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Managing burnout with non-invasive neuromodulation

Submission date
13/11/2019

Recruitment status
No longer recruiting

Registration date
18/12/2019

Overall study status
Completed

Last Edited
03/06/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a participant information sheet

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

Secondary outcome measures
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. BNTmeasured 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

Overall study start date
21/05/2014

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

Age group
Adult

Sex
Both

Target number of participants
20

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

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Sponsor type
University/education

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ROR
https://ror.org/006e5kg04

Organisation
Fonds Wetenschappelijk Onderzoek (FWO)

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Egmontstraat 5
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Sponsor type
Government

Website
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Funder(s)

Funder type
Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Results and Publications

Publication and dissemination plan
PLOS One

Intention to publish date
25/10/2019

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