COVER PAGE

Official Study Title:
Pilot Study on the Effects of Transcranial Direct Current Stimulation (tDCS) in Patients with Fibromyalgia and Chronic Fatigue Syndrome

NCT not yet assigned.

Document:
Study Protocol, Statistical Analysis Plan and Informed Consent Form

Date:

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Sponsor:

University Hospital of Donostia
University of the Balearic Islands

Study Title

Pilot Study on the Effects of Transcranial Direct Current Stimulation (tDCS) in Patients with Fibromyalgia and Chronic Fatigue Syndrome

Protocol / SAP / Informed Consent Form

Brief Summary

This non-controlled pilot study evaluates the feasibility, safety, and preliminary effects of transcranial direct current stimulation (tDCS) on patient-reported outcomes in individuals with fibromyalgia (FM) and chronic fatigue syndrome (CFS). Fifteen participants will receive 10 sessions of tDCS over two consecutive weeks. Outcomes will be assessed at baseline and immediately post-treatment using validated instruments measuring quality of life, fatigue, pain, mood, autonomic symptoms, and sleepiness.

Detailed Description

This is a prospective, non-controlled pilot study designed to explore the feasibility, safety, and preliminary clinical effects of transcranial direct current stimulation (tDCS) in patients diagnosed with fibromyalgia (FM) or chronic fatigue syndrome (CFS).

Participants were recruited from outpatient clinics of the Neurology and Physical Medicine and Rehabilitation services by specialist consultants. Patients continued their usual clinical care during the study period without interference.

A total of 20 patients were initially recruited; however, 5 were excluded due to concurrent diagnoses of both FM and CFS. The final sample included 15 participants meeting diagnostic criteria for either FM (n = 5) or CFS (n = 10).

FM diagnosis was established according to the 2016 revisions to the American College of Rheumatology (ACR) criteria. CFS diagnosis was established following the diagnostic algorithm proposed by the Institute of Medicine (2015).

The FM group consisted of 5 women (median age: 55 years), while the CFS group included 3 men and 7 women (median age: 56 years), reflecting the higher prevalence of these conditions in women.

All participants provided written informed consent prior to enrollment. The study protocol was approved by the local Ethics Committee of the University of the Balearic Islands (Spain) (reference #061CER24) and conducted in accordance with ethical standards.

Given the exploratory nature of this pilot study, no formal sample size calculation was performed.

Study Design

- **Study Type:** Interventional
- **Allocation:** N/A (Single Group Assignment)
- **Intervention Model:** Single Group Assignment

- **Masking:** None (Open Label)
- **Primary Purpose:** Treatment

Intervention

Experimental: tDCS Intervention

Participants received transcranial direct current stimulation (tDCS) using a bipolar montage.

- Device: HDCStim electrical stimulator
- Intensity: 2 mA
- Duration: 20 minutes per session
- Frequency: 5 sessions per week
- Total: 10 sessions over 2 consecutive weeks
- Montage: Bipolar with extra-cephalic cathode placed on the arm

Stimulation parameters followed established safety and tolerability guidelines for clinical neuromodulation. Adverse effects, including severe side effects, were monitored and recorded throughout the intervention period.

Outcome Measures

Primary Outcome Measures

1. Change in Health-Related Quality of Life (SF-36)

- Time Frame: Baseline and immediately post-treatment
- Description: The Short Form-36 Health Survey assesses eight domains of health-related quality of life. Higher scores indicate better perceived health status.

Secondary Outcome Measures

2. Change in Fibromyalgia Impact (FIQ)

- Time Frame: Baseline and post-treatment
- Description: Measures functional impact and symptom severity in fibromyalgia. Higher scores indicate greater disease burden.

3. Change in Anxiety and Depression (HADS)

- Time Frame: Baseline and post-treatment
- Description: A 14-item questionnaire assessing anxiety and depression symptoms. Higher scores indicate greater severity.

4. Change in Autonomic Symptoms (COMPASS)

- Time Frame: Baseline and post-treatment

- Description: Evaluates autonomic dysfunction across multiple domains. Higher scores indicate greater dysfunction.

5. Change in Pain Intensity (VAS)

- Time Frame: Baseline and post-treatment
- Description: Visual analogue scale measuring subjective pain intensity. Higher scores indicate greater pain.

6. Change in Daytime Sleepiness (Epworth Sleepiness Scale)

- Time Frame: Baseline and post-treatment
- Description: Assesses likelihood of dozing in daily situations. Higher scores indicate greater sleepiness.

7. Change in Fatigue Severity (FSS)

- Time Frame: Baseline and post-treatment
- Description: Evaluates fatigue impact on daily functioning. Higher scores indicate greater fatigue.

8. Change in Fatigue Levels (FAS)

- Time Frame: Baseline and post-treatment
- Description: Assesses physical and mental fatigue. Higher scores indicate higher fatigue levels.

Eligibility Criteria

Inclusion Criteria

- Diagnosis of fibromyalgia (FM) according to 2016 ACR criteria OR
- Diagnosis of chronic fatigue syndrome (CFS) according to Institute of Medicine (2015) criteria
- No contraindications to transcranial electrical stimulation
- Ability to provide informed consent

Exclusion Criteria

- History of epilepsy
- Presence of cochlear implants or metallic implants
- Previous treatment with electrical or magnetic brain stimulation
- Contraindications to transcranial neuromodulation
- Concurrent diagnosis of both FM and CFS

Enrollment

- **Estimated Enrollment:** 15 participants

Sex and Age

- **Sex:** All
- **Age Range:** Adult (specify if needed, e.g., 18–70 years)

Statistical Analysis Plan

Descriptive statistics will be used to summarize baseline characteristics. Pre–post comparisons will be conducted for the overall sample to assess changes following the intervention. Exploratory subgroup analyses will be performed based on diagnosis (FM vs. CFS). Given the pilot nature of the study, analyses will be considered exploratory.

Ethics and Dissemination

The study was approved by the Ethics Committee of the University of the Balearic Islands (Spain) (reference #061CER24). All participants provided written informed consent. Results will be disseminated through scientific publications and conferences.

PATIENT INFORMATION SHEET AND INFORMED CONSENT

Study Title
Pilot study on the effects of transcranial direct current stimulation (tDCS) in patients with fibromyalgia and chronic fatigue syndrome

Center
[University Hospital of Donostia]

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Study Sponsor
Donostia University Hospital
University of the Balearic Islands

1. Introduction

You are invited to participate in a biomedical research study. Before deciding, it is important that you understand what the study involves, its risks and benefits, and how your personal data will be handled.

2. Study Objective

To evaluate the safety, feasibility, and potential effects of transcranial direct current stimulation (tDCS) on symptoms such as pain, fatigue, quality of life, mood, and other symptoms in patients with fibromyalgia or chronic fatigue syndrome.

3. Procedure

If you agree to participate:

- You will receive 10 sessions of tDCS
- Frequency: 5 sessions per week for 2 weeks
- Duration: 20 minutes per session
- Intensity: 2 mA
- Application via electrodes placed on the head and arm

Additionally:

- You will complete questionnaires before and after treatment
- Your usual treatment will not be modified

4. Risks and Discomforts

tDCS is a safe technique, although it may produce mild effects:

- Tingling or itching
- Skin redness

- Mild headache

Serious adverse effects are very rare. In the event of any incident, you will be attended by the medical team.

5. Benefits

No direct benefit is guaranteed. However, you may experience symptom improvement and contribute to scientific progress.

6. Alternatives

Participation is voluntary. You may continue with your usual treatment without participating in this study.

7. Confidentiality and Data Protection

Your data will be processed in accordance with:

- General Data Protection Regulation (GDPR)
- Organic Law 3/2018

Data Controller
Donostia University Hospital and University of the Balearic Islands

Purpose
Management and conduct of the research study.

Legal Basis
Participant consent.

Data Retention
Data will be retained for the time necessary to fulfill the purpose of the study and legal obligations.

Measures
Your data will be coded (pseudonymized), preventing direct identification.

Recipients
Data may be used for scientific purposes and published in journals, always in anonymous form.

8. Participant Rights

You may exercise your rights to:

- Access
- Rectification
- Erasure
- Restriction of processing
- Objection
- Data portability

You may also lodge a complaint with the Spanish Data Protection Agency.

9. Voluntary Participation

Your participation is voluntary. You may withdraw at any time without affecting your medical care.

10. Insurance / Coverage

Participants are covered by institutional liability insurance in accordance with applicable regulations.

11. Ethical Approval

This study has been approved by the corresponding Research Ethics Committee for Medicines (CEIm) (ref. #061CER24).

INFORMED CONSENT

I, Mr./Ms. _____

Declare that:

- I have read the patient information sheet
- I have received sufficient information about the study
- I have been able to ask questions and have received satisfactory answers
- I understand the risks and benefits
- I understand how my personal data will be processed
- I participate voluntarily

I agree to participate in the study:
☐ YES
☐ NO

Participant's signature: _____
Date: ____ / ____ / _____

Investigator's signature: _____
Date: ____ / ____ / _____

Consent for Personal Data Processing

☐ I consent to the processing of my data for the purposes of the study
☐ I consent to the use of anonymized data for scientific publications

Signature: _____