

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	An intervention to reduce sedentary behaviour and improve outcomes after stroke (Get Set Go): A study protocol for the process evaluation of a pilot cluster randomised controlled trial (RECREATE)
AUTHORS	Johansson, Jessica; Shannon, Rosie; Mossabir, Rahena; Airlie, Jennifer; Ozer, Seline; Moreau, Lauren; Farrin, Amanda; Mead, Gillian; English, Coralie; Fitzsimons, Claire F.; Clarke, David; Forster, Anne; RECREATE Programme, Management Group

VERSION 1 – REVIEW

REVIEWER	Pellegrini, Christine University of South Carolina
REVIEW RETURNED	07-Jun-2023

GENERAL COMMENTS	While I recognize this protocol was focused on the process evaluation as compared to the actual intervention, it was challenging to understand the process evaluation without basic information on the intervention. Most descriptions of the Get Set Go intervention were minimal (only could find in the introduction section on page 4) and lacked any specific details about what was actually done. For example, on page 16, it mentions observations where done at 3 times to explore the intervention fidelity; however, I'm not sure what the intervention was, nor was any specific things listed for what observers were assessing. It would be helpful to expand on the actual intervention and also describe specifically what observers actually were assessing. It was also not clear what the roles within the intervention were for the patient, carer, and staff. Finally, very little was actually mentioned on the stroke population but would be helpful to build more purpose and significance of this study.
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REVIEWER	Handlery, Reed Arkansas Colleges of Health Education
REVIEW RETURNED	11-Jun-2023

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. This well-written, theory-driven manuscript describes the protocol for a process evaluation of a randomized controlled trial which aims to reduce sedentary behavior in individuals with stroke. This protocol represents important work in stroke rehabilitation as survivors are one of the most sedentary populations and stand to benefit a great deal from increasing physical activity (and decreasing sedentary behavior). Describing the process for evaluating intervention implementation and contextual factors is necessary to truly understand a complex intervention such as the one described and
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	<p>how the outcomes will be (or not be) achieved. Because the manuscript is clear and detailed, I have only a few minor comments/suggestions.</p> <ol style="list-style-type: none"> 1. Table 2 outlines the semi-structured interviews to be conducted with individuals with stroke, carers and select staff. There is further description of what will be asked under the heading "Topic guides". If possible at this stage of the research, an interview guide (s), with specific questions to be asked for each group (i.e., patients, carers, staff) would be a welcome addition to the manuscript. 2. For observational sessions, it states "conversations with staff will help to identify whether patients may need the accessible information sheets and consent forms...". For interviews, is the process still the same to ensure interviewees are capable of providing informed consent or is there another process such as a cognitive screen? Please state under the heading "Semi-structured interviews". 3. Table 1. For staff inclusion criteria, "working in a participating stroke service for a significant amount of time each week". Was there a criteria to determine what the minimal hours/week would be (e.g., 20 hours/week)? 4. Figure 1. Please add time points in the boxes "interviews with a sample of stroke survivors, and carers"; This information appears to be in table 2 but would be helpful to see in Figure 1. 5. Figure 1. Please add time point(s) for when staff are to be interviewed; This information appears to be in table 2 but would be helpful to see in Figure 1. 6. A description of the researchers/assessors (and their level of training) completing the observations would be helpful; this may or may not have been looked at in the pilot study mentioned. Is the intent for one or two assessors to conduct all observations or is this known? 7. The detailed description of qualitative data analysis is appreciated. One line about the training of those (JFJ, RS) conducting the analysis would be appreciated. For example, "by a minimum of two researchers (JFJ, RS) with XX years experience conducting qualitative inquiries. 8. Page 18 L42-55. "...and provides opportunity for participants to share their experience of the intervention". I believe this is stating that those who did not consent to be in the study but were involved in the Get up and Go program will be approached for possible interviews. Consider calling these individuals patients as the term participant implies they were involved in the research study.
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VERSION 1 – AUTHOR RESPONSE

Reviewers	Comments	Responses to reviewers
Reviewer 1: Dr. Christine Pellegrini, University of South Carolina	<p>While I recognize this protocol was focused on the process evaluation as compared to the actual intervention, it was challenging to understand the process evaluation without basic information on the intervention. Most descriptions of the Get Set Go intervention were minimal (only could find in the introduction section on page 4) and lacked any specific details about what was actually done. For example, on page 16, it mentions observations where done at 3 times to explore the intervention fidelity; however, I'm not sure what the intervention was, nor was any specific things listed for what observers were assessing. It would be helpful to expand on the actual intervention and also describe specifically what observers actually were assessing. It was also not clear what the roles within the intervention were for the patient, carer, and staff.</p>	<p>Thank you for this comment. We made a conscious decision to not include too much information about the intervention at this stage because we hope to progress to a definitive trial and widespread knowledge of the intervention could undermine that. However, we agree that further information is important for the readers, so we have added a level of information that we deem to be appropriate without divulging too much detail. To address this we have added more information about the intervention on pages 4 and 5 and have stated within the manuscript that a Template for Intervention Description and Replication (TIDieR) checklist will be published with trial findings at a later date. To address the point about it being clear what is being observed we have added examples to pages 17 and 18. We hope all this additional text provides more clarity.</p>
	<p>Finally, very little was actually mentioned on the stroke population but would be helpful to build more purpose and significance of this study.</p>	<p>Thank you for this comment. We have added some sentences to the first paragraph in the introduction to emphasise the importance of developing and evaluating interventions aimed at reducing SB in stroke survivors.</p>
Reviewer 2: Dr. Reed Handlery, Arkansas Colleges of Health Education	<p>Thank you for the opportunity to review this manuscript. This well-written, theory-driven manuscript describes the protocol for a process evaluation of a randomized controlled trial which aims to reduce sedentary behaviour in individuals with stroke. This protocol represents important work in stroke rehabilitation as survivors are one of the most sedentary populations and stand to benefit a great deal from increasing physical activity (and decreasing sedentary behaviour). Describing the process for evaluating intervention implementation and contextual factors is necessary to truly understand a complex intervention such as the one described and how the outcomes will be (or not be) achieved. Because the manuscript is clear and detailed, I have only a few minor comments/suggestions.</p>	<p>Thank you for this positive feedback, we have outlined how we have addressed each point in the boxes that follow.</p>

	<p>1. Table 2 outlines the semi-structured interviews to be conducted with individuals with stroke, carers and select staff. There is further description of what will be asked under the heading "Topic guides". If possible at this stage of the research, an interview guide (s), with specific questions to be asked for each group (i.e., patients, carers, staff) would be a welcome addition to the manuscript.</p>	<p>Thank you. We acknowledge this would be a helpful resource to readers. We have made some amendments to the topic guides as these divulge too much information about the intervention. For example specific questions about each intervention component. The majority of questions are still included indicating key areas of exploration. These are in supplementary file 1 (staff intervention, staff control patient/carer intervention, patient/carer control). We have added 'supplementary file 1' to the text on page 22.</p>
	<p>2. For observational sessions, it states "conversations with staff will help to identify whether patients may need the accessible information sheets and consent forms...". For interviews, is the process still the same to ensure interviewees are capable of providing informed consent or is there another process such as a cognitive screen? Please state under the heading "Semi-structured interviews".</p>	<p>Thank you for highlighting this. We have added a sentence to page 19 to state that participants will be asked if an accessible information sheet is required. We have also added more information to page 19 about how JFJ and RS will make judgements about capacity. Capacity will have already been established by the research teams recruiting patients to the trial but JFJ and RS will make a judgement if there are changes to circumstances. In this section we have also included a point about the possibility of witness consent if someone is unable to write due to difficulties in arm function.</p>
	<p>3. Table 1. For staff inclusion criteria, "working in a participating stroke service for a significant amount of time each week". Was there a criteria to determine what the minimal hours/week would be (e.g., 20 hours/week)?</p>	<p>Thank you for this point, we have added hours per week for clarity in table 1.</p>
	<p>4. Figure 1. Please add time points in the boxes "interviews with a sample of stroke survivors, and carers"; This information appears to be in table 2 but would be helpful to see in Figure 1.</p>	<p>Thank you, we have added this information to figure 1.</p>
	<p>5. Figure 1. Please add time point(s) for when staff are to be interviewed; This information appears to be in table 2 but would be helpful to see in Figure 1.</p>	<p>Thank you, we have added this information to figure 1.</p>
	<p>6. A description of the researchers/assessors (and their level of training) completing the observations would be helpful; this may or may not have been looked at in the pilot study mentioned. Is the intent for one or two assessors to</p>	<p>Thank you we have included content about the expertise of researchers JFH and RS on page 6 under the 'methods and analysis' heading. Within the 'study setting' section that follows, we have added information about how the data collection is shared between JFJ and RS.</p>

	conduct all observations or is this known?	
	7. The detailed description of qualitative data analysis is appreciated. One line about the training of those (JFJ, RS) conducting the analysis would be appreciated. For example, “by a minimum of two researchers (JFJ, RS) with XX years experience conducting qualitative inquiries.	Thanks. This is addressed in the text that has been added in the above on page 6 under the ‘methods and analysis’ heading.
	8. Page 18 L42-55. “...and provides opportunity for participants to share their experience of the intervention”. I believe this is stating that those who did not consent to be in the study but were involved in the Get up and Go program will be approached for possible interviews. Consider calling these individuals patients as the term participant implies they were involved in the research study.	Thank you for this consideration, we have made the change as suggested (now on page 20).

VERSION 2 – REVIEW

REVIEWER	Pellegrini, Christine University of South Carolina
REVIEW RETURNED	02-Aug-2023

GENERAL COMMENTS	Citations should be added to support the new sentence on page 3 (Epidemiological studies indicate that stroke survivors are in the highest quartile for cardiovascular risk and increased sedentary behaviour adds to this rising risk.) All other concerns were addressed.
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REVIEWER	Handlery, Reed Arkansas Colleges of Health Education
REVIEW RETURNED	29-Jul-2023

GENERAL COMMENTS	The authors addressed all my comments/concerns.
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