# ReSET: Strategic Executive Training, cognitive rehabilitation for dysexecutive functioning in Parkinson's disease

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36783

**Source**
ToetsingOnline

**Brief title**
ReSET:Strategic Executive Training

### Condition

- Other condition

**Synonym**
deficits in planning, execution and regulation of goal directed behaviour

**Health condition**

neurodegeneratieve aandoeningen (Parkinson), stoornissen in executieve functies

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** NWO

## Intervention

**Keyword:** cognitive rehabilitation, executive dysfunctioning, Parkinson's disease (PD)

## Outcome measures

### Primary outcome

Improvement of executive functioning on participation level, defined as a

significant difference between pre- and postmeasurement on the Role Resumption

List (Spikman et al., 2010).

### Secondary outcome

Tests executive functions (included social cognition)

• Behavioral Assessment of Dysexecutive Syndrome (BADS, Wilson et al., 1996),

• Letterfluency ( ), Category fluency (GIT, Luteijn & van der Ploeg, 1998)

• Executive Secretarial Task (follow-up EST, Lamberts, Evans & Spikman, 2009),

• Digit span backwards (WAIS, Stinissen et al., 1970)

• Virtual supermarket (Klinger, 2009).

• Sociale cognition: Facial Expression of Emotional Stimuli Test (FEEST, Young

et al., 2002)

• Strange stories (Happé, 1994)

• Iowa Gambling Task (IGT, Bechara et al., 1994),

• Sustained attention to Response Task (SART, Robertson et al., 1997).

Tests general cognitive functioning

• 15 Words Test (Deelman et al., 1980)

• Premorbid estimation of IQ: Dutch version of the NART (NLV, Schmand et al., 1992).

• Test of Everyday Attention (TEA, Robertson et al., 1994)

• Stroop Color Word Test (Stroop, 1935)

• Trail Making Test (TMT, Reitan, 1958).

Questionnaires/checklists executive functioning

• Rating Of Perceived Participation (Sandström & Lundin-Olsson, 2007)

• Goal attainment scaling: list of treatment goals (Spikman, 2009)

• Dysexecutive Questionnaire (DEX, Wilson et al., 1996)

• Executive Observation List (EO, Pollens, McBratnie & Burton, 1988, vertaling J.M. Spikman, 1996)

• Parkinson*s Disease Questionnaire-39 (PDQ-39, Jenkinson et al., 1997).

• Brock Adaptive Functioning Questionnaire (BAFQ, Dywan & Segalowitz, 1996)

Questionnaire quality of life

• Quality of Life after Brain Injury (QOLIBRI, Von Steinbuchel et al., 2005)

# Study description

**Background summary**

Next to motor impairments Parkinson's disease patients develop cognitive impairments too, due to dysfunctioning of the striatal-prefrontal circuits. 25% Of the recently diagnosed patients already have some kind of cognitive impairments, mainly problems with executive functioning. These executive

impairments negatively influence patients functioning, because it consequently will impair the ability to learn new things and the independence of the patient. It are just these functions that are necessary to cope with impairments like these and to compensate for them. For Parkinson's patients with impairments in executive functions, it can be very difficult to produce strategies by there own. Therefore functioning in daily life becomes severe restricted with respect to activities and level of participation. Besides, cognitive impairments lead to an increase of dependence. For example, patients are not capable anymore of doing the administration because they loose the overall picture or making repeatedly errors. Or they are not capable of selling their car, because they don't know what should be the first step. These restrictions on participation level often lead to a lot of negative feelings and thoughts within patients and to an increase of the care partners have to take care for. Patients who live on their own, can loose their independence because of executive impairments. Especially the aquirement and use of strategies that helps to avoid this kind of problems in daily life requires executive functions. During this study the effect of a cognitive rehabilitation treatment for executive dysfunctioning is determined, which is previously found to be highly effective in a group of patients with acquired brain injury that suffer from executive impairments also. During the treatment patients will learn to use individual strategies that gives them the opportunity to compensate for the executive problems in daily life. In this study for the first time the treatment is used with Parkinson patients. The treatment contains 3 modules: education and awareness (1), goal setting, planning and (2) initiative, implementation and regulation (3).

**Study objective**

The primary objective of this study is to adjust the treatment protocol to specific cognitive problems related to Parkinson's disease and subsequently to evaluate the effectiveness of the protocol. Secundary objective is to get an overview of disease specific variables that possibly influence the treatment effect. Further, we want to study which subgroup of Parkinson's disease patients benefits the most of our treatment (i.e. onset, course, age etc.)

**Study design**

A randomized controlled trial (RCT) in a repeated measures design (pre- and postmeasurement) on the effect of a cognitive rehabilitation treatment for deficits in executive functioning in Parkinson's disease.

**Intervention**

Strategic Executive Training

Module 1 (min. 3 sessions max. 4): in this module the emphasis lies on

providing information about and increasing the patient*s insight into their deficits. First, information will be given about cognitive functions and executive functions in general. Subsequently information will be obtained about the content of the treatment and the importance of the treatment. We are also aiming to increase patient*s motivation (for the treatment). Based on the NPO and specific examples given by patient or proxy, an overview will be made of the quality as well as deficits concerning patient*s daily functioning. Eventually, these results will be used to set the goals, which need to be reached during the period of treatment.
Module 2 (min. 4 sessions max. 5): during this sessions procedures for planning will be introduced and patient are learning to set realistic and achievable goals. These goals can be short-term goals, medium-term or long-term goals. During this module attention is also paid to formulate and structure an action plan that is needed to reach a specific goal and to estimating how much time is needed to complete the action plan.
Module 3 (min. 5 sessions max. 7): the final module focuses on initiative, implementation and regulation, meaning that patients will learn to work on the action plan himself/herself, resulting in reaching a goal. It is important to formulate a concrete action plan and to connect the first step of the action plan to a fixed moment in time. Furthermore, patients will learn to be aware of unexpectedly problems that can arise during execution of the action plan and will learn to regulate their own actions and to change them, if necessary.

Computertraining Cogniplus - control treatment

The control treatment contains a computer training, named Cogniplus, which aims at improving basal cognitive processes. Possibly, training of basal cognitive processes leads to an improvement of executive functioning in the long run (Friedman et al., 2010). Cogniplus emphasizes on training attention processes, which can be divided into: alertness, vigilance, visual-spatial attention, selective attention, focused attention and divided attention. The training contains several tasks that are designed in a realistic way. Therefore, the training situations are recognizable and resembles situations out of daily life which motivates patients. The program adapts to the patients level and is therefore challenging and gives the opportunity to rehearse tasks in order to train specific attention deficits. In principle, patients are able to entirely accomplish the training by himself/herself, but there always will be a supervisor who can give instruction whenever needed. The control treatment has as much sessions as the Strategic Executive Training, 1 session will take 1 hour and there will be 2 sessions per week.

## Study burden and risks

There will be no adverse consequences of the treatment nor risks for the patients involved. The burden is small, that is, the treatment will be rather intensive and requires patients to be motivated. However, this will be carefully supervised and coached by the psychologist who gives the treatment

and who has ample experience with these patient group. The physical burden of coming to the UMCG twice a week can be aggravating for Parkinson patients. Therefore, if necessary one session per week can take place at the patients home to make it less aggravating to participate in the study.

# Contacts

**Public**
Dr. J.M. Spikman

UMCG, Hanzeplein 1
9700 RB Groningen
NL
**Scientific**
Dr. J.M. Spikman

UMCG, Hanzeplein 1
9700 RB Groningen
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

1)Deficient score on the Behavioral Assessment of the Dysexecutive Syndrome (BADS, Wilson et al. 1996), based on the same criteria as in former study by Spikman et al. (2010).
2)Deficient score on the Dysexecutive Questionnaire for patients and proxies (DEX, Wilson et al., 1996), meaning some degree of experienced problems with executive functioning in daily life. The criteria is a total score of 20 or more, based on former study by Spikman et al. (2010).

## Exclusion criteria

-Advanced stage of dementia (SCales for Outcomes in PArkinson*s disease-cognition, Marinus et al., 2003):totalscore 14 or lower or disturbing cognitive problems based on the different SCOPA-cog scores of subscales (memory, perception, language).
-Severe depression (Hospitial Anxiety and Depression Scale, Zigmond & Snaith, 1983): defined
as a score of 15 or higher on the different scales.
-Symptoms like hallucinations and delusions (Neuropsychiatric Inventory, Cummings, 1994):defined as frequency of 3/4 and severity as 2/3 per scale.
-Impulsive-compulsive disorders (ICD's) (Questionnaire for Impulsive-compulsive disorder in Parkinson's disease, Weintraub et al., 2009).
-Cerebral comorbidity
-Stage 5 of Hoehn & Yahr, stage 4 needs to be judged by the neuropsychologist who gives the
treatment

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 03-08-2011 |
| Enrollment: | 80 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 14-04-2011 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 15-12-2011 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| CCMO | NL34792.042.11 |