Reviewer’s report

Title: Efficacy of a church-based lifestyle intervention programme to control high normal blood pressure and/or high normal blood glucose in church members: a randomized controlled trial in Pretoria, South Africa

Version: 2
Date: 28 October 2013
Reviewer: David Simmons

Reviewer’s report:

This paper describes a protocol for a community based Randomised cluster controlled Trial to prevent IGT and reduce BG and blood glucose across 12 African church congregations over 36 months. The intervention compares a lifestyle programme with a health education leaflet. Participants will be aged 40-65 years and diagnosed with pre-diabetes and/or per hypertension.

Such a trial is important and many of the issues have been thought through major

This paper describes a protocol for a community based Randomised cluster controlled Trial to prevent IGT and reduce BG and blood glucose across 12 African church congregations over 36 months. The intervention compares a lifestyle programme with a health education leaflet. Participants will be aged 40-65 years and diagnosed with pre-diabetes and/or per hypertension.

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Major Comments

1. Community based trials can be fraught – where is the evidence that the community will accept such a trial?
2. How will those doing measurements be blinded after randomisation at the different time points?
3. If randomisation is to occur after baseline measurements, what is the predicted time between baseline measures and randomization - how will retention be affected with such a delay?
4. How well does the diabetes risk score tool work in this population - Africans are all seen as high risk in most tools developed in eg the USA or Europe
5. why did the researchers select a high risk rather than a population based strategy?
6. how will the blood pressure measurements actually be taken? What standardization methods will be used?
7. the method for the glucose measurement/testing for ‘prediabetes’ is not stated but is presumably fasting glucose? What about those with IGT if an OGTT is not
undertaken? How will the fasting glucose be taken? What standardization methods will be used besides ‘fasting’? is this a lab glucose or some other way? How will the samples be handled?

8. how can the researchers be sure they will identify 1200 people with pre diabetes/prehypertension?

9. what is the evidence a Finnish type of intervention will work among South Africans? Has there been a pilot? Has the been formative evaluation?

10. reference 7 is a protocol for another study but is stated as data from pervious trials-a proper reference is required

11. The power calculations have not included the intra cluster coefficient-the trial would be underpowered with clusters of this size

12. The SD of the glucose is not given for the power calculation

minor

discretionary

1. Background-Para 1: Although IGT/IFG do not produce symptoms-nor does diabetes until there is significant hyperglycaemia-it is also associated with increased risk of cardiovascular disease-this sentence should be amended with there reference to symptoms removed and the risk factor for cvd included

2. Background para 2:it is not true to say that effort to prevent morbidity and mortality from diabetes and cvd have largely focused on clinical management-there are multiple large prevention trials including eg North Karelia programme in Finland

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

no competing interests