Reviewer's report

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

Version: 2 Date: 25 February 2013

Reviewer: Erik Cobo

Reviewer's report:

In order to achieve the maximum impact, final report should be written in accordance to the CONSORT statement (http://www.consort-statement.org/), I would like authors to improve it with the following comments.

1) Sample size should be specified following item 7a.

2) Randomization details (items 8 to 10) should be provided.

3) 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).

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 you 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).

5) 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-interventions/ 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.