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Methods & protocols

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Circuit Class Training in water versus land in Post-Stroke patients: a protocol for a randomized controlled trial

Treinamento de classe em circuito em água versus terra em pacientes pós-acidente vascular cerebral: um protocolo para um estudo controlado randomizado

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RESUMO | INTRODUÇÃO: Uma alta porcentagem de pacientes pós-AVC tem consequências permanentes, apesar da reabilitação convencional. O treinamento em circuito oferece uma maneira eficiente de realizar a prática estruturada de atividades relacionadas à tarefa durante a reabilitação do AVC. A terapia aquática é outra abordagem terapêutica que oferece uma grande variedade de opções para ser um ambiente altamente dinâmico, o que ajuda a melhorar a funcionalidade e recuperar a qualidade de vida e a independência das pessoas com deficiência. **OBJETIVO:** Determinar os efeitos de um treinamento de classe em circuito em água versus terra em pacientes pós-AVC. **MÉTODOS:** Quarenta participantes serão randomizados em dois grupos: treinamento de classe em circuito aquático (ACCT) e treinamento em circuito de terra (LCCT). Em ambos os grupos, a intervenção será uma terapia de 7 semanas, 3 vezes por semana, dando um total de 20 sessões, 60 minutos cada uma. Os avaliadores cegos conduzirão avaliações, utilizando ferramentas padronizadas: linha de base, pós-intervenção e 20 dias de acompanhamento para a eficácia da terapia em termos de marcha, equilíbrio e função motora do membro superior. **RESULTADOS / CONCLUSÃO:** Este estudo examinará o efeito imediato e de médio prazo de um programa ACCT em comparação com um programa LCCT em pessoas com AVC. Tem o potencial de identificar intervenções que possam melhorar a reabilitação desses pacientes. Ambos os programas do CCT são baseados no modelo da Classificação Internacional de Função, Incapacidade e Saúde, com atividades voltadas para os níveis de deficiência, atividade e participação.

PALAVRAS-CHAVE: Terapia aquática. Treinamento de classe em circuito. AVC.

ABSTRACT | INTRODUCTION: A high percentage of post-stroke patients have permanent aftermaths despite conventional rehabilitation. Circuit class training offers an efficient way to achieve structured practice of task-related activities during stroke rehabilitation. Aquatic therapy is another therapeutic approach that offers a great variety of options to be a highly dynamic environment, which helps to improving functionality and recover quality of life and independence in people with disabilities. **OBJECTIVE:** To determine the effectiveness of a circuit class training in water versus land in post-stroke patients. **METHODS:** Forty participants will be randomized in two groups: aquatic circuit class training (ACCT) and land circuit class training (LCCT). In both groups, the intervention will be a 7-week class therapy, 3-times weekly, giving a total of 20 sessions, 60 minutes each. Blinded assessors will conduct assessments, using standardized tools: baseline, post-intervention, and 20 days follow-up for the effectiveness of the therapy in terms of gait, balance and upper limb motor function. **RESULTS/CONCLUSION:** This trial will examine the immediate and medium term effect of an ACCT program as compared to a LCCT program in people with stroke. It has the potential to identify interventions that may improve rehabilitation of these patients. Both CCT programs are based in International Classification of Function, Disability and Health model with activities aimed at impairment, activity and participation levels.

KEYWORDS: Aquatic therapy. Circuit class training. Stroke.

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Introduction

A high percentage of stroke survivors' have permanent aftermaths[1], despite conventional rehabilitation. Post-stroke recovery is influenced by the size, type and location of brain damage but also by the quality and intensity of rehabilitation[2]. Hence the importance of effective programs of physiotherapy to reduce disability and improve the quality of life of these patients. In last years, task-oriented therapy has increased its potential due to the good results shown by the studies[3-5]. Task-oriented approaches focus on the interaction of multiple systems and assume that motor control and behavior are organized around activities with directed and functional objectives, not on muscles or movement patterns[6]. Circuit class training offers an efficient way to achieve structured practice of task-related activities during stroke rehabilitation[7]. This practice consists of performing a series of workstations that are usually arranged as a circuit[8]. The exercises are progressive, in terms of number of repetitions or complexity and are adapted to the individual needs of the patient[9]. The circuit class training (CCT) may offer a more intensive and specific exercise in an enriched rehabilitative setting with no detrimental effects on subjective fatigue[10].

Aquatic therapy (AT) is a therapeutic approach in which the properties of water are used together with specific interventions, in order to facilitate the function and the achievement of the proposed objectives[11]. Neurological patient's treatment in water offers a great variety of options, in a highly dynamic environment, which helps to improving functionality and recover quality of life and independence in people with disabilities[12-13]. People suffering from symptoms such as muscle weakness, balance disturbances or movement limitations may have difficulty to performing exercises on the floor[14]. In water, the reduction of weight can facilitate the realization of movements and reduce the risk of falls, which helps to achieve greater exploratory movements and functional activity training[15-16].

Previous studies in post-stroke patients have shown beneficial effects of the two therapies CCT[17-18] and aquatic therapy[19-20], as separate forms of treatment, which allow us to be optimistic in predicting good results by applying both therapies together. The objective of this study is to determine the effectiveness of a circuit class training in water versus land in post-stroke patients.

Methods/Design

Study design

The study proposed is a single-blinded randomized controlled trial.

Participants and eligibility criteria

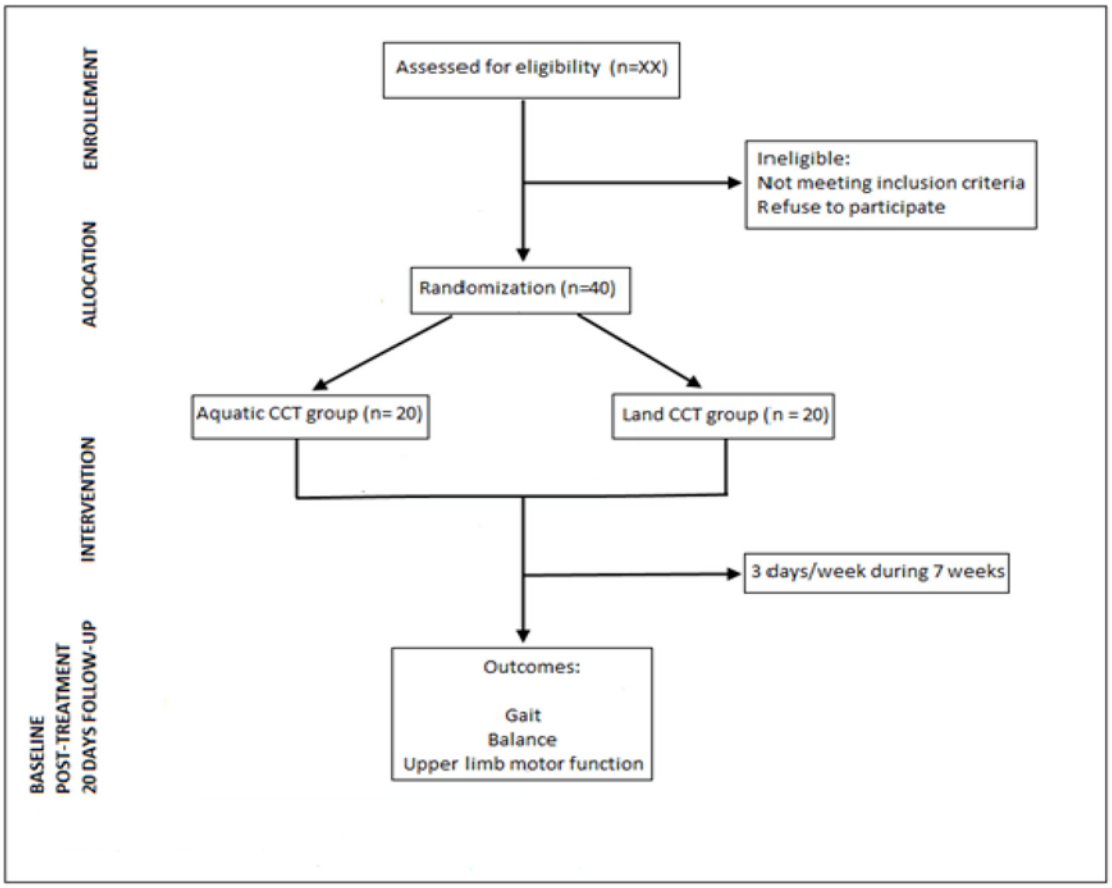
All participants will be considered eligible only who meet the inclusion criteria: Patients with diagnosis of stroke (ischemic or hemorrhagic) onset ≤ 3 years, with hemiparesis secondary; age ≥18 to ≤ 90; provide a written informed consent; able to walk for at least 10 m without assistance. The exclusion criteria will be: patients with uncontrolled or risky conditions (acute myocardial infarction, arrhythmia, heart failure, uncontrolled hypertension or unstable cardiovascular state); with infectious diseases, ulcers or urinary and / or fecal incontinence; additional neurological and / or orthopedic deficits that affects ambulation; unable to follow treatment (cognitive, visual ...).

Randomization

Patients who meet the eligibility criteria, once have given consent for participation, will be considered for randomization into one of two groups of the study, intervention group (ACCT) or control group (LCCT). The randomization scheme will be generated by using a computer generated random allocation sequence.

Assessments of all participants will be carried out in the same place and dates, alternating participants of both groups, guaranteeing in this way, the blinding of the assessors. Participants will also be instructed not to divulge information regarding their type of intervention to the assessors. The flow diagram of the study is summarized in Figure 1.

Figure 1. Flow diagram of the study



Outcome measures

All participants will be assessed in three stages: baseline assessment (including socio-demographic characteristics information), post-intervention assessment, and 20-days follow-up assessment. The table 1 presents the outcomes measures and assessment tools.

Table 1. Outcome measures and assessment tools

Outcomes measures		Assessment tools
Social-demographic characteristics (personal, demographic and lifestyle information)		Interview/ Ad Hoc questionnaire
Disease and rehabilitation information		Interview/ Ad Hoc questionnaire
Motor parameters	Gait:	10 Meter Walk Test (10MWT) Two-minute Walk Test (2MWT) Computer Vision Mobility software (CvMob)
	Balance:	Berg Balance Scale (BBS) Timed Up & Go test (TUG) Functional Reach Test (FRT) Activities-Specific Balance Confidence Scale (ABC)
	Upper limb motor function:	Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA) Box and block test (BBT)

All assessors will be trained in the collection of outcome measures for the standardization of the data. Each assessor will have their outcomes, which will be carried out by the same person in the three assessments. Double data entry will be performed by two independent researchers, blind to group allocation.

Gait

CvMob Software

Computer Vision Mobility (CvMob) software is an open-source tool, capable of analyzing the trajectories and measuring mechanical parameters of the movement through algorithms based on computer vision applied to videos of moving objects[21].

Two videos of each participant will be recorded in each of the three assessments, which will be later analyzed with CvMob. Markers will be placed on the pterion (to obtain the data of the stand-up parameters) and external malleolus of the affected side (to obtain the data of the gait parameters). The camera used to record the videos will be the Casio Exilim EX ZR 1000, adapted to a tripod with adjustable height, which will be placed at a distance of 3.52 meters from the center of the corridor. Videos will be recorded at 120 frames/sec. The calibration of the software CvMob will be always done at the beginning of each video, using the distance between two points previously marked on the ground, located in the same plane and distance of the camera as the participants .

The table 2 shows the descriptions of outcomes that will be obtained with the CvMob software in this study. For this, it will be calculated analyzing the images recorded in video during the test of the 10MWT (although only will be recorded four meters of the test) and another video during the TUG (to obtain the data of the stand-up).

Table 2. Outcomes analyzed with the CvMob software

Outcomes	Test recorded	Definitions of CvMob outcomes	Expression of results
Stride time	10MWT	The average of the time needed to take a stride, in completes strides captured by the video.	seconds
Stride speed	10MWT	The average of the stride speed during the horizontal displacement (x-axis), in completes strides captured by the video.	meters/ second
Maximum stride speed	10MWT	The average of the maximum stride speed during the horizontal displacement (x-axis), in completes strides captured by the video.	meters / second
Stride length	10MWT	The average of the horizontal distance (x axis) of the stride, in completes strides captured by the video. The software calculated the size of each stride by measuring the distance between the first foot contact on the ground and the next foot contact.	meters
Maximum step height	10MWT	The average of the maximum step height, vertical displacement (y-axis), in completes strides captured by the video.	centimeters
Stand-up time	TUG	The time the individual need to complete the stand-up action.	seconds
Stand-up speed	TUG	The average speed at which the individual performs the stand-up action	meters / second

10MWT=10 Meter Walk Test (10MWT); TUG= Timed Up & Go test

10 Meter Walk Test (10MWT)

10MWT is a measurement of gait speed, calculate by the time required to walk a ten meters distance. The patient will be instructed to walk along a fourteen meter straight walkway, with their usual shoes, at preferred walking speed. The first two meters as well as the last two will not be timed to avoid the effects of acceleration and deceleration. Therefore, it will ensure a steady velocity within the central ten meters. The distance covered is divided by the time it took the individual to walk that distance. Average speed is calculated after performing the test three times. Assistive devices may be used but must be kept consistent and documented from test to test. The calculation starts from the first contact of the heel with the ground after crossing the line of the two meters, marked on the catwalk, and ends at the time of removal of the heel of the ground before passing the line of twelve meters of the runway.

Two-minute Walk Test (2MWT)

2MWT is a measurement of endurance by assessing walking maximum distance over two minutes. The patient walks down a thirty-meters-long hallway taking as many meters as he can, in order to get the maximum distance. The patient will be instructed to walk as fast as possible, being able to slow down and stop if necessary, being aware that the time would not stop. The test will only be carried out once each assessment.

Balance

Berg Balance Scale (BBS)

The BBS is a objective measure designed to assess balance and fall risk through 14 items in which different tasks are evaluated. Static and dynamic activities of varying difficulty are performed. Each item is scored from 0 to 4, where 4 represents the ability to perform the proposed activity in its entirety and without difficulty, and 0 represents the inability to achieve such activity. The points of each item are added together to obtain the final result. The maximum total score on the scale is 56 points. The higher the result, the better the balance.

Timed Up & Go test (TUG)

The TUG is a dual-task dynamic measure for identifying individuals who are at risk for falls. In TUG, the patient will be sitting in a chair with armrests, resting on the back of the chair and feet on the floor. Individuals are given verbal instructions to stand up from a chair, walk 3 meters as quickly and safely as possible, cross the line marked on the floor, turn around, walk back, and sit down. Individuals are allowed to use the assistive device they typically use in the community, but without the assistance of another person. Time begins when the "now" instruction is given and stops when the patient is seated again. The time it takes to complete the entire sequence is counted in seconds. It will be done three times and the final result will be the numerical average of the result of the three attempts.

Functional Reach Test (FRT)

FRT is a clinically useful measure of patient's stability by measuring the maximum distance an individual can reach forward while standing in a fixed position. A tape measure is placed on the wall. Patients are instructed to stand close to the tape without touching it and raise the arm that is closer to the wall at 90° of shoulder flexion with a closed fist. The evaluator records the starting position at the 3rd metacarpal head on the yardstick. The patient is asked to "reach as far as you can forward without taking a step". The new location of the 3rd metacarpal head is recorded. The results are the difference between the start and end position, measured in centimeters. Participants will perform 3 trials, the average obtained is the person's score.

Activities-Specific Balance Confidence Scale (ABC)

Subjective measure of confidence in performing various ambulatory activities without falling or experiencing a sense of unsteadiness. The ABC assesses 16 items about the confidence in the balance, associated to performing activities of the daily life. For each activity, the individual must indicate, with the help of an 11-point visual analogue scale, the level of confidence in performing a specific task without fear of losing balance and / or falling. This stem is used to lead into each activity considered: "How confident are you that you will not lose your balance or become unsteady when you..." Subjects can assign scores ranging from 0 (no confidence) to 100% (completely safe). The total score on the ABC scale will be obtained by adding the scores (0-1,600) and dividing by 16. The confidence scores are as follows: >80% indicates a high level of balance confidence; 50-80%, moderate level and <50%, a low level of balance confidence. Values <67% in older adults are predictive of future falls.

Upper limb motor function

Fugl-Meyer Assessment of Motor Recovery after Stroke (FMA)

The Fugl-Meyer Assessment (FMA) it is designed to assess motor function, balance, sensation and joint function in patients with post-stroke hemiplegia. As subscales can be administered without using the full test, in this study will only be performed subscale of motor function. This subscale is divided in four parts (A-D): A. Upper limb (I. Reflex activity; II. Voluntary movement with synergies and without gravitational help; III. Movement by mixing synergies and without compensation; IV. Voluntary movement with little or no synergies; V. Normal reflex activity assessed, when the 6 total points are reached in part IV), B. Wrist, C. Hand and D. Coordination / speed (tremor, dysmetria, time). Each requested move will be scored on a 3-point ordinal scale 0 = cannot perform, 1 = performs partially, 2 = performs complete. The maximum total score is 66 points. The higher the score, the greater the skill.

Box and block test (BBT)

The BBT evaluates unilateral thick manual dexterity. Mathiowetz et al. 1985 have provided standardized dimensions for test materials and procedures for test and score management. The box is divided into two square compartments of equal size by means of a division. One hundred and fifty wooden blocks of 2.5 cm of color are placed in one of the compartments. Patients will be instructed to move as many blocks as possible, one at a time, for a period of 60 seconds. The number of blocks transported from one compartment to another will be counted. The patient's hand must cross the partition to give a point, and blocks falling or bouncing out of the second chamber on the floor are still rewarded with a point. Multiple blocks carried at the same time count as a single point. Higher scores on the test will indicate better gross manual dexterity of the person at the extremity with which the test will be performed (affected arm).

Interventions

Interventions developed for this study will be two CCT programs. One of the groups will perform the exercises in aquatic environment (experimental group) and the other on land environment (active control group).

In both groups, the intervention will be a 7-week class therapy, 3-times weekly, completing a total of 20 sessions. One session will be held before starting CCT program, in both groups. This session will have two aims: explain all information about CCT session's development and achieve a good adaptation to the work environment.

Sessions will be established according to the hours of free disposal of the facilities of the center, as well as the possibilities of participants.

Both groups' sessions will involve the same structure. The table 3 shows distribution and time of each session.

Table 3. Distribution of session

Parts of intervention	Time (minutes)
Warm-up	5
CCT (10 workstations)	50 (5 each workstation)
Ai-chi / Stretching	5
Total session	60

CCT= circuit class training

Sessions will start with warm-up, doing always the same sequence of exercises. Warm-up section will be designated for the contact of the patient with the environment and to prepare body for the circuit exercises. Warming will include global aerobic exercises that will increase intensity and O_2 consumption of the body. The exercises will be the same in both groups. Thereafter, the CCT section will start, which will be the main part of the session. It will include 10 different workstations, arranged to progress in complexity, in order to work several segments of the body, oriented towards a goal of functional recovery. These stations will be made up of task-specific activities for gait, balance and upper limb motor function. After 50 minutes, each patient will have covered the 10 workstations (5 minutes each), thus working in all of the objectives pursued in the realization on this CCT. By last, an Ai-Chi sequence will be carried out in the water group, while in the land group, a stretching sequence of the main muscle groups will be made.

We tried to carry out two CCT protocols as similar as possible, whose main difference will be the environment in which they will be made.

Difficulty, intensity and / or speed of the exercises will increase gradually in order to achieve progression in patients.

Sample size

For a bilateral hypothesis contrast, using power calculations to detect a between-group difference of 0.07 m/s in gait speed (0.35 effect size)[22], 95% confidence level and 80% statistical power, 10% loss estimated, a total sample size of 40 participants was generated.

Data analysis

A descriptive analysis of the variables included in the study will be performed. The qualitative variables will be expressed in absolute values and percentages with their corresponding 95% confidence interval. Quantitative variables will be expressed as mean and standard deviation. The normality of the data will be verified by the Shapiro-Wilk test.

To know the homogeneity between groups of categorical variables, the chi-square test (χ^2) will be performed. For the homogeneity of the quantitative sociodemographic variables, a comparison of two means will be made by the Student's t-test as parametric test and by the Mann-Whitney test as a non-parametric test, as appropriate after checking normality. The homogeneity of variables related to gait, balance and function of the upper limb will be verified with the analysis of the ANOVA-MR as a parametric test and with Mann-Whitney test as a non-parametric test.

To analyze the effect of therapies will be proceeded the comparison of two means through the analysis of the variance (ANOVA) of repeated measures of two factors like parametric test. As non-parametric tests, the Wilcoxon test will be used to compare related variables for two moments within each group and the Mann-Whitney test for comparisons between groups.

Discussion

The main objective of this randomized controlled trial is to investigate the effectiveness of an ACCT program in comparison with a LCCT program in post-stroke patients. With the study conclusion, we expect to determine if there are differences in gait, balance and/ or upper limb motor function for participants. There are elements that suggest that the combination of these two types of therapy can offer a more integral way of attending these patients.

Circuits' exercises will be adapted individually to meet the intensity of exercise and the personal needs of each patient. At same time, they will take the advantages of a group environment that encourages participation, activity and well-being. Water environment, thanks to its unique characteristics, facilitate activity in people with disabilities. In many cases, this environment is the only one where free active exercises and movements can be carried out safely, thus offering exclusive opportunities for more complex movements and increasing the benefits of rehabilitation of patients. In this study inclusion criteria are related to land-based walking skills, nevertheless AT might be also suitable for patients not able to walk on land.

The present study proposes will try to get the highest profitability of CCT and AT together, which separately have proved to be more effective than many of the techniques commonly used in neurological patients. This will be the first study to verify the use of CCT in water in post-stroke patients.

It is expect that the results of this study will contribute to providing evidence, which is currently lacking, that the CCT is an effective approach in the management of post-stroke consequences and that both environments, land and water, can be complementary tools to offer an integral rehabilitation of these patients.

Abbreviations

2MWT: Two-minute walk test; 10MWT: 10 Meter walk test; ABC: Activities-Specific Balance Confidence Scale; AT: Aquatic therapy; BBS: Berg Balance Scale; BBT: Box and block test; CCT: Circuit class training; CvMob: Computer Vision Mobility; FMA: Fugl-Meyer Assessment; FRT: Functional Reach Test; TUG: Timed Up & Go.

Ethical considerations

This study protocol is registered in ClinicalTrials.gov (a U.S. National Institutes of Health service) with the identifier NCT02999971. It was approved by the Research Ethics Committee of A Coruña-Ferrol (Spain) with registration code 2015/732. It will be ensured the principle of beneficence, guaranteeing the welfare, protection and dignity of the participants. Participants must sign the consent document before the study begins.

Author contributions

JVC and JL conceived the idea for the study. IP and JVC contributed to the research design. IP, JVC, MT and JL contributed in deciding the choice of intervention and outcome measures of the study. JVC, JL and JGVM provided scientific research advice. IP elaborated the drafted the study protocol. JVC, JL and JGVM critically reviewed the manuscript. IP, JVC and JL assisted in editing the final submitted manuscript. All authors read and approved the final manuscript.

Competing interests

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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