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Development and validation of a new tool to assess quality of decision-making by older children and parents about research participation

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ABSTRACT

Objective: Effective decision-making is crucial for children and young people's trial participation, but specific tools to measure it are lacking. The TRECA (TRials Engagement in Children and Adolescents) Decision-Making Questionnaire (DMQ) was developed to fill this gap and has been evaluated for reliability and validity

Methods: We created the TRECA Decision-Making Questionnaire, based on similar measures for adults, and recruited participants through seven Studies-Within-a-Trial (SWATs). Participants were randomly assigned to receive trial information either as a printed Participant Information Sheet or Multimedia Information, or both, and asked to complete the DMQ. We calculated item completion rates, item-remainder statistics and Cronbach's Alpha, and conducted factor analysis.

Results: 549 participants (433 parents/guardians, 116 older children) completed a DMQ. It had high completion rates and internal consistency (Alpha = 0.88 for parents/guardians and 0.84 for older children) and moderate to high inter-item correlations. The DMQ had a single factor accounting for 53 % of variance.

Conclusions: The TRECA DMQ is a useful tool for evaluating research participation decisions in older children, as well as parents and guardians.

Practice implications: Our study suggests that the TRECA DMQ can be used to assess the quality of decision-making about trials in parents, guardians and older children.

1. Introduction

Treatments for children and young people for various health conditions are under-researched, with findings from adult research trials not always applicable to children and young people. The lack of safety, dosage, and effectiveness data in paediatric populations has resulted in many medical treatments for children and young people being used off-label [1]. However, medication safety and efficacy profiles differ significantly for children and adults due to developmental factors and disease pathophysiology, which can increase the risk of harm [2,3]. High quality trials involving children and young people are essential, particularly in ensuring a diverse and representative range of participants, to ensure that medication and other treatments are effective and safe [4–6]. Participant or proxy consent must be obtained for trials, and the involvement of children in consent or assent decisions will vary according to individual circumstances and what has been agreed for each trial.

Guidelines for obtaining informed consent in clinical trials place more emphasis on providing information to potential participants rather than evaluating their understanding and the quality of decision-making. As a result, significant numbers of trial participants may withdraw prematurely, often due to a lack of understanding, negatively affecting the integrity and value of research [7,8]. While knowledge and understanding are important, they are not the only components required for informed decision-making about research participation [9–11]. Existing measures often emphasise how much a person knows about the research and fail to consider important aspects such as the influences on decision-making and what matters most to an individual.

Recent studies have explored children's decision-making about research [12], their understanding of health, illness and healthcare [13,

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14], and their level of involvement in decisions [14,15]. The research indicates that many children have the capacity to be fully involved in decision-making. For example, when materials are tailored to the age of the child, children from the age of six years can comprehend concepts about their involvement in biomedical research [16]. Most children also have capacity to understand information about research assent [16]. However, within healthcare there tends to be a lack of record-keeping on whether research choices have been given to children [17,18].

Over the past 15–20 years, there has been growing interest in ways to increase both the rates of recruitment and retention to research, particularly trials, and the quality of decision-making about participation. While there has been significant research on the recruitment strategies for clinical trials in adults, there is a notable lack of attention given to paediatric trials. Also, children from socioeconomically deprived backgrounds may be underrepresented, which may affect the generalisability of trial findings and the effectiveness of treatments across diverse populations [19]. A 2018 Cochrane review about strategies to increase recruitment to trials, reported that none of the 68 included studies addressed recruitment to paediatric trials [20]. Similarly, tools to assess decisions about research participation have exclusively involved adults, and there is currently no validated tool to measure the quality of decision-making by children and young people about whether to participate in research [21].

The TRECA (TRials Engagement in Children and Adolescents) was a SWATs (Studies Within A Trial) study [22,23], funded by the UK National Institute for Health and Care Research (NIHR HS&DR 14/21/21). TRECA evaluated the use of multimedia information resources as an alternative, or supplement, to a traditional printed participant information sheet (thereafter referred to as printed information) when recruiting children and young people to trials. A SWAT is a research method used to improve the design, conduct, and reporting of randomised controlled trials. SWATs are self-contained studies embedded within clinical trials (also known as host trials), aiming to address uncertainties in the processes of designing, conducting, analysing, or reporting trials [24–26]. In the TRECA study, there were six host trials set within a range of health conditions and recruiting children of various ages, namely FORCE (The Forearm Fracture Recovery in Children Evaluation), CHAMP UK (The Childhood Atropine for Myopia Progression), THERMIC-3 (Intermittent Antegrade Warm Blood versus Cold Blood Cardioplegia in Children Undergoing Open Heart Surgery), BALANCE (Binocularly Balanced Viewing Study), BAMP (Bone-anchored maxillary protraction), and UKALL 2011 (United Kingdom Trial for children and young adults with Acute lymphoblastic Leukaemia and Lymphoma 2011). We also included one SWAT within a hypothetical trial setting, the BAMP sub-study [27], which used the setting and materials of the BAMP trial. After the BAMP clinical trial had closed to recruitment, there was an opportunity to evaluate the two forms of trial information with a larger number of older children awaiting orthodontic treatment, who were not being recruited to the BAMP trial itself. During this process, we requested them to imagine being invited to participate in the BAMP clinical trial.

The multimedia information used a website to deliver information which included videos, animations, text, and audio to children and young people and their parents/guardians. The study was designed to evaluate whether the use of multimedia information was more effective than traditional printed information for informing and recruiting children and young people and their parents /guardians about clinical trials. The TRECA SWATs were embedded in of the six host paediatric trials in the UK.

When developing the Decision-Making Questionnaire (DMQ) we wanted to capture participants' and their parents/guardians' opinions about whether the host trial information they received supported decision-making about participation in a trial. If the questionnaire was able to identify the quality of decision-making, this questionnaire could be used more widely within paediatric trials, as a way of assessing the need for changes to recruitment and retention processes.

1.1. Aim

The aim of this study was to assess the psychometric properties of the developed TRECA DMQs, by assessing completion rates and the contribution of individual questionnaire items, the DMQ internal consistency, and the presence of underlying factors.

2. Methods

2.1. Development of the DMQ

We identified existing decision-making questionnaires by undertaking a search within PubMed and through discussion with the wider TRECA team who have used decision-making questionnaires in previous studies. The TRECA Decision Making Questionnaire (DMQ) was developed and derived conceptually from existing measures used in adult trials, including one used within the REFORM trial [28], and the SURE [29] and DelibeRATE measures [30], which relate to decisions about treatments. We used these tools to develop statements that aligned with those used in existing tools but were appropriate for children and young people and their families when deciding whether to take part in a paediatric trial. The draft DMQ was reviewed by the wider TRECA team, including our PPI members, and refined to ensure the statements were clear. Likert scale options were modified from those used in adult questionnaires. For example, SURE uses 'strongly agree through to strongly disagree', whereas we felt children and young people would find it easier to respond to the options 'very hard through to very easy'.

The DMQ for included nine items with Likert options, which covered three areas (appraisal of information clarity; effects on behaviours; and confidence in decisions) plus an overall assessment of information utility. Each Likert item had five response options: 'very hard', 'hard', 'ok', 'easy' and 'very easy' for the first question, and 'not at all', 'not really', 'not sure', 'yes mostly' and 'yes completely' for the remaining eight questions. These were followed by three open-ended questions allowing respondents to appraise the information (see Appendix 2 and 3).

The DMQ was developed for older children (intended for ages 12 and over) and parents/guardians, to obtain decision quality scores both from individuals who decided to take part in the host trial and from those who decided to decline. We also developed a DMQ for younger children aged 6 to 11, but this version has not been reported in this paper due to a low number of completed questionnaires.

The TRECA study involved extensive Patient and Parent Involvement (PPI) work [31] and prior to use, potential DMQ questions were piloted by our Patient and Public Involvement team, including three young people aged 19–24 years (two female, one male) with long-term health conditions, and three parents (all female) of young people with long-term health conditions. All six respondents had prior experience of PPI work. The draft DMQ was reviewed by our PPI members (and the wider TRECA team) and refined to ensure the statements were clear. Consequently, minor changes were made to question wording. Furthermore, four participants (one parent, one adolescent and one parent and child pair) took part in pilot testing to assess the wording, suitability and timings.

2.2. Item scoring and missing data

In the DMQ, answers to each question were allocated a value of 0–4, with higher scores indicating more positive appraisals of information quality and decisions. The individual scores were combined to generate overall scores out of 36.

It was agreed in advance of analysis that a total score would be calculated if there were no more than three missing responses. However, for the purposes of the psychometric analysis reported here, we have only included questionnaires with responses to all Likert items.

2.3. TRECA study

The TRECA study compared multimedia information with printed information within seven SWATs (over 2018–2021), six of which were embedded within host randomised controlled trials and one of which was embedded within a hypothetical trial (see Table 1). Host trials were able to choose between a two-arm (multimedia versus printed information) or three-arm (multimedia versus printed information versus multimedia plus printed information) SWAT, and the DMQ items were designed to be suitable for participants in any SWAT group.

We have also included in the analysis of the DMQ data from the seventh SWAT, BAMP sub-study [27]. This SWAT used a hypothetical trial setting involving older children, which was initiated after the main BAMP trial (and its associated SWAT) had to close to recruitment. It was a two-arm study comparing printed and multimedia information, using the same study information as the BAMP trial. These data have been included as they make a valid contribution to the psychometric analyses.

2.4. Research ethics and registration

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) on 14th July 2017. The study was registered on the ISRCTN registry (ISRCTN73136092) and the Northern Ireland Hub for Trials Methodology Research SWAT Repository (SWAT 97).

2.5. Participants

Participants who completed the DMQ were recruited through the seven SWATs. All children and young people (aged under 18 years) identified as potentially eligible for participation/approach by the host trials were eligible for TRECA; there were no additional eligibility criteria.

2.6. Sample size

The sample size for each SWAT was determined and constrained by the number of people approached to take part in the host trial. The minimum sample size for conducting psychometric analyses suggested by Rouquette and Falissard (2011) [32] and Charter (1999) [33] is 300–400 respondents.

2.7. Procedure

Within each host trial children and young people and their parents/guardians were provided, according to random allocation, a printed copy of the printed information or access to the multimedia information which was displayed on a tablet computer during the discussion about possible participation in the trial, or they received both. After potential trial participants had decided whether to take part in the host trial or not, they were asked to complete a DMQ.

When patients had agreed to take part in the host trial, they were given the DMQ after they had completed all consent materials, to prevent disruption to the trial processes. Participants could complete the DMQ at the recruitment site or later at home (and return it using Freepost envelopes to the TRECA team at the University of York). For the host trial that contacted potential participants by email (CHAMP UK), DMQ completion was undertaken digitally via the Qualtrics survey tool [34]. For those who declined to participate in the host trial, the questionnaire was completed either in the clinic or sent to them by post or email as appropriate. The host trials were asked to give all patients the DMQ to complete, but DMQ provision was not recorded and as such there may be patients who were not asked to complete the questionnaire, both those who went on to participate and those who did not.

Table 1
Summaries of the six host trials.

Trial	Summary (URL for multimedia link)
FORCE (The Forearm Fracture Recovery in Children Evaluation)	https://morph.co.uk/the-force-study/
CHAMP UK (The Childhood Atropine for Myopia Progression)	https://morph.co.uk/the-champ-study/
THERMIC−3 (Intermittent Antegrade Warm Blood versus Cold Blood Cardioplegia in Children Undergoing Open Heart Surgery)	https://morph.co.uk/the-thermic-3-study/
BALANCE (Binocularly Balanced Viewing Study)	https://morph.co.uk/the-balance-study/
BAMP & BAMP sub-study (Bone-anchored maxillary protraction)	https://morph.co.uk/the-bamp-study/
UKALL 2011 (United Kingdom Trial for children and young adults with Acute lymphoblastic Leukaemia and Lymphoma 2011)	https://morph.co.uk/the-ukall-2011-trial/

2.8. Data analysis

We first undertook a descriptive summary of the percentage of returned questionnaires in each category, namely completion by parents/guardians, older children and younger children, and recorded data on item non-completion. For older children, our primary source of data comes from the hypothetical trial.

To evaluate DMQ internal consistency, we used the Cronbach's Alpha statistic and then calculated Cronbach's Alpha after removing each DMQ item in turn. Inter-item correlations were calculated to determine the inter-relatedness of individual items. Following the recommendation of Clark and Watson (1995) [35], we used an inter-item correlation of 0.15–0.50 as a reference for internal consistency. The item-total correlation statistics were calculated to assess how well each item was correlated with the total scale score.

Finally, we performed factor analysis to explore underlying latent factors within the DMQ. We used the Kaiser-Meyer Olkin measure of sampling adequacy and Bartlett's test to determine the adequacy of performing a factor analysis on the selected data. According to Hu and Bentler (1999) [36], a Kaiser-Meyer Olkin above 0.70 is acceptable. The number of factors that were examined was determined by the eigenvalues and scree plots, and eigenvalues of 1 or greater were retained and used in the factor solution [37]. We used principal components analysis as the method of factor extraction and oblimin as the method of factor rotation. Factor loadings indicate the strength of the relationship between an item and the overall factor or total scale score. The cut-off point used for retaining items for interpretation was 0.40 [38].

Statistical analyses were conducted using IBM SPSS Statistics Version 28.0 for Windows.

3. Results

3.1. Descriptive summary

A total of 549 participants across the trials completed a DMQ, including 433 parents/guardians, 116 older children, details of the responses from each host trial can be found in Table 2. For the parental version 14 (3 %) had incomplete Likert items in their questionnaires (a total of 20 questions unanswered). Only 1 (1 %) of the 116 older children version had any incomplete Likert items (1 question unanswered).

Out of the nine Likert items on the DMQ for parents/guardians, item 9 ("In all, the information about the proposed study helped me make my decision about whether or not my son or daughter should take part") had the most missing answers (five incomplete), with item 7 ("The information about the proposed study helped me discuss taking part with my son or daughter") having four incomplete answers. The other seven items each had either one or two incomplete answers. On the older children version item 3 ("The information helped me understand how

Table 2
Number of completed questionnaires by host trial and participant group.

Trial	Parents/ Guardians	Older Children (ages 12 and over)	Number participants randomised to TRECA*	Total number of DMQ returned n (%)
BALANCE	9	N/A	21	9 (43 %)
CHAMP	91	N/A	201	91 (45 %)
FORCE	311	N/A	1410	311 (22 %)
THERMIC−3	19	0	147	19 (13 %)
UKALL	3	2	5	5 (100 %)
BAMP	-	10	10	10 (100 %)
BAMP sub-study	N/A	104	104	104 (100 %)
TOTAL	**433**	**116**	**1896**	**549 (29 %)**

N/A= Not applicable (The DMQ was only administered to the younger children group in the host trial)
*The host trials did not record the provision of the DMQ to all participants, and there may be participants who were not asked to complete the measure.

my treatment or care might change if I took part in the study") was the only missing response.

After excluding the partial responses, a total of 539 questionnaires were included in the psychometric analysis.

3.2. Psychometric properties

Analysis of the 9 items in the TRECA DMQ found that the Cronbach's Alpha for the parental DMQ was 0.88, and for older children it was 0.84, indicating high internal consistency. This suggests that the questions in the DMQ are effectively assessing the same underlying aspect of quality of decision-making. The items were all highly inter-correlated, so removing any one item did not significantly change the internal consistency of the scale (range 0.859 - 0.880 for parent version and 0.813 - 0.827 for older children version) (see Appendix 1, Table 1). This suggests that the contribution of the scale items to the total scores is coherent, and as such, all items were maintained for further analysis.

When exploring the inter-item correlations, all DMQ items had moderate to high correlations, with values ranging from 0.2 to 0.6 for parents/guardians and 0.2 to 0.5 for older children (see Appendix 1, Table 2). As per Clark and Watson [35], these values are generally considered to be acceptable in relation to the predefined range of 0.15–0.50, indicating that the items are measuring the same underlying construct.

The corrected item-total correlations showed that all items were positively correlated with the DMQ total score, with values ranging from 0.4 to 0.7 for the parents/guardians and 0.4 to 0.6 for older children (see Appendix 1, Table 1). This suggests that the items on the DMQ are all measuring the same underlying construct(s), and that the total score is a reliable measure of that construct.

3.3. Factor analysis

For the parental responses, the Kaiser-Meyer Olkin measure of sampling adequacy of the DMQ was 0.90, indicating that the data were suitable for factor analysis, and Bartlett's test reached statistical significance ($p < 0.05$), supporting factor analysis of the data (approximate chi-square 1714.89, degrees of freedom 36, $p < 0.001$). A single factor was extracted using the screen test criterion, accounting for 53 % of the variance. The factor loadings were 0.57–0.81, indicating that items were all strongly related to the factor. This suggests that the items effectively measure the aspects of decision-making quality they are designed to assess (See Appendix 1 for further details). We did not conduct factor analysis for the older children's DMQ as the sample size was insufficient [39].

4. Discussion and conclusion

4.1. Discussion

The findings of this study suggest that the DMQ designed for use in TRECA is a useful tool to measure the quality of decision making. Among those who completed the DMQ, all-item completion rates were very high and the Cronbach's Alpha for the parent/guardian and older child versions indicated high levels of internal consistency. Factor analysis showed that the TRECA DMQ questionnaire has a single factor accounting for more than 50 % of the variance. This indicates that the items in the questionnaire are strongly associated with each other and contribute to a common underlying construct related to decision-making quality. The factor loadings provide further support for the strength and direction of the relationship between each item and the extracted factor. These results are consistent with the Cronbach's Alpha analysis, which showed that the questionnaire has high internal consistency. Overall, these analyses provide robust evidence that the TRECA DMQ effectively measures what it purports to measure. This is similar to the SURE decision-making questionnaire [29] which measured the psychometric properties to screen for clinically significant decisional conflict in clinical practice in adults.

There are several study strengths and limitations. The DMQ was developed by drawing conceptually on existing validated measures for adult decision-making [29,30] and key elements of research on participation decision-making. The dataset was derived from seven SWATs (including one in a hypothetical trial setting), investigating a diverse group of interventions, health conditions and patient ages. However, there are also limitations. Firstly, most of the included data for older children were derived from a hypothetical trial scenario, which may not be the same as considering participation in a real trial. Secondly, most of our SWATs, with the exception of FORCE, faced unexpected obstacles such as financial limitations, significant delays in obtaining research ethics and governance approvals, and recruitment postponements due to COVID-19. As a result, most of the overall DMQ data were obtained from parents or guardians, limiting the evidence on the questionnaire's ability to evaluate decision-making by children and young people themselves. Even though we aimed to capture the perspectives of parents and children, only a few younger children completed the questionnaires, which we did not anticipate when creating the DMQ. In future trials, researchers need to consider this issue and work on the availability of data from younger children on research participation. Due to the ethical restrictions, we were unable to analyse DMQ scores according to gender, ethnicity, or education status, and consequently were also unable to look at any effect of these factors on DMQ completion rates or performance within this study. The DMQ return rates were considerably higher in participants who decided to take part in the host trials than in those who declined participation (on average, 25 % of consenters returned the DMQ, compared to 11 % of decliners; DMQ scores for each host trial were reported in Knapp et al., TRECA NIHR report [40]). While this finding is common in studies of research participation decisions, it could produce biased appraisals of the quality of information; however, it is unlikely to affect the psychometric properties of the DMQ.

It would be helpful for future research evaluating the TRECA DMQ to assess the effects of gender, ethnicity, and education on DMQ scores and DMQ psychometrics. It would also be helpful for research to assess the psychometric properties of the younger child version of the DMQ, and assess DMQ scores and DMQ properties when data are derived from people who decline research participation; this is a recurrent gap in the understanding of recruitment to research.

4.2. Conclusion

Effective decision-making regarding participation in clinical trials for children and young people and their parents/guardians is paramount. To get a better understanding of children and young people's

knowledge, understanding and satisfaction with the decision-making process, specialised instruments are required. Prior to TRECA, no instruments existed to assess the quality of decision-making by children and young people and their parents/guardians when considering research or trial participation. The development of a new tool to measure the quality of decision-making by children and young people and their parents/guardians is an important step forward, with potential to be an asset for future paediatric trials. Overall, the TRECA DMQ is a reliable, coherent instrument for measuring decision-making by older children and their parents/guardians. These findings enhance our confidence in the ability of the questionnaires to effectively evaluate the quality of decision-making and support its use in future clinical trials with these populations.

4.3. Practice implications

Currently, there is a lack of understanding as to why some children and young people and their parents/guardians choose to participate in health research while others do not. Additionally, there is no validated tool to measure the quality of decisions about taking part in research by children and young people and parents/guardians. Our study suggests that the TRECA DMQ is a useful tool for assessing informed decisions about taking part in health research, although further work is needed, particularly with younger children and in non-trial research settings. It would also be helpful to assess the ability of the DMQ to accurately capture decision making processes around research participation. This tool can be used to assess the quality of decision-making in future paediatric trials involving older children.

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CRediT authorship contribution statement

Elizabeth Coleman: Writing – review & editing, Methodology, Formal analysis, Conceptualization. **Jacqueline Martin-Kerry:** Writing – review & editing, Methodology, Conceptualization. **Thirimon Moe-Byrne:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis, Data curation, Conceptualization. **Peter Knapp:** Writing – review & editing, Methodology, Funding acquisition, Formal analysis, Conceptualization. **Rebecca Sheridan:** Writing – review & editing, Methodology, Conceptualization. **Jonathan Graffy:** Methodology, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data Avaialbility

Materials will be made available upon request to Peter Knapp (Peter.knapp@york.ac.uk).

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pec.2024.108417.

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