The effectiveness of additional core stability exercises in improving dynamic sitting balance, standing balance, lower-limb spasticity, falls and gait in subacute stroke patients (CORE-trial). Study protocol for a Randomized Controlled Trial

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Study protocol

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Abstract

Background

Trunk impairment produces disorders of motor control, balance, and gait that are correlated with increased risk of falls and reduced mobility in stroke survivors. This creates disability and dependency to perform their activities of daily living. Alterations in body alignment occur, requiring treatment strategies focused on improving the postural control. bearing. Core stability exercises (CSE) are a good strategy to improve local strength of trunk, dynamic sitting, standing balance, and gait. There is some evidence about its effectiveness but it is still necessary to run a large multicenter trial to ratify that existing evidence.

Methods

This is a single-blind multicenter randomized controlled trial. Two parallel groups are compared and both perform the same type of therapy. A control group (CG) (n=110) performs conventional physiotherapy (CP) (1 hour per session) focused on improving balance. An experimental group (EG) (n=110) performs CSE (30 minutes) in addition to CP (30 minutes) (1 hour/session in total). EG is divided in two subgroups, in which only half of patients (n=55) perform CSE plus transcutaneous electrical nerve stimulation (TENS). Primary outcome measures are dynamic sitting, assessed by Spanish-version of Trunk Impairment Scale and stepping, assessed by Brunel Balance Assessment. Secondary outcomes are postural control, assessed by Postural Assessment Scale for Stroke patients; standing balance and risk of fall assessed by Berg Balance Scale; gait speed by BTS G-Walk (accelerometer); rate of falls, lower-limb spasticity by Modified Ashworth Scale; activities of daily living by Barthel Index; and quality of life by EQ-5D-5L. These are evaluated at baseline (T0), at 3 weeks (T1), at 5 weeks -at the end of the intervention (T2), at 17 weeks (T3) and at 29 weeks (T4). Study duration per patient is 29 weeks (a 5-week intervention, followed by a 24-week post-intervention).

Discussion

The study will provide useful information on the short and long term effects of a physiotherapy rehabilitation program based on core stability exercises performed in subacute phase.

Trial registration

ClinicalTrials.gov Identifier NCT03975985. Data registration June 5th, 2019. Retrospectively registered. Date of registration in primary registry: June 5, 2019. Protocol version 1

Introduction

Backgroundand rationale

Stroke has a high morbidity and it also results in up to 50% of survivors being chronically disabled. Thus, stroke is a disease of public health importance with serious economic and social consequences (1). Over 80% experience balance disturbance in the subacute phase (2). It reduces ability to perform daily tasks, and at 6 months after stroke, 40% of stroke survivors have difficulties with basic activities of daily living and 30% report participation restrictions, even at 4 years after stroke (3).

This balance dysfunction is usually due to a combination of reduced limb, pelvis and trunk motor control, altered sensation (proprioception) of one side and sometimes, centrally determined alteration in body representation (4). Trunk impairment is closely associated with postural imbalance and functional performance instability in gait (5) and in standing balance, increasing the risk of falls and fear of falling (6). It can lead to reduction in independence to undertake activities of daily living (ADL) and reduced quality of life (QoL) (7).

Falls may have serious physical and psychological consequences, including increased risk of hip fracture (usually on the weaker side) and greater mortality and morbidity compared to people without stroke (8). Fear of falling may lead to decreased physical activity, social isolation and loss of independence (9). Any postural control disorder increases the risk of falling and injury (10). Consequently, balance improvement is associated with decreased risk and fear of falling, and with improved QoL (7).

Balance is achieved through an interaction of central anticipatory and reflexive actions assisted by the active and passive restraints caused by the muscular system. The perception of verticality is based on the construction of a body-centred frame of reference in the gravitational environment. This frame of reference consists of afferent visual and vestibular information and of somatosensory information of the body (11) that translate into an adequate motor response in order to guarantee both anticipatory and adaptive aspects of balance control. Particularly, the position sense of the trunk could be important to provide information about the alignment of the trunk in relation to gravity (12). Trunk control and dynamic sitting balance are a fundamental requirement to be able to lead an independent life and to carry out activities of the daily living, such as combing, dressing, or going to the bathroom. When walking, the human body is never balanced, most of the time the trunk is supported by one leg and the centre of mass ‘falls’ onto the contralateral side. Therefore, trunk control in gait is an essential component (5).

Sitting lateral balance control appears to be the function critically affected by stroke, as well as the most sensitive one to functional changes induced by rehabilitation (13). Therefore, this will be the first goal to achieve with the neurorehabilitation treatment. Another aim is to achieve walking ability at discharge for minimizing activity limitations and for maximizing QoL. The control of the lower trunk, pelvis and leg muscles allows maintaining the centre of mass inside a stable base of support (14).

Rehabilitation is offered to all stroke survivors in subacute phase after receiving initial medical treatment, in order to reduce their disability and accelerate their independence and resume ADL. An earlier and more intensive rehabilitation program in the early phase of stroke is related to a good recovery of walking and functional independence status according to the concept “time is brain recovery” (15). Furthermore, it is important to conduct rehabilitation trials during the initial days and weeks after stroke since it is then

when spontaneous biological recovery takes place and when rehabilitation is delivered in the 'real world' (16). The first week until the first month post-stroke (acute and early subacute phase) is critical for neuroplasticity (17,18). Recovery after a stroke follows a curve; it is not linear, with most of the improvement occurring during the first days to 6 months (19).

A Cochrane systematic review concludes that 30 to 60 minutes per day delivered five to seven days per week is effective to recover function and mobility after stroke (20). A good rehabilitation strategy which might help improve trunk performance, trunk control, and dynamic sitting balance are approaches using trunk training therapeutic exercises (today commonly known as Core Stability Exercises (CSEs)(21-23). Recent studies (21,24,25) suggest that core stability plays a critical role in maintaining balance, functional mobility, gait, fear of falls and in improving anticipatory postural adjustment (26) in stroke survivors. Findings suggest that CSEs plus conventional physiotherapy has a positive long-term effect on improving dynamic sitting, standing balance and gait at 3 months after end of treatment (27). However, there is no consensus about which are the most effective intervention parameters, about intensity, and how early and training of exercises in stroke subacute phase should be (28).

CSEs are voluntary movements and aim at promoting the neuromuscular control, coordination, strength and endurance of muscles that are central to maintaining dynamic stability of the spine and trunk. It is the ability to control the position and motion of the trunk over the pelvis and leg that allows optimal production, transfer and control of force and motion to the terminal segment in integrated kinetic chain activities (29,30). It is essential to providing a solid base of core to exert or resist force as it stabilizes the pelvis and spinal column for "proximal stability for distal mobility" (31). Static core functionality is the ability of the core to align the skeleton to resist a force that does not change. The body core corresponds to the synergy 2 described by Israely (32).

Several studies have shown that transcutaneous electrical nerve stimulation (TENS) applied to the trunk muscles during CSE training could increase the motor output of trunk muscles. CSEs training combined with TENS could be more effective than CSEs alone for improving dynamic sitting balance (33). TENS has shown to excite large sensory fibers, predominantly in the A-beta range through the cutaneous stimulation of muscles, it increases the excitability of the sensorimotor cortex (34-36).

Any intervention in the stroke subacute phase that reduces disability will probably be cost-effective. It should be noted that stroke rates are multiplied by 10 in the population over 75 years of age. This population usually suffers from sarcopenia in addition to muscle weakness caused by stroke. For this reason it is important to activate and strengthen the core muscles since it has been shown that muscle atrophy and a significant impairment of postural reactive responses in the trunk rapidly occur (37). This has led to shorter inpatient stays at the hospital becoming increasingly essential to have rehabilitation programs that are more efficient, which implies that patients have greater autonomy when discharged from hospital.

There are few high-quality large multicenter randomized controlled trials (RCT) with patients recruited within 30 days after stroke (38). There is a clear need for larger trials conducted early after stroke in the

real-world clinical setting (39). To determine effectiveness, safety, and optimal training parameters of CSEs, homogeneous post-stroke populations and follow-up measures are necessary (40).

Objectives

The primary objective of this study is to evaluate the effectiveness of CSEs protocol (with and without TENS) in addition to conventional physiotherapy (CP) to improve dynamic sitting balance and gait (stepping) at short and mild-term in subacute phase of stroke.

Secondary objectives are to evaluate the effectiveness of CSEs (with and without TENS) in addition to CP to improve postural control, standing balance, fall rate, risk of falls, gait speed, lower limb spasticity, ADL and QoL. Another secondary objective is to explore the sustainability of the effects of CSEs over time. It is important to know whether the treatment effects are sustainable over time or if continuous therapeutic input is necessary to maintain the level of function even after discharged (home).

Methods/design

This study is an assessor-blinded, multicenter randomized controlled trial, with a 5-week treatment period followed by a 3 and 6-month follow-up. It follows the consensus-based core recommendations from the stroke recovery and rehabilitation expert group (41) and the SPIRIT statement (42). Participants will be randomly allocated (at a ratio 2:1:1) to the control group (CG) (n=110) or the experimental group (EG with and without TENS) (n=110), <15 and >15 days after stroke

Study setting

Patients are being recruited by inpatient rehabilitation hospitals in four centers in Catalonia: Hospital Universitari Parc Taulí de Sabadell, Consorci Sanitari de Terrassa, Hospital de la Santa Creu de Vic, and Germanes Hospitalaries Sagrat Cor de Martorell.

Recruitment

Treatments are randomly assigned using a computer program. To guarantee allocation concealment, treatments are assigned centrally via web, through Clinapsis®, an application designed to assist in the design and management of epidemiological and non-commercial clinical studies (www.clinapsis.com). Recommendations for Interventional Trials (SPIRIT) guidelines were followed.

Each clinical center involved in the CORE-trial was chosen based in the documentation for patient availability. Patients are recruited and screened for eligibility in three consecutive steps. Firstly, the principal investigator of each hospital is thoroughly briefed concerning the inclusion and exclusion criteria of the study since they provide therapists with the information for possible inclusion. Secondly, the main researcher gives information about the study to potential participants including the objective and description of the study, the duration, and risks and benefits. If the patients are interested in the study, an appointment is made to provide more detailed information and to answer questions. When the patient

agrees to participate in the study, the informed consent is signed before obtaining the medical record at admission to guarantee privacy. Lastly, after obtaining informed consent the patients are screened by the primary investigator to assure inclusion.

After group allocation and before starting treatment (T0), pre-intervention tests are performed to assess baseline values of primary and secondary outcome measures. At week 3, an assessment (T1) of only primary outcomes is performed. Within one day after completing the intervention (T2), data will be collected for all efficacy outcomes (see outcome measures section). Same data will be collected at 3 months after the end of the intervention (T3), and again at 6 months (T4). During the 5-week intervention period, each session data will be collected regarding to intervention adherence (number of sessions and duration), physiotherapy intensity, which exercises were performed for each patient and incidences.

All visits and efficacy assessments are performed at the rehabilitation center where patients have been initially treated for 5 weeks (whenever possible during routine clinical follow-up visits). Only when the patient is not able to attend personally the site due to a medical condition, the assessment is taken place at home.

All data are recorded on-line using an electronic data form Clinapsis®, available from the study coordinating center. All investigators were trained in the use of the application and have a help guide, as well as a consultation service directly with the logistics coordinator of the study. Access to the study database is restricted to authorized study personnel by password.

No adverse events were recorded in other studies with core stability exercises. However, all adverse events occurring after entry into the study and until hospital discharge will be recorded.

Through the combination of our electronic data form (Clinapsis®), instantaneous electronic validation, the data coordinating centre daily visual cross-validation of the data for complex errors, and regular on-site monitoring, the quality and completeness of the data will be reflective of the state of the art in clinical trials.

Patient and Public Involvement subsection

Patients and the public were not involved in any way as co-production of this research.

Blinding

Due to the nature of the interventions, the study has a single-blind design. Therapists and participants cannot be blinded to treatment allocation. To avoid detection bias, efficacy outcomes are evaluated by an independent assessor blinded to the intervention. Each center has a therapist evaluator. They had a training day by principal investigator for correct use of scales and questionnaires. This information is available via online and in paper. Also, statistical analysis will be conducted blinded to the allocation.

Eligibility criteria

Patients will have to meet the following eligibility criteria to be included in the study:

Inclusion criteria

1) first ever-stroke ≤ 30 days (diagnostic criteria according to the World Health Organization definition; corresponding to ICD-9 code 434) whether cortical or subcortical, and ischemic or hemorrhagic, 2) unilateral localization of the stroke verified by computed tomography, in case a patient shows previous problems, but does not have any neurological or clinical impairment (Rankin 0-1), he/she would be included in the study, 3) both sexes and age ≥ 18 years old, 4) ability to understand and execute simple instructions, 5) impairment of sitting balance assessed by Spanish Version of Trunk Impairment Scale.2.0 (S-TIS 2.0) ≤10 points (43,44), 6) severity of stroke by Spanish National institute of Health Stroke Scale (S-NIHSS) (45) score ≥ 2 points.

Exclusion criteria

Modified Rankin Scale > 2 points before stroke, 2) concurrent neurological disorder (e.g., Parkinson's disease) or major orthopedic problem (e.g., amputation) that hampers sitting balance, 3) relevant psychiatric disorders that may prevent from following instructions, 4) other treatments that could influence the effects of the interventions, 5) contraindication to physical activity (e.g., heart failure), 6) use of cardiac pacemakers, 7) patients with hemorrhagic stroke that have undergone surgery intracranial decompression, 8) patients whose stroke occurs exclusively and only in the cerebellum and brainstem. Patients whose main stroke is localized on another area and who also have a small lesion in the cerebellum and brainstem would not be excluded

Interventions

All interventions will be performed by trained experts in neurological physiotherapy with extensive/over 5 years of experience treating stroke survivors and with a Master's Degree in Neurology. Before starting the study, a 1-day training session was carried out in order to standardize the procedures and provide the physiotherapists with specific training in the CSE program and TENS by the clinical director. If there are doubts, they can always get in touch with the clinical coordinator and principal investigator. Each centre has a dossier with the program and videotapes of all CSEs and their explanations. In the meeting with all therapists of the different hospitals involved, a protocol for conventional physiotherapy focused to improve patients' disabilities was agreed upon.

The follow-up period is not controlled. At this stage, patients will not follow a specific treatment supervised by the research team, i.e. "usual care", and duration can also be variable **(see Figure 1)**. Patients of experimental and control group may continue to perform CP and/or aerobic-based therapy as prescribed by the responsible physician, or on their own initiative (private physiotherapy) if they wish. In this case, this additional physiotherapy will not be provided in the same rehabilitation unit by the same previous physiotherapist, but in outpatient physiotherapy centers. Conventional therapy and aerobic-based therapy for long term are recorded.

Intervention description

CSEs were designed to improve endurance of core muscles that stabilize the trunk and pelvis **(see Table 1).** CSEs program consists of 24 exercises focused on trunk muscle strengthening, proprioception, selective movements of the trunk and pelvis muscle, and coordination. They are carried out in supine position, sitting on a stable surface and on an unstable surface (ball). The exercises involve changes in the position of the body with or without resistance. Training is determined by the patient's ability to perform easy exercises and their progress to more challenging exercises. For monitoring the perceived individual's exertion of CSE training Borg scale of perceived exertion will be used (46). The intensity of effort perceived by the patient during training will remain moderate (4-5 points-score). They would not move on to higher levels until they had mastered the exercise they were engaged in. Adequate rest periods are allowed between exercises. The physiotherapists perform the therapy with their hands on the patient to ensure proper quality of movement and do not participate in the patient's evaluation. When the patient performs them correctly, they will perform them again alone.

Transcutaneous electrical nerve stimulation (TENS). The high frequency of TENS is 100 Hz; 0.2 μs pulse width, mm diameter electrodes placed on the skin over the lumbar erector spinae muscles (3 cm lateral to the L3 and L5 spinous process). The intensity of stimulation is twice the sensory threshold (the minimum intensity the subject could feel), which was barely below the motor threshold. The pulse trains were delivered with a two-channel stimulation device (Cefar PRIMO PRO, tens. 2 channels).

The comparator of EG is CP. CP involves different interventions improving functional capacity and reducing disability. The common feature of CP is that it consists of a treatment performed by the physiotherapist according to the degree of affectation of the particular patient and according to the degree of accomplishment of the objectives set. CP may consist in a variety (or combination) of multiple components such as tone normalization based on hands-on therapy interventions (47) with sensory feedback by manual contact, passive or active joint mobilization (48) for maintaining range of motion, and active or active-assisted exercise of affected side. Sit to stand training (49) with or without gripping on wall bars, sitting balance (50) (without core stability exercises), standing balance training (51) and gait re-education (walking between parallel bars or with a physiotherapist).

Participant timeline

The study has five assessments: T0 (baseline), T1 (week 3, only primary outcome), T2 (week 5, end-point, 25 sessions), T3 (week 12, after end of intervention), and T4 (week 24, after end of intervention). Study duration per patient: 29 weeks **(See Figure 2).**

The study groups consist in: 1) CG: CP total 1-hour. 2) EG: patients receive 30 minutes of CP in addition to 30 minutes of CSE program (with or without TENS) total 1-hour.

Sample size calculation

For the calculation of the sample size, we have assumed that conventional rehabilitation will be associated with a clinically relevant change in the S-TIS 2.0 scale at 5 weeks compared to baseline. The minimal clinically relevant difference has been established as 3-point (52). We have also assumed that rehabilitation by CSEs program will add a benefit of 1.6 points at 5 weeks, equivalent to 10% in the scale. That is, the experimental group with CSE will present a change of 4.6 points at 5 weeks with respect to the baseline situation (intragroup). Assuming a common standard deviation of 4 (53), and estimating a 10% lost at follow-up; accepting an alpha risk of 0.05 and a beta risk of less than 0.2 in a bilateral contrast, it will be necessary to include 110 patients in each group to detect a difference between groups of 1.6 points or higher on the total S-TIS 2.0 scale. The calculation of the sample size was done with the GRANMO program.

If a patient, either in CG or EG, has to withdraw from the treatment sessions due to a transient disease or mind trauma, he or she may be re-included if dropout period is shorter than 10 days. Patients are allowed to withdraw from the study for any reason and no adverse events have been described previously.

Strategies to improve adherence to interventions

In this phase of the stroke, the patient is usually highly motivated to recover and especially regain balance in sitting, standing and walking, and thus being able to perform their ADLs. It is very unlikely that the treatment cannot be carried out. It could only be the case for patients with cognitive impairment, but these are initially excluded from the study.

Relevant concomitant care permitted or prohibited during the trial

Co-interventions: during the 5-week intervention phase, patients can receive other usual types of rehabilitation management (such as occupational therapy, speech therapy, and neuropsychology) in accordance with local practices. All these co-interventions are being recorded and measures will be taken to control for possible performance bias. Interventions normally last 30-45 minutes.

Baseline assessment

Information concerning stroke diagnosis, medical history, and stroke onset will be acquired from patient records, from which participant characteristics will be collected too: sex, age, medication use, co-morbidities, side and location of the lesion, days post-stroke, stroke severity as assessed by NIHSS and modified Rankin Scale (mRS) (54) and immediate treatment for stroke (thrombolysis/ thrombectomy).

Outcomes Measures

Primary outcome measures include 1) dynamic sitting balance and coordination measured by S-TIS 2.0 (44). There are two subscales. The first one has 10 items and the second one has six. The highest possible total score is consequently 16 points, which indicates an optimal dynamic sitting balance and sitting coordination. If the patient cannot maintain a sitting position for 10 seconds without back and arm support, with hands on thighs, feet in contact with the ground and knees bent at 90° (starting

position), the total score for the scale is 0 points. 2) and gait by stepping section of Brunel Balance Assessment (BBA) (55). It consists of six items to assess standing functional balance and a 5-meter walk. The higher score is six points.

Secondary outcome measures include 1) sitting functional balance assessed by Spanish version of Function in Sitting test (S-FIST) (56). It assesses sensory, motor, proactive, and reactive and steady balance factors. The S-FIST consists of 14 tested parameters, corresponding to functional sitting everyday activities. The higher score is 56 points. 2) standing balance and risk of falling evaluated by Berg Balance Scale (BBS) (57,58). It provides a psychometrically sound measure of balance impairment with 14 items. 3) postural control evaluated by Spanish version of Postural Assessment Scale for Stroke (S-PASS) (59). It comprises 12 items with increasing difficulty that measure balance in lying, sitting, and standing. It measures the ability of an individual to maintain stable postures and balance during positional changes. The higher score is 36 points. 4) lower limb spasticity by Modified Ashworth Scale (MAS) (60). This tool measures resistance during passive soft-tissue stretching of muscle and it is performed while the assessor moves the limb. 5) activities of daily living by Barthel Index (BI) (61). It shows the degree of independence of a patient from any assistance. It covers 10 domains of function (activities): bowel and bladder control, as well as help with grooming, toilet use, feeding, transfers, walking, dressing, climbing stairs, and bathing. 6) Health-related quality of life measured by the Spanish-version of 5-Dimensions Questionnaire (EQ-5D-5L) (62,63). It is a generic patient's health-related quality of life measurement with evidence of good reliability and validity in various disease populations, including stroke. Patients chose five levels of severity (1, no problem; 2, slight problem; 3, moderate problem; 4, severe problem; and 5, unable to/extreme problem) in five dimensions (mobility, self-care, usual activity, pain/discomfort, and depression/anxiety) and rated their overall health status via the EQ-VAS. 7) rate of falls is measured by a specific registry created specifically for this study. The outcome is defined as the average number of falls per patient during the intervention period and follow-up. 8) gait speed assessed by BTS G-Walk. It is a wireless system consisting of an inertial sensor composed by a triaxial accelerometer, a magnetic sensor, and a triaxial gyroscope that positioned on L5-S1 vertebrae. From the data acquired, the system extrapolates all spatial-temporal gait. The patient walks during one minute (10-m) without aids. This variable is performed only if the patient has a 6-point of stepping section of BBA.

Statistical Analysis

The main analysis population will be defined by intention-to-treat, comprising all randomised participants with a baseline assessment, regardless of later events such as protocol violations, missing data or loss to follow-up. Missing data will be imputed and the impacts of imputation on results will be explored. Secondary analyses will be conducted restricted to the population of participants who followed the study protocol and had no missing data.

General linear models with repeated measures design will be used to test the effect of CORE program (with or without TENS) on the change in the outcome of interest (total S-TIS 2.0 score or any other

outcome) between baseline and follow up (5 weeks), using a repeated measures design with 2 levels (baseline, 5 weeks), and a 2-level factor testing the intervention (CORE, usual care). The models will adjust for clinically relevant covariates, such as site, age, baseline levels of the dependent outcomes, or severity of stroke. Similar models will be built to explore the effect of CORE at different time points (3 months, 6 months). Similar models will test the effect of TENS added to CORE on primary and secondary outcomes, and primary and secondary endpoints.

Ethics and dissemination

The study will be carried out in accordance with the principles enunciated in the current version of the Declaration of Helsinki and the requirements of Spanish law and the Spanish regulatory authority. Ethical approval was obtained from the Hospital de la Sant Creu I Sant Pau of Barcelona and the others hospitals that participate in this study. All participants will receive written and verbal information about the aim of the study. They will be informed that participation is voluntary, that they have the right to withdraw without specifying why, and that confidentiality will be assured **(Appendix 1).** All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. Informed consent will be assigned by all patients.

All reports, data collection, process, and administrative forms will be identified by a coded ID (identification) number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access. Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol.

Patients that are enrolled into the study are covered by indemnity for their hospital. The findings will be disseminated through conference presentations and peer-reviewed publications.

Discussion

Motor rehabilitation after stroke continues to be an area in need of substantial financial and scientific investment. There is also a need for more pragmatic trials to test interventions in a way that assists their translation into clinical practice. The analysis of recovery in subacute phase profiles is important because this information can provide a more specific plan for stroke rehabilitation in this phase. Exercise intensity and type is not only the most challenging parameter to determine, but it is also the most critical one to ensure that a dose that is safe, attainable, and adequate to elicit a training effect.

We hope that dynamic sitting balance and gait will be better in EG than CG. Concerning gait, a minimal detectable change of 1 point for BBA (stepping) would be a good result (55). Regarding standing balance, a difference change of ± 6 points for BBS is necessary to be 90% confident about a genuine change during inpatient stroke rehabilitation (64,65). It has been reported more recently that a change of 4.8 points in the FIST are clinically important (66). According to Barthel Index, a minimally clinically important difference is ≈2 points (67). As to EQ-5D-5L, values of 0.10 on the EQ-Index and 8.61–10.82 on the EQ-VAS are likely to have a clinically important change (62). Regarding PASS, 2.22 points is a minimally detectable change (68).

A decrease in gait velocity and double support time could represent an attempt at increasing postural stability to reduce fall risk (64). Specifically, decreased velocity may reduce the body's momentum, increasing the likelihood of recovering from a loss of balance (64). A walking speed of 0.8 m/s is predictive of weak functional abilities, while a speed of 0.6 m/s establishes a threshold below which the risk of falling is critical (69).

One of the first objectives of rehabilitation in the subacute phase of the stroke, is to achieve optimal trunk control and dynamic balance while sitting. The proposal of this study is to achieve this by training the core muscles. This results in a better balance in sitting, standing and in a more efficient gait. The earlier these patients can be autonomous, the less time they will be inactive (70) and in this way the adverse effects of immobilization can be reduced (71).

Data sharing statement: No later than 3 years after the collection of the 1-year post-randomisation interviews, we will deliver a completely de-identified data set to an appropriate data archive for sharing purposes.

Abbreviations

ADL: Activities of daily living, BBA: Brunel Balance Assessment, BBS: Berg Balance Scale, BI: Barthel Index, CG: Control group, CP: Conventional physiotherapy, CSEs: Core stability exercises, EG: Experimental group, EQ-5D-5L: Spanish-version of 5-Dimensions Questionnaire, EQ-VAS: Visual analogue scale of quality of life, ID: identification, MAS: Modified Ashworth Scale, QoL: Quality of life, RCT: Randomized controlled trial, S-FIST: Spanish version of Function in Sitting test, S-NIHSS: Spanish National institute of Health Stroke Scale, S-PASS: Spanish version of Postural Assessment Scale for Stroke, S-TIS 2.0: Spanish Version of Trunk Impairment Scale.2.0, TENS: Transcutaneous electrical nerve stimulation.

Declarations

Trial status

At the time of submission ethics approval has been granted with protocol version number 1, June 27th 2018. The study started recruiting patients in February 15th 2019. Recruitment of the study is still ongoing

and, so far, 49 patients have been recruited for this trial. We anticipate that it will be completed approximately on February 2022 but it will depend of Covid-19 pandemic.

Ethics approval and consent to participate

Ethical approval was granted by ethic committee of Hospital de la Santa Creu I Sant Pau de Barcelona, Spain number IIBSP-CSE-2017-56. Written, informed consent to participate will be obtained from all participants.

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Authors' contributions

RCV, GU and MSR conceived the study. GU and MSR initiated the study design and FCG helped with implementation. MR provided statistical expertise in clinical trial design and she is conducting the primary statistical analysis. All co-authors contributed to refinement of the study protocol and approved the final manuscript.

Competing interests statement

The authors declare no competing interests

Availability of data and material

The datasets during and/or analyzed during the current study are available

from the corresponding author on reasonable request.

Consent for publication

Not applicable

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Appendices

Appendix 1

Each Ethics Committee or Institutional Review Board will revise and adapt according to their own institution's guidelines.

Sample patient informed consent

Tittle of study: The effectiveness of additional core stability exercises in improving dynamic sitting balance, standing balance, lower-limb spasticity, falls and gait in subacute stroke patients (CORE-trial). Study protocol for a Randomized Controlled Trial

Participant number:

I, << name and surname of the representative >> in the capacity of << relationship with the participant >> as << name of the participant >>

 I have read the information sheet given to me about the study.

 I have been able to ask questions about the study.

 I have received enough information about the study.

 I have spoken with << investigator name >>

 I understand that my participation is voluntary.

 I understand that I can withdraw from the study:

- Whenever you want.

- Without having to explain.

- Without this affecting my medical care.

I will receive a signed and dated copy of this informed consent document.

I freely give my consent to participate in the study.

Signature of representative or patient *Signature of researcher*

Date: ____ / ____ / ____ *Date: ____ / ____ / ____*

(Name, signature and date in handwriting by the representative)

Tables

Table 1: Program experimental group intervention. The patient performs 2 times of each exercise with eyes closed if in the sitting exercises on a ball the patient is afraid, he will not be forced to close them.
Core Stability Exercises Program
Supine position
1. Selective flexion/extension of the lower trunk: The hips and knees at 90º flexion and the patient's feet and hands resting on the plinth. Selective pelvis anteversion-retroversion. The physiotherapist helping the patient may be placed in front of her/his or on the affected side and keep the patient's leg. The exercises intensity increased by flexing the patient's elbows. 20 times.
2. Upper trunk rotation: The patient resting his/her trunk on the plinth with knees flexed at 90º and the feet flat on the support surface. His/her arms are flexed on the ribcage. The physiotherapist steadied the patient's pelvis and patient rotates from affected side to unaffected side and *vice versa*. When patient do correctly this exercise, the physiotherapy apply a slow resistance on patient's shoulder. 20 times.
3. Single bridging: Starting position is the same that exercise 1. The patient lifts the pelvis of the plinth maintaining a neutral lumbar and pelvic alignment. The exercises intensity increased by flexing the elbows, when patient does this exercise easily an elastic band is put on your iliac crests to increase difficulty. 30 times.
4. Lateral pelvis movement: Starting position is the same that exercise 1. Patient lift the pelvis of the plinth and moves from the right side to left side. The physiotherapist steadied the patient's knees and feet if it is necessary and her/his hand is under patient's sacrum to help her/him. The exercises intensity increased by flexing the patient's elbows. 30 times.
5. Pre-unilateral bridging (a): Starting position is the same that exercise 1. Unaffected patient's leg is forward 20 centimetres of affected foot and she/he lifts the pelvis. The exercises intensity increased by flexing the patient's elbows. 30 times.
6. Pre-unilateral bridging (b): Starting position is the same that exercise 1. Unaffected patient's leg is resting on the ball and patient lifts the pelvis with his/her affected leg at 90º knee and hip flexion. The exercises intensity increased by flexing the patient's elbows. 30 times.
7. Unilateral bridging: Starting position is the same that exercise 1. Lifting the unaffected leg off the plinth, with the patient maintaining the pelvic bridge position, the physiotherapist steadying the affected leg. The exercises intensity increased by flexing the patient's elbows. 20 times.
8. Unilateral bridging with ball: The patient's leg rest on a ball and she/her lifts the pelvis and the unaffected leg. The physiotherapist steadying the affected leg if it is necessary. 10 times.
9. Lower trunk rotation: The patient's legs rest on a ball at 90º flexion knees and hips. The patient rotates lower trunk from affected side to unaffected side and *vice versa*. The physiotherapist steadied the patient's chest and supported the affected leg. The exercises intensity increased by flexing the patient's elbows. 30 times.
10. Lower trunk flexion: The same position that exercise 9, but legs patient bend on her/his chest. The exercises intensity increased by flexing the patient's elbows. 30 times.
Stable Sitting Position / **Unstable Sitting Position**
11. Trunk flexion-extension of the lower limb: The feet rest on the ground, 90º knees and hips flexion The physiotherapist moves the patient's chest to flexion-extension of the trunk (involving selective pelvis anteversion-retroversion). 30 times. / **18.** The same exercise 11 but on a ball. It is allowed separate the knees. 20 times.

12. Upper trunk rotation: Starting position is the same that exercise 11. The patient rotates the upper trunk, she/he moves each shoulder forwards and backwards with crossed arms on the ribcage, the physiotherapist steadying the patient's pelvis. 30 times.	**19:** The same exercise 12 but on a ball. It is allowed separate the knees. 20 times.
13. Upper limb lateral flexion: Starting position is the same that exercise 11, initiating movement from the shoulder girdle. The patient touches with her/his unaffected elbow the plinth, if patient could not do this a pillow is put on the plinth and she/he touches the pillow. Secondly the patient touches the plinth with affected elbow. When patient does this exercise correctly without pillow. 20 times.	**20:** The same exercise 13 but is not necessary that the patient touch with her/his elbow the ball. It is allowed separate the knees.
14. Lower limb lateral flexion: The same exercise 13 but initiating movement from the shoulder girdle. 20 times.	**21:** The same exercise 14 but on a ball. It is allowed separate the knees.
15. Lower trunk rotation: Starting position is the same that exercise 11. The patient moves his/her unaffected knee forwards and backwards, with the physiotherapist helping the patient with his/her hand on iliac bone. Secondly patient moves affected leg. 20 times.	**22:** The same exercise 15 but on a ball. It is allowed separate the knees.
16. Forward reach in three directions with unaffected upper limb: Starting position is the same that exercise 11. Forwards (90° flexion), ipsilateral (90° abduction) towards the unaffected side and (90º horizontal adduction) across the body towards the affected side. 10 times in each direction.	**23:** The same exercise 16 but on a ball. It is allowed separate the knees.
17. Forward reach in three directions with affected upper limb: The physiotherapist put the affected patient's arm on a ball in front of her/him. The patient moves her/his arm and trunk forward. Secondly, the same exercise but the patient moves to ipsilateral with a ball. Finally, across. 10 times in each direction.	**24:** The same exercise 17 but on a ball. 5 times in each direction.

Figures

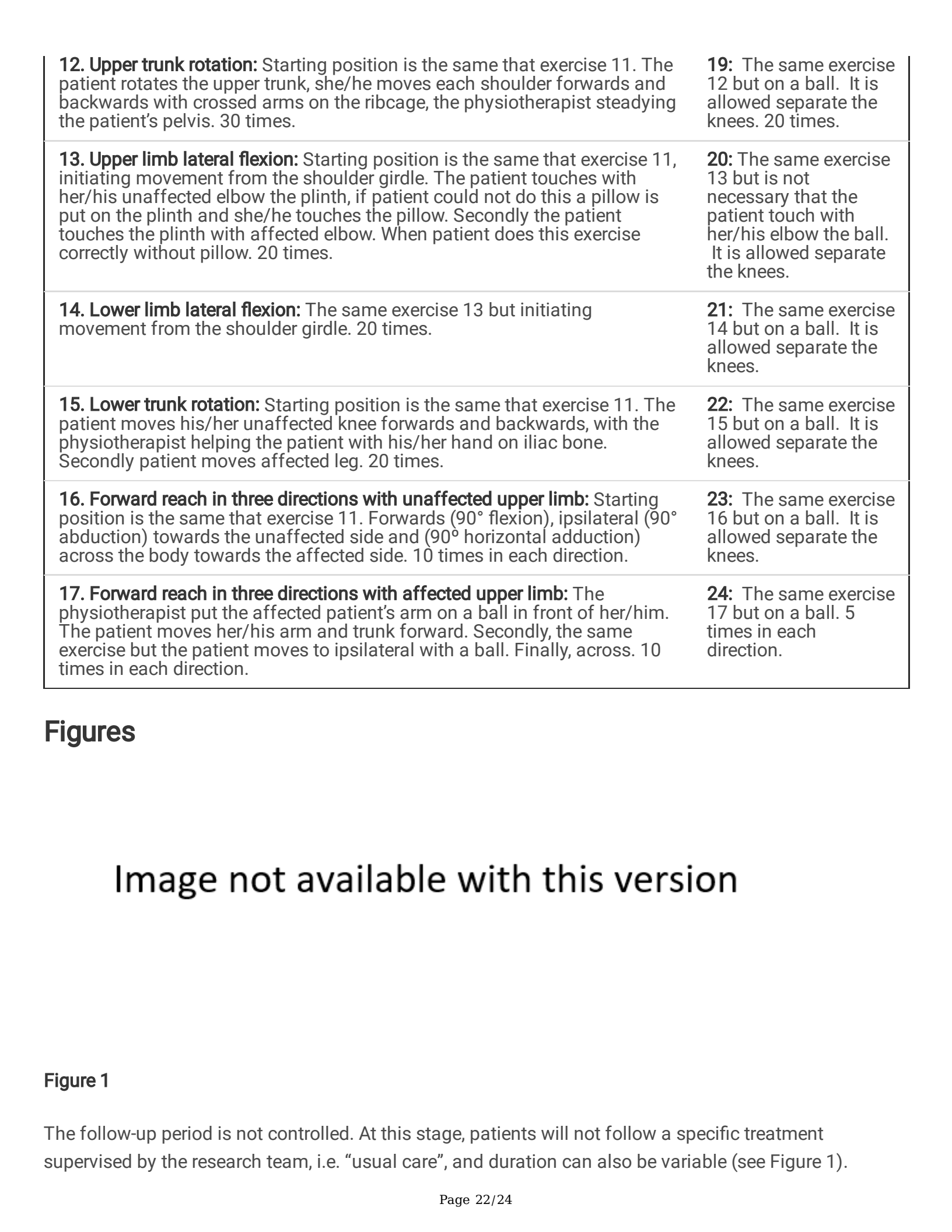

Figure 1

The follow-up period is not controlled. At this stage, patients will not follow a specific treatment supervised by the research team, i.e. "usual care", and duration can also be variable (see Figure 1).

	STUDY PERIOD						
	Enrolment	Allocation	Baseline assessment	Post-allocation			
TIMEPOINT**	$-t_1$	week 0	week 0	week3	week 5	week 12	week 24
ENROLMENT:							
Study information	X						
Informed consent	X						
Eligibility	X						
Allocation	X	X					
INTERVENTIONS							
Core stability exercise (experimental group)			X	X	X		
Conventional physiotherapy (control group)			X	X	X		
Usual care						X	X
ASSESSMENTS							
Eligibility: Spanish-TIS 2.0, NIHSS	X						
Primary outcomes Spanish-TIS 2.0		X	X	X	X	X	X
BBA (stepping)			X	X	X	X	X
Secondary outcomes Spanish-FIST			X	X	X	X	X
BBS			X	X	X	X	X
Spanish-PASS			X	X	X	X	X
MAS			X	X	X	X	X
BI			X	X	X	X	X
EQ-5D-5L			X	X	X	X	X

Figure 2

The schedule of enrollment, interventions, and assessments. Abbreviations: BBA: Brunel Balance Assessment, BBS: Berg Balance Scale, BI: Barthel Index, EQ-5D-5L: EuroQol 5 dimensions and 5 levels, FIST: Function in Sitting Test, MAS: Modified Ashworth Scale, NIHSS: National institute of Health Stroke Scale, PASS: Postural Assessment Scale for Stroke, TIS 2.0: Trunk Impairment Scale.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITchecklistCoretrial.docx
- RESUMENProtocoloCORETrial.pdf