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The first BCI clinical trial for stroke neurorehabilitation in Latin America: The ReHand-BCI trial

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Introduction: More than 20 million people are estimated to live with stroke sequalae in Latin America, with limited access to rehabilitation, particularly for upper extremity (UE) neurorehabilitation [1]. Brain-Computer Interfaces (BCI) could increase neurorehabilitation access for the region. However, more clinical trials are needed for assessing their clinical and physiological effects. For these reasons, an electroencephalography-based BCI for stroke UE neurorehabilitation, the ReHand-BCI, was developed and assessed in the National Institute of Rehabilitation at Mexico City in the first clinical trial of its type in Latin America (NCT04724824).

Material, Methods and Results: The study was a triple-blinded randomized controlled clinical trial, that aimed to assess the clinical and neuroplastic effects of 30 sessions of therapy with the ReHand-BCI (depicted in Fig. 1) [2]. In the experimental group (EG), patients attempted to control the movement of a 3D-printed robotic orthosis that provided passive finger movement by decoding hand movement intention from electroencephalography (EEG). The control group (CG) was comprised by a sham-BCI intervention. Nineteen patients completed the trial. There were no significant between-group differences. However, only the EG had significant improvements in both clinical measures after the intervention and at follow-up, and a tendency of higher ipsilesional corticospinal integrity measured with the ratio of fractional anisotropy computed from magnetic resonance imaging, as shown in Fig. 2.

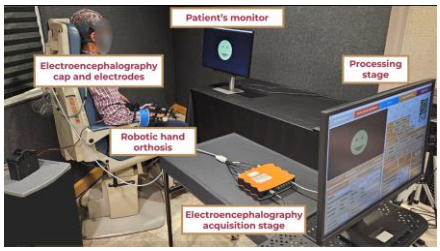

Figure 1: *The ReHand-BCI system.*

Conclusion: Stroke patients can improve their upper extremity function with both a BCI and sham-BCI intervention, but functional performance of the upper extremity and ipsilesional enhancement of corticospinal tract integrity seems to be promoted in a greater degree if kinesthetic feedback is provided according to hand motor intention.

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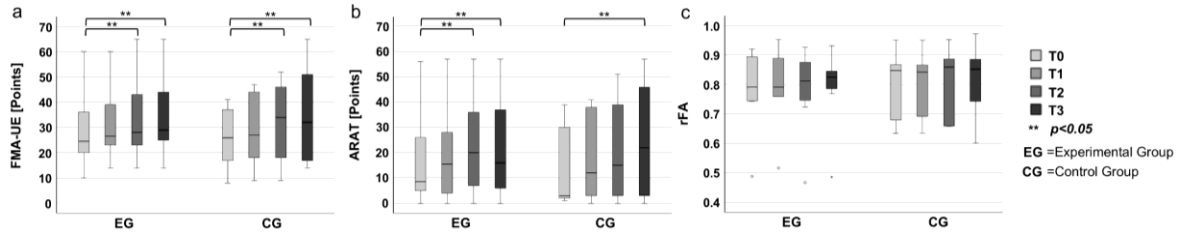

Figure 2: a) *Outcomes of the Fugl-Meyer of the Upper Extremity (FMA-UE), b) Action Research Arm Test (ARAT) c) Ratio of fractional anisotropy (rFA) for pre (T0), intermediate (T1), post (T2), and 6-month follow-up (T3) intervention measurements.*

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