PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Dancing to improve balance control, cognitive-motor functions and quality of life after stroke: a study protocol for a randomized controlled trial
AUTHORS	Morice, Emmanuel; Moncharmont, Julien; Jenny, Clémentine; Bruyneel, Anne-Violette

VERSION 1 - REVIEW

REVIEWER	Professor Meg E Morris La Trobe University Australia
REVIEW RETURNED	02-Feb-2020

GENERAL COMMENTS	This manuscript addresses an important topic, whether dance can improve movement, health and wellbeing in people living with neurological disorders, such as stroke. The manuscript is engaging and of interest to the scientific community, as well as being clinically relevant. The manuscript, however, needs considerable revisions before being ready for publication in this leading international BMJ journal. Some of the changes needed are summarised as follows: 1. The literature review and discussion focus solely on the dance literature for stroke, which is very sparse. It overlooks a vast body of research literature on dance therapy in closely related neurological conditions such as Parkinson's disease, MS, and cerebral palsy. The introduction and discussion especially need to be re-written after a new search of the broader literature is conducted. 2. The references in this manuscript are mainly older ones and a new systematic search of the literature is needed to update the text. Much more discussion of the ideas and findings in the light of publications by authors such as Earhart, Hackney, Shanahan, Volpe, Rocha, Morris, Aguir, Clifford and many others. 3. The broader literature on other targeted therapeutic physical activities such as boxing, aqua therapy, cycling, physiotherapy in neurological patients could also be considered and cited (eg Bernhardt, Rochester, Ellis, Canning, Slade) 4. The standard of written English in this entire document is not at the international standard required and it is recommended that a professional editor be appointed to do a detailed revision of the final revised manuscript. 5. The hypotheses need to be clearly stated in a testable manner 6. The primary and secondary endpoints in this study need to be clearly presented and justified. 7. The methods for randomisation need to given and justified in more detail.

	8. The actual content of the dance classes needs to be given in much more detail and arguments given for why specific music, dance genres and dance steps are used – and details about warm up and cool down sections. 9. Much more detail needs to be given on the specific elements of usual care. 10. The measurement tools used to quantify outcomes need to have the reliability and validity presented. 11. The strategy for statistical analysis needs to be presented in more detail, and in relation to each of the primary and secondary outcome measures. 12. The consort diagram is hard to follow – why are the top boxes left blank whereas further down numbers population the boxes – are these predicted numbers? Should they be removed? 13. The discussion does not adequately refer to the global literature on dancing for neurological patients and to compare and contrast the current study with that body of evidence. 14. The discussion section needs a larger section on limitations 15. Currently the concluding statements cannot be directly derived from the findings.

REVIEWER	Kara Patterson University of Toronto, Canada I am currently running a randomized controlled trial investigating dance for people with chronic stroke living in the community.
REVIEW RETURNED	19-Feb-2020

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. The authors outline a protocol for a randomized controlled trial of a 6-week dance program for people with subacute stroke. The strengths of this study include a double baseline measurement, quality visit by a person external to the study, and timing of the intervention early during stroke recovery when it is likely to capitalize on a period of heightened neuroplasticity. However, I do have some concerns to be addressed. MAJOR CONCERNS 1) The title could be more descriptive. Suggestion: “Dance as a means to improve cognitive and motor functions, and quality of life after a stroke: a study protocol for a randomized controlled trial.” 2) At times, particularly in the introduction, the writing could benefit from editing for clarity. • Examples • Pg 7, lines 12-14 “Dance is thus particularly suitable for the multidimensional component of patients after stroke” • Pg 7, line 30 “aerobic physical stimulation” • Pg 14, line 21 “The incidence of dance practice on adverse effects will be assessed” • Pg 147 line 35 “Dance’s popularity is increasing among persons with chronic diseases.” Do you mean people with chronic diseases are exhibiting increased interest, or that interest in the use of dance as a therapeutic tool for people with chronic diseases is increasing? Also – do you have a reference for this statement? • Pg 6, line 37 and Pg 18, line 17. The term “natural activity” is used with respect to dance. What does this mean? • 3) Some of the citations can be described more precisely.

	• Examples • Pg 6, lines 32-37. The authors describe a review article by Green and coauthors. However, the wording “showed that natural training with complex tasks […] such as the pratice of art ” suggests this was an experimental paradigm investigating the effects of art. In fact the authors do not specifically investigate art and instead review principles of ‘slow learning’ including concepts like ‘task difficulty’ and ‘feedback’ • Pg 7, lines 35-39. The authors describe a study by O’Connell and coathors and state that “dance was the most common activity undertaken before stroke”. However, the O’Connell study used a survey that asked specifically about ‘arts related activities’. So a more precise way to describe these findings is “of arts related activities, dance was the most common one undertaken before stroke.” 4) Pg 3, line 3. The authors note that outcomes will be measured at 4 and 6 weeks. The timing of these measurements with respect to the start of the intervention and the rationale for measuring at these time points is not stated. At certain points it seems like the first assessment is at week 4 of the 6 week dance intervention and then the second assessment is at the end of the intervention. However, at other points (e.g. pg 3, lines 43-46) it seems as though the second assessment is actually a follow-up 6 weeks after the end of the dance intervention. Please clarify and describe the assessment timing consistently throughout the manuscript. 5) Pg 3, lines 30-55 – Article summary. The first 3 points listed are neither strengths nor limitations of the study. They are restating the rationale and methods employed. 6) Methods. The authors note in the intro and discussion that ‘adherence’ is a parameter of interest in their study. However, adherence is not defined nor is the approach to tracking adherence described in the methods. Have the authors set an a priori level (e.g. % of classes to attend) for adherence? 7) Pg 10, lines 13-18. The authors describe the demographic and clinical characteristics to be collected. Please specify how these will be collected (e.g. from patient medical charts? Self-report?) 8) Pg 10, lines 34-37. The authors describe the dose of the dance intervention. Is there a rationale for this dose. (e.g. why only 1 class per week, why not 2 classes? Or why a 6 week duration, why not 4 weeks or 8 weeks?) 9) Pg 10, lines 58. The authors have described the dance classes very well. However, it would be helpful to the reader if the authors provided examples of “social dance” to be taught in the classes. 10) Pg 13, lines 3-6. The authors describe the strength testing well. However, please specify what position the knee joint will be in during the measurement. Also, please specify what will be the measure of strength; will it be an average of the 3 trials or will it be the best score out of the 3 trials? 11) Pg 14, lines 21-30. The measures of pain and fatigue are described but what is missing is when these measures will be taken? (e.g. before/after each class? Before/after the 6 week

	intervention?) 12) Pg 17, line 46. The authors describe two feasibility studies on the use of dance for people with stroke and then note that the lack of a control group is a "methodological flaw." This is misleading because a flaw implies that the study methods were not adequate to test the hypothesis or meet the study objective. The aims/objectives of these studies (and feasibility studies in general) were to demonstrate that a dance intervention can be implemented, that there is demand for it and that it is safe, rather than to demonstrate the effects of dance. Therefore, the design of these studies and the methods employed met the study objectives. (Please see Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, Fernandez M. How we design feasibility studies. American journal of preventive medicine. 2009 May 1;36(5):452-7.) (The authors note this fact themselves on pg 7, lines 19-21.) The lack of a control group in these studies (and in feasibility studies in general) can be described as a limitation (rather than a flaw). 13) Pg 18, lines 10-15. The authors note the originality of the study is that it evaluates cognitive-motor recovery and QoL. However, a lot of post-stroke exercise intervention studies have evaluated these variables. I suggest the originality of the study is the use of dance and the fact it is an RCT which has not yet been done to investigate the use of dance in people with subacute stroke. MINOR CONCERNS 1) Pg 2, lines 52-54. Add the duration of the dance class (i.e. 60 minutes) in the description of the intervention. 2) Pg 5, line 37. Please clarify what is meant by "unlimited adaptability of dance". Every intervention has its limitations. 3) Pg 5, lines 50-53. The authors note "following a brain lesion, variable cognitive-motor deficits …" Since they have touched on the epidemiology of stroke, I suggest the authors also insert a line describing the etiology of stroke and more specifically how the 'brain lesion' is caused. 4) Pg 6, line 23. Consider revising "fighting cognitive and motor deficits" to "addressing cognitive and motor deficits" or "reducing cognitive and motor deficits". 5) Pg 13, line 23. The acronym for Functional Independence Measure is FIM. 6) Assuming the authors are describing the separate categories of impairments including motor and cognition, I suggest the authors consider using 'cognitive and motor impairments' throughout the manuscript rather than 'cognitive-motor' impairments which suggests these impairments are always linked. 7) Consider using person-centered terms. For example, instead of "persons suffering from stroke," use "persons living with stroke" or "persons with stroke." 8) Consider using "dance class" or "dance program" instead of "dance practice". When I read "dance practice", what comes to mind is professional dance training rather than a therapeutic intervention.

REVIEWER	RUTH PICKERING UNIVERSITY OF SOUTHAMPTON UK
REVIEW RETURNED	11-Mar-2020

GENERAL COMMENTS	This sounds an interesting, but small trial. I wonder whether it might be better styled as a pilot RCT. I have the following specific points. 1 Article summary, page 3, final bullet point. This should be omitted, its obvious a trial like this can't be double blind, so its neither a strength or a limitation. 2 Page 4, Patient consent section. They say here just "Obtained". The past tense suggests that it has already been obtained for participants. If the trial hasn't started yet they could say something like patients will be asked for consent to participate in the trial. 3 They do need to say somewhere whether the trial is ongoing or is yet to start. A date of starting recruitment needs to be given and also how long recruitment is planned to continue. The trial shouldn't already be complete. 4 Page 4, Provenance and peer review. I wasn't sure what they meant by "Not commissioned" here. 5 Page 6, lines 33-35. The CONSORT statement concerns the writing up of the report of an RCT. So it's the write-up of an RCT, not the RCT itself, that conforms to CONSORT. I don't think they should mention CONSORT at all at this stage. 6 Page 8. Lines 37-40. I thought this sentence on the setting might be better moved and combined with the first sentence of the Recruitment procedure, page 9, line 12. They do need to say in the Recruitment section where participants are recruited from. The sentence on page 9, line 12 should specify whether recruiting staff are employed in the clinical centre or whether they are research staff employed by the trial. 7 Page 9, lines 21-23. In this sentence about obtaining informed consent, it should be clear which member of staff will be interacting with the patient to get consent, I assumed the physiotherapist. Presumably it will be a member of the research team not center staff. Also will the same member of staff return to the potential participant after 24 hours. I'm assuming, though I don't think its actually stated here or as an eligibility criterion, that participants have to be inpatient at the neurorehabilitation center. Are they considering recruiting patients after they've gone home? 8 Page 10 & 11, the interventions section. Its not actually stated where the dance group (or control group physiotherapy) is to take place. I assumed in the neurorehabilitation center. But could participants have been discharged and return for classes? What sort of room is required to hold the dance class? How many participants take part in a class – I'd assumed it was a group class, but could they be individual classes? 9 Page 8, Eligibility criteria. I was surprised that they were intending to recruit within 3 months of stroke and it would be useful to state any when the actual dance classes are meant to start in relation to stroke onset (there may be a delay between randomisation and a participant being able to join a class). Do the stated criteria limit recruitment to patients with mild stroke and would such people have gone home quite quickly after stroke onset? 10 Page 9, Randomisation section. Concerning the final sentence stating block sizes of 4 and 6, will they be random block sizes, or are

	they planning to have a schedule of blocks of 4 and 6 fixed in advance? On lines 37-41, they describe features to ensure concealed allocation. Its not enough to say that the allocations will be created by an independent person, they need to describe the method of delivery of the next allocation to a participant after consent. The current sentence is consistent with the use of sealed envelopes (allocations created by an independent person then put in envelopes and left at the center for the recruiting staff to open for the next participant) – and use of sealed envelopes is no longer considered acceptable. They need to describe the process by which recruiting staff get the next allocation, and make it clear that they can't find out what the allocation is until the participant is clearly in the trial. 11 Pages 10 and 11, description of the dance groups. If the classes are to have more than one participant, this impacts on the recruitment process, in that they have to recruit enough participants to be able to fill a class, without having participants waiting for long periods of time after randomisation till their class begins. How will this be managed? They do need to state how many participants will be in classes, and also how many staff will be present to manage the class. On Page 11, line 9 there is mention of a dance teacher, but if the dance involves participants standing up and dancing I would have thought more staff would be needed to minimise the risk of a participants falling. On line 18, they say that participants can be sitting or standing, if they are sitting can it really be described as dance? Earlier on they mention participants repeating dance moves but don't describe any of the move they intend to include in detail. I did wonder whether they are talking about ball room dancing requiring a partner. If so, there needs to be some description of who the partners will be, and what they will do if a participant doesn't have a suitable partner. Would they provide a partner and what sort of people would they be? 12 Page 11, the control intervention. With both groups getting the physio and occupational therapy described, I think it will be difficult to show the additional dance classes giving any benefit. They say that participants will get physio 2-3 times a week, but don't say for how many weeks they will get it. Also whether this is when they are still in hospital, does conventional follow-up (the physio described) continue after a patient is discharged? Also can they describe whether all stroke patients get this physio in Switzerland, or do patients have to have insurance, for example? Or is the physio described, just for trial participants (control and intervention groups)? 13 Page 11, Primary outcomes section. They need to state which outcome is primary and at which follow-up time-point. The first outcome mentioned is the MoCA – is the primary outcome the MoCA at 6 weeks? On Page 16 sample size calculation is done with respect to the Mini-Bestest. Is the Mini-Bestest at 6 weeks the primary outcome? In the primary outcome section they describe: MoCA, Mini-Bestest, ABC, knee extension, LEMOCOT and MIF. Some of these outcomes have multiple domains, and they are measured at 4 and 6 weeks. So they haven't actually stated a primary outcome. 14 Page 14, line 48, they will collect two baselines to evaluate stability of parameters, and they will be compared, page16 line 34. Its not clear what they will do if baseline readings aren't close, will they use the second one, treating the first as a run-in? Or average them? In the sentences on page 14 describing the timing of measurements, they need to say (which I assumed was the case) that at these assessment all the measures described on pages 11, 12, 13 and 14 as primary and secondary outcomes would be

	measured. It is quite a long list of outcomes – could they estimate how long they think it will take to measure all of them? In relation to SPIRIT item 18b, plans to promote participant retention and complete follow-up, if a participant is clearly finding the assessment schedule too burdensome, perhaps they could restrict the outcomes, to a much reduced and key list. Obviously the primary outcome would be included, but they haven't stated what that is. 14 The Data collection section. I think they need to mention something about collecting data on harms, they should be accessing any adverse events recorded in either group, and in particular any falls. Also they need to mention collecting data on adherence to the dancing. The comment on adherence in the Discussion, page 18, penultimate paragraph. Do they mean the amount of time in class, willing ness to participate in classes (and if so how assessed) or, if participants have gone home, are they expected to carry on dancing? Also they should be collecting data on the amount of conventional and all other therapy participants in both arms of the trial receive. 15 Page 15, lines 14-20, personal information. Do they mean here identifiable information, that identifiable information will be kept separate from the main dataset. 16 Page 15, line 43. They start this off as "the criteria for subjects withdrawal…". They need rather to state that participants are free to withdraw from the trial at any point, but then list situations in which they anticipate some participants might wish to withdraw early. They should say that where possible they will record reasons why participants withdrew. The sentences should distinguish between withdrawal from the dance classes (or control rehabilitation?) and withdrawal from trial follow-up, and they could state here a plan of reducing the numbers of outcomes to measure as an attempt to keep people in trial follow-up wherever possible (even if they've stopped dancing classes. 17 Page 15, at the end of the withdrawals section they talk about possibly extending recruitment. Do they mean by this that if a participant withdraws, they intend to recruit replacements to achieve their target of 22 participants yielding outcome data, rather than 44 being enrolled? 18 Page 16, first paragraph, "intention-to-treat". They don't need to say this here. It is stated again in the statistical analysis section, page 17, second paragraph. They say that the analysis will be done on an intention-to-treat basis, with last evaluations carried forwards if data is missing. This is not a recommended method. Would they carry the baseline reading forwards in the event of not getting outcome at either 4 or 6 weeks? 19 Page 16, sample size section. Their stated effect size with 90% power only leads to a target of 22 per group if they plan to perform one-sided tests at the 5% level. Its standard in health studies to do all testing two-sided, and this leads to a larger number. They should state that tests will be done at the two-sided 5% level on page 17, third paragraph. They should also make some allowance for likely drop-out by the primary endpoint. The calculation was done for the Mini-Bestest which leads me to assume that this was in fact the primary outcome. They are looking to achieve a difference of 3.5on the test and anticipate the SD will be 3.9. Its not clear whether this SD relates to change scores or to individual readings at 6 weeks say. They should justify these assumptions perhaps referencing earlier work or audit data. If they cannot justify the assumptions, and along with the large number of outcomes included in the primary section, it is this that made me think that the current trial might better be described as a pilot RCT.

	20 Page 16, final paragraph statistical analysis. They start by saying that analysis will be descriptive. This suggests that significance tests will not be carried out – but the sample size section related to a significance test. They then say that the low number of subjects won't allow them to do parametric tests – but the power calculation should have ensured they will have an adequate number to do the test (which was parametric, a two sample t-test). Then because they won't have large enough numbers to do a parametric test they will do a non-parametric test – this is illogical because larger numbers are required for non-parametric tests than the parametric equivalent - usually. They mention Wilcoxon tests first, but this is a before after test of change, whereas the key comparison (which should be described first) in an RCT is between the two groups. I would suggest they do an ANCOVA, a linear regression including the group comparator controlled for the baseline reading of the outcome in question as a regressor. This would also facilitates a power calculation as the information needed is the SD of the outcome at the end point along with the correlation between readings anticipated at baseline and the endpoint. They do need to specify here which of the two readings they will use as the baseline. And this is equally true of the analysis of change compared between groups that they currently describe – they need to specify which of the two baseline they will be using as the initial reading in the change (or whether they will use the average). It would be helpful for them to get a statistician on board with the trial. I notice there isn't a statistician as an author. 21 Page 17, 25 it would be useful if they planned to let a statistician have access to the final dataset. 22 Page 17, line 45, they mention that a methodological flaw of the earlier feasibility studies is that they didn't include a control group. This isn't necessarily a flaw, it depends what the feasibility objectives of these studies were, they could for example have been attempting to assess whether the intervention was acceptable to participants, or assessing how burdensome the assessment schedule was. Such objectives wouldn't require a control group. A control group is necessary in evaluating the efficacy/effectiveness of an intervention, but a feasibility study shouldn't be addressing efficacy/effectiveness. 23 Page 18, line 28. They say here that the risks associated with dancing are low. I think they should consider the risk of falling both in the class itself, or afterwards (if participants are empowered to move more freely). But if their "dancing" only involves participants moving their body in a sitting position I guess there isn't a risk of falling during the class. 24 Figure 1 and the sample size calculation suggest they are aiming for a sample size of 44, but in the Abstract, page 2, line 45, they say that they will randomise 48.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Professor Meg E Morris
Institution and Country:
La Trobe University
Australia
Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below.

This manuscript addresses an important topic, whether dance can improve movement, health and wellbeing in people living with neurological disorders, such as stroke. The manuscript is engaging and of interest to the scientific community, as well as being clinically relevant. The manuscript, however, needs considerable revisions before being ready for publication in this leading international BMJ journal.

Our answer: We thank the reviewer #1 for these constructive remarks. You will find the answer to each comment below.

Some of the changes needed are summarised as follows:

1. The literature review and discussion focus solely on the dance literature for stroke, which is very sparse. It overlooks a vast body of research literature on dance therapy in closely related neurological conditions such as Parkinson's disease, MS, and cerebral palsy. The introduction and discussion especially need to be re-written after a new search of the broader literature is conducted.

Our answer: Thank you for this relevant remark. We modified the introduction and discussion parts with literature reviews about other pathologies.
We modified the text as:
Introduction:
"A previous review highlighted the benefits of dance in terms of physical, mental and social well-being in 51 articles about chronic pathologies [22]. Motor function, balance and symptoms are the most studied factors in their relation to dance [22,23]. No adverse effect was reported, and patient adherence seems excellent. These positive effects were observed for neuromusculoskeletal, psychiatric, cardiovascular, metabolic and oncological pathologies [22]. Regarding Parkinson's disease, 2 reviews showed improvements in symptoms and speed of the Timed Up and Go test when compared to other exercises [5,24]. Patterson et al. highlighted that dance classes are suitable for adults with neurological conditions and improve gait and balance parameters, but there are few studies on stroke [25]. Only two studies on subjects with stroke, with no control group, showed the feasibility of a dance program, a high satisfaction rate of participants, some benefits regarding balance and no adverse effect [20,26]. Dance seems particularly adapted to the multidimensional impairments of patients with stroke, e.g. cognitive, motor, balance, quality of life and social impairments [9]."
Discussion:
"There is a growing interest in the use of dance as a therapeutic tool for people with chronic diseases [22]. Previous reviews showed that dance is an activity that involves the whole body in movements with variable constraints, which seems to have positive impacts on physical, motor, cognitive and relational disorders [5,23–25,46,47]. Parkinson's disease and cancer are the most studied pathologies [5,22,24]. For neurological pathologies, dance is deemed suitable and seems beneficial to adherence, mental health, psychosocial aspects, as well as cognitive, balance and motor skills [22]. However, no RCT studies have been conducted for people after stroke, so the actual effectiveness of dance cannot be determined.
The originality of this RCT study is that it evaluates the impact of a dance program for people with subacute stroke on cognitive and motor recovery, quality of life and the motivation to engage in physical activity. We expect to see the benefits of dance on recovery after stroke, as this activity fosters neuroplasticity [14] and also entails pleasure and social interaction [3] – which are factors in regaining motivation. The social component and adaptability of dance could be important motivational factors that favor the improvement of well-being and the fight against sedentariness [9]."

2. The references in this manuscript are mainly older ones and a new systematic search of the literature is needed to update the text. Much more discussion of the ideas and findings in the light of

publications by authors such as Earhart, Hackney, Shanahan, Volpe, Rocha, Morris, Aguir, Clifford and many others.

Our answer: 27 out of 36 references are less than 10 years old. We targeted references associated with stroke and dance. However, we have added references on other conditions as requested by the reviewer.

3. The broader literature on other targeted therapeutic physical activities such as boxing, aqua therapy, cycling, physiotherapy in neurological patients could also be considered and cited (eg Bernhardt, Rochester, Ellis, Canning, Slade)

Our answer: We have focused this protocol on artistic activities. We could mention many other activities, but the number of words is limited, so we have just added a small sentence on those other activities after the Cochrane review.
“A Cochrane review showed that rehabilitation should be considered effective in promoting motor recovery, reducing cognitive and motor deficits and improving independence [8]. Nevertheless, the exercises’ modalities are unclear. Aqua-therapy [10], split-bell training [11], aerobic training [12] and cycling [13] have shown interesting effects on rehabilitation after stroke, and also show a willingness to diversify the exercises.”

4. The standard of written English in this entire document is not at the international standard required and it is recommended that a professional editor be appointed to do a detailed revision of the final revised manuscript.

Our answer: Spelling/grammatical concerns have been addressed by a professional English translator.

5. The hypotheses need to be clearly stated in a testable manner

Our answer: We modified the text as:

“Primary objective
This study is a randomized controlled trial (RCT) which aims to investigate the effects of dance program – associated with conventional treatments – on the cognitive and motor recovery of subjects with stroke (subacute phase), compared to conventional treatment alone. Our hypothesis is that a 6-week dance program associated with conventional rehabilitation will improve cognitive and motor (balance, strength, coordination and function) recovery when compared to conventional rehabilitation alone.
Secondary objectives
Our secondary objective is to assess the effects of dance program combined with conventional rehabilitation on quality of life and motivation to engage in physical activity, as well as satisfaction and adherence. Our hypothesis is that the practice of dance during 6 weeks will induce strong satisfaction and adherence, and increase quality of life and motivation to engage in physical activity – compared to conventional rehabilitation alone. The adverse effects of dance in subjects with post-stroke hemiparesis in the subacute phase will be checked.”

6. The primary and secondary endpoints in this study need to be clearly presented and justified.
Our answer: We added in the text: “Stroke mainly induces cognitive and motor disturbances (balance, gait, muscle tone, muscle power, coordination, proprioception) that must be included into the rehabilitation process [9]. Thus, the recovery assessment should primarily focus on these aspects.”

The primary and secondary endpoints are clearly presented in the outcome's measures chapter. All parameters were selected according to psychometric qualities (added in table 1) and according to clinical practice standards. These choices were validated by the funds and the ethics commission.

7. The methods for randomisation need to given and justified in more detail.
Our answer: we modified the text as:
"Participants who meet the eligibility criteria and sign the informed consent form will have baseline data collected prior to the randomization procedure. To ensure allocation concealment, randomization to groups (dance or control group) will be undertaken by an independent investigator not involved in the experiment, using a computer-generated randomization tool. We will choose a randomization method using permuted-block randomization (i.e. random block sizes of 4 and 6), with a 1:1 allocation ratio, ensuring complete randomness of subject assignment to each randomized group. The random assignment sequence will be computer generated and stored electronically by the independent investigator. The dance teacher will remain unaware of the allocation until participants have been fully accepted. The dance teacher will be informed of the allocation by email (allocation concealment will not be possible for this person at this point). But research assistants entering data, raters and researchers conducting the final analysis will remain unaware of the allocation until the analysis is complete."

8. The actual content of the dance classes needs to be given in much more detail and arguments given for why specific music, dance genres and dance steps are used – and details about warm up and cool down sections.

Our answer: The word limit of the article does not allow us to detail the content of each session. We added a table with more information about dance class:

Elements	Duration (minutes)	Description
1. Warm-up	10	In a seated position, warm-up including active range of motion of all joints (from neck to toes), slow passive stretching of the most affected legs and muscular awakening of the different segments and balance exercises. Basic dance step to increase heart rate.
2. Technical exercices	10	Mirror work. Learning a sequence of movements (basic technical dance step) that the participants will have to reproduce. Standing and/or chair choreography will be focused on strength, balance and coordination.
3. Improvisation	15	Creative and relational work. Participants will have to interact with one or more partners. Participant were instructed to move freely according to some directions (large and big movements, unilateral or bilateral movements, environmental constraints). In turn, they must either guide and be followed or follow the sequence proposed by another dancer.
4. A short dance routine	15	Learning dance routines performed with the dance instructor such as traditional, ballroom or sports dance. The interest is to work mainly on memory, coordination and balance work with or without a partner. Inclusion of the most affected side in the dance movements.
5. Cool down/feedback	10	Breathing exercises. Phase of return to calm (slow

time	range of motion of all joints) and exchanges on the session.

9. Much more detail needs to be given on the specific elements of usual care.

Our answer: We modified the text as: “The control group will also receive the same 6-week follow-up, only without the dance class. The conventional treatment includes 45 to 60 minutes of physiotherapy per day by the Lavigny center therapy team. This therapy consists of sensory stimulation, motor activation, strengthening, coordination, balance, physical training according to the objectives set up from the assessment. The physical therapists will choose the adapted exercises according to the rehabilitation process’ main objective. In addition, group sessions are scheduled 2 to 3 times per week depending on the patient's abilities. The group sessions of 2 to 8 patients can be “walking groups”, “fitness training groups”, “assistive biking groups”, “cooking groups” and “speak training groups”. They will be led by an interdisciplinary team of 2 different therapists. Every day, patients will also have an occupational therapy session which will include training in daily activities. From 3 to 5 times a week, patients will have neuropsychology and speech therapy sessions which will include cognitive function training through paper or computer exercises.”

10. The measurement tools used to quantify outcomes need to have the reliability and validity presented.

Our answer: we added these information’s in the text and with a table for motor tests.

- Cognitive function will be measured using the Montreal Cognitive Assessment scale [31]. This tool is better than mini-mental state evaluation (MMSE) with less of a ceiling effect, higher internal reliability and stronger predictor of functional status [31].

Table 2: Psychometric qualities for tests.

Test / Psychometric quality	Mini-Best	Balance with app	ABC-s	Strength (quadriceps)	LEMOCOT	FIM	SS-QoL	Motivation PA
Intra-rater reliability	ICC > 0.99	ICC > 0.76	ICC > 0.87	ICC > 0.94	ICC > 0.97	ICC > 0.83	ICC > 0.88	ICC > 0.60
Inter-rater reliability	ICC > 0.99			ICC > 0.89	ICC > 0.97	ICC > 0.83	ICC > 0.88	
Validity	BBS (r=0.96)	BBS (r=-0.42)	Cronbach's Alpha = 0.973 (internal validity)	Other strength tool: ICC>0.82	r>0.62 (functional tests)	Cronbach's Alpha ≥0.84 (internal validity) Barthel index: r > 0.74	Cronbach's Alpha = 0.65-0.91 (internal validity)	Cronbach's Alpha = 0.61-0.91 (internal validity)
Literature	*Chinsongkram et al. 14*	*Hou et al. 19*	*Cleary et al. 14*	*Mentiplay et al. 18, 15*	*Menezes et al. 15, Desrosiers et al. 05*	*Hsueh et al. 02*	*Legris et al. 18*	*Boiché et al. 19*

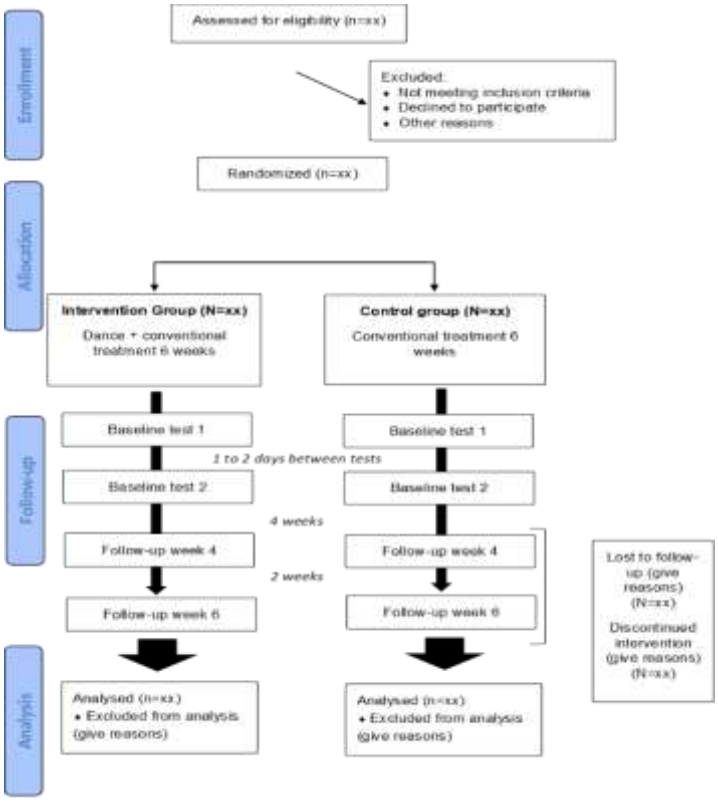
App= phone application ; ABC-s= Activities-Specific Balance confidence test; LEMOCOT= lower extremity motor coordination limb motor ; FIM= functional independence measurement; MoCA= Montreal cognitive assessment; SS-QOL= Stroke-specific quality of life scale; Motivation PA = Echelle de Motivation envers l'Activité Physique en contexte de Santé; ICC= Intra-class correlation coefficient; Spearman's correlation coefficient

11. The strategy for statistical analysis needs to be presented in more detail, and in relation to each of the primary and secondary outcome measures.

Our answer: We added statistical analysis with more detail in relation with outcome measures.
We modified the text as:

"An independent examiner, who will be blinded to group allocation, will perform the statistical analysis, using the software SPSS (SPSS Inc., Chicago, IL, USA).
The first data treatment will include normalization with body weight for quadriceps strength, data extraction for balance measures and, if necessary, different trials' mean calculation for each condition (e.g. strength test).
Absolute and relative frequencies will be determined for categorical variables. Quantitative data will be analysed with the Shapiro-Wilk test in order to confirm their distribution and to determine the correct statistical tests. Means and standard deviations will be calculated for normally distributed variables. The numerical median and range will be calculated for non-normally distributed variables. The calculations will be performed for each data acquisition time point and each group.
According to the primary outcome, the motor and cognitive variables will be treated (MiniBest test score, ML and AP displacements for standing balance, ABC-scale score, knee extension strength, LEMOCOT, FIM score and MoCa score). For the secondary outcomes, variables will be SSQoL, MS-PA, pain, fatigue, satisfaction with dance class, adherence and adverse effects.
If the variables present a normal distribution, then a two-way repeated measures ANOVA will be used. The ANOVA incorporated the groups (dance vs. control), time (baseline, 4-weeks and 6-weeks) and the group x interaction. When a significant F value is found, the Bonferroni post-hoc test will be applied to identify the differences. If there are baseline differences between the groups, analysis of covariance will be used to eliminate the influence of extraneous factors.
Otherwise, the non-parametric Mann Withney U test will be used to compare the groups in each time evaluation, and the Wilcoxon test to compare evaluation time for each group baseline, 4-weeks and 6-Weeks. In case of qualitative data, the Chi Square test will be applied.
A threshold value of $p < 0.05$ will be adopted to rule out non-significant differences."

12. The consort diagram is hard to follow – why are the top boxes left blank whereas further down numbers population the boxes – are these predicted numbers? Should they be removed?
Our answer: Thank you for this comment. We removed all numbers population in the boxes.
We modified the figure as:



13. The discussion does not adequately refer to the global literature on dancing for neurological patients and to compare and contrast the current study with that body of evidence.

Our answer: we included global literature (especially systematic reviews) about dance and chronic pathologies.

We modified the text as:
“There is a growing interest in the use of dance as a therapeutic tool for people with chronic diseases [22]. Previous reviews showed that dance is an activity that involves the whole body in movements with variable constraints, which seems to have positive impacts on physical, motor, cognitive and relational disorders [5,23–25,46,47]. Parkinson's disease and cancer are the most studied pathologies [5,22,24]. For neurological pathologies, dance is deemed suitable and seems beneficial to adherence, mental health, psychosocial aspects, as well as cognitive, balance and motor skills [22]. However, no RCT studies have been conducted for people after stroke, so the actual effectiveness of dance cannot be determined.
The originality of this RCT study is that it evaluates the impact of a dance program for people with subacute stroke on cognitive and motor recovery, quality of life and the motivation to engage in physical activity. We expect to see the benefits of dance on recovery after stroke, as this activity fosters neuroplasticity [14] and also entails pleasure and social interaction [3] – which are factors in regaining motivation. The social component and adaptability of dance could be important motivational factors that favor the improvement of well-being and the fight against sedentariness [9].”

14. The discussion section needs a larger section on limitations

Our answer: thank you for this comment. We included more details on limitations.
“This study presents limitations. There may be a risk associated with subject recruitment, as hospital eligibility criteria vary and may decrease or increase the number of eligible subjects. Because subjects are recruited in the subacute phase, it is possible that some subjects may have complications that prevent them from completing the program. Therefore, they will be recruited in a stable medical situation and two baseline assessments will be planned to verify the stability of the parameters. A limitation could be time and site availability. However, since there is already a dance program in the service’s rehabilitation program, this should not change the center’s general organization. Blinding is impossible for the subjects and for the dance teacher. Nevertheless, raters are external to the center and will be unaware of the allocation of subjects between the dance group and the control group.”

15. Currently the concluding statements cannot be directly derived from the findings.
Our answer: We removed the text about concluding statements.

Reviewer: 2
Reviewer Name: Kara Patterson
Institution and Country: University of Toronto, Canada
Please state any competing interests or state ‘None declared’:
I am currently running a randomized controlled trial investigating dance for people with chronic stroke living in the community.

Please leave your comments for the authors below

Thank you for the opportunity to review this manuscript. The authors outline a protocol for a

randomized controlled trial of a 6-week dance program for people with subacute stroke. The strengths of this study include a double baseline measurement, quality visit by a person external to the study, and timing of the intervention early during stroke recovery when it is likely to capitalize on a period of heightened neuroplasticity. However, I do have some concerns to be addressed.

Our answer: We thank the reviewer #2 for these constructive comments and your articles about dance and stroke. Your very precise and relevant remarks are very pleasant because they help to improve the work in a constructive way.
You will find the answer to each comment below.

MAJOR CONCERNS

1) The title could be more descriptive. Suggestion: “Dance as a means to improve cognitive and motor functions, and quality of life after a stroke: a study protocol for a randomized controlled trial.”

Our answer: thank you for this proposition. We modified the title as:
“Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial”

2) At times, particularly in the introduction, the writing could benefit from editing for clarity.

Our answer: thank you for these relevant comments. We modified the text.

Examples

- Pg 7, lines 12-14 “Dance is thus particularly suitable for the multidimensional component of patients after stroke”

Our answer: We modified the text as: “Dance seems particularly adapted to the multidimensional impairments of patients with stroke, e.g. cognitive, motor, balance, quality of life and social impairments [9].”

- Pg 7, line 30 “aerobic physical stimulation”

Our answer: We modified the text as: “. During the subacute phase, aerobic physical activity and the enriched environment provided by dance programs should enhance recovery while working specifically on balance, coordination, strength, mobility and cognitive aspects.”

- Pg 14, line 21 “The incidence of dance practice on adverse effects will be assessed”

Our answer: We modified the text as: “The adverse effects of dance in subjects with post-stroke hemiparesis in the subacute phase will be assessed.”

- Pg 147 line 35 “Dance’s popularity is increasing among persons with chronic diseases.” Do you mean people with chronic diseases are exhibiting increased interest, or that interest in the use of dance as a therapeutic tool for people with chronic diseases is increasing? Also – do you have a reference for this statement?

Our answer: We modified the text as: “There is a growing interest in the use of dance as a therapeutic tool for people with chronic diseases [22].”

- Pg 6, line 37 and Pg 18, line 17. The term “natural activity” is used with respect to dance. What does this mean?

Our answer: We added more information’s about the definition: “Green et al. highlighted that natural training is better than specific exercises [4]. Natural activities are characterized by complex tasks, with

self-feedback, integrating the whole body and diversified in terms of attentional, cognitive, motor and relational requirements. Thus, these tasks promote generalized learning, not only leading to a more energy-efficient movement strategy throughout the target task, but also to applying this learning to new tasks and contexts [4]. These natural activities also have the advantage of developing a motor and cognitive dual-task training that was more effective in improving balance and gait abilities than single-task training [16]. The physical activities that seem to be the most effective for recovery are the ones that can be adapted to the patient's level, offer varied and complex constraints for the whole body, induce motivation, have a social component and provide self-feedback [4,17]."

3) Some of the citations can be described more precisely.

Examples

- Pg 6, lines 32-37. The authors describe a review article by Green and coauthors. However, the wording "showed that natural training with complex tasks […] such as the pratice of art " suggests this was an experimental paradigm investigating the effects of art. In fact the authors do not specifically investigate art and instead review principles of 'slow learning' including concepts like 'task difficulty' and 'feedback'

Our answer: Thank you for this comment.
We modified the text as:
"Green et al. highlighted that natural training is better than specific exercises [4]. Natural activities are characterized by complex tasks, with self-feedback, integrating the whole body and diversified in terms of attentional, cognitive, motor and relational requirements. Thus, these tasks promote generalized learning, not only leading to a more energy-efficient movement strategy throughout the target task, but also to applying this learning to new tasks and contexts [4]. These natural activities also have the advantage of developing a motor and cognitive dual-task training that was more effective in improving balance and gait abilities than single-task training [16]."

- Pg 7, lines 35-39. The authors describe a study by O'Connell and coathors and state that "dance was the most common activity undertaken before stroke". However, the O'Connell study used a survey that asked specifically about 'arts related activities'. So a more precise way to describe these findings is "of arts related activities, dance was the most common one undertaken before stroke."

Our answer: Thank you for this comment.
We modified the text as:
"Moreover, O'Connell et al. [18] highlighted that of all artistic activities, dance was the most common before stroke, and that patients express their desire to continue this activity inside the hospital."

4) Pg 3, line 3. The authors note that outcomes will be measured at 4 and 6 weeks. The timing of these measurements with respect to the start of the intervention and the rationale for measuring at these time points is not stated. At certain points it seems like the first assessment is at week 4 of the 6 week dance intervention and then the second assessment is at the end of the intervention. However, at other points (e.g. pg 3, lines 43-46) it seems as though the second assessment is actually a follow-up 6 weeks after the end of the dance intervention. Please clarify and describe the assessment timing consistently throughout the manuscript.

Our answer: thank you for this comment. We checked the consistency in the text.

We modified the text as:
"The first follow-up will be an intermediate evaluation justified by the evolution of the patients in the subacute phase [44] and because studies have shown the positive effects of dance after 4 weeks [26]. Given that the decreased hospitalization time in the hospital strategies, it will be interesting to

assess the effectiveness after one month. The 6-week follow-up is in line with the usual hospital stay of patients with stroke at the rehabilitation center. During the entire process, each adverse event will be registered and reported to the medical staff."

5) Pg 3, lines 30-55 – Article summary. The first 3 points listed are neither strengths nor limitations of the study. They are restating the rationale and methods employed. Page 2 of 3

Our answer: thank you for this remark.
We removed two items and add more details about other points:
"• • This study's main objective is to assess the effects of dance program on cognitive and motor functions for individuals with stroke in subacute phase.
• A double-baseline assessment is planned to evaluate participant stability.
• After the baseline assessment, cognitive and motor functions, quality of life, motivation and satisfaction will be measured at weeks 4 and 6 in both groups.
• A person external to the rehabilitation center will make the assessments for blinding reasons.
• Because subjects are recruited in sub-acute phase, it is possible that some have complications that prevent them from completing the program."

6) Methods. The authors note in the intro and discussion that 'adherence' is a parameter of interest in their study. However, adherence is not defined nor is the approach to tracking adherence described in the methods. Have the authors set an a priori level (e.g. % of classes to attend) for adherence?

Our answer: We added this information in the text:

"This point is exceedingly important because tasks that are too difficult or too easy will lead to lower levels of motivation, reduced motor learning and adherence (extent to which patients' behaviors are in accordance with the recommendations of healthcare) [4]."

"Adherence will be evaluated by the number of sessions actually attended compared to the number of dance classes and conventional interventions planned."

7) Pg 10, lines 13-18. The authors describe the demographic and clinical characteristics to be collected. Please specify how these will be collected (e.g. from patient medical charts? Self-report?)

Our answer: We modified the text as:
"In order to identify the demographic and clinical characteristics of the participants, information regarding their age, sex, type of stroke, affected brain areas and medical history will be collected from their medical charts."

8) Pg 10, lines 34-37. The authors describe the dose of the dance intervention. Is there a rationale for this dose. (e.g. why only 1 class per week, why not 2 classes? Or why a 6 week duration, why not 4 weeks or 8 weeks?)

Our answer: The 6-week duration had already justified in the data collection part. The choice of this 60 minutes once a week is motivated by :
- Previous studies that have shown the effectiveness of dance in the case of neurological pathologies as early as 1 session per week of 60 minutes on balance [Hashimoto et al. 2015, Shanahan et al. 2015, Duncan et al. 2014, Mc Kee et al. 2013, De Silva Borges et al. 2013];

- Feasibility with regard to the organization of the Lavigny rehabilitation service (in fact, this frequency corresponds to the current organization of one physical activity per week different from the rehabilitation sessions).

We modified the text as:
“One group of 2 to 8 participants will attend a 60-minute dance class weekly over a six-week period during their rehabilitation at the Lavigny Hospital in a gym. This one-class-per-week frequency is justified by previous studies [29,30] and the availability of the center’s resources.”

9) Pg 10, lines 58. The authors have described the dance classes very well. However, it would be helpful to the reader if the authors provided examples of “social dance” to be taught in the classes.

Our answer: we added a table for improve the dance description. We modified the text: “The dance style will be a combination of contemporary and social dance (e.g. tango), with a focus on body/space interaction and the interaction with other persons in the same space.”

10) Pg 13, lines 3-6. The authors describe the strength testing well. However, please specify what position the knee joint will be in during the measurement. Also, please specify what will be the measure of strength; will it be an average of the 3 trials or will it be the best score out of the 3 trials?

Our answer: We modified the text as:
“Participants will be in a sitting position with their feet free and a 90-degree knee flexion.”
In statistical part:
“The first data treatment will include normalization with body weight for quadriceps strength, data extraction for balance measures and, if necessary, different trials’ mean calculation for each condition (e.g. strength test).”

11) Pg 14, lines 21-30. The measures of pain and fatigue are described but what is missing is when these measures will be taken? (e.g. before/after each class? Before/after the 6 week intervention?)

Our answer: we modified the text as:
“The adverse effects of the dance program will be assessed. Pain and fatigue will be measured using the numeric rating scale (NRS) before and after each dance class.”

12) Pg 17, line 46. The authors describe two feasibility studies on the use of dance for people with stroke and then note that the lack of a control group is a “methodological flaw.” This is misleading because a flaw implies that the study methods were not adequate to test the hypothesis or meet the study objective. The aims/objectives of these studies (and feasibility studies in general) were to demonstrate that a dance intervention can be implemented, that there is demand for it and that it is safe, rather than to demonstrate the effects of dance. Therefore, the design of these studies and the methods employed met the study objectives. (Please see Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, Bakken S, Kaplan CP, Squiers L, Fabrizio C, Fernandez M. How we design feasibility studies. American journal of preventive medicine. 2009 May 1;36(5):452-7.) (The authors note this fact themselves on pg 7, lines 19-21.) The lack of a control group in these studies (and in feasibility studies in general) can be described as a limitation (rather than a flaw).

Our answer: thank you for this relevant comment.

We removed this part.

13) Pg 18, lines 10-15. The authors note the originality of the study is that it evaluates cognitive-motor recovery and QoL. However, a lot of post-stroke exercise intervention studies have evaluated these variables. I suggest the originality of the study is the use of dance and the fact it is an RCT which has not yet been done to investigate the use of dance in people with subacute stroke.

Our answer: we modified the text as:
“The originality of this RCT study is that it evaluates the impact of a dance program for people with subacute stroke on cognitive and motor recovery, quality of life and the motivation to engage in physical activity.”

MINOR CONCERNS

1) Pg 2, lines 52-54. Add the duration of the dance class (i.e. 60 minutes) in the description of the intervention.

Our answer: We modified the text as: “One group of 2 to 8 participants will attend a 60-minute dance class weekly over a six-week period during their rehabilitation at the Lavigny Hospital in a gym.”

2) Pg 5, line 37. Please clarify what is meant by “unlimited adaptability of dance”. Every intervention has its limitations.

Our answer: this is a mistake, thank you. We modified the text as:
“Moreover, high adaptability of dance makes it an easy practice for patients, for it can cover very broad motor and cognitive aspects.”

3) Pg 5, lines 50-53. The authors note “following a brain lesion, variable cognitive-motor deficits …” Since they have touched on the epidemiology of stroke, I suggest the authors also insert a line Page 3 of 3 describing the etiology of stroke and more specifically how the ‘brain lesion’ is caused.

Our answer: thank you for this remark. We added in the text:
“[6]. Following a brain lesion – due to ischemic or hemorrhagic disturbances of cerebral blood circulation –, various deficits will impact patients' functional abilities, autonomy and health costs [7].”

4) Pg 6, line 23. Consider revising “fighting cognitive and motor deficits” to “addressing cognitive and motor deficits” or “reducing cognitive and motor deficits”.

Our answer: we modified the text as:
“A Cochrane review showed that rehabilitation should be considered effective in promoting motor recovery, reducing cognitive and motor deficits and improving independence [8].”

5) Pg 13, line 23. The acronym for Functional Independence Measure is FIM.

Our answer: we added the acronym:
“Motor level will be assessed using a Functional Independence Measure Instrument (FIM) [40].”

6) Assuming the authors are describing the separate categories of impairments including motor and cognition, I suggest the authors consider using ‘cognitive and motor impairments’

throughout the manuscript rather than ‘cognitive-motor’ impairments which suggests these impairments are always linked.

Our answer: We followed your recommendation.

7) Consider using person-centered terms. For example, instead of “persons suffering from stroke,” use “persons living with stroke” or “persons with stroke.”

Our answer: We followed your recommendation (persons with stroke).

8) Consider using “dance class” or “dance program” instead of “dance practice”. When I read “dance practice”, what comes to mind is professional dance training rather than a therapeutic intervention.

Our answer: We followed your recommendation (dance program).

Reviewer: 3
Reviewer Name: RUTH PICKERING
Institution and Country:
UNIVERSITY OF SOUTHAMPTON
UK
Please state any competing interests or state ‘None declared’: NONE

Please leave your comments for the authors below

Our answer: We thank the reviewer #3 for these constructive remarks. We tried to answer precisely by respecting the limit of the number of words. You will find the answer to each comment below.
This sounds an interesting, but small trial. I wonder whether it might be better styled as a pilot RCT. I have the following specific points.
1 Article summary, page 3, final bullet point. This should be omitted, its obvious a trial like this can’t be double blind, so its neither a strength or a limitation.
Our answer: We removed this point.

2 Page 4, Patient consent section. They say here just “Obtained”. The past tense suggests that it has already been obtained for participants. If the trial hasn’t started yet they could say something like patients will be asked for consent to participate in the trial.
Our answer: thank you for this comment. We modified the text as requested:
“Patient consent: To be obtained.”

3 They do need to say somewhere whether the trial is ongoing or is yet to start. A date of starting recruitment needs to be given and also how long recruitment is planned to continue. The trial shouldn’t already be complete.
Our answer: we added this information:
“Study start: February 3 2020 / Study completion: September 2021”

4 Page 4, Provenance and peer review. I wasn’t sure what they meant by “Not commissioned” here.
Our answer: This is the mention proposed by the journal. We have had a peer review for funds and ethics process, but since the fund is not the Swiss National Fund, it should write "not commissioned".

5 Page 6, lines 33-35. The CONSORT statement concerns the writing up of the report of an RCT. So it's the write-up of an RCT, not the RCT itself, that conforms to CONSORT. I don’t think they should mention CONSORT at all at this stage.

Our answer: we removed this information about CONSORT.

6 Page 8. Lines 37-40. I thought this sentence on the setting might be better moved and combined with the first sentence of the Recruitment procedure, page 9, line 12. They do need to say in the Recruitment section where participants are recruited from. The sentence on page 9, line 12 should specify whether recruiting staff are employed in the clinical centre or whether they are research staff employed by the trial.
Our answer: thank you for this comment. We modified the text as:
“Two physiotherapists from the Institution de Lavigny (Lavigny, Vaud, Switzerland) neurorehabilitation center and the study investigator will be responsible for the recruitment.” In recruitment procedure.

7 Page 9, lines 21-23. In this sentence about obtaining informed consent, it should be clear which member of staff will be interacting with the patient to get consent, I assumed the physiotherapist. Presumably it will be a member of the research team not center staff. Also will the same member of staff return to the potential participant after 24 hours. I’m assuming, though I don’t think its actually stated here or as an eligibility criterion, that participants have to be inpatient at the neurorehabilitation center. Are they considering recruiting patients after they’ve gone home?
Our answer: we modified the text as:
“Two physiotherapists from the Institution de Lavigny (Lavigny, Vaud, Switzerland) neurorehabilitation center and the study investigator will be responsible for the recruitment. All individuals will be consecutively recruited. During their hospitalization, patients will be identified as potentially eligible based on data from their clinical file (date of birth, date of stroke, stage of stroke, presence of hemiparesis, clinical data).”

8 Page 10 & 11, the interventions section. Its not actually stated where the dance group (or control group physiotherapy) is to take place. I assumed in the neurorehabilitation center. But could participants have been discharged and return for classes? What sort of room is required to hold the dance class? How many participants take part in a class – I’d assumed it was a group class, but could they be individual classes?
Our answer: Thank you for this comment. We modified the text as requested:
“One group of 2 to 8 participants will attend a 60-minute dance class weekly over a six-week period during their rehabilitation at the Lavigny Hospital in a gym. This one-class-per-week frequency is justified by previous studies [29,30] and the availability of the center’s resources.”

9 Page 8, Eligibility criteria. I was surprised that they were intending to recruit within 3 months of stroke and it would be useful to state any when the actual dance classes are meant to start in relation to stroke onset (there may be a delay between randomisation and a participant being able to join a class). Do the stated criteria limit recruitment to patients with mild stroke and would such people have gone home quite quickly after stroke onset?
Our answer: This is precisely one of the strong points of this work. Subjects can participate in the dance class as soon as their medical situation has stabilized, and they meet the inclusion criteria. The mean duration of hospitalization at the center is three months, which allows subjects to be included.

10 Page 9, Randomisation section. Concerning the final sentence stating block sizes of 4 and 6, will they be random block sizes, or are they planning to have a schedule of blocks of 4 and 6 fixed in advance? On lines 37-41, they describe features to ensure concealed allocation. Its not enough to say that the allocations will be created by an independent person, they need to describe the method of delivery of the next allocation to a participant after consent. The current sentence is consistent with the use of sealed envelopes (allocations created by an independent person then put in envelopes and left at the center for the recruiting staff to open for the next participant) – and use of sealed envelopes is no longer considered acceptable. They need to describe the process by which recruiting staff get

the next allocation, and make it clear that they can't find out what the allocation is until the participant is clearly in the trial.
Our answer: we modified the text as:
"Participants who meet the eligibility criteria and sign the informed consent form will have baseline data collected prior to the randomization procedure. To ensure allocation concealment, randomization to groups (dance or control group) will be undertaken by an independent investigator not involved in the experiment, using a computer-generated randomization tool. We will choose a randomization method using permuted-block randomization (i.e. random block sizes of 4 and 6), with a 1:1 allocation ratio, ensuring complete randomness of subject assignment to each randomized group. The random assignment sequence will be computer generated and stored electronically by the independent investigator. The dance teacher will remain unaware of the allocation until participants have been fully accepted. The dance teacher will be informed of the allocation by email (allocation concealment will not be possible for this person at this point). But research assistants entering data, raters and researchers conducting the final analysis will remain unaware of the allocation until the analysis is complete."

11 Pages 10 and 11, description of the dance groups. If the classes are to have more than one participant, this impacts on the recruitment process, in that they have to recruit enough participants to be able to fill a class, without having participants waiting for long periods of time after randomisation till their class begins. How will this be managed? They do need to state how many participants will be in classes, and also how many staff will be present to manage the class. On Page 11, line 9 there is mention of a dance teacher, but if the dance involves participants standing up and dancing I would have thought more staff would be needed to minimise the risk of a participants falling. On line 18, they say that participants can be sitting or standing, if they are sitting can it really be described as dance? Earlier on they mention participants repeating dance moves but don't describe any of the move they intend to include in detail. I did wonder whether they are talking about ball room dancing requiring a partner. If so, there needs to be some description of who the partners will be, and what they will do if a participant doesn't have a suitable partner. Would they provide a partner and what sort of people would they be?
Our answer: we added more information's about this part:
"One group of 2 to 8 participants will attend a 60-minute dance class weekly over a six-week period during their rehabilitation at the Lavigny Hospital in a gym. This one-class-per-week frequency is justified by previous studies [29,30] and the availability of the center's resources. A physiotherapist-dance teacher will lead the classes, supported by volunteers (physiotherapists or physical activity specialists). The number of volunteers (1 to 2) may change according to the needs of the participants. The group can include other participants with other neurological disabilities to complete the number of participants, however they will not be included in this study."
Dancing in a seated position is quite possible and is proposed by many articles in the case of people with motor disorders. On the other hand, dancing in a sitting position is a frequent proposition in the case of contemporary dance.

12 Page 11, the control intervention. With both groups getting the physio and occupational therapy described, I think it will be difficult to show the additional dance classes giving any benefit. They say that participants will get physio 2-3 times a week, but don't say for how many weeks they will get it. Also whether this is when they are still in hospital, does conventional follow-up (the physio described) continue after a patient is discharged? Also can they describe whether all stroke patients get this physio in Switzerland, or do patients have to have insurance, for example? Or is the physio described, just for trial participants (control and intervention groups)?
Our answer : The methodological choices are well-argued and respect previous studies showing the effectiveness of dance in neurological conditions. The ethics commission has validated the project and verifies the proposed choices to be in conditions favorable to the effectiveness of the treatment.

The questions here refer to the national organization of care in Switzerland. Due to the word limit, it is not possible to detail this organization in detail.
We modified the text:
“The control group will also receive the same 6-week follow-up, only without the dance class. The conventional treatment includes 45 to 60 minutes of physiotherapy per day by the Lavigny center therapy team.”

13 Page 11, Primary outcomes section. They need to state which outcome is primary and at which follow-up time-point. The first outcome mentioned is the MoCA – is the primary outcome the MoCA at 6 weeks? On Page 16 sample size calculation is done with respect to the Mini-Bestest. Is the Mini-Bestest at 6 weeks the primary outcome? In the primary outcome section they describe: MoCA, Mini-Bestest, ABC, knee extension, LEMOCOT and MIF. Some of these outcomes have multiple domains, and they are measured at 4 and 6 weeks. So they haven’t actually stated a primary outcome.
Our answer: We have clarified this point in the text with the comments of the other reviewers.

14 Page 14, line 48, they will collect two baselines to evaluate stability of parameters, and they will be compared, page16 line 34. Its not clear what they will do if baseline readings aren’t close, will they use the second one, treating the first as a run-in? Or average them? In the sentences on page 14 describing the timing of measurements, they need to say (which I assumed was the case) that at these assessment all the measures described on pages 11, 12, 13 and 14 as primary and secondary outcomes would be measured. It is quite a long list of outcomes – could they estimate how long they think it will take to measure all of them? In relation to SPIRIT item 18b, plans to promote participant retention and complete follow-up, if a participant is clearly finding the assessment schedule too burdensome, perhaps they could restrict the outcomes, to a much reduced and key list. Obviously the primary outcome would be included, but they haven’t stated what that is.
Our answer: we clarify the text as:
“Data will be collected twice (at baseline 1 and baseline 2) to evaluate the stability of the studied parameters. If the results of baseline 1 and baseline 2 are different, we will use baseline 2’s and treat baseline 1 as a run-in test. The follow-up will include two assessments with data collection: at 4 weeks of intervention and then at 6 weeks to evaluate the changes from baseline (figure 1). The first follow-up will be an intermediate evaluation justified by the evolution of the patients in the subacute phase [44] and because studies have shown the positive effects of dance after 4 weeks [26]. Given that the decreased hospitalization time in the hospital strategies, it will be interesting to assess the effectiveness after one month. The 6-week follow-up is in line with the usual hospital stay of patients with stroke at the rehabilitation center. During the entire process, each adverse event will be registered and reported to the medical staff.”
The estimated duration of the tests is 1h50 for the first baseline and 55 minutes for the other follow-ups. This duration has been validated by the ethics commission. When it is too long for the subjects, it is possible to spread the tests over the day. The primary outcome: MiniBestest, Balance tests, strength, LEMOCOT, FIM and MoCa are essentials.

14 The Data collection section. I think they need to mention something about collecting data on harms, they should be accessing any adverse events recorded in either group, and in particular any falls. Also they need to mention collecting data on adherence to the dancing. The comment on adherence in the Discussion, page 18, penultimate paragraph. Do they mean the amount of time in class, willing ness to participate in classes (and if so how assessed) or, if participants have gone home, are they expected to carry on dancing? Also they should be collecting data on the amount of conventional and all other therapy participants in both arms of the trial receive.
Our answer : Thank you for these comments. We modified the text as:
“During the entire process, each adverse event will be registered and reported to the medical staff.”
The adverse event file corresponds at the ethical committee template.

“Adherence will be evaluated by the number of sessions actually attended compared to the number of dance classes and conventional interventions planned.”

15 Page 15, lines 14-20, personal information. Do they mean here identifiable information, that identifiable information will be kept separate from the main dataset.
Our answer: we modified the text as requested:
“Identifiable information data will be kept separate from the main dataset and will not be shared.”

16 Page 15, line 43. They start this off as “the criteria for subjects withdrawal…”. They need rather to state that participants are free to withdraw from the trial at any point, but then list situations in which they anticipate some participants might wish to withdraw early. They should say that where possible they will record reasons why participants withdrew. The sentences should distinguish between withdrawal from the dance classes (or control rehabilitation?) and withdrawal from trial follow-up, and they could state here a plan of reducing the numbers of outcomes to measure as an attempt to keep people in trial follow-up wherever possible (even if they’ve stopped dancing classes.
Our answer: thank you for this comment. We modified the text as:
“Participants will be free to withdraw from the trial at any point. The criteria for subject withdrawal will be: end of hospitalization; a deterioration of medical stability; a misunderstanding of the tests or the activity not delivering satisfying results; pain during tests and/or dance classes (NRS>5); withdrawal of informed consent; the procedure or routine will be stopped for safety reasons; behavioral disorders during dance classes. Withdrawal motivations will be reported for both groups. In case of withdrawal, a final assessment will be conducted for safety. Since recruitment is consecutive, it is possible to extend the recruitment phase to complete the trial.”

17 Page 15, at the end of the withdrawals section they talk about possibly extending recruitment. Do they mean by this that if a participant withdraws, they intend to recruit replacements to achieve their target of 22 participants yielding outcome data, rather than 44 being enrolled?
18 Page 16, first paragraph, “intention-to-treat”. They don’t need to say this here. It is stated again in the statistical analysis section, page 17, second paragraph. They say that the analysis will be done on an intention-to-treat basis, with last evaluations carried forwards if data is missing. This is not a recommended method. Would they carry the baseline reading forwards in the event of not getting outcome at either 4 or 6 weeks?
Our answer : we modified the text as:
“Since recruitment is consecutive, it is possible to extend the recruitment phase to complete the trial.”
We removed the paragraph “intention-to-treat”.

19 Page 16, sample size section. Their stated effect size with 90% power only leads to a target of 22 per group if they plan to perform one-sided tests at the 5% level. Its standard in health studies to do all testing two-sided, and this leads to a larger number. They should state that tests will be done at the two-sided 5% level on page 17, third paragraph. They should also make some allowance for likely drop-out by the primary endpoint. The calculation was done for the Mini-Bestest which leads me to assume that this was in fact the primary outcome. They are looking to achieve a difference of 3.5on the test and anticipate the SD will be 3.9. Its not clear whether this SD relates to change scores or to individual readings at 6 weeks say. They should justify these assumptions perhaps referencing earlier work or audit data. If they cannot justify the assumptions, and along with the large number of outcomes included in the primary section, it is this that made me think that the current trial might better be described as a pilot RCT.
Our answer: Thank you for your comment. The sample size has been verified and validated by an internal statistician and a statistician from the ethics committee. The choices are argued and explain the subjects number obtained. The other reviewers agree with this number.

20 Page 16, final paragraph statistical analysis. They start by saying that analysis will be descriptive.

This suggests that significance tests will not be carried out – but the sample size section related to a significance test. They then say that the low number of subjects won't allow them to do parametric tests – but the power calculation should have ensured they will have an adequate number to do the test (which was parametric, a two sample t-test). Then because they won't have large enough numbers to do a parametric test they will do a non-parametric test – this is illogical because larger numbers are required for non-parametric tests than the parametric equivalent - usually. They mention Wilcoxon tests first, but this is a before after test of change, whereas the key comparison (which should be described first) in an RCT is between the two groups. I would suggest they do an ANCOVA, a linear regression including the group comparator controlled for the baseline reading of the outcome in question as a regressor. This would also facilitates a power calculation as the information needed is the SD of the outcome at the end point along with the correlation between readings anticipated at baseline and the endpoint. They do need to specify here which of the two readings they will use as the baseline. And this is equally true of the analysis of change compared between groups that they currently describe – they need to specify which of the two baseline they will be using as the initial reading in the change (or whether they will use the average). It would be helpful for them to get a statistician on board with the trial. I notice there isn't a statistician as an author.
Our answer: There is no statistician as author because in the case of an external service there are no plans to mention the statistician. The statistical method has been validated by the funds and the ethics commission. However, we have reworked the statistical chapter to bring clarity as requested by the first reviewer and yourself.
We modified the text as:
"An independent examiner, who will be blinded to group allocation, will perform the statistical analysis, using the software SPSS (SPSS Inc., Chicago, IL, USA).
The first data treatment will include normalization with body weight for quadriceps strength, data extraction for balance measures and, if necessary, different trials' mean calculation for each condition (e.g. strength test).
Absolute and relative frequencies will be determined for categorical variables. Quantitative data will be analysed with the Shapiro-Wilk test in order to confirm their distribution and to determine the correct statistical tests. Means and standard deviations will be calculated for normally distributed variables. The numerical median and range will be calculated for non-normally distributed variables. The calculations will be performed for each data acquisition time point and each group.
According to the primary outcome, the motor and cognitive variables will be treated (MiniBest test score, ML and AP displacements for standing balance, ABC-scale score, knee extension strength, LEMOCOT, FIM score and MoCa score). For the secondary outcomes, variables will be SSQoL, MS-PA, pain, fatigue, satisfaction with dance class, adherence and adverse effects.
If the variables present a normal distribution, then a two-way repeated measures ANOVA will be used. The ANOVA incorporated the groups (dance vs. control), time (baseline, 4-weeks and 6-weeks) and the group x interaction. When a significant F value is found, the Bonferroni post-hoc test will be applied to identify the differences. If there are baseline differences between the groups, analysis of covariance will be used to eliminate the influence of extraneous factors.
Otherwise, the non-parametric Mann Withney U test will be used to compare the groups in each time evaluation, and the Wilcoxon test to compare evaluation time for each group baseline, 4-weeks and 6-Weeks. In case of qualitative data, the Chi Square test will be applied.
A threshold value of $p < 0.05$ will be adopted to rule out non-significant differences."

21 Page 17, 25 it would be useful if they planned to let a statistician have access to the final dataset.
Our answer: We added this information:
"Only the investigators and a statistician will have access to the final dataset."

22 Page 17, line 45, they mention that a methodological flaw of the earlier feasibility studies is that they didn't include a control group. This isn't necessarily a flaw, it depends what the feasibility objectives of these studies were, they could for example have been attempting to assess whether the

intervention was acceptable to participants, or assessing how burdensome the assessment schedule was. Such objectives wouldn't require a control group. A control group is necessary in evaluating the efficacy/effectiveness of an intervention, but a feasibility study shouldn't be addressing efficacy/effectiveness.
Our answer: we modified this part in the text.

23 Page 18, line 28. They say here that the risks associated with dancing are low. I think they should consider the risk of falling both in the class itself, or afterwards (if participants are empowered to move more freely). But if their "dancing" only involves participants moving their body in a sitting position I guess there isn't a risk of falling during the class.
Our answer: thank you for your comment, we modified the text as:
"Dance may induce imbalances and risks of falls. But the adverse effects and risks of dance seem very low for persons with neurological conditions [25]."

24 Figure 1 and the sample size calculation suggest they are aiming for a sample size of 44, but in the Abstract, page 2, line 45, they say that they will randomise 48.
Our answer: thank you for this comment. We modified the text as requested:
"To detect this difference, 22 participants per group are needed with a standard deviation of 3.9/28, power at 90% and a significant threshold of $p<0.05$. To deal with possible withdrawals, we will include 24 subjects per group."

VERSION 2 – REVIEW

REVIEWER	Kara Patterson University of Toronto, Canada I am currently running a RCT for dance in people with chronic stroke.
REVIEW RETURNED	20-Apr-2020

GENERAL COMMENTS	Thank you for the opportunity to review this revised manuscript. The others have addressed all of my concerns stated in my previous review.

REVIEWER	Ruth Pickering University of Southampton
REVIEW RETURNED	28-Apr-2020

GENERAL COMMENTS	I felt this revised version set out quite a bit more detail than befor. A few issues remain which I list below. 1 I don't think they state when the trial / recruitment is to start - this was addressed in the authors response but should be included in the paper. 2 Statement of primary objective, page 7. On lines 46-48 it appears that there are 5 outcomes stated as primary. On page 16, starting at line 55 its clearer that counting subscales, there are in fact 8. This is a problem , if they find significant results they could be due to multiplicity. 3 Page 9, sentence on lines 36-41. This shouldn't be in the

	randomisation section, but moved to the next section on Blinding - if it replicates information already there it can be omitted. 4 Page 14, lines 46-48 detail what will happen if the two baseline differ (the second will be used), but don't say what will happen if they appear similar - will they be averaged? In the Discussion, page 18, lines 41-46, they say participants will be recruited in a stable situation to be verified by the two baseline assessments. This suggests that if the two baselines differ a patient won't be recruited, so all participants will have similar baselines - and so what happens in this case is more important to state. If recruitment depends on stability of the bselines, they need to consider what would happen if they are similar on some variables but not others. Medical stability is included as an eligibility criterion (page 8, line 35), but it isn't mentioned there as depending on the baseline assessments. 5 The timing of the final assessment at 6 weeks, starting on page 14 line 59. Here they say the length of follow-up is designed to match length of stay in the rehabilitation center. Its specified earlier that the dance classes will take place at the center. I think they should include somewhere what will happen if a particiapnt is discharged before the end of follow-up, I'm assuming that they will have to go back to the center for classes and follow-up, but follow-up could take place at home. In the Withdrawal and Discontinuation section, page 15, line 48, they state end of hospitalization as a crierion of withdrawal, possibly with such a participant being replaced by continued recruitment. Does this mean that a participant who has some classes but goes home before 6 weeks will be withdrawn? This doesn't sound reasonable to me. 6 The sample size section on page 16. The calculation is done with respect to the Mini-Bestest, this means that the trial isn't necessarily adequately powered for the remaining 7 primary outcomes. Another issue is that the trial is only powered to detect a difference in a one-sided test - and so wouldn't necessarily find the assumed difference to be significant in a two-sided test. On line 25, they need to be specific about this - "... a significant threshold of P<0.05 in a one-sided test". Testing of outcomes in RCTs is usually performed in two-sided tests so they need be clear about their departure from current practice. 7 Page 16, line 32, Rather than saying "an independent examiner" will perform the statistical analysis, it would be better to say "the statistical analysis will be performed blinded to group allocation, using...". 8 Page 16, line 39, I didn't understand what was meant by including "... if necessary, different trial's mean calculation for each condition...". If this is being considered more detail should be given. 9 Page 17, lines 12-14, when the baseline and 6 week data are analysed as repeated measures, the treatment effect appears as the interaction between time and group. On line 12, they say that if the F statistic for this interaction is significant they will do Bonferoni post-hoc tests. This isn't necessary as the 4-week outcome isn't primary, they need to extract the part of teh F test specifically relating to interaction between group and change from baseline to 6 weeks, which isn't subject to multiplicity. But there is the issue of the 8 primary outcomes and they have done nothing about this aspect of multiplicity.

	10 Page 17, line 25, they state that significance will be judged by P<0.05. The sample size was done for a one-sided test. And it should be consistent in this section and stated if significance is to be judged with P<0.05 in one-sided tests. Also how one-sided significance will be determined in the F-test approach they outline above. If in the sample size section they went for 80% power (instead of 90%) then the current numbers would be adequate in a two-sided test (for the assumed difference and SD, and for the mini-Bestest). 11 Page 18, lines 3 and 8, omit "studies/y". Line 3 would be better as "... no RCT has been conducted...". Line 8 would be better as "The originality of this RCT is that...". 12 Page 18, line 37, they mention here a risk to rcruitment as hospital eligibility criteria vary. I didn't understand this as the trial recruits from one center only.

VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 2
Reviewer Name: Kara Patterson
Institution and Country: University of Toronto, Canada
Please state any competing interests or state ‘None declared’: I am currently running a RCT for dance in people with chronic stroke.

Please leave your comments for the authors below
Thank you for the opportunity to review this revised manuscript. The others have addressed all of my concerns stated in my previous review.

Our answer: We thank the reviewer #2 for this comment and the review of our manuscript.

Reviewer: 3
Reviewer Name: Ruth Pickering
Institution and Country: University of Southampton
Please state any competing interests or state ‘None declared’: NONE

Please leave your comments for the authors below

Our answer: We thank the reviewer #3 for these constructive comments. Your very precise and relevant remarks are very pleasant because they help to improve the work in a constructive way.

I felt this revised version set out quite a bit more detail than before. A few issues remain which I list below.

1 I don't think they state when the trial / recruitment is to start - this was addressed in the authors response but should be included in the paper.

Our answer: This information has already included in the previous version:
“Study start: February 3 2020 / Study completion: September 2021”

2 Statement of primary objective, page 7. On lines 46-48 it appears that there are 5 outcomes stated as primary. On page 16, starting at line 55 its clearer that counting subscales, there are in fact 8. This is a problem , if they find significant results they could be due to multiplicity.

Our answer: We modified the objectives and outcomes sections. One outcome stated as primary objective (MiniBesTest).

3 Page 9, sentence on lines 36-41. This shouldn't be in the randomisation section, but moved to the next section on Blinding - if it replicates information already there it can be omitted.
Our answer: We removed this sentence.

4 Page 14, lines 46-48 detail what will happen if the two baseline differ (the second will be used), but don't say what will happen if they appear similar - will they be averaged? In the Discussion, page 18, lines 41-46, they say participants will be recruited in a stable situation to be verified by the two baseline assessments. This suggests that if the two baselines differ a patient won't be recruited, so all participants will have similar baselines - and so what happens in this case is more important to state. If recruitment depends on stability of the bselines, they need to consider what would happen if they are similar on some variables but not others. Medical stability is included as an eligibility criterion (page 8, line 35), but it isn't mentioned there as depending on the baseline assessments.

Our answer: The stable medical situation (inclusion criteria) describes a situation where the patient will not have any medical complications (e.g. new co-morbidities, important changes in vital parameters) that affect his or her care management. It is therefore different from the parameters measured for baseline 1 and 2.
We modified the text as:
“Data will be collected twice (at baseline 1 and baseline 2) to evaluate the stability of the studied parameters. If the results of baseline 1 and baseline 2 are different, we will use baseline 2’s and treat baseline 1 as a run-in test. If the results appear similar, we will use the average.”

5 The timing of the final assessment at 6 weeks, starting on page 14 line 59. Here they say the length of follow-up is designed to match length of stay in the rehabilitation center. Its specified earlier that the dance classes will take place at the center. I think they should include somewhere what will happen if a particiapnt is discharged before the end of follow-up, I'm assuming that they will have to go back to the center for classes and follow-up, but follow-up could take place at home. In the Withdrawal and Discontinuation section, page 15, line 48, they state end of hospitalization as a crierion of withdrawal, possibly with such a participant being replaced by continued recruitment. Does this mean that a participant who has some classes but goes home before 6 weeks will be withdrawn? This doesn't sound reasonable to me.

Our answer : We added this information:
“If the participant is discharged before the end of the follow-up, they will have to go back to the center for the dance classes.” And we removed the information in the withdrawal and discontinuation section.

6 The sample size section on page 16. The calculation is done with respect to the Mini-Bestest, this means that the trial isn't necessarily adequately powered for the remaining 7 primary outcomes. Another issue is that the trial is only powered to detect a difference in a one-sided test - and so wouldn't necessarily find the assumed difference to be significant in a two-sided test. On line 25, they need to be specific about this - "... a significant threshold of $P<0.05$ in a one-sided test". Testing of outcomes in RCTs is usually performed in two-sided tests so they need be clear about their departure from current practice.

Our answer: The mini-BESTest is the most well-documented test for stroke and is therefore considered the main outcome for the calculation of the sample size (this process has been validated by the statistician of the ethics commission). We changed the power at 80% and applied two-tailed test.

We modified the text as:
“To detect this difference, 21 participants per group are needed with a standard deviation of 3.9/28, power at 80% and a significant threshold of p<0.05 in two-tailed test.”

7 Page 16, line 32, Rather than saying "an independent examiner" will perform the statistical analysis, it would be better to say "the statistical analysis will be performed blinded to group allocation, using...".

Our answer: We modified the text as: “The statistical analysis will be performed blinded to group allocation, using the software SPSS (SPSS Inc., Chicago, IL, USA).”

8 Page 16, line 39, I didn't understand what was meant by including "... if necessary, different trial's mean calculation for each condition...". If this is being considered more detail should be given.

Our answer: We added information: “The first data treatment will include normalization with body weight for quadriceps strength and data extraction for balance measures. When different trials are conducted, the different trials’ mean calculation for each condition will be calculated.”

9 Page 17, lines 12-14, when the baseline and 6 week data are analysed as repeated measures, the treatment effect appears as the interaction between time and group. On line 12, they say that if the F statistic for this interaction is significant they will do Bonferoni post-hoc tests. This isn't necessary as the 4-week outcome isn't primary, they need to extract the part of teh F test specifically relating to interaction between group and change from baseline to 6 weeks, which isn't subject to multiplicity. But there is the issue of the 8 primary outcomes and they have done nothing about this aspect of multiplicity.

Our answer : We modified the primary outcome and we modified the statistical part with your recommendations and a statistician from the Clinical Research Center (Geneva University) validated the statistical part.

10 Page 17, line 25, they state that significance will be judged by P<0.05. The sample size was done for a one-sided test. And it should be consistent in this section and stated if significance is to be judged with P<0.05 in one-sided tests. Also how one-sided significance will be determined in the F-test approach they outline above. If in the sample size section they went for 80% power (instead of 90%) then the current numbers would be adequate in a two-sided test (for the assumed difference and SD, and for the mini-BESTest).

Our answer: In the sample size section we adopted for 80% power, thus the current numbers are adequate for two-sided test.

We modified the text as:
“A threshold value of p < 0.05 (two-tailed test) will be adopted to rule out non-significant differences.”

11 Page 18, lines 3 and 8, omit "studies/y". Line 3 would be better as "... no RCT has been conducted...". Line 8 would be better as "The originality of this RCT is that...".

Our answer: We modified the text as:

“However, no RCT have been conducted for people after stroke, so the actual effectiveness of dance cannot be determined.
The originality of this RCT is that it evaluates the impact of a dance program for people with subacute stroke on cognitive and motor recovery, quality of life and the motivation to engage in physical activity.”

12 Page 18, line 37, they mention here a risk to recruitment as hospital eligibility criteria vary. I didn't understand this as the trial recruits from one center only.

Our answer: We removed this sentence. This study is in one center, but in this center the inclusion criteria vary according to the hospital strategy.