

# Treatment of chronic fatigue by transcranial direct current stimulation (tDCS)

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
31/10/2025	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
19/11/2025	Ongoing	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
30/12/2025	Nervous System Diseases	<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study is looking at ways to help people with chronic fatigue (CF), a condition that causes long-lasting tiredness and affects daily life. Researchers are testing whether a type of brain stimulation called transcranial direct current stimulation (tDCS), used at home, can reduce fatigue and improve overall wellbeing.

### Who can participate?

Adults diagnosed with chronic fatigue syndrome or similar long-term fatigue, whose symptoms have lasted at least six months and have affected their ability to work or study, were invited to take part.

### What does the study involve?

Participants were randomly placed into one of three groups:

- One group received standard care (called TAU).
- Another group received standard care plus active tDCS.
- The third group received standard care plus sham (inactive) tDCS.

The tDCS treatment was done at home using a small device for 30 minutes a day, five days a week, over three weeks. If the treatment helped or showed some effect, participants could continue for another three weeks.

### What are the possible benefits and risks of participating?

The main benefit may be reduced fatigue and improved mental and physical wellbeing. tDCS is generally well tolerated, with few side effects reported. Home-based treatment has also been shown to be safe. However, as with any treatment, there may be individual differences in response.

### Where is the study run from?

The study is run from the HUS Outpatient Clinic for Persistent Symptom Rehabilitation in Finland.

### When is the study starting and how long is it expected to run for?

May 2024 to May 2026

Who is funding the study?  
HUS Helsinki University Hospital (Finland)

Who is the main contact?  
Dr Kirsi Riihimäki at the HUS Outpatient Clinic.  
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## Contact information

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Public, Scientific, Principal investigator

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
HUS20974277

## Study information

**Scientific Title**  
Intervention with tDCS in chronic fatigue, a randomized controlled trial

**Acronym**  
tDCS in CFS

**Study objectives**

The aim of this study was to evaluate the use of tDCS (transient direct current stimulation) in the treatment of Finnish patients suffering from chronic fatigue syndrome (CFS). We hypothesized that patients with CFS may benefit from tDCS treatment, resulting in symptom relief and improved functional capacity.

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

approved 15/01/2024, HUS Medical ethics committee (00029 HUS, Helsinki, 00029, Finland; +358 49 359 4618; eettinen.toimikunta@hus.fi), ref: HUS/4202/2023

### **Study design**

Interventional randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Chronic fatigue syndrome (CFS)

### **Interventions**

The study was conducted in addition to the unit's treatment-as-usual (TAU). It was a prospective, comparative, blinded study. Patients were randomized (by sealed envelopes, in groups of 10 patients) to receive either: TAU only (40%), TAU plus active tDCS (40%), or TAU plus sham tDCS (20%). Sham stimulation was administered in a double-blind manner, and staff were unaware of whether the treatment was active or sham.

Previous studies have targeted stimulation to the primary motor cortex or the dorsolateral prefrontal cortex (DLPFC) (Antani et al., 2017). In this study, the DLPFC was selected based on results from rTMS studies and tDCS studies in other conditions such as depression (Fregni et al., 2021). Electrodes were placed bitemporally, with the anode over the left DLPFC and the cathode over the right DLPFC. The method involves transcranial application of a weak electrical current (typically <2.5 mA), which theoretically alters neuronal membrane potentials (reducing the threshold for action potentials), thereby modulating cortical activity and improving brain function, leading to symptom relief. Under the anode, neurons depolarize due to increased membrane potential, while under the cathode, the opposite occurs.

Patients received tDCS at home for 30 minutes per day, five times per week, over a three-week period. If the response was good (recovery), absent (no change), or partial, an additional three-week treatment period was provided (total of six weeks).

### **Intervention Type**

Device

### **Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Transcranial direct current stimulation

**Primary outcome(s)**

Fatigue measured using Chalder at baseline, 3 weeks, 6 weeks, 3 months and 6 months

**Key secondary outcome(s)**

1. Stress is measured using CORE-10 at baseline, 3 weeks, 6 weeks, 3 months and 6 months
2. Functional capacity is measured using the Sheehan Disability Scale (SDS) at baseline, 3 weeks, 6 weeks, 3 months and 6 months
3. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, 3 weeks, 6 weeks, 3 months and 6 months
4. Anxiety is measured using the Generalized Anxiety Disorder-7 (GAD-7) at baseline, 3 weeks, 6 weeks, 3 months and 6 months
5. Quality of life is measured using EuroHIS-8 at baseline, 3 weeks, 6 weeks, 3 months and 6 months
6. Quality of life is measured using WHODAS 2.0 at baseline, 3 weeks, 6 weeks, 3 months and 6 months
7. Health-related quality of life is measured using 15D at baseline, 3 weeks, 6 weeks, 3 months and 6 months

**Completion date**

31/05/2026

## Eligibility

**Key inclusion criteria**

1. Patients diagnosed with chronic fatigue syndrome (ICD-10: G93.3) or similar prolonged fatigue (R68.88) were recruited from the HUS Outpatient Unit for Persistent Symptom Rehabilitation (functional disorders).
2. Fatigue symptoms had:
  - 2.1. Persisted continuously for at least six months.
  - 2.2. Caused a decline in functional capacity affecting work or study ability.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

65 years

**Sex**

All

**Total final enrolment**

93

**Key exclusion criteria**

1. Psychotic symptoms
2. Suicidal risk
3. Pregnancy
4. Substance use disorder
5. Metal implants in the head
6. Pacemaker
7. Acute skin conditions at the stimulation site

**Date of first enrolment**

02/05/2024

**Date of final enrolment**

30/11/2025

## Locations

**Countries of recruitment**

Finland

**Study participating centre**

HUS

00029 HUS

Helsinki

Finland

00029 HUS

## Sponsor information

**Organisation**

Helsinki University Hospital

**ROR**

<https://ror.org/02e8hzf44>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

HUS Helsinki University Hospital

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Data sharing statement to be made available at a later date

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	in Finnish	03/11/2025	No	Yes	
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes