Reviewer’s report

Title: Response bias to a randomised controlled trial of a lifestyle intervention in people at high risk of cardiovascular disease: a cross-sectional analysis

Version: 0 Date: 04 Jul 2018

Reviewer: Mark Harris

Reviewer's report:

This study compares respondent to non-respondent patients invited to participate in a trial of lifestyle intervention from 60 general practices in England. This is an important methodological issue informing the interpretation of trial data and the design of future trials and this paper makes an important contribution to our understanding. There are however some issues of concern:-

The Introduction tends to conflate participation in interventions with participation in trials. Trials usually involve greater respondent burden because of the need for informed consent, collection of evaluation data from patients and concerns about the privacy and confidentiality of data collected (including routinely collected data). The latter issues warrant more discussion.

The authors refer to the trial protocol for details of the recruitment methodology. While this is available in open access, the reader would reasonably expect to be provided with more details of the recruitment process in a study evaluating the participation rate. This paper does not say what was actually said to patients - the reference simply states "Following screening via the patient records database, the GP will invite those who are potentially eligible to participate in the study." It goes on to say later that those who agreed were invited to meet the researcher to obtain consent. The current paper states that patients were "invited to participate via a standardised letter" - presumably this was from the GP. This letter should be provided as an appendix. Also, it is unclear whether there were any deviations from this published protocol. The overall response rate was 16.7%, which is at the lower end of participation in similar trials - thus the detail of recruitment communication is important to include either in the body of the paper or an appendix.

I was surprised by the way in which ethnicity was classified. Skin colour has little anthropological or cultural meaning and has been discredited as a measure of ethnicity (the journal may have some policy about this). For example, presumably "white" could include recent migrants or refugees from Eastern Europe or the middle east who other research suggests may be suspicious of participating in trials or signing consent documents and have varying attitudes towards a lifestyle intervention. This is unfortunate given the findings that ethnicity appeared to be correlated with response rate.

The findings and discussion are otherwise appropriate.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
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I am able to assess the statistics

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