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A strategic executive treatment for executive dysfunction in patients with Parkinson’s disease

Submission date
02/11/2016

Recruitment status
No longer recruiting

Registration date
04/11/2016

Overall study status
Completed

Last Edited
01/12/2022

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Parkinson's disease is a condition in which parts of the brain become progressively damaged over many years. The main symptoms are related to movement, but there are also a variety of mental symptoms. Executive functions are mental skills that help the brain organize and act on information. Problems with executive functions (impairments) are frequently found in Parkinson's disease patients and can already be present in the early stages of the disease. This can lead to reduced independence in daily life and to a lower quality of life. It is already common in other patient groups to offer cognitive rehabilitation programs for these impairments. Cognitive rehabilitation is a behavioural treatment which focuses on improving everyday functioning through management of cognitive (thinking) difficulties. However, this is not yet part of standard treatment for Parkinson's disease patients. Therefore, the aim of this study is to find out whether strategic executive training (ReSET, teaching general planning strategies) is better at improving daily life executive functioning and quality of life than computerized function training (Cogniplus, repeated practice of attention tasks).

Who can participate?
Patients aged 18-80 with Parkinson's disease

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in one group receive the ReSET treatment. ReSET contains three modules: information and awareness; goal setting and planning; and initiative and regulation, in which participants are taught several strategies that can be applied to a broad range of daily life situations. Participants in the other group receive the Cogniplus treatment. Cogniplus aims at training several aspects of attention (e.g. selective, sustained attention) by repeated practice of several tasks. Both treatments are individually administered and consist of 14 one-hour sessions. Before treatment, at maximum 2 weeks after treatment and at 3-5 months follow-up participants’ executive functions are assessed with tests and questionnaires.

What are the possible benefits and risks of participating?
Possible benefits are improvements of executive impairments in daily life functioning and maybe even an improvement of quality of life. There are no risks involved when participating in this study.

Where is the study run from?
1. University Medical Centre Groningen (Netherlands) (lead centre)
2. Maastricht University Medical Centre (Netherlands)
3. Nij Smellinghe, a medical centre in Drachten (Netherlands)

When is the study starting and how long is it expected to run for?
September 2010 to November 2014

Who is funding the study?
The Dutch Organization for Scientific Research (NWO), the National Initiative Brain and Cognition (NIHC) (Netherlands)

Who is the main contact?
1. T. Vlagsma (public)
2. Prof. Dr J.M. Spikman (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL34792.042.11

Study information

Scientific Title
The efficacy of ReSET, a Strategic Executive Treatment for executive dysfunction in patients with Parkinson’s disease

Acronym
ReSET

Study objectives
ReSET, a Strategic Executive Treatment, is more effective at improving Parkinson’s disease (PD) patients' executive dysfunctions in daily life functioning and their related participation in societal domains and quality of life than a computerized training for aspects of attention (Cogniplus).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical ethics committee of the University Medical Center Groningen, 14/04/2011, ref: NL34792.042.11

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Patients are blindly allocated to the following two groups by drawing lots. In order to balance the allocation of patients to both treatment conditions, lots are drawn per 4 patients (i.e. 2 experimental and 2 control lots). A co-worker who is not actively involved in the study is responsible for drawing lots.
1. Experimental treatment - ReSET: strategic executive training for dysfunctions in executive functions. ReSET contains three modules: information and awareness; goal setting and planning; and initiative and regulation. Patients are taught several strategies that can be applied to a broad range of daily life situations.
2. Control treatment - Cogniplus: computerized cognitive training for aspects of attention. Cogniplus aims at training several aspects of attention (e.g. selective, sustained attention) by repeated practice of several tasks.
Both treatment programs are individually administered to patients and consist of 14 one-hour sessions. Before, at maximum 2 weeks post-treatment and at 3-5 months follow-up an extensive neuropsychological assessment focused on executive functions (including tests and questionnaires) is administered.

Intervention Type
Behavioural

Primary outcome measure
Patients' level of participation in different societal domains (i.e. work, social relations, leisure activities and mobility), measured using the Role Resumption list (RRL) at baseline, two weeks post-treatment and at 3-5 months follow-up

Secondary outcome measures
Measured at baseline, 2 weeks post-treatment and at 3-5 months follow-up:
1. Attainment of three individual executive goals set by patients during the third session of ReSET or Cogniplus, measured using the Treatment Goal Attainment scale
2. Problems in executive functioning in daily life, measured using the Dysexecutive Questionnaire, completed by participants and someone who had a good insight into the patients' functioning in daily life
3. Quality of life, measured using the Parkinson's Disease Questionnaire (PDQ-39)
4. Behavioural functioning, measured using executive subscales of the Brock Adaptive Functioning Questionnaire (BAFQ) (participant and significant other ratings)
5. Caregiver burden, measured using the Zarit Burden Interview
6. Executive functions (planning skills, inhibition, abstract reasoning, problem solving and estimation of time), measured using the Behavioural Assessment of the Dysexecutive Syndrome (BADS)
7. Selective attention and attentional switching or cognitive flexibility, measured using the Test of Everyday Attention (TEA)

Overall study start date
01/09/2010

Completion date
01/11/2014

Eligibility

Key inclusion criteria
1. Patients diagnosed with idiopathic Parkinson's disease according to the UK Parkinson's Disease Brain Bank Criteria, with disease severity ≤ Hoehn & Yahr (H&Y) stage 3
2. Age range 18-80 years
3. Patients had to be motivated for treatment
4. Patients had to report problems with EF in daily life that were experienced as burdensome (based on semi-structured interview and/or a total score of ≥18 on the Dysexecutive Questionnaire (DEX) and/or showed impairments on objective neuropsychological tests of executive function (EF):
4.1. A standard score of ≤2 on the subtests Zoo Map Test or Six Elements Test of the Behavioural Assessment of the Dysexecutive Syndrome (BADS) and/or
4.2. A standard age total score on the BADS categorized as "low average" or lower and/or
4.3. A discrepancy of 15 points between standard age score and premorbid IQ as measured with the short version of the Dutch Groninger Intelligence Test
5. Patients had to speak and understand the Dutch language

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
90

Total final enrolment
40

Key exclusion criteria
1. Severe neurological comorbidity, such as traumatic brain injury or stroke
2. Severe psychiatric symptoms, such as hallucinations, delusions or depression
3. Severe cognitive comorbidity: e.g. amnestic syndrome, global aphasia, neglect, severe memory problems, PD dementia (i.e. SCales for Outcomes in PArkinson's disease-COGnition scale score ≤17)
4. Hoehn & Yahr stage 4 and 5

Date of first enrolment
03/08/2011

Date of final enrolment
16/07/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen (UMCG)
Groningen
Netherlands
9700RB

Study participating centre
Maastricht University Medical Center (MUMC)
Maastricht
Netherlands
6229 HX

Study participating centre
Medical center Nij Smellinghe
Drachten
Netherlands
9202 NN

Sponsor information

Organisation
Dutch Organization for Scientific Research (NWO), the National Initiative Brain and Cognition (NIHC)

Sponsor details
National Initiative Brain and Cognition
Laan van Nieuw Oost-Indië 300
The Hague
Netherlands
2593 CE

Sponsor type
Research organisation

Website
http://www.nwo.nl/en/about-nwo/organisation/nwo-divisions/nihc

ROR
https://ror.org/04jsz6e67

Funder(s)

Funder type
Research organisation

Funder Name
Dutch Organization for Scientific Research (NWO), the National Initiative Brain and Cognition (NIHC)

Results and Publications

Publication and dissemination plan
The results of the study are expected to be published in February/March 2017.

Intention to publish date
01/03/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2020	29/01/2019	Yes	No
Other publications		17/04/2017	01/12/2022	Yes	No