Author's response to reviews

Title: Promoting smoking cessation in Bangladeshi and Pakistani male adults: Design of a pilot cluster randomised controlled trial of trained community smoking cessation workers

Authors:

Rachna A Begh (r.begh@bham.ac.uk)
Paul Aveyard (p.n.aveyard@bham.ac.uk)
Penney Upton (p.upton@worc.ac.uk)
Raj S Bhopal (raj.bhopal@ed.ac.uk)
Martin White (martin.white@newcastle.ac.uk)
Amanda Amos (amanda.amos@ed.ac.uk)
Robin J Prescott (robin.prescott@ed.ac.uk)
Raman Bedi (raman.bedi@kcl.ac.uk)
Pelham Barton (p.m.barton@bham.ac.uk)
Monica Fletcher (m.fletcher@educationforhealth.org.uk)
Paramjit Gill (p.s.gill@bham.ac.uk)
Qaim Zaidi (zaidiq@bhf.org.uk)
Aziz Sheikh (aziz.sheikh@ed.ac.uk)

Version: 3 Date: 5 August 2009

Author's response to reviews: see over
05 August 2009

Editors-in-Chief, Trials

RE: Promoting smoking cessation in Bangladeshi and Pakistani male adults: Design of a pilot cluster randomised controlled trial of trained community smoking cessation workers

Dear Editors,

We thank you for the opportunity to revise our study protocol for Trials. We have studied carefully the reviewer’s helpful comments and have included the following additional details as requested.

1. Randomisation: Please describe the sequence generation process and actual allocation process such that readers can determine whether allocation concealment was maintained. Allocation concealment is still relevant in this trial. For example, it may be important to understand that Investigators with knowledge of socioeconomic status could not influence which clusters received which treatments.

The text has been modified to show that the statistician undertook the randomisation without knowledge of the geographical areas. This is now detailed on page 11:

“Randomisation will be undertaken by the study statistician who has no knowledge of the geographical areas using permuted blocks.”

2. Analysis: Please provide the appropriate references for your Poisson model such that the reader can determine whether it adequately adjusts for the effects of clustering.

A reference has been provided as requested (reference 35, Brown H, Prescott R. Applied Mixed Models in Medicine, 2nd ed, John Wiley & Sons, Chichester, 2006.) This has been added on page 18:

“The randomised areas will be included in the model as a random effect, thereby allowing for the clustering inherent in the design[35].”

3. Since one of your most important objectives is to estimate potential treatment effects to allow an accurate sample size estimation for a future trial, please present the specific formula that will be used along with appropriate references.

The wording has been modified to show how the intraclass correlation will be used to adjust the standard sample size calculation, and a reference to this has been provided on pages 18-19, (reference 36, Gulliford M, Ukoumunne O, Chinn S, Sterne J, Burney P, Donner A Methods for evaluating organisation- or area-based health interventions in The Advanced Handbook of Methods in Evidence Based Healthcare ed by Stevens A, Abrams K, Brazier J, Fitzpatrick R, Lilford R, 295-313 Sage, London,2001).

We now state:
“The randomised areas will be included in the model as a random effect, thereby allowing for the clustering inherent in the design[35]. This will be used in estimating the intra-class correlation coefficient, which in turn will determine the design effect. This is the multiplier which has to be applied to standard sample size formulae to allow for the effect of randomising at the cluster level instead of the individual level[36].”

4. Please specifically state which variables will be assessed for baseline balance and what specific rule will be employed to determine whether balance is achieved. What will occur if imbalance is detected?

The text has been modified to clarify that there will be no attempt to determine baseline balance, as we are using data from the previous year as a covariate in our analysis. This is detailed on page 18:

“As noted above, the before-after design will allow control for intrinsic variability between areas. As such there will be no attempt to assess baseline balance between the intervention and control areas.”

5. Will stratified analysis be conducted to account for stratification at randomisation?

We have now made explicit that the stratification used in preparing the randomisation will not be included in our models. This has been clarified on page 19:

“The stratification used in producing the randomisation will not be utilised in the analysis.”

We hope that with these modifications the protocol is now acceptable.

With best wishes

Professor Aziz Sheikh