE trial, but participants rated multimedia as easier to understand and were more likely to evaluate it positively.

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STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The Study Within A Trial design allowed different patient information formats to be evaluated with random allocation.
⇒ The multimedia information was developed following extensive qualitative, user testing and readability work, to ensure it was age appropriate and easy to use.
⇒ Rates of recruitment were high in both groups, reducing room for improvement.
⇒ Questionnaires were returned by 25% participants, mostly from Forearm Fracture Recovery in Children Evaluation (FORCE) trial consenters and few from FORCE non-consenters, which limits the generalisability of some of the findings.

BACKGROUND

Randomised controlled trials (RCTs) are the best method to test the effectiveness of interventions in healthcare. However, about half of trials do not recruit to time and target, which can cause increased costs, delays and underpowered, inconclusive trials.[1 2] People being approached about trial participation must be provided with information to allow them to make an informed decision. Often the information is combination of spoken information from a clinician or researcher and printed trial information. The written information

should provide a thorough and understandable account of what the research entails. There has been recurrent criticism of printed trial information for being too long and unengaging, hard to navigate and too technical.[3 4] However, a recent 'review of reviews' showed that participant information can potentially facilitate recruitment.[5]

When children or adolescents are being recruited to trials they should have an opportunity to understand what the research entails and, depending on their age and maturity, take part in the decision about participation.[6] However, they may find it more difficult than adults to understand research terms and concepts, the implications of taking part[7–10] and particularly the procedures and risks.[11]

Decisions on trial participation may follow discussion among the child and their family, in which case the problems caused by unclear or difficult information may be magnified. A recent systematic review highlighted the importance of direct provision of research information to children and adolescents, rather than via their parent(s), with a focus on how 'appealing and understandable' the information is.[12] Crucially, however, the participant information should not have a marketing or promotional function, nor prioritise entertainment at the expense of information.

The exploration of non-print media for potential research participants has been recommended by the UK Health Research Authority.[13] One possible approach is multimedia information (MMI), whether offline or as a website, involving the use of video, animations, audio and infographics. MMI may increase engagement, potentially through enhanced choice of information delivery and flexibility, and the presentation of non-linear content. It has been shown to result in higher levels of comprehension of medical information compared with paper-based provision.[14–17] Multimedia can help to inform and recruit research participants[10 18] although notably these studies included only adults. People's increasing familiarity with accessing information digitally means that multimedia has great potential for the delivery of mandated health communication.[19 20] However, not everyone prefers digital or online information and good access to the internet is not universal, which may compound income-related health inequalities.[21] In addition, it is clear that children and adolescents with health conditions have concerns about digital health technologies, such as trustworthiness and privacy.[22]

The Trials Engagement in Children and Adolescents (TRECA) study evaluated the effectiveness of multimedia resources compared with traditional printed information for trial recruitment involving children and adolescents.[23 24] The evaluation was undertaken through six linked Studies Within A Trial (SWATs) to compare the effects of the two information formats on patient recruitment and retention, decision-making and information acceptability.[25 26] We report the SWAT embedded within the Forearm Fracture Recovery in Children Evaluation (FORCE) trial.[27 28]

METHOD

Study design

The SWAT used a two-arm, parallel-group, cluster RCT design.[29] Clusters were UK hospital recruitment sites. Cluster allocation was used because individual allocation would have required recruiting research nurses in emergency departments to randomise patients twice (ie, first for TRECA and then for FORCE), which would have been time consuming and potentially a disincentive to recruitment.

According to cluster, participants received either a printed participant information sheet (PIS) or viewed an MMI resource. The 23 hospital sites were allocated at the University of York, using a random number generator,[30] and allocations were sent to sites by email via the Clinical Trial Unit running the FORCE trial.

The host trial (FORCE) was a National Institute for Health Research Health Technology Assessment-funded, multicentred RCT seeking to improve the treatment of children with a minor wrist injury, called a torus (or buckle) fracture. The aim of the FORCE trial was to evaluate the clinical effectiveness and cost-effectiveness of soft bandage immobilisation and immediate discharge compared with splint immobilisation in children with torus fracture.

Study participants

All children (aged 4–16 years) identified as potentially eligible for FORCE were eligible for TRECA. There were no additional eligibility criteria.

Intervention

Participants received either a printed PIS or digital MMI.

The PIS was the standard written PIS used in the FORCE trial, comprising information for parents and age-appropriate information for children (including a picture booklet), which had been developed with patient and public involvement (PPI) representatives. Three versions of the PIS were used: for young children, older children and adults.

Development of the MMI

The MMI was developed by the TRECA team at the University of York and a website and video creation company (Morph). A summary can be viewed here[31]: https://www.york.ac.uk/healthsciences/research/health-policy/research/force-summary/. Two versions of the MMI were developed: one for children aged 6–11 years, and another for adolescents and parents. The MMI contained all information content of the written PIS, with text amended to improve readability and age appropriateness when required. The TRECA MMI was developed through extensive qualitative research and user testing, where principles of participatory design were used to develop their style and format[32–34] and informed by information design and principles of plain English,[35] readability and age appropriateness. The TRECA PPI Group commented

on the design and content of the MMI during their development.[36]

The MMI included five short video animations, each lasting 45–60 s (one specific to FORCE: 'Summary of the key aspects of the FORCE trial'; and four that were trial generic: 'Why do we do trials?'; 'What are trials?'; 'Who's in a trial team?'; 'Assent and consent').

They also included 12 short 'talking head' video clips, featuring four individuals (five with a study investigator; three with a research nurse; one with an adolescent; and three with parents of children who had taken part in similar studies), each lasting 15–50 s and describing different aspects of the trial and clinical procedures. The FORCE video clips were created on 1 day of filming, with a focus on ensuring that the information was provided without jargon or complicated terms. Often several 'takes' of a video clip were made; the videos were edited afterwards. Neither the animations nor the video clips used subtitles.

The FORCE MMI took 6–8 weeks to create, including the review of text content, script development and subsequent animation for the FORCE explainer, and creation and editing of video clips.

The MMI content was organised on six main web pages with the following headings: 'Home page (including summary animation)'; 'About the trial'; 'Taking part'; 'After the trial'; 'Questions'; 'Contacts'.

The multimedia resources were viewed on tablet computer at the hospital.

Procedure

Children attending the hospital emergency department and meeting the FORCE inclusion criteria were invited to take part. They were given the printed PIS or tablet computer, according to cluster allocation. After reading or viewing the information, they decided whether to take part in the FORCE trial; those who agreed to participate were then randomly allocated to the offer of a bandage or rigid immobilisation. They also received, according to allocation, either a copy of the printed PIS or a card with the URL for the MMI, which they could access at home via personal computer, tablet or smartphone. All patients and their families approached for participation in FORCE, regardless of their decision to take part, were given a printed Decision-Making Questionnaire (DMQ) (and Freepost envelope) for completion. Demographic information was collected from participants (age; gender; ethnicity; English as first language; and home address for national deprivation decile indexing on which 1 is the most deprived decile).

Outcome measures

The primary outcome of the SWAT was the proportion of eligible patients who agreed to participate in FORCE from the total approached. The secondary outcomes were retention in the trial; quality of participation decision-making, assessed through the nine-item decision-making Likert scale (DMQ); and information evaluation and acceptability assessed through three 'free text' questions.

Each item of the DMQ was scored 0–4, deriving a total possible score range of 0–36. A higher DMQ score indicates better quality of decision-making. The DMQ comprised items evaluating aspects of trial participation decision-making indicated as important in the underpinning empirical work,[23 24 34 36] including items on: information content; the experience of participation; participation advantages and disadvantages; the process of decision-making; uncertainty in trials; and decisional confidence. The three 'free text' questions asked respondents to: suggest any further information they would have wanted; identify aspects explained well; and make any other comments.

Masking

The recruitment centres or participants could not be masked to allocation due to the nature of the intervention. Participants were not aware that they were being randomised within the TRECA SWAT, as approved by the National Health Service (NHS) Research Ethics Committee, and they were not aware that participants in other hospitals were being given a different format of information.

Sample size, statistical and 'Free text' analyses

No sample size was calculated for individual SWATs in TRECA; the overall sample size for TRECA was based on a prospective meta-analysis of the six SWATs (10% relative increase in recruitment; 80% power, alpha 0.05; overall n=1816). A 10% relative increase was selected as a meaningful increase that could potentially influence decision-making by Trials Units.

All analyses were conducted in STATA V.16[37] following the principles of intention to treat with participant outcomes analysed according to their original, randomised group. All participant baseline data were summarised descriptively by TRECA trial group.

For the primary analysis, recruitment rates were compared using multilevel mixed-effects logistic regression, with recruitment status as the dependent variable and TRECA allocation included as an independent variable in the model. Recruitment centre was included as a random effect. The results from the regression are presented as an OR, with associated 95% CI and p value. FORCE recruitment status is also broken down by participant baseline characteristics. The same approach was adopted for the secondary outcome, retention, with FORCE trial allocation and age also included as independent variables.

For the DMQ secondary outcome the responses to each question (including the amount of missing responses) and the calculated total scores of the DMQ scale were summarised descriptively overall, and by TRECA group and broken down by participant baseline characteristics. When two adjacent scores for a questionnaire item were given by an individual, the lower score was taken. Up to

three missing values were allowed, with the total score calculated by replacing the missing values with the mean score from the completed responses.

Total DMQ scale scores were analysed using a multilevel mixed-effects linear regression model, including total score as the dependent variable, TRECA allocation and FORCE consent status as independent variables and recruitment centre as a random effect. Due to consent status being missing for some questionnaires this analysis was repeated ad hoc without the inclusion of FORCE consent status as a covariate. A multilevel mixed-effects linear regression was also conducted only on those who went on to be randomised into FORCE, with total score as the dependent variable, TRECA allocation as an independent variable and site as a random effect. To assess the robustness of the method used to replace the missing values, sensitivity analysis was conducted, where the analysis was repeated using only the questionnaires in which all nine questions were answered. Adjusted mean differences (AMDs) from the analyses are presented with 95% CIs and p values. An ad hoc analysis was conducted, comparing scores between TRECA groups on each individual question of the DMQ scale using Wilcoxon-Mann-Whitney tests. Medians, IQRs, z-statistics and p values are presented. Caution should be taken when interpreting these results due to the additional risk of type I error in relation to multiple testing.

Patient involvement

PPI informed the overall research questions within TRECA particularly during the grant-writing stage. The TRECA study also established and maintained an active and engaged Patient and Parent Advisory Group who gave input throughout the study. The Patient and Parent Advisory Group reviewed all design and content of the MMI, including the animations and written content.

RESULTS

A total of 23 recruitment centres (NHS Trusts) were randomised within TRECA. Initially, the FORCE trial opened in January 2019 at six recruitment centres only (using PIS information) without the TRECA SWAT in order to check its processes. The TRECA SWAT then commenced in February 2019.

A total of 1409 participants met the FORCE eligibility criteria at the 23 recruitment centres during February 2019 to July 2020. Baseline characteristics of the 1409 patients who were approached for participation are summarised in table 1. The mean age of participants randomised in TRECA was 9.2 years (SD 2.9). Participants were more likely to be male (59.1%) and a high proportion were ethnically White (77.4%). The majority of participants spoke English as their first language (90.0%). PIS recruitment centres had lower percentages of ethnically White

Table 1 Participant baseline characteristics

	PIS (n=728)	MMI (n=681)	Overall (n=1409)
Age			
n (missing)	728 (0)	681 (0)	1409 (0)
Mean (SD)	9.3 (2.8)	9.2 (3.0)	9.2 (2.9)
Gender, n (%)			
Male	431 (59.2)	401 (58.9)	832 (59.1)
Female	297 (40.8)	280 (41.1)	577 (41.0)
Ethnicity, n (%)			
Asian/Asian British	112 (15.4)	45 (6.6)	157 (11.1)
Black/African/Caribbean/Black British	30 (4.1)	28 (4.1)	58 (4.1)
White	517 (71.0)	574 (84.3)	1091 (77.4)
Mixed/multiple ethnic groups	22 (3.0)	14 (2.1)	36 (2.6)
Other ethnic group	24 (3.3)	11 (1.6)	35 (2.5)
Not stated	23 (3.2)	9 (1.3)	32 (2.3)
English as first language, n (%)			
Yes	640 (87.9)	628 (92.2)	1268 (90.0)
No	65 (8.9)	39 (5.7)	104 (7.4)
Information not available	23 (3.2)	14 (2.1)	37 (2.6)
IMD decile for home address			
n (missing)	728 (0)	680 (1)	1408 (1)
Mean decile score (SD)	4.7 (3.1)	4.4 (3.0)	4.6 (3.0)

MMI, multimedia information; PIS, participant information sheet.

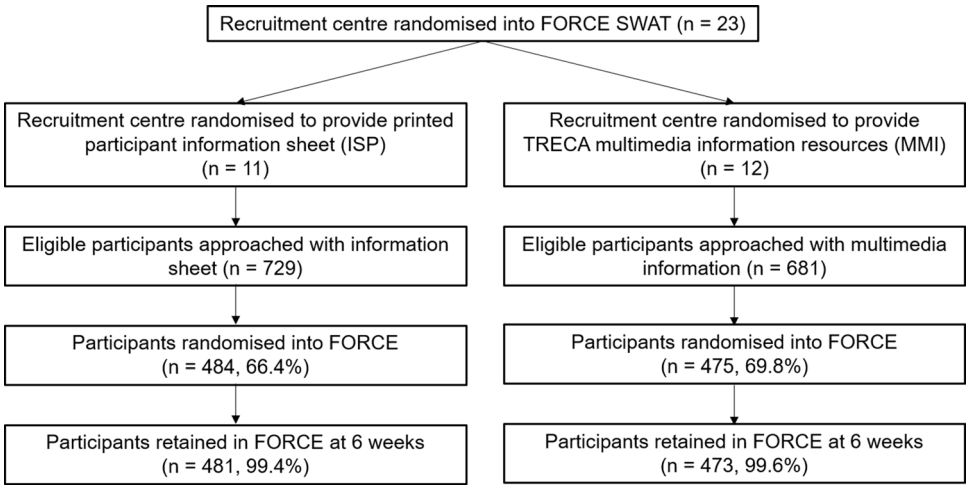

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow chart of participants through the Forearm Fracture Recovery in Children Evaluation (FORCE) Study Within A Trial (SWAT). ISP, participant information sheet; MMI, multimedia information; TRECA, Trials Engagement in Children and Adolescents.

eligible patients (71.0% compared with 84.3% at MMI recruitment centres) and higher proportions of some ethnic minorities. Participants at PIS recruitment centres also had higher (less deprived) Index of Multiple Deprivation (IMD)decile scores (4.7 (SD 3.1) compared with 4.4 (3.0) at MMI centres). The flow of TRECA participants through the FORCE SWAT is shown in figure 1.

Primary analysis

Recruitment

Of the 1409 participants approached to enter FORCE across the 23 recruitment centres during the period of the SWAT, 959 (68.1%) participants provided consent to enter the FORCE trial (MMI n=475 (69.8%); PIS n=484 (66.5%)). FORCE recruitment status is presented alongside participant baseline characteristics in table 2. The mixed-effects logistic regression gave an OR of 1.35 (95% CI 0.76 to 2.40, p=0.31), meaning there was no statistically significant effect of information type on recruitment.

Secondary analyses

Decision-Making Questionnaires

A total of 324 (23.0%) questionnaires were returned and analysed (MMI: n=154; PIS: n=170). Most of the questionnaires (91.3%; 296/324) were returned by those who had consented to take part in FORCE. Among FORCE consenters the DMQ return rate was 30.9% (296/959), whereas among non-consenters it was 6.2% (28/450). The mean age of participants returning questionnaires was 9.3 years (SD 2.8). Of the 324 questionnaires received, 14 (4.3%) contained DMQ scales with free text comments but all nine Likert questions blank (n=12 PIS; n=2 MMI). Table 3 summarises the responses to each question on the DMQ scale; the 14 completely blank scales have been included in the missing counts.

The overall DMQ total mean score was 31.3 (SD 4.7), with means of 31.3 (SD 4.5) in the MMI group and 31.2 (SD 4.9) in the PIS group. A bar chart summarising the total scores for each TRECA group is given in figure 2. Table 4 presents the total scores corresponding to participant baseline characteristics. The AMD from the analysis on all the scored scales was 0.05 (95% CI −1.23 to 1.32, p=0.94). From the additional analysis removing consent status as a covariate the AMD was 0.07 (95% CI −1.08 to 1.22, p=0.91). The AMD from the analysis on only the participants consented to FORCE was −0.10 (95% CI −1.30 to 1.11, p=0.88). All the results from the regression analyses and associated sensitivity analyses are given in table 5.

Table 6 summarises the results from the Wilcoxon-Mann-Whitney tests on individual DMQ questions. Participants in the MMI group were more likely to rate the information as 'very easy' or 'easy to understand' (Z=2.60, p=0.01). The information was rated as 'very easy' by 89 (57.8%) participants in the MMI group and 71 (39.4%) participants in the PIS group. There were no other statistically significant differences.

DMQ 'free text' comments

All participants' responses are available in online supplemental appendix 1.

There were 32 responses to question 10 ('any additional information they would have wanted'): 22/154 (14.3%) in the MMI group and 10/170 (5.9%) in the PIS group, although seven of the responses (PIS n=1; MMI n=6) related to the FORCE trial itself rather than the trial information. Responses about the information were highly varied and included: possible disadvantages of taking part (four respondents); questionnaire follow-up timing and frequency (two respondents); washing the bandage (two respondents); current standard practice for this fracture; as well as more general evaluations ('no, it was all explained really well').

Question 11 ('identify aspects of information that were explained well') was answered by 167 participants (96/154 (62.3%) in the MMI group and 71/170 (41.8%) in the PIS group). However, four participants used Q11

Table 2 Participant baseline characteristics of those recruited into FORCE

	PIS		MMI	
	Recruited	Not recruited	Recruited	Not recruited
	n=484 (66%)	n=244 (34%)	n=475 (70%)	n=206 (30%)
Age				
n (missing)	484 (0)	244 (0)	475 (0)	206 (0)
Mean (SD)	9.3 (2.8)	9.3 (2.8)	9.0 (3.0)	9.6 (3.0)
Gender, n (%)				
Male	302 (62.4)	129 (52.9)	280 (59.0)	121 (58.7)
Female	182 (37.6)	115 (47.1)	195 (41.1)	85 (41.3)
Ethnicity, n (%)				
Asian/Asian British	66 (13.6)	46 (18.9)	31 (6.5)	14 (6.8)
Black/African/Caribbean/Black British	28 (5.8)	2 (0.8)	20 (4.2)	8 (3.9)
White	361 (74.6)	156 (63.9)	408 (85.9)	166 (80.6)
Mixed/multiple ethnic groups	10 (2.1)	12 (4.9)	9 (1.9)	5 (2.4)
Other ethnic group	15 (3.1)	9 (3.7)	6 (1.3)	5 (2.4)
Not stated	4 (0.8)	19 (7.8)	1 (0.2)	8 (3.9)
English as first language, n (%)				
Yes	439 (90.7)	201 (82.4)	452 (95.2)	176 (85.4)
No	43 (8.9)	22 (9.0)	23 (4.8)	16 (7.8)
Information not available	2 (0.4)	21 (8.6)	0 (0.0)	14 (6.8)
IMD decile for home address				
n (missing)	484 (0)	244 (0)	474 (1)	206 (0)
Mean decile score (SD)	4.9 (3.1)	4.5 (3.1)	4.6 (3.0)	4.1 (2.9)

FORCE, Forearm Fracture Recovery in Children Evaluation; MMI, multimedia information; PIS, participant information sheet.

to fault rather than praise the information (PIS n=1; MMI n=3).

Approximately 1 in 8 (12.4%) of those answering question 11 stated that 'all' or 'everything' was explained well (18 in the PIS group and 19 in the MMI group). Of the remaining respondents, Q11 comments fell into eight categories: 'the FORCE trial'; relationship with clinical staff; treatment preference; randomisation/opt out; advantages and disadvantages; future benefits of the FORCE trial; and the rationale for the FORCE trial. Comments from some participants fell into more than one category.

For question 12 ('do you have any other comments?') there were responses from 17/158 (10.8%) participants in the PIS group and 27/152 (17.8%) participants in the MMI group. Comments varied but in a number of cases, the response was used to explain their decision whether or not to take part in the FORCE trial. There were two notable post hoc findings. First, 13 (4.0%) 'free text' respondents mentioned the age appropriateness or age suitability of the trial information. Among those allocated to the MMI there were 10 comments, all of them positive. In those allocated to the PIS there were three comments on age suitability (one negative and two positive).

Second, among participants allocated to the MMI information, 13 mentioned the use of video in the 'free text' comments. Video animations and talking head videos were a key element of the MMI. Eight evaluations were positive: for example, 'helpful video'; 'I liked… video showing what RCTs are'; 'the video was… clear about the different types of treatment'; and 'involving kids in watching the videos makes them feel more involved'. However, two comments were negative: 'the videos didn't have subtitles and it was hard to hear in the hospital' and 'the videos were harder to access due to slow wi-fi and no service at (the hospital)'. A further two comments were mixed or neutral: 'video was a good visual tool, but very minimalistic and not a great deal of detail or content' and 'the video could include what paperwork and questionnaire will need to be undertaken'.

Retention

Of the 959 participants who were randomised into FORCE, 954 (99.5%) reached the 6 weeks' timepoint (MMI: n=473 (99.6%); PIS: n=481 (99.4%)). The logistic regression gave an OR of 1.14 (95% CI 0.11 to 12.32, p=0.91).

DISCUSSION

Approximately two-thirds of eligible patients were recruited to the FORCE trial during the SWAT. The rate

Table 3 Questionnaire item responses

		Very hard	Hard	OK	Easy	Very easy	Missing
1. The information I saw about the FORCE trial was easy to understand.	PIS, n (%)	0 (0.0)	0 (0.0)	14 (8.2)	76 (44.7)	67 (39.4)	13 (7.7)
	MMI, n (%)	1 (0.7)	0 (0.0)	11 (7.1)	50 (32.5)	89 (57.8)	3 (2.0)
	Overall, n (%)	1 (0.3)	0 (0.0)	25 (7.7)	126 (38.9)	156 (48.2)	16 (4.9)
		Not at all	**Not really**	**Not sure**	**Yes, mostly**	**Yes, completely**	**Missing**
2. The information helped me understand what it would be like for my son or daughter to take part in the FORCE study.	PIS, n (%)	0 (0.0)	1 (0.6)	3 (1.8)	54 (31.8)	99 (58.2)	13 (7.7)
	MMI, n (%)	0 (0.0)	2 (1.3)	3 (2.0)	44 (28.6)	103 (66.9)	2 (1.3)
	Overall, n (%)	0 (0.0)	3 (0.9)	6 (1.9)	98 (30.3)	202 (62.4)	15 (4.6)
3. The information helped me understand how my son or daughter's treatment or care might change if he/she took part in the FORCE study.	PIS, n (%)	1 (0.6)	5 (2.9)	6 (3.5)	51 (30.0)	94 (55.3)	13 (7.7)
	MMI, n (%)	0 (0.0)	3 (2.0)	4 (2.6)	48 (31.2)	97 (63.0)	2 (1.3)
	Overall, n (%)	1 (0.3)	8 (2.5)	10 (3.1)	99 (30.6)	191 (59.0)	15 (4.6)
4. The possible benefits of taking part in the FORCE trial were made clear in the information.	PIS, n (%)	0 (0.0)	4 (2.4)	9 (5.3)	47 (27.7)	97 (57.1)	13 (7.7)
	MMI, n (%)	0 (0.0)	4 (2.6)	14 (9.1)	41 (26.6)	92 (59.7)	3 (2.0)
	Overall, n (%)	0 (0.0)	8 (2.5)	23 (7.1)	88 (27.2)	189 (58.3)	16 (4.9)
5. The possible disadvantages of taking part in the FORCE trial were made clear in the information.	PIS, n (%)	1 (0.6)	14 (8.2)	30 (17.7)	34 (20.0)	78 (45.9)	13 (7.7)
	MMI, n (%)	5 (3.3)	7 (4.6)	40 (26.0)	37 (24.0)	62 (40.3)	3 (2.0)
	Overall, n (%)	6 (1.9)	21 (6.5)	70 (21.6)	71 (21.9)	140 (43.2)	16 (4.9)
6. The information about the FORCE trial helped me discuss the trial with the person who asked my son or daughter to take part (usually a doctor, nurse or researcher).	PIS, n (%)	0 (0.0)	3 (1.8)	5 (2.9)	59 (34.7)	90 (52.9)	13 (7.7)
	MMI, n (%)	1 (0.7)	1 (0.7)	5 (3.3)	53 (34.4)	91 (59.1)	3 (2.0)
	Overall, n (%)	1 (0.3)	4 (1.2)	10 (3.1)	112 (34.6)	181 (55.9)	16 (4.9)
7. The information about the FORCE study helped me discuss taking part with my son or daughter.	PIS, n (%)	0 (0.0)	3 (1.8)	4 (2.4)	53 (31.2)	97 (57.1)	13 (7.7)
	MMI, n (%)	0 (0.0)	2 (1.3)	7 (4.6)	49 (31.8)	93 (60.4)	3 (2.0)
	Overall, n (%)	0 (0.0)	5 (1.5)	11 (3.4)	102 (31.5)	190 (58.6)	16 (4.9)
8. I am confident that I have made the right decision about whether or not my son or daughter should take part in the FORCE study.	PIS, n (%)	1 (0.6)	4 (2.4)	2 (1.2)	41 (24.1)	109 (64.1)	13 (7.7)
	MMI, n (%)	0 (0.0)	0 (0.0)	11 (7.1)	37 (24.0)	103 (66.9)	3 (2.0)
	Overall, n (%)	1 (0.3)	4 (1.2)	13 (4.0)	78 (24.1)	212 (65.4)	16 (4.9)
9. In all, the information about the FORCE trial helped me make my decision about whether or not my son or daughter should take part.	PIS, n (%)	1 (0.6)	4 (2.4)	3 (1.8)	53 (31.2)	96 (56.5)	13 (7.7)
	MMI, n (%)	1 (0.7)	1 (0.7)	7 (4.6)	52 (33.8)	88 (57.1)	5 (3.3)
	Overall, n (%)	2 (0.6)	5 (1.5)	10 (3.1)	105 (32.4)	184 (56.8)	18 (5.6)

FORCE, Forearm Fracture Recovery in Children Evaluation; MMI, multimedia information; PIS, participant information sheet.

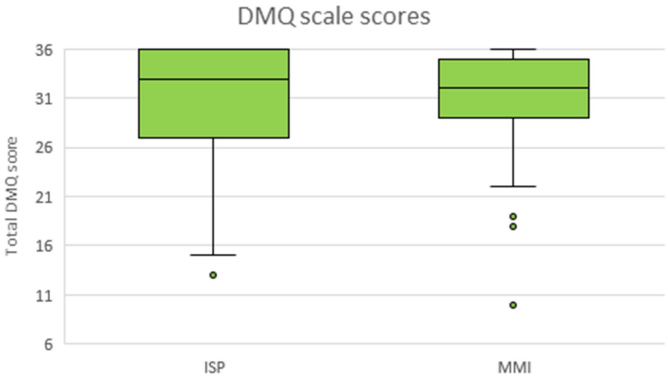

Figure 2 Bar chart summarising scores in Trials Engagement in Children and Adolescents (TRECA) Study Within A Trial (SWAT) arms. DMQ, Decision-Making Questionnaire; ISP, participant information sheet; MMI, multimedia information .

of recruitment was slightly higher in the MMI group, although the difference was not statistically significant. DMQs were returned by almost a quarter of those randomised in TRECA, limiting their representativeness. There was no difference in total DMQ score between groups. Individual item analysis showed that the MMI was more often rated as 'very easy' or 'easy' to understand. In the 'free text' comments more respondents in the MMI group stated that there was additional information they wanted to receive. However, respondents in the MMI group were more likely to identify aspects of the information that were explained well. Small numbers of respondents commented on the age suitability of the information content and delivery, with more positive comments in the MMI group. Trial retention rates were very high in both groups.

This large SWAT used random allocation to assess the impact of information format on trial recruitment and

Table 4 Participant baseline characteristics and corresponding DMQ total scores

	PIS (n=170)		MMI (n=154)		Overall (n=324)	
	n/N*	DMQ score, mean (SD)	n/N*	DMQ score, mean (SD)	n/N*	DMQ score, mean (SD)
Age						
4–7	28/30	31.0 (3.7)	47/47	31.1 (4.5)	75/77	31.1 (4.2)
8–11	86/95	31.3 (4.9)	63/65	31.7 (3.9)	149/160	31.4 (4.5)
12–15	39/40	31.3 (5.9)	26/27	30.4 (6.3)	65/67	30.9 (6.0)
Missing	4/5	33.0 (4.7)	15/15	32.0 (3.8)	19/20	32.2 (3.9)
Gender						
Male	100/105	30.7 (5.3)	73/76	30.7 (5.0)	173/181	30.7 (5.2)
Female	52/59	32.3 (4.1)	60/60	32.0 (3.9)	112/119	32.1 (4.0)
Missing	5/6	32.8 (4.1)	18/18	31.6 (4.0)	23/24	31.8 (4.0)
Ethnicity						
Asian/Asian British	13/15	27.8 (6.0)	8/8	31.5 (3.4)	21/23	29.2 (5.4)
Black/African/Caribbean/Black British	6/6	29.3 (7.7)	1/2	22.0 (–)	7/8	28.3 (7.6)
White	125/135	31.7 (4.5)	120/122	31.3 (4.7)	245/257	31.5 (4.6)
Mixed/multiple ethnic groups	4/4	33.5 (3.8)	1/1	28.0 (–)	5/5	32.4 (4.1)
Other ethnic group	4/4	25.8 (3.1)	3/3	32.3 (2.3)	7/7	28.6 (4.4)
Missing	5/6	32.8 (4.1)	18/18	31.6 (4.0)	23/24	31.8 (4.0)
English as first language						
Yes	138/150	31.4 (4.9)	130/132	31.4 (4.5)	268/282	31.4 (4.7)
No	12/12	28.5 (4.9)	3/4	26.7 (7.5)	15/16	28.1 (5.2)
Missing	7/8	32.4 (4.3)	18/18	31.6 (4.0)	25/26	31.8 (4.0)
Deprivation index for home address						
1–3	45/47	30.2 (5.5)	58/60	31.8 (3.9)	103/107	31.1 (4.7)
4–7	55/61	31.9 (4.2)	37/38	29.9 (5.4)	92/99	31.1 (4.8)
8–10	52/56	31.3 (5.2)	38/38	31.8 (4.6)	90/94	31.5 (4.9)
Missing	5/6	32.8 (4.1)	18/18	31.6 (4.0)	23/24	31.8 (4.0)

*n=number of scores used to calculate mean/SD; N=total number of participants in category.
DMQ, Decision-Making Questionnaire; MMI, multimedia information; PIS, participant information sheet.

Table 5 Decision-Making Questionnaire scale analyses

Analysis (independent variables)	Including imputed values	n	AMD	95% CI	P value
All screened (TRECA allocation, consent status)	Yes	285	0.05	−1.23 to 1.32	0.94
	No	280	0.09	−1.10 to 1.28	0.88
All screened (TRECA allocation)	Yes	308	0.07	−1.08 to 1.22	0.91
	No	302	0.12	−0.95 to 1.19	0.83
All consented to FORCE (TRECA allocation)	Yes	259	−0.10	−1.30 to 1.11	0.88
	No	255	−0.07	−1.25 to 1.11	0.91

AMD, adjusted mean difference; FORCE, Forearm Fracture Recovery in Children Evaluation; TRECA, Trials Engagement in Children and Adolescents.

decision-making. The use of cluster randomisation was pragmatic, and the even distribution of demographic variables across the groups, which can be a concern with cluster randomisation, was generally well achieved. Given the cluster trial design, clinical staff were not masked to allocation, nor was there concealment of allocation. However, there is unlikely to be any substantive effect of either factor: recruiters' main interest at all sites was to recruit eligible, willing patients to the FORCE trial. Furthermore, recruiters played no role in completing questionnaires. Participants were unaware of the information SWAT, so their masking was maintained. While the SWAT design has reduced the potential for bias, it may also be a disadvantage: if participants had been able to view both formats of information, possibly more critical, comparative evaluations may have been returned, although this would have prevented evaluation of recruitment rates.

The SWAT was large and multicentre but questionnaires were returned by only 25% participants, most of whom had consented to take part in FORCE. Furthermore, the low rates of 'free text' comments on some topics have resulted in uncertainty about the extent to which participants' views have been captured fully. Requesting postal questionnaire return rather than completion at the hospital was intended to remove one source of stress from the study, although it may have reduced return rates. Questionnaire completion via email was thought difficult to implement.

Table 6 Exploratory analysis of each question in the Decision-Making Questionnaire scale

Question	Allocation	n	Median (IQR)	Z-statistic	P value
1. The information I saw about the FORCE trial was easy to understand.	PIS	157	3 (1)	−2.60	0.010
	MMI	151	4 (1)		
2. The information helped me understand what it would be like for my son or daughter to take part in the FORCE study.	PIS	157	4 (1)	−0.79	0.446
	MMI	152	4 (1)		
3. The information helped me understand how my son or daughter's treatment or care might change if he/she took part in the FORCE study.	PIS	157	4 (1)	−0.87	0.387
	MMI	152	4 (1)		
4. The possible benefits of taking part in the FORCE trial were made clear in the information.	PIS	157	4 (1)	0.37	0.714
	MMI	151	4 (1)		
5. The possible disadvantages of taking part in the FORCE trial were made clear in the information.	PIS	157	3 (2)	1.34	0.18
	MMI	151	3 (2)		
6. The information about the FORCE trial helped me discuss the trial with the person who asked my son or daughter to take part (usually a doctor, nurse or researcher).	PIS	157	4 (1)	−0.53	0.603
	MMI	151	4 (1)		
7. The information about the FORCE study helped me discuss taking part with my son or daughter.	PIS	157	4 (1)	0.13	0.909
	MMI	151	4 (1)		
8. I am confident that I have made the right decision about whether or not my son or daughter should take part in the FORCE study.	PIS	157	4 (1)	0.34	0.733
	MMI	151	4 (1)		
9. In all, the information about the FORCE trial helped me make my decision about whether or not my son or daughter should take part.	PIS	157	4 (1)	0.39	0.700
	MMI	149	4 (1)		

FORCE, Forearm Fracture Recovery in Children Evaluation; MMI, multimedia information; PIS, participant information sheet.

The multimedia resources and animations were produced by expert developers, and their content was informed by extensive empirical work and PPI: consequently, the design and content of the resources were carefully considered and of high quality. The printed information sheets included a version for young children and a child-friendly information booklet. It is likely that both formats of information in the SWAT may be of higher quality than in many trials. The written text in the MMI was revised to enhance readability and age appropriateness and it is possible that this change, as much as the digital presentation, could have produced the positive DMQ evaluations. Participants in both arms of the SWAT made positive comments about the spoken information provided by recruiting staff; this is likely to be an important influence on some participants' decisions on trial participation and one that is outside the control of the SWAT.

MMI for trial recruitment remains innovative and rarely used, although there has been a recent increase. However, it is little evaluated, particularly in children or adolescents. In two other reported TRECA-embedded studies: first, more adolescents rated MMI as 'easy to understand' than those who saw printed information; multimedia also resulted in greater confidence in decision-making.[38] Second, MMI resulted in higher rates of recruitment than PIS to a children's cardiac surgery trial, although the difference was not statistically significant.[39] Two systematic reviews of trials of MMI to inform consent decisions in adults reported that they may increase comprehension of the research and consent, and retention of information.[40 41] There has been more evaluation of MMI in healthcare delivery, showing a number of benefits for patients, for example, on knowledge, self-management of health condition, satisfaction with care, and anxiety and pain.[42–46] However, most of the studies involved adults. In child or adolescent populations video animations alone have had more evaluation. For example, providing animated videos to children with epilepsy increased knowledge and medicine adherence, and in children with respiratory condition animations it increased the use of medication delivery devices.[47–49]

This SWAT within the FORCE trial showed that digital provision of multimedia recruitment information is feasible, even in the pressured situation of emergency department care. Although the impact of the MMI on trial recruitment was modest and statistically non-significant, it was positively evaluated, suggesting good acceptability by young patients and families. Furthermore, the anecdotal reports are that clinical, recruiting staff liked the MMI and found it easy to use with patients. However, the MMI took several weeks to produce with an approximate cost of £10 000 per trial, both of which factors could have implications for their use in some future trials.

Subsequent TRECA analysis will examine: the patterns of participant use of the various pages and videos on the MMI; and the overall effects of printed information and MMI across all six SWATs within TRECA. However, there remains a need for further evaluation (potentially including qualitative methods) of the preferred design of digital, MMI in children's trials, its impact on outcomes and acceptability, and on trial recruiters' communication with patients.

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Disclaimer The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. The intellectual property for the animations and MMI is owned jointly by the University of York and Morph. As agreed with the funder (NIHR), the animations can be used free of charge in any publicly or charity-funded research. Anyone who would like to request to use the animations can do so by contacting: peter.knapp@york.ac.uk

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval The TRECA study received approval from the NHS Yorkshire and the Humber–Bradford Leeds Research Ethics Committee (17/YH/0082) and the Health Research Authority (IRAS ID 212761). It is also registered on the Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT 97) (Martin-Kerry et al [23]). FORCE received approval from the National Research Ethics Committee (18/WM/0324). Participants did not give consent to the SWAT. The REC agreed that to do so could be confusing for patients and would confound the SWAT objectives.

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Data availability statement Data are available upon reasonable request. We will make available the following anonymised data in response to reasonable request: recruitment centre and SWAT allocation; trial number; patient age; FORCE trial recruitment status; DMQ scores. Requests will be assessed according to the intended purpose for the data. If the request is approved, data will be shared via encrypted third-party transfer. The TRECA study protocol has been published (see Martin-Kerry *et al* [23]). The TRECA statistical analysis plan has not been published but can be provided on request.

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