Reviewer's report

Title: A randomized controlled trial evaluating the effect of family-based multidisciplinary cognitive behavioral treatment in children with obesity

Version: 4 Date: 13 December 2010

Reviewer: David Moher

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This is a protocol of a randomized trial to compare a multidisciplinary cognitive behavioral therapy to control for children with obesity.

The protocol is externally funded and is also registered.

The authors should indicate in their title that this paper is a protocol.

Page 5: the authors should delete “longitudinal” from the design section.

Page 5: the authors should better explain to readers the issues of ‘ethnicity’ in terms of the local community.

Page 6: the “Recruitment and Randomization” section title should be split up into two separate headings, “Recruitment” and “Randomization”. There needs to be another heading “Eligibility criteria”.

Page 6: as described the randomization section is very sparse. The reader knows nothing about the sequence generation, allocation concealment, and implementation. Are there more details elsewhere?

Pages 6 and 7: the intervention is well described. On page 7 (and elsewhere) the authors use the term “subjects”. Please delete this term throughout the protocol and replace it with either “participants” or “children”.

Page 14: the data analysis needs additional clarification. The main analysis described is a paired analysis, presumably compared change scores from pre to post treatment. In a randomized trial the usual data analysis of the primary outcome is a comparison between study groups. In this trial this would presumably be a comparison between cognitive behaviour therapy and control. Can the authors clarify their data analysis for the readers?

Page 14 and 15: the sample size calculations require clarification. The unadjusted calculations are for unpaired means yet the data analysis (see above) is for paired data. Clarification is required. Is the sample size calculation adjusted for stratification?