Author’s response to reviews

Title: Physical Therapy and Deep Brain Stimulation in Parkinson Disease: Protocol for a Pilot Randomized Controlled Trial

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Author’s response to reviews:

Thank you for the opportunity to revise this manuscript. We believe that the revised manuscript is improved given the reviewer’s thoughtful comment. Please see our response below.

Reviewer reports:

There is a serious discrepancy between what appears to be the primary objective of the study and the design (ie. sample size justification). It is important to state clearly what the primary objective is, and what the secondary objectives are. The protocol states the safety outcome of SAE as the primary outcome, but the design is not consistent with this -- because it is based on the efficacy outcome. If it is safety, then the sample size needs to correspond to the primary aim/outcome. If it's about feasibility, then it needs to correspond to this. Otherwise, it currently based on efficacy outcome and it is not even clear whether the primary efficacy outcome is balance or gait, or both are primary. In fact, if this study is a pilot aimed at assessing feasibility, it would make sense to use feasibility outcome as the primary outcome with appropriate criteria for success of feasibility. And the sample size should be based on it.

Thank you for this comment. We apologize for not being clearer about our objectives and their order of importance. We agree that the design of this study is based on efficacy and we powered it for that. This was because if the intervention turned out to be safe and feasible, yet there was no efficacy then there’d be no reason to move forward with a larger study. To clarify, our primary outcome for efficacy will be the measure of balance (i.e. Balance Evaluation Systems Test). This is because balance is most likely to remain impaired following DBS surgery. Based on your feedback, we have revised the manuscript to state that the primary objective is to determine preliminary efficacy of the PT intervention on balance in people with PD with STN-
DBS. Secondary objectives include determining the efficacy of PT intervention on gait as well as safety and feasibility of the PT intervention.