Involving South Asian patients in clinical trials

M Hussain-Gambles,[1] B Leese,[1*] K Atkin,[1] J Brown,[2] S Mason[2] and P Tovey[1]

[1] Centre for Research in Primary Care, University of Leeds, UK
[2] Clinical Trials Research Unit, University of Leeds, UK

* Corresponding author

Involving South Asian patients in clinical trials

Executive summary

Health Technology Assessment 2004; Vol. 8: No. 42

Health Technology Assessment
NHS R&D HTA Programme

Executive summary

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

Hussain-Gambles M, Leese B, Atkin K, Brown J, Mason S, Tovey P. Involving South Asian patients in clinical trials. *Health Technol Assess* 2004;**8**(42).

NHS R&D HTA Programme

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, consumer groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including consumers) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or designing a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a limited time period.

Criteria for inclusion in the HTA monograph series
Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 98/23/19. As funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

ISSN 1366-5278

Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.