

BMJ Open Dancing to improve balance control, cognitive-motor functions and quality of life after stroke: a study protocol for a randomised controlled trial

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ABSTRACT

Introduction Dance is an intrinsically motivating activity that includes social interaction, stimulation through music, the pleasure of moving despite pathology-induced motor limitations, and it also has good perceived benefits among participants. Feeling pleasure while moving is essential to finding the motivation to engage in a rehabilitation programme. It is, therefore, urgent to provide persons in a poststroke situation with motivating physical activity opportunities. Very few studies have examined dance in a stroke context, while it is highly adapted and effective for other chronic conditions.

Our primary objective is to assess the effects of dance programme on patients' balance control after stroke. Our secondary objective is to investigate the effects of dance on cognitive function, strength, coordination, functional status, balance confidence, quality of life, motivation and adherence. Our hypothesis is that dance increases balance and motor capacities, and improves poststroke quality of life, adherence and motivation.

Methods and analysis Forty-eight subjects with stroke in subacute phase will be randomised into two groups: (1) intervention (dance and standard rehabilitation) and (2) control (standard rehabilitation). Before intervention, stroke severity, cognitive abilities and motor capacities will be assessed. Two baseline tests will be planned to evaluate the stability of individuals. Participants will attend a weekly 60-min dance class for 6 weeks. Cognitive and motor functions (balance, lower-limbs strength, coordination and motor level), quality of life (Stroke-Specific Quality of Life Scale) will be measured at weeks 4 and 6 in both groups. Participant satisfaction with regard to dance will be tested, as well as adherence and adverse effects.

Ethics and dissemination Ethics approval has been granted by the Swiss Ethics Committee of the CER Vaud (2019-01467). Outcomes will be disseminated through publication in peer-reviewed journals and presentations at conferences.

Trial registration number NCT04120467.

BACKGROUND AND RATIONALE

Dance seems to be a particularly relevant activity for patients with stroke. It could be an effective way to improve recovery, well-being and tackle sedentariness-related risks.

Strengths and limitations of this study

- This is a pioneering randomised control trial to assess the effects of dance programme in individuals after stroke in subacute phase.
- The primary outcome measure is the balance performance (Mini-BESTest) and assessed by a rater masked to group allocation.
- Since the participants will be in the subacute phase, the stability will be verified by a double-baseline assessment.
- Fidelity to dance practice and usual rehabilitation will be highly monitored.
- It is difficult to perform a double-blind study since participants know what exercise is being performed (dance+usual rehabilitation vs usual rehabilitation).

Joy,¹ satisfaction² and the benefits of dance—which are genuinely perceived by the participants—increase intrinsic motivation, which in turn fosters adherence to physical activity.³ Moreover, high adaptability of dance makes it an easy practice for patients, for it can cover very broad motor and cognitive aspects. 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' behaviours are in accordance with the recommendations of healthcare).⁴ All these elements may explain the success of dance programmes applied to patients with chronic diseases.⁵

Stroke prevalence remains high (15 254 cases in 2016 according to Switzerland's Federal Statistical Office) and is also the country's first cause of disability.⁶ Following a brain lesion—due to ischaemic or haemorrhagic disturbances of cerebral blood circulation—various deficits will impact patients' functional abilities, autonomy and health costs.⁷ Motor recovery is, therefore, an essential part



of the therapeutic strategy in order to optimise patients' capacities and ensure that they age in the best conditions possible despite their disability.⁸ 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.

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. Aquatherapy,¹⁰ split-bell training,¹¹ aerobic training¹² and cycling¹³ have shown interesting effects on rehabilitation after stroke, and also show a willingness to diversify the exercises. Recent research on neuroplasticity mechanisms after stroke has shown the importance of treatment optimisation—such as physical exercises including aerobic modalities and an enriched environment that simultaneously integrates cognitive, motor and social aspects.^{14 15} Green *et al* highlighted that natural training is better than specific exercises.⁴ Natural activities are characterised 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 generalised 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}

There is a growing interest in the practice of art as a means of helping patients, for such activities leave the usual healthcare framework and effectively include physical, mental and social well-being.¹⁸ Indeed, singing shows improvements in relaxation, breathing, posture, social interaction and emotional strain.¹⁹ However, music shows limited physical effects, which is why some authors studied circus and dance—which involve balance, endurance, mobility, muscular strength and coordination.^{20 21}

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, two reviews showed improvements in symptoms and speed of the Timed Up and Go test when compared with 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 programme, a high satisfaction rate of participants, some benefits regarding balance and no adverse effect.^{20 26} Dance seems particularly adapted to the multi-dimensional impairments of patients with stroke, for example, cognitive, motor, balance, quality of life and social impairments.⁹ Participants seem to rediscover the pleasure of moving—despite their disabilities—and enjoy a strong social bond that favours inclusion and adherence. During the subacute phase, aerobic physical activity and the enriched environment provided by dance programmes should enhance recovery while working specifically on balance, coordination, strength, mobility and cognitive aspects. 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. Given all these aspects, dance should be a particularly well-adapted and interesting way of optimising patient recovery after stroke.

Objectives

Primary objective

This study is a randomised controlled trial (RCT), which aims to investigate the effects of dance programme—associated with conventional treatments—on the balance control of subjects with stroke (subacute phase), compared with conventional treatment alone. Our hypothesis is that a 6-week dance programme associated with conventional rehabilitation will improve balance control recovery when compared with conventional rehabilitation alone.

Secondary objectives

Our secondary objective is to assess the effects of dance programme combined with conventional rehabilitation on cognitive function, lower-limb strength, coordination, functional status, balance confidence and quality of life. The motivation to engage in physical activity, satisfaction and adherence will also be tested. 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 with conventional rehabilitation alone. The adverse effects of dance in subjects with poststroke hemiparesis in the subacute phase will be assessed.

METHODS AND ANALYSIS

Trial design and setting

The study protocol is approved by the Swiss Ethical Committee (CER Vaud 2019–01467). A flow chart of the study process is shown in [figure 1](#).

The study protocol conforms to the Standard Protocol Items: Standard Protocol Items for Randomised Trials.

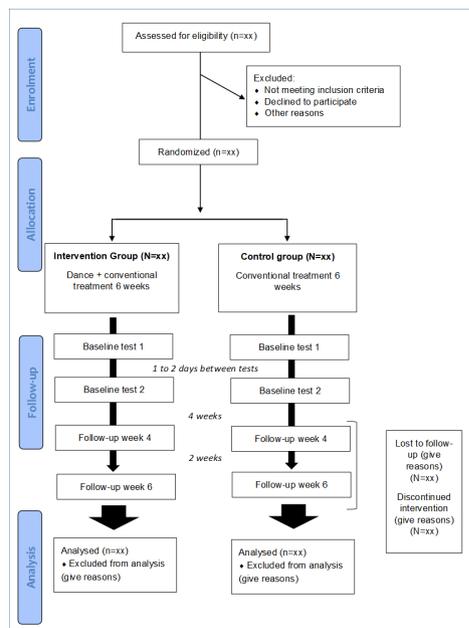


Figure 1 Flow chart of the study protocol.

Patient and public involvement statement

This work does not feature patient and public involvement in clinical research. Instead, we chose to observe dance classes with patients with neurological conditions and we included neurorehabilitation clinicians in the conception of this research. Thus, it is a coproduction between researchers and clinicians.

Participants

Eligibility criteria

Individuals will be eligible for inclusion if the first occurrence of a stroke is less than 3 months old (subacute phase) with medical stability (eg, multiple strokes, cardio-respiratory impairments), if they are 45–80 years old, if they are able to understand the instructions (Mini-Mental State Examination >15), to maintain a sitting position during 30 s and to endure 60 min of moderate physical activity. Participants will be excluded if they present severe hearing loss, pre-existing conditions that affect gait and balance, or major cognitive disturbances. This study will not include vulnerable subjects according to the criteria of the Swiss Human Research law.

Recruitment procedure

Two physiotherapists from the Institution de Lavigny (Lavigny, Vaud, Switzerland) neurorehabilitation centre and the study investigator will be responsible for the recruitment. All individuals will be consecutively recruited. During their hospitalisation, 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). Diagnosis for poststroke hemiparesis should be systematically established by a neurologist, based on medical imaging and clinical examination. Oral and written information about the study will be provided to each patient by a member of

the research team. Patients are recommended to take at least 24 hours to consider and discuss participation with a relative before deciding on participating in the study.

Randomisation

Participants who meet the eligibility criteria and sign the informed consent form will have baseline data collected prior to the randomisation procedure. To ensure allocation concealment, randomisation to groups (dance or control group) will be undertaken by an independent investigator not involved in the experiment, using a computer-generated randomisation tool. We will choose a randomisation method using permuted-block randomisation (ie, random block sizes of 4 and 6), with a 1:1 allocation ratio, ensuring complete randomness of subject assignment to each randomised 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).

Blinding

Researchers responsible for the interventions will be blinded to the participants' initial assessments, and the researcher responsible for the evaluations will be unaware of each participant's group. Moreover, data collected during the evaluations will not be revealed to the researchers responsible for the interventions, and participants will be instructed not to disclose their experience or information related to the intervention. Finally, the researcher responsible for the statistical analysis will be blinded.

Initial clinical information

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. Clinical tests will then be conducted to determine the motor level of the subjects' lower limbs (Chedoke Mc Master Assessment²⁷), the spontaneous and rapid 10 m walking speed,²⁸ the functional mobility (Timed Up and Go), the trunk balance (Trunk Control Test), the hemineglect (Bells test) and the dance experience.²⁰

Interventions

Dance group

One group of 2–8 participants will attend a 60 min dance class weekly over a 6-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 centre's resources. A physiotherapist-dance teacher will lead the classes, supported by volunteers (physiotherapists or physical activity specialists). The number of volunteers (1–2) may change according to the needs of the participants. The group can include

Table 1 Example of the structure of a typical 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 exercises	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 time	10	Breathing exercises. Phase of return to calm (slow range of motion of all joints) and exchanges on the session.

other participants with other neurological disabilities to complete the number of participants, however they will not be included in this study.

All dance classes will be accompanied by music. Each class will be divided into five steps (table 1).^{20 26} Dance exercises will be targeting flexibility, balance, endurance, upper and lower limbs functions, interaction between dancers, perception (visual imagery and inclusion of the affected side) and memory. The dance style will be a combination of contemporary and social dance (eg, tango), with a focus on body/space interaction and the interaction with other persons in the same space. Using choreography or short routine, the class will involve repeating dance moves—which fosters memorisation—with also the additional challenge of remembering a sequence of moves.

Each dance step will be demonstrated by the dance teacher and shall be the same for all participants. However, given the great variability of each participant's functional ability, the complexity and intensity of dance will progress according to each participant's capacity—for it to be an appropriate challenge. All the dance moves will have to be possible sitting or standing.

In parallel, all participants will have the conventional poststroke follow-up care, which respects the Institution de Lavigny Institution's approach.

Control group

The control group will also receive the same 6-week follow-up, only without the dance class. The conventional treatment includes 45–60 min of physiotherapy per day by the Lavigny centre 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 2–3 times per week depending on the patient's abilities. The group sessions of 2–8 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 two 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.

Outcomes measures

The psychometric qualities of the tests used are presented in table 2.

Primary outcomes

The primary outcome is balance control recovery, measured through change assessment (compared with baseline) in cognitive-motor functions for both groups (dance vs control).

Balance recovery will be measured using the Balance Evaluation System test (mini-BESTest). The test has a maximum score of 28 points from 14 items that are each scored from 0 to 2. '0' indicates the lowest level of function and '2' the highest level of function.³¹

Secondary outcomes

Cognitive function will be measured using the Montreal Cognitive Assessment (MoCA) scale.³² This tool is better than the Mini-Mental State Evaluation with less of a ceiling

Table 2 Psychometric qualities for tests

Test	Balance with App	ABC-s	Strength (quadriceps)	LEMOCOT	FIM	SS-QoL	Motivation PA
Psychometric quality							
Intrater reliability	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 >0.89	ICC >0.97	ICC >0.83	ICC >0.88	
Validity	BBS (r=0.96)	Cronbach's alpha=0.973 (internal validity)	Other strength tool: ICC >0.82	r >0.62 (functional tests)	Cronbach's alpha \geq 0.84 (internal validity)	Cronbach's alpha=0.65–0.91 (internal validity)	Cronbach's alpha=0.61–0.91 (internal validity)
References	Chinsongkram et al ⁴⁵ 2014	Hou et al ⁴¹ 2019	Mentiplay et al ³⁵ 2018 to 2015	de Menezes et al ³⁶ 2015, Desrosiers et al ³⁷ 2005	Hsueh et al ³⁸ 2002	Legris et al ⁴² 2018	Boiché et al ⁴³ 2019

Spearman's correlation coefficient. A white box indicates that the parameter has not been studied.

ABC-s, Activities-Specific Balance confidence test; App, phone application; BBS, Berg Balance Scale; FIM, functional independence measurement; ICC, intraclass correlation coefficient; LEMOCOT, lower extremity motor coordination-limb motor; PA, Physical Activity; Motivation PA, Echelle de Motivation envers l'Activité Physique en contexte de Santé; SS-QoL, Stroke-specific quality of life scale.

effect and higher internal reliability; it is a stronger functional status indicator.³² There are 12 items in the cognitive domain: memory is tested through a short-term memory recall task (five points); visuospatial ability is tested using a clock-drawing test (three points) and a three-dimensional cube copy (one point); executive function is tested using a trail-making test (one point), a phonemic fluency task (one point), and a two-item verbal abstraction task (two points); attention, concentration and working memory are tested using an attention task (one point), a serial subtraction task (three points) and digits tasks (one point each); language is tested using a three-item confrontation naming task with animals (three points) and repetition of two complex sentences (two points); orientation in time and place is also tested (six points). The minimum score is 0 and the maximum score is 30. Higher scores indicate better cognition (normal score: >26/30).

Strength will be measured using knee extensors' muscle with a hand-held dynamometer—in Newton (N). Indeed, this muscle group represents very well the strength of other muscles of the lower limb in stroke.³³ Participants will be in a sitting position with their feet free and a 90° knee flexion. The dynamometer will be placed on the distal part of the leg.^{34 35} Participants will apply maximum pressure on the dynamometer for 5 s. Three tests will be carried out for the non-paretic and paretic sides.

Coordination recovery will be tested using the Lower Extremity Motor Coordination (LEMOCOT) test.^{36 37} Subjects will be sat on an adjustable chair with their feet resting flat on thin rigid foam, heels on the proximal target, and with knees and hips at 90° flexion. Then, after a first trial, they will be instructed to alternately touch the proximal and distal targets, placed 30 cm apart, using their big toe, for 20 s, as fast as possible, without trading accuracy for speed. The number of touched targets will be counted and registered for analysis.

Motor level will be assessed using a Functional Independence Measure Instrument (FIM).³⁸ The scale contains 18 items, 13 of which concern physical domains and five of which are cognition related. Based on the level of independence, each item is scored from 1 to 7, where 1 indicates total dependence and 7 represents complete independence. Possible scores range from 18 to 126. Higher values represent a better outcome.

Balance confidence will be measured using the Activities-Specific Balance Confidence scale (ABC-scale).³⁹ The ABC-scale is a self-reported questionnaire providing information on balance confidence in the performance of 16 different daily activities. The questionnaire contains 16 items scored on a range from 0% to 100% (0: no confidence and 100: full confidence). A total score of \leq 67 indicates an increased risk of fall. Standing balance will be tested in standing in single task and dual-task (with phone text task) with an inertial sensor for extracted displacement in anteroposterior and mediolateral directions.^{40 41}

The quality of life of persons with chronic stroke will be measured using the Stroke-specific quality of

life scale (SSQoL). The SS-QOL contains 12 subscales with a total of 49 items. The scoring of the SS-QOL will cover the previous week and is rated on a 5-point Likert scale. Response options are scored as 5 ('no help needed/no trouble at all/strongly disagree'), 4 ('a little help/a little trouble/moderately disagree'), 3 ('some help/some trouble/neither agree or disagree'), 2 ('a lot of help/a lot of trouble/moderately agree'), and 1 ('total help/could not do it at all/strongly agree'). The SS-QOL provides domain scores and a summary score, with higher scores indicating better function. The minimum score is 12 and the maximum score is 245. This questionnaire is adapted to the subacute phase and is validated in French.⁴²

The motivation scale towards health-oriented physical activity (MS-PA) contains a total of 18 items.⁴³ Scoring is rated on a 7-point scale (1='strongly disagree' and 7='strongly agree'). The minimum score=18 and maximum score=126. Higher values represent less motivation.

The adverse effects of the dance programme will be assessed. Pain and fatigue will be measured using the Numeric Rating Scale (NRS) before and after each dance class. The 11-point numeric scale ranges from '0' (eg, 'no pain' or 'no fatigue') to '10' (eg, 'pain as bad as you can imagine' or 'worst pain imaginable' or 'worst fatigue imaginable'). Higher scores indicating greater pain or fatigue intensity.

Participant satisfaction will be assessed with an exit survey adapted from a previous study report that investigated dance for persons with chronic stroke.²⁰ The survey asked participants to rate nine statements about the dance programme using a 5-point scale (where 1 = 'strongly disagree' and 5 = 'strongly agree'). Higher values represent better satisfaction. Adherence will be evaluated by the number of sessions actually attended compared with the number of dance classes and conventional interventions planned.

Data collection and management

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. 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 phase⁴⁴ and because studies have shown the positive effects of dance after 4 weeks.²⁶ Given that the decreased hospitalisation time in the hospital strategies, it will be interesting to assess the effectiveness after 1 month. The 6-week follow-up is in line with the usual hospital stay of patients with stroke at the rehabilitation centre. If the participant is discharged before the end of the follow-up, they will have to go back to the centre for the

dance classes. During the entire process, each adverse event will be registered and reported to the medical staff.

In order to promote data quality, examiners will be physiotherapists/researchers with experience in neurology. All tests were chosen according to our objectives and their psychometric qualities. Measurements will be made at the neurorehabilitation centre by project workers specifically trained in the test protocol in order to standardise the data collection procedure.

The following measures will be taken for data quality: double data entry, weekly data back-up and training of those involved in the study in all important aspects of the study.

Data management has been approved by the Swiss ethics committees. Identifiable information data will be kept separate from the main dataset and will not be shared. All personal data will be stored securely in order to protect confidentiality before, during and after the trial. Data entry and coding of the de-identified data will be conducted by trained staff.

External monitoring

As this study presents no more risks than the usual management of patients after stroke, no external monitoring will be necessary. However, an internal monitoring is planned. A professor, who is not part of the project, will ensure that the rights and welfare of the participants are respected, that the data reported is accurate and verifiable from the source documents, and that the trial is conducted and documented in accordance with the protocol, procedures and applicable regulations.

Withdrawal and discontinuation

Participants will be free to withdraw from the trial at any point. The criteria for subject withdrawal will be: 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; behavioural 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.

In case of withdrawal, all data obtained will be made anonymous by replacing—in all documents—the sources of identification by the subject number. No further identification will then be possible.

Statistical analysis

Sample size calculation

The sample size was calculated from the Mini-BESTest results in patients with subacute stroke.⁴⁵ This test has the highest psychometric characteristics with a low floor/ceiling effect and good sensitivity to change for

subjects after stroke. In addition, in the study of Patterson *et al*²⁰ on dance and stroke, this test was used as an outcome indicator and showed that it correctly identified patient changes. A 3.5/28-point difference in change is considered clinically relevant for persons with stroke in subacute phase.⁴⁵ To detect this difference, 21 participants per group are needed with an SD of 3.9/28, power at 80% and a significant threshold of $p < 0.05$ in two-tailed test. To deal with possible withdrawals, we will include 24 subjects per group.

Data treatment and statistical analysis

The statistical analysis will be performed blinded to group allocation, using the software SPSS (SPSS inc. Chicago, IL, USA, V.22.0, 2020).

The first data treatment will include normalisation 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.

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 SD 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.

The Mini-BESTest score variable will be treated as primary outcome for the 6 weeks measure. If the variable presents a normal distribution, a two-way repeated measures analysis of variance (ANOVA) will be used to determine how this dance intervention impacts on balance control. The ANOVA incorporated the groups (dance vs control), time (baseline, 4 weeks and 6 weeks) and the group x interaction. Primary analysis will assess if mini-BESTest change at 6 weeks compared with baseline is different between intervention and control groups. We will do post hoc comparison between 6 weeks and 4 weeks then between 4 weeks and baseline as secondary analyses.

Multivariate ANOVA will also be performed for each secondary variable of interest, including the MoCa score, knee extension strength, LEMOCOT, FIM score, SSQoL, MS-PA, ABC-Balance confidence, ML and AP displacements for standing balance, pain, fatigue, satisfaction with dance class, adherence and adverse effects. If there are baseline differences between the groups, analysis of covariance will be used to eliminate the influence of extraneous factors.

If the distribution is not normal, the non-parametric Mann Whitney U test will be used to compare the groups in each time evaluation, and the Wilcoxon signed-rank test to compare evaluation time for each group baseline, 4 weeks and 6 Weeks. In case of qualitative data, the χ^2 test will be applied.

A threshold value of $p < 0.05$ (two-tailed test) will be adopted to rule out non-significant differences.

ETHICS AND DISSEMINATION

Recruitment and consent

Prospective, written consent (online supplemental file) will be obtained from all participants.

Data collection, storage and access

Data will be deidentified and entered into a secure folder and electronic database. Only the investigators and a statistician will have access to the final dataset.

Dissemination strategy

Outcomes will be disseminated through publication in peer-reviewed journals and presentations at international conferences.

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 RCTs 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 programme 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 neuroplasticity¹⁴ and also entails pleasure and social interaction³—which are factors in regaining motivation. The social component and adaptability of dance could be important motivational factors that favour the improvement of well-being and the fight against sedentariness.⁹

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 Dance's safety may be linked to its superior adaptability compared with other sport activities,⁴⁸ and also to the self-regulation of movements by the subjects. Indeed, even if all movements are structured, patients are free regarding their self-imposed constraints. Thus, they are in a situation of self-control regarding their movements and in a stable environment that gives them control over their own safety throughout the activity.

This study presents limitations. Because subjects are recruited in the subacute phase, it is possible that some subjects may have complications that prevent them from completing the programme. Therefore, they will be recruited in a stable medical situation. A limitation could be time and site availability. However, since there is

already a dance programme in the service's rehabilitation programme, this should not change the centre's general organisation. Blinding is impossible for the subjects and for the dance teacher. Nevertheless, raters are external to the centre and will be unaware of the allocation of subjects between the dance group and the control group.

The results of this study should contribute to new scientific knowledge, providing support for the use of dance in physiotherapeutic approaches as an effective tool for treating persons after stroke.

Contributors EM conceived and designed the study, recruited the participants, drafted and revised the manuscript; JM conceived and designed the study; CJ managed the clinical practice organisation; A-VB—as the study's principal investigator—conceived and designed the study, supervised the study, drafted and revised the manuscript.

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Competing interests None declared.

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