Author’s response to reviews

Title: Randomized Controlled Pilot Study of a SystemCHANGETM Weight Management Intervention in Stroke Survivors: Rationale and Protocol

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Version: 3 Date: 16 April 2013

Author’s response to reviews: see over
Dear Erik Cobo,

Thank you for your careful review of the manuscript in accordance with the CONSORT statement. We have revised the manuscript with the CONSORT statement in mind.

1) Reviewer: Sample size should be specified following item 7a.
Response: Sample size section has been moved.

2) Reviewer: Randomization details (items 8 to 10) should be provided.
Response: We have now included a section that highlights randomization details.

3) Reviewer: As your trial is open (item 11), please provide information about how you will convince researchers and regulatory bodies that it is protected against performance bias (e.g.: more additional treatments in one arm).
Response: We have added more details describing the rationale for the control group (e.g., controlling for the number of contacts and participants’ learning of guidelines). We also acknowledge the limitation of not being able to blind research participants.

4) Main analysis should follow item 12. You may consider improving your efficiency and power by adjusting for baselines in the final analysis (see, for example, chapter 7 in “Statistical Issues in Drug Development”, by Stephen Senn, Ed Wiley). As your final statistical analysis cannot be fully specified before unmasking, in order to guarantee it is not results-driven, you should fully specify it (maybe with computational details in an appendix) as soon as possible. You may also consider specifying the variables for your subgroup homogeneity sub-analysis (P14, L13). Please, try to follow the NEJM recommendations to prevent (P14, L3) and to treat missing data. (http://www.nejm.org/doi/full/10.1056/NEJMsr1203730).
Response: We have revised the statistical analysis section to provide further details and cite that we are following NEJM recommendations to help prevent missing data. For the between-subjects analysis, we are now taking into account baseline scores.

5) Reviewer: In addition to being ready to follow the CONSORT general statement, please consider also following the extension for non-pharmacologic interventions: http://www.consort-statement.org/extensions/interventions/non-pharmacologic-treatment-interv. It may help you to think about the need to collect data about interventionists’ training and experience. Please consider the convenience to include the interventionist as a random variable in the statistical model to allow for different performance -if you are employing more than one.
Response: Thank you for the suggested reading it was informative. We are only using one interventionist and this is now clarified in the manuscript.