DOUBLE-BLIND CLINICAL TRIAL VS PLACEBO ON THE IMPACT OF TRANCRANIAL PULSED STIMULATION (TPS) ON PATIENTS WITH POST-COVID-19 NEUROLOGICAL INVOLVEMENT (LONG COVID).

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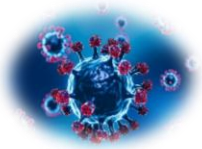
INTRODUCTION

Brain Long-COVID is a post-infectious condition that has emerged following the COVID-19 pandemic. This clinical entity is defined by symptoms that persist for more than 4 to 12 weeks after recovering from COVID-19 infection.

Frequently described symptoms include:

- difficulty breathing and fatigue,
- hair loss,
- autonomic dysfunction,
- neuromuscular disorders,
- headaches, and attention deficits.



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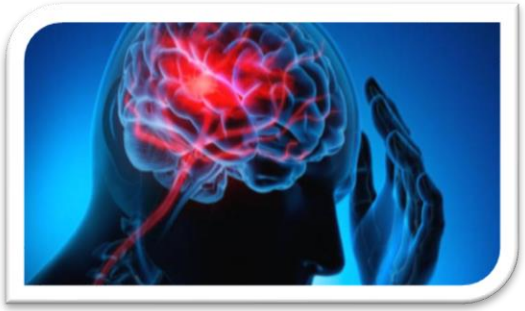
The reported cognitive deficits are typical of syndromes characterized by **frontal** and **prefrontal** functional or structural **impairment.**
These areas are crucial for working memory, inhibition, cognitive flexibility, planning, and problem-solving.

Biological effects of TPS

TPS a new tool that allows you to stimulate the brain up to 8 cm depth

- Pore formation, transendothelial openings, better molecules passing-through
- Blood-brain barrier opening
- Microglia activation and AB plaque reduction
- Increased serotonin and dopamine, BDNF and VEGF and NO
- Stem cell proliferation and differentiation
- Reduction of GABA levels



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OBJECTIVE

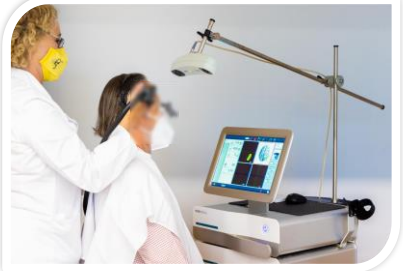
Transcraneal pulse stimulation (TPS) has been shown to improve cognitive performance in patients with mild cognitive impairment, and there are already studies with transcranial stimulation that have improved Neuro Long-Covid.

With our study, we expect to confirm the **usefulness** of TPS on the **"Neuro-Long Covid"**, since there is no specific treatment for this entity.

Secondarily, we propose to increase the number of pulses in these areas to ameliorate cognitive functions related to attentional and executive processes and the speed of information processing.

MATERIALS & METHODS

Study design:
Double-blind clinical trial versus placebo to verify the safety, usefulness, and new treatment protocol for cognitive impairment in Neuro-LongCovid.
This study will recruit a total of 34 subjects aged between 18 and 75 years, diagnosed with Neuro-LongCovid19.
All subjects will be randomized into either the intervention group or the sham TPS group in a 1:1 ratio. All patients will undergo magnetic resonance imaging (MRI).



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Primary outcome:

- Improvement in cognitive functions measured by neuropsychological tests after TPS intervention.

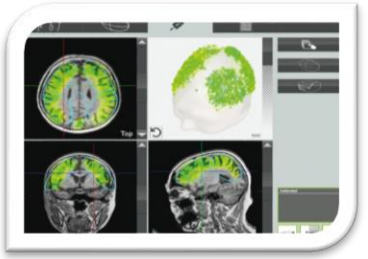
Secondary outcome:

- Improvement in fatigue severity and impact measured by the Fatigue Severity Scale (FSS) and the Modified Fatigue Impact Scale (MFIS).
- Improvement in depressive symptoms measured by the Patient Health Questionnaire-9 (PHQ-9)
- Improvement in quality of life measured by the EuroQoL-5D health questionnaire.

VARIABLE

Neuropsychological Evaluation of Attention & Executive Functions:

- The Trail Making Test
- The Symbol-Digit Modalities Test (SDMT)
- The Stroop test
- Fatigue Severity Scale (FSS)
- Modified Fatigue Impact Scale (MFIS)
- Patient Health Questionnaire-9 (PHQ-9)
- EuroQoL-5D Health/Quality of Life Questionnaire
- Presence of fatigue sequelae: FSS scale



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