

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Feasibility of a ballet-inspired low-impact at-home workout programme for adults with stroke: A mixed-methods exploratory study protocol
AUTHORS	Lo, Suzanne; Chau, Janita P. C.; Choi, Kai Chow; Yeung, Jonas; Li, Siu Hung; Demers, Marika

VERSION 1 – REVIEW

REVIEWER	Chan Yiong Huak Biostatistics Unit Yong Loo Lin School of Medicine National University of Singapore Singapore
REVIEW RETURNED	14-Oct-2020

GENERAL COMMENTS	<p>For the qualitative study, details of how the interviews are to be performed is not specified. Is it individual or group interviews, list of questions to be used?</p> <p>The study aims to look at the feasibility of FBB, what will happen if the feasibility fails? Is this being investigated as a pilot before launching into this study?</p> <p>For the RCT, a power calculations should be performed on a specific outcome should be stated. Since 2 centres are involved, the stats analysis should account for centre-clustering effect. The stats plan is very sketchy, stating GEE is too general, specific should be mentioned on how the various outcomes are to be analysed, multivariate.</p>
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REVIEWER	Kara Patterson University of Toronto, Canada
REVIEW RETURNED	22-Jan-2021

GENERAL COMMENTS	<p>Manuscript BMJOPEN-2020-045064</p> <p>Thank you for the opportunity to review this manuscript. The authors have outlined the protocol for a randomized controlled study to investigate the feasibility of a "ballet-inspired low-impact at-home workout" for adults with stroke. They will employ a mixed-methods approach to achieve several objectives including evaluate the rates of recruitment, attendance, and adverse events, explore the facilitators and barriers for implementation of the program and assess the preliminary effects of the program on balance, gait and memory. A strength of this study is the</p>
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	<p>consultation with stakeholders (i.e. dance instructor and stroke survivors) that has already been completed to create the proposed home exercise program.</p> <p>I have several concerns with the manuscript.</p> <p>1) Introduction. Pg 7, Ln 16-18. It is noted that people with stroke exhibit gait deviations, but then the list of example deviations that follow first start with a description of arm positioning and then the remaining are not the common gait deviations observed. It would be good to clarify this sentence, provide references and note common gait deviations observed post stroke.</p> <p>2) Introduction. Pg 7, Ln 31-33. Is there a reference/study to support the statement “A critical condition to sustain physical gains ... after discharge.”</p> <p>3) Introduction. Pg 7, Ln 45-52. The various benefits of dance are outlined which is helpful to provide context for the protocol. Please provide references to support these statements.</p> <p>4) Introduction. Pg 8, Ln 14-17. Several gaps in the literature related to the use of dance in post-stroke rehabilitation are identified. The first two could be clarified. The first gap – “no consensus on which dance style and regimen is more effective” – is accurate, however the protocol described in this manuscript will not address this gap since only one dance study will be compared to a non-dance control condition. The second gap – “dance interventions examined in previous studies were not underpinned by theoretical frameworks” can be supported by providing some information elsewhere in the introduction about which theoretical frameworks are appropriate for dance interventions and which one the current protocol is adopting. The reviewer recognizes that this is discussed later in the protocol (e.g. pg 10 ‘Bandura’s constructs) but placing the information about the theoretical framework up front when the rationale for the study is discussed in will provide more context for the reader.</p> <p>5) Intervention. Pg 10, Ln 22. It is noted that the FBB group and the control group will receive usual stroke care. Please provide a brief description of what constitutes usual stroke care in the region where this study will be conducted as this can vary across different regions and countries.</p> <p>6) Intervention. Pg 10, Ln 36-37. Please clarify the statement that mental rehearsal of movements is used in ballet.</p> <p>7) Intervention. Pg 11, Ln 41-45. Please clarify how the 90 min at-home support session the 15-minute virtual interactions and the ballet-inspired exercise program fit together. For example, is the exercise program ultimately performed independently by the participant? What are the objectives of the virtual interactions vs the support sessions?</p> <p>8) Intervention. Please elaborate on how safety of each individual participant to perform the ballet-inspired exercise program will be assessed and how it has been considered in the development and eventual implementation of the ballet-inspired exercise program. Is there a concern for falls?</p> <p>9) Control group. Pg 12. The control group will perform usual activities and exercises during the study period. This does not control for the additional social interactions and attention that will be received by the ballet group. Is this a concern and how might it affect the conclusions that can be drawn from the data. Furthermore, please define what usual activities and exercises are; particularly with respect to the term ‘usual’. It is presumed that</p>
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	<p>these participants returning home after their first ever stroke will not be performing the activities and exercises, they did prior to their stroke.</p> <p>10) Data analysis. Pg 14, ln 33-36. Please provide details about the qualitative analysis of transcripts. What type of analysis/approach will be applied? How many people will be coding the data, how will discrepancies in coding be resolved?</p>
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VERSION 1 – AUTHOR RESPONSE

A point-by-point summary of responses to reviewers' comments

1. Please remove all your figures in your main document and upload each of them separately under file designation 'Image' (except tables and please ensure that figures are in better quality or not pixelated when zoomed in).

They can be in TIFF, JPG or PDF format. Make sure that they have a resolution of at least 300 dpi and at least 90mm x 90mm of width. Figures in document, excel and powerpoint format are not acceptable.

Response: Thank you. We have removed Figure 1 from the main manuscript and uploaded Figure 1 (PDF format) under the file designation 'Image'.

2. Please include figure legends at the end of your main manuscript.

Response: Thank you. We have included the figure legend at the end of the main manuscript.

3. BMJ Open adheres to BMJ's Tier 2 data policy. We require that a data sharing plan must be included with trial registration for clinical trials that begin enrolling participants on or after 1st January 2019. Please update the trial registry to include this information.

Response: Thank you. We have updated the trial registry at ClinicalTrials.gov accordingly.

4. Along with your revised manuscript, please provide an example of the patient consent form as a supplementary file as per item #32 of the SPIRIT checklist.

Response: Thank you. We have uploaded the patient consent form as a supplementary file.

5. Why were severe patients excluded? Why only lower limb?

Response: Thank you for your comments. We will test a newly developed package of ballet-inspired workouts for stroke survivors who have mild to moderate lower limb paresis. The package of workouts is aimed to serve as an exercise for these people to continue to train and improve their gait and balancing ability. It requires the survivors to have a certain level of balancing ability including being able to walk with one person. Therefore, we will include the stroke survivors who have mild to moderate lower limb paresis only.

6. We don't know the specifics of the exercises; would this study be reproducible?

Response: Thank you for your comment. We have included the description of the ballet-inspired workouts in the manuscript. A total of eight ballet-inspired workouts are integrated in the training

package including basic body positions, trunk movement, pointed toes, turn in and out, tendus (sliding and extending foot), plies (bending knees), elevés (lifting up on balls of feet) and coupes (shifting body weight). Participants will perform the workouts starting from a sitting position and progress to a standing position with or without physical support as their postural control improves. We will integrate the workouts into a 60-minute structured session adapted from a typical ballet class. Participants will perform the 60-minute session two times per week. The study would be reproducible (refer to manuscript track change version, p. 9)

7. Title – doesn't specify type of strokes included, please add in?

Response: Thank you. We will include people with ischaemic or haemorrhagic stroke. We would like to keep the current study title to make it concise.

8. For the qualitative study, details of how the interviews are to be performed is not specified. Is it individual or group interviews, list of questions to be used?

Response: Thank you. Interviews will be conducted with all participants in the intervention group and all the volunteers who have participated in delivering the programme. Focus group semi-structured interviews will be conducted by an independent research assistant. The questions to be asked are included in the manuscript (refer to manuscript track change version p. 11).

9. The study aims to look at the feasibility of FBB, what will happen if the feasibility fails? is this being investigated as a pilot before launching into this study?

Response: Yes, the proposed study is actually a pilot study aiming to collect some important information for properly planning a full-scale trial.

10. For the RCT, a power calculations should be performed on a specific outcome should be stated. Since 2 centres are involved, the stats analysis should account for centre-clustering effect. The stats plan is very sketchy, stating GEE is too general, specific should be mentioned on how the various outcomes are to be analysed, multivariate.

Response: Sorry for the confusion. The present study is actually a pilot and the sample size was not determined upon hypothesis testing but was anticipated to be adequate for preliminary effect size estimations, as recommended by Lancaster et al. (2004). It was not designed as a confirmatory full-scale trial for hypothesis testing. We understand that our study may be under-powered for such purpose. Indeed, by using the power analysis software GPower 3.1, given the sample size of 20 participants per each of two parallel groups, the study has only 46%, 34% and 23% statistical power to detect outcome of effect sizes of 0.6, 0.5 and 0.4 respectively at 2-sided 5% level of significance. As the study is a pilot and the main purpose of the quantitative analysis is to estimate the effect sizes for various outcomes but not to confirm their statistical significance. We have now removed the GEE analysis in the data analysis part. We also understand that there may be centre-clustering effect but such effect would influence precision of effect estimations or standard errors mainly rather than effect estimates. Furthermore, all our outcomes are physiological parameters, we anticipate that variation between clusters would be ignorable as compared to variation between individual participants and hence intracluster correlation would be ignorable. After all, the trial in the present study is not a cluster RCT, we only recruit participants through two sites. We therefore consider that it is not imperative to account for clustering effect in this pilot. Nevertheless, we will take into account the clustering effect or design effect when we plan our full-scale study. Thank you for the suggestions.

Reference:

Lancaster, G.A.; Dodd, S.; Williamson, P.R. Design and analysis of pilot studies: recommendations

for good practice. J Eval Clin Pract 2004, 10, 307-312.

11. Thank you for the opportunity to review this manuscript. The authors have outlined the protocol for a randomized controlled study to investigate the feasibility of a “ballet-inspired low-impact at-home workout” for adults with stroke. They will employ a mixed-methods approach to achieve several objectives including evaluate the rates of recruitment, attendance, and adverse events, explore the facilitators and barriers for implementation of the program and assess the preliminary effects of the program on balance, gait and memory. A strength of this study is the consultation with stakeholders (i.e. dance instructor and stroke survivors) that has already been completed to create the proposed home exercise program.

Response: Thank you for your comments.

12. Introduction. Pg 7, In 16-18. It is noted that people with stroke exhibit gait deviations, but then the list of example deviations that follow first start with a description of arm positioning and then the remaining are not the common gait deviations observed. It would be good to clarify this sentence, provide references and note common gait deviations observed post stroke.

Response: Thank you for your suggestions. The sentence is revised and references are added (refer to manuscript track change p.5).

13. Introduction. Pg 7, In 31-33. Is there a reference/study to support the statement “A critical condition to sustain physical gains ... after discharge.”

Response: Thank you for your suggestions. A reference is added to support this statement.

14. Introduction. Pg 7, In 45-52. The various benefits of dance are outlined which is helpful to provide context for the protocol. Please provide references to support these statements.

Response: Thank you for your comment. References were added to support these statements.

15. Introduction. Pg 8, In 14-17. Several gaps in the literature related to the use of dance in post-stroke rehabilitation are identified. The first two could be clarified. The first gap – “no consensus on which dance style and regimen is more effective” – is accurate, however the protocol described in this manuscript will not address this gap since only one dance study will be compared to a non-dance control condition.

Response: Thank you for your comment. There has been limited study which examined the effects of ballet and its effective dose in promoting physical rehabilitation of stroke survivors. Therefore, the feasibility study is aimed to examine the feasibility of a package of ballet-inspired workouts in improving gait, balance and memory of stroke survivors. We will continue to examine the effects of different dance styles and regimens in future studies.

16. The second gap – “dance interventions examined in previous studies were not underpinned by theoretical frameworks” can be supported by providing some information elsewhere in the introduction about which theoretical frameworks are appropriate for dance interventions and which one the current protocol is adopting. The reviewer recognizes that this is discussed later in the protocol (e.g. pg 10 ‘Bandura’s constructs’) but placing the information about the theoretical framework up front when the rationale for the study is discussed in will provide more context for the reader.

Response: Thank you for your comments. We have added information about the choice of theoretical

framework in the background (refer to manuscript track change version p.6).

17. Intervention. Pg 10, ln 22. It is noted that the FBB group and the control group will receive usual stroke care. Please provide a brief description of what constitutes usual stroke care in the region where this study will be conducted as this can vary across different regions and countries.

Response: Thank you for your suggestions. We have added information about the usual stroke services in the manuscript (refer to manuscript track change version p. 10).

18. Intervention. Pg 10, ln 36-37. Please clarify the statement that mental rehearsal of movements is used in ballet.

Response: Thank you for your comment. We have revised the sentence to make it clearer. It refers to that ballet emphasises on the rehearsal of body movements mentally before putting the movements into actions (refer to manuscript track change version p.8).

19. Intervention. Pg 11, ln 41-45. Please clarify how the 90 min at-home support session the 15-minute virtual interactions and the ballet-inspired exercise program fit together. For example, is the exercise program ultimately performed independently by the participant? What are the objectives of the virtual interactions vs the support sessions?

Response: Thank you for your comments. The programme will consist of two weekly 90-minute at-home support sessions delivered by two lay volunteers (one of them will be a stroke survivor) in Weeks 1-2, and six weekly 15-minute virtual interactions (by phone or internet media) by either lay volunteer in the remaining weeks. The home-based sessions will introduce participants to the programme, the resources package and safety precautions. The lay volunteers will conduct virtual sessions and discuss strategies to address challenges in performing workouts, reinforcing outcome expectations, appraising incremental progress and reinforcing participation as planned for the following weeks. We have integrated the eight ballet workouts into a 60-minute session. Participants will be asked to perform the 60-minute session two times per week during these eight weeks. The programme will be ultimately performed independently by the stroke participants. We have revised the information to make it clearer (refer to manuscript track change version p.10).

20. Intervention. Please elaborate on how safety of each individual participant to perform the ballet-inspired exercise program will be assessed and how it has been considered in the development and eventual implementation of the ballet-inspired exercise program. Is there a concern for falls?

Response: Thank you for your comments. Strategies to ensure safety of the participants during the programme were added (refer to manuscript track change version p.10).

21. Control group. Pg 12. The control group will perform usual activities and exercises during the study period. This does not control for the additional social interactions and attention that will be received by the ballet group. Is this a concern and how might it affect the conclusions that can be drawn from the data. Furthermore, please define what usual activities and exercises are; particularly with respect to the term 'usual'. It is presumed that these participants returning home after their first ever stroke will not be performing the activities and exercises, they did prior to their stroke.

Response: Thank you for your comments. We have revised the sentences to make it clearer about the differences in care received by the two groups. We have also added information about the usual care (refer to manuscript track change version p. 10).

22. Data analysis. Pg 14, ln 33-36. Please provide details about the qualitative analysis of transcripts.

What type of analysis/approach will be applied? How many people will be coding the data, how will discrepancies in coding be resolved?

Response: Thank you for your comments. We have added details about the qualitative analysis of the transcripts into the manuscript. The transcripts will be analysed thematically by two independent researchers. Discrepancies in coding will be resolved by discussion between the two researchers (refer to manuscript track change version p.13).

VERSION 2 – REVIEW

REVIEWER	Kara Patterson University of Toronto, Canada
REVIEW RETURNED	24-Feb-2021
GENERAL COMMENTS	<p>Thank you for the opportunity to review this revised manuscript. The authors have addressed all of my previous comments satisfactorily except for two minor points.</p> <p>1) Pg 8, lines 52-56. The authors responded to the previous concern about the statement noting that ballet relies on mental rehearsal however, the reviewer is not convinced. This is based on over 20 years of personal experience in ballet training where mental rehearsal was never used. The reviewer acknowledges that there may be regional differences in how ballet is taught. Can the authors please provide references that support the statement that “ballet relies heavily on mental rehearsal of body movements mentally before putting the movements into actions. It mirrors mental imagery to promote motor relearning and to enhance brain plasticity and cognitive functions.”</p> <p>Or perhaps, the authors mean to say that in their intervention or other’s work when ballet is used in rehabilitation with people with stroke, perhaps mental rehearsal was incorporated?</p> <p>In either case, please provide evidence to support the statement or clarify whether it is in the specific use of ballet as an intervention where mental rehearsal was used.</p> <p>2) Pg 6, lines 26-29. The authors responded to the previous concern about one of the identified gaps in the literature. Specifically “First, there has been no consensus on which dance style and regimen is more effective for promoting balance, gait and memory in stroke survivors”. However, the reviewer continues to have concerns.</p> <p>The reviewer agrees that there is a lack of consensus on which dance style or regimen is more effective. What the reviewer is concerned about is the way this section (lines 26-43) is worded, it implies that the proposed study will address the 5 gaps identified. While the current study will provide valuable information about the feasibility of a ballet-based intervention, it cannot provide information to address the first gap to help determine which dance style is more effective, because it will not be comparing the ballet-based intervention to an intervention based on a different dance style.</p>

	The reviewer suggests that the authors remove this statement regarding dance styles or revise the wording to make it clear that this is a gap in the literature, but it is not one that the current study will be addressing.
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VERSION 2 – AUTHOR RESPONSE

A point-by-point summary of responses to reviewers' comments

1. Pg 8, lines 52-56. The authors responded to the previous concern about the statement noting that ballet relies on mental rehearsal however, the reviewer is not convinced. This is based on over 20 years of personal experience in ballet training where mental rehearsal was never used. The reviewer acknowledges that there may be regional differences in how ballet is taught. Can the authors please provide references that support the statement that “ballet relies heavily on mental rehearsal of body movements mentally before putting the movements into actions. It mirrors mental imagery to promote motor relearning and to enhance brain plasticity and cognitive functions.”

Or perhaps, the authors mean to say that in their intervention or other's work when ballet is used in rehabilitation with people with stroke, perhaps mental rehearsal was incorporated? In either case, please provide evidence to support the statement or clarify whether it is in the specific use of ballet as an intervention where mental rehearsal was used.

Response: Thank you. We have revised the sentences and added the reference to make it clearer (refer to manuscript track change version, p. 8)

2. Pg 6, lines 26-29. The authors responded to the previous concern about one of the identified gaps in the literature. Specifically “First, there has been no consensus on which dance style and regimen is more effective for promoting balance, gait and memory in stroke survivors”. However, the reviewer continues to have concerns.

The reviewer agrees that there is a lack of consensus on which dance style or regimen is more effective. What the reviewer is concerned about is the way this section (lines 26-43) is worded, it implies that the proposed study will address the 5 gaps identified. While the current study will provide valuable information about the feasibility of a ballet-based intervention, it cannot provide information to address the first gap to help determine which dance style is more effective, because it will not be comparing the ballet-based intervention to an intervention based on a different dance style.

The reviewer suggests that the authors remove this statement regarding dance styles or revise the wording to make it clear that this is a gap in the literature, but it is not one that the current study will be addressing.

Response: Thank you. We have removed the first gap to make it clearer (refer to manuscript track change version, p. 6)