Supplementary Material 2

Items from de World Health Organization Trial Registration Data Set

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| **Data category** | **Information** |
| Primary registry and trial identifying number | ClinicalTrials.gov NCT05442892  |
| Date of registration in primary registry | 26 June, 2022 |
| Secondary identifying numbers | -- |
| Source(s) of monetary or material support | “La Caixa” Foundation (ID 100010434) |
| Primary sponsor | “La Caixa” Foundation |
| Secondary sponsor(s) | -- |
| Contact for public queries | Lucía Lozano Vicario, MD, email: lucia.lozanovicario@gmail.com |
| Contact for scientific queries | Lucía Lozano Vicario, MD, Geriatric Unit, Hospital Universitario de Navarra, Pamplona (Spain) |
| Public title | Effectiveness of a multicomponent exercise training programme for the management of delirium in hospitalized older adults using Near-Infrared Spectroscopy (NIRS) as a biomarker of brain perfusion: study protocol for a randomized controlled trial |
| Scientific title | Exercise training in older adults with delirium -randomized controlled trial |
| Countries of recruitment | Spain |
| Health condition(s) or problem(s) studied | Delirium, frailty |
| Intervention(s) | *Control group*: normal hospital care*Intervention group*: supervised and individualized multicomponent exercise training program  |
| Key inclusion and exclusion criteria | The inclusion criteria are:* Age: 75 years or older with delirium during hospitalization
* Able to ambulate with or without personal/technical assistance
* Barthel Index > 45 points two weeks before admission
* Informed consent by patients (if possible), relatives or legal representatives

The exclusion criteria are:* Duration of hospitalization < 5 days
* Severe dementia (GDS 6-7)
* Terminal illness (life expectancy less than 3 months)
* Any factor precluding performance of physical exercise. These factors include:
	+ Acute myocardial infarction in the past three months or unstable angina
	+ Severe heart valve insufficiency
	+ Arrhythmia or uncontrolled arterial hypertension
	+ Pulmonary embolism in the past 3 months
	+ Hemodynamic instability
* Pathology that could interfere with NIRS registration:
	+ Facial dermal pathology (front)
	+ Acute intracranial pathology (hemorrhages, cerebral infarcts)
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| Study type | -Interventional-Allocation: randomized, Intervention model: parallel assignment; Masking: double blinded-Primary purpose: treatment -Phase III  |
| Date of first enrolment | February, 2022 |
| Target sample size | 60 |
| Recruitment status | Recruiting |
| Primary outcome(s) | -Duration and severity of delirium (timeframe: 12 months)-Functional status (timeframe:12 months)-Regional oxygen saturation (rSO2), (timeframe: 12 months) |
| Key secondary outcomes | -Cognitive status (timeframe:12 months)-Mortality (timeframe:12 months)-Quality of life (timeframe:12 months)-Use of health sources (timeframe:12 months)-Falls (timeframe:12 months) |