Author's response to reviews

Title: The effect of "living high-training low" on weight loss in overweight Chinese adolescents: study protocol for a randomized controlled trial

Authors:

Ru Wang (wangru0612@163.com)
Dongmei Liu (liudongmei@sus.edu.cn)
Xueqiang Wang (qiang897@163.com)
Weihua Xiao (xiaoweihua1115@163.com)
Nana Wu (xiaogi158158@163.com)
Binghong Gao (gaobinghong@126.com)
Peijie Chen (chenpeijie@sus.edu.cn)

Version: 2
Date: 14 May 2014

Author's response to reviews: see over
May 14, 2014

Doug Altman, Curt Furberg and Jeremy Grimshaw
Editors-in-Chief
Trials

Dear Drs. Altman, Furberg and Grimshaw,
Please find attached our response to the recent review of our manuscript. We would like to thank the editor and the reviewer for their thoughtful critique and helpful comments. We have incorporated their suggestions into a revised version of the manuscript. Revisions made have been highlighted in the manuscript (redlined version).

Sincerely,

Peijie Chen, Ph.D. Professor
School of Kinesiology,
Shanghai University of Sport
399 Changhai Road Yangpu District
Shanghai , China 200438
Tel: 86-21-51253016
Fax: 86-21-51253626
Email: chenpeijie@sus.edu.cn
Editorial request:
1. Please include the reference number given with ethical approval with your ethical statement in the Methods section.

Response: This information has been added in the revised manuscript (page 9).

Reviewer's report
Review of the study protocol entitled, “The effect of living high-training low” on weight loss in overweight Chinese adolescents: study protocol for a randomized controlled trial”. This study will aim at investigating the effectiveness of 4 weeks of intermittent hypoxia in addition to a traditional exercise and diet intervention for short and long term weight loss in overweight/obese adolescents. The authors will perform a randomized controlled clinical trial (RCT) including 40 overweight adolescents (11 to 15 years). In general, this study will deal with a scientifically and clinically interesting issue but should provide more evidence that intermittent hypoxia exposure could really affect appetite and/or weight loss.

Reviewer's report:
1. Will the study design adequately test the hypothesis?
   Of course, a RCT would represent an appropriate design but some additional information is necessary. How did the authors determine the sample size? Please, provide the results of a power calculation. How many males and females will be recruited? Which type of stratification (age, gender??) will be performed to obtain comparable groups?

Response: In the methods section, we added a paragraph describing the results of a power calculation (page 8).
   We will recruit an equal number (n=20) of boys and girls, and perform stratified randomization using gender as the stratification factor to construct hypoxia and normoxia group. We will not do the stratification by age, because we have a very narrow age range (from 11 to 15) in our group and previous studies showed little evidence of the influence of age on weight loss effect of hypoxia or exercise or dieting. Relevant information has been added in the revised manuscript (page 8).

2. Are sufficient details provided to allow replication of the work or comparison with related analyses: if not, what is missing?
   Yes, when providing the above mentioned information. Additionally: Please, indicate which drugs would potentially affect appetite and weight loss. How will authors respond to children who do not tolerate sleeping in normobaric hypoxia? Sometimes authors refer to “sleep low and train high” but in fact, children will sleep high (normobaric hypoxia) and train low; right?
Response: Drugs that would potentially affect appetite and body weight include Orlistat, Lorcaserin, and phenterminetopiramate, as well as appetite suppressants. This information has been added in the revised manuscript (page 10).

Children who do not tolerate sleeping in normobaric hypoxia can elect to stop their participation in the study. However, according to our preliminary study, children tolerated sleeping in a hypoxia chamber very well and no drop out was due to the discomfort experienced in hypoxia exposure. Additionally, we did a series of assessments on the participants in the preliminary study including cardiopulmonary function, immune function and blood routine indexes, and no side effect was noticed.

In regard to “Sleep low and train high”, you are right, it should be “sleep high and train low”, the mistake was corrected in the revised manuscript. Thank you!

3. Is the planned statistical analysis appropriate?
   Yes, o.k.

   Response: Thanks!

4. Is the writing acceptable?
   I would recommend the paper to be read by an English native speaker.

   Response: Thank you for your suggestion. We sent the paper to Dr. Gordon Paul at the Baylor University, U.S. He gave the paper a thorough review, and his suggestions for editing have been incorporated in the revised manuscript. revisions are highlighted.