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Neurofeedback for improved mental functioning

Submission date	Recruitment status	[ ] Prospectively registered
11/12/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/01/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/01/2019	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Executive functions can be defined as the control processes that deal with managing oneself and one's resources in order to achieve a goal. Executive functions are vital for success in daily life and rely on the intact neural functioning of a specific type of brainwaves, the theta oscillations. As executive dysfunctions are linked to abnormal activity of the theta oscillations in various neuropsychological disorders, the question arises if neurofeedback can increase the theta activity and as a result can improve executive functions in people with executive dysfunctions. Neurofeedback is a brain-computer-interface in which the otherwise unobservable theta activity is made visible to participants by providing a feedback signal on a computer screen. Thereby participants can monitor their current theta activity and learn to influence it using mental strategies. The aim of this study is to assess the feasibility and effectiveness of theta neurofeedback as a treatment for these patients.

Who can participate?
Patients aged 18 or older with executive dysfunctions

What does the study involve?
Participants are matched on age, gender and education and are pseudo-randomly allocated to the experimental group or the active control group. Both the experimental group and the active control group receive 8 neurofeedback sessions, provided on a daily basis (total duration 2-3 consecutive weeks). Participants in the experimental group receive immediate feedback on their current theta brain activity. Participants in the active control group receive pseudo/sham feedback, which is a replay of the feedback from the matched participant in the experimental group. Theta oscillations and executive functions are assessed before the neurofeedback training (pre-measurement), immediately after the training (post-measurement), and after 6 months (follow-up measurement).

What are the possible benefits and risks of participating?
In general, adverse effects of neurofeedback are rare.

Where is the study run from?
University of Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
February 2018 to February 2019

Who is funding the study?
University of Groningen (Netherlands)

Who is the main contact?
Dr Stefanie Enriquez-Geppert

Study website
www.neurofeedback-rug.nl

Contact information

Type(s)
Scientific

Contact name
Dr Stefanie Enriquez-Geppert

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NF_EDys-pilot

Study information

Scientific Title
The effect of frontal-midline theta neurofeedback on executive functioning

Acronym
NF_EDys

Study objectives

The trialists predict that the experimental group will show larger increases in theta amplitude over the neurofeedback sessions and show stronger improvements in executive functioning after the training in comparison to the active control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee Psychology (ECP) of the University of Groningen, 21/03/2018, ref: RP_17232-O

Study design
Single-centre pseudo-randomized controlled trial (participants are matched on age, gender and education)

Primary study design
Interventional

Secondary study design
Pseudo-randomized controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Subjective executive dysfunctions

Interventions
Both the experimental group and the active control group receive 8 neurofeedback sessions, provided on a daily basis (total duration 2-3 consecutive weeks). Participants are matched on age, gender and education and pseudo-randomly assigned to either the experimental group or the active control group. Participants in the experimental group receive immediate feedback on their current theta brain activity. Participants in the active control group receive pseudo/sham feedback, which is a replay of the feedback from the matched participant in the experimental group.

Intervention Type
Procedure/Surgery

Primary outcome measure
Power of the theta oscillations measured with EEG before the neurofeedback training (pre-measurement), immediately after the training (post-measurement), and after 6 months (follow-up measurement)

Secondary outcome measures

1. Executive functions:
1.1. Memory updating assessed using the N-back task
1.2. Response inhibition assessed using the Stop-signal task
1.3. Task switching assessed using the letter-number switching task
1.4. Conflict monitoring assessed using the Stroop task
For these tasks the reaction times and accuracy percentage will be calculated. The tasks will be administered before the neurofeedback training (pre-measurement), immediately after the neurofeedback training (post-measurement), and 6 months after the training (follow-up measurement)

Overall study start date
01/02/2018

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Subjective executive dysfunctions based on the BRIEF-A questionnaire
2. Aged 18 years or older

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
Presence of severe psychiatric or neurologic disorder(s)

Date of first enrolment
22/03/2018

Date of final enrolment
15/07/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
University of Groningen
Department of Psychology
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Sponsor information

Organisation
University of Groningen

Sponsor details
Faculty of Behavioural and Social Sciences
Clinical & Developmental Neuropsychology — Department Clinical & Developmental Neuropsych.
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Sponsor type
University/education

Website
https://www.rug.nl/

ROR
https://ror.org/012p63287

Funder(s)

Funder type
University/education

Funder Name
Rijksuniversiteit Groningen

Alternative Name(s)
University of Groningen, RUG

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
28/02/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a non-publically available repository of the University of Groningen, following the local rules for data storage and sharing. Consent from participants are obtained and all data will be anonymized. More exact details are currently unknown and will be made available at a later date.

IPD sharing plan summary
Stored in repository