Author's response to reviews

Title: Tai Chi versus Aerobic Exercise for Fibromyalgia: Study Protocol for Design of a Novel Comparative Effectiveness Randomized Controlled Trial

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Author's response to reviews:

Dear Drs. Alman, Furberg and Grimshaw,

We appreciate the opportunity to respond to the questions on our manuscript entitled “Tai Chi versus Aerobic Exercise for Fibromyalgia: Design of a Novel Comparative Effectiveness Randomized Controlled Trial”. We have addressed the comments in a revised manuscript and giving a point-by-point response to the concerns in our cover letter.

1. Please ensure the title conforms to journal style for study protocol articles. The title should follow the format?___________: study protocol for a randomized controlled trial.?

The title of our manuscript now matches the to journal style for study protocol articles: “Tai Chi versus Aerobic Exercise for Fibromyalgia: Study Protocol for Design of a Novel Comparative Effectiveness Randomized Controlled Trial”.

2. Please include the date of registration with the trial registration number at the end of the Abstract.

The date of registration with the trial registration number is included at the end of the Abstract. “ClinicalTrials.gov identifier: NCT 01420640 registered 18 August 2011”.

3. Please provide the reference numbers given with ethical approval with the ethics statement in the Methods section.

The reference number of our Institutional Review Board at Tufts University/Tufts
Medical Center (# 9945 ) is included in the ethics statement.

4. Please move the table below the reference list.
The Table is now below the list of references.

5. Please include a list of abbreviations used and their meanings, after the Trial Status.
The list of abbreviations used in the protocol is included as requested.

Reviewer:
This is a well-written manuscript describing a clinical trial comparing the effectiveness of tai chi and aerobic exercise for individuals with fibromyalgia. The research question is nicely set up in the introduction, and the methods are sufficiently detailed.

We are pleased to know the reviewer found the protocol well written and the research question nicely set up in the introduction, and that the methods are sufficiently detailed.

1. Background, end of 3rd paragraph, I'm not sure "evidently" is the right word in the last sentence. Perhaps "consequently?".

Thank you for your suggestion. “Consequently” has been substituted for “evidently”.

2. In the introduction it is stated that the factorial arrangement includes the instructor. In the methods the use of multiple instructors is described, but it is not totally clear how this will be treated as a factor in terms of randomization assignment, etc.

The factorial arrangement now has been describe in greater detail in Page 10 and Table 3.

3. In the study overview, there is not a need to list the secondary outcomes, since these are included later. Similarly, in the measures section, it is not necessary to list the general secondary outcomes (beginning of the section) before providing a detailed description of each of these outcome.

Lists have been removed in both locations as per your recommendation. Please see pages 7 and 16.

4. In the Enrollment... section, it is first stated that participants are enrolled in groups of 36 or more, then it says 40-50 are pre-screened together. Although these statements are not in direct conflict, this could be explained more clearly.
For example, if more than 36 are enrolled per cycle, how does this fit in with filling the number of groups that start together (vs. having "extra" people who have no group)?

Page 8 has been revised to explain in greater detail how groups are filled.

5. Recommend omitting the statement, "These procedures are precisely described in the manual of operations."

The statement has been omitted (Page 10, at the end of the Randomization Session).

Thank you for considering our work. Correspondence should be addressed to me at 617-636-3251.

Sincerely,

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