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Participants' perspectives of their involvement in medical device trials: a focus groups study

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Abstract

Background

Medical technologies have the potential to improve quality and efficiency of healthcare. The design of clinical trials should consider participants' perspectives to optimise enrolment, engagement and satisfaction. This study aims to assess patients' perceptions of their involvement in medical device trials, to inform the designs of future medical technology implementation and evaluation.

Methods

Four focus groups were undertaken with a total of 16 participants who had participated in a study testing hospital inpatient remote monitoring devices. Interviews were audio-recorded, transcribed verbatim and underwent thematic analysis.

Results

Four main themes emerged: patients' motivations for participating in medical device research; patients' perceptions of technology in medicine; patients' understanding of trial methodology; and patients' perceptions of the benefits of involvement in medical device trials. The appeal of new technology is a contributing factor to the decision to consent, although concerns remain regarding risks associated with technology in healthcare settings. Perceived benefits of participating in device trials include extra care, social benefits and comradery with other participants seen using the devices, although there is a perceived lack of confidence in using technology amongst older patients.

Conclusion

Future device trials should prioritise information sharing with participants both before and after the trial. Verbal and written information alongside practical demonstrations can help to combat a lack of confidence with technology. Randomised trials and those with placebo- or sham-controlled arms should not be considered as barriers to participation. Study results should be disseminated to participants in lay format as soon as possible, subject to participant permission.

1. Background

Technology has the potential to improve the quality and efficiency of healthcare. Healthcare technology assessment (HTA) refers to the systematic evaluation of properties, effects and impacts of health technology[1]. The efficacy of healthcare technologies is commonly confirmed through carefully designed prospective clinical trials. These are often driven by the collection of quantitative evidence to determine the clinical and cost effectiveness of a health technology[2].

There is growing emphasis on providing patient-focused health care and ensuring patient involvement in the design of health services[2]. Patient and public involvement in HTA is becoming increasingly important internationally[3] and can occur at several levels[2]. Active patient participation in research can lead to higher rates of enrolment and retention, and enhanced applicability of the results[4].

Robust evidence eliciting participants' perspectives can be obtained through social science research[2]. Participants' perspectives of drug trials, particularly in cancer, are well documented through the use of interviews and focus groups[5–9]. It is unknown whether participants in device trials share the perspectives of those recruited to drug trials. A number of papers have reported ways to involve end users in the design process of new technologies and interventions[10], but little is known about the participant experience of device trials.

Eliciting the participants' perceptions of device trials could help to inform the designs of future studies, in order to optimise participant enrolment, engagement and satisfaction with the ultimate aim of expediting the delivery of effective, proven healthcare technologies to the public.

1.1 Aim

In this paper, we report a qualitative study involving focus groups with former participants in a medical device trial. The aim of this study was to investigate participant perceptions of their involvement in medical device trials, in order to inform the designs of future medical technology evaluations. By generating much needed evidence in what is otherwise an area devoid of research, we hope that this paper will serve to enrich the experience of participants in device trials, and help researchers better understand their participants' motivations and concerns.

2. Methods

2.1 Study design

The focus group forum was chosen to encourage participation from groups who may be uncomfortable with individual interviews and to capitalise on the free flow of discussion and debate between participants.

Four focus groups were undertaken with patients who had participated in one medical device trial at a single large teaching hospital in England. This was a randomised controlled study evaluating the SensiumVitals® remote continuous monitoring device

(the “patch”) on two surgical wards. Participants who were randomised to the patch arm of the study received continuous remote vital signs monitoring for the duration of their hospital stay, in addition to standard intermittent vital signs monitoring delivered by nursing staff. These participants were compared to those receiving intermittent vital signs monitoring alone.

2.2 Data collection

Participants were recruited using purposive sampling with the aim to interview a range of participants across both wards, including both sexes, different ages and different durations of monitoring. Participants were permitted to bring a friend or family member to support them if they wished.

Four focus groups were conducted over a single day, face-to-face, at the hospital site. The interviewer used a pre-determined topic guide, informed by *a priori* theories developed by author CD through literature searching and informal interactions with patients and ward staff during the day-to-day management of the randomised controlled study. All interviews were audio recorded.

Focus groups were transcribed verbatim and anonymised. The transcripts were then entered into the software package NVivo 10 for organising and analysing the data.

Research Ethics Committee approval was obtained for this study (REC reference 16/YH/04/26) and written consent was gained from participants.

2.3 Analysis

Transcripts were analysed using Braun and Clarke’s thematic analysis[11]. First, the data were analysed by reading and searching the transcripts for common attitudes and experiences between participants. Emergent themes were coded, and the codes applied line-by-line to the transcripts by CD. The data were then systematically reviewed to ensure the themes worked in relation to the coded extracts. Codes were then independently verified by author WK. Any discrepancies in the application of codes to the transcripts were discussed until agreement was reached by CD and WK.

3. Results

Sixteen participants attended the focus groups (see Table 1), all of whom participated in the SensiumVitals® inpatient monitoring study. One participant brought a family member for support (Participant 2).

Eight participants were male; eight were female. Their ages ranged from 47 to 84 years. The number of days spent participating in the trial ranged from 3 to 12 days.

Participant	Sex	Age	Number of days spent in the trial
1	Male	63	6
2	Female	47	4
3	Male	79	6
4	Female	79	3
5	Male	84	5
6	Female	70	5
7	Female	72	3
8	Male	72	4
9	Male	76	3
10	Male	80	4
11	Female	67	3
12	Male	57	8
13	Female	79	3
14	Female	74	12
15	Female	67	4
16	Male	71	5

Table 1: Demographics of focus group participants

3.1 Themes

Four main themes emerged from the focus groups: (1) participants' motivations for participating in medical device research; (2) participants' perceptions of technology in medicine; (3) participants' understanding of trial methodology; (4) participants' perceptions of the benefits of involvement in medical device trials.

3.1.1 Theme 1 – Motivations for participating in medical device research

Participants were universally in favour of taking part in research. Motivations differed according to their previous experiences and outside influences. Many participants expressed philanthropic motivations. This was often mentioned in tandem with appreciation of the care they had previously received, suggesting that many felt indebted to the healthcare service. [See table 2, quotes 1A, 1B].

There was a keen understanding amongst the participants that research is necessary to further current knowledge, and that they had contributed to this. [See table 2, quotes 1C, 1D, 1E]. A small number of participants consented to take part in the trials due to a perception of personal benefit. For more participants, however, it was the lack of a

perceived 'downside' that motivated their involvement, rather than benefits to either humankind as a whole or themselves as individuals. [See table 2, quotes 1F, 1G, 1H].

A number of participants were influenced by their friends and relatives to take part. The appeal of new technology was an underlying factor behind relatives' enthusiasm. [See table 2, quotes 1I, 1J].

Asked if they would have consented to a trial involving an untested drug, the response was universal. The participants perceived drug trials as being more 'invasive' and would only consent if the drug was 'proven'. [See table 2, quotes 1K, 1L, 1M].

Quote	Participant	Text
1A	16	I'd like to give something back, basically.
1B	2	My brother-in-law had cancer of the oesophagus…he did so many trials after it, because he said that he owed them all that education.
1C	2	It's about progress. You've got to further education, haven't you?
1D	4	You feel as if you're doing something for the future.
1E	10	Well, you can't investigate…and improve yourselves in the hospital if we don't get involved with these things.
1F	16	You're helping yourself, aren't you?
1G	1	You're not doing anything else, are you? You…might as well try something that might help you or somebody in the future.
1H	16	[The trial] was the least of your problems.
1I	15	My wife was as interested in the technology behind it all as I was indifferent…She made the choice for me.
1J	Partner of 2	It was the…relative, us, husband, partner, whatever…you're more at ease. You can go home and think, oh, they're still…being monitored.
1K	4	[Compared to] something like medicine, this is obviously quite mild.
1L	16	It's not something which you're going to put inside your body. So…you didn't mind the monitoring but with a drug, I think I'd question it.
1M	12	It depends on which stage of a drug trial you were talking about. I did my training in Northwick Park which, as you know, is where there was a real trial disaster a few years ago, involving deaths, so I wouldn't get involved [in a Phase I trial].

Table 2: Quotes related to motivations for participating in medical device research

3.1.2 Theme 2 – Perceptions of technology in medicine

In contrast, many participants expressed concerns about the emerging preponderance of technology in healthcare, especially in terms of practical considerations such as cost and malfunction. [See table 3, quotes 2A, 2B].

In one focus group, concerns were raised about the abilities of older patients to understand and utilise new devices. [See table 3, quote 2C].

It was widely felt that to overcome these difficulties, there should be a protocol in place to fully explain the new technology with adequate time for demonstration, if applicable. [See table 3, quote 2D].

This echoed a recurring theme of appreciating personal contact. Although participants could see how technology could deflect workload from healthcare professionals, they were unanimously averse to losing personal interaction with staff due to the increased use of technology. [See table 3, quotes 2E, 2F].

Quote	Participant	Text
2A	10	What happens if the phone goes down? Or the computers?
2B	11	I was thinking about the price for the NHS.
2C	5	You've got to like technology. I don't!
2D	7	I think that would be better; someone to actually [demonstrate] so you can feel, and then know.
2E	2	It helps because of the nursing shortage as well.
2F	2	Patients like to talk to nurses.

Table 3: Quotes related to perceptions of technology in medicine

3.1.3 Theme 3 – Understanding of trial methodology

The theme of trial methodology could be divided into perceptions about consent, randomisation, placebos and dissemination.

Participants conveyed their understanding of informed consent, especially in terms of the timing of consent, and the amount of information they received. Overall, they expressed the need for more information, as soon as possible, with plenty of time allowed to fully understand the trial and to find out more for themselves. In particular, getting information ahead of their hospital admission seemed preferable to being approached as an inpatient. [See table 4, quotes 3A, 3B, 3C, 3D, 3E].

When asked about randomisation and placebo-controlled trials, many participants understood the need for such trial designs, and indicated that they would be happy to be randomised to a control arm or even a sham arm, as long as they were fully informed ahead of the trial. [See table 4, quote 3F]. That said, a number of participants were anxious about the idea of receiving a sham device. [See table 4, quote 3G].

Participants were very enthusiastic about the dissemination of the trial results directly to the participants themselves, outwith scholarly publications and presentations. In fact, many people confessed that their attendance at the focus group was to find out the results of the study they had been involved with. [See table 4, quotes 3H, 3I].

Quote	Participant	Text
3A	4	I don't remember much about the discussion, just remember agreeing to it. Basically thinking that sounds okay.
3B	5	Sometimes, somebody comes to see you… and you don't quite get what it's about. I thought maybe that if… you had a [Participant Information Sheet] like this…when you get your letter for admission…then you would have known more about it. I think it would encourage people to say yes. The more information you have, the more confident you feel about everything.
3C	4	You think right, I'll research that, and you go…research, so a bit of prior warning [would be preferable].
3D	12	I would probably have said yes to anything at the time.
3E	4	I felt that I was on a university course when I was in hospital…So that's all to be processed.
3F	2	It's not deception because nobody would know, would they? You know that you don't know.
3G	10	I think [the possibility of randomisation to a sham device] would be a sort of feeling of stress, if you don't know whether it's right or wrong.
3H	12	I think the general public needs to know that these trials are going on, and the results of them.
3I	2	It's like getting the information before, but the information after.

Table 4: Quotes related to understanding of trial methodology

3.1.4 Theme 4 – Perceptions of the benefits of involvement in medical device trials

Participants universally expressed that they felt they received 'extra' care whilst participating in a trial, which was perceived as a positive outcome. There was an expressed perception of wellbeing through being part of the trial. [See table 5, quote 4A].

This was widely attributed to the social benefits of involvement, both from research staff and other patients. [See table 5, quotes 4B, 4C, 4D].

Many people felt a sense of comradery with fellow research participants on the wards. By observing other patients who were using the devices, participants were able to find other commonalities in their conditions, which was a source of great comfort to some. A few participants found this to be true again during the focus groups themselves, and expressed their gratitude for a forum in which they could share their experiences with likeminded individuals. [See table 5, quotes 4 E, 4F, 4G, 4H].

Quote	Participant	Text
4A	10	It made you feel better.
4B	2	And there [was] a smiley face.
4C	2	I think it's nice when people come, because the nurses have got a lot to do. And sometimes you've got no one to talk to.
4D	11	I enjoyed the conversation. I quite enjoyed that part of it.
4E	2	You compared yourself to the patient over the ward, because they [used the device]. 'The gadget,' we used to call it.
4F	2	It helps you talk to other people who've been through the same experience. People don't want to be secretive…if you find someone that's like-minded. Whereas when you go home, you don't tell anybody that you've got a [colostomy] bag. And then, if you live on your when it's just within yourself sometimes.
4G	7	[Other people] will listen for a while, but [it's better] if it's somebody who has suffered the same kind of thing. It gives you a bit of confidence if you meet somebody…who's gone through something.
4H	4	I've been to other National Health meetings…and I was bored to death, to be honest.

Table 5: Quotes related to perceptions of the benefits of involvement in medical device trials

4 Discussion

Technology and its assessment are becoming increasingly important in the provision of healthcare, but little is known about the experience of participants in device trials.

To our knowledge, this is the first study to investigate participants' perceptions of their involvement in medical device trials. Other studies consider patients' views regarding using medical devices[12-15], but not their thoughts on being involved in the device trial itself. This study therefore adds novel information to an otherwise sparse literature base.

Consideration of the factors delineated within this paper could allow researchers to better inform the strategies they use for communicating with patients before, during and after trials, leading to more active patient involvement in future medical technology research, with a more satisfied and better engaged patient cohort.

Participants consented to their involvement in device trials for several different reasons (theme 1), including philanthropy and a wish to repay their perceived debt to the health service. This is in direct contrast with equivalent data regarding drug trials [5-9], where altruism is 'inconsequential' and participants are motivated by the hope of therapeutic benefit[16]. The appeal of new technology (theme 2) is a contributing factor to the decision to consent, although concerns remain about the risks associated with technology in the healthcare setting. Particularly amongst older patients, there is also a perceived lack of confidence in using technology; compensating for this may make patients feel more comfortable as trial participants, particularly when working with less technologically capable cohorts. Potential mitigation strategies may include education, reassurance, and simplification of any interface that the patients themselves are required to operate.

Despite being an essential element of research methodology (theme 3), randomisation continues to be a concept that influences participation in drug trials[5-6]; this was not perceived to be a significant barrier in device trials. Patients display concerns about potential harms posed by drug trials [5], but this did not emerge as a theme here. This may, though, reflect the fact that the focus group members had all been involved in the trial of a monitoring device, rather than a therapeutic instrument. The former may be perceived to be more benign than the latter.

Perceived benefits of participating in device trials (theme 4) include extra care, social benefits and comradery with other participants seen using the devices.

Clinician behaviour is important across all clinical studies, and communication between research staff and participants remains paramount to ensure informed consent and greater participant satisfaction[5].

This work has limitations which must be considered when interpreting the findings. The study was limited to a sample of participants from a single geographical location (Yorkshire, England). The findings are likely to be influenced by the context in which it was conducted and may not be valid in other contexts. This project also only considered a trial involving monitoring devices, rather than devices with therapeutic purposes. Certain themes, such as the comradery of seeing other patients using the devices, will only be applicable to external devices, although they may have wider implications for patient compliance across other technologies. While the number of participants was small, the researchers were satisfied with the recurrence of themes over the four focus groups and across a wide demographic.

5 Conclusion

Future device trialists should prioritise information sharing both before and after the trial. Participants may lack confidence in using technology, which can be ameliorated by the provision of information and demonstrations of the device under assessment.

Providing information in verbal and written form allows participants the opportunity to adequately understand and research the technology before consenting. Randomised trials and those with placebo- or sham-controlled arms should not be considered as barriers to participation. The results of the study should be disseminated to participants in lay format as soon as they are known, subject to participant permission. In addition, participants should be offered the opportunity to continue their involvement through Patient and Public Involvement forums where they can maintain the perception of comradery and altruism gained during the trial.

1	Disseminate patient information sheets as early as possible.
2	Include links on patient information sheets to direct interested participants to relevant websites for extra information.
3	Include demonstrations of the medical device as part of information sharing; consider face-to-face demonstrations and online videos.
4	Consider randomised design and the inclusion of placebo- or sham-controlled arms where appropriate.
5	Include an opt-in option on consent forms to allow the dissemination of study results directly to the participants.
6	Allow time and funds to create a lay summary of results to send directly to consenting participants.
7	Consider pathways for participants who wish to continue their involvement in the research, such as the creation of a Patient and Public Involvement forum.

Table 6: Key suggestions for future research designs

Authors' contributions

CD and DJ were involved in the conception of the work. CD designed the study. RR provided methodological expertise. CD and WK undertook the data collection and performed the analysis and interpretation. CD drafted the article. All authors were involved in critical revision of the article and have given final approval of the version to be submitted.

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The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, Health Education England or the Department of Health.

Conflicts of Interest

There are no known conflicts of interest associated with this work and there has been no significant financial support for this work that could have influenced its outcome.

Summary table

What was already known on the topic?
• Clinical trials of medical devices are increasing. • The success of device trials depends on participant enrolment, engagement and satisfaction.
What this study adds to our knowledge
• Participants' consent to enrolment in device trials depends on the balance between the appeal of new technology, and the perception of risk in the healthcare setting. • Perceived benefits of participating in device trials include extra care, social benefits and comradery with other trial participants. • Participants value information sharing both before and after the trial. • Randomised trials and those with placebo- or sham-controlled arms should not be considered as barriers to participation.

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