Author’s response to reviews

Title: Individualized behaviour change strategies for physical activity in multiple sclerosis (IPACMS): protocol for a randomized controlled trial

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Reviewer #1: This is the editorial comment.

This is a well written protocol on a potential intervention to address individualized behaviour change strategies for physical activity in multiple sclerosis. Trials is trying to ensure as much information as possible is in the published Trials protocol using the SPIRIT checklist so try and minimise the information readers need to get from looking up additional sources of information. So we would be grateful for your assistance.

SPIRIT checklist - you submitted a SPIRIT checklist but it is not acceptable for Trials journal for the authors to state N/A in the SPIRIT checklist for any items. Further information is required. So please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

- Thank you for the supportive and helpful comments, and the opportunity to submit a revised manuscript. We have addressed each comment below.

Item 2b: All items from the World Health Organization Trial Registration Data Set. This is in your protocol so please state in SPIRIT checklist: "Please refer to Item 2a and registration information in ClinicalTrials.gov: NCT04027114 Item

3: Date and version identifier cannot be N/A eg Version 2.0. Date.

- We have added a protocol version and date. This is the date that the protocol/application was submitted to the governing Research Ethics Board.
Item 5d: This cannot be N/A. On page 6 you state "a collaborative effort of interdisciplinary researchers, clinicians, and patient and family advisors" It connects with information in 21a which refers to page 16. It would be helpful if you could give further information on the composition, roles and responsibilities of the coordinating centre and trial steering committee and all groups providing day to day support for the trial. We also need information on who is responsible for all aspects of local organisation including identifying potential recruits and taking consent. Who is supervising the trial and how often they will meet, plus information on the Trial Steering Committee (TSC), and how often they will meet over the course of the trial to oversee conduct and progress. Plus, information and how often the Stakeholder and Public Involvement Group (SPIG) if there is one, and their specific role.

- We have added a section at the end of the Methods titled Monitoring that addresses this. It reads: This study, including the participant consent form, has received ethical approval from the University of Saskatchewan Biomedical Research Ethics Board. As this is a low risk intervention, no data monitoring review committee is required. However, the University of Saskatchewan Biomedical Research Ethics Board has the authority to audit the study at any time to ensure compliance to approved protocols. Monthly research meetings involving the research team will be held to discuss day-to-day management and organization of the study including participant recruitment, delivery of the intervention, participant monitoring. Finally, a Trial Steering Committee, comprised of the principal investigators, co-investigators, patient and family advisors, funders, and other stakeholders will meet quarterly over the course of the study period to monitor the overall study conduct and progress.

Item 11b: please remove N/A. I note you state "each intervention is individualised" but please consider stating something like "There will be no special criteria for discontinuing or modifying allocated interventions".

- We have revised the statement as suggested.

Item 11c: I note that you state "Participant is involved in intervention/treatment plan, so good adherence is expected." But please insert this into the protocol as it is relevant to the readers' understanding.

- We have added a line addressing this in the Methods (page 8).

Item 17b: Please delete N/A and consider inserting something like "as there is no blinding of participants and neurophysiotherapists there is no need for unblinding" in the SPIRIT checklist.

- We have added this statement as suggested.

Item 21a: This information should be in the protocol and not just in the checklist. Please remove N/A

- We have added a statement related to this in both the Checklist and a section related to Monitoring in the manuscript (page 11)

Item 21b: Please remove N/A from checklist and insert into the protocol. "As this is a low risk intervention interim analyses and stopping guidelines will not be required."

- We have modified the statement in the Checklist as suggested.
Item 23: please put auditing procedures into protocol and insert into Checklist.

- We have added a statement related to this in both the Checklist and a section related to Monitoring in the manuscript (page 11)

Item 26b: There is some information on page 6: "At the time of enrollment in the SMSDP, individuals are offered the chance to consent to be contacted about participating in future MS-related research; those who consent are also asked to complete the Godin Leisure-Time Exercise Questionnaire (GLTEQ" You could also state if this is relevant: "On the consent form, participants will be asked if they agree to use of their data should they choose to withdraw from the trial. Participants will also be asked for permission or the research team to share relevant data with people from the University of Saskatchewan taking part in the research or from regulatory authorities, where relevant. This trial does not involve collecting biological specimens for storage."

- We will not be collecting or using participant data for ancillary studies. We have added this statement to the Checklist.

Item 29: Please complete this information it cannot be N/A. Please consider adding to the statement on page 13 (see 31c).

- We have added a section in the Methods related to Dissemination that addresses this (page 11).

Item 30: Provisions for post-trial care - you could state "There is no anticipated harm and compensation for trial participation" and it would be helpful to know if there will be any provision for post-trial continuation of this intervention.

- We have added the suggested statement to the Checklist.

Item 31a: Please insert a sentence or two for the reader who cannot easily read the protocol submitted previously: "Dissemination strategy not discussed in study protocol, but provided in REB application and grant submission." Please document dissemination in the protocol and in the checklist. Perhaps you could state how results will be communicated to X and X and other relevant groups via publications, reporting results in databases, data sharing arrangements, twitter - social media or through the sponsor etc

- We have added a section in the Methods related to Dissemination that addresses this (page 11).

Item 31c: Access to data cannot be N/A, this is stated on page 13 "Not applicable; study protocol only." It refers to the dataset that will be gathered during the RCT, it is really important so complete this information. Consider stating "The datasets analysed during the current study are available from the corresponding author on reasonable request."

- We have revised this statement, and included a section in the Methods related to Dissemination that mentions this. We have also altered the statement on (now) page 14.

Item 32: delete N/A and consider inserting this information "Available upon request" into the protocol.

- We have made the suggested change in the Checklist.

Item 33: See above 26bm there will be no biological specimens collected.
- We have revised this statement in the Checklist.

References: There were 3 articles that could not be validated so please check references. There are also 7 articles that could not be checked, please check format for websites, include date checked and check for typos. (https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol/#references).

- Thank you for identifying these errors. We have corrected the references, and confirmed that all referenced webpages are accessible at the listed links.

English: page 4 "due to a lack details about the actual interventions." Edit to "insufficient detail about the actual interventions to replicate". TIDieR checklist can help with this https://www.bmj.com/content/348/bmj.g1687
- We have edited this sentence.