Reviewer’s report

Title: The Impact of a Structured Lifestyle Intervention on Body Composition and Exercise Capacity in Overweight Children With Operated Heart Defects. Pilot and feasibility study protocol: "Smart Heart Trial"

Version: 0 Date: 29 Sep 2017

Reviewer: Susanna Dodd

Reviewer's report:

Thank you for submitting this well-written protocol. I have a few comments relating to the feasibility outcomes and analysis of your pilot study.

Feasibility outcomes/criteria: The primary aim of a pilot study should relate to the feasibility of the study (in terms of process measures such as recruitment, acceptability to patients, compliance, retention, appropriateness of outcomes, etc.) or valid estimation of sample size parameters for a future trial. The manuscript states that "The objective of this pilot study is to examine the feasibility and impact of a one-year, structured lifestyle intervention program…" However, the primary outcomes include only clinical outcomes. It would therefore be useful if the authors could add primary feasibility outcomes along with the primary and secondary clinical outcomes. These feasibility outcomes should relate directly to criteria that could be used to determine whether or not the pilot study will be executable as a future definitive trial. The authors should list these criteria along with some benchmark or threshold levels for each criterion, which in turn would inform the authors/reader if a future study is indeed feasible (e.g. if retention is above 70%, outcome assessment is achieved in >80% of patients, etc).

Analysis: Analysis of pilot studies should focus on confidence interval estimation rather than hypothesis testing, as pilot studies are not powered to determine treatment effects with any confidence. Therefore, all inferential statistics should be treated with caution. I would suggest that the authors rewrite the statistical analysis section, stating that analysis will focus on confidence interval estimation, and that all hypothesis testing will be viewed as entirely explorative. Useful references relating to this issue that may be helpful for the authors to consult include:


Please add "Study protocol for pilot study" before "Smart Heart Trial" in the title of the study.
Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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