Reviewer’s report

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

Version: 0 Date: 30 Sep 2017

Reviewer: William Meurer

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Review 17-00544

This is a very interesting and well written protocol.

There are two issues that need to be addressed.

1. I think the use of the term pragmatic is problematic. You seem to use a general term of broad inclusion criteria. Stroke patients who can walk and tolerate 60 minutes of activity and who are not currently in rehabilitation seems actually like a fairly specific population. The term pragmatic is frequently abused or misused in the clinical trial literature. In addition, it also tends to mean comparing things that are fairly easy to do in practice (like randomizing to acetaminophen/paracetamol versus an NSAID for pain). Getting a stroke specific physical therapy program going at the local YMCA does not actually seem like something that is easy to scale out worldwide. (And then why shouldn't the YMCA have TBI specific classes, hip replacement classes, cognitive decline after sepsis specific classes, etc.) My preference is that you remove it (the term pragmatic), however if you are insistent, please provide additional information and references that better justify that this is indeed a pragmatic trial (bearing in mind there is not truly a broadly agreed upon definition).

2. What if patients are already well re-integrated into the community? It would seem such patients might be very willing to get free exercise and would contribute little to your analytic design if they already would have high scores on the primary endpoint. Is there more detail on how you are handling this analytically? Are you measuring change from baseline? Are you accounting for baseline level or reintegration as a covariate? If you are doing neither, I appreciate that it is too late to change you analytic design - but you may wish to state this as a limitation.

3. How long after a stroke can people be included in this study? Trajectory of recovery is typically non-linear. If you enroll many patients 30 days after a stroke in one group and the other group has more people who are 120 days out (and may have plateaued) that could introduce bias. Again, if you have no plan to account for this, at this stage you will need to add this to your limitations. Additionally problematic would be only including those who have not re-integrated. At 120 days, the population of stroke patients who have not re-integrated well will look much different than looking at a group at 30 days who has not re-integrated.

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