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# Dance as a Means to Improve Functions and Quality of Life After a Stroke: a study protocol for a randomized controlled trial

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# Dance as a Means to Improve Functions and Quality of Life After a Stroke: a study protocol for a randomized controlled trial

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# Dance as a Means to Improve Functions and Quality of Life After a Stroke: a study protocol for a randomized controlled trial


## ABSTRACT

***Introduction:*** Dance is an intrinsically motivating activity comprising social interaction, stimulation through music, the joy of moving despite motor limitations induced by pathology, and which has good perceived benefits among participants. Moving with pleasure is essential to finding the motivation to engage in rehabilitation program and physical activity. In stroke context, physical activity and rehabilitation were difficult to carry out because of cognitive and motor disabilities. Moreover, when the rehabilitation is over, the diminishing motor stimulation gradually limits autonomy in daily tasks. It is therefore urgent to provide persons in a post-stroke situation with motivating physical activity opportunities. Very few studies have studied dance in a context of stroke, while this physical activity is highly adapted and effective for other chronic conditions.

The main objective is to assess the effects of dance practice on cognitive and motor functions for persons after stroke. The secondary objective is to investigate the effects of dance on quality of life, motivation and adherence. The hypothesis is that the practice of dance induces an increase of balance and motor capacities, and improving the quality of life, adherence and motivation after a stroke.

***Methods and analysis***

Forty-eight subjects with stroke in subacute phase will be randomized 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 tested. Two baseline tests will occur to assess the stability of individuals will be planned. Participants will attend a dance class weekly during 6 weeks. The cognitive and motor functions (balance, lower-limbs strength, coordination and motor level), the quality of life (Stroke-specific quality of life scale) will be


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measured at 4 and 6 weeks 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

***Protocol version:*** V1 (December 2020)

**Key Words:**

Stroke – rehabilitation - dance – motor functions – recovery – quality of life

## ARTICLE SUMMARY:

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- Dance is an intrinsically motivating aerobic activity which includes social interaction, stimulation through music and the joy of moving despite the motor limitations induced by a pathology.
- This study's main objective is to assess the effects of dance practice on cognitive and motor functions for persons after stroke (subactute phase).
- This is a single-center protocol, parallel-arm randomized controlled trial (dance and conventional therapy vs. conventional therapy) with a six-week follow-up.
- After a baseline assessment, cognitive and motor functions, quality of life, motivation and satisfaction will be measured at weeks 4 and 6 in both groups.
- Performing a double-blind study with exercises is difficult, since participants are aware that dance is being performed.

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**Author contributions:**

EM conceived and designed the study, recruited the participants, drafted and revised the manuscript, JM conceived and designed the study, CJ manage the clinical practice organization, AVB is the study principal investigator, conceived and designed the study, supervised the study, drafted and revised the manuscript.

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**Competing interest:** None declared.

**Patient consent:** Obtained.

**Ethics approval:** Ethics approval has been granted by the Swiss Ethics Committee of the CER Vaud (2019-01467).

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**Data statement:** At the end of the project the dataset will be deposited in the Yareta repository developed by the University of Geneva OR in an institutional repository (data will be archived and shared in accordance with the FAIR principles).



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**Patient and public involvement:** In this work, the patient and public involvement in clinical research was not applied. But we observed dance class in neurological condition and we included the clinicians in neurorehabilitation in the conception of this research. Thus, it is a co-production between researchers and clinicians.

# TEXT

## Dance as a Means to Improve Functions and Quality of Life After a Stroke: a study protocol for a randomized controlled trial

## BACKGROUND AND RATIONALE

Dance seems to be a particularly relevant activity for patients who suffered a stroke. It could therefore be an effective way to improve recovery, well-being and combat the risks related to sedentariness. Joy [1], satisfaction [2] and the benefits of dance – which are genuinely perceived by participants – increase intrinsic motivation, which fosters adherence to physical activity [3]. Moreover, unlimited 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 and thus substantially reduced motor learning and adherence [4]. All these elements may explain the success of dance programs applied to patients with chronic diseases [5].

Stroke prevalence remains high (15,254 cases in 2016 according to Switzerland's Federal Statistical Office or SFSO) and is also the country's first cause of disability [6]. Following a brain lesion, variable cognitive-motor 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 optimize patients' capacities and ensure that they age in the best conditions possible despite their disability [8].



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Persons after stroke are little aware of complication and isolation risks related to sedentariness (e.g. excess weight, hypertension, depression, motor impairments) [9]. However, when the rehabilitation is over, the diminishing motor stimulation gradually limits autonomy in daily tasks and motor capacities. The factors that contribute to sedentariness are mainly motor impairments, fatigue, cognitive disorders and lack of motivation [9]. Besides, it is often difficult to continue the treatment because of patients' decreasing adherence and increasing weariness of treatment. Thus, it is interesting for health professionals to guide their patients toward physical activities that foster social interaction and quality of life in order to tackle sedentariness in the long run.

A Cochrane review showed that rehabilitation should be regarded as effective in promoting motor recovery, fighting cognitive and motor deficits and improving independence [8]. Nevertheless, the modalities of exercises are unclear. Recent research on neuroplasticity mechanisms after stroke has shown the importance of treatment optimization – such as physical exercise including aerobic modalities and an enriched environment which simultaneously integrates the cognitive, motor and social aspects [10,11]. Green et al. showed that natural training with complex tasks (including cognitive and motor variable constraints), such as the practice of art, is better than specific exercises for fostering motor learning and for transferring the capacities to new daily tasks [4]. These natural activities also have the advantage of developing dual-task movements by simultaneously soliciting both motor and cognitive functions. With persons suffering from strokes, Kim et al. [12] showed that a motor and cognitive dual-task training was more effective in improving balance and gait abilities than single-task training. The physical activities that seem to be the most effective for the recovery of motor and cognitive abilities 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 [4,9].

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 [13]. Indeed, singing shows improvements in relaxation, breathing, posture, social



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interaction and emotional strain [14]. However, music shows limited physical effects, which is why some authors studied circus and dance – which involve balance, endurance, mobility, muscular strength and coordination [15,16]. Dance seems to develop cognitive and physical abilities as well as quality of life, all the while fostering well-being and social interaction [3], while stroke pathology disrupts all of these aspects [9,15]. Dance is thus particularly suitable for the multidimensional component of patients after stroke. Only two studies on subjects who suffered a stroke showed the feasibility of a dance program, a high satisfaction rate of participants and benefits on balance [15,17]. Nevertheless, in these studies, the main objective was feasibility and there was no control group, which limits the conclusions on the effectiveness of dance practice for patients after stroke. No adverse effects were reported and, in both studies, the authors highlighted the satisfaction of participants [15,17]. Dance seems to allow participants to rediscover the pleasure of moving, despite their motor and cognitive disabilities and provides a strong social bond that favors inclusion and adherence. During the subacute phase, aerobic physical stimulation and the enriched environment induced by dance practice should enhance recovery while working specifically on balance, coordination, strength, mobility and cognitive aspects. Moreover, O'Connell et al. [13] highlighted that dance was the most common activity undertaken before stroke and that patients would like to continue this activity in the hospital. Given all these aspects, dance should be a particularly well-adapted and interesting way of optimizing patient recovery after a stroke.

***Objectives***

*Primary objective*

This study is a randomized controlled trial (RCT) which aims to investigate the effects of dance practice associated with conventional treatments on the cognitive-motor recovery of subjects after a stroke (subacute phase), compared to conventional treatment. Our hypothesis is that dance associated with conventional rehabilitation improves cognitive-motor recovery when compared to conventional rehabilitation alone.

*Secondary objectives*



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Secondary objectives aim to assess the effects of dance practice combined with conventional rehabilitation on quality of life and motivation to engage in physical activity, as well as satisfaction and adherence to the dance program. Our hypothesis is that the practice of dance induces strong satisfaction and adherence and increases quality of life and motivation to engage in physical activity. The study also aims to verify the absence of adverse effects of dance in subjects with post-stroke hemiparesis in the subacute phase.

## METHODS AND ANALYSIS

***TRIAL DESIGN AND SETTING:***

This is a study protocol for a single-center, parallel-arm RCT, registered with ClinicalTRials.gov (NCT04120467) and approved by the Swiss Ethical Committee (CER Vaud 2019-01467). A flow chart of the study process is shown in *figure 1.*

***Please insert figure 1.***

The study protocol conforms to the Standard Protocol Items: Standard Protocol Items for Randomized Trials (SPIRIT) while the RCT will conform to the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting RCT.

The neurorehabilitation center of the *Institution de Lavigny* (Lavigny, Vaud, Switzerland) will recruit participants for the study.

***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, if the age is between 45-80 years old, if the subject is able to understand the instructions (mini-Mental State Examination > 15), and if they are able to maintain sitting position during 30s and to endure 60 minutes of moderate physical activity. Participants will be excluded if they present severe hearing loss, pre-existing conditions that affect gait and balance,



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or major cognitive disturbances. This study does not include the participation of vulnerable subjects according to the criteria of the Swiss Human Research law.

***Recruitment procedure***

A physiotherapist from the neurorehabilitation center and the study investigator will be responsible for the recruitment. All individuals will be consecutively recruited. 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 post-stroke 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. Patients are recommended to take at least 24hours to consider and discuss participation with a relative before deciding on participating in the study.

***Randomization***

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 investigator not involved in the recruitment using a computer-generated randomization schedule. We will use a randomization method using blocks of 4 and 6, which allows for a balanced distribution, even if the study stops early.

***Blinding***

Researchers responsible for interventions will be blinded to participants' initial assessments, and the researcher responsible for evaluations will be unaware of each participant's group. Moreover, data collected during evaluations will not be revealed to the researchers responsible for interventions,



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and participants will be instructed not to disclose their experience and information related to the intervention. Finally, the researcher responsible for statistical analysis will be blinded.

***Initial clinical information***

In order to identify the demographic and clinical characteristics of the participants, age, sex, type of stroke (hemorrhagic or ischemic), affected brain areas, side of stroke and medical history will be collected. Clinical tests will then be conducted to determine the motor level of the subjects' lower limbs (Chedoke Mc Master Assessment, [18]), the spontaneous and rapid 10-metre walking speed [19], the functional mobility (Timed Up and Go), the trunk balance (Trunk Control Test) and the hemineglect (bell's test), and the previous dance experience [15].

***INTERVENTIONS***

***Dance group***

One group of participants with subacute stroke will attend a 60-minute dance class weekly over a six-week period. A physiotherapist - dance teacher (with experience working with people with stroke diseases) will lead the classes, supported by at least one volunteer (physiotherapist or specialist in physical activity).

All dance classes will be accompanied by music. Each class will be divided into five steps [15,17]: warm up (10 minutes), technical exercises (10 minutes), improvisation (15 minutes), a short routine (15 minutes) and a cool down/feedback time (10 minutes). Dance exercises will be targeting flexibility, balance, endurance, upper and lower limbs functions, interaction between dancers (partner dance or circle dance), perception (visual imagery and inclusion of the affected side for individuals with hemineglect) and memory. The dance style will be a combination of contemporary dance and social dance. Using choreography or short routine, the class will include repeating the



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dance moves – which fosters memorization – and 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 exercises will progress according to each participant's capacity, in order to fulfill an appropriate challenge at moderate treatment intensity. All the dance moves will have to be possible sitting or standing.

In parallel, all participants will have the conventional post-stroke follow-up care that respects the Institution de Lavigny Institution's approach (description in control group chapter).

***Control group***

The control group will also receive the same follow-up, only without the weekly dance class. The conventional follow-up includes 45 to 60 minutes of physiotherapy per day with sensory stimulation, motor activation, strengthening, coordination, balance, and physical training according to the objectives set up during the assessment. In addition, group sessions are scheduled 2 to 3 times per week depending on the patient's abilities (cognitive, motor, fatigue). Every day, the patient also will have an occupational therapy session. From three to five times a week, patients will have neuropsychology and speech therapy sessions.

***OUTCOMES MEASURES***

***Primary outcomes***

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



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Cognitive function will be measured using the Montreal Cognitive Assessment scale [20]. There are 12 items for cognitive domain: memory is tested through a short-term memory recall task (5 points); visuospatial ability is tested using a clock-drawing test (3 points) and a 3-dimensional cube copy (1 point); executive function is tested using a trail making test (1 point), a phonemic fluency task (1 point), and a 2-item verbal abstraction task (2 points); attention, concentration, and working memory are tested using a attention task (1 point), a serial subtraction task (3 points), and digits tasks (1 point each); language is tested using a 3-item confrontation naming task with animals (3 points) and repetition of 2 syntactically complex sentences (2 points); orientation in time and place was also tested (6 points). The minimum score is 0 and the maximum score is 30. Higher scores indicate better cognition (normal score: >26/30).

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 0-2. “0” indicates the lowest level of function and “2” the highest level of function. The minimum score is "0" and the maximum score is "28" [21]. In addition, standing balance will be tested in bipedal condition in single task and dual-task (with phone text task) with inertial sensor for extracted displacement in anteroposterior and mediolateral directions [22]. Balance confidence will be measured using the Activities-Specific Balance Confidence scale (ABC-scale) [23]. The ABC-scale is a self-reported questionnaire providing information on balance confidence in the performance of 16 different daily activities, such as stair climbing, walking in the house, and walking on slippery floors. The questionnaire contains 16 items scored on a range from 0% to 100% (0 indicating no confidence and 100 indicating full confidence). A total ABC scale score of ≤67 indicates an increased risk of fall.

Strength recovery will be measured using knee extensors’ muscle strength 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 [24]. The participant will be in a sitting position with his feet free. The pressure dynamometer will be placed on the front face of the distal part of the leg. The rater will



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be stretched out at right angles to the leg. The participant will apply maximum pressure on the dynamometer for 5s. 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 [25]. The subject 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° of flexion. Then, after a familiarization trial, they will instructed to alternately touch the proximal and distal targets, placed 30cm apart, with their big toe, for 20s, as fast as possible, without sacrificing accuracy in order to increase speed. The number of touched targets will be counted and registered for analysis.

Motor level will be assessed using a Functional Independence Measure Instrument (MIF) [26]. The scale contains 18 items, 13 of which concern physical domains and five of which are cognition-related. Motor items measure self-care, sphincter control, locomotion, and transfer. Cognitive ones evaluate the subject's communication and social cognition. 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.

***Secondary outcomes***

The secondary outcome is the change (from baseline) in quality of life for both groups (dance vs. control).

The quality of life of persons with chronic strokes will be measured using the Stroke-specific quality of life scale (SSQoL). The SS-QOL contains 12 subscales with a total of 49 items. Scoring of the SS-QOL concerns the past 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



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provides domain scores and a summary score, with higher scores indicating better function. The total score is calculated by averaging the domain scores. The minimum score is 12 and the maximum score is 245. This questionnaire is adapted to the subacute phase and validated in French [27].

A motivation scale towards health-oriented physical activity [28]. The motivation scale towards health-oriented physical activity (MS-PA) contains a total of 18 items. Scoring is rated on 7-point scale (1 = " strongly disagree " and 7 = "strongly agree "). The minimum score = 18 and maximum score = 126. Higher values represent less motivation.

The incidence of dance practice on adverse effects will be assessed. Pain and fatigue will be measured using the numeric rating scale (NRS). The 11-point numeric scale ranges from '0' – representing one extreme (e.g. “no pain” or “no fatigue) – to '10' – representing the other extreme (e.g. “pain as bad as you can imagine” or “worst pain imaginable” or “worst fatigue imaginable”). Scores range from 0-10 points, with 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 [15]. The survey asked participants to rate nine statements about the dance program using a 5-point scale (where 1 = “strongly disagree” and 5 = “strongly agree”). Higher values represent better satisfaction.

***DATA COLLECTION AND MANAGEMENT***

Data will be collected twice at baseline (baseline 1 and baseline 2) to evaluate the stability of the studied parameters. The follow-up will include two assessments with data collection: at 4 weeks of intervention and then after 6 weeks to evaluate the changes from baseline *(see figure 1)*.
In order to promote data quality, examiners will be physiotherapists/ researchers experienced in neurology. All the tests have been chosen according to our objectives and their psychometric



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qualities in stroke context. Measures will be assessed at the neurorehabilitation center by project workers specifically trained in the test protocol in order to standardize the data collection procedure. The following measures will be taken for data quality: double data entry, weekly data back-up, training of those involved in the study in all important aspects of the study, quality visit planned by a professor external to the study.

The data management procedures have been approved by the Swiss ethics committees. Personal information about patients 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***

Since this is a longitudinal study, but in a rehabilitation center, the risk of dropout is moderate. The criteria for subjects withdrawal will be: end of hospitalization; a deterioration of medical stability; a misunderstanding of the tests and the activity not allowing to obtain results in satisfactory conditions; 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. In case of dropout, a final assessment will be conducted for safety. Since recruitment is consecutive, it is possible to extend the recruitment phase if necessary.



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In case of dropout, 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. All the data will be treated in “intention-to-treat”.

***STASTISTICAL ANALYSIS***

***Sample size calculation***

The sample size was calculated from the Mini-Bestest results in patients with subacute stroke [29]. This test has the highest psychometric characteristics with a low floor/ceiling effect and good sensitivity to change for subjects after a stroke. In addition, in the study of Patterson et al. 2018 [15] on dance and stroke this test was used as an outcome indicator and showed that this test correctly identified patient changes. A 3.5/28-point difference in change is considered clinically relevant for persons after a stroke in subacute phase [29]. 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 $p<0.05$.

***Data treatment and statistical analysis***

Analyses will compare: 1) first and second baseline tests (participants’ clinical stability), 2) both groups for baseline, 4 weeks and 6 weeks follow-up and 3) the data of each test between the baseline and follow-up assessments (baseline vs. 4 weeks vs. 6 weeks) in dance group and control group.

The first data treatment will include the normalization with body weight for quadriceps strength, the data extraction for balance measures and if necessary, different trials’ mean calculation for each condition.

The analysis will be descriptive for all outcomes included in the study, expressing quantitative outcomes with their mean and standard deviation (SD) and qualitative outcomes with their absolute value and/or percentage. The low number of subjects included does not allow us to perform parametric tests. Thus, we will be using the Wilcoxon test for all paired comparisons or U Mann



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Withney test for unpaired comparisons. In case of qualitative data, the Chi Square test will be applied.

An intention-to-treat analysis will be used to assess the response to intervention, with the last evaluation carried forward used when necessary.

A threshold value of $p < 0.05$ will be adopted to rule out non-significant differences. All statistical analyses will be performed using SPSS©.

## ETHICS AND DISSEMINATION

**Recruitment and consent:** Prospective, written consent will be obtained from all participants.

**Data collection, storage and access:** Data will be de-identified and entered into a secure folder and electronic database. Only the investigators 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

Dance's popularity is increasing among persons with chronic diseases. In neurological conditions, a previous systematic review reports a beneficial effect of dance [30]. Indeed, the pleasure of moving and the enriched environment which includes cognitive, motor and social stimulations, are two central components that support the motor learning process according to neuroplasticity knowledge [10,11]. However, in individuals after stroke only two feasibility studies have tested dance as a practice [15,17]. In both studies, the main methodological flaw is the lack of a control group. It is therefore difficult to attribute the evolution of patients to the practice of dance, especially in the subacute phase – because there the cognitivo-motor recovery is maximal. Thus, the lack of existing studies and the low methodological quality does not allow to transfer results in clinical practice, while some rehabilitation centers are using dance programs with their patients after stroke but only clinical experience can explain the subjective benefits obtained. It is therefore urgent



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to propose a study with a better methodological design in order to produce evidence for dance practice in stroke context.

This study is the first RCT to assess the benefits of a dance program on motor and cognitive recovery and quality of life in persons after stroke in subacute phase. The originality of this study is that it evaluates cognitive-motor recovery, quality of life and the motivation to engage in physical activity. We expect to see the benefits of dance on cognitive-motor recovery after stroke, as this activity is natural [4], includes the whole body [3], is highly suitable for patients' disorders [17], and also entails joy and social interaction [3], which are factors in regaining pleasure in movement and therefore 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].

The adverse effects and risks of dance seem very low for persons with neurological conditions [31]. Dance's safety may be linked to its superior adaptability compared with other sport activities [32], 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 (e.g. amplitude, muscular strength, imbalance). 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. Moreover, dance exercises will progress according to each participant's level, in order to reach an appropriate challenge.

It is very important that adherence to treatment be reported, mainly in interventions for chronic disorders. It is our hope that the volunteers in this study will show good adherence to the dance classes, considering that dance is a stimulating activity with music, social interaction and creative aspect.

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.



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## FIGURE CAPTION:

***Figure 1:*** flow chart of the study protocol.



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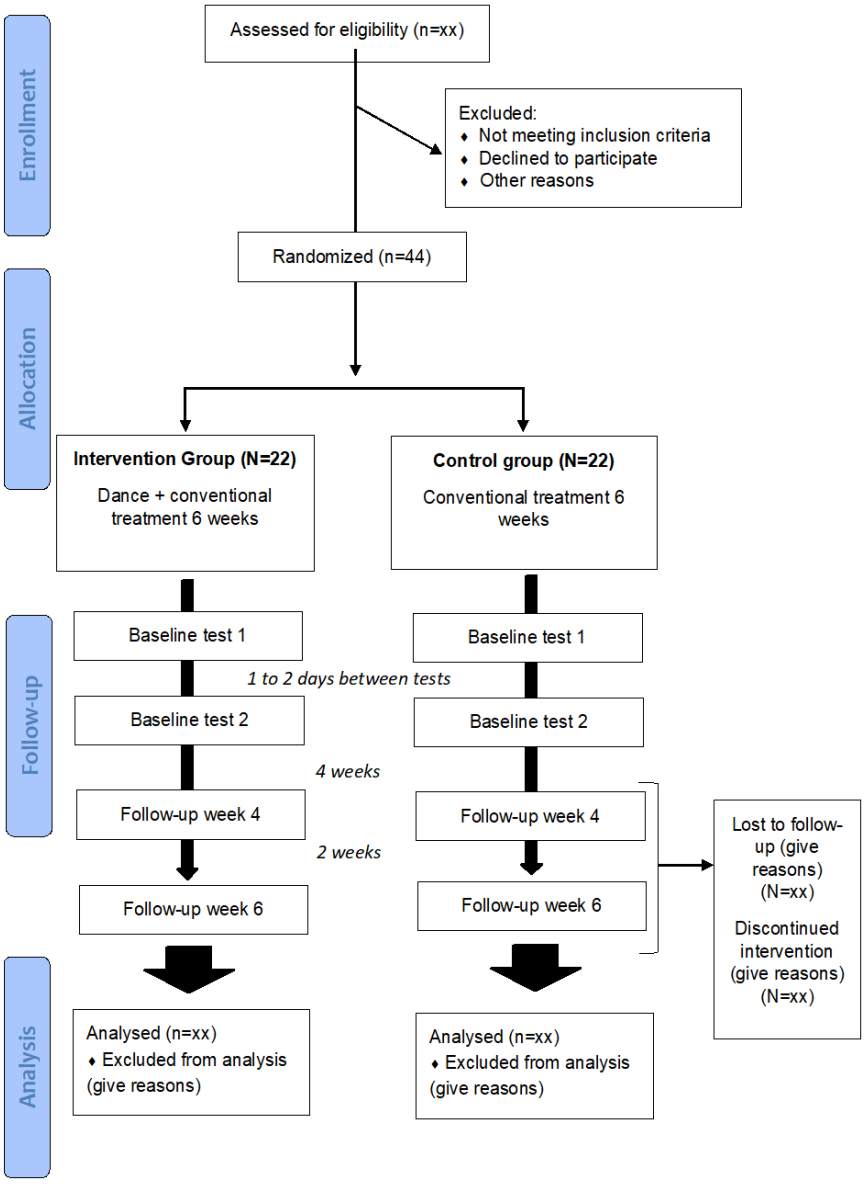


Figure 1: flow chart of the study protocol.

198x276mm (120 x 120 DPI)



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ClinicalTrials.gov PRS
Protocol Registration and Results System

**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: October 8, 2019

**ClinicalTrials.gov ID: [Not yet assigned]**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | SchoolHSG |
| Brief Title: | Dance as a Means to Improve Functions and Quality of Life After a Stroke ( HEMI'DANCE ) |
| Official Title: | Dance After a Stroke to Restore Pleasure in Physical Activity to Improve Cognitive and Motor Functions, Quality of Life and Well-being |
| Secondary IDs: | |

## Study Status

| | |
|---|---|
| Record Verification: | October 2019 |
| Overall Status: | Not yet recruiting |
| Study Start: | December 2019 [Anticipated] |
| Primary Completion: | August 2020 [Anticipated] |
| Study Completion: | September 2021 [Anticipated] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Anne-Violette Bruynnel |
| Responsible Party: | Sponsor-Investigator<br>Investigator: Anne-Violette Bruynnel [avbruyneel]<br>Official Title: Professor (associate)<br>Affiliation: School of Health Sciences Geneva |
| Collaborators: | Institution de Lavigny |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | No |
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Pending |
| Data Monitoring: | No |
| FDA Regulated Intervention: | No |

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## Study Description

Brief Summary: Context Dance is an intrinsically motivating activity comprising social interaction, stimulation through music, the joy of moving despite motor limitations induced by pathology, and which has good perceived benefits among participants. Moving with pleasure is essential to finding the motivation to engage in rehabilitation program and physical activity. In stroke context, physical activity and rehabilitation were difficult to carry out because of cognitive and motor disabilities. Moreover, when the rehabilitation is over, the diminishing motor stimulation gradually limits autonomy in daily tasks. It is therefore urgent to provide persons in a post-stroke situation with motivating physical activity opportunities. Very few studies have studied dance in a context of stroke, while this physical activity is highly adapted and effective for other chronic conditions.

Objectives: The main objective is to assess the effects of dance practice on cognitive and motor functions for persons after stroke. The secondary objective is to investigate the effects of dance on quality of life, motivation and adherence. The investigator's hypothesis is that the practice of dance induces an increase of balance and motor capacities, and improving the quality of life, adherence and motivation after a stroke.

Materials and method :

Forty-eight subjects with stroke in subacute phase will be randomized 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 tested. Two baseline tests will occur to assess the stability of individuals will be planned. Participants will attend a dance class weekly during 6 weeks. The cognitive and motor functions (balance, lower-limbs strength, coordination and motor level), the quality of life (Stroke-specific quality of life scale) will be measured at 4 and 6 weeks in both groups. Participant satisfaction with regard to dance will be tested, as well as adherence and adverse effects.

Perspectives:

The joy of dancing and the possibility of including other non-disabled people should facilitate adherence and motivation and increase the recovery of cognitive and motor functions.This project should motivate physiotherapists and dance teachers to increase the offer of dance classes for persons with motor and cognitive impairments.This action will be a basis for combating people's sedentary lifestyle after a stroke.

Detailed Description:

## Conditions

Conditions: Stroke

Keywords: Stroke
Rehabilitation
Dance

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: N/A

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| | |
|---|---|
| Interventional Study Model: | Parallel Assignment |
| Number of Arms: | 2 |
| Masking: | Single (Outcomes Assessor) |
| Allocation: | Randomized |
| Enrollment: | 48 [Anticipated] |

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: Dance<br>Dance Standard rehabilitation post-stroke | Dance<br>One group will receive a 60-minute dance class weekly over a 6 weeks period. A physiotherapist - dance teacher will lead the classes, supported by at least one volunteer. The class structure will consist of five components: warm up (10 minutes), technical exercises (10 minutes), improvisation (15 minutes), a short routine (15 minutes) and a cool down/feedback time (10 minutes). Dance exercises will be targeting flexibility, balance, endurance, upper and lower limbs functions, interaction between dancers, perception and memory. Using choreography or short routine, the class will include repeating the dance moves - which fosters memorization - and also the additional challenge of remembering a sequence of moves. Given the great variability of each participant's functional ability, the complexity and the intensity of the dance exercises will progress according to each participant's capacity, in order to fulfill an appropriate challenge at moderate treatment intensity.<br>Standard rehabilitation<br>The control group will have conventional rehabilitation as usually planned in the rehabilitation center: 45 to 60 minutes of physiotherapy per day integrating sensory stimulation, motor activation, strengthening, coordination, balance and exercise training. Patients also receive 45 to 60 minutes of occupational therapy per day. |
| Active Comparator: Control<br>Standard rehabilitation post-stroke | Standard rehabilitation<br>The control group will have conventional rehabilitation as usually planned in the rehabilitation center: 45 to 60 minutes of physiotherapy per day integrating sensory stimulation, motor activation, strengthening, coordination, balance and exercise training. Patients also receive 45 to 60 minutes of occupational therapy per day. |

## Outcome Measures

Primary Outcome Measure:

1. Change from Baseline cognitive-motor functions in both groups (dance vs. control): cognitive recovery
   The cognitive function will be measured with the Montreal Cognitive Assessement scale.There are 12 items for cognitive domains: memory is tested by a short-term memory recall task (5 points); visuospatial ability is tested using a clock-drawing test (3 points) and a 3-dimensional cube copy (1 point); executive function is tested using a trail-making test (1 point), a phonemic fluency task (1 point), and a 2-item verbal abstraction task (2 points); attention, concentration, and working memory is tested using a attention task (1 point), a serial subtraction task (3 points), and



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digits tasks (1 point each); language is tested using a 3-item confrontation naming task with animals (3 points) and repetition of 2 syntactically complex sentences (2 points); orientation in time and place was also tested (6 points).

The minimum score is 0 and the maximum score is 30. Higher scores indicate better cognition. Normal score: >26/30.

[Time Frame: 6 weeks]

2. Change from baseline cognitive-motor functions in both groups (dance vs. control): balance recovery
The balance will be measured with Balance Evaluation System test (miniBest test).

The test has a maximum score of 28 points from 14 items that are each scored from 0-2. “0” indicates the lowest level of function and “2” the highest level of function. The minimum score is "0" and maximum score is "28".

[Time Frame: 4 weeks and 6 weeks]

3. Change from baseline cognitive-motor functions in both groups (dance vs. control): standing balance recovery
The standing balance will be tested in bipedal condition in single task and dual-task (with phone text task) with inertial sensor. Parameters: displacement in anteroposterior and mediolateral directions (in mm).

[Time Frame: 4 weeks and 6 weeks]

4. Change from baseline cognitive-motor functions in both groups (dance vs. control): balance confidence recovery
The balance confidence will be measured with the Activities-Specific Balance Confidence scale (ABC-scale).

The ABC-scale is a self-reported questionnaire providing information on balance confidence in the performance of 16 different daily activities, such as stair climbing, walking in the house, and walking on slippery floors. The questionnaire contains 16 items scored on a range from 0% to 100% (0 indicating no confidence and 100 indicating full confidence). The total ABC scale score of ≤67 indicates an increased risk of fall.

[Time Frame: 4 weeks and 6 weeks]

5. Change from baseline cognitive-motor functions in both groups (dance vs. control): lower limbs muscle strength recovery
The knee extensors muscle strength will be measured with an hand-held dynamometer in Newton (N).

[Time Frame: 4 weeks and 6 weeks]

6. Change from baseline cognitive-motor functions in both groups (dance vs. control): coordination recovery
The coordination will be tested using the Lower Extremity Motor Coordination (LEMOCOT) test.

The subject 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° of flexion. Then, after a familiarization trial, they will instructed to alternately touch the proximal and distal targets, placed 30cm apart, with their big toe, for 20s, as fast as possible, without sacrificing the accuracy to increase speed. The number of touched targets will be counted and registered for analyses.

[Time Frame: 4 weeks and 6 weeks]

7. Change from baseline cognitive-motor functions in both groups (dance vs. control): functional ability recovery
Motor level will be assessed with a Functional Independence Measure Instrument (MIF). Motor level will be assessed with a Functional Independence Measure Instrument. The scale contains 18 items, of which 13 items are in physical domains and 5 items are related to cognition. Motor items measure self-care, sphincter control, locomotion, and transfer. Cognitive ones evaluate subject’s communication and social cognition. Based on 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.

[Time Frame: 6 weeks]

Secondary Outcome Measure:

8. Change from baseline Quality of life in both groups (dance vs. control)
The quality of life of persons with chronic strokes will be measured using the Stroke-specific quality of life scale (SS-QoL).

The SS-QOL contains 12 subscales with a total of 49 items. Scoring of the SS-QOL concerns the past 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 nor disagree"), 2 ("a lot of help/a lot of trouble/moderately agree"), and 1 ("total help/could not do it at all/strongly agree").

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The SS-QOL provides domain scores and a summary score, with higher scores indicating better function. The total score is calculated by averaging the domain scores. The minimum score is 12 and the maximum score is 245.

[Time Frame: 6 weeks]

9. Change from baseline Motivation for Physical Activity practice in both groups (dance vs. control)
A motivation scale towards health-oriented physical activity. The motivation scale towards health-oriented physical activity (MS-PA) contains a total of 18 items. Scoring is rated on 7-point scale (1 = " strongly disagree " and 7 = " strongly agree "). The minimum score = 18 and maximum score = 126. Higher values represent a worse motivation.

[Time Frame: 4 weeks and 6 weeks]

10. Incidence of dance practice on adverse effects: existence of pain and fatigue after each dance class
The pain and fatigue will be measured with numeric rating scale (NRS). The 11-point numeric scale ranges from '0' representing one extreme (e.g. “no pain” or “no fatigue) to '10' representing the other extreme (e.g. “pain as bad as you can imagine” or “worst pain imaginable” or “worst fatigue imaginable”). Scores range from 0-10 points, with higher scores indicating greater pain or fatigue intensity.

[Time Frame: up to 6 weeks (after each dance class)]

11. Level of participant's satisfaction with dance class
Participant satisfaction assessed with an exit survey adapted from a previous study report that investigated dance for a person with chronic stroke. The survey asked participants to rate nine statements about the dance program using a 5-point scale (where 1 = “strongly disagree” and 5 = “strongly agree”). Higher values represent a better satisfaction.

[Time Frame: 6 weeks]

## Eligibility

| | |
|---|---|
| Minimum Age: | 45 Years |
| Maximum Age: | 80 Years |
| Sex: | All |
| Gender Based: | |
| Accepts Healthy Volunteers: | No |
| Criteria: | Inclusion Criteria: |

- Post stroke
- Subacute phase
- Able to endure 60 minutes of physical activity
- Medical stability
- Able to understand the consign

Exclusion Criteria:

- Medical complications
- Hearing disorders
- Previous pathologies associated with balance disorders

## Contacts/Locations


| | |
|---|---|
| Central Contact Person: | Anne-Violette Bruyneel<br>Telephone: +41223883488<br>Email: anne-violette.bruyneel@hesge.ch |
| Central Contact Backup: | Emmanuel Morice<br>Email: emmanuel.morice@yahoo.fr |
| Study Officials: | Anne-Violette Bruyneel<br>Study Principal Investigator |


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Haute Ecole de Santé de Genève (SchoolHSG)

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Lavigny, Vaud, Switzerland, 1175
Contact: Anne Bruyneel +41223883488 anne-violette.bruyneel@hesge.ch
Contact: Emmanuel Morice emmanuel.morice@yahoo.fr

## IPDSharing

Plan to Share IPD: Yes
De-identified individual participant data for all primary and secondary outcome measure will be made available.

Supporting Information:

Time Frame:
Data will be available within 6 months of study completion

Access Criteria:
At the end of the project the data will be deposited in the Yareta repository developed by the University of Geneva OR in an institutional repository. This choice will ensure that data is archived and shared in accordance with FAIR principles.

URL:

## References

Citations: Bruyneel AV. Effects of dance activities on patients with chronic pathologies: scoping review. Heliyon. 2019 Jul 20;5(7):e02104. doi: 10.1016/j.heliyon.2019.e02104. eCollection 2019 Jul. PubMed 31372555

Patterson KK, Wong JS, Nguyen TU, Brooks D. A dance program to improve gait and balance in individuals with chronic stroke: a feasibility study. Top Stroke Rehabil. 2018 Sep;25(6):410-416. doi: 10.1080/10749357.2018.1469714. Epub 2018 May 10. PubMed 29745307

Patterson KK, Wong JS, Prout EC, Brooks D. Dance for the rehabilitation of balance and gait in adults with neurological conditions other than Parkinson's disease: A systematic review. Heliyon. 2018 Mar 29;4(3):e00584. doi: 10.1016/j.heliyon.2018.e00584. eCollection 2018 Mar. Review. PubMed 29862347

Demers M, McKinley P. Feasibility of delivering a dance intervention for subacute stroke in a rehabilitation hospital setting. Int J Environ Res Public Health. 2015 Mar 16;12(3):3120-32. doi: 10.3390/ijerph120303120. PubMed 25785497

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# Clinical Protocol Template for ClinO, Chapter 4 »Other Clinical Trials«

## Protocol Title

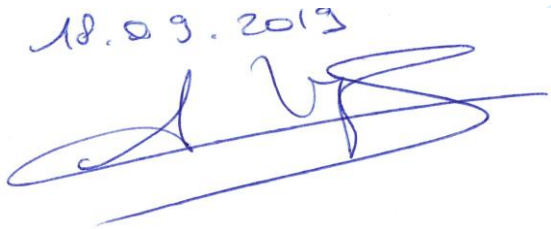
**TITRE :** Danser après un accident vasculaire cérébral (AVC) pour retrouver du plaisir dans le mouvement afin d'améliorer la récupération cognitivo-motrice, la qualité de vie et le bien-être (projet Hemi'danse).

**TITRE COURT :** Danse et récupération après un AVC

Rédactrice : Anne-Violette Bruyneel

Date : 18.09.2019

Version : 2




For peer review only

**TITRE :** Danser après un accident vasculaire cérébral (AVC) pour retrouver du plaisir dans le mouvement afin d'améliorer la récupération cognitivo-motrice, la qualité de vie et le bien-être (projet Hemi'danse).

**TITRE COURT :** Danse et hémiparésie post-AVC

---

| | |
|---|---|
| Study Type: | Other Clinical Trial according to ClinO, Chapter 4 |
| Risk Categorisation: | Risk category A |
| Study Registration: | ClinicalTrials.gov Identifier: NCT04120467 |
| Sponsor: | Anne-Violette Bruyneel<br>Professeure assistante Filière Physiothérapie, Haute école de santé, HES-SO//Haute Ecole Spécialisée de Suisse Occidentale, Genève, Suisse<br>Rue des Caroubiers 25<br>CH- 1227 Carouge<br>Suisse<br>Tél: +33 6 76 58 34 68 / +41 22 388 34 95<br>Anne-violette.bruyneel@hesge.ch |
| Principal Investigator | Anne-Violette Bruyneel<br>Professeure assistante Filière Physiothérapie, Haute école de santé, HES-SO//Haute Ecole Spécialisée de Suisse Occidentale, Genève, Suisse<br>Rue des Caroubiers 25<br>CH- 1227 Carouge<br>Suisse<br>Tél: +33 6 76 58 34 68 / +41 22 388 34 95<br>Anne-violette.bruyneel@hesge.ch |
| Correspondant clinique | Dr Pierre-André Rapin |
| Investigated Intervention: | Evaluation des effets de la danse sur la récupération cognitivo-motrice et la qualité de vie de personnes ayant eu un AVC |
| Protocol ID | HEMIDANSE19-LAV |
| Version and Date: | Version 02 (date 18.09.2019) |

## CONFIDENTIALITY STATEMENT

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Institut de Recherche

## PROTOCOL SIGNATURE FORM

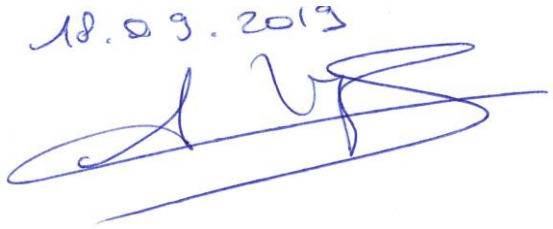
| | |
|---|---|
| Study Title | Danser après un accident vasculaire cérébral (AVC) pour retrouver du plaisir dans le mouvement afin d'améliorer la récupération cognitivo-motrice, la qualité de vie et le bien-être (projet Hemi'danse). |
| Study ID | HEMIDANCE19-LAV |

The Sponsor-Investigator has approved the protocol version 2 (dated 18/09/2019) and confirm hereby to conduct the study according to the protocol, current version of the World Medical Association Declaration of Helsinki, and ICH-GCP guidelines as well as the local legally applicable requirements.

**Sponsor - Investigator:**

Name: *ANNE-VIOLETTE BRUYNEEL*

Date: 18.09.2019 _____ Signature:

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h e d s Haute école de santé Genève Institut de Recherche

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## GLOSSARY OF ABBREVATIONS

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| *AE* | *Adverse Event* |
| *ASR/DSUR* | *Annual Safety Repot / Development Safety Report* |
| *BASEC* | *Business Administration System for Ethical Committees* |
| *CRF* | *Case Report Form* |
| *CTCAE* | *Common Terminology Criteria for Adverse Events* |
| *FADP* | *Federal Act on Data Protection (in German: DSG, in French: LPD, in Italian: LPD)* |
| *eCRF* | *electronic Case Report Form* |
| *FOPH* | *Federal Office of Public Health* |
| *GCP* | *Good Clinical Practice* |
| *HRA* | *Human Research Act (in German: HFG, in French: LRH, in Italian: LRUm)* |
| *ICH* | *International Conference on Harmonisation* |
| *ClinO* | *Ordinance on Clinical Trials in Human Research (in German: KlinV, in French: OClin, in Italian: OSRUm)* |
| *SAE* | *Serious Adverse Event* |

Please expand the list of abbreviations as needed.

SPECIFIC TERMS OF THIS PROJECT:

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| AVC | Accident Vasculaire Cérébral |
| MMSE | Mini Mental State Examination |
| MoCA | Montreal Cognitive Assessment |
| CRF | Case Report Form |
| TUG | Timed Up and Go test |
| ABC-s | Activities-Specific Balance confidence test |
| LEMOCOT | Lower extremity motor coordination-limb motor |
| MIF | Mesure d'indépendance fonctionnelle |
| SS-QOL | Stroke-specific quality of life scale |

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# 1 STUDY SYNOPSIS

| | |
|---|---|
| **Sponsor / Sponsor-Investigator** | Anne-Violette Bruyneel, PhD, Pt, Professeure HEdS, filière physiothérapie. |
| **Study Title** | Danser après un accident vasculaire cérébral (AVC) pour retrouver du plaisir dans le mouvement afin d'améliorer la récupération cognitivo-motrice, la qualité de vie et le bien-être (projet Hemi'danse). |
| **Short Title / Study ID** | Danse et hémiparésie post-AVC (Study number : HEMIDANCE19-LAV) |
| **Protocol Version and Date** | Version 2 (dated 18/09/2019) |
| **Study Registration** | ClinicalTrials.gov Identifier: NCT04120467 |
| **Study Category and Rationale** | Essai clinique de risque A de type „other" |
| **Background and Rationale** | L'accident vasculaire cérébral (AVC) est la première cause de handicap de l'âge adulte. Cette pathologie est de plus en plus fréquente compte-tenu du vieillissement de la population et de l'augmentation des facteurs de risques. La plupart des patients sont atteints d'hémiparésie (troubles sensori-moteurs d'un hémi corps) avec des conséquences fonctionnelles variables pouvant impacter fortement l'autonomie dans les activités quotidiennes. La rééducation est le traitement de choix, évalué comme efficace par la Cochrane pour lutter contre les déficits moteurs et donc la dépendance. La récupération motrice est donc un enjeu essentiel de la stratégie thérapeutique afin d'optimiser les capacités du patient.<br>Les activités physiques et les exercices proposés pour les patients sont souvent très spécifiques, ce qui rend difficile la transposition des capacités développées vers d'autres activités quotidiennes. Or, les procédures d'entraînement naturelles, telles que la danse, ont été montrées comme optimales, car elles sont complexes, intègrent l'entièreté du corps et sont variables au niveau de la demande attentionnelle, cognitive, motrice et sociale. Un apprentissage généralisé est alors favorisé ce qui permet un mouvement plus économique et un transfert des acquisitions plus faciles vers d'autres tâches quotidiennes. De plus, la danse est une activité artistique intrinsèquement motivante, grâce à l'interaction sociale, à la stimulation par la musique, à la joie de bouger malgré les limitations induites par la pathologie et à la perception consciente des bénéfices.<br>La pratique de la danse en complément de la rééducation devrait, grâce à son aspect aérobique (facilitateur de la neuroplasticité), aux mouvements variés et à la motivation, améliorer la récupération cognitive et motrice, la qualité de vie et favoriser la découverte d'une activité faisable après un AVC. |
| **Risk / Benefit Assessment** | **Les risques associés à la participation à l'investigation clinique sont les suivants :**<br>Effets indésirables habituels liés aux tests fonctionnels et d'équilibre (ex. fatigue, déséquilibre, chute,…) ; les mesures de force que nous effectuons durant cette étude peuvent provoquer une fatigue des muscles du tronc ; les cours de danse peuvent induire de la fatigue et des courbatures passagères ; il n'est pas possible d'exclure d'autres risques encore inconnus.<br>Une étude de faisabilité de la pratique de la danse n'a montré aucun effet indésirable de cette pratique pour les patients ayant eu un AVC. Les risques ne sont pas plus élevés que ceux habituellement rencontrés lors des bilans en physiothérapie dans le suivi habituel des patients.<br>**Les avantages associés à la participation à l'investigation clinique sont les** |

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| | **suivants:**<br>Les patients auront l'avantage de participer à une nouvelle activité qui diversifiera leur prise en charge. Celle-ci ne sera pas en concurrence avec la prise en charge rééducative habituelle. |
| **Objective(s)** | **Objectif primaire:**<br>L'objectif primaire est d'évaluer l'effet de la pratique de la danse associée à une prise en charge habituelle sur la récupération cognitivo-motrice des personnes ayant eu un AVC et étant en phase subaiguë, comparé à une prise en charge habituelle seule.<br><br>**Objectifs secondaires:**<br>1) Evaluer l'effet de la pratique de la danse associée à la prise en charge habituelle sur :<br>- La qualité de vie ;<br>- La motivation face à l'activité physique.<br>2) Evaluer la satisfaction et l'adhérence au programme de danse<br><br>**Objectif de sécurité :**<br>Evaluer les effets indésirables éventuels de la pratique de la danse. |
| **Endpoint(s)** | **Primary endpoint:**<br>Evolution de la récupération cognitivo-motrice des personnes en comparant les données « baseline » aux follow-up de 4 semaines et 6 semaines pour les tests d'équilibre, de coordination, de force musculaire, d'échelle de récupération et des tests de cognition. Les données seront comparées à un groupe contrôle (rééducation habituelle seule) à chaque phase.<br><br>**Secondary endpoint:**<br>1) Evolution de la qualité de vie et de la motivation des personnes en comparant les données « baseline » aux follow-up de 4 semaines et 6 semaines grâce à une échelle de qualité de vie, de satisfaction des participants aux cours de danse et de motivation face à l'activité physique.<br>2) Quantification de la satisfaction et de l'adhérence au cours de danse<br><br>**Safety endpoint**:<br>Récolte des événements indésirables lors du programme de danse. |
| **Study Design** | Essai contrôlé randomisé en simple aveugle |
| **Statistical Considerations** | Sample Size :<br>Pour une différence clinique pertinente à 3.5/28 points au miniBest test et un écart type à 3.9, il faut inclure 22 sujets par groupe pour une puissance à 90%. Par sécurité 24 sujets par groupe seront inclus.<br><br>Objectifs statistiques : |

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| | - Vérifier que les deux groupes ont des caractéristiques démographiques et cliniques similaires en début d'étude (baseline);<br>- Vérifier que les patients soient stables en comparant la baseline 1 et la baseline 2;<br>- Comparer les deux groupes à chaque phase de test: baseline 1, baseline 2, follow-up 4 semaines, follow-up 6 semaines;<br>- Comparer pour chaque groupe, la baseline et les deux tests de follow-up.<br><br>Méthode statistique :<br>Des tests non paramétriques de U Mann Whitney, Wilcoxon et Chi2 seront appliqués selon les variables (quantitative / qualitative) et les comparaisons (intra ou inter-groupes). Une valeur de p inférieur à 0.05 sera considérée comme significative. Tous les tests seront réalisés sur le logiciel SPSS®. |
| **Inclusion- / Exclusion Criteria** | Cette étude ne comprend pas la participation de sujets vulnérables selon les critères de la loi LRH.<br><br>Pour être inclus, les sujets doivent avoir entre 45 et 80 ans, avoir eu un AVC il y a moins de 3 mois, présenter une stabilité médicale, être capable de comprendre les consignes, être capable de tenir assis sans aide 30 sec et de tolérer une activité physique modérée pendant 60 minutes.<br>Les sujets seront exclus s'ils refusent de participer, ont des complications médicales importantes, des troubles majeurs de l'audition et si ils ont eu des pathologies préalables affectant l'équilibre, la motricité et la cognition. |
| **Number of Participants with Rationale** | Le nombre de sujets à inclure par groupe a été calculé à partir d'une étude sur les caractéristiques des tests d'équilibre. Le miniBest test a les caractéristiques psychométriques les plus élevées avec un effet plancher et plafond faible ainsi qu'une bonne sensibilité au changement. Pour une différence clinique pertinente à 3.5/28 points et un écart type à 3.9, il faut inclure 22 sujets par groupe pour une puissance à 90%. Pour faire face à d'éventuels désistements, le nombre sera augmenté à 24. |
| **Study Intervention** | Les participants recevront un cours de danse hebdomadaire pendant 6 semaines d'une durée de 60 minutes. La danse en musique (danse contemporaine et sociale) sera axée sur la souplesse, l'équilibre, l'endurance, la fonction des membres, l'interaction entre les danseurs (danse en couple ou en cercle), l'improvisation, la perception et la mémoire. La structure du cours comprendra 5 composantes : échauffement (10 minutes), exercices techniques (10 minutes), improvisation (15 minutes), une courte routine (15 minutes) et une période de récupération - feedback (10 minutes). La danse peut être pratiquée en position assise ou debout selon les capacités des participants. |
| **Control Intervention** | Le groupe contrôle aura de la rééducation conventionnelle comme planifiée habituellement dans l'Institution de Lavigny, c'est-à-dire 45 à 60 minutes de physiothérapie par jour intégrant de la stimulation sensorielle, de l'activation motrice, du renforcement, coordination, équilibre, entrainement à l'effort, etc. en fonction des objectifs mis en place. Les patients ont également 45 à 60 minutes par jour d'ergothérapie. |


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| **Study procedures** | Il y aura des tests cliniques de caractérisation des sujets, puis deux tests de baseline pour tester la stabilité des sujets et deux tests de follow-up à 4 semaines et 6 semaines d'intervention.<br><br>Tests cliniques réalisés : échelle de récupération (Chedoke), de la marche de 10m à vitesse spontanée et rapide, et de la mobilité fonctionnelle (Timed Up and Go Test), de l'équilibre du tronc (trunk control test), d'héminégligence (test des cloches).<br><br>Tests de suivi : douleur au repos et à l'activité (EVA), équilibre (miniBest test), confiance dans l'équilibre (Activities-Specific Balance Confidence test), équilibre unipodal simple et double tâche, coordination (LEMOCOT), force musculaire des membres inférieurs (dynamomètre), mesure d'indépendance fonctionnelle (MIF), Montréal Cognitive Assessment (MoCA), l'échelle de qualité de vie (Stroke-specific quality of life scale), de motivation face à l'activité physique (Echelle de Motivation envers l'Activité Physique en contexte de Santé), évaluation de la satisfaction des participants en 10 questions, de l'adhérence et des effets indésirables. |
| **Study Duration and Schedule** | 2 ans.<br>Première inclusion: décembre 2019<br>Dernière inclusion: septembre 2021 |
| **Investigator(s)** | Anne-Violette Bruyneel<br>Professeure assistante Filière Physiothérapie, Haute école de santé, HESSO//Haute Ecole Spécialisée de Suisse Occidentale, Genève, Suisse<br>Rue des Caroubiers 25<br>CH- 1227 Carouge<br>Suisse<br>Tél: +33 6 76 58 34 68 / +41 22 388 34 95<br>Anne-violette.bruyneel@hesge.ch |
| **Study Center(s)** | Institution de Lavigny<br>Rte du Vignoble 60 –<br>1175 Lavigny<br>Tél. 021 821 46 69 |
| **Data privacy** | Toutes les données humaines seront traitées conformément aux accords de consentement officiels présignés. Toutes les données personnelles seront rendues anonymes par un code de telle sorte qu'il sera impossible d'attribuer des données à des personnes spécifiques.<br>Les transferts de données sensibles seront cryptés de bout en bout et les clés de cryptage seront gérées uniquement par des personnes de l'étude autorisées.<br>Les données seront conservées sous clé pendant une durée de 10 ans. |
| **Ethical consideration** | La scoping review réalisée préalablement à ce projet montre qu'aucune étude de ce type (hormis faisabilité) n'a été réalisée auprès des personnes ayant eu un AVC, alors que la danse a pu être montrée comme particulièrement bénéfique pour les |

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| | pathologies chroniques générant des conséquences cognitive-motrices. Les deux études préalables étaient des études de faisabilité qui ont montré une bonne faisabilité et l'absence d'effets indésirables majeurs.<br>La danse par son aspect social, moteur et cognitif et grâce à sa grande variation d'adaptation devrait être particulièrement bénéfique pour les patients. De plus, c'est l'occasion de proposer de bouger dans la joie et le plaisir du mouvement malgré le handicap. Plusieurs expériences ont été réalisées en Suisse dans les services de rééducation, mais, malgré les retours positifs, aucune étude n'a été menée. Les résultats devraient donc permettre de mieux statuer de l'efficacité et de développer ce type d'approche favorable à un maintien de l'activité en dehors des structures de soins.<br>Aucun sujet vulnérable selon la définition de la loi LRH ne sera inclus dans cette étude. |
| **GCP Statement** | This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP, the HRA as well as other locally relevant legal and regulatory requirements. |

Please only fill out the study synopsis if the finished protocol exceeds the length of 25 pages.

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## 2 BACKGROUND AND RATIONALE

Ce projet a pour objet d'investiguer l'intérêt de la pratique de la danse en centre de rééducation pour des patients présentant une hémiparésie après un accident vasculaire cérébral (AVC). Actuellement, certaines actions isolées de cours de danse pour les patients après un AVC sont menées (ex : Hôpitaux Universitaires de Genève, Institution de Lavigny) avec des retours très positifs, mais, aucune étude n'a été réalisée pour quantifier l'efficacité réelle de la danse dans ce contexte. Au niveau international, seules deux études de faisabilité ont été conduites au Canada.

**Contexte**

L'incidence de l'accident vasculaire cérébral (AVC) est de 296 cas/100'000 personnes en Suisse, avec un risque augmenté à partir de l'âge de 55 ans (Meyer et al., 2009). Cette pathologie, qui résulte de l'interruption de la circulation sanguine dans le cerveau, est la cause la plus fréquente de handicap moteur à l'âge adulte. Deux semaines après l'AVC, 60% des patients ont besoin d'aide pour leurs activités quotidiennes et après 1 an, 43.2% des patients sont très dépendants physiquement (Meyer et al., 2009). En 2008, le coût moyen de traitement était de 31'115CHF la première année, avec une nette augmentation en cas de dépendance (Mahler et al., 2008). Après un AVC, 51% des patients présentent une hémiparésie, qui est la perte plus ou moins complète de la motricité volontaire dans une moitié du corps, le plus souvent du côté opposé à la lésion hémisphérique (Haque and Nasreen, 2008). Une revue Cochrane a montré que la physiothérapie est un traitement efficace pour améliorer la récupération motrice, l'autonomie et le retour à une vie la plus normale possible, mais, les modalités de traitement restent floues (Pollock et al., 2014). Les travaux récents sur les mécanismes de neuroplasticité après un AVC donnent des pistes d'optimisation de traitement, telles que les exercices physiques incluant un travail aérobique ou encore l'intérêt d'un environnement enrichi intégrant concomitamment l'aspect cognitif, moteur et social (Mang et al., 2013; Ploughman, 2002).

Les patients ont des troubles de la sensori-motricité des membres qui induisent une instabilité posturale et une diminution de la motricité fonctionnelle (Brewer et al., 2013). Ces perturbations impactent fortement la santé mentale, l'autonomie et la qualité de vie dans un contexte où les patients ont souvent des perturbations cognitives, des difficultés d'intégration sociale et de la fatigue qui constituent un frein à l'activité physique (Ezeugwu et al., 2017). Cela peut limiter la motivation face à la rééducation et favoriser un comportement sédentaire lors du retour à domicile. Or, les patients qui présentent des pathologies chroniques avec atteintes motrices sont peu sensibilisés aux risques de complications et d'isolement liés à la sédentarité. Dès lors, lorsque la rééducation s'arrête après un AVC, ils sont en général très inactifs, ce qui constitue un comportement favorable aux complications médicales, au surpoids, à l'hypertension, à la dépression ainsi qu'à la perte progressive de l'autonomie et de l'insertion sociale (Ezeugwu et al., 2017). Il est donc nécessaire de trouver des activités qui motivent les patients à bouger pour optimiser la rééducation et pour développer un comportement bénéfique à la santé sur le long terme, d'autant plus que l'offre d'activités physiques à l'attention de ces personnes est assez faible.

L'enjeu est donc de trouver des activités physiques particulièrement adaptées aux patients après un AVC pour favoriser une récupération plus optimale en phase subaigüe et induire du plaisir dans le mouvement malgré le handicap pour favoriser la pratique d'une activité physique régulière dans l'objectif de lutter contre les effets négatifs de la sédentarité dans un contexte de chronicité.

**Intérêts de la danse en cas de pathologies chroniques**

Un intérêt croissant s'est développé récemment pour la pratique des activités artistiques avec les patients. Ces activités sortent du cadre de soin et englobent le bien-être physique, mental et social qui sont les trois dimensions-clés de la santé décrites par l'Organisme Mondial de la Santé (OMS) (WHO 2019).

La danse nécessite la coordination de mouvements intentionnels, exécutés de manière synchronisée avec de la musique et, généralement, d'autres personnes (Murcia et al., 2010). Les


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mouvements incorporent également une valeur créative et esthétique ce qui donne du sens au mouvement. Cet art comporte les avantages d'être universel (pratiqué partout dans le monde), adaptatif (tous les âges, tous les niveaux moteurs), social (relation avec un public ou danse en groupe) et peu coûteux (Schroeder et al., 2017).

La première phase de ce projet a été la réalisation d'une scoping review sur les effets bénéfiques de la danse en cas de pathologies chroniques (Bruyneel, 2019). Cette étude a montré que la danse était particulièrement adaptée aux pathologies chroniques et qu'elle induisait de très nombreux effets bénéfiques au niveau moteur, cognitif, mental et social.

Actuellement, en cas d'AVC, les activités physiques et les exercices proposés sont souvent très spécifiques, ce qui limite la transposition des capacités développées vers d'autres mouvements et activités quotidiennes (Green and Bavelier, 2008). La danse fait partie des procédures d'entraînement dites « naturelles » qui sont optimales car elles intègrent l'ensemble du corps, proposent des activités complexes et sont variables au niveau de la demande attentionnelle, cognitive, motrice et relationnelle. Dès lors, elles favorisent un apprentissage généralisé qui permet non seulement d'obtenir une stratégie de mouvement plus efficiente et économique dans la tâche ciblée, mais également, de transférer les acquisitions dans de nouvelles tâches et de nouveaux contextes (Green and Bavelier, 2008).

Les essais cliniques menés sur les effets de la danse pour d'autres pathologies que l'AVC ont montré que la danse développe les aspects cognitifs, physiques et la qualité de vie, tout en favorisant le bien-être et les interactions sociales (Bruyneel, 2019; Murcia et al., 2010; Schroeder et al., 2017), éléments qui sont concomitamment perturbés par les pathologies chroniques (Ezeugwu et al., 2017). Dès lors, cette activité physique artistique répond à la composante multidimensionnelle de ces troubles. De plus, la joie, la satisfaction et les bénéfices qui sont bien perçus par les pratiquants induisent une augmentation de leur motivation intrinsèque, favorable à leur adhérence (Murcia et al., 2010). L'adaptabilité infinie de la pratique de la danse rend cette activité très accessible car il est possible de couvrir des niveaux moteurs et cognitifs très larges. Tous ces éléments expliqueraient la réussite des programmes de danse auprès des patients.

**Danse et hémiparésie post-AVC**

Patterson et al. et Demers et al. ont mené deux études pilotes qui ont montré une bonne faisabilité et des risques très faibles de la pratique de la danse pour des sujets présentant une hémiparésie post-AVC en phase chronique et subaiguë (Demers and McKinley, 2015; Patterson et al., 2018). La sécurité observée serait liée à la meilleure adaptabilité de la danse aux caractéristiques cognitivo-motrices des patients que celle de nombreuses activités sportives, ainsi qu'à l'auto-régulation des mouvements produits. En effet, même si les mouvements sont structurés, le participant est libre dans les contraintes qu'elle s'impose (amplitudes, force musculaire, déséquilibre, etc.). Dès lors, il est en situation d'auto-contrôle du mouvement, dans un environnement stable (studio de danse), ce qui lui confère une gestion de sa propre sécurité dans l'activité. La danse peut être pratiquée assis ou debout selon les niveaux des participants.

La danse est une activité intrinsèquement motivante, grâce à l'interaction sociale, à la stimulation par la musique, à la joie de bouger malgré les limitations induites par la pathologie et à la perception consciente des bénéfices (Murcia et al., 2010). Dès lors, la mise en place précoce de la danse en complément de la rééducation devrait permettre d'optimiser la récupération grâce à la motivation, mais aussi, par ses caractéristiques très favorables à la neuroplasticité (Ploughman, 2002). En effet, c'est une activité aérobique, avec des sollicitations physiques, cognitives et relationnelles variées et adaptables qui sont des éléments considérés comme essentiels pour favoriser la neuroplasticité (Mang et al., 2013). Cette activité complète devrait donc améliorer la récupération cognitivo-motrice, mais, également la qualité de vie tout en offrant une bonne satisfaction de la pratique de la danse. L'intérêt est de pouvoir également intégrer d'autres personnes proches dans une activité non thérapeutique et de favoriser un lien dans le plaisir de bouger dans une activité différente des soins (Schroeder et al., 2017).

Les physiothérapeutes ont un rôle essentiel à jouer pour motiver les patients à être actif afin de


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favoriser la récupération et la participation des patients, mais également, pour lutter contre la sédentarité à long terme chez les personnes atteintes d'hémiparésie post-AVC.

**Catégorie de risque**

Le risque d'une étude sur l'apport de la danse en cas d'AVC est de catégorie A. En effet, il n'y a pas plus de risque que pour une prise en charge rééducative habituelle après un AVC (Demers and McKinley, 2015; Patterson et al., 2018). De plus, des essais de cours de danse ont été menés avec succès dans le centre de rééducation de Lavigny (centre partenaire).

# 3 STUDY OBJECTIVES AND DESIGN

## 3.1 Hypothesis and primary objective

***Objectif primaire***

L'objectif primaire est d'évaluer l'effet de la pratique de la danse associée à une prise en charge habituelle sur la récupération cognitivo-motrive des personnes ayant eu un AVC (phase subaiguë), comparé à une prise en charge habituelle seule.

→ **Notre hypothèse** est que l'amélioration devrait être observable dans les deux groupes de sujets étant donné qu'ils sont en phase subaiguë, mais, que la danse induirait une meilleure récupération que dans le groupe contrôle, particulièrement pour la coordination et l'équilibre en double tâche.
Cette amélioration serait liée au fait que la danse est une activité dite « naturelle » qui englobe l'entièreté du corps avec une composante physique, sociale et cognitive (tâches complexes), est une activité qui a des caractéristiques favorables à la neuroplasticité et qu'elle induit du plaisir dans le mouvement malgré les déficiences ce qui motive.

***Objectifs secondaires***

1) Evaluer l'effet de la pratique de la danse associée à la prise en charge habituelle sur :

- La qualité de vie ;

  → **Notre hypothèse** est que la danse améliore la qualité de vie en phase subaigüe dès 4 semaines de cours et que cette évolution est plus importante que dans le groupe ne participant pas au cours de danse. L'amélioration de la motivation et la stimulation sociale dans l'activité faciliteraient les activités quotidiennes et le sentiment de bien-être malgré les conséquences de l'AVC.

- La motivation face à l'activité physique.

  → **Notre hypothèse** serait que la danse augmente la motivation face à l'activité physique des patients après un AVC. Cette motivation augmentée serait principalement due au sens du mouvement, aux bénéfices perçus, à la joie que la danse procure et au côté social / interactif entre les participants.

2) Evaluer la satisfaction et l'adhérence au programme de danse

→ **Notre hypothèse** est que la satisfaction des cours est excellente pour cette activité différente des soins et que le taux d'absentéisme est faible pour les cours de danse.

***Objectif de sécurité***

L'étude vise également à vérifier l'absence d'effet indésirable de la danse auprès des sujets ayant une hémiparésie post-AVC en phase subaiguë.

→ **Notre hypothèse** est que la danse n'induit que très peu d'effet indésirable pour les patients présentant une hémiparésie post-AVC.

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## 3.2 Primary and secondary endpoints

**PRIMARY ENDPOINT: récupération cognitivo-motrice**

Evolution intra-groupe :

Comparaison des valeurs obtenues lors de la baseline et du follow-up (4 semaines et 6 semaines) pour :

- Les tests d'équilibre ;
- Les tests de coordination ;
- De force musculaire ;
- D'échelle de récupération ;
- De la cognition.

Comparaisons inter-groupes :

Pour évaluer les différences entre les groupes (danse vs. contrôle) les résultats seront comparés pour chaque test à chaque séquence (baseline, follow-up 4 semaines et follow-up 6 semaines) et l'évolution (delta) sera comparée entre les groupes.

**SECONDARY ENDPOINTS :**

***Qualité de vie et motivation***

Evolution intra-groupe :

Comparaison des valeurs obtenues lors de la baseline et du follow-up pour l'échelle de qualité de vie (6 semaines) et pour la motivation (4 et 6 semaines).

Comparaisons inter-groupes :

Pour évaluer les différences entre les groupes (danse vs. contrôle) les résultats seront comparés pour chaque test à chaque séquence (baseline, follow-up 4 semaines et follow-up 6 semaines) et l'évolution (delta) sera comparée entre les groupes.

***Satisfaction des cours de danse et adhérence***

Pendant toute la durée de l'intervention, l'adhérence sera évaluée et quantifiée (nombre de cours réalisés, nombre d'absences et raisons). Le résultat à un questionnaire de satisfaction de 10 questions permettra d'évaluer la satisfaction des participants sur 50 points.

**SAFETY ENDPOINTS :**

La sécurité des tests sera évaluée selon les variables mesurées suivantes :

- Fatigue (NRS) ;
- Douleur (NRS) ;
- Observation et enregistrement des événements indésirables non prévus.

**FACTEURS DE BASE POUVANT INFUENCER LES RESULTATS :**

Les facteurs des participants pouvant le plus influencer les résultats sont :

- Le niveau cognitif des patients (évalué par le mini mental state évaluation - MMSE pour exclure des patients ayant des troubles cognitifs limitant la compréhension des tests et des consignes des cours de danse) ;
- La stabilité médicale des participants (deux tests de baseline seront réalisés pour nous assurer de la stabilité des participants) ;

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- Les co-morbidités (les critères d'inclusion veillent à éviter l'influence des co-morbidités sur les résultats) ;
- La participation au cours de danse (les données seront traitées en « intention de traiter » et l'adhérence est évaluée) ;
- La motivation (celle-ci sera évaluée par un questionnaire).

Tous les critères d'inclusion et d'exclusion visent à limiter les risques de biais liés aux conditions médicales des participants (voir chapitre recrutement).

## 3.3 Study design

**ORGANISATION GENERALE**

**Type d'étude :** étude randomisée contrôlée monocentrique (figure 1).

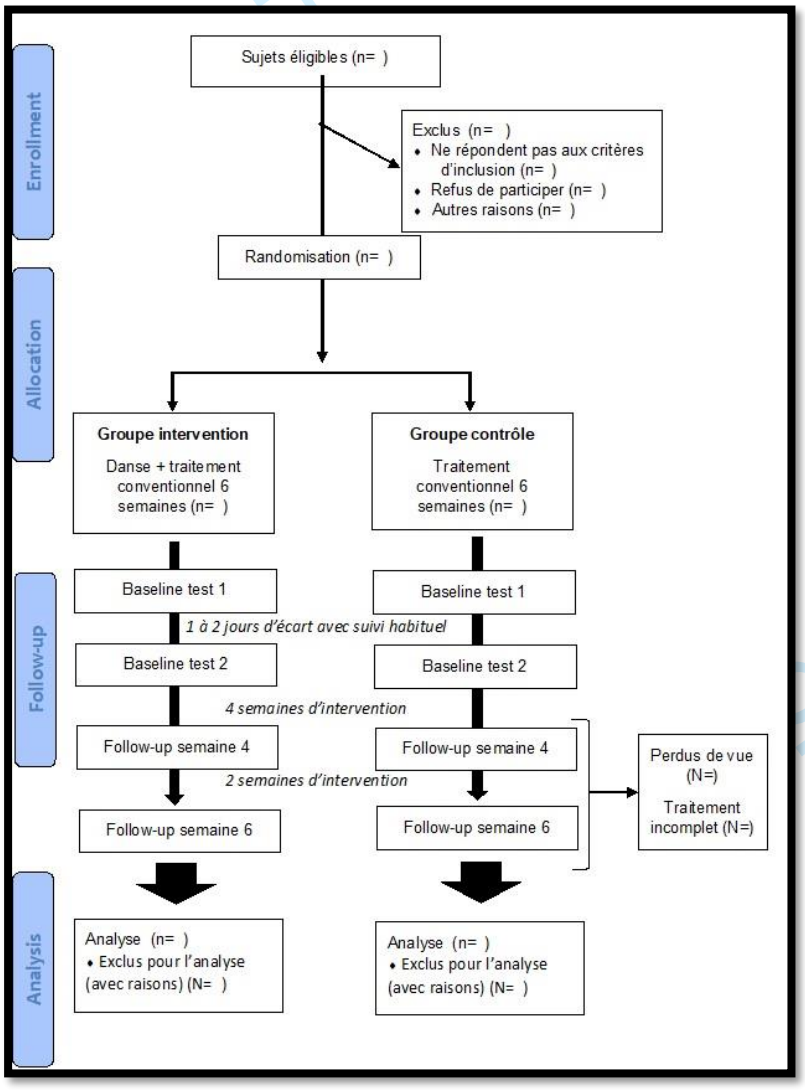


***Figure 1 :*** *schéma expérimental de l'étude*

**Nombre de groupes :** 2 (groupe intervention et groupe contrôle)

**Randomisation :** un tirage au sort sera réalisé en assignation secrète afin de déterminer dans quel groupe va chaque sujet inclus.

**Ordre des tests :** les tests seront réalisés dans un ordre aléatoire afin de contrôler les biais de fatigue et d'apprentissage.

**Durée de l'intervention et de suivi :** 6 semaines.

**Intervention :** danse + traitement conventionnel.

**Contrôle :** traitement conventionnel.

**Aveugle :** l'aveugle sera mis en place pour l'évaluateur.

**Standardisation des tests :** Une phase de pré-tests permettra de réaliser un apprentissage de la procédure par les évaluateurs afin de standardiser les tests. La phase de pré-tests consiste à réaliser quelques tests entre les personnes impliquées dans l'étude pour que la passation soit homogène et vérifiée. C'est l'investigatrice principale qui donnera les consignes et vérifiera la qualité des tests menés par les évaluateurs. Cette phase a pour objectif de limiter les risques de biais liés à la différence de passation entre les évaluateurs.

**Compétence des évaluateurs :** tous les évaluateurs seront des physiothérapeutes. Ils seront 3 physiothérapeutes en charge des évaluations.

**Compétence du professeur de danse :** celui-ci a une compétence double de physiothérapeute et de professeur de danse. Ce point est essentiel pour préserver des cours de danse de qualité conservant les règles de la danse.

**COMPARAISONS**

- Entre les deux tests de baseline pour s'assurer de la stabilité des sujets ;
- Entre les deux groupes à la baseline pour s'assurer que les groupes sont similaires en début d'étude en regard des caractéristiques principales ;
- Entre la baseline et les deux tests de follow-up dans chaque groupe pour tester l'évolution des paramètres ;
- Entre les deux groupes à chaque follow-up et pour les deltas.

**MOYENS POUR MINIMISER LES BIAIS**

**Randomisation:**

La randomisation sera appliquée préalablement à l'expérimentation pour :

1) le tirage au sort du groupe dans lequel le sujet va être assigné (danse vs. contrôle) ;

3) l'ordre des tests de suivi.

L'objectif est de limiter les biais de fatigue et d'apprentissage pour les participants.

*Méthode de randomisation :*

Pour l'attribution des sujets dans les groupes, nous utiliserons une méthode de randomisation par blocs de 4 et de 6. Cette méthode permet d'avoir une répartition équilibrée, y compris si l'étude s'arrête de manière anticipée.

Préalablement à l'expérimentation, des enveloppes opaques scellées seront constituées avec les différentes combinaisons possibles. Un tirage au sort sera effectué par une personne indépendante à l'étude et ne connaissant pas les critères ni les tests.

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**Aveugle:** L'évaluateur sera en aveugle pour la réalisation des tests. Il sera donc différent de la personne qui réalisera les cours de danse pour ne pas savoir quelle est l'attribution du groupe des participants.

**Choix des tests:** Tous les tests choisis sont des « gold standard » et ont des qualités psychométriques suffisantes pour être utilisés dans le contexte de l'AVC.

**Autres procédures pour minimiser les biais :**

- Les examinateurs seront des physiothérapeutes expérimentés en neurologie ;
- Le thérapeute sera un physiothérapeute – danseur ayant une double compétence idéale pour la réalisation de l'intervention ;
- Des pré-tests permettant de prévoir une phase d'apprentissage des tests pour les examinateurs et une standardisation de la procédure seront effectués ;
- Le nombre d'essais pour chaque test a été choisi selon les standards utilisés dans la recherche afin de limiter les biais (compensations, concentration, compréhension des tests, …) ;
- Les critères d'inclusion et d'exclusion ont pour vocation d'homogénéiser les participants et de limiter les autres pathologies pouvant affecter les résultats, afin de favoriser une extrapolation des résultats dans de bonnes conditions ;
- L'intervention et sa structure sont basées sur les études qui ont préalablement montré un effet bénéfique de la danse en cas de pathologie chronique (pour cela, une scoping review publiée a précédé la construction de ce projet).

## 3.4. Study intervention

***Organisation générale***

Les cours de danse seront organisés et dispensés par un physiothérapeute professeur de danse et une personne assistante pour aider les participants. Cette double compétence est favorable à une meilleure adaptabilité des mouvements demandés par rapport au niveau cognitivo-moteur des patients et permet de s'assurer que la danse respecte les règles de cette activité et ne soit pas de la danse-thérapie ou de simples mouvements en musique.

Un cours de danse hebdomadaire sera dispensé auprès des participants sur une durée de 60 minutes pendant une durée de 6 semaines. Lors de ce cours, un proche aura la possibilité de venir participer sur base du volontariat et sans obligation régulière de leur participation.

Le choix de cette durée de 60 minutes une fois par semaine est motivé par :

- Les précédentes études qui ont pu montrer une efficacité de l'apport de la danse en cas de pathologies neurologiques dès 1 séance par semaine de 60 minutes sur l'équilibre [Hashimoto et al. 2015, Shanahan et al. 2015, Duncan et al. 2014, Mc Kee et al. 2013, De Silva Borges et al. 2013);
- La faisabilité en regard de l'organisation du service de rééducation de Lavigny (en effet, cette fréquence correspond à l'organisation actuelle d'une activité physique par semaine différente des séances de rééducation).

De plus, à partir de la littérature existante pour d'autres pathologies, la danse devrait induire du plaisir dans le mouvement qui devrait être favorable à une augmentation de l'activité motrice des patients en dehors des cours de danse. L'impact devrait être donc plus large qu'uniquement lors des séances pratiquées.

***Définition des règles des cours de cours***

Emmanuel Morice sera le thérapeute chargé des cours de danse. Il est physiothérapeute – danseur ce qui assurera la qualité des cours dispensé en sécurité pour les participants. Ce sera le même pour tous les cours et toute la durée du projet.

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Tous les cours de danse se dérouleront en musique.
La structure du cours comprendra cinq composantes : échauffement (10 minutes), exercices techniques (10 minutes), improvisation (15 minutes), une courte routine (15 minutes) et une période de récupération - feedback (10 minutes).
Les exercices de danse viseront la souplesse, l'équilibre, l'endurance, la fonction des membres supérieurs et inférieurs, l'interaction entre les danseurs (danse en couple ou en cercle), la perception (imagerie visuelle et incorporation du côté affecté pour les personnes atteintes d'héminégligeance) et la mémoire.
Le style de danse utilisé pour ce groupe sera une combinaison de danse contemporaine et de danse sociale. En utilisant la chorégraphie ou une courte routine, elle permettra de répéter les pas de danse appris pour favoriser la mémorisation et ajoute le défi supplémentaire de se souvenir d'une séquence de pas.
Les pas de danse montrés par le professeur de danse seront les mêmes pour tous les participants. Cependant, étant donné la grande variabilité des capacités fonctionnelles de chaque participant, la complexité et l'intensité des exercices de danse évolueront en fonction de chaque participant pour atteindre un défi approprié à une intensité de traitement modérée. Tous les pas de danse peuvent être exécutés en position assise ou debout.

***Les règles suivantes seront respectées :***

- La danse sera réalisée en musique car celle-ci facilite le déclenchement du mouvement et induit un travail sur le temps de réaction et la coordination ;
- Les consignes devront inclure la production de mouvements rythmés en musique ;
- La danse sera réalisée en groupe en favorisant l'interaction entre plusieurs personnes ;
- Des mouvements en étant guidé ou en guidant seront intégrés (travail en miroir, créativité gestuelle, …);
- Des mouvements basés sur l'équilibre et la coordination seront inclus ;
- Une sollicitation de la mémoire gestuelle (« retenir une séquence de danse ») sera incluse ;
- Les demandes seront adaptées aux participants (possibilité de danser debout, assis, augmenter la base de support ;
- Selon le niveau moteur des participants, des déplacements spatiaux devront être proposés.

***Contenu des cours***

Chaque cours inclura ces éléments (tableau 1) (Demers and McKinley, 2015; Patterson et al., 2018):

| **Eléments** | **Exemple d'activités** |
|---|---|
| 1. Echauffement | En position assise, travail d'échauffement incluant un éveil musculaire, de la mobilité douce des différents segments et du travail d'équilibre. |
| 2. Activation cardio-respiratoire | Des mouvements improvisés sur une musique rythmée auront pour objectif d'activer le système cardio-respiratoire et de proposer un travail de type aérobique |
| 3. Mouvements chorégraphiques | Apprentissage d'une séquence de mouvements que les danseurs devront reproduire |
| 4. Danse avec partenaire | Les participants devront interagir avec un ou plusieurs partenaires. A tour de rôle, ils devront soit guider et être suivi ou suivre la séquence proposée par un autre danseur |
| 5. Apprentissage de danse existante | Apprentissage de danse comme la danse traditionnelle ou de salon ou sportive… L'intérêt |


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| | |
|---|---|
| | est de travailler principalement la mémoire et la coordination. |
| 6. Récupération | Phase de retour au calme et d'échanges sur la séance. |

Les participants auront tous un suivi habituel de prise en charge post-AVC respectant la démarche habituelle de l'Institution de Lavigny.

# 4 STUDY POPULATION AND STUDY PROCEDURES

## 4.1 Inclusion and exclusion criteria, justification of study population

Le nombre de sujets ciblé sera de 44 participants divisés en deux pour le groupe danse (N=22) et le groupe contrôle (N=22).

***Justification du choix de la population***

La population cible correspond aux patients ayant une hémiparésie post-AVC de 45 à 80 ans. Cette catégorie d'âge est la plus représentée dans le cas de l'AVC et représente donc la typologie de patients qui est la plus présente dans les services de neuro-rééducations. Nous avons mis une limite supérieure à 80 ans afin de limiter les biais liés à l'âge des patients, tout en nous préservant la possibilité d'inclure suffisamment de participants. L'hémiparésie est la conséquence motrice la plus fréquente après un AVC. En choisissant cette population, nous nous assurons de développer un contexte fréquemment rencontré en pratique clinique ce qui facilitera la transposition des résultats dans de bonnes conditions vers les services de rééducation hospitaliers.

Aucune personne vulnérable selon la définition de la LRH ne sera incluse dans ce projet.

***Critères d'inclusion :***

Pour être inclus, les sujets doivent :

- avoir entre 45 et 80 ans ;
- phase subaiguë (AVC max 3 mois avant l'inclusion) ;
- présenter une stabilité médicale ;
- être capable de comprendre les consignes (mini mental state examination – MMSE > 15) ;
- être capable de maintenir la position assise pendant une durée de 30 secondes ;
- être capable de réaliser une activité physique pendant 60 minutes ;
- être capable de donner leur consentement.

Etant donné que la danse peut être pratiquée en position assise ou en position debout, seule la position assise de 30 secondes sera le niveau moteur minimal pour être inclus dans l'étude.

***Critères d'exclusion:***

Les sujets seront exclus si :

- ils refusent de participer ou ont des problèmes de comportement;
- situation médicale empêchant le consentement ;
- ont des complications médicales importantes ;
- ont des contre-indications médicales à l'activité physique ;
- des troubles majeurs de l'audition non corrigeables ;
- ont des difficultés de compréhension des consignes ;

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- si ils ont eu des pathologies préalables affectant l'équilibre, la motricité et la cognition.

Etant donné le risque de femmes enceintes est très faible, mais, si c'était le cas, ce serait un critère d'exclusion.

## 4.2 Recruitment, screening and informed consent procedure

**LIEU DE RECRUTEMENT :**

La population cible correspond aux personnes ayant une hémiparésie post-AVC. Le recrutement sera réalisé à l'Institution de Lavigny (Lavigny, Vaud, Suisse – étude monocentrique) en collaboration avec nos collaborateurs de terrain E. Morice, C. Jenny et J. Moncharmont. Tous les patients seront hospitalisés à Lavigny pendant toute la durée de l'étude, il n'y aura donc pas de frais de déplacement à prévoir.

**PROCEDURE DE RECRUTEMENT :**

Les participants seront identifiés comme potentiellement admissibles par Mr. E. Morice, physiothérapeute du service de neuro-rééducation, à partir des données issues du dossier (date de naissance, date de l'AVC, stade de l'AVC, présence d'une hémiparésie, données cliniques, …) et par A. Reinmann, responsable de l'organisation des tests et du recrutement. Le diagnostic d'hémiparésie post-AVC aura systématiquement été établi par un médecin neurologue à partir de l'imagerie médicale et de l'examen clinique.

Le recrutement sera ensuite procédé de manière consécutive « consecutively recruitement », par E. Morice lors de la présence des patients dans le service.

Les participants seront informés de l'étude (conformément à la lettre d'information) lors d'un premier rendez-vous dans le service de neuro-rééducation. Lors de la phase d'information, la nature de l'étude, son but, les procédures impliquées, la durée prévue, les risques et avantages potentiels et tout inconfort qu'elle peut entraîner sera expliqué à chaque personne. Chaque personne sera informée que sa participation à l'étude est volontaire et qu'elle peut se retirer de l'étude à tout moment et que le retrait du consentement n'affectera pas son assistance médicale et son traitement ultérieur. La personne sera informée que son dossier médical peut être examiné par des personnes autorisées autres que son médecin traitant, mais, directement associée au projet de recherche.

Toutes les personnes contactées pour l'étude recevront un feuillet d'information et un formulaire de consentement décrivant l'étude et fournissant suffisamment d'information pour permettre aux participants de prendre une décision éclairée quant à leur participation à l'étude.

Le délai de réflexion pour la décision des participants sera d'une journée.

La personne devra lire et examiner la déclaration avant de signer et de dater le formulaire de consentement éclairé. Le participant recevra une copie du consentement signé et daté par lui-même et par l'investigateur (ou son représentant). Un autre exemplaire sera conservé dans le dossier de l'étude.

Ce consentement formel d'un participant, au moyen du formulaire de consentement approuvé, devra être obtenu avant que le participant ne soit soumis à toute procédure d'étude.

Aucune compensation financière n'est prévue pour la participation à l'étude.

***Tests cliniques d'inclusion:***

1. *Données démographiques*

Afin de connaitre les caractéristiques démographiques d'inclusion, à partir du dossier médical seront relevés : l'âge, le sexe, le type d'AVC, les zones atteintes, le côté de l'AVC, les antécédents médicaux et les moyens diagnostics (imagerie) et la profession.

2. *Maintien de la position assise indépendante pendant 30s*

Le participant sera placé sur une chaise en position assise. Il devra être capable de maintenir la position pendant une durée de 30s sans aide (Jung et al., 2014).

3. *Capacité à réaliser une activité physique modérée pendant 60 minutes*

Les patients étant pris en charge en interne dans le centre de rééducation, des séances de physiothérapie d'une durée de 60 minutes font partie de la prise en charge de base des patients. De ce fait, les physiothérapeutes référents nous indiquerons si les patients cibles sont capables de supporter une activité modérée de 60 minutes (Demers and McKinley, 2015; Patterson et al., 2018).

4. *Mini Mental State Examination (MMSE)*

Le MMSE, validé en français pour les patients âgés, évalue les capacités cognitives à partir de questions et d'actions testant l'orientation, l'apprentissage, l'attention, le calcul et le langage. Les participants devront avoir un score supérieur à 15 pour être inclus (Faria et al., 2016). Cela permet de s'assurer qu'ils ont la capacité de comprendre les consignes.

**PROCEDURE DE CONSENTEMENT ECLAIRE:**

Les chercheurs expliqueront à chaque personne la nature de l'étude, son but, les procédures à suivre, la durée prévue, les risques et les avantages potentiels et tout inconfort qu'elle peut entraîner. Chaque personne sera informée que sa participation à l'étude est volontaire et qu'il peut se retirer de l'étude à tout moment et que le retrait de son consentement n'affectera pas son assistance médicale et son traitement ultérieur.

La personne sera informée que son dossier médical peut être examiné par des personnes autorisées autres que son médecin traitant.

Toutes les personnes à l'étude recevront un feuillet d'information et un formulaire de consentement décrivant l'étude et fournissant suffisamment d'information pour leur permettre de prendre une décision éclairée quant à leur participation à l'étude. Chaque personne aura une journée pour décider de sa participation ou non à l'essai.

Le consentement formel d'un participant, au moyen du formulaire de consentement approuvé, sera obtenu avant que le participant ne soit soumis à toute procédure d'étude.

Le formulaire de consentement sera signé et daté par l'investigateur ou son représentant en même temps que la signature du participant. Une copie du consentement éclairé signé sera remise au participant à l'étude. Le formulaire de consentement sera conservé dans les dossiers de l'étude. Le processus de consentement éclairé doit être documenté dans le dossier du patient et tout écart par rapport au processus décrit dans le protocole doit être expliqué.

## 4.3 Study procedures

**CALENDRIER GLOBAL DE L'ETUDE (figure 2) :**

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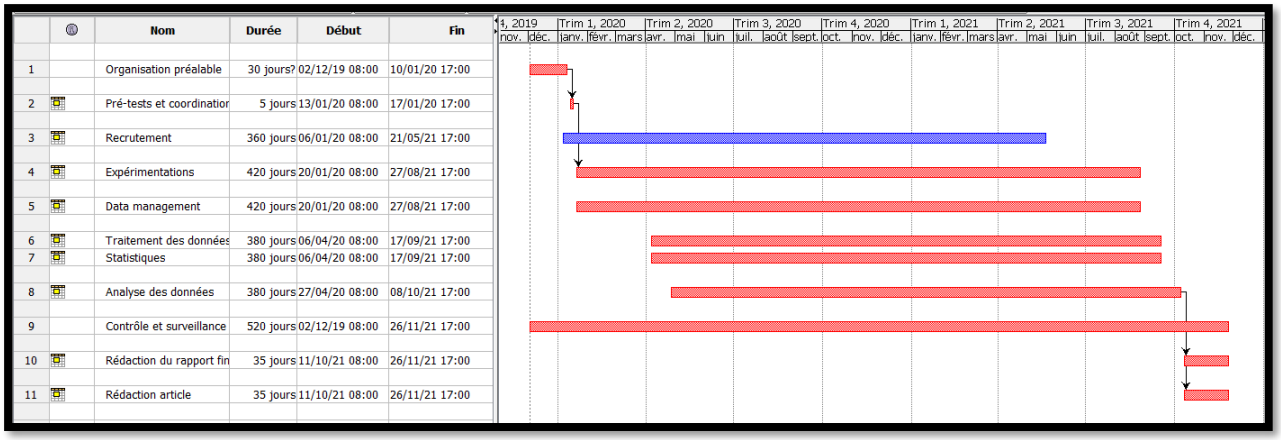


***Figure 2:*** *calendrier global de l'étude.*

**PROCEDURE POUR CHAQUE VISITE :**

| **Study Periods** | **Information** | **Screening** | **Observation period** | | **Follow-up** | |
|---|---|---|---|---|---|---|
| Visit | | | Baseline 1 | Baseline 2 | 4 weeks | 6 weeks |
| Time (hour) | -48h | -24h | 0h | +24h / max 24h | | |
| Oral and written patient information | x | | | | | |
| Written Consent | | x | | | | |
| Demographics | | x | | | | |
| Medical History | | x | | | | |
| In- /Exclusion Criteria | | x | x | | | |
| Physical Examination | | x | x | | | |
| Clinical tests for inclusion (30s sitting, MMSE; 60min physical activity) | | x | | | | |
| Clinical test for characterization (Chedoke, gait 10m, TUG, trunk control test, bells test) | | | x | | | x |
| Motor and balance tests (miniBest test, balance, activities-Specific Balance confidence test, LEMOCOT, muscular strength, MIF) | | | x | x | x | x |
| Cognitive test (Montreal Cognitive Assessment) | | | x | x | | x |
| Quality of life (Stroke-specific quality of life scale) | | | x | | | x |

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| | | | | | | |
|---|---|---|---|---|---|---|
| Motivation | | | x | | x | x |
| Dance satisfaction | | | | | | x |
| Pain and fatigue during dance | | | | x | x | x |
| Adverse Events | | x | x | x | x | x |
| Film | | | | | | x |

***Tableau 1 :*** *procédure des tests par participant.*

***Visite 1 « screening » :***

Tout d'abord les patients pouvant être potentiellement inclus seront repérés à partir du dossier médical. Ensuite ils auront une visite de recrutement (-24h).

Les éléments nécessaires au recrutement sont :

- Détails personnels (age, sexe) ;

- Histoire médicale (taille, poids, date de l'AVC, localisation de l'AVC, type d'AVC, situation médicale stable, antécédents) ;

- Mini-Mental State Evaluation (MMSE);

- Position assise stable 30s sans aide ;

- Tolérance à une activité modérée pendant 60min ;

- Expérience antérieure avec la danse.

Identification de l'éligibilité du patient. Si oui, organisation de la date et l'heure de la visite baseline 1.

***Baseline 1 :***

- Tests cliniques de caractérisation des participants : Chedoke, marche sur 10m à vitesse normale et à vitesse rapide, timed up and go test, trunk control test, test de barrage des cloches.
- Tests moteurs : miniBest test, équilibre en simple et double tâches, activities-Specific Balance confidence test, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF)
- Test cognitive: Montreal Cognitive Assessment
- Qualité de vie : Stroke-specific quality of life scale
- Motivation face à l'activité : Echelle de Motivation envers l'Activité Physique en contexte de Santé

***Repos :*** 24 à 48h

***Baseline 2 :***

Les tests réalisés seront identiques à la session « baseline 1 » afin d'évaluer la stabilité des sujets, excepté pour l'échelle de qualité de vie et de motivation face à l'activité.

***Evaluation de la fatigue et de la douleur lors des cours de danse***

Une évaluation de la fatigue et de la douleur sera réalisée par numeric rate scale après chaque cours de danse.

***Follow-up 4 semaines :***

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- Tests moteurs : miniBest test, équilibre en simple et double tâches, activities-Specific Balance confidence test, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF)
- Motivation face à l'activité : Echelle de Motivation envers l'Activité Physique en contexte de Santé

***Follow-up 6 semaines :***

- Tests cliniques de caractérisation des participants : Chedoke, marche sur 10m à vitesse normale et à vitesse rapide, timed up and go test, trunk control test, test de barrage des cloches.
- Tests moteurs : miniBest test, équilibre en simple et double tâches, activities-Specific Balance confidence test, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF)
- Test cognitive: Montreal Cognitive Assessment
- Qualité de vie : Stroke-specific quality of life scale
- Motivation face à l'activité : Echelle de Motivation envers l'Activité Physique en contexte de Santé
- Satisfaction par rapport aux cours de danse (questionnaire de Patterson)
- Douleur et fatigue lors des cours de danse

## DUREE ESTIMEE DE CHAQUE PHASE POUR LES PARTICIPANTS :

| *Phase* | *Tests* | *Durées* | *Total* |
|---|---|---|---|
| Examen clinique | Test cognitif (MMSE) | 10 minutes | 10 minutes |
| | Test d'équilibre assis 30s | | |
| Baseline 1 | Chedoke, marche sur 10m à vitesse normale et à vitesse rapide, timed up and go test, trunk control test, test de barrage des cloches. | 20 minutes | 1h50 minutes |
| | Repos | 10 minutes | |
| | miniBest test, équilibre en simple et double tâches, activities-Specific Balance confidence test, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF) | 50 minutes | |
| | Repos | 10 minutes | |
| | Montreal Cognitive Assessment | 20 minutes | |
| | Stroke-specific quality of life scale | | |
| | Echelle de Motivation envers l'Activité Physique en contexte de Santé | | |
| Baseline 2 | miniBest test, équilibre en simple et double tâches, activities-Specific Balance confidence test, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF) | 45 minutes | 55 minutes |
| | Montreal Cognitive Assessment | 10 minutes | |
| Follow-up 4 semaines | miniBest test, équilibre en simple et double tâches, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF) | 45 minutes | 1h05 minutes |
| | Repos | 10 minutes | |
| | Activities-Specific Balance confidence test | 10 minutes | |
| | Echelle de Motivation envers l'Activité Physique en contexte de Santé | | |
| Follow-up 6 semaines | Chedoke, marche sur 10m à vitesse normale et à vitesse rapide, timed up | 20 minutes | 1h55 |

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| | | | |
|---|---|---|---|
| | and go test, trunk control test, barrage des cloches. | | |
| | Repos | 10 minutes | |
| | miniBest test, équilibre en simple et double tâches, activities-Specific Balance confidence test, LEMOCOT, force musculaire et mesure d'indépendance fonctionnelle (MIF) | 50 minutes | |
| | Repos | 10 minutes | |
| | Montreal Cognitive Assessment | 25 minutes | |
| | Stroke-specific quality of life scale | | |
| | Echelle de Motivation envers l'Activité Physique en contexte de Santé | | |
| | Satisfaction des cours de danse | | |

***Tableau 2:*** *tableau synthétique du déroulement et durées estimées pour les patients*

## BIAIS ATTENDUS LIES AUX TESTS ET PROCÉDURES GÉNÉRALES FAVORISANT LA QUALITÉ DES TESTS:

1. Biais attendus :

- Compétence des évaluateurs ;
- Compétence du thérapeute pour pratiquer les cours de danse ;
- Fatigabilité des participants ;
- Mauvaise standardisation du dispositif (procédure différente, apprentissage, …) ;
- Apprentissage/ fatigue des participants lors des tests ;
- Mauvais choix des tests cibles ;
- Faisabilité de la danse pour les personnes après un AVC.

2. Actions pour limiter les biais :

- Caractéristiques des évaluateurs : Pour être inclus, les évaluateurs devront être physiothérapeutes, avec une expérience clinique avérée auprès des patients présentant une hémiparésie post-AVC. Des pré-tests seront réalisés afin de s'assurer que les évaluateurs maitrisent la procédure des tests préalablement à la phase expérimentale.

- Caractéristique du thérapeute : Le thérapeute a une compétence double de physiothérapeute et de danseur ce qui permet de s'assurer que les cours de danse respectent bien les standards de la danse et son correctement adaptés au contexte clinique.

- La fatigue sera évaluée entre les tests par l'échelle NRS. En cas de fatigue, un plus long temps de repos sera respecté.

- Pré-tests : Standardisation du dispositif : préalablement à l'expérimentation, des pré-tests seront réalisés pour tester le protocole dans le milieu clinique et pour organiser le dispositif expérimental (repères, cahier de manipulation, disponibilité des salles, installation du matériel, organisation du lieu, …) afin d'obtenir une standardisation de ce dispositif, préparer le stockage des fichiers brutes et pré-remplir un tableau .xls avec les formules pré-encodées. Cette phase de rodage a pour objectif de développer une procédure systématique et d'éviter le risque d'erreurs.

- Effet d'apprentissage / fatigue lors des tests pour les patients : la procédure décrite comme référence dans la littérature sera parfaitement respectée, y compris pour le nombre d'essais à réaliser et sera


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similaire pour chaque passation.

- Choix des tests : Pour les tests cibles nous avons pris des tests qui ont montré de bonnes qualités psychométriques et qui ont déjà été utilisés pour des patients présentant une hémiparésie post-AVC.

- La danse pour les personnes ayant eu un AVC a déjà été l'objet d'une étude de faisabilité en centre de rééducation et les résultats de faisabilité étaient très bons (Demers and McKinley, 2015; Patterson et al., 2018).

## DESCRIPTION DES TESTS

### DESCRIPTION DE LA PROCEDURE DES TESTS CLINIQUES D'INCLUSION

*Mini Mental State Examination*

Le MMSE, validé en français pour les patients âgés, évalue les capacités cognitives à partir de questions et d'actions testant l'orientation, l'apprentissage, l'attention, le calcul et le langage. Les participants devront avoir un score supérieur à 15 pour être inclus (Faria et al., 2016). Nous avons pris ce test pour l'inclusion car il est simple et le niveau seuil de compréhension est bien décrit. En revanche, il est moins sensible au changement que la Montreal Cognitive Assessement (MoCA), c'est pourquoi pour le suivi ce sera cette échelle qui sera utilisée (Toglia et al., 2011; Van Heugten et al., 2015).

Procédure détaillée :

http://www.sgca.fr/outils/mms.pdf

Risque/limite : trouble aphasique ne permettant pas de réaliser le test.

*Test d'équilibre assis 30s*

Le participant sera placé sur une chaise en position assise, pieds au sol. Il devra être capable de maintenir la position pendant une durée de 30s sans aide (Jung et al., 2014). C'est ce critère qui a été retenu pour une étude avec des mouvements du tronc en position assise (Jung et al., 2014).

Risque/limite : Incapacité du patient à tenir la position. En cas de déséquilibre, le physiothérapeute sera à côté du participant pour le sécuriser.

*Evaluation de la tolérance physique à l'activité*

Le niveau de tolérance à une activité physique sera évalué pour une durée de 60 minutes dans le cadre de la prise en charge rééducative habituelle (Demers and McKinley, 2015; Patterson et al., 2018).

Risque/limite : aucun car l'effort visé est modéré et que le patient peut s'arrêter à tout moment pour récupérer.

### DESCRIPTION DE LA PROCEDURE DES TESTS CLINIQUES DE CARACTERISATION

*Evaluation du niveau de récupération – Chedoke Mc Master Stroke Assessment*

Le niveau de récupération sera évalué au moyen de l'échelle de *Chedoke Mc Master Stroke Assessment* (Gowland et al., 1993) qui est un inventaire des déficiences, pour la jambe et le pied. Le niveau moteur est évalué successivement sur le dos genoux fléchis, en position assise puis debout selon 7 stades de récupération motrice. La reproductibilité inter-évaluateurs est excellente (Won and Kim, 1997).

Procédure détaillée :


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https://www.strokengine.ca/fr/assess/chedoke-mcmaster-stroke-assessment/

| STADE | D/G | JAMBE | D/G | PIED |
|---|---|---|---|---|
| 1 | | Stade 2 non-atteint | | Stade 2 non-atteint |
| 2 | **Sur le dos genoux fléchis** | Résistance à la flexion passive de la hanche ou de genou | **Sur le dos genoux fléchis** | Résistance à la flexion dorsale passive |
| | | Flexion de hanche avec facilitation | | Flexion dorsale ou extension des orteils avec facilitation |
| | | Extension avec facilitation | | Flexion plantaire avec facilitation |
| 3 | | Abduction: abduction à neutre | **Sur le dos** | Flexion plantaire > ½ amplitude |
| | | Flexion de hanche à 90° | **Assis** | Un peu de flexion dorsale |
| | | Extension complète | | Extension des orteils |
| 4 | | Flexion de hanche à 90° puis synergie d'extension | | Un peu d'éversion |
| | | Pont avec mise en charge égale | | Inversion |
| | **Assis** | Flexion du genou au-delà de 100° | | Jambes croisées: flexion dorsale puis flexion plantaire |
| 5 | **Sur le dos genoux fléchis** | Synergie d'extension puis synergie de flexion | | Jambes croisées: extension des orteils avec flexion plantaire de la cheville |
| | **Assis** | Soulever la cuisse du lit | | Assis avec genou étendu: flexion plantaire de la cheville puis flexion dorsale |
| | **Debout** | Extension de la hanche avec flexion du genou | **Debout** | Talon au sol: éversion |
| 6 | **Assis** | Soulever le pied du sol 5x en 5 sec | | Talon au sol: taper du pied 5x en 5 sec |
| | | Rotation interne d'amplitude complète | | Pied non-appuyé: circumduction du pied |
| | **Debout** | Tracer une figure: devant, de côté, derrière, retour | | Genou en extension, talon non-appuyé : éversion |
| 7 | **Debout** | Sans appui: marche rapide sur place, 10x en 5 sec | | Talon touchant devant puis orteils touchant derrière, répéter 5x en 10 sec |
| | | Sans appui: tracer une figure rapidement: devant, de côté, derrière, retour | | Pied non- appuyé: circumduction rapide, inversion |
| | | Sur jambe faible avec léger appui : sauter sur la jambe faible | | Sur la pointe des pieds puis sur les talons, 5x |
| | | **STADE DE LA JAMBE** | | **STADE DU PIED** |

Date Date

***Figure 3 :*** *Echelle Chedoke Mc Master (jambe et pied).*

Risque/limite : déséquilibre ou incapacité à maintenir une position. Le physiothérapeute sera présent pour sécuriser le participant.

*Vitesse de marche sur 10m à vitesse spontanée et rapide*

La durée de marche sur 10m est évaluée à vitesse spontanée (s) et rapide (s) (Nascimento et al., 2012). L'évaluateur donnera pour la vitesse rapide comme consignes « d'aller le plus vite possible » et il fera une démonstration au sujet. L'aide ambulatoire est autorisée, mais, notée dans le case report form. Deux essais sont réalisés par condition et la vitesse moyenne est calculée. La reproductibilité intra et inter-évaluateurs du test est excellente en cas d'AVC (Hutin et al., 2018).

Risque/limite : Pour éviter les risques de déséquilibres, l'aide ambulatoire est autorisée et l'évaluateur sera à côté du participant.

*Timed Up and Go test (TUG)*

Le *Timed Up and Go (TUG) Test* sera utilisé pour évaluer la mobilité fonctionnelle des participants. Le participant est assis sur une chaise, il se lève, marche 3m, réalise un demi-tour dans $1m^2$, re-marche 3m et revient s'asseoir sur la chaise. La durée (s) pour réaliser la tâche est mesurée. Ce test a une bonne fiabilité en cas d'hémiparésie (Chan et al., 2017).

Risque/limite : L'aide ambulatoire est autorisée et le participant sera sécurisé par le physiothérapeute qui sera à côté de lui.


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*Trunk control test*

Le trunk control test consiste à évaluer les capacités motrices des sujets en position assise. Quatre items sont évalués : rouler vers le côté faible, rouler vers le côté fort, tester l'équilibre assis au bord du lit et passer de la position couchée à assise. Chaque item est évalué de 0 à 25 points. 0= pas capable de réaliser le mouvement sans assistance, 12 = capable de réaliser le mouvement avec une aide non musculaire ou dans un style anormal et il se sert des membres supérieurs pour se stabiliser en position assise, 25= capable de réaliser le mouvement normalement.

*Test d'héminégligence du barrage des cloches*

Ce test mesure la négligence spatiale unilatérale. Une feuille avec des dessins est placée devant le sujet sur la ligne médiane. Dans les dessins, il y a des cloches. Le sujet doit les entourer une à une. Le nombre de cloches sur 35 est relevé, ainsi que le nombre d'oublis à droite et à gauche et la durée de réalisation du test. L'évaluateur fait une démonstration préalable au test.

*Expérience antérieure de la danse*

Nous utiliserons le questionnaire de Patterson et al. pour évaluer l'expérience antérieure de danse des participants.

**DESCRIPTION DE LA PROCEDURE DES TESTS MOTEURS DE SUIVI**

*Mini-Best test*

*L'équilibre* sera mesuré par le mini-BESTest (score sur 28 points), car ce test a d'excellentes qualités psychométriques (Godi et al., 2013). Ce test a déjà été utilisé pour évaluer l'impact de la danse sur l'équilibre, mais pour des sujets en phase chronique (Patterson et al., 2018).
La procédure consiste à évaluer successivement des tâches d'ajustements posturaux anticipatoires (assis à debout, monter sur la pointe des pieds, se tenir sur une jambe) et du contrôle postural réactif (stratégie de pas compensatoire antérieur, postérieur et latéral).

Procédure détaillée :

https://readaptation.umontreal.ca/wp-content/uploads/sites/21/2018/05/MiniBEST_CC_V7-1.pdf

Risque/limite : Déséquilibre lors des tâches. Le participant sera sécurisé par le physiothérapeute qui sera à côté de lui.

*Equilibre en simple et double tâche*

Etant donné que la danse est une activité qui sollicite concomitamment plusieurs aspects moteurs et cognitifs, et que cet entrainement en double/triple tâche a pu montrer des effets bénéfiques pour les personnes après un AVC (Song and Park, 2015), nous testerons l'équilibre simple et l'équilibre en double tâche.

Le participant sera en position bipodale pendant une durée de 30s yeux ouverts. Pour la double tâche, il devra composer un numéro de téléphone sur le smartphone (Laatar et al., 2017). L'équilibre sera enregistré par les données gyroscopiques et accélérométriques d'un smartphone positionné au niveau du bassin du sujet (aucun contact direct avec le sujet car il sera sur une ceinture ajustable prévue à cet effet). Des études ont pu montrer que les applications sur smartphone basé sur ces capteurs pour évaluer l'équilibre étaient utilisables en pratique clinique, fiables et permettait de discriminer correctement une situation stable et instable (Moral-Munoz JA et al., 2018 ; Patterson et al., 2014 ; Marinsek et al., 2014 ; Hsieh et al. 2019). Seul le code du sujet sera entré sur l'application ce qui évitera tout problème d'anonymat. Les données brutes seront extraites et seront ensuite traitées par le logiciel Matlab.

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Deux essais sont réalisés par condition.

Risque/limite : Le participant sera sécurisé par le physiothérapeute qui sera à côté de lui.

*Activities-Specific Balance confidence test* (ABC-s)

La confiance des sujets dans leur équilibre sera évaluée car il semble que ce soit un déterminant important pour les patterns de marche adoptés par le sujet après un AVC (Park et al., 2018). De plus, la danse étant en auto-organisation du mouvement et de l'équilibre devrait améliorer cet aspect. Cette échelle donne une bonne indication de la confiance des patients dans leur équilibre lors de plusieurs tâches quotidiennes et elle semble être un prédicteur du risque de chutes (Cleary and Skornyakov, 2017).

L'ABC-s (version simplifiée de l'ABC) proposée par l'institut universitaire de gériatrie de Montréal sera utilisée. L'échelle comprend 15 items de tâches quotidiennes qui sont notés de 0 (pas confiant) à 3 (très confiant). Le score total est de 45 points ramenés en pourcentage.

Procédure détaillée :

http://www.criugm.qc.ca/fr/la-recherche/outilscliniques/188-activities-specific-balance-confidence-abc-scale.html

Risque/limite : pour toutes les échelles, il faut bien vérifier à ce que le participant ait ses lunettes. L'évaluateur aidera le participant en accord avec les règles de passation.

*LEMOCOT*

La coordination des membres inférieurs sera testée par le test *lower extremity motor coordination-limb motor* (LEMOCOT) qui a pu montrer de bonnes qualités psychométriques dans le contexte de l'AVC (de Menezes et al., 2015).

Le participant est en position assise avec une cible de 6cm de diamètre à 30cm du gros orteil. En 20s, le participant doit toucher le plus souvent possible la cible du côté non parétique puis du côté parétique. La dysmétrie est notée ainsi que les tremblements lors du mouvement avec une notation de 0 à 3.

Deux essais sont réalisés par condition.

Risque/limite : Le risque pour ce test est très faible, toutefois le physiothérapeute sera à côté du participant pour éventuellement le stabiliser.

*Force musculaire du quadriceps*

La force musculaire des extenseurs du quadriceps sera mesurée par un dynamomètre à pression. En effet, ce groupe musculaire représente très bien la force des autres muscles du membre inférieur en cas d'AVC (Aguiar et al., 2019).

Le participant sera en position assise, pieds libres. Le dynamomètre à pression sera placé sur la face antérieure de la partie distale de la jambe. L'évaluateur sera bras tendu perpendiculaire à la jambe. Le participant exerce une pression maximale sur le dynamomètre pendant 5s. Trois essais seront réalisés pour le côté non parétique et parétique.

Risque/limite : le risque est une douleur à l'appui du dynamomètre à pression. Celle-ci sera évaluée à chaque essai.

*Mesure d'indépendance fonctionnelle (MIF)*

La MIF permet d'évaluer le niveau fonctionnel et le niveau de récupération des sujets dans les activités quotidiennes pour les soins personnels, la mobilité et les transferts, la locomotion, la communication et la conscience du monde extérieur. La notation pour chaque item va de 2 à 7. Si un élément n'est pas vérifiable il faut cocher 1. Les qualités psychométriques de la MIF sont excellentes (Hsueh et al., 2002).

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Etant donné que cette mesure est basée sur les activités quotidiennes, elle ne comprend pas plus de risque que les activités habituelles du sujet.

Procédure détaillée :

http://fr.scale-library.com/pdf/Mesure_independance_Fonctionnelle_MIF.pdf

Risque/limite : aucun.

**DESCRIPTION DE LA PROCEDURE DU TEST COGNITIF**

L'échelle MoCA sera utilisée car elle a montré une bonne sensibilité au changement en cas d'AVC (Toglia et al., 2011). Elle a été conçue pour évaluer des dysfonctions cognitives au travers de : l'attention, la concentration, les fonctions exécutives, la mémoire, le langage, les capacités visuoconstructives, les capacités d'abstraction, le calcul et l'orientation. Le temps d'exécution est de dix minutes approximativement. Le nombre de points maximum est de 30 ; un score de 26 et plus est considéré normal.

Procédure détaillée :

https://www.strokengine.ca/fr/quick/tableau-synthese-de-la-montreal-cognitive-assessment-moca/

Risque/limite : pour toutes les échelles, il faut bien vérifier que le participant ait ses lunettes. L'évaluateur aidera le participant en accord avec les règles de passation.

**DESCRIPTION DE LA PROCEDURE DE L'EVALUATION DE LA QUALITE DE VIE**

La qualité de vie sera évaluée par la Stroke-specific quality of life scale (SS-QOL) qui est adaptée à la phase subaiguë et qui est validée en français (Legris et al., 2018). Cette échelle auto-administrée évalue l'énergie, le rôle familial, le langage, la mobilité, la motivation, la personnalité, les soins, le rôle social, la concentration, la fonction des membres supérieurs, la vision et le travail/productivité. Chaque item est noté de 1 (aide complète) à 5 (pas besoin d'aide).

L'échelle a été validée en français (Legris et al., 2018).

Risque/limite : pour toutes les échelles, il faut bien vérifier que le participant ait ses lunettes. L'évaluateur aidera le participant en accord avec les règles de passation.

**DESCRIPTION DE LA PROCEDURE DE L'EVALUATION DE LA MOTIVATION FACE A L'ACTIVITE PHYSIQUE**

Une *Echelle de Motivation envers l'Activité Physique en contexte de Santé* sera utilisée. Celle-ci a été validée en français pour des personnes âgées (Boiché et al., 2019). Elle consiste à évaluer la motivation intrinsèque, la régulation intégrée, la régulation identifiée, la régulation projetée, la régulation externe et l'a-motivation. Pour chaque item, il y a trois réponses possibles (score sur 18 items).

Risque/limite : pour toutes les échelles, il faut bien vérifier que le participant ait ses lunettes. L'évaluateur aidera le participant en accord avec les règles de passation.

**DESCRIPTION DE LA PROCEDURE DES TESTS DE DOULEUR ET DE FATIGUE PENDANT LES COURS DE DANSE**

Le participant évaluera son niveau de fatigue musculaire sur une échelle visuelle numérique graduée entre 0 et 10 (Moumdjian et al., 2018). Il répondra à la question suivante : « quelle est votre niveau de fatigue musculaire au niveau des membres inférieurs ? 0 correspond à aucune fatigue musculaire et 10 correspond à une fatigue musculaire maximale. Le test sera réalisé à chaque fin de cours de danse.

La douleur sera également testée sur le même principe en utilisant une échelle visuelle numérique. Toutefois, en cas de douleur, le participant devra préciser la localisation de celle-ci.


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Risque/limite : aucun.

## DESCRIPTION DE LA PROCEDURE DE L'EVALUATION DE LA SATISACTION DES COURS DE DANSE

La satisfaction pour le programme de danse sera évaluée par le questionnaire de Patterson et al., basé sur 10 questions (figure 4) (Patterson et al., 2018). Celui-ci sera traduit en français de manière libre, mais, il est à noter que ce questionnaire n'a pas de processus d'évaluation psychométrique.

Risque/limite : pour toutes les échelles, il faut bien vérifier que le participant à ses lunettes. L'évaluateur aidera le participant en accord avec les règles de passation.

Participant satisfaction questionnaire.
*Participant Satisfaction*
Please provide your honest answers to these questions:

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| Strongly disagree | Somewhat disagree | Neither disagree nor agree | Somewhat agree | Strongly agree |

Since starting this dance program:

| | | | | | |
|---|---|---|---|---|---|
| I **enjoyed** participating in this dance program. | 1 | 2 | 3 | 4 | 5 |
| My **balance** has improved. | 1 | 2 | 3 | 4 | 5 |
| My **walking** has improved. | 1 | 2 | 3 | 4 | 5 |
| My **mood** has improved. | 1 | 2 | 3 | 4 | 5 |
| My **coordination** has improved. | 1 | 2 | 3 | 4 | 5 |
| My **strength** has improved. | 1 | 2 | 3 | 4 | 5 |
| My **endurance** has improved. | 1 | 2 | 3 | 4 | 5 |
| If I could, I would **continue** participating. | 1 | 2 | 3 | 4 | 5 |
| I have been more **physically active**. | 1 | 2 | 3 | 4 | 5 |

***Figure 4 :*** *Questionnaire de la satisfaction envers la danse.*

## DESCRIPTION DE LA PROCEDURE DE L'EVALUATION DE L'ADHERENCE

Pour évaluer l'adhérence, nous relèverons les éléments suivants :

- nombre de personnes intéressées par la danse ;
- nombre de personnes prêtes à participer ;
- nombre de personnes présentent à chaque cours de danse. En cas d'absence, la raison sera identifiée.

## DESCRIPTION DE LA PROCEDURE DE L'EVALUATION DES EFFETS INDESIRABLES

Un cahier des événements indésirables a été créé et il contient : la date, l'heure, le numéro du sujet, la description de l'événement, son caractère attendu et les implications pour l'étude.

# DESCRIPTION DETAILLEE DE L'INTERVENTION ET DU CONTRÔLE

- ***INTERVENTION : LA DANSE***

***Organisation générale***

Les cours de danse seront organisés et dispensés par un physiothérapeute professeur de danse et une personne assistante pour aider les participants. Cette double compétence est favorable à une meilleure adaptabilité des mouvements demandés par rapport au niveau cognitivo-moteur des patients.
Un cours de danse hebdomadaire sera dispensé auprès des participants sur une durée de 60 minutes pendant une durée de 6 semaines. Lors de ce cours, un proche aura la possibilité de venir participer sur base du volontariat et sans obligation régulière de leur participation.

***Définition des règles des cours de cours***


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Tous les cours de danse se dérouleront en musique. La structure du cours comprendra cinq composantes : échauffement (10 minutes), exercices techniques (10 minutes), improvisation (15 minutes), une courte routine (15 minutes) et une période de récupération - feedback (10 minutes).
Les exercices de danse viseront la souplesse, l'équilibre, l'endurance, la fonction des membres supérieurs et inférieurs, l'interaction entre les danseurs (danse en couple ou en cercle), la perception (imagerie visuelle et incorporation du côté affecté pour les personnes atteintes d'héminégligeance) et la mémoire.
Le style de danse utilisé pour ce groupe sera une combinaison de danse contemporaine et de danse sociale. En utilisant la chorégraphie ou une courte routine, elle permettra de répéter les pas de danse appris pour favoriser la mémorisation et ajoute le défi supplémentaire de se souvenir d'une séquence de pas.
Les pas de danse montrés par le professeur de danse seront les mêmes pour tous les participants. Cependant, étant donné la grande variabilité des capacités fonctionnelles de chaque participant, la complexité et l'intensité des exercices de danse évolueront en fonction de chaque participant pour atteindre un défi approprié à une intensité de traitement modérée. Tous les pas de danse peuvent être exécutés en position assise ou debout.

***Les règles suivantes seront respectées :***

- La danse sera réalisée en musique car celle-ci facilite le déclenchement du mouvement et induit un travail sur le temps de réaction et la coordination ;
- Les consignes devront inclure la production de mouvements rythmés en musique ;
- La danse sera réalisée en groupe en favorisant l'interaction entre plusieurs personnes ;
- Des mouvements en étant guidé ou en guidant seront intégrés (travail en miroir, créativité gestuelle, …);
- Des mouvements basés sur l'équilibre et la coordination seront inclus ;
- Une sollicitation de la mémoire gestuelle (« retenir une séquence de danse ») sera incluse ;
- Les demandes seront adaptées aux participants (possibilité de danser debout, assis, augmenter la base de support ;
- Selon le niveau moteur des participants, des déplacements spatiaux devront être proposés ;
- Evaluation à chaque cours du niveau de fatigue et de douleur par NRS.

***Contenu des cours***

Chaque cours inclura ces éléments (tableau 1) (Demers and McKinley, 2015; Patterson et al., 2018):

| **Eléments** | **Exemple d'activités** |
|---|---|
| 7. Echauffement | En position assise, travail d'échauffement incluant un éveil musculaire, de la mobilité douce des différents segments et du travail d'équilibre. |
| 8. Activation cardio-respiratoire | Des mouvements improvisés sur une musique rythmée auront pour objectif d'activer le système cardio-respiratoire et de proposer un travail de type aérobique |
| 9. Mouvements chorégraphiques | Apprentissage d'une séquence de mouvements que les danseurs devront reproduire |
| 10. Danse avec partenaire | Les participants devront interagir avec un ou plusieurs partenaires. A tour de rôle, ils devront soit guider et être suivi ou suivre la séquence proposée par un autre danseur |
| 11. Apprentissage de danse existante | Apprentissage de danse comme la danse traditionnelle ou de salon ou sportive… L'intérêt |


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| | |
|---|---|
| | est de travailler principalement la mémoire et la coordination. |
| 12. Récupération | Phase de retour au calme et d'échanges sur la séance. |

Les participants auront tous un suivi habituel de prise en charge post-AVC respectant la démarche habituelle de l'Institution de Lavigny (cf. description contrôle).

- ***CONTRÔLE***

Le groupe contrôle aura la prise en charge habituelle isolée. Celle-ci est constituée de 45 à 60 minutes de physiothérapie par jour incluant de la stimulation sensorielle, de l'activation motrice, du renforcement, de la coordination, de l'équilibre, de l'entrainement à l'effort en fonction des objectifs mis en place à partir du bilan. Une séance de groupe est prévue par semaine selon les capacités du patient (cognitives, motrices, de fatigue). Chaque jour, le patient a également une séance d'ergothérapie. De 3 à 5 fois par semaine, les patients ont des séances de neuropsychologie et de la logopédie. La durée de prise en charge oscille entre 3 à 6 mois à l'Institution de Lavigny.

### 4.4 Withdrawal and discontinuation

Etant donné que c'est une étude longitudinale, mais, en centre de rééducation, le risque de drop-out est modéré.

*Critères de retrait des sujets :*

- Arrêt de l'hospitalisation à Lavigny ;
- Dégradation de la stabilité médicale ;
- Incompréhension des tests et de l'activité ne permettant pas d'obtenir des résultats dans des conditions satisfaisantes ;
- Apparition de douleurs trop importantes lors des tests et des cours de danse (NRS>5) ;
- Retrait du consentement éclairé ;
- La procédure ou la routine doivent être arrêtées pour des raisons de sécurité ;
- Trouble du comportement lors des cours de danse.

En cas de retrait du sujet, si c'est au niveau des tests de baseline, il sera exclu de l'étude, si c'est en cours d'intervention, un examen final sera réalisé.
Etant donné que le recrutement est consécutif il est possible de prolonger la phase de recrutement pour les sujets exclus. Afin d'éviter la perte de sujets, des tests vérifiant les capacités cognitives et d'équilibre des participants sont prévus avant l'inclusion définitive.

En cas de retrait, toutes les données obtenues seront rendues anonymes en remplaçant dans l'ensemble des documents les sources d'identification par le numéro du sujet. Aucune identification ne sera alors possible pour la suite.

## 5 STATISTICS AND METHODOLOGY

### 5.1. Statistical analysis plan and sample size calculation

***Qui?*** Emmanuel Morice et Aline Reinman sous la supervision de Anne-Violette Bruyneel


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***Quand?*** Une première phase d'analyse après 10 sujets par groupe (pour le travail de master d'Emmanuel Morice) puis à la fin de la récolte des données.

***Sample size***

Le nombre de sujets à inclure par groupe a été calculé à partir d'une étude sur les caractéristiques des tests d'équilibre et plus particulièrement du miniBest test chez des patients ayant un AVC en phase subaiguë (Chinsongkram et al., 2014). Le miniBest est une évaluation reconnue considérée comme le gold standard pour évaluer le contrôle postural et l'équilibre. Ce test a les caractéristiques psychométriques les plus élevées avec un effet plancher et plafond faible ainsi qu'une bonne sensibilité au changement pour les personnes ayant eu un AVC. De plus, l'étude de Patterson et al. sur la danse et l'AVC a également utilisé ce test comme outcome et a montré que ce test permettait d'identifier correctement les évolutions des patients (Patterson et al., 2018).

La formule utilisée est la suivante (Pocock et al.) : $n = \frac{f\left(\frac{\alpha}{2}\beta\right) x\ 2\ x\ \sigma^2}{(\mu 1 - \mu 2)^2}$

Pour une différence minimale d'intérêt à 3.5/28 points, un écart type inter-sujets à 3.9/28 et une puissance à 90%, il faut inclure 22 sujets par groupe pour cette étude.

Pour faire face à d'éventuels désistement, nous inclurons 24 sujets par groupe.

***Hypothèses statistiques***

Objectif primaire:
H0: il n'y a pas de différence significative entre les groupes pour la récupération cognitive-motrice
H1: il y a une différence significative entre les groupes pour la récupération cognitive-motrice

Objectif secondaire: qualité de vie
H0: il n'y a pas de différence significative entre les groupes pour la qualité de vie
H1: il y a une différence significative entre les groupes pour la qualité de vie

Objectif secondaire: motivation face à l'activité physique
H0: il n'y a pas de différence significative entre les groupes pour la motivation face à l'activité physique
H1: il y a une différence significative entre les groupes pour la motivation face à l'activité physique

Objectif secondaire: satisfaction et adhérence
H0: les cours de danse n'apportent pas de satisfaction et l'adhérence n'est pas bonne (<80%)
H1: les cours de danse apportent de la satisfaction et l'adhérence est excellente (>80%)

***Comparaisons statistiques***

- Vérifier que les deux groupes ont des caractéristiques démographiques et cliniques similaires en début d'étude;
- Vérifier que les participants soient stables en comparant les tests baseline 1 et baseline 2;
- Evolution des participants : Pour le groupe danse et pour le groupe intervention, comparer chaque phase de test: baseline 1, baseline 2, follow-up 4 semaines, follow-up 6 semaines;
- Comparer les groupes (danse vs. contrôle) : comparer les tests à chaque phase : baseline et follow-up 4 semaines et follow-up 6 semaines ; comparer le delta (test final – test initial).

Les statistiques seront toutes réalisées en « intention de traiter ».

***Variables mesurées :*** Chedoke Mc Master (score 14 points) ; durée de marche 10m spontanée (s) et rapide (s) ; TUG (s) ; trunk control scale(score sur 100 points) ; test du barrage des cloches (sec / nombre de réussites) ; MiniBest test (score 28 points) ; équilibre simple et double tâche : longueur de

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déplacement (mm), le delta (valeur max – valeur min) et les pics (mm) seront extraits en x (antéro-postérieur) et en y (médio-latéral) ; ABC-s (%) ; LEMOCOT (nombre de mouvement –n et cotation sur 3 points des tremblements et dysmétrie) ; force musculaire (N) ; MIF (score 126 points) ; MoCA (score 30 points) ; SS-QOL (moyenne non pondérée des items associés) ; motivation face à l'activité physique (score 54 points) ; douleur et fatigue pendant la danse (NRS de 0 à 10) ; satisfaction des cours de danse (score 50 points), adhérence (nombre de présence), événements indésirables (nombre).

***Traitement initial des données***

- Lorsque plusieurs essais ont été réalisés, une moyenne sera calculée entre les essais pour chaque condition et chaque test;
- Pour les tests d'équilibre debout avec le capteur inertiel, la longueur de déplacement, le delta (valeur max – valeur min) et les pics seront extraits en x (antéro-postérieur) et en y (médio-latéral) en utilisant le logiciel Octave GNU.
- La valeur de force du quadriceps sera normalisée par le poids du sujet:

$$x = \frac{\text{Valeur force}}{\text{Poids du sujets}} x\ 100$$

***Statistiques descriptives***

Les statistiques descriptives consisteront à calculer la moyenne et l'écart-type pour chaque groupe de données ou pour les variables qualitatives, de calculer la fréquence. Une représentation graphique sera réalisée sous forme d'histogramme pour les variables quantitatives continues et sous forme de diagramme pour les variables qualitatives ou ordinales.

***Statistiques inférentielles***

Pour les comparaisons de variables qualitatives, un test de ChiSquare sera appliqué.
Pour les données quantitatives, pour comparer les groupes, étant donné que le nombre de sujets est inférieur à 25, nous utiliserons un test non paramétrique de U de Mann Withney. Pour la comparaison entre les phases de tests (baseline 1, baseline 2, follow-up 4 semaines et follow-up 6 semaines), nous utiliserons un test non paramétrique pour données dépendantes de Wilcoxon.
La valeur seuil de p est établie à $p<0.05$. Les statistiques seront réalisées sur R Studio©.

Toute modification par rapport au plan statistique initial sera notifiée dans le rapport final.

### 5.2. Handling of missing data and drop-outs

En cas de données manquantes sur les tests comprenant plusieurs essais, la moyenne des autres essais sera reportée. En cas de données manquantes sur des tests où il n'y a qu'un essai, l'analyse avec ce test ne pourra être réalisée. Dans ce cas, la valeur précédente sera reportée.

En cas d'arrêt des participants à la baseline, nous recruterons un sujet supplémentaire. En cas d'arrêt au cours du follow-up, un examen final sera réalisé.

Nous prévoyons peu de drop-out pour ce projet.

## 6 REGULATORY ASPECTS AND SAFETY

### 6.1 Local regulations / Declaration of Helsinki

Cette étude est menée conformément au protocole, à la version actuelle de la Déclaration d'Helsinki, aux BPC de l'ICH et aux BPC.

### 6.2 (Serious) Adverse Events

***Un événement indésirable (AE)*** est tout événement médical fâcheux chez un patient ou un sujet


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d'investigation clinique qui n'a pas nécessairement un lien de cause à effet avec la procédure de l'essai. Un EI peut donc être tout résultat, symptôme ou maladie défavorable ou non intentionnel associé dans le temps à une procédure d'essai, qu'il soit ou non lié à celle-ci.

***Un événement indésirable grave (SAE)*** (ClinO, art. 63) est tout événement médical fâcheux qui

- Cause la mort ou met la vie en danger,
- Nécessite une hospitalisation ou la prolongation d'une hospitalisation existante,
- entraîne une invalidité ou une incapacité persistante ou importante, ou
- Provoque une anomalie congénitale ou une malformation congénitale.

Le chercheur et le promoteur-investigateur évaluent la causalité de l'événement par rapport à l'intervention de l'essai (voir le tableau ci-dessous basé sur les termes donnés dans les directives ICH E2A). Tout événement évalué comme étant possiblement, probablement ou définitivement lié est classé comme étant lié à l'intervention de l'essai.

Tous les événements indésirables graves seront suivis jusqu'à résolution.

| **Relationship** | **Description** |
|---|---|
| Definitely | Temporal relationship<br>Improvement after dechallenge*<br>Recurrence after rechallenge<br>(or other proof of drug cause) |
| Probably | Temporal relationship<br>Improvement after dechallenge<br>No other cause evident |
| Possibly | Temporal relationship<br>Other cause possible |
| Unlikely | Any assessable reaction that does not fulfil the above conditions |
| Not related | Causal relationship can be ruled out |
| *Improvement after dechallenge only taken into consideration, if applicable to reaction | |

***Tableau 3.***

Le chercheur et le promoteur-investigateur évaluent la gravité de l'événement comme étant légère, modérée ou grave. Légère signifie que la complication est tolérable, modérée qu'elle interfère avec les activités quotidiennes et grave qu'elle rend les activités quotidiennes impossibles.

**Reporting of SAEs** (see ClinO, Art. 63)

Toutes les SAEs sont documentées et signalées immédiatement (dans un délai maximal de 24 heures) au promoteur-investigateur de l'étude.


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S'il ne peut être exclu que l'événement survenant en Suisse soit imputable à l'intervention faisant l'objet de l'enquête, l'investigateur en informe le Comité d'éthique par l'intermédiaire du BASEC dans les 15 jours.

**Follow up of (Serious) Adverse Events**

Notre étude est de catégorie A.

Tous les événements indésirables (EI), y compris tous les événements indésirables graves (EIG), sont recueillis, examinés et documentés dans le document des événements indésirables pendant toute la durée de l'étude, c'est-à-dire depuis le consentement éclairé du patient jusqu'à la dernière procédure spécifique au protocole, y compris une période de suivi de la sécurité qui sera de 7 jours pour cette étude.

Le document comprend les dates de l'événement, le traitement, la résolution, l'évaluation de la gravité et la relation de cause à effet avec le dispositif et/ou la procédure d'étude [ISO 14155, 6.4.1].

Les risques pour la santé qui nécessitent des mesures sont signalés à l'investigateur dans les 24 heures suivant la prise de connaissance de l'événement et au médecin référent de l'Institution de Lavigny du patient. Le médecin appliquera alors un suivi médical adapté au participant et celui-ci sera sorti de l'étude.

A noter que cette étude n'implique pas des patients vulnérables et l'âge exclu les risques de grossesses.

## 6.3 (Periodic) safety reporting

Un rapport annuel de sécurité (ASR/DSUR) est soumis une fois par an au comité d'éthique local par l'investigateur (ClinO, art. 43 Abs).

## 6.4 Radiation

Non applicable.

## 6.5 Pregnancy (if applicable)

Non applicable.

## 6.6 Amendments

Les modifications substantielles apportées à la structure et à l'organisation de l'étude, au protocole et aux documents pertinents de l'étude sont soumises à l'approbation du Comité d'éthique avant leur mise en œuvre. En cas d'urgence, des dérogations au protocole visant à protéger les droits, la sécurité et le bien-être des sujets humains peuvent être faites sans l'approbation préalable du Comité d'éthique. Ces écarts doivent être documentés et signalés au Comité d'éthique le plus tôt possible.

Les modifications substantielles sont des changements qui affectent la sécurité, la santé, les droits et les obligations des participants, les changements dans le protocole qui affectent les objectifs de l'étude ou le sujet central de recherche, les changements de site(s) de l'étude ou de responsable et de sponsor (ClinO, article 29).

Une liste de toutes les modifications non substantielles sera soumise une fois par an à la CE compétente en même temps que les REV.

## 6.7 (Premature) termination of study

L'investigateur-promoteur peut mettre fin prématurément à l'étude en fonction de certaines circonstances, par exemples :

- Préoccupations éthiques,
- Recrutement insuffisant des participants,

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- Lorsque la sécurité des participants est douteuse ou à risque (p. ex. lorsque l'évaluation avantages-risques n'est plus positive),
- des modifications dans la pratique clinique acceptée qui rendent la poursuite de l'étude imprudente, ou
- Preuves précoces des effets nocifs ou bénéfiques de l'intervention expérimentale.

La CCER sera avisée de la fin de l'étude dans les 90 jours par l'intermédiaire du BASEC (ClinO, art. 38).

En cas d'interruption prématurée ou d'interruption de l'étude, le Comité d'éthique est informé par l'intermédiaire du BASEC dans les 15 jours (ClinO, art. 38).

### 6.8 Insurance

Pour les études de catégorie A : En cas de dommages ou de blessures liés aux études, la responsabilité de l'établissement HES-SO est engagée, à l'exception des réclamations résultant d'une faute professionnelle ou d'une négligence grave.

## 7 FURTHER ASPECTS

### 7.1 Overall ethical considerations

***Généralisation des résultats***

L'étude cible :

- Une population fréquemment rencontrée dans le cadre de la rééducation ;
- Une population « type » d'AVC la plus rencontrée ;
- Des tests cliniques habituels de suivi lors de la prise en charge de l'AVC ;
- Une technique (la danse) qui est déjà proposée en complément de la rééducation dans certains centres ;
- Une demande de cliniciens ;
- Une demande des patients (trouver des moyens de bouger plus motivants et attractifs).

L'étude a été soigneusement construite afin de respecter les standards méthodologiques d'une étude d'évaluation d'une intervention tout en réfléchissant sur des actions préventives de limitation des biais. Ces éléments doivent conférer une situation favorable à des résultats de bonne qualité permettant la généralisation des résultats en milieu clinique auprès des patients présentant une hémiparésie post-AVC. Pour la recherche, la meilleure connaissance de l'efficacité de la pratique de la danse pour des personnes ayant eu un AVC doit constituer une base de réflexion pour préciser les mécanismes de récupération et les modalités d'application d'une telle approche.

***Les modalités de publication*** respecteront les recommandations de la Haute Ecole de Santé, c'est-à-dire un choix de revue Open Access et un anonymat des données sera parfaitement respecté, y compris pour le partage de données. Quelque soit les résultats, nous nous engageons à les publier, y compris aucun effet bénéfique de la danse n'a été trouvé.

***Justification de la conception de l'étude***

La conception de l'étude respecte les éléments les plus importants de guideline de la grille CONSORT et PEDRO.

Elle répond à une demande importante de la part des cliniciens et à un manque en recherche (cf. background). Tous les éléments de conception sont justifiés dans les chapitres attenants.

***Justification de la population étudiée***

Nous souhaitons inclure des patients présentant une hémiparésie post-AVC (ischémique ou hémorragique) car la danse n'a pas été testée sur les capacités cognitivo-motrices sur la qualité de vie en


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phase subaiguë.

La population cible correspond aux patients ayant une hémiparésie post-AVC de 45 à 80 ans. Cette catégorie d'âge est la plus représentée dans le cas de l'AVC et représente donc la typologie de patients qui est la plus présente dans les services de neuro-rééducations. Nous avons mis une limite supérieure à 80 ans afin de limiter les biais liés à l'âge des patients, tout en nous préservant la possibilité d'inclure suffisamment de participants.

L'hémiparésie est la conséquence motrice la plus fréquente après un AVC. Nous ciblerons des patients en phase sub-aigue car les enjeux de récupération sont majeurs dans cette phase et que nous pensons que l'apport de la danse devrait être particulièrement intéressant pour cette phase de traitement.

En choisissant cette population, nous nous assurons de développer un contexte fréquemment rencontré en pratique clinique ce qui facilitera la transposition des résultats dans de bonnes conditions vers les services de rééducation hospitaliers.

***Procédure de l'étude***

Tous les tests utilisés et les interventions sont justifiés dans les chapitres attenants.

***Droit à l'information des sujets***

Tous les sujets ont un droit à l'information sur le déroulement de l'étude et les résultats.
*Cf. Lettre information et consentement*

***Points critiques méthodologiques***

Biais attendus :

- Compétence des évaluateurs ;
- Compétence du thérapeute pour pratiquer les cours de danse ;
- Fatigabilité des participants ;
- Mauvaise standardisation du dispositif (procédure différente, apprentissage, …) ;
- Apprentissage/ fatigue des participants lors des tests ;
- Mauvais choix des tests cibles ;
- Faisabilité de la danse pour les personnes après un AVC.

Tous ces éléments ont été prévus et des actions préventives ont été mises en place pour limiter les risques.

- Randomisation ;
- Evaluateur en aveugle ;
- Choix des tests ;
- Les examinateurs seront des physiothérapeutes expérimentés en neurologie ;
- Le thérapeute sera un physiothérapeute – danseur ayant une double compétence idéale pour la réalisation de l'intervention ;
- Des pré-tests permettant de prévoir une phase d'apprentissage des tests pour les examinateurs et une standardisation de la procédure seront effectués ;
- Le nombre d'essais pour chaque test a été choisi selon les standards utilisés dans la recherche afin de limiter les biais (compensations, concentration, compréhension des tests, …) ;
- Les critères d'inclusion et d'exclusion ont pour vocation d'homogénéiser les participants et de limiter les autres pathologies pouvant affecter les résultats, afin de favoriser une extrapolation des résultats dans de bonnes conditions ;
- L'intervention et sa structure sont basées sur les études qui ont préalablement montré un effet bénéfique de la danse en cas de pathologie chronique (pour cela, une scoping review publiée a précédé la construction de ce projet).

***Population vulnérable***


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L'étude ne recrute pas de participants vulnérables ni de risque de grossesses ou irradiation.

*Cf. critères d'inclusion / exclusion*

***Participation volontaire à l'étude***

Tous les patients seront volontaires et pourront à tout moment se retirer de l'étude comme défini dans la lettre d'information et de consentements.

*Cf. Information et consentement*

***Juste équilibre pour les participants***

Cette étude ne comprend pas de risque supérieur à la prise en charge habituelle en rééducation suite à un AVC. Les risques sont donc faibles.

En revanche, cette étude est une opportunité pour

- avoir un suivi plus exhaustif de la récupération ;
- favoriser une meilleure récupération grâce à des conditions favorables à la neuroplasticité ;
- découvrir une activité physique adaptée à ces patients
- retrouver du plaisir dans le mouvement malgré les déficiences ;
- rendre plus actives les personnes après un AVC grâce à une activité répondant bien à leurs difficultés sans mettre les pratiquants en échec ;
- développer à long terme un comportement favorable à sa santé qui permettra une amélioration motrice, psycho-sociale et de la qualité de vie tout en favorisant l'autonomie et en limitant les facteurs de risques sur la santé liés à la sédentarité.

*Cf. bénéfices / risques*

## 7.2 Risk-benefit assessment

**Les risques associés à la participation à l'investigation clinique sont les suivants :**

- effets indésirables habituels liés aux tests fonctionnels et d'équilibre (ex. fatigue, déséquilibre, chute,…) ;

- les mesures de force que nous effectuons durant cette étude peuvent provoquer une fatigue des muscles extenseurs de genou;

- la pratique de la danse peut provoquer de la fatigue ;

- il n'est pas possible d'exclure d'autres risques encore inconnus.

Les tests appliqués et la danse ne comprennent aucun risque d'interaction avec les interventions médicales concomitantes.

Les risques ne sont pas plus élevés que ceux habituellement rencontrés lors des bilans en physiothérapie dans le suivi habituel des patients.

**Les avantages associés à la participation à l'investigation clinique sont les suivants:**

S'ils participent à l'étude, elle pourrait apporter aux participants les éléments suivants :

- avoir un suivi plus exhaustif de la récupération cognitivo-motrice et une évaluation de la qualité de vie et de la motivation face à l'activité physique.

Pour le groupe danse, les participants ont la possibilité de découvrir une activité physique faisable malgré leurs déficiences qui leur permet de redécouvrir le plaisir dans le mouvement. Si les résultats montrent des effets bénéfiques, ces participants pourraient avoir une meilleure récupération grâce à des conditions favorables à la neuroplasticité.

L'étude pourrait constituer un bénéfice pour les futurs participants en raison, de la mise en évidence d'une approche complémentaire à la prise en charge proposée pour les patients après un AVC. Ce type d'action


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pourrait aider à rendre plus actives les personnes après un AVC grâce à une activité répondant bien à leurs difficultés sans mettre les pratiquants en échec. Un comportement favorable à la santé pourrait être favorisé par la danse ce qui pourrait limiter les facteurs de risques sur la santé liés à la sédentarité.

**Mesures de contrôles et d'atténuation des risques :**

Pour les risques de fatigue, nous avons organisé le planning en conséquence pour les tests avec des temps de repos. Pendant tous les tests, le niveau de fatigue et de douleur (test de force) sera évalué par une échelle visuelle numérique (NRS).

Pour les risques de déséquilibres pendant les tests d'équilibre assis et d'équilibre debout, l'environnement des tests sera organisé afin que le patient en cas de chutes ne se fasse pas mal (suppression d'objets ou de contraintes externes, mise en place de tapis et de barres latérales pour utiliser un appui si nécessaire). Nous veillerons également à sécuriser les patients grâce à la présence d'un physiothérapeute prêt à retenir le patient si nécessaire. Les tests initiaux permettent de s'assurer que le patient a suffisamment de capacités motrices pour réaliser l'étude.

Tous les tests seront réalisés dans une salle dédiée ce qui permet de s'assurer de conditions environnementales stables.

Pour les cours de danse, la fatigue et la douleur seront évaluées à chaque séance. Selon le niveau moteur, la danse se fera en position debout ou assise et tous les exercices seront adaptés au niveau des participants. Les cours seront réalisés en petits groupes (maximum 6 personnes) avec un physiothérapeute-danseur et un physiothérapeute assistant pour sécuriser les participants.

Pour les risques liés à la mauvaise compréhension des consignes, nous avons mis en place le MMSE pour évaluer l'aspect cognitif des participants avant les tests. Cette démarche doit nous prémunir de difficultés majeures de compréhension.

Pour les risques inconnus, nous ferons une observation minutieuse du déroulement des tests afin d'identifier ces risques.

**Organisation des soins après l'essai :**

Les participants poursuivront les traitements conformément au suivi habituel du service. La participation à l'essai ne modifie aucunement la prise en charge.

# 8 QUALITY CONTROL AND DATA PROTECTION

## 8.1 Quality measures

Le protocole écrit incluant toutes les instructions sera soumis aux différentes personnes inclues dans l'étude, c'est-à-dire :

- Anne-Violette Bruyneel, investigatrice
- Emmanuel Morice, partenaire de terrain, responsable des cours de danse (Lavigny)
- Dr Pierre-André Rapin (directeur médical), correspond clinique Lavigny
- Aline Reinmann, responsable organisation des tests et des données
- Vincent Pittet, responsable organisation des tests et des données
- Axelle Baud-Grasset, réalisation des tests
- Sonia Kleinmann, réalisation des tests
- Pascal Weber, réalisation des tests
- Clara James, monitoring.

Lors des pré-tests, nous réaliserons les tests entre nous afin de nous assurer que la procédure est bien respectée et que les tests sont compris et bien réalisés par les évaluateurs. Cette étape sera donc une étape de formation et de standardisation pour tous les intervenants.

Ensuite, avant chaque séquence de tests, les évaluateurs doivent relire le protocole et organiser le

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dispositif expérimental. Après chaque séquence de test, l'investigatrice aura un retour sur la procédure et elle viendra réaliser des contrôles aléatoires afin de vérifier le respect de la procédure.

Mesures prises pour la qualité et le contrôle des données :

- Double saisie des données ;
- Sauvegarde hebdomadaire des données ;
- Formation des personnes impliquées dans l'étude pour tous les aspects importants de l'étude ;
- Visite de qualité prévues par un professeur externe à l'étude.

Pour l'assurance de la qualité, le promoteur, le comité d'éthique ou un surveillant d'essai indépendant peut visiter les sites de recherche. L'accès direct aux données de base et à tous les fichiers relatifs à l'étude est accordé dans de telles occasions. Toutes les parties concernées gardent les données des participants strictement confidentielles.

### 8.2 Data recording and source data

Le document de recrutement contenant les noms et prénoms des patients sera dans une armoire sous clé dans un bureau et uniquement accessible par l'investigatrice et la personne responsable de l'organisation sur le terrain et du recrutement. Ce formulaire d'information et de consentement ainsi que le document de clés de codage seront les seuls qui contiennent les coordonnées des patients. Un numéro codé sera ensuite attribué et utilisé pour tous les autres documents.

Les documents vierges du p-CRF seront positionnés dans des classeurs avec le matériel nécessaire pour l'expérimentation qui sera gardé dans une armoire fermée. Le CRF sera un CRF papier.

Après les tests, les p-CRF complétés et les données informatisées sauvegardées de manière sécurisée seront dans une armoire fermée dans le bureau de l'investigatrice principale.

L'ensemble des documents (documentation source, CRF, enregistrements, protocole, tableau des événements indésirables, consentements, …) liés à l'étude seront archivés et conservées de manière sécurisée (papiers et électroniques sur disque dur externe protégé par un mot de passe) dans une armoire fermée dans le bureau de l'investigatrice principale (adresse : rue des Caroubiers 25, 1227 Carouge, 2ème étage, bureau 204) pendant une durée de 10 ans. Après ce délai, ces documents seront effacés ou détruits par une broyeuse.

La bonne réalisation de cette procédure sera réalisée par un audit de la Professeure Clara James ne participant pas à la récolte des données.

Liste des documents (les documents sources sont notés par le signe « * »):

- * Protocole
- * Lettre d'information
- * Lettre de consentement
- * p-CRF (c'est un document source car certaines données sont directement notées sur le CRF)
- * échelles détaillées (le score global est dans le p-CRF) : MMSE, Chedoke, MiniBestTest, MIF, MoCA, SS-QOL, motivation, satisfaction
- * Fichiers pour le capteur inertiel
- * Fichier d'événement indésirable

| Données | Lieu |
|---|---|

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| | |
|---|---|
| *Date de la visite | p-CRF |
| *Age | Dossier patient |
| *Sex | Dossier patient |
| *Poids | Dossier patient |
| *Taille | Dossier patient |
| *Date AVC | Dossier patient |
| *Localisation AVC | Dossier patient |
| *Côté AVC | Dossier patient |
| *Situation médicale stable | Dossier patient |
| *Antécédents | Dossier patient |
| *MMSE | p-CRF |
| *Stable sitting position 30s | p-CRF |
| *Tolérance à une activité modérée pendant 60minutes | p-CRF |
| *Chedoke McMaster | p-CRF et document détaillé |
| *Vitesse de marche spontanée et rapide | p-CRF |
| *TUG | p-CRF |
| *MiniBest Test | p-CRF et document détaillé |
| *Equilibre simple et double tâche | Fichiers informatisés codés |
| *ABC-s | p-CRF et document détaillé |
| *LEMOCOT | p-CRF |
| *Force musculaire | p-CRF |
| *MIF | p-CRF et document détaillé |
| *MoCA | p-CRF et document détaillé |
| *SS-QOL | p-CRF et document détaillé |
| *Motivation face à l'activité | p-CRF et document détaillé |
| *Fatigue | p-CRF |
| *Douleur | p-CRF |
| *Satisfaction des cours de danse | p-CRF |
| *Adhérence | p-CRF |
| Adverse events | Fichier événements indésirables |

***Tableau 4 :*** liste des données et documents. Les données sources sont notées par le signe « * ».

### 8.3 Confidentiality and coding

Les données relatives aux essais et aux participants seront traitées avec la plus grande discrétion et ne seront accessibles qu'au personnel autorisé qui en a besoin pour remplir ses fonctions dans le cadre de l'étude. Dans le p-CRF et les autres documents propres à l'étude, les participants ne sont identifiés que par un numéro de participant unique (code).

Les données de l'étude sont enregistrées sur un p-CRF papier. Chaque participant aura un p-CRF rendu anonyme et personnel. Toutes les données seront inscrites sur le p-CRF. Les participants ne pourront pas être identifiés dans le p-CRF par leur nom, leurs initiales et leur date de naissance. Un numéro sera systématiquement attribué au moment du recrutement, il contiendra le code de l'étude, suivi du numéro successif du patient recruté (ex : HemiGDaS01 / HemiGCS01).


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L'investigateur, l'organisateur du recrutement, et les évaluateurs sont autorisés à avoir accès au p-CRF.

Les données du p-CRF seront systématiquement entrées dans une base de données électronique pour l'analyse afin d'avoir une double saisie de données.

L'accès direct aux documents sources sera autorisé à des fins de suivi (12.3), d'audits et d'inspections (12.4) (ICHE6, 6.10).

L'investigatrice sera la seule personne ayant un accès permanent aux données avant, pendant et après l'étude.

| Type de documents | Accès autorisé | Quand ? |
|---|---|---|
| Protocole | Investigatrice, organisateur, évaluateurs, collaborateur de terrain, collaborateur scientifique | Tout le temps |
| Document avec les coordonnées des patients | Investigatrice, organisateur du recrutement, évaluateurs pour les RDV et professeur des cours de danse | Pendant uniquement |
| p-CRF vierges | Investigatrice, organisateur, évaluateurs, collaborateur scientifique | Tout le temps |
| p-CRF complétés | Investigatrice, organisateur, évaluateurs, collaborateur scientifique | Pendant les tests et après pour l'investigateur et le collaborateur scientifique |
| Fichier d'événements indésirables | Investigatrice, organisateur, professeur de danse | Pendant et après |
| Fichiers brutes plate-forme et capteurs inertiels | Investigatrice, organisateur et collaborateur scientifique | Pendant et après |
| Fichiers statistiques | Investigatrice, partenaire de terrains et collaborateur scientifique | Pendant et après |
| Tous les fichiers pour publication | Investigatrice | Tout le temps, y compris après la fin des expérimentations |

***Tableau 7 :*** accès aux documents

### 8.4 Retention and destruction of study data and biological material

Toutes les données de l'étude sont archivées pendant une durée de 10 ans après la fin de l'étude ou la fin prématurée de l'étude.

En cas de révocation du consentement, les données personnelles liées à la santé seront anonymisés après avoir été analysés. L'anonymisation des données personnelles n'est pas nécessaire lorsque la personne concernée y a expressément renoncé au moment de la révocation.

Le suivi médical habituel dans le contexte de la prise en charge rééducative sera continué sans aucune modification. La révocation ne changera rien à la prise en charge habituelle du patient.

## 9 MONITORING AND REGISTRATION

Etant donné que c'est une étude de catégorie A qui ne comprend pas plus de risque que la pris en charge habituelle des patients après un AVC, aucun monitoring externe ne sera proposé car il n'est pas nécessaire dans ce type d'étude.

En revanche un monitoring interne est prévu. Professeure Clara James ne faisant pas partie du projet s'assurera du bon déroulement du projet. Elle s'assurera que les droits et bien-être des participants sont bien respectés, que les données reportées sont exactes et vérifiables à partir des documents sources et que l'essai est conduit et documenté conformément au protocole, aux procédures et à la réglementation applicable.

Une visite initiale, une visite intermédiaire et une visite de clôture sont prévues.

Documents vérifiés :


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- lettre de consentement (vérification que les consentements ont été obtenus avant la participation à l'essai) ;
- p-CRF ;
- Documents sources ;
- Document de report des événements indésirables.

Un rapport sera rédigé à chaque visite.

Les données/documents sources sont accessibles aux contrôleurs et des réponses aux questions seront apportées pendant le contrôle.

**Enregistrement :**

L'étude est enregistrée dans clinical trials (NCT04120467) et sera enregistrée sur Kofam via le site BASEC en langue française.

## 10. FUNDING / PUBLICATION / DECLARATION OF INTEREST

Ce projet est majoritairement financé en interne par la Haute Ecole de Santé (60%) et par la contribution d'un généreux mécène conseillé par CARIGEST SA (40%).

Ces fonds couvrent les frais matériels et les ressources humaines du projet.

Pas d'autres fonds ne sont prévus sur ce projet.

Il n'y a aucun conflit d'intérêt et les données sont gérées de manière totalement indépendante par rapport au fond.

## 10 REFERENCES

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3. Federal Act on Data Protection (FADP) https://www.admin.ch/opc/en/classified-compilation/19920153/index.html
4. Human Research Act (HRA) https://www.admin.ch/opc/de/classified-compilation/20061313/index.html
5. International Conference on Harmonization (ICH) E6(R2) Guideline for Good Clinical Practice http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf
6. International Conference on Harmonization (ICH) E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002749.pdf
7. Ordinance on Clinical Trials in Human Research (ClinO) https://www.admin.ch/opc/de/classified-compilation/20121176/index.html


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STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | 3 |
| Funding | 4 | Sources and types of financial, material, and other support | 4 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 - 4 |
| | 5b | Name and contact information for the trial sponsor | 4 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | |
| **Introduction** | | | 5 - 7 |

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| | | | |
|---|---|---|---|
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | |
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 7 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 8 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 15 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 15 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 11 |



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| | | | |
|---|---|---|---|
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 14 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 15 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 9 |
| **Methods: Data collection, management, and analysis** | | | |



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| | | | |
|---|---|---|---|
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 15 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 14 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 15-16 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 16 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 16 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 15 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | |



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| | | | |
|---|---|---|---|
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 15 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 15 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 8 and 16 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | Accordance with swiss ethics process |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 and 16 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 16 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 4 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 4 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 16 |



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| | | | |
|---|---|---|---|
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 4 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Accordance with swiss ethics process |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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# Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial

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# Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial

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# Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial


## 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 program. In a post-stroke context, physical activity and rehabilitation can be difficult tasks because of cognitive and motor impairments. It is therefore urgent to provide persons in a post-stroke 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 programs on patients' cognitive and motor functions after stroke. Our secondary objective is to investigate the effects of dance on quality of life, motivation and adherence. Our hypothesis is that dance increases balance and motor capacities, and improves post-stroke quality of life, adherence and motivation.

***Methods and analysis***

Forty-eight subjects with stroke in subacute phase will be randomized 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 sixty-minute 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.


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***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

***Protocol version:*** V1 (December 2020)

**Key Words:**

Stroke – rehabilitation - dance – motor functions – recovery – quality of life

## ARTICLE SUMMARY:

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- 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.

**Author contributions:**

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 organization; AVB – as the study's principal investigator – conceived and designed the study, supervised the study, drafted and revised the manuscript.



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**Competing interest:** None declared.

**Patient consent:** To be obtained.

**Study start:** February 3 2020 **/ Study completion:** September 2021

**Ethics approval:** Ethics approval has been granted by the Swiss Ethics Committee of the CER Vaud (2019-01467).

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**Data statement:** At the end of the project, the dataset will be deposited in the Yareta repository developed by the University of Geneva OR in an institutional repository (data will be archived and shared in accordance with the FAIR principles).

**Patient and public involvement:** 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 co-production between researchers and clinicians.

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# TEXT

## Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial

## 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. Joy [1], satisfaction [2] and the benefits of dance – which are genuinely perceived by 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' behaviors are in accordance with the recommendations of healthcare) [4]. All these elements may explain the success of dance programs 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 ischemic or hemorrhagic 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 optimize 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,



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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. Recent research on neuroplasticity mechanisms after stroke has shown the importance of treatment optimization – 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 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].

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,



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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]. Participants seem to rediscover the pleasure of moving – despite their disabilities – and enjoy a strong social bond that favors inclusion and adherence. 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. 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 optimizing patient recovery after stroke.

***Objectives***

*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



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to conventional rehabilitation alone. The adverse effects of dance in subjects with post-stroke hemiparesis in the subacute phase will be assessed.

## METHODS AND ANALYSIS

***TRIAL DESIGN AND SETTING:***

This is a study protocol for a single-center, parallel-arm RCT, registered with ClinicalTRials.gov (NCT04120467) and approved by the Swiss Ethical Committee (CER Vaud 2019-01467). A flow chart of the study process is shown in *figure 1.*

***Figure 1.***

The study protocol conforms to the Standard Protocol Items: Standard Protocol Items for Randomized Trials (SPIRIT).

***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, 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 30s and to endure 60 minutes 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 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). Diagnosis for post-stroke hemiparesis should be systematically established



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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 24hours to consider and discuss participation with a relative before deciding on participating in the study.

***Randomization***

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.

***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.



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***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 Assessment, [27]), the spontaneous and rapid 10-metre walking speed [28], the functional mobility (Timed Up and Go), the trunk balance (Trunk Control Test), the hemineglect (bell's test) and the dance experience [20].

***INTERVENTIONS***

***Dance group***

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.

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 (e.g. 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 memorization – with also the additional challenge of remembering a sequence of moves.



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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 post-stroke 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 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.

***OUTCOMES MEASURES***

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

*Table 2.*



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***Primary outcomes***

The primary outcome is recovery, measured through change assessment (compared to 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 0-2. "0" indicates the lowest level of function and "2" the highest level of function [31]. 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 [32,33]. Balance confidence will be measured using the Activities-Specific Balance Confidence scale (ABC-scale) [34]. 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 ≤67 indicates an increased risk of fall.

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 [35]. Participants will be in a sitting position with their feet free and a 90-degree knee flexion. The dynamometer will be placed on the distal part of the leg [36,37]. Participants will apply maximum pressure on the dynamometer for 5s. 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 [38,39]. 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-degree flexion. Then, after a first trial, they will be instructed to alternately touch the proximal and distal targets, placed 30cm apart, using their big toe, for 20s, as fast as possible, without trading accuracy for speed. The number of touched targets will be counted and registered for analysis.



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Motor level will be assessed using a Functional Independence Measure Instrument (FIM) [40]. 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.

Cognitive function will be measured using the Montreal Cognitive Assessment scale [41]. This tool is better than the mini-mental state evaluation (MMSE) with less of a ceiling effect and higher internal reliability; it is a stronger functional status indicator [41]. There are 12 items in the cognitive domain: memory is tested through a short-term memory recall task (5 points); visuospatial ability is tested using a clock-drawing test (3 points) and a 3-dimensional cube copy (1 point); executive function is tested using a trail-making test (1 point), a phonemic fluency task (1 point), and a 2-item verbal abstraction task (2 points); attention, concentration, and working memory are tested using an attention task (1 point), a serial subtraction task (3 points), and digits tasks (1 point each); language is tested using a 3-item confrontation naming task with animals (3 points) and repetition of 2 complex sentences (2 points); orientation in time and place is also tested (6 points). The minimum score is 0 and the maximum score is 30. Higher scores indicate better cognition (normal score: >26/30).

***Secondary outcomes***

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



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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 program 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' (e.g. “no pain” or “no fatigue) to '10' (e.g. “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 program 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 to 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. 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



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with stroke at the rehabilitation center. 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 center by project workers specifically trained in the test protocol in order to standardize 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: 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.



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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.

***STASTISTICAL 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. 2018 [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, 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.

***Data treatment and statistical analysis***

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,



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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.

## ETHICS AND DISSEMINATION

**Recruitment and consent:** Prospective, written consent will be obtained from all participants.

**Data collection, storage and access:** Data will be de-identified 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].



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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].

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. 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.

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.



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## FIGURE CAPTION:

***Figure 1:*** flow chart of the study protocol.

## 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 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.<br>Participants will have to interact with one or more partners.<br>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 |



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| | | |
|---|---|---|
| | | 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. |

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***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) |
| References | *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. A white box indicates that the parameter has not been studied.



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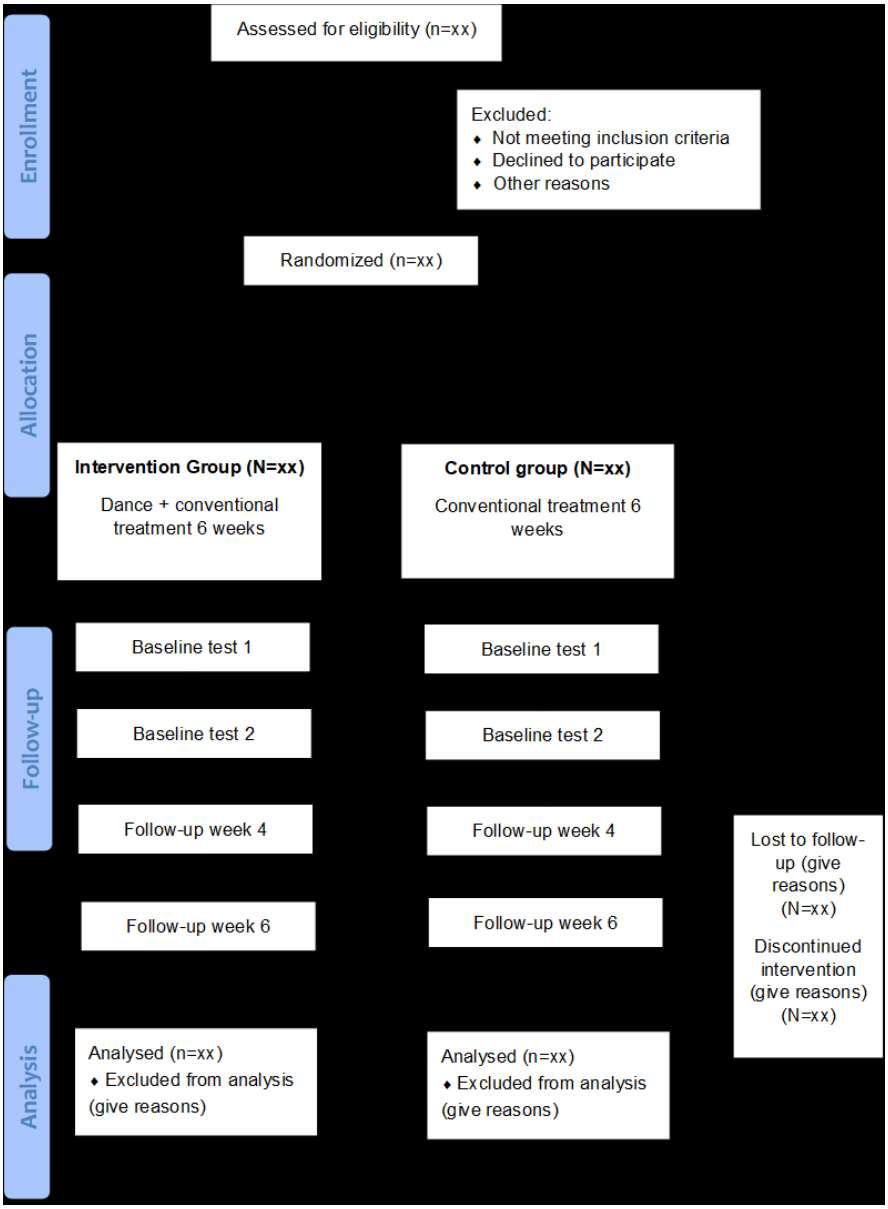


Figure 1: Flow chart

67x91mm (300 x 300 DPI)



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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | 3 |
| Funding | 4 | Sources and types of financial, material, and other support | 4 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 - 4 |
| | 5b | Name and contact information for the trial sponsor | 4 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | |
| **Introduction** | | | 5 - 7 |

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| | | | |
|---|---|---|---|
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | |
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 7 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 8 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 15 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 15 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 11 - 12 |



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| | | | |
|---|---|---|---|
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 14 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 16 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 9 |
| **Methods: Data collection, management, and analysis** | | | |

| | | | |
|---|---|---|---|
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 15 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 14 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 16 - 17 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 17 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 17 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 15 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | |



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|---|---|---|---|
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 15 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 15 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 8 and 17 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | Accordance with swiss ethics process |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 and 17 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 17 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 4 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 4 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 17 |

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|---|---|---|---|
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 4 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Accordance with swiss ethics process |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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



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

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


## 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 program. It is therefore urgent to provide persons in a post-stroke 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 programs 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 post-stroke quality of life, adherence and motivation.

***Methods and analysis***

Forty-eight subjects with stroke in subacute phase will be randomized 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 sixty-minute 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.


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***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

***Protocol version:*** V1 (December 2020)

**Key Words:**

Stroke – rehabilitation - dance – motor functions – recovery – quality of life

## ARTICLE SUMMARY:

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- 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.

**Author contributions:**

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 organization; AVB – as the study's principal investigator – conceived and designed the study, supervised the study, drafted and revised the manuscript.



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**Competing interest:** None declared.

**Patient consent:** To be obtained.

**Study start:** February 3 2020 **/ Study completion:** September 2021

**Ethics approval:** Ethics approval has been granted by the Swiss Ethics Committee of the CER Vaud (2019-01467).

**Provenance and peer review:** Not commissioned; externally peer reviewed.

**Data statement:** At the end of the project, the dataset will be deposited in the Yareta repository developed by the University of Geneva OR in an institutional repository (data will be archived and shared in accordance with the FAIR principles).

**Patient and public involvement:** 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 co-production between researchers and clinicians.

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# TEXT

## Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial

## 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. Joy [1], satisfaction [2] and the benefits of dance – which are genuinely perceived by 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' behaviors are in accordance with the recommendations of healthcare) [4]. All these elements may explain the success of dance programs 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 ischemic or hemorrhagic 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 optimize 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,



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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. Recent research on neuroplasticity mechanisms after stroke has shown the importance of treatment optimization – 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 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].

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,



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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]. Participants seem to rediscover the pleasure of moving – despite their disabilities – and enjoy a strong social bond that favors inclusion and adherence. 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. 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 optimizing patient recovery after stroke.

***Objectives***

*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 balance control 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 balance control 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 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



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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 assessed.

## METHODS AND ANALYSIS

***TRIAL DESIGN AND SETTING:***

This is a study protocol for a single-center, parallel-arm RCT, registered with ClinicalTRials.gov (NCT04120467) and approved by the Swiss Ethical Committee (CER Vaud 2019-01467). A flow chart of the study process is shown in *figure 1.*

***Figure 1.***

The study protocol conforms to the Standard Protocol Items: Standard Protocol Items for Randomized Trials (SPIRIT).

***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 (e.g. 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 30s and to endure 60 minutes 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 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



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based on data from their clinical file (date of birth, date of stroke, stage of stroke, presence of hemiparesis, clinical data). Diagnosis for post-stroke 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 24hours to consider and discuss participation with a relative before deciding on participating in the study.

***Randomization***

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).

***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.



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***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 Assessment, [27]), the spontaneous and rapid 10-metre walking speed [28], the functional mobility (Timed Up and Go), the trunk balance (Trunk Control Test), the hemineglect (bell's test) and the dance experience [20].

***INTERVENTIONS***

***Dance group***

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.

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 (e.g. 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 memorization – with also the additional challenge of remembering a sequence of moves.



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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 post-stroke 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 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.

***OUTCOMES MEASURES***

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

*Table 2.*



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***Primary outcomes***

The primary outcome is balance control recovery, measured through change assessment (compared to 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 0-2. “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 scale [32]. This tool is better than the mini-mental state evaluation (MMSE) with less of a ceiling 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 (5 points); visuospatial ability is tested using a clock-drawing test (3 points) and a 3-dimensional cube copy (1 point); executive function is tested using a trail-making test (1 point), a phonemic fluency task (1 point), and a 2-item verbal abstraction task (2 points); attention, concentration, and working memory are tested using an attention task (1 point), a serial subtraction task (3 points), and digits tasks (1 point each); language is tested using a 3-item confrontation naming task with animals (3 points) and repetition of 2 complex sentences (2 points); orientation in time and place is also tested (6 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-degree knee flexion. The dynamometer will be placed on the distal part of the leg [34,35]. Participants will apply maximum



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pressure on the dynamometer for 5s. 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-degree flexion. Then, after a first trial, they will be instructed to alternately touch the proximal and distal targets, placed 30cm apart, using their big toe, for 20s, 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 ≤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



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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 program 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' (e.g. “no pain” or “no fatigue) to '10' (e.g. “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 program 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 to 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



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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. 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. 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 center by project workers specifically trained in the test protocol in order to standardize 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



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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.

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.

***STASTISTICAL 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. 2018 [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 a standard deviation 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).

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.

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



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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 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 to baseline is different between intervention and control groups. We will do posthoc comparison between 6 weeks and 4 weeks then between 4 weeks and baseline as secondary analyses.

Multivariate Analysis of Variance (MANOVA) 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 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 $p < 0.05$ (two-tailed test) will be adopted to rule out non-significant differences.

## ETHICS AND DISSEMINATION

**Recruitment and consent:** Prospective, written consent will be obtained from all participants.

**Data collection, storage and access:** Data will be de-identified 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



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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 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. 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].

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 program. 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 program in the service's rehabilitation program, this should not change the center's general organization. Blinding is impossible for the subjects and



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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.

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.

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## FIGURE CAPTION:

***Figure 1:*** flow chart of the study protocol.

## 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 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.<br>Participants will have to interact with one or more partners.<br>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. |



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| | | |
|---|---|---|
| *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. |

***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) |
| References | *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. A white box indicates that the parameter has not been studied.



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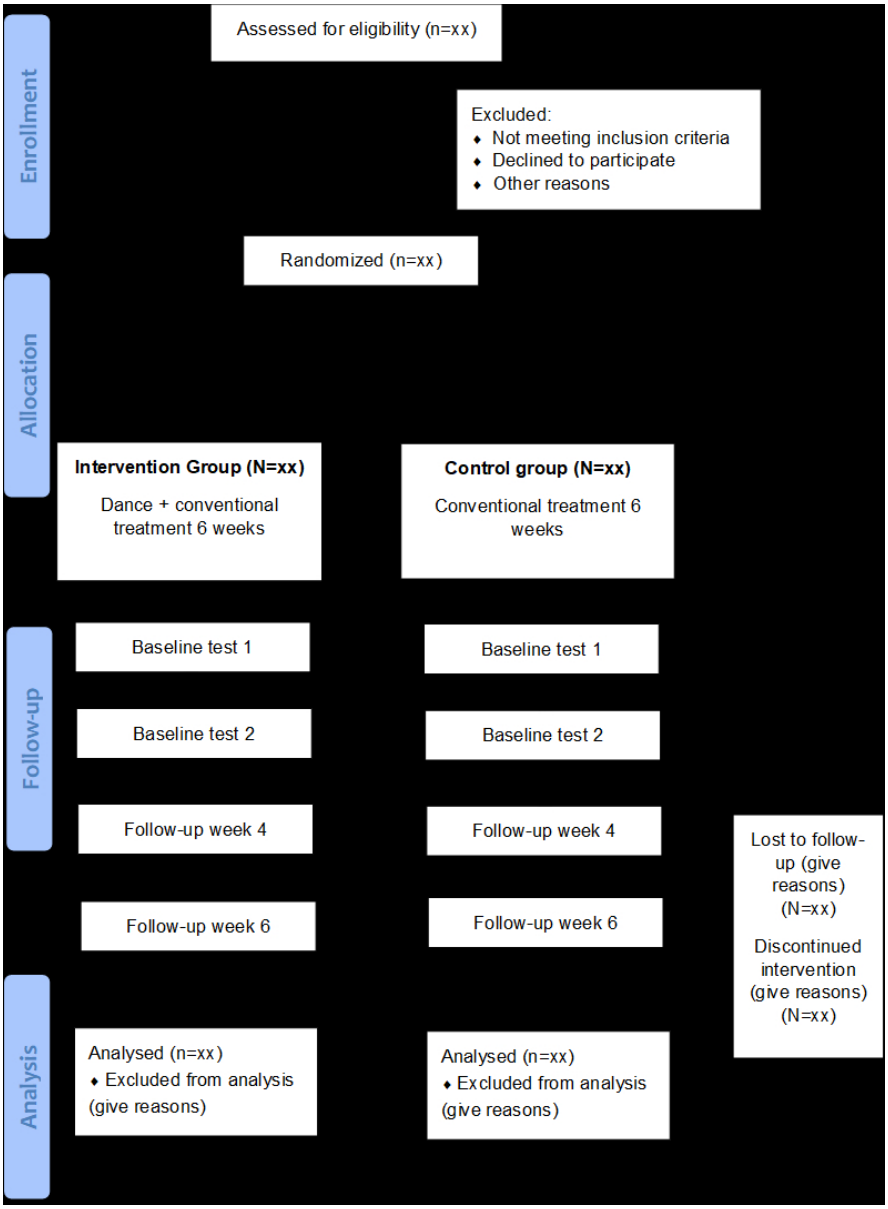


Figure 1: Flow chart

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | 3 |
| Funding | 4 | Sources and types of financial, material, and other support | 4 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 - 4 |
| | 5b | Name and contact information for the trial sponsor | 4 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | |
| **Introduction** | | | 5 - 7 |

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| | | | |
|---|---|---|---|
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | |
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 7 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 8 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 15 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 15 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 11 - 12 |



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| | | | |
|---|---|---|---|
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 14 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 16 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 9 |
| **Methods: Data collection, management, and analysis** | | | |

| | | | |
|---|---|---|---|
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 15 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 14 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 16 - 17 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 17 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 17 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 15 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | |



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| | | | |
|---|---|---|---|
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 15 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 15 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 8 and 17 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | Accordance with swiss ethics process |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 and 17 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 17 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 4 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 4 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 17 |

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|---|---|---|---|
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 4 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Accordance with swiss ethics process |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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



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

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


## 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 program. It is therefore urgent to provide persons in a post-stroke 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 programs 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 post-stroke quality of life, adherence and motivation.

***Methods and analysis***

Forty-eight subjects with stroke in subacute phase will be randomized 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 sixty-minute 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.


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***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

***Protocol version:*** V1 (December 2020)

**Key Words:**

Stroke – rehabilitation - dance – motor functions – recovery – quality of life

## ARTICLE SUMMARY:

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- This is a pioneering randomised control trial to assess the effects of dance program 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).

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# TEXT

## Dancing to improve cognitive and motor functions and quality of life after stroke: a study protocol for a randomized controlled trial

## 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. Joy [1], satisfaction [2] and the benefits of dance – which are genuinely perceived by 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' behaviors are in accordance with the recommendations of healthcare) [4]. All these elements may explain the success of dance programs 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 ischemic or hemorrhagic 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 optimize 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,



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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. Recent research on neuroplasticity mechanisms after stroke has shown the importance of treatment optimization – 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 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].

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,



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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]. Participants seem to rediscover the pleasure of moving – despite their disabilities – and enjoy a strong social bond that favors inclusion and adherence. 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. 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 optimizing patient recovery after stroke.

***Objectives***

*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 balance control 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 balance control 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 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



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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 assessed.

## METHODS AND ANALYSIS

***TRIAL DESIGN AND SETTING:***

This is a study protocol for a single-center, parallel-arm RCT, registered with ClinicalTRials.gov (NCT04120467) and approved by the Swiss Ethical Committee (CER Vaud 2019-01467). A flow chart of the study process is shown in *figure 1.*

***Figure 1.***

The study protocol conforms to the Standard Protocol Items: Standard Protocol Items for Randomized Trials (SPIRIT).

***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 co-production 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 (e.g. 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 30s and to endure 60 minutes of moderate physical activity. Participants will be excluded if they present severe hearing loss, pre-existing conditions that affect gait



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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 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). Diagnosis for post-stroke 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 24hours to consider and discuss participation with a relative before deciding on participating in the study.

***Randomization***

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).



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***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 Assessment, [27]), the spontaneous and rapid 10-metre walking speed [28], the functional mobility (Timed Up and Go), the trunk balance (Trunk Control Test), the hemineglect (bell's test) and the dance experience [20].

***INTERVENTIONS***

***Dance group***

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.



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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 (e.g. 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 memorization – 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 post-stroke 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 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



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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*.

*Table 2.*

***Primary outcomes***

The primary outcome is balance control recovery, measured through change assessment (compared to 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 0-2. "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 scale [32]. This tool is better than the mini-mental state evaluation (MMSE) with less of a ceiling 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 (5 points); visuospatial ability is tested using a clock-drawing test (3 points) and a 3-dimensional cube copy (1 point); executive function is tested using a trail-making test (1 point), a phonemic fluency task (1 point), and a 2-item verbal abstraction task (2 points); attention, concentration, and working memory are tested using an attention task (1 point), a serial subtraction task (3 points), and digits tasks (1 point each); language is tested using a 3-item confrontation naming task with animals (3 points) and repetition of 2 complex sentences (2



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points); orientation in time and place is also tested (6 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-degree 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 5s. 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-degree flexion. Then, after a first trial, they will be instructed to alternately touch the proximal and distal targets, placed 30cm apart, using their big toe, for 20s, 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 ≤67 indicates an increased risk of fall. Standing balance will be tested in standing in single task and dual-task (with phone text



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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 program 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' (e.g. “no pain” or “no fatigue) to '10' (e.g. “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 program 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 to the number of dance classes and conventional interventions planned.



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***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 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. 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. 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 center by project workers specifically trained in the test protocol in order to standardize 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



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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; 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.

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.

***STASTISTICAL 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. 2018 [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 a standard deviation 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).



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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.

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.

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 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 to baseline is different between intervention and control groups. We will do posthoc comparison between 6 weeks and 4 weeks then between 4 weeks and baseline as secondary analyses.

Multivariate Analysis of Variance (MANOVA) 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 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 $p < 0.05$ (two-tailed test) will be adopted to rule out non-significant differences.

## ETHICS AND DISSEMINATION



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**Recruitment and consent:** Prospective, written consent (supplementary file) will be obtained from all participants.

**Data collection, storage and access:** Data will be de-identified 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 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. 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].

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-



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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 program. 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 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.

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.

## DECLARATIONS:

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**Competing interest:** None declared.

**Data Sharing:** At the end of the project, the dataset will be deposited in the Yareta repository developed by the University of Geneva OR in an institutional repository (data will be archived and shared in accordance with the FAIR principles).

**Author contributions:**

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 organization; AVB – as the study's principal investigator – conceived and designed the study, supervised the study, drafted and revised the manuscript.



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**Patient consent:** To be obtained.

**Study start:** February 3 2020 **/ Study completion:** September 2021

**Ethics approval:** Ethics approval has been granted by the Swiss Ethics Committee of the CER Vaud (2019-01467).

**Provenance and peer review:** Not commissioned; externally peer reviewed.

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## FIGURE CAPTION:

***Figure 1:*** flow chart of the study protocol.

## 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 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.<br>Participants will have to interact with one or more partners.<br>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 |



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| | | |
|---|---|---|
| | | 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. |

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***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) |
| References | *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. A white box indicates that the parameter has not been studied.



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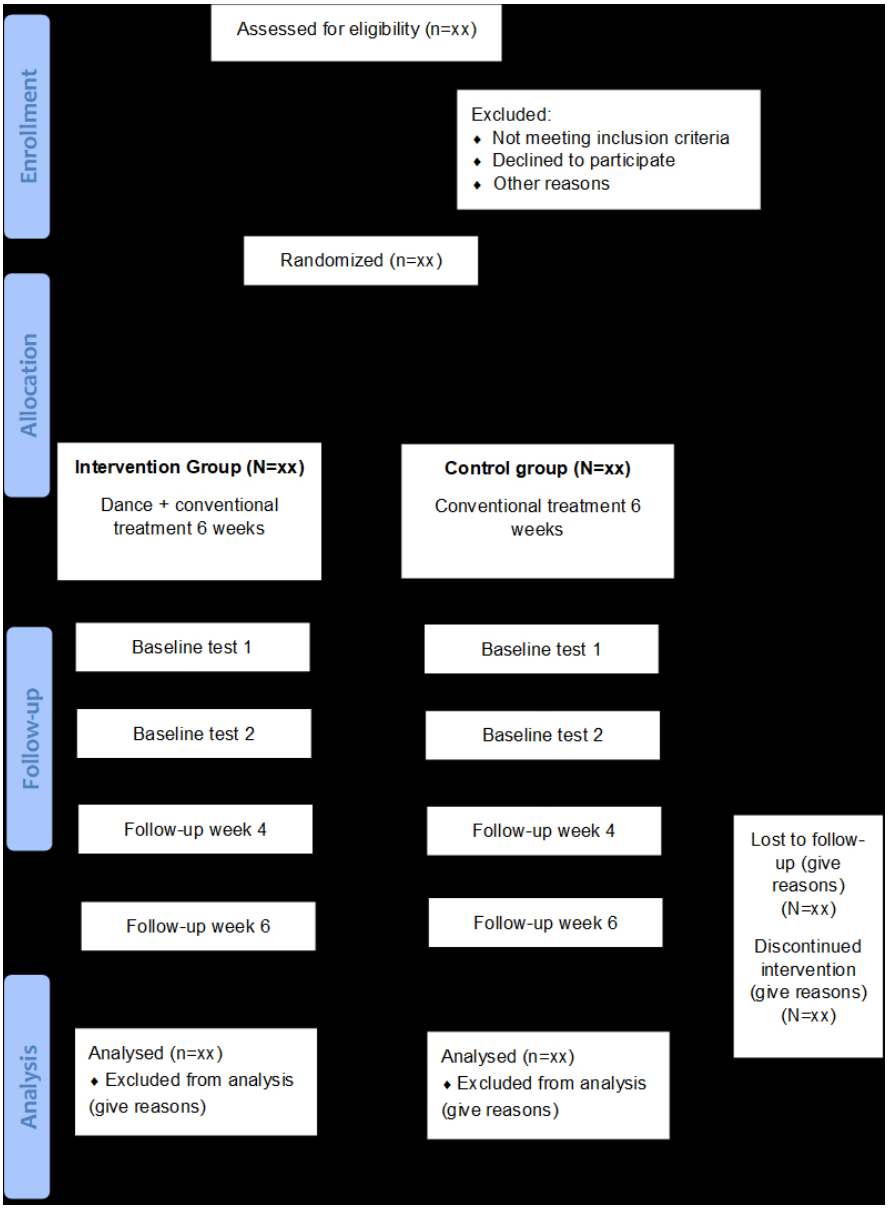


Figure 1: flow chart of the study protocol.

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Dr Anne-Violette Bruyneel
Principal investigator

**Date : September 18th 2019**

**Version : 2 (translate in English)**

**Redaction : Anne-Violette Bruyneel (**Sponsor-Investigator**)**

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## *Information for patients*

**Title**

***Acronym :*** Hemi'Danse.

***Full official title:***
Dance After a Stroke to Restore Pleasure in Physical Activity to Improve Cognitive and Motor Functions, Quality of Life and Well-being

***Public title :***
Dance after a stroke to regain pleasure in movement in order to improve recovery, quality of life and well-being.

**Sponsor :** Geneva School of Health Sciences, HES-SO University of Applied Sciences and Arts Western Switzerland, physiotherapy department.

**Clinical correspondant (Lavigny Institution) :** reffering physician.

Dear Madam, Dear Sir,

We invite you to participate in our research project that studies the effect of dance practice in addition to conventional rehabilitation on the recovery and quality of life of patients after a stroke.

This fact sheet describes the research project.

## Detailed information

### 1. Objectives

This study should allow us to know if the dance practice as a complement to the usual rehabilitative care for patients with stroke allows :
- to improve motor and cognitive recovery;
- to improve quality of life and motivation to be physically active.
The objective is also to evaluate the satisfaction of the participants of this dance program and their participation.

### 2. Selection of potential study participants

Forty-eight participants will be involved in this project.
Participation is open to all people who suffer from hemiparesia (motor and sensitivity disorders of one half of the body) after a stroke episode and who, in addition, are between 45 and 80 years old, male or female, have medical stability, sufficient capacity to understand the instructions of the tests, a stable balance to perform the tests and dance classes, and an ability to make a moderate effort for a period of 60 minutes.



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It is, however, closed to people with significant medical complications, major uncorrectable hearing problems and when there are previous pathologies affecting balance, motor capacities and cognition. Following the initial clinical tests, we may also be led to exclude people who would have difficulty performing the tests throughout the entire procedure.

## 3. General information on the study

- This study, carried out in Switzerland, will have a total duration of 24 months. Forty-eight participants with hemiplegia will be included in the sub-acute phase (the stroke must be less than 3 months old). The participants will be recruited at the Institution of Lavigny.
- All patients included in the study will have the same testing procedure (2 baseline tests and 2 follow-up tests).
- Individuals who meet the inclusion criteria and who have signed the informed consent will be invited to come to two sessions spaced 24 to 48 hours apart to test their balance, motor capacities, functional level, cognition and motivation for physical activity.
- For the study duration, all patients will have the usual care after a stroke. Half of the participants will also have a weekly dance class with a physiotherapist-dance teacher. Participation in the dance course will be determined by a random process.
- Two follow-up tests will be conducted: the first at 4 weeks and the second at 6 weeks.
- The 4 test sessions duration is between 1 and 2 hours, including rest periods.
- The total duration of the follow-up is 6 weeks per participant.
- Participants who express the wish to do so can receive their results on an individual basis.
- We are conducting this study in accordance with the Swiss legislation. In addition, we follow all internationally recognized guidelines. The competent cantonal ethics commission has monitored and authorised the study.
- A description of the study can also be found on the website of the Federal Office of Public Health: www.kofam.ch.

## 4. Procedure for the participants

- You will undergo a clinical examination during which we will measure your orientation, memory, attention and language capacities (all in one test) as well as your ability to remain seated during 30 seconds. These 2 tests, lasting a maximum of 10 minutes, allow us to evaluate your ability to carry out the measurements over the entire study.

If you are included in the study:

- You will have two successive appointments to check your clinical stability, with 24 to 48 hours of rest in between. These tests will evaluate your motor capacities, balance, coordination, muscular strength and daily activities. Four questionnaires/scales will also be applied to assess your confidence in balance, cognition, quality of life and motivation for physical activity. The first appointment will last 1 hour and 50 minutes, including 20 minutes of rest. The second appointment is 60 minutes in length. These tests do not include any invasive examination.
- Following this phase, you will either have the usual rehabilitation care or you will have the same care, but with the addition of a weekly dance class for 6 weeks. The dance classes do not require previous dance practice. Dance is a very adaptable practice for all levels because it can be practised in a sitting or standing position. A physiotherapist-dance teacher will give the classes in small groups.
- After 4 weeks and 6 weeks, the same tests will be performed. The examination at 4 weeks lasts 1h30 and the examination at 6 weeks lasts 1h55, including rest periods. During these exams, for the participants of the dance classes, the satisfaction related to this activity will be evaluated by questionnaire.
- Throughout the tests and dance classes, fatigue and pain will be rated from 0 to 10 to make sure everything is going well for you.



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Dr Anne-Violette Bruyneel
Principal investigator

**Test schedule and durations :**

| Step | Test | Duration | Total |
|---|---|---|---|
| Clinical examination | Cognitive test (MMSE) | 10 minutes | 10 minutes |
| | Sitting balance 30s | | |
| First appointement | Motor, gait, trunk function, neglect tests | 20 minutes | 1h50 minutes |
| | Rest | 10 minutes | |
| | Balance, coordination, muscular strength, functional independence tests | 50 minutes | |
| | Rest | 10 minutes | |
| | Cognition scale | 20 minutes | |
| | Quality of life scale | | |
| | Motivation scale for physical activity in health context | | |
| Second appointement | Balance, coordination, muscular strength, functional independence tests | 45 minutes | 55 minutes |
| | Cognition scale | 10 minutes | |
| Follow-up four weeks | Balance, coordination, muscular strength, functional independence tests | 45 minutes | 1h05 minutes |
| | Rest | 10 minutes | |
| | Balance confidence scale | 10 minutes | |
| | Motivation scale for physical activity in health context | | |
| Follow-up six weeks | Motor, gait, trunk function, neglect tests | 20 minutes | 1h55 |
| | Rest | 10 minutes | |
| | Balance, coordination, muscular strength, functional independence tests | 50 minutes | |
| | Rest | 10 minutes | |
| | Cognition scale | 25 minutes | |
| | Quality of life scale | | |
| | Motivation scale for physical activity in health context | | |
| | Dance practice satisfaction | | |

We may have to exclude you from the study before the scheduled term. This may happen if you are unable to perform the tests (difficulties in understanding, excessive fatigue, difficulty concentrating). In this case, we will offer you a final examination for your own safety.
Your medical doctor responsible for your rehabilitation at the Lavigny Institution will be informed of your participation in the study.

## 5. Benefits for participants

If you participate in the study, it may eventually bring you :
- Additional information on your evolution;
- An experience / discovery of a different therapeutic activity.

The results of the study could prove important later for people who will be affected by the same disease as you. Indeed, dance is an activity that has shown very interesting results in other chronic conditions but has not yet been studied in the stroke context. If the results prove to be beneficial, dance can be developed and offered as a complement to rehabilitation to vary the treatment and help patients to move more easily despite their difficulties.

## 6. Right of participants

Your participation is entirely free. If you choose not to participate or if you choose to participate and reconsider your decision during the study, you will not have to justify your refusal. This will not



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change your usual medical care. You can ask any questions about the study at any time. Please contact the person listed at the end of this information sheet.

## 7. Obligations of participants

As a participant in the study, you will be required to:

- Follow your investigator's instructions and to comply with the study plan (follow the instructions that will be given to you for each test and respect the rest periods and follow the instructions in the dance class);
- Inform your investigator about the course of the disease and report any new symptoms, disorders and changes in your condition (during the day and during each test).

## 8. Risks and constraints for participants

- This study carries the same risks as those associated with usual rehabilitation after stroke (e.g. fatigue, imbalance, falls);
- The strength measurements we are performing during this study may cause fatigue of the quadriceps muscles (therefore, it is not impossible that these tests will cause you temporary muscle soreness);
- Dance classes may generate fatigue, and we cannot exclude temporary fatigue and pain;
- We can't rule out other as yet unknown risks.

## 9. Other treatment options

You are not required to participate in the study. If you decide not to take part in this study, your usual treatment will continue under normal conditions of service with the same professionalism and attention to take care of you in the best possible way.

## 10. Findings during the study

The investigator will notify you during the study of any new findings that may affect the benefits of the study or your safety, and thus your consent to participate. You will be informed orally and in writing.
If you do not wish to be informed ("right not to know"), please tell the person in charge of the study.

## 11. Confidentiality of the data and sample

For the purposes of the study, we will record your personal and medical data. Only a limited number of people may access your data in an unencrypted form and exclusively in order to be able to carry out tasks necessary for the project.

Data collected for research purposes are coded at the time of collection. Coding means that all data that can identify you (e.g. name, date of birth, etc.) is replaced by a code (coding complies with swissethics recommendations). The code remains permanently within the institution / hospital. People who do not know this code cannot link this data to you.

In the case of a publication, the aggregated data is therefore not attributable to you as a person. Your name will never appear on the Internet or in a publication. Sometimes scientific journals require the transmission of individual data (raw data). If individual data is to be transmitted, it is always coded and therefore does not allow you to be identified as a person.

All persons involved in the study in any way whatsoever are bound by professional secrecy. All data protection guidelines are complied with and you have the right to access your data at any time.

All data and documents (paper and electronic on password-protected external hard disk) will be archived and stored securely in a locked cabinet in the principal investigator's office (address: rue des Caroubiers 25, 1227 Carouge, 2nd floor, room 204) for a period of 10 years.



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During the study, the study may be subject to inspections. These may be carried out by the ethics commission that has taken charge of its initial control and authorized it or by the body that initiated it. The investigator may have to disclose your personal and medical data for the purposes of these inspections.

In the event of damage, an insurance representative may also need to consult your data. All persons are bound by professional secrecy.
It is possible that the medical doctor in charge of your medical follow-up may be contacted about your state of health.

**12. Withdrawal from study**

You can withdraw from the study at any time if you wish. The medical data collected so far will still be analysed, so as not to compromise the value of the study as a whole.
After the analysis we will make your data anonymous, by permanently erasing the code linking it to your person. After that, no one will be able to know that this data and material is yours.

**13. Participants compensation**

If you take part in this study, you will not receive any compensation for doing so. As you will be in hospital, no transportation costs are expected.
Your participation will have no financial consequences for you or your health insurance.
Your usual check-up and rehabilitation will be covered by your health insurance, while additional tests (recovery assessment, functional tests, balance, muscle strength, coordination, quality of life, satisfaction, cognition and motivation scales) and dance classes will be covered by the study sponsor.

**14. Repair of damage**

The Lavigny Institution is liable for any damage you may suffer in connection with the substance under study or with research activities (e.g. examinations). The conditions and procedure are set by law. If you have suffered damage, please contact the study investigator indicated below.

**15. Financing of the study**

The study is mainly financed by the Geneva University of Health (two thirds of the funding) and by the contribution of a generous sponsor advised by CARIGEST SA.

**16. Contact person(s)**

If you have any doubts, fears or emergencies during or after the study, you can contact one of the following contacts at any time:

Investigator :
Anne-Violette Bruyneel
Professeure assistante HES, filière physiothérapie
Rue des Caroubiers 25
CH – 1227 Carouge
Tél : +41 22 388 34 94 (direct).
anne-violette.bruyneel@hesge.ch

Clinical collaborator:
Emmanuel Morice
Institution de Lavigny
Rte du Vignoble 60
CH - 1175 Lavigny
Tél: +41 78 713 76 50
Emmanuel.morice@ilavigny.ch



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| | |
|---|---|
| Dr Anne-Violette Bruyneel<br>Principal investigator | INSTITUTION DE LAVIGNY Agir pour la vie<br>h e d s Haute école de santé Genève Institut de Recherche |

**Consent Statement**

**Written statement of consent for participation in a research project**
Please read this form carefully. Do not hesitate to ask questions if you do not understand something or if you need clarification.

| | |
|---|---|
| **BASEC number:** | 2019-01467 |
| **Study title :** | Dance After a Stroke to Restore Pleasure in Physical Activity to Improve Cognitive and Motor Functions, Quality of Life and Well-being |
| **Sponsor :** | Haute Ecole de Santé de Genève<br>Avenue de Champel 47<br>1206 Genève |
| **Location of the study:** | Institution de Lavigny<br>Rte du Vignoble 60<br>CH - 1175 Lavigny |
| **Sponsor-Investigator:** | ANNE-VIOLETTE BRUYNEEL |
| **Participant :**<br>(first and second names in block letters) :<br>Date of birth : | ☐ woman ☐ men |

- I declare that I have been informed, orally and in writing, by the investigator in charge of this undersigned study, of the objectives and the conduct of the study as well as the presumed effects, advantages, possible disadvantages and possible risks.
- I am participating in this study on a voluntary basis and accept the contents of the fact sheet provided to me on the above-mentioned study. I have had sufficient time to make my decision.
- I received satisfactory answers to the questions I asked in relation to my participation in the study. I retain the information sheet and receive a copy of my written consent statement.
- I agree that my medical doctor referent may be informed of my participation in the study.
- I accept that the competent specialists of the study sponsor, of the competent Ethics Commission, may consult my raw data in order to carry out checks, provided that the confidentiality of these data is strictly guaranteed.
- I am aware that my personal data may be transmitted for research purposes within the scope of this project only and in encrypted form.
- I may, at any time and without having to justify myself, revoke my consent to participate in the study, without this having an adverse effect on my further treatment. However, the medical data that have been collected so far will be analysed.
- I am informed that the civil liability of the hospital/institution covers any damage I may suffer as a result of the project.
- I am aware that the obligations outlined in the Participant Information Sheet must be adhered to for the duration of the study. The study management may exclude me from the study at any time in the interest of my health.

| Location, date | Participant's signature |
|---|---|
| | |



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|---|---|
| Dr Anne-Violette Bruyneel<br>Principal investigator | INSTITUTION DE LAVIGNY Agir pour la vie<br>h e d s Haute école de santé Genève Institut de Recherche |

**Investigator's statement:** I hereby certify that I have explained to the participant the nature, importance and scope of the study. I declare that I meet all obligations in relation to this project in accordance with applicable law. Should I become aware, at any time during the project, of any elements that could affect the participant's consent to take part in the project, I undertake to inform him/her immediately.

| | |
|---|---|
| Location, date | First and second names Name and surname of the investigator providing information to participants in block letters.<br><br>Investigator signature : |

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Page Number on which item is reported |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | 3 |
| Funding | 4 | Sources and types of financial, material, and other support | 4 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1 - 4 |
| | 5b | Name and contact information for the trial sponsor | 4 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | |
| **Introduction** | | | 5 - 7 |

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|---|---|---|---|
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | |
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 7 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 8 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 15 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 15 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 10 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 11 - 12 |



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| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 14 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 16 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 8 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 9 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 9 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 9 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 9 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | 9 |
| **Methods: Data collection, management, and analysis** | | | |

| | | | |
|---|---|---|---|
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 14 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 15 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 14 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 16 - 17 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 17 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 17 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 15 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | |



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| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 15 |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 15 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 8 and 17 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | Accordance with swiss ethics process |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 8 and 17 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 17 |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 4 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 4 |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | NA |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 17 |

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| | 31b | Authorship eligibility guidelines and any intended use of professional writers | |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | 4 |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Accordance with swiss ethics process |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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