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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057508
Article Type:	Original research
Date Submitted by the Author:	21-Sep-2021
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Keywords:	MEDICAL ETHICS, Hand & wrist < ORTHOPAEDIC & TRAUMA SURGERY, Paediatric A&E and ambulatory care < PAEDIATRICS, STATISTICS & RESEARCH METHODS

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Keywords: SWAT, trial, recruitment, information, multimedia.

Word count: 3,768.

ABSTRACT

- **Objectives:** to evaluate digital, multimedia information for its effects on trial recruitment, retention, decisions about participation, and acceptability by patients, compared with printed information.
- **Design:** SWAT (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:** 1,409 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 text, animated videos and talking-head videos) 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 (9 Likert items, analysed summatively and individually), 3 'free text' questions (deriving subjective evaluations), and trial retention.
- **Results:** Multimedia information 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). 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 (57.8% vs. 39.4%; Z 2.60, p=.01) and identify information that was explained well (62.3% vs. 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:** Multimedia information 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.
- **Trial registration:** TRECA ISRCTN73136092 and NINTMR SWAT97. FORCE ISRCTN13955395.

Strengths and limitations of this study

- The SWAT design allowed different recruitment methods 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 FORCE trial consenters and few from FORCE non-consenters.

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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. The 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 amongst 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, whether offline or as a website, involving the use of video, animations, audio and infographics. Multimedia information (MMIs) may increase engagement, potentially through enhanced choice 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 TRECA (TRials Engagement in Children and Adolescents) study evaluated the effectiveness of multimedia resources compared to traditional printed information, for trial recruitment involving children and adolescents.(23, 24) The evaluation was undertaken through six linked SWATs (Studies Within A Trial), 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 FORCE (Forearm Fracture Recovery in Children Evaluation) 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 (i.e. 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 a multimedia information resource (MMI). The 23 hospital sites were allocated at the University of York, using a random number generator,(30) and sent to sites by email via the Clinical Trial Unit (CTU) running the FORCE trial.

The host trial (FORCE) was a NIHR Health Technology Assessment funded, multi-centred randomised controlled trial 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- and cost-effectiveness of soft bandage immobilisation and immediate discharge compared to 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 participant information sheet used in the FORCE trial, comprising information for parents and age-appropriate information for children (including a picture booklet), which had been developed with PPI representatives.

The MMI was developed by the TRECA team at the University of York and a website and video creation company (Morph). Two versions of the MMI were developed: one for children aged 6-11 years, and another for adolescents and parents. The MMIs contained all information content of the written participant information sheet, with text amended to improve clarity when required.

The multimedia resources were viewed on tablet computer at the hospital. The resource included five short video animations, each lasting 45-60 seconds (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'), and 12 short 'talking head' videos, featuring four individuals (5 with a study investigator; ; 3 with a Research Nurse; 1 with an adolescent and 3 with parents of children who had taken part in similar studies), each lasting 15-50 seconds and describing different aspects of the trial and clinical procedures. The MMI content was organised on six main webpages with the following headings: 'Home page (including summary animation)'; 'About the trial'; 'Taking part'; 'After the trial'; 'Questions'; 'Contacts'. (A summary can be viewed here:31). The TRECA MMIs were developed through extensive qualitative research and user testing, where principles of participatory design were used to develop their style and format (32, 33, 34) and informed by information design and principles of Plain English,(35) readability and age-appropriateness. The TRECA Patient and Public Involvement Group commented on the design and content of the MMIs during their development.(36)

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 PC, 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 9-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 NHS REC, and they 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=1,816).

All analyses were conducted in STATA v16(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 odds ratio (OR), with associated 95% confidence interval (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 a using multi-level 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 multi-level 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, inter-quartile ranges (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.

Ethical approval

The TRECA study received approval from the NHS Yorkshire & 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., 2017). FORCE received approval from National Research Ethics Committee (18/WM/0324).

Funding Details

TRECA was funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research Programme (NIHR HS&DR 14/21/21).

FORCE was funded by the NIHR Health Technology Assessment programme (17/23/02) and further supported by the NIHR Oxford Biomedical Research Centre.

The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

RESULTS

INSERT: Figure 1. CONSORT flow chart of participants through the FORCE SWAT

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 1,409 participants met the FORCE eligibility criteria at the 23 recruitment centres during February 2019 to July 2020. Baseline characteristics of the 1,409 patients that 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 eligible patients (71.0% compared to 84.3% at MMI recruitment centres), and higher proportions of some ethnic minorities. Participants at PIS recruitment centres also had higher (less deprived) IMD decile scores (4.7 (SD 3.1) compared to 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 1,409 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

DMQs

A total of 324 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 9 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= .01). The information was rated as ‘very easy’ by 57.8% participants in the MMI group and 39.4% participants in the PIS group. There were no other statistically significant differences.

Insert: Figure 2.

DMQ ‘free text’ comments

All participants’ responses are available in Appendix 1 (supplementary material).

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 (4 respondents); questionnaire follow-up timing and frequency (2 respondents); washing the bandage (2 respondents); current standard practice for this fracture; as well as more general evaluations ("no, it was all explained really well"). T

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 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. Firstly, thirteen (4.0%) 'free text' respondents mentioned the age-appropriateness or age-suitability of the trial information. Among those allocated to the MMI there were ten comments, all of them positive. In those allocated to the PIS there were three comments on age-suitability (one negative and two positive).

Secondly, 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 MMIs. 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 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. There was no difference in total DMQ score between groups. Individual item analysis showed that the MMIs were 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 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 multi-centre 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 has resulted in uncertainty about the extent to which participants' views have been captured accurately. The multimedia resources and animations were produced by expert developers, and their content was informed by extensive empirical work and Patient and Public Involvement: 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.

Multimedia information 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 one other reported TRECA embedded study more adolescents rated multimedia information as 'easy to understand' than those who saw printed information. Multimedia also resulted in greater confidence in decision making.(38) Two systematic reviews of trials of multimedia information to inform consent decisions in adults reported that they may increase comprehension of the research and consent, and retention of information.(39, 40). There has been more evaluation of multimedia information 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.(41-45) 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 conditions animations it increased the use of medication delivery devices.(46-48)

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

REFERENCES

1. Treweek, S., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E., Sullivan, F., Jackson, C., Taskila, T. K. & Gardner, H. 2018a. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev, 2, Mr000013.

2. McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., Elbourne, D. R., Francis, D., Garcia, J., Roberts, I. & Snowdon, C. 2006. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials, 7, 9.

3. Caldwell, P. H., Dans, L., De Vries, M. C., Newman Ba Hons, J., Sammons, H., Spriggs, M. B. M., Tambe, P., Van't Hoff, W., Woolfall, K., Young, B. & Offringa, M. 2012. Standard 1: consent and recruitment. Pediatrics, 129 Suppl 3, S118-23.

4. Eder, M. L., Yamokoski, A. D., Wittmann, P. W. & Kodish, E. D. 2007. Improving informed consent: suggestions from parents of children with leukemia. Pediatrics, 119, e849-59.

5. Sheridan, R., Martin-Kerry, J., Hudson, J., Parker, A., Bower, P. & Knapp, P. 2020a. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. Trials, 21, 259.

6. Nuffield Council on Bioethics. 2015. Children and clinical research: ethical issues. London.

7. Simon, C. M., Siminoff, L. A., Kodish, E. D. & Burant, C. 2004. Comparison of the informed consent process for randomized clinical trials in pediatric and adult oncology. J Clin Oncol, 22, 2708-17.

8. Barfield, R. C. & Church, C. 2005. Informed consent in pediatric clinical trials. Curr Opin Pediatr, 17, 20-4.

9. Stryker, J. E., Wray, R. J., Emmons, K. M., Winer, E. & Demetri, G. 2006. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. Patient Educ Couns, 63, 104-9.

10. Tait, A. R., Voepel-Lewis, T. & Levine, R. 2015a. Using digital multimedia to improve parents' and children's understanding of clinical trials. Archives of disease in childhood, 100, 589-593.

11. Hunfeld, J. A. M. & Passchier, J. 2012. Participation in medical research; a systematic review of the understanding and experience of children and adolescents. Patient Education and Counseling, 87, 268-276.

12. Crane, S. and Broome, M. E. 2017. Understanding Ethical Issues of Research Participation From the Perspective of Participating Children and Adolescents: A Systematic Review. World Views on Evidence-Based Nursing, 14, 200-209. https://doi.org/10.1111/wvn.12209

13. Health Research Authority . 2016. Applying a proportionate approach to the process of seeking consent: HRA Guidance.

14. Hermann, M. 2002. [3-dimensional computer animation--a new medium for supporting patient education before surgery. Acceptance and assessment of patients based on a prospective randomized study--picture versus text]. Chirurg, 73, 500-7.

15. Hopper, K. D., Zajdel, M., Hulse, S. F., Yoanidis, N. R., Tenhave, T. R., Labuski, M. R., Houts, P. S., Brensinger, C. M. & Hartman, D. S. 1994. Interactive method of informing patients of the risks of intravenous contrast media. Radiology, 192, 67-71.

16. Tait, A. R., Voepel-Lewis, T., Mcgonegal, M. & Levine, R. 2012b. Evaluation of a prototype interactive consent program for pediatric clinical trials: a pilot study. J Am Med Inform Assoc, 19, e43-5.

17. Tait, A. R., Voepel-Lewis, T., Moscucci, M., Brennan-Martinez, C. M. & Levine, R. 2009c. Patient comprehension of an interactive, computer-based information program for cardiac catheterization: a comparison with standard information. Arch Intern Med, 169, 1907-14.

18. Hutchison, C., Cowan, C., McMahon, T. & Paul, J. 2007. A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. British journal of cancer, 97, 705-711.

19. Antoniou, E. E., Draper, H., Reed, K., Burls, A., Southwood, T. R. & Zeegers, M. P. 2011. An empirical study on the preferred size of the participant information sheet in research. Journal of Medical Ethics, 37, 557.

20. Shneerson, C., Windle, R. & Cox, K. 2013. Innovating information-delivery for potential clinical trials participants. What do patients want from multi-media resources? Patient Education and Counseling, 90, 111-117.

21. Office for National Statistics. 2019. Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04 (Accessed 20 January 2021).

22. Blower, S., Swallow, V., Maturana, C., Stones, S., Phillips, R., Dimitri, P., Marshman, Z., Knapp, P., Dean, A., Higgins, S., Kellar, I., Curtis, P., Mills, N. & Martin-Kerry, J. 2020. Children and young people's concerns and needs relating to their use of health technology to self-manage long-term conditions: a scoping review. Archives of Disease in Childhood, 105, 1093.

23. Martin-Kerry, J., Bower, P., Young, B., Graffy, J., Sheridan, R., Watt, I., Baines, P., Stones, C., Preston, J., Higgins, S., Gamble, C. & Knapp, P. 2017. Developing and evaluating multimedia

information resources to improve engagement of children, adolescents, and their parents with trials (TRECA study): Study protocol for a series of linked randomised controlled trials. Trials, 18, 265.

24. Martin-Kerry, J. M., Parker, A., Arundel, C., Torgerson, D., Tilbrook, H., Watt, I., Bower, P., Treweek, S., Knapp, P. 2019c. SWATted away: the challenging experience of setting up a SWAT in paediatric trials. Trials; 20: 141.

25. Rick, J., Graffy, J., Knapp, P., Small, N., Collier, D. J., Eldridge, S., Kennedy, A., Salisbury, C., Treweek, S., Torgerson, D., Wallace, P., Madurasinghe, V., Hughes-Morley, A. & Bower, P. 2014. Systematic techniques for assisting recruitment to trials (START): study protocol for embedded, randomized controlled trials. Trials, 15, 407.

26. Treweek, S., Bevan, S., Bower, P., Campbell, M., Christie, J., Clarke, M., Collett, C., Cotton, S., Devane, D., El Feky, A., Flemyng, E., Galvin, S., Gardner, H., Gillies, K., Jansen, J., Littleford, R., Parker, A., Ramsay, C., Restrup, L., Sullivan, F., Torgerson, D., Tremain, L., Westmore, M. & Williamson, P. R. 2018b. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials, 19, 139.

27. Achten, J., Knaight, R., Dutton, S., Costa, M., Mason, J., Dritsaki, M., Appelbe, D., Messahel, S., Roland, D., Widnall, J., Perry, D. A multi-centre prospective randomised equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilisation for torus fractures of the distal radius in children: Protocol for the Forearm Fracture Recovery in Children Evaluation Trial (FORCE). Bone & Joint Open; 2020. https://doi.org/10.1302/2633-1462.16.BJO-2020-0014.R1

28. Perry, D., et al. (FORCE trial paper, under review)

29. Madurasinghe, V.W., Sandra Eldridge on behalf of MRC START Group and Gordon Forbes on behalf of the START Expert Consensus Group. Guidelines for reporting embedded recruitment trials. Trials 17, 27 (2016). https://doi.org/10.1186/s13063-015-1126-y

30. Sealed envelope. 2019. Available at: https://www.sealedenvelope.com/ (Assessed 12 May 2020).

31. Morph, 2021. https://digitrial.com/case-study-the-force-study/

32. Martin-Kerry, J. M., Knapp, P., Atkin, K., Bower, P., Watt, I., Stones, C., Higgins, S., Sheridan, R., Preston, J., Horton Taylor, D., Baines, P. & Young, B. 2019b. Supporting children and young people when making decisions about joining clinical trials: qualitative study to inform multimedia website development. BMJ Open, 9, e023984.

33. Martin-Kerry, J. M., Higgins, S., Knapp, P., Liabo, K., Young, B. Engaging children, young people, parents and health professionals in interviews about abstract topics: using a ranking exercise to elicit views on health research. (under review).

34. Sheridan, R., Martin-Kerry, J., Watt, I., Higgins, S., Stones, S. R., Taylor, D. H. & Knapp, P. 2019. User testing digital, multimedia information to inform children, adolescents and their parents about healthcare trials. J Child Health Care, 23, 468-482.

35. Knapp, P., Raynor, D. K., Silcock, J. & Parkinson, B. 2011. Can user testing of a clinical trial patient information sheet make it fit-for-purpose? - a randomized controlled trial. BMC Medicine, 9, 89.

36. Sheridan, R., Preston, J., Stones, S., Ainsworth, S., Horton-Taylor, D., Challinor, R., Ainsworth, S., Martin-Kerry., J.M., Brady, L-M. & Knapp, .P. 2020b, 'Patient and public involvement in a study of multimedia clinical trial information for children, young people and families', Research for All, vol. 4, no. 1, pp. 47-65.

37. StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC.

38. Knapp, P., Mandall, N., Hulse, W., Roche, J., Moe Byrne, T., Martin-Kerry, J. M., Sheridan, R., Higgins, S., (for the TRECA study group). Evaluating the use of multimedia information when recruiting adolescents to orthodontics research: a randomised controlled trial. Journal of Orthodontics 2021; https://doi.org/10.1177/14653125211024250.

39. Palmer, B. W., Lanouette, N. M. & Jeste, D. V. 2012. Effectiveness of multimedia aids to enhance comprehension of research consent information: a systematic review. Irb, 34, 1-15.

40. Nishimura, A., Carey, J., Erwin, P.J., Tilburt, J.C., Murad, M.H. and McCormick, J.B., 2013. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC medical ethics, 14(1), pp.1-15.

41. Ciciriello, S., Johnston, R. V., Osborne, R. H., Wicks, I., Dekroo, T., Clerehan, R., O'neill, C. & Buchbinder, R. 2013. Multimedia educational interventions for consumers about prescribed and over-the-counter medications. Cochrane Database Syst Rev, Cd008416.

42. Tuong, W., Larsen, E. R., Armstrong, A. W. 2014. Videos to influence: a systematic review of effectiveness of video-based education in modifying health behaviors. J Behav Med, 37: 218-233.

43. Dekkers, T., Melles, M., Groeneveld, B. S. & De Ridder, H. 2018. Web-Based Patient Education in Orthopedics: Systematic Review. Journal of medical Internet research, 20, e143-e143.

44. Dahodwala, M., Geransar, R., Babion, J., De Grood, J. & Sargious, P. 2018. The impact of the use of video-based educational interventions on patient outcomes in hospital settings: A scoping review. Patient Educ Couns, 101, 2116-2124.

45. Knox, E. C. L., Quirk, H., Glazebrook, C., Randell, T. & Blake, H. 2019. Impact of technology-based interventions for children and young people with type 1 diabetes on key diabetes self-management behaviours and prerequisites: a systematic review. BMC Endocr Disord, 19, 7.

46. Indradat, S., Jirapongsananuruk, O. & Visitsunthorn, N. 2014. Evaluation of animated cartoon-aided teaching of intranasal corticosteroid administration technique among Thai children with allergic rhinitis. Asian Pac J Allergy Immunol, 32, 166-70.

47. Saengow, V. E., Chancharoenchai, P., Saartying, W., Pimpa, W., Chotichanon, N., Lewsirirat, T. & Srisantisuk, P. 2018. Epilepsy video animation: Impact on knowledge and drug adherence in pediatric epilepsy patients and caregivers. Clin Neurol Neurosurg, 172, 59-61.

48. Frémont, A., Abou Taam, R., Wanin, S., Lebras, M. N., Ollier, V., Nathanson, S., Hadchouel, A. & Drummond, D. 2018. Cartoons to improve young children's cooperation with inhaled corticosteroids: A preliminary study. Pediatr Pulmonol, 53, 1193-1199.

Contributors

PK obtained funding for TRECA and led the study. PK, JM-K, RS and SH developed the TRECA multimedia with Morph, and liaised with DP and JA on the FORCE-specific elements. RS and JM-K liaised with the TRECA PPI group. DP led the FORCE study. JM-K, JA, LS, TMB and DA set up the SWAT and obtained data. JR analysed the data. PK and TMB drafted the manuscript. All authors contributed to its revision.

We wish to acknowledge the significant contributions made by the TRECA PPI group, the TRECA advisory group, and the TRECA NIHR Study Steering Committee. The multimedia were developed in collaboration with Morph.

Table 1. Participant baseline characteristics

	PIS (n=728)	MMI (n=681)	Overall (n=1,409)
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 Deprivation index 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)

Table 2. Participant baseline characteristics of those recruited into FORCE

	PIS		MMI	
	Recruited (n = 484)	Not recruited (n = 244)	Recruited (n = 475)	Not recruited (n = 206)
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 Deprivation index 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)

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's or daughter's treatment or care might change if s/he 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	PIS, n (%)	0 (0.0)	4 (2.4)	9 (5.3)	47 (27.7)	97 (57.1)	13 (7.7)

trial were made clear in the information.	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	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)

the FORCE study.	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)

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 calculated mean/SD, N = total number of participants in category

Table 5. Decision Making Questionnaire scale analyses

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

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's or daughter's treatment or care might change if s/he 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	PIS	157	4 (1)	0.39	0.700
	MMI	149	4 (1)		

son or daughter should take part.					

Figure 1. CONSORT flow chart of participants through the FORCE SWAT

604x305mm (59 x 59 DPI)

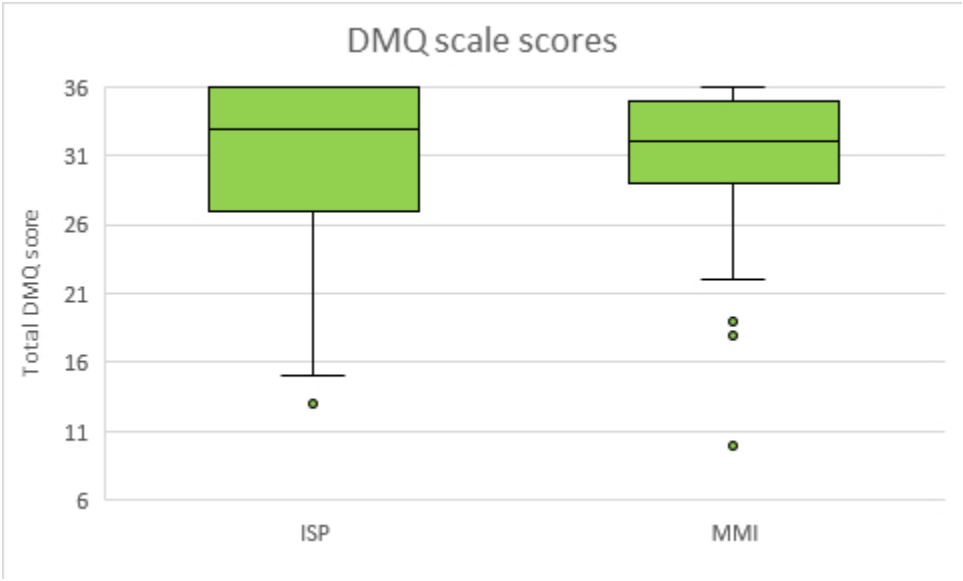

Figure 2. DMQ scale total scores boxplots

320x192mm (38 x 38 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7-8
	13b	For each group, losses and exclusions after randomisation, together with reasons	7-8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16-17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10-11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	Reference Martin-Kerry,2017
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	6

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057508
Article Type:	Original research
Date Submitted by the Author:	21-Sep-2021
Complete List of Authors:	Knapp, Peter; University of York; Perry, Daniel; University of Oxford Achten, Juul; University of Oxford, NDORMS Spoors, Louise; University of Oxford, Oxford Trauma, NDORMS; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, University of Oxford Appelbe, Duncan Roche, Jenny Moe-Byrne, Thirimon; University of York Martin-Kerry, Jacqueline; University of York, Health Sciences; Sheridan, Rebecca; University of York Higgins, Steven; University of Durham, School of Education
Keywords:	MEDICAL ETHICS, Hand & wrist < ORTHOPAEDIC & TRAUMA SURGERY, Paediatric A&E and ambulatory care < PAEDIATRICS, STATISTICS & RESEARCH METHODS

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

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Keywords: SWAT, trial, recruitment, information, multimedia.

Word count: 3,768.

ABSTRACT

- **Objectives:** to evaluate digital, multimedia information for its effects on trial recruitment, retention, decisions about participation, and acceptability by patients, compared with printed information.
- **Design:** SWAT (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:** 1,409 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 text, animated videos and talking-head videos) 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 (9 Likert items, analysed summatively and individually), 3 'free text' questions (deriving subjective evaluations), and trial retention.
- **Results:** Multimedia information 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). 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 (57.8% vs. 39.4%; Z 2.60, p=.01) and identify information that was explained well (62.3% vs. 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:** Multimedia information 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.
- **Trial registration:** TRECA ISRCTN73136092 and NINTMR SWAT97. FORCE ISRCTN13955395.

Strengths and limitations of this study

- The SWAT design allowed different recruitment methods 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 FORCE trial consenters and few from FORCE non-consenters.

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

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. The 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 amongst 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, whether offline or as a website, involving the use of video, animations, audio and infographics. Multimedia information (MMIs) may increase engagement, potentially through enhanced choice 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 TRECA (TRials Engagement in Children and Adolescents) study evaluated the effectiveness of multimedia resources compared to traditional printed information, for trial recruitment involving children and adolescents.(23, 24) The evaluation was undertaken through six linked SWATs (Studies Within A Trial), 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 FORCE (Forearm Fracture Recovery in Children Evaluation) 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 (i.e. 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 a multimedia information resource (MMI). The 23 hospital sites were allocated at the University of York, using a random number generator,(30) and sent to sites by email via the Clinical Trial Unit (CTU) running the FORCE trial.

The host trial (FORCE) was a NIHR Health Technology Assessment funded, multi-centred randomised controlled trial 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- and cost-effectiveness of soft bandage immobilisation and immediate discharge compared to 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 participant information sheet used in the FORCE trial, comprising information for parents and age-appropriate information for children (including a picture booklet), which had been developed with PPI representatives.

The MMI was developed by the TRECA team at the University of York and a website and video creation company (Morph). Two versions of the MMI were developed: one for children aged 6-11 years, and another for adolescents and parents. The MMIs contained all information content of the written participant information sheet, with text amended to improve clarity when required.

The multimedia resources were viewed on tablet computer at the hospital. The resource included five short video animations, each lasting 45-60 seconds (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'), and 12 short 'talking head' videos, featuring four individuals (5 with a study investigator; ; 3 with a Research Nurse; 1 with an adolescent and 3 with parents of children who had taken part in similar studies), each lasting 15-50 seconds and describing different aspects of the trial and clinical procedures. The MMI content was organised on six main webpages with the following headings: 'Home page (including summary animation)'; 'About the trial'; 'Taking part'; 'After the trial'; 'Questions'; 'Contacts'. (A summary can be viewed here:31). The TRECA MMIs were developed through extensive qualitative research and user testing, where principles of participatory design were used to develop their style and format (32, 33, 34) and informed by information design and principles of Plain English,(35) readability and age-appropriateness. The TRECA Patient and Public Involvement Group commented on the design and content of the MMIs during their development.(36)

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 PC, 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 9-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 NHS REC, and they 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=1,816).

All analyses were conducted in STATA v16(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 odds ratio (OR), with associated 95% confidence interval (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 a using multi-level 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 multi-level 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, inter-quartile ranges (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.

Ethical approval

The TRECA study received approval from the NHS Yorkshire & 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., 2017). FORCE received approval from National Research Ethics Committee (18/WM/0324).

Funding Details

TRECA was funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research Programme (NIHR HS&DR 14/21/21).

FORCE was funded by the NIHR Health Technology Assessment programme (17/23/02) and further supported by the NIHR Oxford Biomedical Research Centre.

The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

RESULTS

INSERT: Figure 1. CONSORT flow chart of participants through the FORCE SWAT

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 1,409 participants met the FORCE eligibility criteria at the 23 recruitment centres during February 2019 to July 2020. Baseline characteristics of the 1,409 patients that 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 eligible patients (71.0% compared to 84.3% at MMI recruitment centres), and higher proportions of some ethnic minorities. Participants at PIS recruitment centres also had higher (less deprived) IMD decile scores (4.7 (SD 3.1) compared to 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 1,409 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

DMQs

A total of 324 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 9 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= .01). The information was rated as ‘very easy’ by 57.8% participants in the MMI group and 39.4% participants in the PIS group. There were no other statistically significant differences.

Insert: Figure 2.

DMQ ‘free text’ comments

All participants’ responses are available in Appendix 1 (supplementary material).

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 (4 respondents); questionnaire follow-up timing and frequency (2 respondents); washing the bandage (2 respondents); current standard practice for this fracture; as well as more general evaluations ("no, it was all explained really well"). T

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 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. Firstly, thirteen (4.0%) 'free text' respondents mentioned the age-appropriateness or age-suitability of the trial information. Among those allocated to the MMI there were ten comments, all of them positive. In those allocated to the PIS there were three comments on age-suitability (one negative and two positive).

Secondly, 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 MMIs. 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 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. There was no difference in total DMQ score between groups. Individual item analysis showed that the MMIs were 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 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 multi-centre 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 has resulted in uncertainty about the extent to which participants' views have been captured accurately. The multimedia resources and animations were produced by expert developers, and their content was informed by extensive empirical work and Patient and Public Involvement: 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.

Multimedia information 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 one other reported TRECA embedded study more adolescents rated multimedia information as 'easy to understand' than those who saw printed information. Multimedia also resulted in greater confidence in decision making.(38) Two systematic reviews of trials of multimedia information to inform consent decisions in adults reported that they may increase comprehension of the research and consent, and retention of information.(39, 40). There has been more evaluation of multimedia information 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.(41-45) 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 conditions animations it increased the use of medication delivery devices.(46-48)

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

REFERENCES

1. Treweek, S., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E., Sullivan, F., Jackson, C., Taskila, T. K. & Gardner, H. 2018a. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev, 2, Mr000013.

2. McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., Elbourne, D. R., Francis, D., Garcia, J., Roberts, I. & Snowdon, C. 2006. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials, 7, 9.

3. Caldwell, P. H., Dans, L., De Vries, M. C., Newman Ba Hons, J., Sammons, H., Spriggs, M. B. M., Tambe, P., Van't Hoff, W., Woolfall, K., Young, B. & Offringa, M. 2012. Standard 1: consent and recruitment. Pediatrics, 129 Suppl 3, S118-23.

4. Eder, M. L., Yamokoski, A. D., Wittmann, P. W. & Kodish, E. D. 2007. Improving informed consent: suggestions from parents of children with leukemia. Pediatrics, 119, e849-59.

5. Sheridan, R., Martin-Kerry, J., Hudson, J., Parker, A., Bower, P. & Knapp, P. 2020a. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. Trials, 21, 259.

6. Nuffield Council on Bioethics. 2015. Children and clinical research: ethical issues. London.

7. Simon, C. M., Siminoff, L. A., Kodish, E. D. & Burant, C. 2004. Comparison of the informed consent process for randomized clinical trials in pediatric and adult oncology. J Clin Oncol, 22, 2708-17.

8. Barfield, R. C. & Church, C. 2005. Informed consent in pediatric clinical trials. Curr Opin Pediatr, 17, 20-4.

9. Stryker, J. E., Wray, R. J., Emmons, K. M., Winer, E. & Demetri, G. 2006. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. Patient Educ Couns, 63, 104-9.

10. Tait, A. R., Voepel-Lewis, T. & Levine, R. 2015a. Using digital multimedia to improve parents' and children's understanding of clinical trials. Archives of disease in childhood, 100, 589-593.

11. Hunfeld, J. A. M. & Passchier, J. 2012. Participation in medical research; a systematic review of the understanding and experience of children and adolescents. Patient Education and Counseling, 87, 268-276.

12. Crane, S. and Broome, M. E. 2017. Understanding Ethical Issues of Research Participation From the Perspective of Participating Children and Adolescents: A Systematic Review. World Views on Evidence-Based Nursing, 14, 200-209. https://doi.org/10.1111/wvn.12209

13. Health Research Authority . 2016. Applying a proportionate approach to the process of seeking consent: HRA Guidance.

14. Hermann, M. 2002. [3-dimensional computer animation--a new medium for supporting patient education before surgery. Acceptance and assessment of patients based on a prospective randomized study--picture versus text]. Chirurg, 73, 500-7.

15. Hopper, K. D., Zajdel, M., Hulse, S. F., Yoanidis, N. R., Tenhave, T. R., Labuski, M. R., Houts, P. S., Brensinger, C. M. & Hartman, D. S. 1994. Interactive method of informing patients of the risks of intravenous contrast media. Radiology, 192, 67-71.

16. Tait, A. R., Voepel-Lewis, T., Mcgonegal, M. & Levine, R. 2012b. Evaluation of a prototype interactive consent program for pediatric clinical trials: a pilot study. J Am Med Inform Assoc, 19, e43-5.

17. Tait, A. R., Voepel-Lewis, T., Moscucci, M., Brennan-Martinez, C. M. & Levine, R. 2009c. Patient comprehension of an interactive, computer-based information program for cardiac catheterization: a comparison with standard information. Arch Intern Med, 169, 1907-14.

18. Hutchison, C., Cowan, C., McMahon, T. & Paul, J. 2007. A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. British journal of cancer, 97, 705-711.

19. Antoniou, E. E., Draper, H., Reed, K., Burls, A., Southwood, T. R. & Zeegers, M. P. 2011. An empirical study on the preferred size of the participant information sheet in research. Journal of Medical Ethics, 37, 557.

20. Shneerson, C., Windle, R. & Cox, K. 2013. Innovating information-delivery for potential clinical trials participants. What do patients want from multi-media resources? Patient Education and Counseling, 90, 111-117.

21. Office for National Statistics. 2019. Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04 (Accessed 20 January 2021).

22. Blower, S., Swallow, V., Maturana, C., Stones, S., Phillips, R., Dimitri, P., Marshman, Z., Knapp, P., Dean, A., Higgins, S., Kellar, I., Curtis, P., Mills, N. & Martin-Kerry, J. 2020. Children and young people's concerns and needs relating to their use of health technology to self-manage long-term conditions: a scoping review. Archives of Disease in Childhood, 105, 1093.

23. Martin-Kerry, J., Bower, P., Young, B., Graffy, J., Sheridan, R., Watt, I., Baines, P., Stones, C., Preston, J., Higgins, S., Gamble, C. & Knapp, P. 2017. Developing and evaluating multimedia

information resources to improve engagement of children, adolescents, and their parents with trials (TRECA study): Study protocol for a series of linked randomised controlled trials. Trials, 18, 265.

24. Martin-Kerry, J. M., Parker, A., Arundel, C., Torgerson, D., Tilbrook, H., Watt, I., Bower, P., Treweek, S., Knapp, P. 2019c. SWATted away: the challenging experience of setting up a SWAT in paediatric trials. Trials; 20: 141.

25. Rick, J., Graffy, J., Knapp, P., Small, N., Collier, D. J., Eldridge, S., Kennedy, A., Salisbury, C., Treweek, S., Torgerson, D., Wallace, P., Madurasinghe, V., Hughes-Morley, A. & Bower, P. 2014. Systematic techniques for assisting recruitment to trials (START): study protocol for embedded, randomized controlled trials. Trials, 15, 407.

26. Treweek, S., Bevan, S., Bower, P., Campbell, M., Christie, J., Clarke, M., Collett, C., Cotton, S., Devane, D., El Feky, A., Flemyng, E., Galvin, S., Gardner, H., Gillies, K., Jansen, J., Littleford, R., Parker, A., Ramsay, C., Restrup, L., Sullivan, F., Torgerson, D., Tremain, L., Westmore, M. & Williamson, P. R. 2018b. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials, 19, 139.

27. Achten, J., Knaight, R., Dutton, S., Costa, M., Mason, J., Dritsaki, M., Appelbe, D., Messahel, S., Roland, D., Widnall, J., Perry, D. A multi-centre prospective randomised equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilisation for torus fractures of the distal radius in children: Protocol for the Forearm Fracture Recovery in Children Evaluation Trial (FORCE). Bone & Joint Open; 2020. https://doi.org/10.1302/2633-1462.16.BJO-2020-0014.R1

28. Perry, D., et al. (FORCE trial paper, under review)

29. Madurasinghe, V.W., Sandra Eldridge on behalf of MRC START Group and Gordon Forbes on behalf of the START Expert Consensus Group. Guidelines for reporting embedded recruitment trials. Trials 17, 27 (2016). https://doi.org/10.1186/s13063-015-1126-y

30. Sealed envelope. 2019. Available at: https://www.sealedenvelope.com/ (Assessed 12 May 2020).

31. Morph, 2021. https://digitrial.com/case-study-the-force-study/

32. Martin-Kerry, J. M., Knapp, P., Atkin, K., Bower, P., Watt, I., Stones, C., Higgins, S., Sheridan, R., Preston, J., Horton Taylor, D., Baines, P. & Young, B. 2019b. Supporting children and young people when making decisions about joining clinical trials: qualitative study to inform multimedia website development. BMJ Open, 9, e023984.

33. Martin-Kerry, J. M., Higgins, S., Knapp, P., Liabo, K., Young, B. Engaging children, young people, parents and health professionals in interviews about abstract topics: using a ranking exercise to elicit views on health research. (under review).

34. Sheridan, R., Martin-Kerry, J., Watt, I., Higgins, S., Stones, S. R., Taylor, D. H. & Knapp, P. 2019. User testing digital, multimedia information to inform children, adolescents and their parents about healthcare trials. J Child Health Care, 23, 468-482.

35. Knapp, P., Raynor, D. K., Silcock, J. & Parkinson, B. 2011. Can user testing of a clinical trial patient information sheet make it fit-for-purpose? - a randomized controlled trial. BMC Medicine, 9, 89.

36. Sheridan, R., Preston, J., Stones, S., Ainsworth, S., Horton-Taylor, D., Challinor, R., Ainsworth, S., Martin-Kerry., J.M., Brady, L-M. & Knapp, .P. 2020b, 'Patient and public involvement in a study of multimedia clinical trial information for children, young people and families', Research for All, vol. 4, no. 1, pp. 47-65.

37. StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC.

38. Knapp, P., Mandall, N., Hulse, W., Roche, J., Moe Byrne, T., Martin-Kerry, J. M., Sheridan, R., Higgins, S., (for the TRECA study group). Evaluating the use of multimedia information when recruiting adolescents to orthodontics research: a randomised controlled trial. Journal of Orthodontics 2021; https://doi.org/10.1177/14653125211024250.

39. Palmer, B. W., Lanouette, N. M. & Jeste, D. V. 2012. Effectiveness of multimedia aids to enhance comprehension of research consent information: a systematic review. Irb, 34, 1-15.

40. Nishimura, A., Carey, J., Erwin, P.J., Tilburt, J.C., Murad, M.H. and McCormick, J.B., 2013. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC medical ethics, 14(1), pp.1-15.

41. Ciciriello, S., Johnston, R. V., Osborne, R. H., Wicks, I., Dekroo, T., Clerehan, R., O'neill, C. & Buchbinder, R. 2013. Multimedia educational interventions for consumers about prescribed and over-the-counter medications. Cochrane Database Syst Rev, Cd008416.

42. Tuong, W., Larsen, E. R., Armstrong, A. W. 2014. Videos to influence: a systematic review of effectiveness of video-based education in modifying health behaviors. J Behav Med, 37: 218-233.

43. Dekkers, T., Melles, M., Groeneveld, B. S. & De Ridder, H. 2018. Web-Based Patient Education in Orthopedics: Systematic Review. Journal of medical Internet research, 20, e143-e143.

44. Dahodwala, M., Geransar, R., Babion, J., De Grood, J. & Sargious, P. 2018. The impact of the use of video-based educational interventions on patient outcomes in hospital settings: A scoping review. Patient Educ Couns, 101, 2116-2124.

45. Knox, E. C. L., Quirk, H., Glazebrook, C., Randell, T. & Blake, H. 2019. Impact of technology-based interventions for children and young people with type 1 diabetes on key diabetes self-management behaviours and prerequisites: a systematic review. BMC Endocr Disord, 19, 7.

46. Indradat, S., Jirapongsananuruk, O. & Visitsunthorn, N. 2014. Evaluation of animated cartoon-aided teaching of intranasal corticosteroid administration technique among Thai children with allergic rhinitis. Asian Pac J Allergy Immunol, 32, 166-70.

47. Saengow, V. E., Chancharoenchai, P., Saartying, W., Pimpa, W., Chotichanon, N., Lewsirirat, T. & Srisantisuk, P. 2018. Epilepsy video animation: Impact on knowledge and drug adherence in pediatric epilepsy patients and caregivers. Clin Neurol Neurosurg, 172, 59-61.

48. Frémont, A., Abou Taam, R., Wanin, S., Lebras, M. N., Ollier, V., Nathanson, S., Hadchouel, A. & Drummond, D. 2018. Cartoons to improve young children's cooperation with inhaled corticosteroids: A preliminary study. Pediatr Pulmonol, 53, 1193-1199.

Contributors

PK obtained funding for TRECA and led the study. PK, JM-K, RS and SH developed the TRECA multimedia with Morph, and liaised with DP and JA on the FORCE-specific elements. RS and JM-K liaised with the TRECA PPI group. DP led the FORCE study. JM-K, JA, LS, TMB and DA set up the SWAT and obtained data. JR analysed the data. PK and TMB drafted the manuscript. All authors contributed to its revision.

We wish to acknowledge the significant contributions made by the TRECA PPI group, the TRECA advisory group, and the TRECA NIHR Study Steering Committee. The multimedia were developed in collaboration with Morph.

Table 1. Participant baseline characteristics

	PIS (n=728)	MMI (n=681)	Overall (n=1,409)
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 Deprivation index 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)

Table 2. Participant baseline characteristics of those recruited into FORCE

	PIS		MMI	
	Recruited (n = 484)	Not recruited (n = 244)	Recruited (n = 475)	Not recruited (n = 206)
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 Deprivation index 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)

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's or daughter's treatment or care might change if s/he 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	PIS, n (%)	0 (0.0)	4 (2.4)	9 (5.3)	47 (27.7)	97 (57.1)	13 (7.7)

trial were made clear in the information.	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	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)

the FORCE study.	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)

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 calculated mean/SD, N = total number of participants in category

Table 5. Decision Making Questionnaire scale analyses

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

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's or daughter's treatment or care might change if s/he 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	PIS	157	4 (1)	0.39	0.700
	MMI	149	4 (1)		

son or daughter should take part.					

Figure 1. CONSORT flow chart of participants through the FORCE SWAT

604x305mm (59 x 59 DPI)

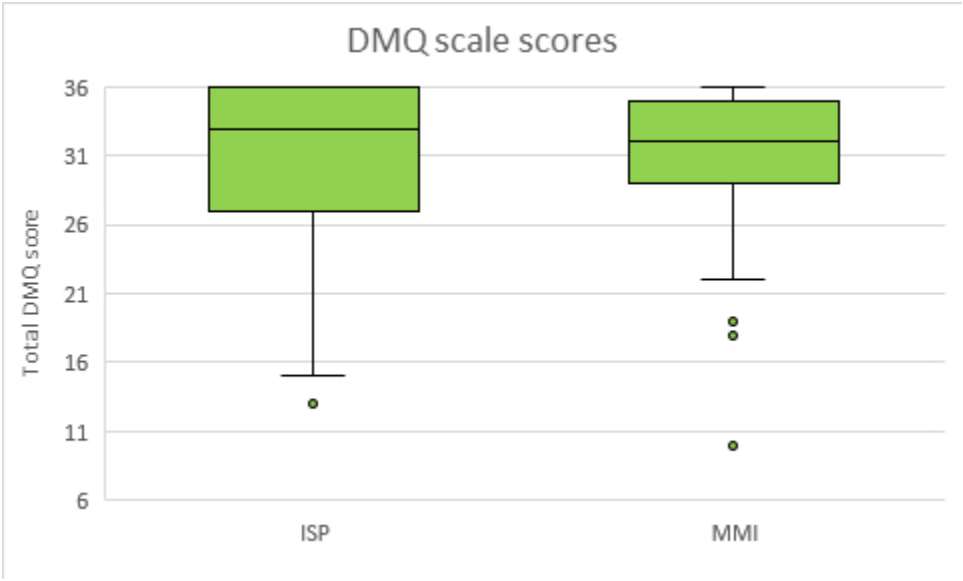

Figure 2. DMQ scale total scores boxplots

320x192mm (38 x 38 DPI)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7-8
	13b	For each group, losses and exclusions after randomisation, together with reasons	7-8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16-17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10-11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	Reference Martin-Kerry,2017
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	6

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

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)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-057508.R2
Article Type:	Original research
Date Submitted by the Author:	08-Jun-2022
Complete List of Authors:	Moe-Byrne, Thirimon; University of York Knapp, Peter; University of York; Perry, Daniel; University of Oxford Achten, Juul; University of Oxford, NDORMS Spoors, Louise; University of Oxford, Oxford Trauma, NDORMS; University of Oxford Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences, University of Oxford Appelbe, Duncan; University of Oxford, NDORMS Roche, Jenny; University of York, Health Sciences Martin-Kerry, Jacqueline; University of York, Health Sciences; Sheridan, Rebecca; University of York Higgins, Steven; University of Durham, School of Education
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Evidence based practice, Ethics, Paediatrics, Emergency medicine
Keywords:	MEDICAL ETHICS, Hand & wrist < ORTHOPAEDIC & TRAUMA SURGERY, Paediatric A&E and ambulatory care < PAEDIATRICS, STATISTICS & RESEARCH METHODS

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Title: 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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Keywords: SWAT, trial, recruitment, information, multimedia.

Word count: 3,768.

ABSTRACT

- **Objectives:** to evaluate digital, multimedia information for its effects on trial recruitment, retention, decisions about participation, and acceptability by patients, compared with printed information.
- **Design:** SWAT (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:** 1,409 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 (9 Likert items, analysed summatively and individually), 3 'free text' questions (deriving subjective evaluations), and trial retention.
- **Results:** Multimedia information 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=.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:** Multimedia information 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.
- **Trial registration:** TRECA ISRCTN73136092 and NINTMR SWAT97. FORCE ISRCTN13955395.

Strengths and limitations of this study

- The SWAT 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 FORCE trial consenters and few from FORCE non-consenters, which limits the generalisability of some of the findings.

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)

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 amongst 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, whether offline or as a website, involving the use of video, animations, audio and infographics. Multimedia information (MMIs) 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 TRECA (TRials Engagement in Children and Adolescents) study evaluated the effectiveness of multimedia resources compared to traditional printed information, for trial recruitment involving children and adolescents.(23, 24) The evaluation was undertaken through six linked SWATs (Studies Within A Trial), 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 FORCE (Forearm Fracture Recovery in Children Evaluation) 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 (i.e. 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 a multimedia information resource (MMI). 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 (CTU) running the FORCE trial.

The host trial (FORCE) was a NIHR Health Technology Assessment funded, multi-centred randomised controlled trial 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- and cost-effectiveness of soft bandage immobilisation and immediate discharge compared to 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 participant information sheet 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 MMIs contained all information content of the written participant information sheet, with text amended to improve readability and age-appropriateness when required. The TRECA MMIs were developed through extensive qualitative research and user testing, where principles of participatory design were used to develop their style and format (32, 33, 34) and informed by information design and principles of Plain English,(35) readability and age-appropriateness. The TRECA Patient and Public Involvement Group commented on the design and content of the MMIs during their development.(36)

The MMIs included five short video animations, each lasting 45-60 seconds (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 (5 with a study investigator; 3 with a Research Nurse; 1 with an adolescent and 3 with parents of children who had taken part in similar studies), each lasting 15-50 seconds and describing different aspects of the trial and clinical procedures. The FORCE video clips were created on one 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 MMIs took six-eight 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 webpages 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 PC, 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 9-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 NHS REC, 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=1,816). 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 v16 (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 odds ratio (OR), with associated 95% confidence interval (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 a using multi-level 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 multi-level 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, inter-quartile ranges (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.

Ethical approval

The TRECA study received approval from the NHS Yorkshire & 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., 2017). FORCE received approval from 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.

Funding Details

TRECA was funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research Programme (NIHR HS&DR 14/21/21).

FORCE was funded by the NIHR Health Technology Assessment programme (17/23/02) and further supported by the NIHR Oxford Biomedical Research Centre.

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 MMIs 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

Patient involvement

Patient and public involvement 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 MMIs, including the animations and written content.

Data sharing statement

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 questionnaire 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.

RESULTS

INSERT: Figure 1. CONSORT flow chart of participants through the FORCE SWAT

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 1,409 participants met the FORCE eligibility criteria at the 23 recruitment centres during February 2019 to July 2020. Baseline characteristics of the 1,409 patients that 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 eligible patients (71.0% compared to 84.3% at MMI recruitment centres), and higher proportions of some ethnic minorities. Participants at PIS recruitment centres also had higher (less deprived) IMD decile scores (4.7 (SD 3.1) compared to 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 1,409 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 (DMQs)

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 9 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= .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.

Insert: Figure 2.

DMQ 'free text' comments

All participants' responses are available in Appendix 1 (supplementary material).

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 (4 respondents); questionnaire follow-up timing and frequency (2 respondents); washing the bandage (2 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 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. Firstly, thirteen (4.0%) 'free text' respondents mentioned the age-appropriateness or age-suitability of the trial information. Among those allocated to the MMI there were ten comments, all of them positive. In those allocated to the PIS there were three comments on age-suitability (one negative and two positive).

Secondly, 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 MMIs. 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 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 MMIs were 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 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 multi-centre 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 has 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.

The multimedia resources and animations were produced by expert developers, and their content was informed by extensive empirical work and Patient and Public Involvement: 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 MMIs 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.

Multimedia information 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: firstly, more adolescents rated multimedia information as 'easy to understand' than those who saw printed information; multimedia also resulted in greater confidence in decision making.(38)

Secondly, MMIs 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 multimedia information 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 multimedia information 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 conditions 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 multimedia information 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 multimedia information and found it easy to use with patients. However, the MMIs 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 MMIs; and the overall effects of printed and multimedia information across all six SWATs within TRECA. However, there remains a need for further evaluation (potentially including qualitative methods) of the preferred design of digital, multimedia information in children's trials, its impact on outcomes and acceptability, and on trial recruiters' communication with patients.

REFERENCES

1. Treweek, S., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E., Sullivan, F., Jackson, C., Taskila, T. K. & Gardner, H. 2018a. Strategies to improve recruitment to randomised trials. Cochrane Database Syst Rev, 2, Mr000013.

2. McDonald, A. M., Knight, R. C., Campbell, M. K., Entwistle, V. A., Grant, A. M., Cook, J. A., Elbourne, D. R., Francis, D., Garcia, J., Roberts, I. & Snowdon, C. 2006. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials, 7, 9.

3. Caldwell, P. H., Dans, L., De Vries, M. C., Newman Ba Hons, J., Sammons, H., Spriggs, M. B. M., Tambe, P., Van't Hoff, W., Woolfall, K., Young, B. & Offringa, M. 2012. Standard 1: consent and recruitment. Pediatrics, 129 Suppl 3, S118-23.

4. Eder, M. L., Yamokoski, A. D., Wittmann, P. W. & Kodish, E. D. 2007. Improving informed consent: suggestions from parents of children with leukemia. Pediatrics, 119, e849-59.

5. Sheridan, R., Martin-Kerry, J., Hudson, J., Parker, A., Bower, P. & Knapp, P. 2020a. Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. Trials, 21, 259.

6. Nuffield Council on Bioethics. 2015. Children and clinical research: ethical issues. London.

7. Simon, C. M., Siminoff, L. A., Kodish, E. D. & Burant, C. 2004. Comparison of the informed consent process for randomized clinical trials in pediatric and adult oncology. J Clin Oncol, 22, 2708-17.

8. Barfield, R. C. & Church, C. 2005. Informed consent in pediatric clinical trials. Curr Opin Pediatr, 17, 20-4.

9. Stryker, J. E., Wray, R. J., Emmons, K. M., Winer, E. & Demetri, G. 2006. Understanding the decisions of cancer clinical trial participants to enter research studies: factors associated with informed consent, patient satisfaction, and decisional regret. Patient Educ Couns, 63, 104-9.

10. Tait, A. R., Voepel-Lewis, T. & Levine, R. 2015a. Using digital multimedia to improve parents' and children's understanding of clinical trials. Archives of disease in childhood, 100, 589-593.

11. Hunfeld, J. A. M. & Passchier, J. 2012. Participation in medical research; a systematic review of the understanding and experience of children and adolescents. Patient Education and Counseling, 87, 268-276.

12. Crane, S. and Broome, M. E. 2017. Understanding Ethical Issues of Research Participation From the Perspective of Participating Children and Adolescents: A Systematic Review. World Views on Evidence-Based Nursing, 14, 200-209. https://doi.org/10.1111/wvn.12209

13. Health Research Authority. 2016. Applying a proportionate approach to the process of seeking consent: HRA Guidance.

14. Hermann, M. 2002. [3-dimensional computer animation--a new medium for supporting patient education before surgery. Acceptance and assessment of patients based on a prospective randomized study--picture versus text]. Chirurg, 73, 500-7.

15. Hopper, K. D., Zajdel, M., Hulse, S. F., Yoanidis, N. R., Tenhave, T. R., Labuski, M. R., Houts, P. S., Brensinger, C. M. & Hartman, D. S. 1994. Interactive method of informing patients of the risks of intravenous contrast media. Radiology, 192, 67-71.

16. Tait, A. R., Voepel-Lewis, T., McGonegal, M. & Levine, R. 2012b. Evaluation of a prototype interactive consent program for pediatric clinical trials: a pilot study. J Am Med Inform Assoc, 19, e43-5.

17. Tait, A. R., Voepel-Lewis, T., Moscucci, M., Brennan-Martinez, C. M. & Levine, R. 2009c. Patient comprehension of an interactive, computer-based information program for cardiac catheterization: a comparison with standard information. Arch Intern Med, 169, 1907-14.

18. Hutchison, C., Cowan, C., McMahon, T. & Paul, J. 2007. A randomised controlled study of an audiovisual patient information intervention on informed consent and recruitment to cancer clinical trials. British journal of cancer, 97, 705-711.

19. Antoniou, E. E., Draper, H., Reed, K., Burls, A., Southwood, T. R. & Zeegers, M. P. 2011. An empirical study on the preferred size of the participant information sheet in research. Journal of Medical Ethics, 37, 557.

20. Shneerson, C., Windle, R. & Cox, K. 2013. Innovating information-delivery for potential clinical trials participants. What do patients want from multi-media resources? Patient Education and Counseling, 90, 111-117.

21. Office for National Statistics. 2019. Exploring the UK's digital divide. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04 (Accessed 20 January 2021).

22. Blower, S., Swallow, V., Maturana, C., Stones, S., Phillips, R., Dimitri, P., Marshman, Z., Knapp, P., Dean, A., Higgins, S., Kellar, I., Curtis, P., Mills, N. & Martin-Kerry, J. 2020. Children and young people's concerns and needs relating to their use of health technology to self-manage long-term conditions: a scoping review. Archives of Disease in Childhood, 105, 1093.

23. Martin-Kerry, J., Bower, P., Young, B., Graffy, J., Sheridan, R., Watt, I., Baines, P., Stones, C., Preston, J., Higgins, S., Gamble, C. & Knapp, P. 2017. Developing and evaluating multimedia information resources to improve engagement of children, adolescents, and their parents with trials (TRECA study): Study protocol for a series of linked randomised controlled trials. Trials, 18, 265.

24. Martin-Kerry, J. M., Parker, A., Arundel, C., Torgerson, D., Tilbrook, H., Watt, I., Bower, P., Treweek, S., Knapp, P. 2019c. SWATted away: the challenging experience of setting up a SWAT in paediatric trials. Trials; 20: 141.

25. Rick, J., Graffy, J., Knapp, P., Small, N., Collier, D. J., Eldridge, S., Kennedy, A., Salisbury, C., Treweek, S., Torgerson, D., Wallace, P., Madurasinghe, V., Hughes-Morley, A. & Bower, P. 2014. Systematic techniques for assisting recruitment to trials (START): study protocol for embedded, randomized controlled trials. Trials, 15, 407.

26. Treweek, S., Bevan, S., Bower, P., Campbell, M., Christie, J., Clarke, M., Collett, C., Cotton, S., Devane, D., El Feky, A., Flemyng, E., Galvin, S., Gardner, H., Gillies, K., Jansen, J., Littleford, R., Parker, A., Ramsay, C., Restrup, L., Sullivan, F., Torgerson, D., Tremain, L., Westmore, M. & Williamson, P. R. 2018b. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? Trials, 19, 139.

27. Achten, J., Knaight, R., Dutton, S., Costa, M., Mason, J., Dritsaki, M., Appelbe, D., Messahel, S., Roland, D., Widnall, J., Perry, D. A multi-centre prospective randomised equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilisation for torus fractures of the distal radius in children: Protocol for the Forearm Fracture Recovery in Children Evaluation Trial (FORCE). Bone & Joint Open; 2020. https://doi.org/10.1302/2633-1462.16.BJO-2020-0014.R1

28. Perry, D., et al. (FORCE trial paper, under review)

29. Madurasinghe, V.W., Sandra Eldridge on behalf of MRC START Group and Gordon Forbes on behalf of the START Expert Consensus Group. Guidelines for reporting embedded recruitment trials. Trials 17, 27 (2016). https://doi.org/10.1186/s13063-015-1126-y

30. Sealed envelope. 2019. Available at: https://www.sealedenvelope.com/ (Assessed 12 May 2020).

31. Morph, 2021. https://www.york.ac.uk/healthsciences/research/health-policy/research/force-summary/

32. Martin-Kerry, J. M., Knapp, P., Atkin, K., Bower, P., Watt, I., Stones, C., Higgins, S., Sheridan, R., Preston, J., Horton Taylor, D., Baines, P. & Young, B. 2019b. Supporting children and young people

when making decisions about joining clinical trials: qualitative study to inform multimedia website development. BMJ Open, 9, e023984.

33. Martin-Kerry, J. M., Higgins, S., Knapp, P., Liabo, K., Young, B. Engaging children, young people, parents and health professionals in interviews about abstract topics: using a ranking exercise to elicit views on health research. J Child Health Care (in press).

34. Sheridan, R., Martin-Kerry, J., Watt, I., Higgins, S., Stones, S. R., Taylor, D. H. & Knapp, P. 2019. User testing digital, multimedia information to inform children, adolescents and their parents about healthcare trials. J Child Health Care, 23, 468-482.

35. Knapp, P., Raynor, D. K., Silcock, J. & Parkinson, B. 2011. Can user testing of a clinical trial patient information sheet make it fit-for-purpose? - a randomized controlled trial. BMC Medicine, 9, 89.

36. Sheridan, R., Preston, J., Stones, S., Ainsworth, S., Horton-Taylor, D., Challinor, R., Ainsworth, S., Martin-Kerry., J.M., Brady, L-M. & Knapp, .P. 2020b, 'Patient and public involvement in a study of multimedia clinical trial information for children, young people and families', Research for All, vol. 4, no. 1, pp. 47-65.

37. StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC.

38. Knapp, P., Mandall, N., Hulse, W., Roche, J., Moe Byrne, T., Martin-Kerry, J. M., Sheridan, R., Higgins, S., (for the TRECA study group). Evaluating the use of multimedia information when recruiting adolescents to orthodontics research: a randomised controlled trial. Journal of Orthodontics 2021; https://doi.org/10.1177/14653125211024250.

39. P Knapp, R Heys, L Dabner, R Heys, K Sheehan, H Smartt, T Walker-Smith, CA Rogers, S Stoica, J Roche, T Moe-Byrne, J M Martin-Kerry, R Sheridan, E Coleman, S Higgins (for the TRECA study group). The effects of multimedia information on recruitment and retention in a children's cardiac surgery trial: A SWAT (Study Within A Trial). F1000Research 2022, 11: 340. https://f1000research.com/articles/11-340/v1

40. Palmer, B. W., Lanouette, N. M. & Jeste, D. V. 2012. Effectiveness of multimedia aids to enhance comprehension of research consent information: a systematic review. Irb, 34, 1-15.

41. Nishimura, A., Carey, J., Erwin, P.J., Tilburt, J.C., Murad, M.H. and McCormick, J.B., 2013. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. BMC medical ethics, 14(1), pp.1-15.

42. Ciciriello, S., Johnston, R. V., Osborne, R. H., Wicks, I., Dekroo, T., Clerehan, R., O'neill, C. & Buchbinder, R. 2013. Multimedia educational interventions for consumers about prescribed and over-the-counter medications. Cochrane Database Syst Rev, Cd008416.

43. Tuong, W., Larsen, E. R., Armstrong, A. W. 2014. Videos to influence: a systematic review of effectiveness of video-based education in modifying health behaviors. J Behav Med, 37: 218-233.

44. Dekkers, T., Melles, M., Groeneveld, B. S. & De Ridder, H. 2018. Web-Based Patient Education in Orthopedics: Systematic Review. Journal of medical Internet research, 20, e143-e143.

45. Dahodwala, M., Geransar, R., Babion, J., De Grood, J. & Sargious, P. 2018. The impact of the use of video-based educational interventions on patient outcomes in hospital settings: A scoping review. Patient Educ Couns, 101, 2116-2124.

46. Knox, E. C. L., Quirk, H., Glazebrook, C., Randell, T. & Blake, H. 2019. Impact of technology-based interventions for children and young people with type 1 diabetes on key diabetes self-management behaviours and prerequisites: a systematic review. BMC Endocr Disord, 19, 7.

47. Indradat, S., Jirapongsananuruk, O. & Visitsunthorn, N. 2014. Evaluation of animated cartoon-aided teaching of intranasal corticosteroid administration technique among Thai children with allergic rhinitis. Asian Pac J Allergy Immunol, 32, 166-70.

48. Saengow, V. E., Chancharoenchai, P., Saartying, W., Pimpa, W., Chotichanon, N., Lewsirirat, T. & Srisantisuk, P. 2018. Epilepsy video animation: Impact on knowledge and drug adherence in pediatric epilepsy patients and caregivers. Clin Neurol Neurosurg, 172, 59-61.

49. Frémont, A., Abou Taam, R., Wanin, S., Lebras, M. N., Ollier, V., Nathanson, S., Hadchouel, A. & Drummond, D. 2018. Cartoons to improve young children's cooperation with inhaled corticosteroids: A preliminary study. Pediatr Pulmonol, 53, 1193-1199.

Figures

Figure 1. CONSORT flow chart of participants through the FORCE SWAT

Figure 2. Barchart summarising scores in TRECA SWAT arms

Contributors

PK obtained funding for TRECA and led the study. PK, JM-K, RS and SH developed the TRECA multimedia with Morph, and liaised with DP and JA on the FORCE-specific elements. RS and JM-K liaised with the TRECA PPI group. DP led the FORCE study. JM-K, JA, LS, TMB and DA set up the SWAT and obtained data. JR analysed the data. PK and TMB drafted the manuscript. All authors contributed to its revision.

Acknowledgement

We wish to acknowledge the significant contributions made by the TRECA PPI group, the TRECA advisory group, and the TRECA NIHR Study Steering Committee. We thank Izzy Coleman and Ian Watt for their advice. The multimedia were developed in collaboration with Morph.

Competing interests

There are no competing interests for any author

Table 1. Participant baseline characteristics

	PIS (n=728)	MMI (n=681)	Overall (n=1,409)
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 Deprivation index 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)

Table 2. Participant baseline characteristics of those recruited into FORCE

	PIS		MMI	
	Recruited n = 484 (66%)	Not recruited n = 244(34%)	Recruited n = 475(70%)	Not recruited 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 Deprivation index 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)

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's or daughter's treatment or care might change if s/he 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	PIS, n (%)	0 (0.0)	4 (2.4)	9 (5.3)	47 (27.7)	97 (57.1)	13 (7.7)

trial were made clear in the information.	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	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)

the FORCE study.	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)

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 calculated mean/SD, N = total number of participants in category

Table 5. Decision Making Questionnaire scale analyses

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

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's or daughter's treatment or care might change if s/he 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	PIS	157	4 (1)	0.39	0.700
	MMI	149	4 (1)		

son or daughter should take part.					

Figure 1. CONSORT flow chart of participants through the FORCE SWAT

604x305mm (59 x 59 DPI)

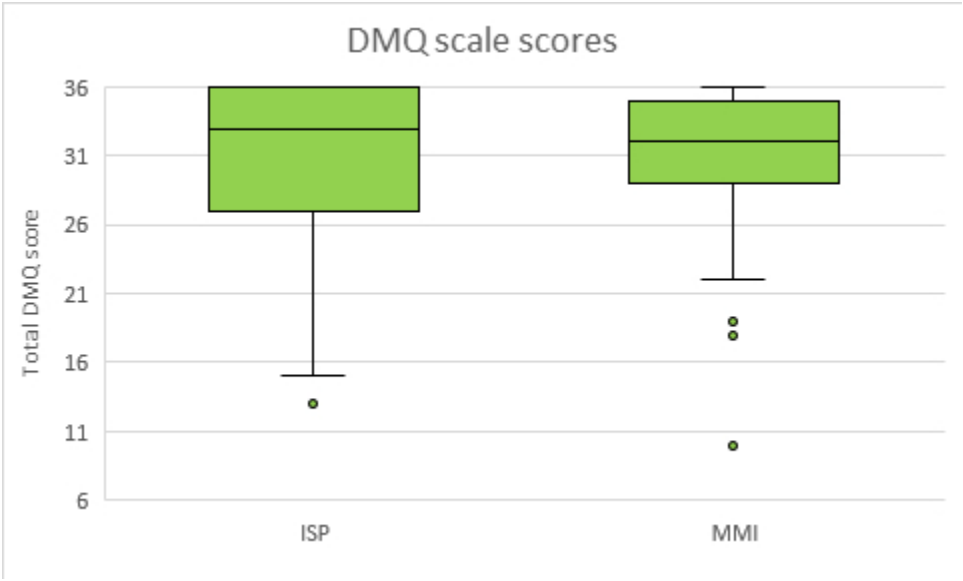

Figure 2. DMQ scale total scores boxplots

320x192mm (38 x 38 DPI)

Appendix 1. Free text comments

FORCE PIS FREE TEXT

10b. Was there anything you wanted to know about FORCE study but which wasn't included in the information you saw? If yes, please write them here.
The question that would be asked. Allowance for deviation -eg-have splint but child feeling ok - could it come off early. Soft bandage -how long ?? Return if child still uncomfortable
About the disadvantages of taking part in study.
What the hospitals current practice was- I asked this question whilst in A+E
The length of the follow on questionnaires we would be sent on day1 , day 3 etc.
I WANTED MORE INFO ON TREATMENT RISKS BUT PURPOSE OF STUDY IS TO ASSESS THEM! MY SON IS 14 AND I WANTED HIM TO BE DECISION MAKER HAVING HEARD+CONSIDERED INFO.
There should be a child friendly leaflet included, I had to ask my son whether he is happy with answering questions on the i-pad, as well as the computer selecting the treatment bandage or splint.
I wasn't completely sure if my child would get the best treatment if we took the study but the Dr said normally there would be no treatment so something felt better than nothing at all.
It was not mentioned if the splint gets dirty from perspiration due to change of weather or what to do in these circumstances.
I may have missed it but I felt the need to seek clarification from the staff member about whether we could change the treatment part-way through the study.
Good description of possible risks of taking part. I didn't properly read the explanation whilst in hospital as I had two young children with me but it was well explained when I read it at home. A bit more explanation of what buckle fracture are and maybe a picture/photo/diagram would have been helpful. I found this later on NH's website.

11. Can you tell us which aspect(s) about FORCE study was explained well in the information you saw? Please write them here:
All of them
Everything was explained really well. And the consultant was really helpful.
About my daughter's fracture
Reason for doing study
All aspects were explained well.
Treatment plan, Reason why
Not really
Benefits of potentially improving care for others as a result of finding out more about which treatment option is best to promote speedy recovery.
How to help the children Nationwide for better treatment.

All of it.
Section 5
Why the study was important.
No1- important things you need to know and no2. what treatment will my child receive. That helped me make my decision about taking part.
The two types of treatment possible in the study.
I THOUGHT IT WAS WELL WORDED AND DIDN'T NEED TO CLARIFY ANYTHING.
All of it.
That it will help others in the same situation as us.
Everything was covered just a lot of info to read.
Why it was being conducted. That we could change our mind at any time and opt for a different treatment.
That if we wasn't happy at all with anything we could change our minds.
The reasons for doing the study and how the study would happen/involvement/expectation
Why my child was chosen. How the study would benefit treatment in the future. How much correspondence I would receive. That my child would receive a voucher for taking part. That we could leave the study at any time. Essentially all was well explained.
Information sheet and Patient Information Leaflet
The introductory section 'What is Force'? Was precise and clear and gave an informative snapshot of the research. (age 10)my daughter information sheet was excellent. She understood exactly and could discuss the information with clarity.
I liked the idea of my child wearing a stretchy bandage! As I am legal guardian of my nephew, he has Foetal Alcohol Syndrome and would have been very distressed wearing a splint bandage. So, him being part of this study gave him another option.
I am very happy about everything and also my son. Very nice explanation, approach, empathy. Very positive.
SELECTION PROCESS. ONE AREA NOT COVERED IS PERCEPTION.PEOPLE UNDERSTAND CASTS/SPLINTS. THEY RECOGNISE THE NEED TO EXERCISE CARE TOWARDS AND FOR THEMSELVES. MY CONCERN IS PEOPLE (PARTICULARLY OTHER STUDENTS) WILL NOT PERCEIVE THE NEED FOR CARE BECAUSES INJURY TREATMENT PLAN IS LESS OBVIOUS.
The nurse we saw took time to explain which treatment my child could have, she broke it down in to easy language for my child who has Asperger's. We understood that this study was to determine what treatment is more successful in children.
POSSIBLE BENEFITS OF BANDAGE VS SPLINT IN RANGE OF MOTION IN WRIST. IF MY CHILD CHANGES HIS MIND ABOUT TAKING PART IN THE STUDY IT IS OK. THERE ARE NO RISKS TO TAKING PART. IT WILL HEAL WHETHER BANDAGE OR SPLINT USED.
No, all of it.
The reasons for the study.
Treatment, when we would be contacted, that it was our choice whether to take part.

It was made clear that my Daughter didn't have to take part if she didn't want to and that this study will help others in the future.
The difference in treatment options
What the intention of the study was and how it may help future treatment decisions for buckle fractures.
EVERYTHING. THANK YOU.
What the study covers and how it will be use for future treatment or care.
Purpose, potential outcomes+reasons for study.
THE NEED FOR BETTER EVIDENCE ON THE PREFERRED TREATMENT ROUTE. THE NEGATIVE ASPECT OF THE SPLINT (REDUCED MOBILITY FOR A PERIOD AFTER/STIFFNESS)
Why there is no risk to the healing of the injury based on taking part in the study
All of it.
Two different causes of treatment depending on answers from initial questionnaire on ipad. How this study could help future treatment for children.
You can withdraw at any time. What the study was trying to achieve.
All aspects.
How long it takes
I am happy with all aspects
The purpose of the study was explained well.
The reason of the study.
The doctor's explanation persuaded me to take part. NOT the printed material.
We can withdraw at any time during the study.
If we were to change our mind, we can pull out of the study at any point.
Information about how the procedure would be done, how long it would take.
The reason for the study. What they were hoping to achieve.
The fact that my child would be given a bandage or a splint to support their healing.
How the study could reduce the need for X-rays for children.
How it may help future diagnosis
It was all explained well.
About things to look out for and how to deal with them.
The reason for doing the study
It was clear and the information given to my daughter explained it well.

Available options
Everything really but In particular:- When + how we will be contacted over the next few weeks.
All aspects
the reasons why the study was undertaken i.e improve management of buckle fractures, making it better for the child. The option to opt out at anytime/ not taking part at all was fully explained, felt no pressure to undertake the study. Decision was solely based on improving care and in my child's case, he 50/50 option of having 'bandage' really appealed.
I thought the information regarding children maybe not needing a brace in future with this injury and the reasons behind was interesting.
The reason why the study is taking place and how the study is being conducted.
All of it.
All aspects.
The study would help understanding of pain management.
Aim of the study. Comparison of the 2 treatments.
Clear instructions. Colourful.

12. If you have any other comments about the information you were given about the FORCE study, please write them here:
None
None
Person was very informative, but decision was based on how active my child is
We decided not to take part in the study because we were concerned about our daughter and her healing. She is quite a clumsy girl and we were worried if she only had a bandage, and fell again, she would cause more damage. More information about this to ease our concerns would of been helpful.
The study was explained well by the nurse in charge.
THERE COULD BE MORE INFORMATION UP IN THE WAITING ROOM SO IF YOUR GIVEN THE OPTION YOU'VE ALREADY NOTICED INFROMATION. WE DID SEE A SIGN ON THE WALL SAYING FORCE STUDY+MY SON ASKED WHAT IT WAS BUT I COULDN'T TELL HIM.
N/A
The next day the hospital rang us to have a follow up appointment at the fracture clinic. We therefore attended straight away. My daughter was examined by a doctor and asked questions. She then said she would get a soft cast applied to my daughter's arm. I was somewhat confused as at A&E we were told the treatment for this injury was usually a splint or as part of the study it would be a splint or the soft bandage. I then mentioned the study to which she said to not worry about what she had said but this has left me questioning what the usual treatment procedure is and the decision I had made. I therefore hope there is no detrimental effect to the health and wellbeing of my daughter.
The last question referring to health/wellbeing wasn't specific enough - was it referring to general health before injury or after injury??

Detailed and clear
Very informative doctor and study coordinator through paperwork, no queries whatsoever. Good Luck!
Good clear choice! Not clear about second paragraph- what is an optional bandage? Or a hard splint? - Perhaps a small picture to show what those are.
None
I WAS PARTICULARLY IMPRESSED WITH THE NURSE WHO EXPLAINING THE STUDY TO US. HE TOOK THE TIME TO ENSURE MY SON KNOW WHAT WAS INVOLVED AND THAT HE WAS HAPPY TO TAKE PART. ALSO HAVING THE CHILD SEEN THE SCREEN WAS A NICE TOUCH TO MAKE MY SON FEEL INVOLVED.
No
I like it that the computer choose to randomise which trial a patient will be group.
As soon as I saw the information sheet and was asked I said yes. My company is all about innovation/NPD/insight and this research is vital. All I would say is having gone through (and sort of been sold) the ipad induction we felt disappointed to be allocated the traditional method. Needs slightly different intro to the study.
I decided on a splint due to the doctor advising this and my son holding his arm up to support it as it's causing him a lot of pain.
Yes, the question to asked of the children were not applicable e.g. can you brush your teeth - the accident had only just happened.
Staff explained enough to understand
What to do if the children tells you if the splint is causing an itch or other discomfort which cannot avoided.
N/A
N/A
The researcher was very clear about the study and said early on that it was a random allocation between soft bandage/splint. As I have an active child I didn't feel confident with a soft bandage. My daughter fractured her other wrist 2 years ago and had a splint then. She wanted a splint again as she felt it was helpful. So, in short, I stopped the researcher before she could offer us written information.

FORCE MMI FREE TEXT

10b. Was there anything you wanted to know about FORCE study but which wasn't included in the information you saw? If yes, please write them here.
But the team who dealt with my son were fantastic and very informative
Our treatment was opted as 'bandage'. I would like to have known how long the bandage have to stay on for. I would like to have known what the current treatment option nationally is recommended for a compound fracture.
No, everything I needed to know was explained in full by the doctor carrying out the study and the short film.
If my son had not taken part would his treatment be any different as he got a bandage for a fracture but would he have had something different?

No, very useful.
How many surveys these would be to complete and on what frequency.
It would have been good to have more written information rather than the videos as they didn't have subtitles and it was hard to hear in the hospital.
Yes it was fully explained by the ENP e.g whether she would have any problems with either course of action.
Evidence for and against each type of support/bandage.
cost of replying to text messages, If over 12 ?card text go to child, It wasn't really clear what advantages/disadvantages were, lots of questions were n/a such as how it feels to brush teeth, put on clothing, n/a in ED setting.
The benefits and disadvantages for my child.
I didn't ask if my son would be in more pain not having a splint and that it's purely a recovery study and not about pain management.
I am not sure I understand whether there are any disadvantages of not taking part in the FORCE study?
Why the reason for the study? I understand that we aren't certain on the best treatment for this injury but what is the research and science behind undertaking the trials? Do we have evidence that this trial is trying to prove?
The disadvantages it could cause comparing pro's and con's to each treatment.
I WAS NOT MADE AWARE OF ANY DISADVANTAGES TO THE STUDY? WOULD BE INTERESTED TO KNOW WHAT THEY ARE.
NO, IT WAS ALL EXPLAINED REALLY WELL.
Whether you can opt out of FORCE after you answered questions
THE FORCE THEY ARE DOING EXCELLENT JOB I AM VERY PLEASE WITH THEM. THEY ARE HARD WORKING STAFF I AM VERY PLEASE WITH THEM.
Will this study be published/when? Why are children with minor fractures being used for a research? (especially when they are still growing up and so are their bones). After long waits in A&E is difficult to spend even more time answering questions for a study.
1. How often do I change bandage? 2. How long should the bandage be left on? 3. Where do I obtain clean bandages from?
Would the study differ on the healing of each child? E.g some children heal faster than others.

11. Can you tell us which aspect(s) about FORCE study was explained well in the information you saw? Please write them here:
I thought it was all explained well. I don't remember seeing any disadvantages.
Everything from why it was being ?called out, to how my child would take part to how I can find out results
The questions were age appropriate for my son. Ultimately, I would want the best treatment for my son. I like the way you can change treatment if necessary and taking part will help treatment in the future for children with the same sort of injury.

All explained well.
The rationale behind the study was well explained.
All of it was explained in detail to both me and (*child's name*).
All of it.
Everything was explained well.
All information was clearly explained in regards to the main reasons for the study and why the research was being undertaken.
The study design was straight forward and the information provided explained this clearly.
What the study was for and why they were doing it.
All aspects explained in detail, especially about the different healing ways/ (splint) or (bandage).
How my child's wrist injury would be managed weekly by text and if any issues came up I could always return to the hospital for support.
IT WAS ALL EXPLAINED WELL.
The fact that it is not clear whether splint or bandage works better.
The importance of research into dealing with fractures treatment.
The research nurse made the whole study very clear. The videos on the website were harder to access due to slow wifi and no service at (*hospital name*) so maybe more written information with video's would be helpful on the website.
The doctor was fantastic and delivered all information, the above question was just something I thought afterwards.
Type of fracture and different course of treatment
It was all good and well explained.
Everything about what's been doing and how it will help people/children in the future.
IT WAS ALL EXPLAINED WELL.
THE REASON'S FOR THE STUDY. THE TREATMENT
All aspects were explained well including the reasons for the research.
It was all explained well and showed very good.
The overall aim.
Information on the injury and how the child felt.
The goals of the study and the different treatment types
The reason behind the study and how you may get a splint or not to help work out which treatment is best.
Everything was explained very well. Both my son and I knew what to expect and was happy to take part.
The doctor explained clearly.

the study between the different types of methods used for the repair of bones and the difference between a splint and bandage and if there are different benefits/results. That we would be asked questions as a patient and carer about the pain etc and this would be used as part of the trial and we would monitor progress. That if we were unhappy at any stage during the study we could withdraw participation.
How the ability to move the limb was particularly better for the child.
Can't remember the info really.
Why you were doing the study, options we had, what you will do with info collected. How the study was implemented.
Video was a good visual tool, but very minimalistic and not a great deal of detail or content.
How it worked and what was going to happen.
It helped to determine what will be the best treatment. Also, it gave my little daughter the ability to know about her treatment.
A&E my daughter broke her arm.
What will happen and why study taking place.
the comparison of outcome before splint vs bandage . -the outcome. -the random selection.
2 different support options
Felt happy with how the whole FORCE study has explained.
The treatment options and how what treatment my son would get was decided. Why this study being carried out.
Presentation style easy to understand for all age groups.
The benefit to future patients and the impact on the ~500K similar fractures per annum treated by the NHS
The medical practitioner was so kind and explained the different types of fractures and difference between young and old bones.
Why the study was being done. How it is decided.
Everything was explained very well to me and my son, so we could make an informative decision.
How you were selected to determine which treatment option you had. Overall all aspects were clear for children to understand.
How times have changed and no longer need a cast as only a bump in bone on wrist
Why the study was being done was explained clearly.
THAT THERE WOULD BE NO ADVERSE EFFECTS FROM NOT HAVING A BRACE/SPLINT IF THAT WAS THE OPTION CHOSEN.
The reasoning behind the study was explained well.
The random selection of either a splint or a sling and that this study will help provide more information on how best to treat buckle fractures or not at all. (In children)
I found it difficult to answer questions for my 4 years old that are not age appropriate eg, can he do his zip up? -he can't do that yet anyway. There were lots of things like that e.g pour from a jug, tie shoes laces etc etc. I suggest having

an option for 'not learnt yet' or make the example something a younger child can do. this questionnaire sound like you want to know about information given before choosing to participate in the study than the study itself?
Treatment was very clear.
All of it- simple and clear. Direct
Where it clearly talked about the random selection of treatments.
The advantages of choosing the right treatment.
The positives and negatives of the study were all explained very well and to our son
The information about how they wanted to know what was better use for a fractured wrist (a splint or bandage)
I was all explained well, from the doctor to the researcher.
How the trial will be carried out and why it is being carried out to a point.
How the data collected could help to better decide the treatment given for the type of injury to the age group.
All aspects were well explained
How it will help treatment for fractures in the future.
Everything
All aspects explained well including reasons why the study was being conducted, how, the various conditions of the study and the proposed findings.
Missing data
All of it. Helpful video and explanation.
The benefits of the study, how it will help future patients and how new methods can be tested.
Why it is needed. How the study works.
All the info displayed and shown on the tablet was clear.
About the research
The outline of the study was clear and the fact we would be contacted during the study for updates etc.
Why they are carrying out the research what the research was and what they are hoping to achieve.
I HAD NO IDEA IT EXISTED, BUT WAS FILLED IN REALLY WELL.
The differences between the different types of treatment and what they meant.
It was good that if you didn't want to take part you don't have to??? It a choice
liked the video for children
THEY EXPALINED SO CLEARLY AND POLITE WAY. THEY ARE DOING WELL DONE JOB AND HONESTLY THE JOB STATISFACTORY. GREAT.
National study/research. Ways of treating a buckle fracture: with or without splint.

I like the fact there's a video showing what RCTs are.
That it would help in future treatment of similar injuries.
How it's going to help to decide what best action to use in treatment
1. What is a clinical trial and why we have them. 2. Consent-What is consent/informed decision making
How the treatment my son would receive would be down to the computer but still help his recovery. If the treatment didn't work we could withdraw anytime.
N/A as my son opted for a splint rather than taking part and watching on video
Very well presented. Clear and quite easy to understand.
Using the splint to a bandage I personally would choose splint for protection but make parents aware or coach them to help their child to do physio.
The video we saw explained what the study was looking for very well. It was clear about the different types of treatment we would receive depending on what was randomly allocated.
I had never heard of a buckle fracture before but the nurse explained everything I needed to know in detail and answered all my questions.
It was clear+colourful+engaged adult + child. Suitable for age of my child (10 yrs) to understand.
All aspects
All aspects of the Force study was told to me correctly and as my daughter has autism, this way of doing things has enabled my child to be led stressed about her accidents
The purpose for the study in gathering information on the best way to treat children for a quick/best recovery.

12. If you have any other comments about the information you were given about the FORCE study, please write them here:
It would be interesting to know the outcome once complete.
Very informative
I think it is a good idea my daughter has her 2nd buckle fracture and says the splint feels like a hug on her wrist
We elected not to participate as I felt that the study design was not appropriate for us. We attended due to my child's pain after good simple analgesic at home and if we had been allocated to the study arm she would have received only a bandage which would have been unlikely to have alleviated her pain as effectively as the splint. Given that the aim of the study was to avoid consequences of longer term use of the splint, but that patients presenting are in acute pain due to the fracture. i was not clear why the study design had not been to allow short term use of a splint for pain management an the study arm. if this had been the design, we would have participated. I am happy with the decision not to participate as the splint was very effective in alleviating my child's pain. Thankfully, my child has not had any pain, stiffness or difficulty since removal of the splint.
At first I was slightly worried about taking part in the study allowing my child's wrist to heal without help but I am extremely happy so far with progress at the end of week 2 although she is still in a little pain at times. She is improving.
We got lots of information about the study but that got in the way slightly of information about what my son should or shouldn't do with his injured wrist whilst it heals.

THE CONSULTANT WAS CLEAR AND CONCISE.
ALL STAFF WERE VERY HELPFUL AND INFORMATIVE. GREAT TO BE DOING RESEARCH.
It was good, it was all electronic, so quick and easy for us and staff.
I think it is a very good research programme and if it works hopefully the findings will help children and help save the NHS money.
Question seem to lack purpose when being asked in on ED setting. I hadn't waited long to be seen, but if I had been there a long time, I would find these question inappropriate and a waste of time.
I think involving kids in watching the videos makes them feel more involved and plays on important role in helping them to feel better physiologically.
All the information given was fine. Being in A+E is stressful as my daughter was in a lot of pain and I was naturally protective. If the trial had suggested that she would not wear a splint I think this would have caused me and my daughter a lot more anxiety.
VERY GOOD ONLINE FOLLOW-UP/QUESTIONNAIRE
Again just to reiterate question 10. I am a little worried as a mum that am I causing him more pain choosing this as his treatment was a bandage , not a splint.
Information given at the hospital about taking part was very clear but the study itself wasn't easy to do because it wasn't age appropriate and the wording of some questions was confusing eg 'since the accident can your child do x---- rather than making it clear you mean at a specified point in time.
The film we watched on an ipad in the hospital has much too fast moving for us to be able to follow.
had a small child with me and therefore needed to leave quickly
Firstly diagnosed as sprain, 2nd X-ray review next day spotted fracture, had call re: trial but not qualify as delay in diagnosis
As our son is exceptionally active and sports orientated both of us as parents and our son preferred the splint option on this occasion
No
The video could include what paperwork and questionnaire will need to be undertaken whilst participating in the trial. More guidance on if your child needs alter their treatment and where to go? Hospital or GP?
Friendly staff and help was good.
N/A
I AM GLAD WE TOOK PART AS MY SON WOULD HAVE JUST HAD A CAST BUT HE ACTUALLY DOES NOT NEED ONE.
I did not 'view' the information about the study at the hospital. I spoke with the research nurse and she gave me clear, comprehensive information. I am a nurse, so I was automatically interested in taking part. I have since looked at the website at home. I thought it was beautifully designed. The graphics were very engaging and the clear information made it very effective. It was great to have the section for kids specifically.
I AM HAPPY AND PLEASED WITH THEIR SERVICES. THE FORCE THEIR WORK IS EXCELLENT
We should (as a country) do way more of these - hopefully the site, videos and tools can be rolled out to trial everything

I was relieved when we got the 'splint' so not sure if I could have continued without any support for my son's arm. Perhaps reassurance that there wouldn't be any negative outcomes if you did end up with 'nothing' would have made me feel less nervous about agreeing to the trial.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	3
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	3
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	7-8
	13b	For each group, losses and exclusions after randomisation, together with reasons	7-8
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16-17
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	8
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8-9
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	10-11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10-11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10-11
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	Reference Martin-Kerry,2017
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	6

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.