

Neurofeedback for improved mental functioning

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

Contact information

Type(s)
Scientific

Contact name
Dr Stefanie Enriquez-Geppert

Contact details
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Additional identifiers

Protocol serial number
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

Study type(s)

Other

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Grote Kruisstraat 2/1

Groningen

Netherlands

9712 TS

Sponsor information**Organisation**

University of Groningen

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

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be stored in a non-publicly 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes