EFFICACY OF A PROGRAMME OF STABILITY EXERCISES OF CORE IN DYNAMIC BALANCE WHEN SEATED, CONTROL OF TRUNK AND FUNCTIONAL REHABILITATION IN PATIENTS WITH SUBACUTE STROKE: RANDOMISED CLINICAL TRIAL

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1. Summary of the Study

Stroke is a major health problem worldwide due to its high frequency, associated mortality as well as long-term disability, all of which generates a significant health and social impact.

A high percentage of individuals who have suffered a stroke for the first time show alterations in balance and postural control in the subacute phase of the event. Decreased balance and impaired postural control correlate with increased risk of falls and decreased long-term mobility, leading to disability and dependency for activities of daily living and decreased quality of life. The lumbopelvic area or the core is the centre of all the kinetic chains of the body. Several clinical trials and systematic reviews have shown that applying a rehabilitation program based on muscle stability exercises of the lumbopelvic (core) area can be a good strategy to improve trunk control and dynamic balance, gait and activities of daily living in individuals who have suffered a stroke.

OBJECTIVE

To compare the effectiveness of conventional physiotherapy versus an approach based on muscle exercises for lumbopelvic stability or core stability (CSE), in terms of dynamic balance in sitting, standing, walking, spasticity, activities of daily living, quality of life, and number of falls, at the end of the intervention (5 weeks) and in the medium term (sustained effect at 3 months), applied in the subacute phase of the stroke (≤ 30 days).

METHODS

Multi-centre, parallel group, outcome assessor-blinded, randomized controlled trial. The study compared two intervention groups consisting of 25 rehabilitation sessions lasting 1 hour (25 hours in total per patient), where the following was performed: i) Conventional physiotherapy (CP) according to the rehabilitation protocol of the centre where the patient was admitted (control group) and ii) conventional physiotherapy for 30 minutes followed by a core exercise protocol (CSE) for 30 minutes (experimental group).

Outcomes were assessed at the end of the intervention (5 weeks) and also at 3 months after discharge to home.

Recruitment was severely affected by the successive waves of the COVID-19 pandemic and the significant alteration in the admission criteria and care activity in the participating rehabilitation centres for two years, making it impossible to reach the planned sample and justifying changes in the objectives and design of the study.

2. Results

Recruitment

Between February 2019 and December 2021 a total of 87 patients were included, 42 (48.3%) in the intervention group (CORE) and 45 (51.7%) in the control group. Of these, 83 were assessable (there were three losses due to voluntary dropouts and one death). The vast majority of individuals completed the planned 25 rehabilitation sessions.

Table 1. Recruitment by participating centre.

Centre	N	%
Hospital Universitari de la Santa Creu (Vic)	30	34.5
Consorci Sanitari de Terrassa	19	21.8
Germanes Hospitalàries del Sagrat Cor (Martorell)	16	18.4
Corporació Sanitària del Parc Taulí (Centre Alabada)	15	17.2
MUTUAM Girona	4	4.6
Centre Forum – Hospital del Mar	3	3.4
Total	87	100%

Characteristics of the study population: Table 2 presents the baseline characteristics of the study population, with no clinically relevant differences between the two groups. As a whole, it is a population affected by stroke in the subacute phase, predominantly men, of advanced age, mainly with ischemic stroke, most of whom had not received previous non-pharmacological treatment, with a high presence of risk factors (mainly hypertension and to a lesser extent obesity and diabetes) and a moderate degree of neurological involvement or severity.

Table 2. Baseline characteristics of the study population.

	CORE	Control	Total
Sex:			
Male	30	27	57 (65.5%)
Female	12	18	30 (34.5%)
Age (years)	71.2 (11.6)	68.9 (15.2)	
S_NISHH (mean, DS)	8.02 (4.3)	7.04 (4.2)	
Type of stroke:			
Ischaemic	35	37	72 (82.8%)
Haemorrhagic	7	8	15 (17.2%)
Hemiparesis:			
Right	22	18	40 (46%)
Left	20	26	46 (52.9%)
			1 missing
BMI	26.5 (5.5)	27.3 (4.9)	27.0 (5.2)
Medical treatment:			
Thrombolysis	2	1	3 (3.4%)
Thrombectomy	2	6	8 (9.2%)
None	37	36	73 (83.9%)
			3 missing
Hypertension	34 (81%)	34 (75.6%)	68 (78.2%)
Obesity	16 (39%)	20 (45.5%)	36 (41.4%)
Smoker	8 (19.5%)	8 (17.8%)	16 (18.4%)
Diabetes mellitus	19 (46.3%)	15 (33.3%)	34 (39.1%)
Alcohol abuse	6 (14.6%)	4 (8.9%)	10 (11.5%)
Chronic pulmonary disease	5 (12.2%)	12 (26.7%)	17 (19.5%)
Physical activity	21 (50%)	19 (42.2%)	40 (46%)
Previous falls	2 (4.8%)	4 (8.9%)	6 (6.9%)

Table 3 presents the baseline scores on the different clinical scales used in the study. No significant differences were observed between both groups.

Table 3. Baseline clinical characteristics of the study population.

Scales	CORE	Control	Total
MAS modified	0.56 (0.92)	0.62 (0.78)	0.60 (0.86)
S_FIST	43.3 (18.3)	44.4 (15.6)	43.5 (17.0)
BBA	1.24 (1.9)	1.62 (2.3)	1.37 (2.12)
BBS	21.2 (18.2)	23.9 (19.0)	21.9 (18.5)
Barthel	42.4 (25.5)	44.3 (27.8)	41.9 (25.8)
RANKIN	3.93 (1.00)	3.89 (1.13)	3.94 (1.08)
S_PASS mob.	14.2 (5.7)	14.8 (5.1)	14.3 (5.4)
S_PASS balance	6.65 (3.63)	7.12 (3.89)	6.89 (3.75)
S_PASS total	20.4 (9.5)	22.1 (8.6)	21.2 (8.8)
S_TIS 2.0 balance	3.38 (2.84)	3.69 (2.58)	3.39 (2.65)
S_TIS 2.0 coordination	1.45 (1.13)	1.89 (1.43)	1.66 (1.30)
S_TIS 2.0 total	4.83 (3.45)	5.58 (3.23)	5.39 (3.23)

Comparative effectiveness between conventional physiotherapy (CP) and conventional physiotherapy plus core exercises (CSE) at the end of the intervention (ΔT0 – T2)

The main efficacy analysis consisted of comparing the change in the scores of the various scales at the end of the intervention at 5 weeks (T2) with the baseline value (T0). The summary of the main results is presented in Table 4 and Figure 1.

At the end of the intervention, we observed a significant difference in the **Trunk Impairment Scale (TIS 2.0)** score (sitting balance and postural control of the trunk), favourable to CSE, both in the total score (P 0.000) as in the TIS balance (P 0.000) and TIS coordination (P 0.003) subscales.

At the end of the intervention, we observed a significant difference in the **Modified Ashworth Scale (MAS)** score (spasticity), favouring CSE (P 0.018). While the CP group experienced a significant worsening in the degree of spasticity, the CSE group slightly improved.

Table 4. Comparative effectiveness between CP and CSE at the end of the intervention (ΔT0 – T2

Escalas	CORE	Control	T2 – T0
MAS modificado	0,58 (0,93)	0,63 (0,79)	
T0	0,47 (0,64)	1,05 (1,15)	
T2	Dif. -0,11 (es 0,16)	Dif. 0,42 (es 0,15)	P 0,018
S_FIST	43,0 (18,4)	43,9 (15,9)	
T0	48,9 (14,1)	50,1 (11,6)	
T2	Dif. 5,95 (es 2,02)	Dif. 6,12 (es 1,95)	P 0,953
BBA	1,18 (1,89)	1,56 (2,3)	
T0	2,30 (2,4)	2,44 (2,4)	
T1	3,05 (2,2)	2,84 (2,4)	
T2	Dif. 1,88 (es 0,26)	Dif. 1,28 (es 0,25)	P 0,188
BBS	20,8 (18,3)	22,9 (19,0)	
T0	35,7 (20,1)	35,5 (18,0)	
T2	Dif. 14,90 (es 2,19)	Dif. 12,56 (es 2,12)	P 0,445
Barthel	40,38 (24,29)	43,26 (27,34)	
T0	63,46 (27,44)	66,98 (27,26)	
T2	Dif. 23,08 (es 3,36)	Dif. 23,72 (es 3,20)	P 0,890
RANKIN	3,98 (1,00)	3,91 (1,15)	
T0	3,28 (1,06)	3,28 (1,08)	
T2	Dif. -0,70 (es 0,18)	Dif. -0,63 (es 0,17)	P 0,769
S_PASS movilidad	13,98 (5,70)	14,60 (5,09)	
T0	18,20 (4,85)	17,81 (4,40)	
T2	Dif. 4,33 (es 0,70)	Dif. 3,21 (es 0,68)	P 0,258
S_PASS equilibrio	6,65 (3,63)	7,12 (3,89)	
T0	9,93 (3,38)	9,23 (3,69)	
T2	Dif. 3,28 (es 0,40)	Dif. 2,12 (es 0,38)	P 0,039
S_PASS total	20,62 (9,01)	21,72 (8,62)	
T0	28,23 (7,83)	27,05 (7,73)	
T2	Dif. 7,60 (es 0,97)	Dif. 5,33 (es 0,93)	P 0,095
S_TIS 2.0 equilibrio	3,20 (2,78)	3,56 (2,56)	
T0	5,87 (3,18)	6,02 (2,80)	
T1	9,15 (2,34)	6,35 (2,84)	
T2	Dif. 5,95 (0,45)	Dif. 2,79 (es 0,43)	P 0,000
S_TIS 2.0 coordinación	1,43 (1,06)	1,88 (1,47)	
T0	2,82 (1,87)	2,49 (1,70)	
T1	4,22 (1,41)	2,98 (2,77)	
T2	Dif. 2,80 (es 0,39)	Dif. 1,09 (es 0,37)	P 0,003
S_TIS 2.0 total	4,97 (3,36)	5,78 (3,10)	
T0	9,67 (3,98)	9,08 (3,42)	
T1	13,53 (3,22)	9,95 (4,46)	
T2	Dif. 8,56 (0,67)	Dif. 4,18 (0,63)	P 0,000

On the other hand, the patients in both groups experienced a significant improvement at the end of the intervention in the score of the scales **Function In Sitting Test (FIST)** (functionality in sitting), the stepping section of **Brunel Balance Assessment (BBA)** (stepping balance), **Berg Balance Scale (BBS)** (sitting balance), **Barthel index** (activities of daily living), **RANKIN** (degree of disability or dependence) and **Postural Assessment Scale for Stroke (PASS)** (balance and postural control), with no statistically significant differences between both study groups.

The BBA and TIS 2.0 scales (total score and coordination and balance subscales) were also evaluated 3 weeks after starting the intervention (T1), with a statistically significant early effect of CSE rehabilitation being observed in all of them.

**Figure 1**. Comparative effectiveness at the end of intervention (ΔT0– T2)
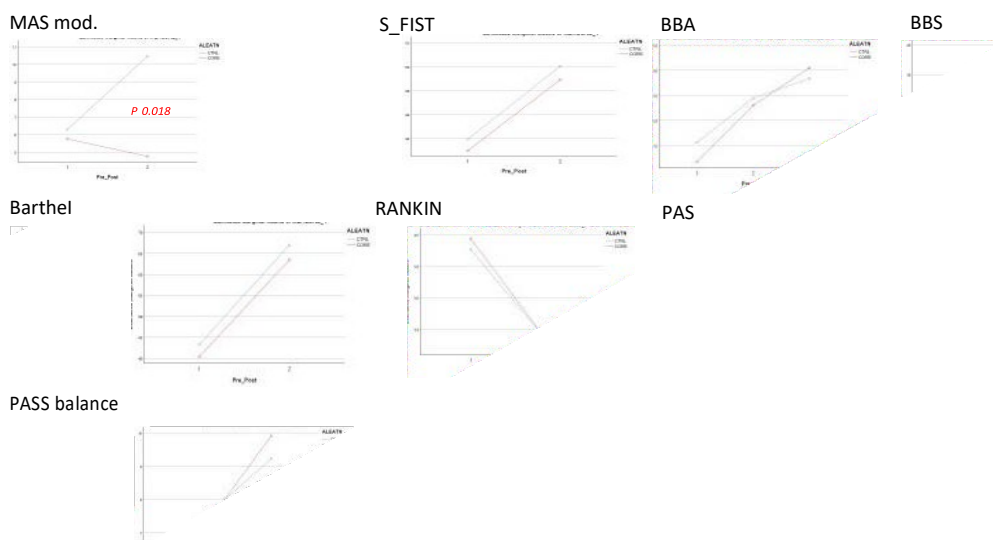
Evaluation at 3 months after discharge (T3)

At the 3-month follow-up after the end of the intervention (T3) we no longer observed a significant difference between the groups in the MAS scale score, at the expense of a significant late improvement in the CP group while the CSE group remained unchanged. Regarding the TIS 2.0 scale (total and coordination and balance subscales), although an improvement continues to be observed in the CSE group, the effect seems to be lessened (the improvement observed between T2 and T3 in this group is no longer statistically significant). On the other hand, a late effect of CP seems to be observed on this scale.

Regarding the rest of the scales (FIST, BBA, BBS, Barthel, RANKIN and PASS), although the differences at 3 months compared to the baseline score continue to be statistically significant in both study groups, the effect observed between T2 and T3 seems to lessen in the CSE group for the BBA and BBS scales, while it is significant for the FIST, Barthel, RANKIN and PASS scales. The summary of these results can be seen in Figure 2.

Figure 2. Comparative effectiveness at 3 months after discharge (ΔT0– T3)

SD Significant diff. (T2–T3)
NS Non–significant diff. (T2–T3)
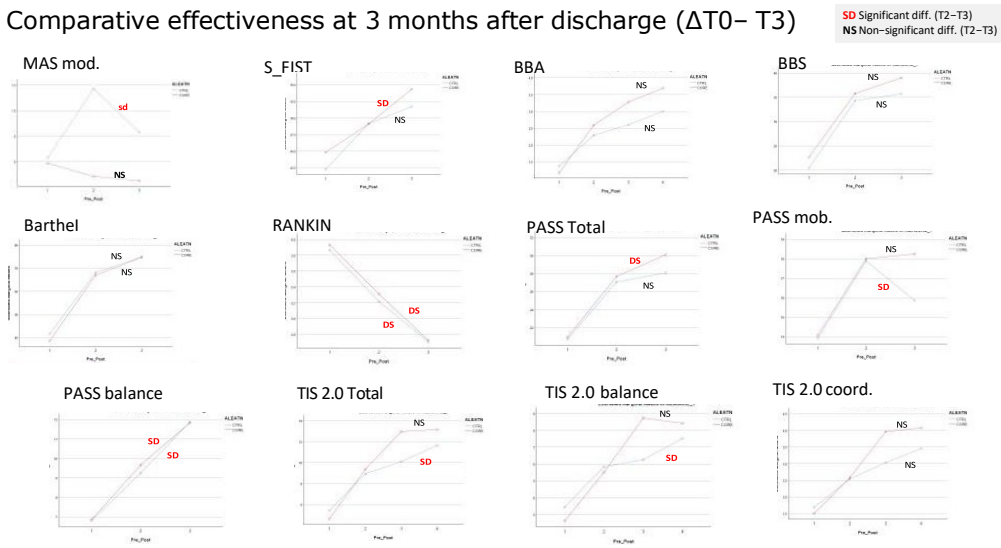
Regarding quality of life (EuroQol EQ-5D-5L), there were statistically significant differences between the groups in the scores observed at the end of the intervention (CSE: 66.67 ±15.57 versus CP: 54.65 ±17.78

(P 0.002)), favourable to CSE. When comparing the scores of T2 with T3, the differences between the groups were no longer significant, due to a delayed improvement observed in the CP group.

The study had planned to assess the comparative results of CSE+TENS (n=19) versus CSE alone (n=21), as part of a secondary objective (random allocation to CSE was followed by subsequent randomization to receive or not TENS [transcutaneous electrical nerve stimulation]). No differences were observed between the two groups, probably due to the limited sample finally analyzed compared to what was planned.

We were not able to perform the comparison at 6 months after the end of the intervention in all patients due to the profound alterations in care caused by the COVID-19 pandemic.

Substudy No. 1: Telerehabilitation in subacute patients
A telerehabilitation substudy was conducted on the first 49 individuals from the CORE Trial at discharge to home (NCT03975985). Twenty participants from the CSE group were offered support through an app (FARMALARM®) that informed and supported them in carrying out home-based unsupervised rehabilitation with CSE for 3 months. Twenty-nine individuals from the CP group (controls) were not offered this tool and followed the usual management according to their care provider criteria. Although some effects were observed in some analyzed variables (quality of life [CP group], Barthel [CSE group], Lawton & Brody [CSE group] and RANKIN [CP group]), there were no significant differences between the groups. Adherence to the app monitored with the tool's control panel was very low, with a low score in usability and satisfaction of the patients who were offered this support.

Substudy No. 2: Telerehabilitation in chronic patients
A telerehabilitation substudy was conducted in 30 chronic-phase stroke survivors recruited from a single private rehabilitation centre (NCT04477252). Subjects were randomly assigned to receive (n=15) or not (n=15) support through an app (FARMALARM®) that provided information and support in carrying out home-based unsupervised rehabilitation with CSE in addition to the usual, personalized management that they received in this centre with a 12-week follow-up. Some favourable pre-post differences were observed in sitting balance, postural control and

gait, suggesting that CSE associated with conventional physiotherapy (CP) may also be effective in the chronic phase of stroke. Adherence to the app was very low, which could limit the performance of CSE.

3. Relevance and possible implications

Rehabilitation through a program that includes CSE in the subacute phase of stroke shows beneficial effects on balance, postural control, spasticity, dependency and activities of daily living, and quality of life, at the end of the intervention at 5 weeks. These benefits are superior to those observed with only conventional physiotherapy without CSE (sitting balance, trunk postural control, motor activity and quality of life). However, the size of these effects is small.

The effect at 3 months after finishing the intervention persists in most of the analysed outcome measures.

The use of telerehabilitation as a support tool in the performance of long-term home-based neurorehabilitation seems to be a very interesting strategy to overcome the limitations in access to healthcare services and optimize the performance of rehabilitation within the first 3 months after the stroke. However, additional research is needed in developing applications that ensure a greater degree of adherence and that are well valued by users. These tools should take into account that stroke patients are mostly older adults and therefore their usability needs to be optimized.

The benefits of neurorehabilitation through a program that includes CSE seem to extend beyond the subacute phase, requiring new specific studies. Although data are limited, extending rehabilitation for at least 3 months, rather than just 5 weeks, appears to provide greater clinical benefits to stroke patients, which would warrant further studies assessing the benefits of more extended rehabilitation interventions.

The negative impact of the COVID-19 pandemic on the care activity of rehabilitation centres, which has persisted during the years 2020 and 2021, has prevented the initially planned sample from being recruited, thus limiting the study's power to confirm the hypotheses raised. Therefore, these results should be taken as preliminary.

However, they suggest a favourable potential for CSE-based programs in the subacute phase of a stroke. This should be confirmed through new robust and well-designed studies which also explore specific methods of administration of CSE (content, intensity and duration) that may be more effective.

4. Publications

Cabanas-Valdés, R., Boix-Sala, L., Grau-Pellicer, M., Guzmán-Bernal, J. A., Caballero-Gómez, F. M., & Urrútia, G. (2021). The Effectiveness of Additional Core Stability Exercises in Improving Dynamic Sitting Balance, Gait and Functional Rehabilitation for Subacute Stroke Patients (CORE-Trial): Study Protocol for a Randomized Controlled Trial. International journal of environmental research and public health, 18(12), 6615. https://doi.org/10.3390/ijerph18126615

Salgueiro, C., Urrútia, G., & Cabanas-Valdés, R. (2022). Telerehabilitation for balance rehabilitation in the subacute stage of stroke: A pilot controlled trial. NeuroRehabilitation, 10.3233/NRE-210332. Advance online publication. https://doi.org/10.3233/NRE-210332

Salgueiro, C., Urrútia, G., & Cabanas-Valdés, R. (2022). Influence of Core-Stability Exercises Guided by a Telerehabilitation App on Trunk Performance, Balance and Gait Performance in Chronic Stroke Survivors: A Preliminary Randomized Controlled Trial. International journal of environmental research and public health (accepted for publication: manuscript ID: ijerph-1697785)

The main publication of the CORE Trial is currently in process