# Effectiveness of transcraneal direct current stimulation (tDCS) for the treatment of fibromyalgia: Comparison of cortical targets effects on main fibromyalgia symptoms (tDCS for the treatment of fibromyalgia)

**First published:** 02/06/2018

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Study Planned

## Administrative details

**EU PAS number**

EUPAS24294

**Study ID**

24295

**DARWIN EU® study**

No

**Study countries**

☐ Spain

**Study description**

Fibromyalgia is a common cause of diffuse, chronic musculoskeletal pain in adults, with an estimated prevalence between 2 and 5% in the general population. Even though its aetiology and pathophysiology are not fully understood, current evidence suggests that, similarly to other chronic pain syndromes, this is a disorder of pain regulation characterized by altered pain and sensory processing in the central nervous system, likely due to maladaptive plasticity in pain-related neural circuits. Thus, the use of neuro-stimulation approaches is of particular relevance in fibromyalgia, a chronic pain disorder where pain can be characterized by a lack of inhibitory control over somatosensory processing and that is often refractory to multiple therapeutic strategies.Transcranial direct current stimulation (tDCS) is a promising technique that allows to non-invasively modulate brain activity by applying a low intensity current (1 to 2 mA) via scalp electrodes. Stimulation effects and after-effects depend on the current polarity under each electrode. Indeed, motor cortex stimulation studies have shown that with standard parameters, anodal stimulation enhances cortical excitability, while cathodal stimulation decreases cortical excitability.Some studies have explored the analgesic effects of tDCS in chronic pain, including fibromyalgia, both stimulating M1 and/or the dorso-lateral prefrontal cortex (DLPFC, F3). However, a recent meta-analysis has stressed the poor methodological quality of most previous studies, leading to non-significant results of and the need for larger, rigorously designed studies. This study aims to obtain more information on the therapeutic use of tDCS for pain relief, and to respond to two important challenges of this area of research: (a) the need of more sham-controlled studies with a sufficient number of patients and long follow-up, (b) the need to explore novel targets in pain-related brain regions, such as the operculo-insular cortex.

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**Study status**

Planned

## Research institutions and networks

## Institutions

### Health Research Institute of Santiago de Compostela (IDIS)

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Institution

### Hospital Complex of Pontevedra Pontevedra (Spain)

## Contact details


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**Primary lead investigator**

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Primary lead investigator


## Study timelines

**Date when funding contract was signed**
Planned: 02/06/2018

**Study start date**
Planned: 02/06/2018

**Data analysis start date**
Planned: 02/06/2018

**Date of interim report, if expected**
Planned: 02/06/2018

**Date of final study report**
Planned: 03/09/2018

## Sources of funding

- Other

## More details on funding

Spanish National Plan

## Study protocol

PROTOCOLO-TCS_REGISTER EU.pdf(190.08 KB)

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

# Methodological aspects

## Study type

## Study type list

**Study type:**

Clinical trial

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**Scope of the study:**

Effectiveness study (incl. comparative)

Other

**If ‘other’, further details on the scope of the study**

Explore novel targets in pain-related brain regions, such as the operculo-insular cortex

**Main study objective:**

1) to compare the analgesic effect of M1 active tDCS vs sham tDCS in a group of patients with FM, 2) to analyze long-term effects (6, 12 m) of tDCS on pain and associated symptoms, 3) to check the effect of DLPFC active tDCS vs sham tDCS on cognitive function, 4) to determine the optimum tDCS stimulation place (M1, OIC or DLPFC) for each of a group of four symptoms considered in FM

patients.

## Study Design

**Clinical trial randomisation**

Randomised clinical trial

## Study drug and medical condition

**Medical condition to be studied**

Fibromyalgia

Pain management

## Population studied

**Age groups**

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

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**Estimated number of subjects**

92

## Study design details

**Outcomes**

To assess treatment effectiveness we will consider 4 groups of symptoms, each with defined outcome measures.1. Pain, fatigue (mean threshold by algometry, FIQ items 5 and 6)2. Mood state (HADS score)3. Cognitive dysfunction (MFE score)4. Sleep disorders (PSQI score)A 20% of change between the pre and post treatment in any of the groups will be consider an index of a clinical improvement. Assessment of general quality of life, functional impact and electroencephalogram (EEG) parameters.

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**Data analysis plan**

Patients agreeing to participate will be scheduled for a 1st evaluation session. Once informed about the characteristics of the tDCS, results of previous studies with chronic pain patients, and safety aspects, a written informed consent will be required of them. We'll use strict inclusion/ exclusion criteria.For inclusion: fulfillment of both the ACR criteria of 1990 and 2010 (Wolfe et al.), moderate to high severity of the disease (indicated by a FIQ score >/=70 or a VAS Pain >/= 7), presence of cognitive dysfunction (item 2 "cognitive troubles" of the Symptom SS >/=2).For exclusion: no immune system pathology or comorbidities that could explain the main symptomatology of FM, risk factors for the tDCS procedure, such as existence of a history of previous convulsions (epilepsy or family history), use of anticonvulsant treatment (e.g, pregabalin, caarbamazepine, gabapentin), substance abuse, psychiatric diseases, other than depression and anxiety, brain damage, dementia, Parkinson's

# Data management

## Data sources

**Data sources (types)**

Other

**Data sources (types), other**

Fibromyalgia patients of the sanitary areas will be informed about the study in the Neurology service of the Universitary Hospital Complex of Santiago de Compostela (CHUS) or in the Rheumatology service of the Hospital Complex of Pontevedra. Also, we have a pool of 543 patients that participated in the Genetic study of Fibromyalgia that were already informed about the tDCS project.

## Use of a Common Data Model (CDM)

**CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

**Check completeness**

Unknown

**Check stability**

Unknown

**Check logical consistency**

Unknown

## Data characterisation

## Data characterisation conducted

No