Involving South Asian patients in clinical trials

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Executive summary

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Background

Many randomised controlled trials have fewer South Asian participants than expected. There is a lack of ethnic minority recruitment data in many trials, making assessment problematic. This study was prompted by a lack of knowledge about how South Asian people perceive trial involvement and the risks and benefits involved.

Objectives

1. Investigation of how South Asian patients conceptualise the notion of clinical trials.
2. Identification of the key processes that impact on trial participation and the extent to which communication difficulties, perceptions of risk and attitudes to authority influence these decisions.
3. Identification of whether ‘South Asian’ patients are homogeneous in these issues, and which factors differ between different South Asian subgroups.
4. Identification of how professionals regard the involvement of South Asian patients and their views on strategies to increase participation.

Design

A review of the literature on minority ethnic participation in clinical trials was followed by three qualitative interview studies. Interviews were taped and transcribed (and translated if required) and subjected to framework analysis.

Setting

The study took place in the Leeds and Bradford areas of England.

Subjects

Face-to-face interviews were conducted with 25 health professionals (consultants, GPs, nursing staff, academics, non-medically trained trial coordinators, Local Research Ethics Committee and Multicentre Research Ethics Committee members); 60 South Asian lay people (20 Indians, 20 Pakistanis and 20 Bangladeshis) who had not taken part in a trial and 15 South Asian trial participants.

Results

South Asian conceptualisation of trial participation

Motivations for trial participation were identified as follows: to help society, to improve own health or that of family and friends, out of obligation to the doctor and to increase scientific knowledge. Deterrents were identified as follows: concerns about drug side-effects, busy lifestyles, language, previous bad experiences, mistrust and feelings of not belonging to British society.

Key processes impacting on trial participation

There was no evidence of antipathy amongst South Asians to the concept of clinical trials and, overall, the younger respondents were more knowledgeable than the older ones. Problems are more likely to be associated with service delivery. Lack of being approached was a common response. Lay-reported factors that might affect South Asian participation in clinical trials include age, language, social class, feeling of not belonging/mistrust, culture (importance of families, gender issues, community gossip and health beliefs) and religion (modesty, meat-derived and non-Halal medicine).

Homogeneity of views about participation

Awareness of clinical trials varied between each group. Indian respondents were most likely to be aware and less than half of the Pakistani and Bangladeshi respondents were aware of clinical trials. There are more similarities than differences in attitudes towards clinical trial participation between the South Asian and the general population. Important decisions, such as participation in clinical trials, are likely to be made by those family members who are fluent in English and younger. Social class appears to be more important than ethnicity, and older South Asian people and those from working class backgrounds appear to be more mistrustful.
Professional views
Approachable patients (of the same gender, social class and fluent in English) tend to be ‘cherry picked’ to clinical trials. This practice was justified because of a lack of time and resources and inadequate support. South Asian patients might be systematically excluded from trials owing to the increased cost and time associated with their inclusion, particularly in relation to the language barrier. Under-representation might also be due to passive exclusion associated with cultural stereotypes. Other characteristics such as gender, age, educational level and social class can also affect trial inclusion.

Discussion
There are a number of reasons, identified from this study, why South Asians should not be excluded from clinical trials. Exclusion is inequitable since evidence suggests that people who take part in trials have better clinical outcomes. Unless South Asian people are routinely included in trials, the diseases to which they are disproportionately disposed (including diabetes and heart disease) will remain poorly understood and treated. Furthermore, exclusion of minority ethnic groups from trials undermines the government’s NHS plan for tackling inequalities. It is also important to sustain the widespread applicability of trial findings to the whole population. Exclusion of a subset of the population could have implications regarding the safety and efficacy of new drugs. Finally, participation of minority ethnic groups in trials would help to reduce alienation and mistrust and emphasise that they are an integral part of British society.

Conclusions
The following suggestions may provide effective strategies for South Asian recruitment to clinical trials:

- use multi-recruitment strategies
- define the demographic and social profiles of the population to be included
- use focus groups to identify any potential barriers
- consult representative community members to provide assistance in the study
- ensure eligibility criteria are set as wide as possible to achieve wider applicability of results
- develop educational and recruitment approaches to attract ethnic minority health professionals
- ensure health professionals are adequately trained in culturally and ethnically orientated service provision
- determine the most effective mass media to use in study promotion and recruitment
- target inner-city, single-handed practices likely to have high ethnic minority populations.

Future research
The following areas of further research are recommended:

- responses when invited to participate
- role of methodological and organisational barriers to recruitment
- complexities of recruitment from a health professional perspective
- developing culturally sensitive research methods
- magnitude of the problem of under-recruitment
- strategies to encourage inner-city, single-handed GP participation
- investigation of other factors affecting trial inclusion, such as age, gender, educational level and socio-cultural background.

Publication
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