Author’s response to reviews

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"

Authors:

Meghan Rombeek1 (Meghan.Rombeek@lhsc.on.ca)
Stefanie De Jesus (sdejesus@uwo.ca)
Luis Altamirano-Diaz (Luis.Altamiranodiaz@lhsc.on.ca)
Eva Welisch (eva.welisch@lhsc.on.ca)
Harry Prapavessis (hprapave@uwo.ca)
Jamie Seabrook1 (jseabro2@uwo.ca)
Kambiz Norozi (kambiz.norozi@lhsc.on.ca)

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Author’s response to reviews:

Dear Dr. Dodd,

I very glad to receive the review of our study protocol. We have read the reviewers comments and suggestions and have revised the study protocol accordingly. All requested changes have been implemented in the revised study protocol. The recommended revisions from Reviewer #1 are highlighted in blue and revisions from Reviewer #2 are highlighted in yellow. We would like to thank the reviewers for their insightful comments and believe their recommendations have greatly improved the quality of our study protocol.

With kind regards,

Kambiz Norozi
Reviewer reports:

Reviewer #1: Dear authors,

It is very good paper and it is well written. An interesting study with nice presentation, and discussion. The treatment of the young patient with congenital heart disease is sometimes very hard and I am very glad that you used new approach. I noticed that you measured parameters for metabolic syndrome, but I didn't noticed that you had some young patients with metabolic syndrome in this study? I think it is important to notice metabolic syndrome especially in young patient with congenital heart disease due to the subsequent development of coronary heart disease and that the quality of life these patient is worse. I suggest to write a small conclusion with the final message useful for the clinicians.

Best regards and congratulation for the authors.

Thank you for your kind words and taking the time to review our study protocol. As part of the study, we decided that measuring blood lipid profiles and indicators of diabetes may offer valuable information regarding the outcome of a lifestyle intervention on nutrition and fitness. It's not common practice in our clinic to evaluate our patients for metabolic syndrome, so we have not included this indication as part of our inclusion or exclusion criteria for this particular study. We do agree that it's of great interest and importance, especially in the context of congenital heart disease in children. Thus, we have revised the study protocol to include some information and citations regarding metabolic syndrome into the introduction of the current protocol (page 4, lines 15-16, 19-20; page 24 lines 12-15; highlighted in blue), but we hope that you agree that any further discussion on metabolic syndrome would be better suited for the follow-up report once the pilot study is completed.

Reviewer #2: Thank you for submitting this well-written protocol. I have a few comments relating to the feasibility outcomes and analysis of your pilot study.

We greatly appreciate the time taken and the effort you have put into thoroughly reviewing our study protocol. Your comments and recommendations have been very insightful. As a result, we have revised our study protocol according to your suggestions as indicated below.
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).

We have revised the objective of the study to better reflect the purpose of a pilot and feasibility study (page 2, lines 10-15; page 5, lines 15-19; highlighted in yellow).

Feasibility outcomes and metrics have been added according to the guidelines provided in the suggested references (page 2, lines 10-15; page 6, lines 16-23; page 7, lines 1-5; pages 12, lines 1-22; page 13, lines 1-20: highlighted in yellow).

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:

We have revised the study protocol to include confidence interval estimation and have stated that the inferential statistics in the analysis are purely exploratory and only part of piloting the study (page 18, lines 17-20; highlighted in yellow).


Thank you for providing these references. They were very helpful for making the suggested revisions and have cited them in our manuscript (page 5, line 16; page 13, line 14; page 25, lines 11-14; page 26, lines 2-3; highlighted in yellow).

Please add "Study protocol for pilot study" before "Smart Heart Trial" in the title of the study.

We have made the suggested revision to the title (Page 1, line 3; highlighted in yellow).