Trial registration dataset	
Data Category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT03371225
Date of registration in primary registry	December 13, 2017
Secondary identifying numbers	2017P002524
Source of monetary or material support	National Institutes of Health (NIH)
Primary sponsor	National Institutes of Health (NIH)
Contact for public queries	Felipe Fregni, MD, PhD, MPh, MMSc
Contact for scientific queries	Felipe Fregni, MD, PhD, MPh, MMSc
Public title	Optimized tDCS for fibromyalgia: targeting the endogenous pain control system
Scientific title	Optimized tDCS for fibromyalgia – targeting the endogenous pain control system: A randomized, double-blind, factorial clinical trial protocol
Countries of recruitment	United States
Health condition(s) or problem(s) studies	Fibromyalgia
Interventions	Device: Active tDCS; Procedure: Active Exercise; Device: Sham tDCS; Procedure: Sham Exercise
Key inclusion and exclusion criteria	**Inclusion criteria:** 1) 18-65 years; 2) Diagnosis of FM pain according to the ACR 2010 criteria; 3) Pain resistant to common analgesics and medications for chronic pain; 4) Must have the ability to feel sensation by Von-Frey fiber on the forearm; 5) Able to provide informed consent to participate in the study. **Exclusion criteria:** 1) Clinically significant or unstable medical or psychiatric disorder; 2) History of substance abuse within the past 6 months as self-reported; 3) Previous significant neurological history; 4) Previous neurosurgical procedure with craniotomy; 5) Severe depression; 6) Pregnancy; 7) Current opiate use in large doses; 8) increased risk for exercise

Study type	Interventional
	Randomized, double-blind, factorial clinical trial
Date of first enrolment	May 2019
Target sample size	148
Recruitment status	Recruiting
Primary outcome(s)	Conditioned Pain Modulation (CPM); Temporal Slow Pain Summation (TSPS)
Key secondary outcomes	Intracortical inhibition assessed by TMS; thalamocortical dysrhythmia (TCD) and event related desynchronization (ERD) assessed by EEG; Average pain intensity as assessed by Modified Brief Pain Inventory (BPI); Revised Fibromyalgia Impact Questionnaire (FIQ-R); Quality of life assessed by Quality of Life Scale (QoLS), Patient Reported Outcomes Measurement Information System (PROMIS); Pittsburgh Sleep Quality Index (PSQI) and Beck Depression Inventory (BDI).

Protocol Version:
Issue date: 05/16/2019
Protocol amendment number: 08

Revision Chronology
18/01/2018: Original submission
08/23/2018: Amendment 01- Primary reason for amendment: clarification of inclusion/exclusion criteria
11/02/2018: Amendment 04 - Primary reason for amendment: clarification of TMS protocol
16/05/2019: Amendment 08- Primary reason for amendment: clarification of CPM and TSPS procedures

All other Amendments (01, 03, 05, 06, 07) were related to changes in study staff. Any further amendments will follow Partners Healthcare institutional policies.