Author's response to reviews

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

Authors:

Supa Pengpid (Supa_Pengpid@embanet.com)
Karl Peltzer (kpeltzer@hsric.ac.za)
Pendile Mntla (Pindile.Mntla@ul.ac.za)
Busi Ntuli (Busi_Ntuli@embanet.com)
Mashudu Manafe (Mashudu.Manafe@ul.ac.za)
Christophe DeBlock (christophe.deblock@ua.ac.be)

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Author's response to reviews:

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 Comments

1. Community based trials can be fraught – where is the evidence that the community will accept such a trial?

Response [R]: below is added

To have a significant public health impact, benefits of proven lifestyle interventions have to be translated to community settings [18,19]. Evidence from varied community including church-based settings has shown that lifestyle interventions can be effective in lowering diabetes and hypertension risk. Ackerman et al. [20] found positive results in an implementation evaluation of the delivery of a group-based Diabetes Prevention Programme (DPP) lifestyle
intervention in a community setting. Boltri et al. [21] describe the successful translation of the National Institutes of Health Diabetes Prevention Programme (DPP) in African American churches. A 6-session modified DPP was associated with decreased fasting glucose and weight similar to the 16-session programme. Simmons et al. [22,23] was able to reduce risk factors for diabetes among Western Samoans in New Zealand based on a church-based programme. Likewise, Oexmann et al. [24] describe a successful church-based approach to lifestyle change on cardiovascular disease risk in African Americans. The church is an important community intervention setting for health promotion in South Africa [25,26,27].

2. How will those doing measurements be blinded after randomisation at the different time points?

R: They are not informed about the different types of interventions in the different churches

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?

R: This is corrected, randomized occurs prior to baseline measurements.

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

R: Below is added

In the absence of a diabetes risk screen developed in an African population, the Finnish diabetes risk score (FINDRISC) questionnaire will be used [10,33]. In a recent systematic review on risk scores based on self-reported or available clinical data to detect undiagnosed type 2 diabetes found that "An important but tentative conclusion (given the small number of studies) is that there is no reason to believe that risk scores in low and middle income settings perform differently compared to high income settings." [Brown, p.382]

5. why did the researchers select a high risk rather than a population based strategy?

R: because a rather intensive group face-to-face intervention would be more cost-effective for people with prediabetes and/or prehypertension

6. how will the blood pressure measurements actually be taken? What standardization methods will be used?

R: Below is added

Blood pressure (BP) is measured with a validated automated digital BP monitor (BpTRU) based on South African guidelines [Seedat] three times at two different visits each, a week apart.
7. The method for the glucose measurement/testing for ‘prediabetes’ is not stated but is presumably fasting glucose?
R: This, fasting glucose, is more clearly stated

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?
R: Below is added
- Collect fasting venous blood samples

Serum total cholesterol, HDL, and triglycerides are determined using an enzymatic assay method. Plasma glucose is determined according to standard guidelines. All laboratory tests will be made and analysed following laboratory quality guidelines in the local tertiary hospital. The same methodology will be used during the whole study period.

8. How can the researchers be sure they will identify 1200 people with pre diabetes/prehypertension?
R: Data is added showing that at a population level in our study age groups we can expect more than 10% prediabetes and more than 30% prehypertension, so really it would not be a problem to reach 1200, as we enrol prediabetes and/or prehypertensives

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?
R: Similar interventions have been implemented in low resourced settings, so should also work in South Africa

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

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
R: Corrected as below

As reviewed by Petrella et al. [41], data from previous intervention studies found a change in systolic blood pressure after the intervention between 5.32 and 5.92 mmHg providing a 90% power [34], while a reduction of blood glucose levels of 0.1 to 0.3 mmol. are noted as important in terms of the risk for the development of type 2 diabetes [35]. The Trial Protocol Tool for RCTs software (2004) was used to calculate sample size at power 90%, average cluster size 20, A median intracluster correlation (ICC) of 0.005 (average Standard Deviation 0.3), as
suggested by Adams and Gulliford [42], was used assuming a 80% success rate in achieving suitable recordings in two test sites the minimum unadjusted sample size is 96 and number of clusters per group is 6. From previous similar researches, the dropout rate of approximately 20%, hence recruit 120 subjects; for preventing of loss of two follow up, we increase to 150 subjects in 6 clusters per treatment arm.

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
   R: Corrected

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
   R: Removed

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

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:2Date:9 April 2014
Reviewer:Mary Beth Weber
Reviewer's report:
Translating proven diabetes prevention programs is of paramount public health importance. I applaud the researchers for seeking to address this in such a high need environment. However, this manuscript has some major issues, which need to be addressed before publication.

Major Compulsory Revisions
- The Background section jumps around a lot, making it very difficult to follow the authors’ arguments justifying the study.
R: This has been restructured.
- I was unsure after reading the background of the focus of this study – is it diabetes? Or metabolic syndrome? Cardiovascular risk factors? This section needs more focus.
R: This has now been more clarified.
- The authors barely discuss other church-based interventions. How does this trial add to the existing data?
R: below is added

To have a significant public health impact, benefits of proven lifestyle interventions have to be translated to community settings [15,16]. Evidence from varied community including church-based settings has shown that lifestyle interventions can be effective in lowering diabetes and hypertension risk. Ackerman et al. [17] found positive results in an implementation evaluation of the delivery of a group-based Diabetes Prevention Programme (DPP) lifestyle intervention in a community setting. Boltri et al. [18] describe the successful translation of the National Institutes of Health Diabetes Prevention Programme (DPP) in African American churches. A 6-session modified DPP was associated with decreased fasting glucose and weight similar to the 16-session programme. Simmons et al. [19,20] was able to reduce risk factors for diabetes among Western Samoans in New Zealand based on a church-based programme. Likewise, Oexmann et al. [21] describe a successful church-based approach to lifestyle change on cardiovascular disease risk in African Americans. The church is an important community intervention setting for health promotion in South Africa [22,23,24]. There is lack of evidence that such a community (church-based) lifestyle intervention to lower diabetes and hypertension risk is effective in an African setting. Therefore, a cluster randomized controlled implementation trial to control high normal blood pressure and/or high normal blood glucose in church members in South Africa is proposed.

- The authors provide no discussion about either of the programs they are translating.
R: More is added in the discussion

What are the designs of the original programs and what components will you use?

R: Below is added

The lifestyle intervention contents areas [14,34,35,36] are summarized in Table 2: Lifestyle intervention contents
Session Major intervention content

1 - Life-style influence health diabetes, hypertension, risk factors and development, effects, prevention
   - Goals, planning, homework and other exercises, including sensible alcohol use
   - Homework assignments: monitoring own behaviour with food diary (including identifying sodium content of foods) and physical activity schedule

2 - Returning of food diaries
   - Comparison of own habits with the diet and physical activity goals sufficient for prevention,
     Role modelling, analysis and re-attribution
     - Homework assignments: preparation for goal setting, monitoring physical activity and eating habits

3 - Feedback from the physical activity schedule
   - Goal planning
     - Homework assignments: feedback and re-inforcement; monitoring physical activity and eating habits

4 - Feedback based on findings from food diaries
   - Education on how to eat healthy?
     - Goal planning, Goal setting
     - Homework assignments: positive feedback in getting social support; monitoring physical activity and eating habits

5 - Evaluating and refining the goals
   - Routines, changed; intermediate goals
     - Exercise: how to overcome barriers, how to use resources in maintaining the behaviour changes
     - Homework assignments: monitoring physical activity and eating habits

6 - Evaluating the goals
   - Routines, changed; analysis and re-attribution of success and failure
   - Future goals and evaluation

Also, please provide some scientific justification for using a diabetes prevention program here. The focus of the DPS was not on reducing hypertension. I am not sure about the PREMIER trial design and the authors never described it.

R: The PREMIER trial design is clearly described, in particular to reduce hypertension risk. It is now more clarified that both programmes DPS and PREMIER are integrated in this trial to reduce both diabetes and hypertension.
risk

- The Methods/Design section is likewise very repetitive. Please reorganize this section to avoid repeating information.
R: Procedures and methods have been reorganized

- I think you are planning to enroll individuals with EITHER prediabetes or prehypertension, but the way it was described in the manuscript was sometimes unclear.
R: It is clearly stated throughout that prediabetic and/or prehypertensive clients are enrolled; not EITHER

- Table 1 should either be made into a figure or made into a proper table with row/column headings.
R: Changed into figure, and rearranged

- The quality assurance section is very vague. Please provide more details. For example, what measures will be used to ensure that diabetes risk screening is delivered as intended? How will you assess and assure fidelity of the intervention delivery between sites?
R: below is added

Assessment and intervention quality assurance
Assessment and intervention quality assurance procedures ensure that project activities are standardized across the churches and across the cohorts and that assessment and intervention process data are collected accurately. To achieve this, standardized protocols, procedures, and training manuals are prepared, and staff are systematically trained in their use. In addition, the performance of the assessors and programme implementers is routinely monitored by the research coordinators. This will require the development of mechanisms for determining that adequate levels of competence have been attained by those who have received training and that their continuing performance does not fall below these levels. A random sample of group sessions interactions will be tape-recorded and analysed for that purpose. Feedback will be provided to the field work staff and protocol deviations or other problems addressed and corrected in a timely manner.

- The measures sections should be written as text or put in a table. Also, please provide a better description of methods to be used. Many are vague or not present (for example, there is no section on laboratory methods).
R: This is reworked, and below on lab methods added

Serum total cholesterol, HDL, and triglycerides are determined using an enzymatic assay method. Plasma glucose is determined according to standard
guidelines. All laboratory tests will be made and analysed following laboratory quality guidelines in the local tertiary hospital. The same methodology will be used during the whole study period.

- Your intervention evaluation should mirror the aims of the study.
R: Reworked

- The discussion is really weak. How does this trial compare to other studies? What are the potential impacts?
R: Reworked as below

This integrative lifestyle intervention trial for both the reduction of diabetes and hypertension risk offers the unique opportunity to evaluate the effect of a community (church)-based intervention delivered by trained lay health promoters targeting a high risk population. The integration of a lifestyle intervention for both the reduction of diabetes and hypertension risk and evaluating the effectiveness of this intervention in a community-based setting is both innovative and can facilitate research translation into primary health care practice. Moreover, this intervention utilizes community health workers to enhance lifestyle modification for the reduction of both diabetes and hypertension risk through group sessions, which can be easily adapted in real world settings. This study will present a new analysis of the effectiveness a community (church)-based lifestyle intervention programme to control high normal blood pressure and/or high normal blood glucose in a low and middle income setting. If data confirm our hypothesis, this may help policymakers to increase resources in prevention rather than treatment. It is important to consider that the study data will be collected from a real life community setting.

Minor Essential Revisions
- Throughout the manuscript, the authors switch between past, present and future tenses when describing the study. Please correct.
R: Corrected

- Under Step II, you have a typo. Please change “Fasten” to fasting.
R: Corrected

Discretionary Revisions
None

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

Quality of written English: Needs some language corrections before being Published
R: Corrected

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests