

Managing burnout with non-invasive neuromodulation

Submission date 13/11/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/12/2019	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/06/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Burnout is a state of emotional, physical, and mental exhaustion caused by excessive and prolonged stress. Burnout is characterized by deficiencies in attention and several components of the working memory, of which the lingering effects of impaired attention and executive functions are the most frustrating

Who can participate?

Patients aged 18 years or above with a score of > 4 on the Dutch version of the Maslach Burnout Scale (MBS)

What does the study involve?

Patients with burnout received three weeks of daily sessions (15 sessions in total) of atDCS or sham stimulation in addition to three weekly sessions of standard behavioral therapy

What are the possible benefits and risks of participating?

Potential benefits for the participants in the real tDCS group will be that their attention skills will be improved much quicker than those of the participants in the sham group. Behaviorally, no negative effects of tDCS have been registered yet. However, temporary skin irritation, headaches, nausea, dizziness, exhaustion, and visual deficits have been reported.

Where is the study run from?

DIADIS NV, Belgium

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

February 2016 to May 2017

Who is funding the study?

Fonds Wetenschappelijk Onderzoek, Belgium

Who is the main contact?

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Contact information

Type(s)

Public

Contact name

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

tDCS_burnout

Study information

Scientific Title

Transcranial direct current stimulation and attention skills in burnout patients: a randomized blinded sham-controlled pilot study

Study objectives

Anodal transcranial direct current stimulation (atDCS) over the left dorsolateral prefrontal cortex (DLPFC) can improve the executive control of attention and possibly also several other components of working memory in patients with burnout

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 05/11/2014, Commissie Medische Ethiek Vrije Universiteit Brussel (Laarbeeklaan 1090 Brussels, Belgium; +32 24775584; commissie.ethiek@uzbrussel.be), ref: B.U.N. 143201422009

Study design

Randomized single centre blinded sham-controlled pilot study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Attention deficits in burnout

Interventions

Real tDCS: daily sessions for 3 weeks, 1 session consisted of 2mA, 20min, anodal tDCS over the left dorsolateral prefrontal cortex (cathode over lateral aspect of contralateral orbit) + 1 session / week of behavioral therapy

Sham tDCS: daily sessions for 3 weeks, 1 session consisted of 2mA, 1min, anodal tDCS over the left dorsolateral prefrontal cortex (cathode over lateral aspect of contralateral orbit) + 1 session / week of behavioral therapy

Randomisation:

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Attention measured using RBANS at baseline and after 3 weeks of stimulation

Key secondary outcome(s)

At baseline and after 3 weeks of stimulation:

1. Burnout measured using MBS
2. Depression measured using BDI
3. Quality of Life measured using QoL
4. Attention measured using RBANS Attention Index

5. Vigilance measured using D2 (s-score)
6. Central executive measured using Inhibition and shifting, Stroop III, TMT B, WCST
7. Processing speed (updating and control) measured using TMT A, Stroop I and II, D2 (Gz, F%, Gz – F)
8. Phonological loop measured using RBANS Language Index
9. BNT measured using Semantic fluency tasks
10. Visuospatial sketchpad measured using Raven and RBANS Visuospatial Index
11. Encoding measured using RBANS Immediate Memory Index
12. Retrieval measured using RBANS Recent Memory Index

Completion date

22/05/2017

Eligibility

Key inclusion criteria

1. Score of > 4 on the Dutch version of the Maslach Burnout Scale (MBS)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

16

Key exclusion criteria

1. Excessive drug or alcohol use
2. Epilepsy
3. Depression
4. Bipolar syndrome
5. Chronic fatigue syndrome or any other history of psychiatric or neurological disorders
6. Implanted neurostimulator or pace-maker
7. Drugs interacting directly with the NMDA receptors
8. Pregnancy

Date of first enrolment

08/02/2016

Date of final enrolment

01/05/2017

Locations

Countries of recruitment

Belgium

Study participating centre

DIADIS NV

De Hoogt 41

Oud-Turnhout

Belgium

2360

Sponsor information

Organisation

Vrije Universiteit Brussel

ROR

<https://ror.org/006e5kg04>

Organisation

Fonds Wetenschappelijk Onderzoek (FWO)

Funder(s)

Funder type

Government

Funder Name

Fonds Wetenschappelijk Onderzoek

Alternative Name(s)

Research Foundation Flanders, Flemish Research Foundation, Research Foundation – Flanders, Fonds voor Wetenschappelijk Onderzoek - Vlaanderen, The FWO, Het FWO, FWO

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	results in preprint	14/02/2020	03/06/2020	No	No