South Asian patients’ views and experiences of clinical trial participation

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**Objectives.** This paper explores South Asian patients’ views and experiences of clinical trial participation, as part of a larger study which sought to assess British South Asian under-representation in clinical trials.

**Methods.** The study was based on semi-structured interviews with South Asian trial participants in primary care and specialist treatment centres in the north of England. Fifteen South Asian patients who had participated in one of six different clinical trials to test pharmaceutical products comprised the study cohort.

**Results.** South Asian motivations to participate in clinical trials are similar to those of the majority ‘White’ population. Clear and concise trial information (provided by caring and understanding trial staff) was considered an important aspect of the respondents’ experiences. Appealing to South Asian peoples’ altruistic nature by making them aware of South Asian under-representation (especially in clinical trials that investigate illnesses prevalent in their community) was also identified as a strong motivational factor. Potential barriers to their participation included: trial burden (which bears heavily on the poor), language, and discriminatory practices in the NHS, which can lead to mistrust of health professionals. In addition, female modesty and preference for female trial staff was recognized as a ‘cultural’ barrier to participation.

**Conclusion.** There are more similarities than differences between the experiences of British South Asians and ‘White’ trial participants. Present findings suggest that ethnicity operates at different levels. In addition to South Asian trial participants’ culture, social class and gender are also as likely to affect their participation in clinical trials. To improve South Asian accrual rates, strategies should be designed to take into consideration linguistic differences and improving overall trust in the clinical trial team.

**Keywords.** Clinical trials, ethnic minority, participation in medical research, South Asian people, under-representation.

**Introduction**

With mounting concern that ethnic minority people are under-represented in clinical trials, there is a need for further research in this area. It is prudent to include them in trials in order to sustain the generalizability of the findings to the broader population. Exclusion also raises issues around equity in health provision, since evidence suggests that people who take part in clinical trials have better outcomes. Studies exploring ethnic minority participation in clinical trials are mainly from the USA, and primarily about African-Americans. Barriers specific to ethnic minority participation include: mistrust of research and cultural beliefs; responsibility to extended family; social commitments; and modesty/gender role, which have been associated with a refusal to participate in clinical trials. However, there cannot be an unquestionable reliance on ‘cultural’ explanations for their under-representation in clinical trials, since this ignores the diversity of attitudes and beliefs held by the members of an increasingly heterogeneous population.

To date, there is no UK-based research exploring South Asian participation in clinical trials (the UK’s largest ethnic minority group comprising 4% of the total population). Learning more about South Asian trial participants’ beliefs and values regarding clinical trial participation would not only inform policy initiatives in
this area, but would also achieve a more equitable basis for trial participation.

This exploratory study, therefore, aims to explore South Asian trial participants’ views and experiences in UK clinical trials, their reasons for participation and potential barriers to their recruitment.

Methods

Qualitative research methods were used, and data were collected using semi-structured, in-depth interviews, using a checklist of topics to guide the discussion. The topic guide (see Appendix) was developed from the literature and refined after interviews with key stakeholders (health professionals, trial participants and South Asian lay people). The topic guide addressed the following broad areas:

- trial participants’ experiences of trial participation
- reasons for taking part in clinical trials
- factors affecting the decision-making process
- barriers to trial participation

Interviews lasted from 30 to 90 min and were fully transcribed. Two of the interviews were conducted in Urdu and Punjabi by the author, who is fluent in these South Asian languages. Data were analysed using framework analysis, designed not only to provide a rigorous approach to making sense of the data, but also to make the analytical process more explicit so that it can be viewed and assessed by people other than the primary researcher. Ethical approval was obtained for the study.

Results

Recruitment was achieved by selecting trial participants from the trials database of CTRU (Clinical Trials Research Unit), and supplemented through contacts with the cancer centre, organ transplant unit, gastroenterology, midwifery, cardiovascular and diabetes departments in both Leeds and Bradford. Attempts were also made to recruit respondents directly by talking about clinical trials on the local South Asian radio station on two separate occasions. Although the listeners showed interest, none of the people who phoned in had ever taken part in a trial. The reality remains that very few South Asian people appear to have taken part in clinical trials in West Yorkshire, and clearly this is a finding of the study.

A total of 15 patients (eight women and seven men), who had taken part in: *Helicobacter pylori*, cardiovascular, cancer, diet, gynaecological and hormone replacement therapy (HRT) trials, were interviewed. Only four of the respondents were aware of clinical trials prior to being approached to take part in them (awareness appeared to be associated with level of education). Eleven of the respondents were aged 45–60 years and four were aged 20–30. The respondents were predominantly from social classes III and IV (partly skilled). All were fluent in English with the exception of two, who preferred to be interviewed in Urdu and Punjabi. As the sample is small, the conclusions drawn may not be entirely valid; nevertheless, several consistent themes emerged repeatedly within and between transcripts, thus adding to the reliability of the findings.

**Reasons for participation**

Altruism was a prominent feature in the majority of the interviews, where taking part in clinical trials was perceived as helping society. Others believed that participating in diabetes or cardiovascular trials would be particularly beneficial to the South Asian community, since the respondents felt they shared a greater disease burden. The knowledge that Asian women were under-represented in HRT trials motivated one respondent to contribute to “help her community”. Two others took part in trials because they wished to share the benefits of the trial with their community.

While it would be naïve to assume from the present findings that altruism is the primary motivation in South Asian peoples’ decision to take part in clinical trials, the desire to help others appears to be a strong motivating factor. It might be the case that altruism was secondary to the hope that the trial might benefit the patient. A female respondent believed that taking part in the trial “might make somebody listen” and help her “make sense” of her illness. Two of the younger females who took part in gynaecological trials did so to help their unborn babies, despite finding the procedures “painful and embarrassing”. Other reasons for participating in clinical trials included: curiosity, to please the doctor, and lack of an alternative treatment (Box 1).

**Box 1  Reasons for participation**

"I wanted to get involved myself. The situation with our people was very bad; I felt there was an increase in illnesses and disease in our community.” (Female 4–2) [Translated from Urdu]  
"...if it’s cured the problem, then I can tell people, ‘Oh, yes, why don’t you go for this test? This might done good for you’. You know, so I can tell the people.” (Male 11–4)  
“Yes, well they said it works much better, so that’s why I tried it, as well as I thought it will be beneficial to other patients at the same time.” (Male 2–3)  
“I think it was just an interest to see what a trial was like basically.” (Male 8–1)  
“I felt the need to participate and support them [doctors]. That is the reason why I got involved.” (Female 10–2) [Translated from Punjabi]
Experiences of participation
A majority of the trial participants had a good or partial recall of the major features of the trial and were generally pleased with all aspects of participation. Trust in the doctor or the trial nurse was apparent in many of the accounts.

Trust in the clinical trials team. Trust in the clinical trials team was expressed in terms of the health professional being an expert, which extended to trust in the trial itself. The respondents were particularly moved by the “friendliness” of the trial staff, who were viewed as being empathic, and who made the respondents “feel at ease” (Box 2). The present findings are also mirrored by the general ‘White’ population, who have been shown to participate in clinical trials due to confidence and trust in trial recruiters.12 In addition, the findings suggest that adopting humane qualities of empathy and understanding fosters trust, a factor considered crucial by all respondents.

Difficulties with understanding clinical trial terminologies. Difficulties with understanding clinical trial terminologies was an issue that came up frequently, in particular for the older South Asian respondents, where lack of fluency in the English language led to uncertainty and confusion. An older female respondent insisted that her daughter (who was fluent in English) accompany her to the surgery, because of her anxieties about the nature of the trial. One respondent, in the case of H. pylori trial, thought he was “summoned” and was not given a choice, and another felt that he had been called for a routine health check. Their views are encapsulated in Box 2.

Decision making. The respondents’ accounts also suggest that patterns of decision making about trial participation may not be dissimilar from those of the majority ‘White’ population; highlighting a mix of paternalistic, shared and family decision making with regard to participation in clinical trials. For instance, three of the respondents had decided to take part in the trial on their own, regardless of their age, gender or social class. Others consulted with their family members and clinical trials staff. One respondent believed that he was not given a choice in the matter and the decision to take part in the trial was made by his GP. He did however, suggest that the trial was not imposed on him, and he took part in the trial out of ‘obligation’ to his GP.

Decision to participate in the trial also depended on the gender of the trial recruiter, especially in those trials which were viewed as ‘embarrassing’. Three of the female respondents stated that they would not have taken part in the gynaecological trials if they involved members of the opposite sex. This was because these women considered “showing their parts to men” as unacceptable. This finding is in keeping with the literature, which suggests that concerns about modesty in ethnic minority women can result in poor participation in gynaecological and breast trials.6,13 Modesty and a preference for female trial staff, however, was not an issue for all female respondents. This implies a degree of diversity in attitudes amongst this group of women.

Issues with consent. With regard to consent, although the majority of the respondents stated that they were happy to sign the consent form, not all fully understood the reasons for signing it. Some viewed it as a “Western formality”, which they were happy to go along with. One respondent signed the consent form as a result of indirect social pressure watching others sign. Others saw consent as a form of protection for the health professionals, in case “something went wrong” (Box 2). It was suggested that only those people who have had surgery in the past would know about consent forms in advance, and the respondents could not see a reason why South Asian people would be any different from the general population in their level of understanding of consent.

Although the present findings suggest that some South Asian trial participants may face uncertainties with regard to the consent process, similar ambiguities are common amongst the general ‘White’ population, where the purpose of the consent form may not always be totally clear to trial participants.14 The difference is that such ambiguities facing South Asian people have their
founding in experiencing discriminatory practices in the NHS, a point I will discuss later. The decision to participate in a trial also depended on the trial burden, which was perceived as a potential barrier to participation.

**Barriers to participation**

Logistic barriers to participation were discussed where respondents contextualized their experiences in relation to other South Asian people by arguing that those who worked long hours, were in manual occupations or low paid jobs, were unable to take time off work, and had no transport, would not be able to participate in clinical trials. In addition, language and mistrust due to discriminatory practices in the NHS were perceived as potential barriers to South Asian participation in clinical trials (Box 3).

**Trial burden.** Trial participants’ accounts reflected a sense of being burdened by trial involvement in some cases. In addition to extra visits, other burdens consisted of dealing with the side effects of the trial treatment, cost associated with travelling long distances, and complicated and often uncomfortable medical procedures. Lack of financial support for childcare was also recognized as a barrier to trial participation, where one respondent stated that since having a child she would be unable to participate in future trials due to childcare costs. An older trial participant had to pull out of a heart trial due to a stroke, which made him unable to use his own transport. His trial nurse had to organize hospital transport for him so that he could complete the trial.

One male respondent recalled difficulties in travelling to the trial site because he was the only driver in the family, and paying for taxis was beyond his means. He also found the chemotherapy trial particularly difficult due to the side effects of treatment, which he was only able to overcome due to ‘encouragement’ and the ‘mental support’ he received from the trial nurses. He went on to suggest that his fluency in English enabled him to understand and respond to such encouragement.

**Language.** All respondents believed that lack of fluency in English should be considered a major barrier to South Asian participation in clinical trials. One argued that non-English-speaking patients would not be able to take part in the chemotherapy trial he was involved in, due to the complicated and demanding nature of the trial. Lack of fluency in the English language was also alleged to lead to the discrimination of those South Asian patients for whom language is a barrier to communication. The presence of any discriminatory practices in the NHS was thought to lead to mistrust of health professionals, and this was perceived as a barrier to South Asian participation in clinical trials.

**Discriminatory practices.** None of the respondents interviewed had personally experienced breaches of trust, although some recalled bad experiences of their friends and close relatives. Others believed that because South Asian people are treated as ‘outsiders’, they might not want to ‘contribute’ to medical knowledge because they are not made to feel a part of British society (Box 3).

‘Breaches of trust’, according to King (2002), may be an important factor in contributing to health care disparities among ethnic minority groups. Further, health professionals have been shown to harbour prejudice towards ethnic minority people, and such attitudes can affect trial recruitment of this group.

Trust is particularly important in the informed consent process during which a lack of trust often leads to the patient’s refusal to enter a clinical trial. It is not unreasonable to assume that South Asian people may respond to discriminatory attitudes with mistrust of health professionals and, therefore, may be reluctant to participate in clinical trials.

**Discussion**

Exploration of South Asian patients’ experiences and views on clinical trial participation indicate that similar to the ‘White’ majority population, motivations to participate in clinical trials include: altruism, hope for a better treatment, to improve scientific knowledge, curiosity and clinician influence. Potential barriers to their participation were identified as trial burden (which bears heavily on the poor), poor language support and discriminatory practices in the NHS, leading to mistrust. Modesty in women (who seem to have a preference for female trial staff) was presented as a ‘cultural’ barrier; albeit a barrier experienced by women from a variety of ethnic backgrounds. These findings suggest that the relevance of ethnicity should not be exaggerated and, in addition to a South Asian trial participants ‘culture’, social class and gender are also as likely to affect their participation in clinical trials.

Although most of the respondents in the present study were fluent in English, their experiences suggest that trial participation would have been difficult for

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**Box 3** Barriers to participation

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<th>Language</th>
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<td>“There was a Asian woman who couldn’t speak English and I could see she was treated differently. Not only just by the staff, also the other patients... people do treat differently if you don’t speak the language.” (Female 1–4)</td>
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<td>Discriminatory practices</td>
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<td>“… he said the nurses and the doctors, they didn’t treat me right... he couldn’t speak English. ‘Look, I have lost confidence in that, I don’t want to go to hospital’. I used to tell him you should go and he said no. So he is scared to go back in case something else might happen.” (Male 2–7)</td>
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<td>“And even though we’re here and we’ve tried to get in with the people, we’re still treated as an outsider, and then we tend to think, ‘Well it’s nothing to do with us’... we have to get on with our business, or run our little shop or whatever and that’s it. So there’s that, the fact that we are treated as aliens or we feel alien, that’s why.” (Male 7–3)</td>
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them if language were a barrier to communication. Language has been suggested as a barrier to ethnic minority participation in research, and a limited command of the English language given as a major reason for non-participation in clinical trials. For English-speaking South Asian people, inclusion in clinical trials should be easier, and this study for the first time bears out this assumption.

Clear and concise trial information, provided by caring and understanding trial staff, was considered an important aspect of the respondents’ experiences. Appealing to a South Asian person’s altruistic nature, by informing them about South Asian under-representation in clinical trials that investigate illnesses prevalent in their community, was also identified as a strong motivational factor. The role of altruism, in order to contribute to science and society, should be recognized and the contribution that South Asian trial participants make through involvement in trials should be acknowledged and feedback. This would provide a sense of purpose and belonging to British society.

Clinical trial methodology is difficult to understand, and the findings from this study suggest that some respondents were confused when first approached to participate in the trial. Consideration, therefore, needs to be given to ways of providing accurate and straightforward information to some South Asian trial participants. This could be achieved through providing translated information sheets, and through training translators in clinical trial terminologies. Strategies could also be tailored to the target group, designed to reflect trust in the medical care team. The use of videos and pictures was also one of the strategies put forward, combined with a system of checking understanding and ongoing education and training in communication skills for health professionals.

What is already known on this subject?

South Asian people (largest ethnic minority group in the UK) are under-represented in clinical trials, and little is known about their motivations and barriers to clinical trial participation. Lack of knowledge about South Asian trial participants’ beliefs and values regarding clinical trial participation leads not only to policy initiatives based on out of date assumptions and speculation, but also to inequitable clinical trial participation.

What does this study add?

South Asian reported motivations for trial participation are similar to those reported in the ‘White’ literature, and include: altruism; hope for a better treatment; to improve scientific knowledge/curiosity, and clinician influence. Female modesty was identified as a possible ‘cultural’ aspect responsible for their under-representation in clinical trials. Lack of language support in the NHS makes participation in clinical trials difficult for those South Asian people for whom language is a barrier to communication. Any discriminatory practices in the NHS can lead to mistrust of health professionals and subsequently South Asian under-representation in clinical trials.

Strategies proposed to facilitate South Asian participation in clinical trials include: clear and concise information delivered by caring and understanding staff; fostering trust; awareness that South Asian people are under-represented in clinical trials investigating illnesses more prevalent in South Asian people; better language support, and same gendered staff for more ‘intimate’ trials.

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Declaration

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Conflicts of interest: None declared.

References


Appendix. Topic guide used in interviews with South Asian trial participants

Background information

Could you start by telling us about your involvement and experience of taking part in the clinical trial?

Were you aware of clinical trials before your (illness)?

Did you understand what was going on when approached to enter a trial?

How was the subject raised, what were your initial reactions?

Did you understand the doctor’s explanation about the trial?

What was your response, were you given enough time to think about your decision?

Did you ask questions? (what kind, why not?)

Where specifically were you recruited?

A hospital or a cancer centre, were there any differences in the way you were treated there?

For instance, what were the health professionals like, their attitudes?

What are your general feelings about medical research?

Are there any benefits or dangers of taking part in trials?

(Explore if they would participate again)

Would your decision to participate depend on factors such as how you get on with your doctor?

Is there anything the doctors should do to make life easier?

In what respect?

In relation to clinical trial process, consent form, information sheet, etc.

Informed consent

Have you heard of the term informed consent, or understand what it means?

Did you have any problems with the idea, what kind of information or advice have you been given?

How easy or difficult has it been to get the information you need?

Where were you given the information? (surgery, hospital, home, community centre).

Who gave you this information?

How was the information given to you (verbal/written/audiotape/ videotaped)?

Has this information been helpful?

Are you aware of legal protections for participants in medical research?

Probe: informed consent

Adequate disclosure of information

Patient’s ability to understand information

Voluntary choice

Did you have enough time to consider your participation in the trial?

Can the process of informed consent or information sheets be made more user friendly in any way?

Did you know what you were agreeing to, what was good, what was bad?

Do you feel that language is a problem (e.g. access to interpreters, use of jargon)?

If English was not good, how was this overcome?

Have you heard of the randomization process in clinical trials? Ask if appropriate/relevant to the trial.

Decision making

Did you make the decision to take part in the trial yourself?

How involved was your family in deciding whether to participate in the trial?

Any gender differences, e.g. wife and husband?

Are you more or less likely to enter a trial if it was somebody you knew?

About your decision to participate, were you influenced by anything or anyone?

Coercion by doctor, should doctors make that decision for you?

Barriers to recruitment

Do you think there is a difference in the way that different health professionals communicate with patients in general, when recruiting for a trial?

Are South Asian patients more likely to respond to an invitation by a nurse or a consultant?

If nurse, is it something about the way they behave?
Do you think there are any reasons which may prevent health professionals from recruiting South Asian patients to clinical trials? Can you think of any reasons why South Asians will be less willing to participate in trials than the ‘White’ population? Do you think there are differences between the South Asian community and the ‘White’ population in terms of the level of and type of information required for them to participate in clinical trials? For example, the need to explain what a trial is, consent forms, etc.

Do you believe that there is anything in the way of life of South Asian patients which influences their decision to participate/or not in trials? For example, do they look at illness and health in a different way to the general population, time keeping, social class, etc. Do you think religious influences play a role in the decision to participate or not in clinical trials? What do you think are the most important things to think about in terms of methods of recruitment from South Asian communities?