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Patient and public involvement in a study of multimedia clinical trial information for children, young people and families

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Abstract

There is increasing recognition of the need to involve the public in health research, but accounts of how best to achieve this are scarce. This article describes public involvement in the TRials Engagement in Children and Adolescents (TRECA) study, which is developing and evaluating multimedia information resources to inform children, young people and their families about clinical trials. A dedicated group of young people with long-term health conditions and their parents met regularly throughout the study; further involvement was sought when specific input was required. Review of formal impact records and informal discussions highlighted how public involvement can positively influence research practice and the people involved. By detailing the methods of involvement used, this work also provides guidance for successfully implementing public involvement in research, and highlights challenges that should be considered in future research projects.

Keywords: children, young people, public involvement, PPI, families

Key messages

- Involvement of young people and parents can have a positive impact on research, despite logistical and governance-related challenges.
- It is important that all members of the research team are committed to public involvement, and that involved members feel their input is valued, even if suggested changes cannot always be incorporated.
- Involvement may allow people to develop new skills and provide unique opportunities that may be of use in many aspects of daily life.

Background

Public involvement in research

Over the past two decades, there has been a significant change in the way that health research is conceived and conducted, with increasing recognition and acceptance of the need to ensure active involvement of the public, including patients, potential patients and carers, in the research process. In the UK, all publicly funded health research is now expected to include public involvement (Evans *et al.*, 2014), and the National Institute for Health Research (NIHR) funds INVOLVE, a national advisory group created to support public involvement in research (www.invo.org.uk). Public involvement can be defined as 'research ... carried out "with" or "by" members of the public rather than "to", "about" or "for" them', as opposed to 'participation', which refers to people as research participants (that is, as sources of data) (INVOLVE, 2020c). It is suggested that by making use of people's knowledge, lived experience and networks, researchers can provide more relevant, higher-quality research that can be widely communicated in an appropriate manner (Barber *et al.*, 2011; Stewart and Liabo, 2012).

While public involvement in research has historically received little empirical evaluation, improvements in both the quality and accountability of research have been observed (Bate *et al.*, 2016). In one systematic review, benefits of public involvement at all stages of the research process were reported, including: identifying research questions; facilitating recruitment; and disseminating study findings (Brett *et al.*, 2014a). A further review observed that improved enrolment to clinical trials as a result of public involvement was especially beneficial if the members had experience of the health condition being studied (Crocker *et al.*, 2018). The importance of pre-planning, involving members early in the study, and being mindful of the use of jargonistic and technical language by researchers has also been noted (Buck *et al.*, 2014). The current body of knowledge in this area is concentrated on the involvement of adults, although there is a growing literature on the experiences of involving children and young people (Bate *et al.*, 2016; Parsons *et al.*, 2018; Alderson *et al.*, 2019; Dovey-Pearce *et al.*, 2019; Brady and Preston, 2017; Bird *et al.*, 2013; Nuffield Council on Bioethics, 2015; Kellett, 2005; Forsyth *et al.*, 2019). For example, children and young people have been involved in the design of interventions for clinical trials (Boote *et al.*, 2016) and in synthesizing evidence from systematic reviews (Oliver *et al.*, 2015). The demand is that such research is carried out in such a way that people are listened to and heard (Roberts, 2000), with involvement leading to research, and ultimately treatments and services, that better reflect children and young people's priorities and concerns (Brady *et al.*, 2018; Fleming and Boeck, 2012). Brady and Preston (2017) argue that more needs to be done to collate, understand and disseminate robust evidence about the nature and impact of children and young people's involvement in research, and the quality and utility of the research. It is also important to acknowledge that there may be unique challenges associated with including children and young people in research, and that the methods used for involving them may differ from those used to involve adults (Bate *et al.*, 2016; Dovey-Pearce *et al.*, 2019; Brady and Preston, 2017). For example, greater flexibility may be needed to fit around their preferences, existing commitments and personal circumstances (Brady *et al.*, 2018).

Despite this increasing interest, reporting of public involvement in research continues to be understated and lacking in detail (Brett *et al.*, 2014a; Staniszewska *et al.*, 2017), limiting understanding of how public involvement works, for whom and why (Brett *et al.*, 2014b; Mockford *et al.*, 2012; Staley, 2015; Popay and Collins, 2014; Staniszewska *et al.*, 2017; Gordon *et al.*, 2018; Gamble *et al.*, 2015). Furthermore,

the manner in which public involvement is reported is not standardized, despite the availability of published reporting checklists (Staniszewska *et al.*, 2017). It has been suggested that the evidence base can be improved by encouraging researchers and public involvement members to report involvement in individual studies (Staniszewska *et al.*, 2011; Buck *et al.*, 2014), detailing both the specific context of public involvement (Staley, 2015), and any demonstrable impact upon the study (Staley, 2015) and members of the group (Ashcroft *et al.*, 2016). Therefore, the aim of this article is to provide detailed information about the involvement of young people and parents in the TRials Engagement in Children and Adolescents (TRECA) study via a dedicated public involvement group, termed the Patient and Parent Advisory Group (PPAG). We will discuss the context and methods of involvement, and the impact of this on both the study and members of the group. Finally, we will highlight the strengths and difficulties that members encountered during the study, as well as some reflections from the perspective of the researchers. The article is informed by the GRIPP2 guidance on reporting patient and public involvement (PPI) in research (Staniszewska *et al.*, 2017).

The TRECA study

Participants invited to take part in research are normally provided with an information leaflet detailing the study and a consent/assent form. However, these documents have been criticized for being too long and complex (Caldwell *et al.*, 2012; Tarnowski *et al.*, 1990), and digital resources may be a promising alternative. The TRECA study, which consists of two phases, aims to develop and evaluate the use of digital, multimedia information resources (MMIs) provided to children, young people and their families when they are invited to take part in a health-care trial (Martin-Kerry *et al.*, 2017). In Phase 1, prototype MMIs containing text, animations, video and pictures were developed with input from study participants including children, young people, families and health-care professionals, to ensure they met people's needs and preferences (Martin-Kerry *et al.*, 2019). The MMIs were then user tested to ensure that they were understandable and intuitive to use (Sheridan *et al.*, 2019). Examples from the TRECA MMIs are available at: <https://morph.co.uk/case-study/treca/>. In Phase 2 (ongoing), the MMIs are being evaluated in six paediatric 'host' trials, in which their effects are being compared to traditional printed information. The impact of the MMIs will be assessed against three outcomes: (1) trial recruitment rates; (2) trial retention rates; and (3) the quality of decision-making by potential trial participants and (where relevant) their parents. Further information about the TRECA study is available in the published protocol (Martin-Kerry *et al.*, 2017).

Method

The model of public involvement chosen was a combination of 'managerial' and 'responsive' involvement, as described in the Evidence Base for Patient and Public Involvement in Clinical Trials (EPIC) study (Buck *et al.*, 2014). Two public involvement approaches were adopted: (1) seeking input as and when required (responsive) from the Liverpool GenerationR Young People's Advisory Group (YPAG; <https://generationr.org.uk/liverpool/>); and (2) establishing a dedicated, TRECA study-specific PPAG to inform decision-making throughout the study (managerial), and review study documentation and tools (responsive). We then adapted these models to suit the specific nature of the TRECA study, which also has an extensive participatory design component where the potential users of the resources, in this case children and young people, contributed to their development as research participants.

The PPAG was set up at the beginning of the TRECA study, after funding had been secured. The role of the group was to: (1) review and provide input into documentation used in the various stages of the study; (2) review prototype and paediatric 'host' trial MMI content; (3) pilot questionnaires to ensure question wording and length were appropriate; (4) advertise the study to relevant audiences; and (5) assist with reporting and disseminating TRECA findings, including contributing to publications and conference proceedings. Two members of the PPAG sat on the TRECA Study Advisory Group (Chalinor and Horton Taylor), and attended all meetings (when available) as representatives of the wider group. All members were regularly asked for their opinions on various study design and conduct queries by email and/or telephone, and the group members were seen as valued and equal partners in the research; their views were considered with the same weight as those of the academic members of the advisory group.

Setting

The PPAG included three young people between 19 and 24 years old with long-term health conditions (two female, one male), and three parents (all female) of young people with long-term health conditions. All members had prior experience of patient involvement. One of the parent members withdrew from the group during the second year of the study due to personal commitments. The group Chair is a TRECA co-investigator with extensive experience of involving children, young people and families in research through her role as a public involvement manager with numerous organizations. A TRECA researcher acted as coordinator for the group, and was responsible for facilitating contact between the group and the TRECA study researchers, organizing meetings and coordinating requests for input. The TRECA research team has a strong commitment to public involvement, and members of the TRECA Study Advisory Group have several years of experience in delivering studies that have embedded public involvement.

The TRECA study was built upon the frustrations of children, young people and their families regarding the standard information provided to them when invited to take part in a research study. As such, the views of young people were sought via the Liverpool GenerationR YPAG prior to the grant application being submitted for the TRECA study. The TRECA team established the PPAG, with members recruited via investigator networks during the set-up phase of the study. Potential members were asked to provide an expression of interest indicating why they would like to join the group. No formal interview was used to select members, and no formal training was provided; however, many members had relevant prior experience. Further, informal training, including small presentations, workshops and group discussions, generated a culture of shared learning and collaboration. The group was funded through an allocated public involvement budget costed in the TRECA study grant award, using the INVOLVE guidance (Mental Health Research Network and INVOLVE, 2013) and payment calculator (INVOLVE, 2020a). It was agreed that an hourly rate for members for all contributions (such as attending meetings and reviewing documentation) would be used, as opposed to daily rates, due to the varied time commitments and opportunities for involvement.

The TRECA study researchers initially developed a draft terms of reference for the PPAG, which was discussed, reviewed and subsequently agreed upon by the PPAG. The terms of reference detailed the aims of the TRECA study, the remit and membership of the group, and information regarding payment and expenses, accountability and confidentiality. This acted as an induction for members and as a resource to fully inform

them about the study and their role, in order to manage expectations with regard to the PPAG from the outset. In addition, an authorship guidance document was developed and shared with all members of the TRECA study team, including the PPAG, setting out agreed eligibility criteria for publication authorship.

Patient and Parent Advisory Group meetings

The first PPAG meeting took place within three months of study set-up, with the group meeting regularly thereafter (typically every three to four months). Ideally, meetings were scheduled to coincide with TRECA Study Advisory Group meetings, on which two members of the PPAG sat. Voting polls were circulated in advance to identify convenient dates and times for the group to meet, which included daytime and evening meetings. Meetings were held in the North of England, where the majority of the PPAG were based. The opportunity to attend via teleconference was also provided. Minutes were recorded by the PPAG coordinator and distributed directly to the group and the TRECA research team. Additional feedback from the group was sought by the PPAG coordinator via email and telephone whenever necessary.

Evaluation

All feedback on the study received from members was recorded in full and summarized in a dedicated document. Data regarding the impact of the PPAG, and the strengths and difficulties of involvement in TRECA, were generated during three writing workshops involving members of the PPAG, the group coordinator and the chairperson. Themes and quotations were identified during these workshops, and further developed using the recorded minutes. Members were aware of how this information would be used and were invited to contribute to writing the present article. The TRECA research team reflected on their experience of the process independently. No formal data analysis was undertaken.

In accordance with relevant reporting guidelines (Staniszewska *et al.*, 2017), a completed GRIPP2 short form is provided (Table 1).

Table 1: Completed GRIPP2 checklist (short form)

Section and topic	Item	Reported on page number
1: Aim	Report the aim of PPI in the study.	50
2: Methods	Provide a clear description of the methods used for PPI in the study.	50–2
3: Study results	Outcomes – report the results of PPI in the study, including both positive and negative outcomes.	53–4
4: Discussion and conclusions	Outcomes – comment on the extent to which PPI influenced the study overall. Describe positive and negative effects.	59–61
5: Reflections/critical perspective	Comment critically on the study, reflecting on the things that went well and those that did not, so others can learn from this experience.	54–9

Results

Impact of the Patient and Parent Advisory Group

Impact on the TRECA study

Group members fulfilled all aspects of their agreed roles, with the majority of feedback being requested and received via email. The feedback provided by members often improved the clarity of study documentation. For example, members edited text, alongside both an education expert who was a co-investigator on the study, and the TRECA research team, to ensure the content was appropriate for children, young people and families without compromising scientific accuracy. This collaborative approach was beneficial, as people picked up on different aspects of the materials that could be improved. They also suggested modifications to participant information sheets for all children and young people invited to take part in the TRECA user testing study to make them more visually appealing. The group were actively involved in reviewing the storyboards for animations, and the written content for use in the prototype and 'host' trial MMIs, ensuring the language used was easily understood. They also contributed to discussions regarding the voice-overs used for the animations in the MMIs. When reviewing the MMIs, members were often able to highlight where concepts needed further explanation and suggest word changes, or identify where images could be improved. For example, one of the animated characters on the prototype MMIs wore a T-shirt with a skull and crossbones. This was changed after members expressed concern about using this image in information about a health-care trial involving unwell children and young people. Other examples included adding eyelashes to an image of an eyeball to make it more recognizable, and editing text regarding blood samples to include an easier measure to visualize (for example, a teaspoon of blood rather than 5 ml).

From a strategic point of view, young person and parent involvement in the running and conduct of the study was mostly achieved during Study Advisory Group meetings. Although demonstrating impact from these meetings was more challenging, minutes showed that members made insightful contributions to discussions. PPAG members also provided a letter of support for a study extension request to the funder, and were consulted on important study decisions via email, such as which trials to accept as 'host' trials in the TRECA study. Regarding dissemination, members actively promoted the study at a variety of regional, national and international research and patient events, through their existing roles as patient research partners. Members also suggested suitable conferences at which to present TRECA work, and have subsequently co-authored conference proceedings and publications. At the time of writing this article, the TRECA study is ongoing, and the PPAG has agreed to continue to provide input for the remainder of the study where possible, by assisting in the analysis process and the dissemination of study findings. This may be in the traditional sense of contributing to the writing of publications, but also via other formats, including the use of social media. Members were particularly vocal about using the latter to enhance the way in which the study engaged with people more broadly, for example via a study-specific Twitter account. While this was initially not a priority for the TRECA researchers, listening and proactively responding to members was an important step in increasing visibility about the study, which made members feel that they had made a positive impact:

The main impact the group has had on the study is challenging the view of the researchers and an example of this was when the group was in agreement that the study should have a Twitter Page as this was a multi-media based study but couldn't use it to promote or advertise the study. (Young person 02)

The impact of the group on the TRECA study is further summarized in Table 2, alongside any relevant barriers to impact that were identified by the study team.

Table 2: Impact of PPI on the TRECA study and relevant barriers encountered

Impact of PPI on the TRECA study	Relevant barriers
Improving the clarity of printed study documentation	Difficulty incorporating suggestions when 'host' trial materials were already approved by research ethics committees.
Reviewing multimedia and written content for the MMIs	Based on the design of TRECA, contributions for the development of the MMIs in Phase 1 were focused on the study participants. If PPI members had different opinions, these were noted but not implemented.
Contributing to decisions regarding study design and governance	No relevant barriers identified.
Promoting the study via social media or attending conferences	Due to PPAG members' other commitments, it has not yet been possible for members to attend conferences at which the TRECA study was being presented.
Contributing to the writing of presentations and publications arising from the TRECA study	No relevant barriers identified.

Impact on individual members

Members reflected on their involvement, both within TRECA and in other studies. The themes generated during discussions are detailed in Table 3.

Table 3: Impact of involvement in research upon members of the Patient and Parent Advisory Group

Theme	Description
Opportunities	New opportunities may be available, for example, the ability to meet new people, meet researchers working in a relevant area and the opportunity for travel. For all age groups, these experiences may also be of use for academic, career and personal development.
Support	Involvement may help people to connect with others with the same condition and/or experiences. The group can therefore act as a support network, even if personal experiences are not explicitly discussed during meetings. Being in the presence of other people with similar perspectives and outlooks can be refreshing.

Theme	Description
Knowledge	People may be able to gain knowledge about their condition, and improve their understanding of it. Members may also have access to the most recent research in the area, which can help them to identify gaps in the current literature, and inform their own health-care decisions. Involvement with different topic areas can broaden horizons and understanding of different health needs and methodological approaches to research.
Empowerment	Involvement can empower both the person with the condition and their family. This empowerment can influence their experiences within public involvement and with their own health care, allowing them to take more control of their health and well-being.
Purpose	Being part of a public involvement group can provide purpose to someone who may feel lost after being diagnosed with a life-changing health condition.

Strengths and challenges of the PPAG process

While reflecting on their role within the PPAG, members also highlighted aspects that they felt were strengths of the model of involvement employed during the TRECA study, as well as the challenges that were encountered.

Strengths

Researchers' attitude to patient and parent involvement

The PPAG felt the TRECA study team appreciated the importance of public involvement, which enabled them to express opinions openly and honestly. They also noted the importance of being treated with the same courtesies as the academic team members to ensure they felt valued. For example, those members of the PPAG who sat on the Study Advisory Group appreciated the use of alphabetical ordering of meeting attendees on agendas as they felt this was more inclusive than including all academic members followed by PPAG members:

We really felt like part of a team, as we began our work on the study. To me [group coordinator]'s leadership of the group was an example of good PPI as she made us feel valued and an equal with a common aim. (Parent 01)

PPI group felt very enthusiastic and cohesive, our contributions felt valued, so we were able to input into design and content, as well as on the SAG [Study Advisory Group]. There was a feeling of egalitarianism so that even on the SAG, our opinions were listened to and taken on board. (Parent 02)

Having a 'PPI champion' [PPI chairperson], who is a co-applicant of the project, who then champions and supports a wider group of PPI members [is important]. (Young person 03)

Motivation of members

While PPAG members were not formally involved in the development of the research question or protocol, all members felt the topic was important and were therefore

committed to being involved. This may be important in retaining members for the duration of the study, even when there are long periods with little input required:

From the outset I was excited to be part of the study. ... I knew as soon as [child's name] was diagnosed that I wanted to try and change things for others in a similar position to us. I wanted to make a direct impact, help to make a change for the better and it was important that this was not just tokenistic. (Parent 01)

Without doubt, my motivation for joining the group was inspired by the aim of the TRECA project, as I had been complaining quite vocally about how much I disliked how we provide information to patients about research – particularly for children, young people and their families. (Young person 03)

Members also felt that it was positive that all members of the group were motivated to be involved for the 'right reasons' – meaning that they were there to contribute to the project and not solely for personal gain. While members acknowledged the personal benefits of being involved in the group, they felt this was secondary to their desire to influence the TRECA study.

Communication

The inclusion of a PPAG coordinator who took time to get to know members was highlighted as a strength. The role of the coordinator was particularly important in communicating to the group where their feedback had been incorporated by the TRECA team, but also where it had not, and why:

I think that the TRECA team in York listened to us and made our opinions and suggestions real and valid. Interestingly, we did not always agree but I still felt that my views were being respected. (Parent 01)

Communicating roles at the beginning of projects was also viewed as an important step in enabling people to assess whether they have the capacity and capability to get involved in projects:

Receiving all of this information upfront was really important in helping me to decide whether or not to join the group. Given that I was about to commence the final few months of my undergraduate degree, without this information (notably on the frequency of meetings and time commitment), I would have probably said no – and I would have missed out on so many wonderful opportunities to influence the project. (Young person 03)

The coordinator aimed to maintain communication throughout the study, with updates provided between meetings where possible. Members felt that continued contact was important to keep momentum going, particularly during quieter periods in the study.

Varied opportunities

Members appreciated the variety of ways they could be involved in the study. This included more traditional public involvement opportunities such as reviewing participant information materials, and also wider opportunities such as being involved in planning and delivering presentations and publications. In addition, the level at which members could get involved was flexible around the needs of individuals. Everyone had the opportunity to get involved in different activities, but there was no

pressure for them to do anything. Members were also invited to assist with participant focus groups during the development of the MMIs, although this was ultimately not possible:

By getting involved in TRECA, I have been able to learn new approaches, methods and opinions which have been an invaluable learning experience. I have also been privileged to be able to contribute to writing and editing different abstracts and papers, which have been incredibly useful, both from the preparation aspect of things, and also from having publications. (Young person 03)

Expenses

It was important for inconveniences and out-of-pocket expenses to be minimized, for example by printing meeting documentation for members, booking travel in advance and providing return stamped addressed envelopes when information was requested via post:

The PPI lead [coordinator] was wonderful in always thinking ahead so we never had to worry about booking trains, getting expense forms – everything was anticipated. (Parent 02)

Challenges

Logistics

Difficulties encountered during the process were largely related to logistical factors. Despite the flexibility of the PPAG with regard to scheduling, it was sometimes not possible to arrange a meeting due to other commitments including work, education, care or health-related factors. Occasionally, teleconferencing was utilized at meetings to reduce travel demands, but face-to-face meetings were preferable as they allowed for greater interaction and the ability to develop positive working relationships. It was suggested that a social-style first meeting would have been useful for relationship building. Members would also have liked to meet the wider TRECA Study Advisory Group, but due to competing work commitments this was difficult to achieve, especially as most members of the Study Advisory Group joined meetings by phone:

Being able to meet face-to-face was a huge benefit as you can react to people's body language and pick up on thoughts and feelings of different people in the room. (Parent 01)

It would also have been nice to have had some sort of social icebreaker at the first meeting, as a sort of get to know you, before settling down into business. (Parent 02)

While this is a logistical nightmare, it would have been beneficial for the entire TRECA PPI group to meet in person with the entire TRECA study team for a kick-off meeting at the start of the project. (Young person 03)

Payment

While transparency regarding expenses and payment was highlighted as a strength, there were a number of difficulties with making appropriate payments. This was largely due to the requirement for members to be officially employed on a casual basis by

the university that hosted the TRECA study to allow payment via cash, which members found preferable to being provided with vouchers. This meant that all payments were taxed, something not anticipated by the research team, and therefore not communicated to members at the outset. This had a negative impact upon members in different ways depending on their current work status. This may be particularly problematic for members who are receiving care- or health-related benefits, as well as members in full-time employment:

The way we were compensated for our time was complicated and affected my salary from my job. This is something that would in future make me say I'd rather not accept any money for my time. (Young person 02)

Appropriate membership

As the focus of the TRECA study is improving information for children, young people and their families, it was important to include members from each of these groups. While a younger child representative was invited to the group, there was no capacity to adapt materials and meetings to be suitable for them. It was discussed that when younger children's input is needed, it may be more beneficial to involve a separate group of children (supported by their parents, if necessary) to appropriately engage them. Members of the group also highlighted the need to be mindful of the inclusion of members with differing levels of experience of public involvement in research, and acknowledged that there is a need to reach out to hard-to-reach groups to ensure diversity in public involvement.

Researcher reflections on the public involvement process

The TRECA research team felt that the involvement of the PPAG was a positive addition to the study. The PPAG coordinator felt that being involved with the group also allowed them to develop as a researcher by improving their ability to communicate with members of the public, and generating an understanding of what factors are important to patients and why. Nevertheless, engagement was not always straightforward and study-specific difficulties were identified. For example, due to the extensive use of participatory design in the TRECA study, researchers occasionally found that incorporating feedback was difficult where study participants (including children, young people and families) and PPAG members had differing opinions. Further, due to the embedded design of TRECA, MMIs for use in the 'host' trials were developed based on the 'host' trials' existing participant information materials, many of which were already approved by research ethics committees and may have had prior public involvement. This meant that valid feedback from members of the PPAG could not always be incorporated into the MMIs as they had to reflect the content of the approved materials. These factors meant sensitivity and honest dialogue were required to explain to members why it was not always possible to incorporate their feedback. In turn, the TRECA research team appreciated PPAG members' attention to detail and the confidence with which they articulated their feedback. PPAG members were often able to highlight aspects that the research team may not have noticed or considered, especially with regard to visual aspects or subtle, but beneficial, changes to wording, for example, changing 'once daily' to 'once a day'.

From a practical perspective, time and resource constraints and ongoing study developments meant that some of the researchers' objectives for public involvement

could not be met. For example, it was not possible to include younger children on the PPAG. The research team had also planned to involve members as co-facilitators in focus groups within the first phase of the TRECA study. However, this was not possible mainly because the study participants' preference was to take part in individual or joint interviews instead of focus groups. There were also some research governance issues related to whether PPAG members would need special permissions (such as an enhanced Disclosure and Barring Service check and a research passport) to assist with the interviews, which researchers should consider and factor into their schedules if necessary. Where focus groups did take place, their location or time was not convenient to the PPAG members. Similarly, we had hoped members would be able to assist with presenting the work at conferences, but while they were invited to attend, this has not yet been possible due to conflicting schedules. These resource constraints were experienced despite allocating a dedicated group coordinator to liaise with PPAG members (although the coordinator also worked on other projects alongside this role). This highlights the time commitment required to appropriately involve members of the public in research. Nevertheless, the TRECA team feel these demands were justified and that the group was able to add unique insights to the study.

Discussion

There is increasing recognition that children and young people should be involved in research that has an impact on them (Bird *et al.*, 2013; Nuffield Council on Bioethics, 2015; Brady *et al.*, 2018). This paper details public involvement in the TRECA study via a dedicated PPAG. We have highlighted the impact of young person and parent involvement in this research, and the strengths and challenges regarding the implementation of involvement in the study. Our results demonstrate that public involvement can positively influence research by, for example, ensuring study documentation and resources are developmentally and age-appropriate, visually appealing and suitable for the study target population. Being part of the group also had a positive impact upon the members themselves; involvement allowed them to meet like-minded people and develop research knowledge, and empowered them to be more involved in other research and their own health care.

Studies using more formal methods to measure impact, including semi-structured interviews and questionnaires, have also found that public involvement can improve study documentation (Brett *et al.*, 2014b; Gordon *et al.*, 2018). While the TRECA study PPAG was only established once the study had begun, research has highlighted that public involvement can also contribute to the development of the research questions and study design (Gordon *et al.*, 2018; Boote *et al.*, 2016). It has been suggested that this relatively late introduction of involvement may lead to more negative experiences and a lack of perceived impact, possibly due to members not feeling any 'ownership' of the trial (Dudley *et al.*, 2015). However, the research team were committed to public involvement and also involved study co-investigators with relevant expertise from the outset, which may have had a protective effect. Further, the PPAG were very motivated by the research topic and had relevant negative experiences with existing trial information materials. This motivation may also explain their willingness to remain involved in the study and assist with dissemination by co-authoring research conference presentations and publications, a form of involvement not often discussed in published research.

Members were generally positive about their experiences of public involvement, both within and outside the study. These positive outcomes, such as learning about their

condition, feeling empowered and gaining social support, are consistent with previous research (Esmail *et al.*, 2015; Devonport *et al.*, 2018; Ashcroft *et al.*, 2016). It is likely that these positive experiences related to the method of public involvement employed in the TRECA study, as highlighted by the strengths that members identified, including the development of good working relationships and mutual respect between members and TRECA research staff. Accordingly, these factors have also been identified as facilitators of public involvement in other research (Brett *et al.*, 2014a; Wilson *et al.*, 2015). While no significant negatives were reported, it is possible that members may not feel comfortable discussing issues with the coordinator and chairperson present; this is thought unlikely, as members noted that they felt comfortable within the group. Nevertheless, one member did leave the TRECA PPAG due to personal commitments. This highlights that research teams need to be aware of the increasing demands that public involvement makes on group members' lives, especially when involving individuals who may also be dealing with additional challenges as a result of a long-term health condition. Where studies run over a long time period, it should also be considered that changing circumstances may mean levels of involvement can vary throughout the study.

Consistent with previous work (Oliver *et al.*, 2015; Alderson *et al.*, 2019), further strengths identified included timely and open communication with members, especially when providing them with feedback on their contributions; poor or non-existent feedback has been criticized by public involvement contributors in other studies (Ashcroft *et al.*, 2016; Brett *et al.*, 2014a). Members also noted the benefit of having clearly defined roles, which are important in ensuring members are not disappointed or confused by the nature of their involvement (Brett *et al.*, 2014a). Previous research has reported that when roles are ill-defined, members may expect to gain personal support in managing their condition, and are then disappointed when this is not forthcoming (*ibid.*). In the TRECA study, role responsibilities were largely managed by co-developing formal terms of reference; the positive feedback may suggest this is a useful method for other researchers to adopt.

The main challenges highlighted by members concerned scheduling, payments and the recruitment of an appropriate group, all of which are commonly reported difficulties (Forsythe *et al.*, 2016; Gamble *et al.*, 2015). By involving young people and parents, varied lifestyle factors were important to consider, including school, employment, illness and carer commitments. To minimize the impact of these factors, it was important to be flexible with meeting formats, timings and locations. This flexible approach may help to ensure that logistical factors are not barriers to involvement in research, which may be especially important when attempting to recruit hard-to-reach groups. Similarly, given the potential for payment issues to exclude people from public involvement, it is important for researchers to consider payment methods in advance of setting up their involvement group. While the NIHR INVOLVE website provides useful guidance on payment of public involvement representatives (INVOLVE, 2020b), the organization hosting the study may also need to be consulted. An open and honest dialogue with members regarding payments, and clearly agreed terms, should ensure that all members are satisfied with how, when and how much they are reimbursed for their time.

Recruitment of members to the PPAG was opportunistic and aided by the chairperson, who already had contacts through her national role as a public involvement manager. We did not actively target hard-to-reach groups, although we did discuss this issue with members during writing workshops and agreed on the need for more diversity within public involvement (Brett *et al.*, 2014a; Alderson *et al.*, 2019;

Ashcroft *et al.*, 2016; Brady *et al.*, 2018; Mitchell *et al.*, 2019). We also acknowledge that the majority of our members were female and were older than the TRECA study demographic (children and young people aged 6 to 18 years). Involving younger children in PPI work should be encouraged, but unfortunately we did not have the time or resources to dedicate to ensuring meetings were accessible. While it has been suggested that PPI should largely be based on achieving valid perspectives, rather than on representativeness (Oliver *et al.*, 2015), we acknowledge that the latter may have been improved had there been a specific recruitment plan. Such plans are commonplace for recruiting research participants, and should be encouraged in this context. Recruitment planning may also enable researchers to consider whether their involvement opportunities are suitable for their target members, or whether they need to be adapted. For example, in the TRECA study, it may have been beneficial to have had two groups, one with young people and parents and one with younger children and parents, to account for the differing needs of these groups. We did not observe any notable differences in the opinions of young people compared to parents within this study, although we acknowledge that this should be considered, alongside the potential role of parents as gatekeepers to young people's involvement (Cree *et al.*, 2002; Brady and Graham, 2018). Further, while members felt they worked well together as a group, we would recommend a social event or icebreaker at the first meeting to ensure all members feel comfortable and able to contribute.

Although reports on researcher impact are scarce, benefits identified in previous research include gains in knowledge to aid their research, as well as more profound changes in both personal and professional values (Staley *et al.*, 2017; Staley, 2017). While not the main focus of this case study, retrospective reflection by the study researchers involved with the PPAG did highlight these factors alongside further logistical and practical considerations. Nevertheless, we acknowledge that researcher impact was not measured formally by, for example, using independent surveys or focus groups, and we encourage researchers to consider this in future work as a matter of best practice.

Conclusion

There is increasing recognition of the need to meaningfully include the public in research that has an impact on them. This article details the benefits of involving young people and parents in the TRECA study, which aims to improve patient information materials for children, young people and their families when they are considering health-care trial participation. Our account includes the perspectives of both researchers and PPAG members, although more formal measurement of the impact and quality of public involvement is warranted in future work. The recently published *National Standards for Public Involvement in Research* may assist with this by providing benchmarks that researchers can use to measure the quality of their involvement with the public (INVOLVE, 2018). Notable strengths of the method of PPI employed in the TRECA study include honest and open communication, varied opportunities and a recognition by the research team of the importance of PPI. Challenges were largely logistical, and the majority could be avoided in future by careful and early planning. We would encourage other researchers to publish their experiences, in line with the GRIPP2 guidance (Staniszewska *et al.*, 2017), and ideally in collaboration with public contributors, in order to determine what works for whom, when and why.

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Simon Stones is an international patient advocate and consultant, inspired by his experience with arthritis, fibromyalgia and Crohn's disease since childhood. He is currently undertaking a PhD at the University of Leeds, exploring how to best support young people with arthritis in managing their health and well-being. He is also a board member of four organizations: the European Network for Children with Arthritis, the European Network of Fibromyalgia Associations, Fibromyalgia Action UK and RAiSE.

Sammy Ainsworth is a parent of a daughter who was diagnosed with lupus at the age of 14. She is the Youth and Family Participation Officer for Alder Hey Children's Hospital Clinical Research Facility in Liverpool, and is a strong advocate for young people and parents to be involved in clinical research and health care in order for their voice to be heard. Sammy is a trustee of Lupus UK and the young people's charity RAiSE. She is also a board member for the European Network for Children with Arthritis.

Danielle Horton Taylor has been involved in the paediatric oncology research arena for a number of years and is a founding member of both PORT (Paediatric Oncology Reference Team) and Unite2Cure. She has been a consumer representative for the National Cancer Research Institute, is a member of the patient panel for the CRUK Grand Challenge and is a member of the Study Advisory Group for the TRECA study.

Robyn Challinor has been involved in health research over four years as a patient research ambassador. She has mainly been involved with research at Alder Hey Children's Hospital, in a young persons' group called GenerationR. This has led her to attend many research conferences and events all over the world, advocating involving patients in research. More recently, she has spoken at the European Medicines Agency as a patients' voice.

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