PEER REVIEW HISTORY

BMJ Paediatrics Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	The effect of a Physical Activity Consultation in the Management of Adolescent Overweight (The PAC-MAnO project): Study rationale, design and methods.
AUTHORS	Videira-Silva, Antonio; Sardinha, Luís; Fonseca, Helena

VERSION 1 – REVIEW

REVIEWER	Bob Phillips Institution and Country University of York, UK Competing interests: None
REVIEW RETURNED	13-Dec-2017

GENERAL COMMENTS	This is a paper reporting the protocol for an ongoing and registered trials. As such, my comments are directed at the paper as a report of the protocol, rather than the trial design itself. Modifying the trial design mid-study would be unhelpful and potentially unethical. The paper is unclear with mixed tenses as to which elements are 'in progress' and which are past tense / done. E.g. "This trial was design" which implies is has been completed - I would prefer, as the trial is ongoing - to use phrase such as "is designed" . As the trial has started, and presumably in 14 months has recruited some patients, an anticipated end-date for enrollment and final data collection would be useful to read. The study primary and secondary outcomes do not match those registered in the main fields in the clinical trial registry. The CT main fields do not mention sedentary behaviours, nor do the secondary outcomes include lipid profile, insulin resistance and sub maximal exercise testing. The 'detailed' section of the CT does have this information; the CT registry needs modifying to show the actual outcomes being considered and an explanation added. I am unclear as to how the proposed statistical testing will assess the non-linear relationships hypothesised in the Figure. The discussion would be improved by discussing the context of prior trials of management of obesity in adolescence, and the complex multifactorial and broadly societal / environmental influences on weight. While the group clearly believe in their intervention, many would identify this as a single small part of a wicked problem (e.g. Foresight Map - Finegold - OBESITY v18, Supp 1, Feb 2010).

VERSION 1 – AUTHOR RESPONSE

This is a paper reporting the protocol for an ongoing and registered trials. As such, my comments are directed at the paper as a report of the protocol, rather than the trial design itself. Modifying the trial design mid-study would be unhelpful and potentially unethical.

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The paper is unclear with mixed tenses as to which elements are 'in progress' and which are past tense / done. E.g. "This trial was design" which implies is has been completed - I would prefer, as the trial is ongoing - to use phrase such as "is designed".

We would like to thank you for this pertinent remark. Indeed, this manuscript reports the protocol of an ongoing trial. Because of this, we were very careful in the use of the correct verb tense according to each reported variable/element.
In the example above (trial design), we have decided to use the past tense since the trial design is already complete. In fact, the trial design was concluded well before the recruitment started.
Heaven though, for this revised version, we have reviewed the entire manuscript in order to track possible misunderstanding sentences.

As the trial has started, and presumably in 14 months has recruited some patients, an anticipated end-date for enrollment and final data collection would be useful to read.
We would like to thank you for your suggestion. As suggested, we have included the anticipated end-date in the abstract ("This is an ongoing non-randomized controlled clinical trial with a six-month duration and follow-up at month 12. It is expected to be concluded in December 2018."), and in the method section ("It is estimated that the present trial will be concluded by the end of December 2018.").
The study primary and secondary outcomes do not match those registered in the main fields in the clinical trial registry. The CT main fields do not mention sedentary behaviours, nor do the secondary outcomes include lipid profile, insulin resistance and sub maximal exercise testing. The 'detailed' section of the CT does have this information; the CT registry needs modifying to show the actual outcomes being considered and an explanation added.
Thank you for your valuable comment. Indeed, the outcomes reported in the method section of the present research protocol did not match with those reported in the clinical trial registry. This was due to the fact that the clinical trial registry was written before the research protocol.
We have now corrected this issue. The missing outcomes were included in the trial registry, and the text of the research protocol was changed as follows:
"This study has as secondary objectives: (i) to analyze the effect of the intervention on cardiorespiratory fitness (CRF). CRF is commonly expressed as VO2 max and represents the ability to uptake, deliver and use oxygen to produce energy. CRF is inversely associated with BMI and waist circumference, and has a potential beneficial effect on the endothelial function and structure (which is known to be impaired among overweight adolescents) even without the occurrence of major changes in the BMI; (ii) To analyze whether changes in BMI z-score, body composition, PA/sedentary behavior and CRF are associated with changes in the endothelial structural health (assessed trough carotid intima-media thickness - cIMT) and function (assessed trough pulse wave velocity - PWV); (iii) To analyze the effect of the intervention on biochemical markers, including glucose metabolism (blood glucose, insulin and insulin sensitivity), lipid profile (Triglycerides - TG, total cholesterol - TC, high-density lipoprotein cholesterol – HDL-C, and low-density lipoprotein cholesterol – LDL-C), and inflammation (C-reactive protein - CRP); (iv) To validate a sub-maximal exercise step test for an overweight adolescent population for future use in the PA consultation routine. Sub-maximal exercise step testing has been considered a timely and cost-effective method of assessing CRF, which can be conducted at the clinical office with minimal risk and discomfort for the participant compared to maximal exercise testing; (v) To assess the cost-effectiveness (CE) of the intervention. CE is considered as an important aid to public health decision-making, with an extra potential additional value in a tertiary health care setting."
I am unclear as to how the proposed statistical testing will assess the non-linear relationships hypothesised in the Figure.
We appreciate the comment and the opportunity to clarify this issue. In fact, we have acknowledged that Figure 1 do not appropriately represent the statistical test suggested (ANCOVA), and the expected results. Figure 1 has been redone.

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We would like to thank you for your suggestion. We have redone the discussion section. So now you can read:
"Weight status, particularly during adolescence, is deeply influenced by biological, physiological, environmental and contextual factors [40]. According to the Foresight Program of the UK Government Office for Science, published in 2007, the complex and multifactorial etiology of overweight/obesity may involve around 108 factors and more than 300 interactions among those factors [41]. Although the Foresights' map may be a good illustration of the complexity and challenge in tackling obesity, which involves several environmental dimensions and system-wide solutions, with the individual representing only a small part, complex issues have no simple or single solutions. Without considering the individual and his role in this complex system, we may fail in inducing successful changes.

According to Bemelmans et al., several community-based initiatives for the management of childhood/adolescent overweight, implemented between 2005 and 2011, have shown confounding results on BMI [42]. These confounding results may be explained by the inconsistent use of behavior change strategies across studies. Behavior is a key factor for most health outcomes, including weight [43]. Adolescence is a critical period for the acquisition of healthy behaviors [18]. Being able of positively and effectively influencing health behaviors during this time period, may prevent future individual health adversities. This trial aims to analyze the impact of a behavioral change intervention (with or without the participation in scheduled physical exercise sessions) on PA behavior and on a range of biomarkers, while trying to understand whether and how health behaviors have the potential to be modified at the clinical setting.

Environmental changes, although crucial for the future, take time to produce physiological effects. Thus, this trial should be considered as a contribution for tackling adolescent overweight at the individual level. To the best of our knowledge there have been no controlled trials with this dimension which have analyzed the impact of a PA consultation on the management of adolescent overweight. In our view, among the strengths of this trial is its focus on the enhancement of intrinsic motivation, individual autonomy and self-efficacy, which are known to be key factors for behavior change and successful weight loss [27]. The individual physical exercise sessions that will be provided to one third of the participants aims to increase self-efficacy perception associated with weight loss, and to understand whether this perception influences autonomy and maintains PA behavior on the long-run. We believe that this clinical trial will contribute to improve the management of adolescents' overweight at the clinical setting, and may simultaneously provide a better understanding of the behavioral mechanisms involved in the process of losing weight and maintaining the weight loss during this critical life stage."

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