# Neurofeedback for improved mental functioning

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

## 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 (premeasurement), 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**

## Kev 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-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

## **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