Author’s response to reviews

Title: FIT for FUNCTION: Study protocol for a randomized controlled trial

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Response to Reviewers

Thank you very much for your helpful comments in the review of our paper.

Comment 1: Is the term pragmatic trial correctly applied to this trial?

We have used the term pragmatic to apply to our trial because we consider it meets the criteria applied to describe pragmatic clinical trials. We have applied the PRECIS criteria in an attempt to demonstrate this.

Ratings according to the PRECIS elements (Thorpe et al., 2009). It should be noted that the majority of ratings indicate a highly pragmatic trial. Ratings also show how the present trial represents a real-world, unrestricted setting versus an efficacy trial carried out under selected and often ideal circumstances.
1. Participant eligibility criteria: Rating = 5. Participants in the trial are not restricted in time since stroke, they can self-refer or be referred from a family member or health care professional, and need medical authorization to participate in the exercise program. In fact, there are a number of wellness programs provided by the YMCA for special populations, including bone and joint disorders, childhood developmental disorders, diabetes, heart disease and cancer and there are a number of centres that plan to adopt the Fit for Function program depending on the outcome of this trial. The structural requirements are in place to deliver the program and both persons who have had stroke and the YMCA support the upscaling of the program.

2. Experimental Intervention Flexibility: Rating = 4. The participants receive this community-based intervention at the YMCA. They perform the exercise program in a circuit that is tailored with adaptations or progressions according to their various physical limitations. We request that they not concurrently participate in another community-based exercise program, but their physical activity is not restricted in any other way.

3. Practitioner expertise (Experimental Intervention): Rating = 4. A physiotherapist who has stroke experience can undertake the supervision of this program. The kinesiologist who leads Fit for Function participates in a 1 day training session which includes: education about stroke, the hemiplegic upper extremity and stroke and exercise; discussion about the principles of the community-based exercise program; participation in Living with Stroke facilitator training. The kinesiologist is not required to have prior experience with stroke.

4. Flexibility of the Comparison Intervention: Rating = 5. The participants in the control group receive exactly what any community member would receive if they signed up for a YMCA membership. They attend the YMCA on a self-determined schedule and participate in an exercise program that has been designed with consultation from a trainer at the initial session. They receive no special treatment or attention.

5. Practitioner expertise (Comparison Intervention): Rating = 5. The fitness trainers for the control group have no previous experience working with persons with stroke. They have minimal training; they are required to attend a 1 hour session to review study procedures and exercise safety as it relates to stroke.

6. Follow-up Intensity: Rating = 4. Participants in the trial are assessed at 12 weeks (at the end of the intervention period) and at 24 weeks (12 weeks after the end of the intervention period). They receive no intervention during the follow-up period.

7. Primary Trial Outcome: Rating = 5. The primary outcome in this trial is the Reintegration to Normal Living Index which is more a long-term than a short-term outcome.

8. Participant compliance with prescribed intervention: Rating = 4. We are measuring attendances, however we are not feeding this information back to participants nor are we in any way applying strategies to increase compliance.

9. Practitioner adherence to study protocol: Rating = 5. There are certain principles that the physiotherapist and kinesiologist adhere to in delivering the exercise program, however the
tailoring of exercises for each individual participant (exercise progression or adaptation) is at their discretion. We do not apply strategies to increase adherence of the practitioners delivering the intervention.

10. Analysis of the Primary Outcome: Rating = 4. Our analysis will use an ITT approach and we will not exclude non-adherers or exclude participants found to be ineligible after randomisation.

In summary, we understand the concern of the overuse of the term pragmatic trial, but we believe that this particular trial is certainly more pragmatic than explanatory.

Comment 2: Participants may already be well integrated into the community and not contribute to the analytic design.

We plan to assess change in the primary outcome between baseline and at 12 weeks (end of trial) and adjust for baseline scores which would take into account their level of integration at the beginning of the trial.

Comment 3: The differential time which persons post stroke will be admitted to the trial could introduce bias.

We are not placing any restriction in terms of time since stroke for admitting persons into the trial. Reintegration post stroke is highly variable, and we may have to adjust for this in the analysis. We have inserted this to our analysis section.

Reference: