ISRCTN42784463 https://doi.org/10.1186/ISRCTN42784463

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

Submission date
31/10/2025

Recruitment status
No longer recruiting

Registration date
19/11/2025

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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.
Email: kirsi.riihimaki@hus.fi or kirsi.riihimaki@fimnet.fi

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Kirsi Riihimäki

ORCID ID
https://orcid.org/0000-0003-3913-5968

Contact details
00029 HUS
Helsinki
Finland
00029
+358 400645883
kirsi.riihimaki@hus.fi

Additional identifiers

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

Primary study design
Interventional

Study design
Interventional randomized controlled trial

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?
Participant information sheet	in Finnish		03/11/2025	No	Yes