

Proyecto de investigación 6

Seguridad y efectividad de un programa de tele-rehabilitación sobre la fatiga y síntomas asociados al síndrome de fatiga crónica y la COVID persistente: protocolo de un ensayo clínico aleatorizado

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Background:

Chronic Fatigue Syndrome / Myalgic Encephalomyelitis (CFS/ME) and Post-COVID Syndrome (PCS) share substantial pathophysiological features. Disrupted interoception is also common. Conventional rehabilitation programs have been associated with patient dissatisfaction and a notable prevalence of adverse events, underscoring the need for safer and more effective interventions. Our recent meta-analysis indicates that interventions targeting interoception and vagal tone—such as conscious-based movement—may help avoiding adverse effects and provide symptomatic relief in these populations.

Objectives:

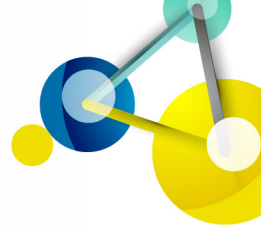
This trial will compare the effects of a tele-rehabilitation program integrating education and conscious-based movement (yoga, breathing techniques, interoceptive awareness) with those of education and conventional low-intensity exercise in individuals with CFS/ME or PCS, focusing on physical, psychosocial, and autonomic outcomes.

Methods:

This is a prospective, three-arm, parallel, randomized, single-blind clinical trial, approved by the Universidad de Sevilla Ethics Committee (C2022_163_3) and registered at ClinicalTrials.gov (NCT06978582). A total of 147 participants (aged 18–70) diagnosed with CFS/ME or PCS will be recruited via convenience sampling and randomly assigned to: (1) conscious movement, (2) conventional exercise, or (3) usual care. All interventions will be delivered via telehealth to maximize accessibility, over 12 weeks, with one 45-minute weekly session combining health education and individually adapted exercises. Participants will be encouraged to practice daily with provided materials. Adherence and adverse events will be recorded.

Primary outcomes are fatigue, heart rate variability, and pain. Secondary outcomes include functional capacity, mental health, interoceptive awareness and accuracy, quality of life, and sleep quality. Measurements will be collected at baseline, post-intervention,





and at 3-month follow-up. Statistical analysis will follow a per-protocol approach, including only participants completing $\geq 70\%$ of sessions.

Expected outcomes:

It is hypothesized that the conscious-based intervention will be safe and produce greater improvements in core symptoms and autonomic regulation than conventional exercise or usual care.

