Reviewer’s report

Title: Protocol: Randomised clinical trial investigating the effectiveness and cost benefit of a lifestyle intervention targeting Type 2 Diabetes in Australia.

Version: 1 Date: 25 Jul 2018

Reviewer: Eva Corpeleijn

Reviewer's report:

The report describes a RCT testing the CHIP lifestyle intervention.

Introduction page 4, paragraph 2.

It is good to mention blood pressure in this list of cardio-metabolic risk factors as well. Now it seems to be overlooked but it is measured in your RCT.

AIMS

The main aim is to look at fasting glucose, but how will you take into account changes in treatment (medication use, change in type or dosage) and have you considered to include HbA1c on top of looking at fasting glucose?

To determine the cost-benefit, it may be important to also have detailed information on the effectuated intervention and do some formal process evaluation. If the effect lags behind because the intervention could not be delivered properly regarding intensity, attrition, logistics or other failure of delivery, this is important to take into account. Furthermore, it may be wise to monitor what the control do, some take action themselves to improve lifestyle.

Question 2, levels of compliance, will you also assess self-reported reasons for dropout and specifically dropout due to medication use (side effects of statins, difficulty controlling low glucose when doing sports).

Question 3, what is your exact outcome for the cost-effectiveness? Is it fasting glucose?

Page 7, study setting. Can you describe the collaboration with the GP?

Page 7, exclusion criteria. Will you monitor how many do not apply to your in/exclusion criteria? To describe this source population would be very important to estimate a 'budget impact analysis'. The main question then is 'what percentage of diabetes patients will be suitable to join the program (successfully)?'.

Page 10, randomization. Will you randomize per practice or per person?

Page 10, interventions. By whom is the intervention delivered? This is a major issue in this field. When
it needs to be implemented by the nurse practitioner, it seem to be less effective (now recently shown for a large German study in limiting weigh gain during pregnancy) than when delivered by someone who is specialized (and properly educated) in diet and exercise.

Also page 12, lines 258-261: by whom is the intervention delivered?

It would be good to check what information you collect, to be able to conclude the results from three points of view: (1) how effective was the intervention (if not, was this due to non-response to a well delivered program?) (2) how well could the intervention be delivered (if not, why was this not optimal and is there room for improvement) and (3) how good was the compliance (determinants at patient level). Also realize that we sometimes tend to have people who drop out because they got the hang of it and can continue themselves without the hassle of a health professional visit and so on. On the other hand, typical in such a condensed intervention period, people need more time to change their ideas about lifestyle. The large RCT's to prevent diabetes (DPS, DPP, Da Qing) were set up very differently, all with a basic program of at least two years, giving people time to go through all the 'stages of change' that are needed for behavior change. Will you monitor their readiness or motivation to change?

Page 12, data collection. It is not specified with which method information on lifestyle will be collected. It is also not described how the endpoint will be standardized. This is essential information.

Page 13, sample size estimate. Line 283 0.5 should probably be 0.05? And what SD was used for the calculations?

Page 13, lines 287-288. Have you considered using an eCRF, electronic Clinical Research Form software?

Page 13, lines 294: with these low numbers visual inspection of normality is also important. You may lack the power to prove a lack of normality.

Page 16. Limitations, To learn about compliance and uptake of the program, I can really recommend to have focusgroups with participants and separately also with professionals involved. This will be a rich source of information to support and interpret your findings and improve implementation.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**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?**
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