

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Adapting the Diabetes Prevention Program for low and middle-income countries: Protocol for a cluster randomized trial to evaluate "Lifestyle Africa"
AUTHORS	Catley, Delwyn; Puoane, Thandi; Tsolekile, Lungiswa; Resnicow, Ken; Fleming, Kandace; Hurley, Emily; Smyth, Joshua; Vitolins, Mara; Lambert, Estelle; Levitt, Naomi; Goggin, Kathy

VERSION 1 – REVIEW

REVIEWER	Max Bachmann University of East Anglia, United Kingdom
REVIEW RETURNED	03-Jun-2019

GENERAL COMMENTS	<p>This is an excellent and thorough RCT protocol for a very important and original study. I have only a few minor comments and suggestions:</p> <p>The abstract should state that participants have BMI ≥ 25 kg/m².</p> <p>If the study has already begun the dates of recruitment and follow-up should be stated if possible.</p> <p>If the protocol has been registered with a trials register, details of this registration should be reported.</p> <p>It is unclear why the 1 year follow-up assessment will be carried out at 8 months and the 2 year assessment at 20 months (flow diagram, page 27).</p> <p>Because of the nature of the intervention and the setting of the study, there is a risk that participants in intervention and control groups may differ at baseline, and in follow-up rates. If they do differ at baseline, instead of comparing changes in outcomes it would be better to estimate effects using analysis of covariance (ie estimate differences in follow-up values with adjustment for baseline values of the same variable) to avoid bias due to regression to the mean [see for example BMJ 2001;323:1123–4]. I suggest that the option of adjusting for baseline values, if they differ substantially, be included in the analysis plan.</p>
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VERSION 1 – AUTHOR RESPONSE

Response to Review Comments

Reviewer: 1

Reviewer Name: Max Bachmann

Institution and Country: University of East Anglia, United Kingdom Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below This is an excellent and thorough RCT protocol for a very important and original study. I have only a few minor comments and suggestions:

The abstract should state that participants have BMI ≥ 25 kg/m².

- We have added this information to the abstract.

If the study has already begun the dates of recruitment and follow-up should be stated if possible.

- As the study is still in progress we have added that enrollment for wave 1 began in February of 2018.

If the protocol has been registered with a trials register, details of this registration should be reported.

- The trial registration is included at the bottom of the abstract in the format requested by the journal. Consistent with BMJ Open format, we have added that the trial is in the Pre-results stage.

It is unclear why the 1 year follow-up assessment will be carried out at 8 months and the 2 year assessment at 20 months (flow diagram, page 27).

- This was designed so that data collection with all clubs could be feasibly completed before participants and staff travel for an extended holiday break. We have provided more detail on the rationale on pg 13.

Because of the nature of the intervention and the setting of the study, there is a risk that participants in intervention and control groups may differ at baseline, and in follow-up rates. If they do differ at baseline, instead of comparing changes in outcomes it would be better to estimate effects using analysis of covariance (ie estimate differences in follow-up values with adjustment for baseline values of the same variable) to avoid bias due to regression to the mean [see for example BMJ 2001;323:1123–4]. I suggest that the option of adjusting for baseline values, if they differ substantially, be included in the analysis plan.

We agree with the reviewer's suggestion and have added this detail to our analysis plan on pg. 16: "If groups differ at baseline, we will add baseline values to the models as covariates."