Author's response to reviews

Title: Recruitment of ethnic minority patients to a cardiac rehabilitation trial: The Birmingham Rehabilitation Uptake Maximisation (BRUM) study [ISRCTN72884263]

Authors:

Kate Jolly (C.B.Jolly@bham.ac.uk)
Gregory YH Lip (G.Y.H.Lip@bham.ac.uk)
Rod S Taylor (R.S.Taylor@bham.ac.uk)
Jonathan W Mant (J.W.Mant@bham.ac.uk)
Deirdre A Lane (Deirdre.Lane@swbh.nhs.uk)
Ken W Lee (kaeng007@doctors.org.uk)
Andrew J Stevens (A.J.Stevens@bham.ac.uk)

Version: 2  Date: 21 April 2005

Author's response to reviews: see over
Dear Editor

Re: MS: 5291606425942086  "Recruitment of ethnic minority patients to a cardiac rehabilitation trial: The Birmingham Rehabilitation Uptake Maximisation (BRUM) study [ISRCTN72884263]"

I have revised the manuscript in line with the reviewers suggestions. The changes to the manuscript have been seen and approved by all the co-authors. Please see below my point-by-point response to the reviewers comments.

Reviewer: Tim Allison

Major compulsory revisions

1. We acknowledge that this study does not give information about the willingness of excluded participants to take part in the study. The study, unusually for a UK based trial, made considerable efforts to recruit and provide a behavioural intervention to patients from the local, predominant minority ethnic group (Punjabi speaking South Asians). The fact that the Indian sub-group had similar rates of eligibility and recruitment to the white population provides some evidence that when the issue of language is dealt with, people from minority ethnic groups are as likely as the majority white population to participate in a study. This point was covered in para 2 of the discussion and further detail has been added. What is of note is the difficulty of meeting the language needs of patients from a multi-ethnic UK inner city population.

In addition it is of interest that for this patient group with heart disease, where one might have expected a higher proportion of the South Asian patients to have been excluded for cardiac causes, the rates for this were very similar between the different ethnic groups.

We agree that the first sentence of the second paragraph of the discussion is not generalisable, and this has been amended.

2. The different proportions of people who declined to take part giving no reason for their refusal is discussed in paragraph 2 of the discussion. The differences reported do not reflect the evidence from the US literature which suggests that people from minority ethnic groups are less likely to agree to participate in trials because of a lack of trust. Should a similar reason be the case in the UK, which does not have the past history of the Tuskegee Syphilis study, we would have expected a higher proportion of the patients in the minority ethnic groups to have given the reason for non-participation as 'not wishing to take part in research'. This was not the case. However, as more of the people from the minority ethnic groups gave no reason for their refusal to participate there could be no difference between the groups. This has been acknowledged in the discussion.

3. We have given more detail about the implications of this study (see conclusion). Despite a number of reports from the USA about recruiting people from minority ethnic groups to research studies, there has been little from the UK. In addition, we are not aware of any other published study which is able to relate the recruitment to the actual ethnicity of the presenting patients. The most important implication of this particular study is that even with considerable effort, time and resources to try to recruit a representative population to the trial, we were unable to meet the wide language requirements. This must be considered in the context that this trial involved a behavioural intervention and had a psychological questionnaire as a major outcome measure. In
other trials, with only objective clinical measurements as endpoints it might be possible to exclude less patients due to language restrictions.

Other necessary changes

Table 1: the presentation of the percentages and contents of the brackets has been altered.

Table 2: The suggested changes have been made.

Minor essential revisions

Abstract line 4: “are” has been added.

Background line 2: the sentence has been changed to: ‘This is essential for the generalisability of the results [8,9], and to achieve this, trial participants need to mirror the demographic profile of the disease group being studied’.

References: the style of these has been checked.

Reviewer: Kimlin Ashing

Major compulsory revisions

The results for the recruitment of women have been added to table 1 and the results paragraph 2.

Minor compulsory revisions

Background section:

Passive voice has been removed paragraph 2, first sentence.
Pronoun “it” removed, para 2, last sentence;
“had” deleted from para 3, last sentence.

Discretionary revisions

We have realised that we were incorrect to state that we did not have socio-economic data. Whilst we do not have individual social class, we do have post-code data. This data has been reported in the form of the Index of Multiple Deprivation 2004 (calculated from the post-code). The data has been reported in table 1, where it is clearly a potential confounder, with the Index of Deprivation higher for the minority ethnic groups. It has also been included as a variable in the regression analysis, where the effect of ethnic group on the relative risk of eligibility has reduced. The South Asian group still has a significantly lower relative risk of being eligible and being recruited.

I look forward to receiving your decision about the paper.

Yours sincerely

Dr Kate Jolly