GoMaP: Goal Management Training in Parkinson's disease.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26834

Source
NTR

Brief title
GoMaP

Health condition

Parkinson's disease

Sponsors and support

Primary sponsor: Donders Institute for Brain, Cognition and Behaviour, Centre for Cognition, Radboud University Nijmegen, Nijmegen, The Netherlands
Source(s) of monetary or material Support: Hersenstichting Nederland

Intervention

Outcome measures

Primary outcome

The primary outcome is a standardized scale measuring performance of IADL tasks before (baseline), after treatment (post treatment) and at follow-up. IADL tasks will be divided into multiple steps using the GMT method. These step will be assessed using three categories: 1) competent; 2) questionable/ineffective 3) deficit, using task-specific assessment forms.

Secondary outcome

1. GAS: subjective experience of cognitive deficits of participants, measured by the Goal Attainment Scale (GAS). Goal attainment scaling is a mathematical technique for quantifying the achievement of goals
set, used in rehabilitation.
2. Cognitive functioning (executive functioning and the other important domains) measured with a neuropsychological assessment at baseline and post-treatment.
3. Questionnaires will be administered at baseline, post-treatment and at follow-up:
- PDQ-39 (Parkinson's Disease Questionnaire): a measure for health related quality of life.
- CFQ (Cognitive Failures Questionnaire): a measure for subjective cognitive complaints.
- Brief-A, self (Behavior Rating Inventory of Executive Function–Adult): a measure for executive functioning.
- AMI (Apathy-Motivation Index): a brief self-report index of apathy and motivation.
- USER-P (Utrecht Scale for Evaluation of Rehabilitation-Participation): a measure for participation.
- Inventarisatielijst strategieën: a measure for strategy use.

Study description

Background summary

Rationale: Individuals with Parkinson's disease often experience difficulties with planning skills and memory. Cognitive impairments are common in patients with Parkinson’s disease (PD). In particular, executive dysfunction is present already in the early stages. Even subtle executive impairments may lead to real-life everyday disorganization and difficulties in instrumental activities of daily living (IADL tasks).
Goal management training (GMT) is a successful treatment for these deficits and helps to structure activities in daily life. GMT entails learning and applying an algorithm, in which a daily task is subdivided into multiple steps to handle executive difficulties of planning and problem-solving. The acquisition of the algorithm and the steps, however, relies on self-control, which is impaired in many patients with executive problems. Consequently, errors that occur during learning the algorithm are not corrected and may interfere with the correct algorithm and the correct steps. Preventing the occurrence of errors during learning, also known as errorless learning, may enhance treatment effects. Both Goal management training and errorless learning are two methods well studied and demonstrated to be effective. These two methods have been combined in ABI patients with positive results. However, these two methods have never been combined in people with Parkinson’s disease. Our hypothesis is that combining errorless learning and Goal management training will contribute to a more effective (re)learning of IADL tasks and thus to a better treatment of executive deficits in cognitive rehabilitation for people with Parkinson’s disease.

Objective: The primary objective is to examine the efficacy of a combined errorless learning and GMT intervention for treatment of executive problems of patients with Parkinson’s

disease, focusing on instrumental activities of daily living (IADL).
Secondary objectives are the subjective experience of cognitive deficits of participating patients as measured by GAS (Goal Attainment Scaling) and health-related quality of life as measured by the PDQ-39 (Parkinson's Disease Questionnaire).
Study design: The study will be an assessor blind randomized controlled trial in which the efficacy of GMT with an errorless learning approach will be compared with conventional GMT (treatment as usual, no errorless learning but trial and error learning).

Study population: The study population consists of patients with PD. Participants eligible for the study must have to experience everyday cognitive failures or report problems with everyday executive function specifically which they experience as burdensome. Furthermore, PD has to be diagnosed according to the UK Brain Bank criteria. Age has to be between 35 and 80 years old and participants have to live independently at home. Executive disorders will be assessed by extensive neuropsychological examination. The PD group will be recruited through our affiliation with rehabilitation centre Klimmendaal Revalidatiespecialisten (Arnhem) and MUMC+ (Maastricht), which both have a department specialized in the treatment of people with PD. Over the course of 3 years 52 participants will be recruited.

Intervention: The investigational treatment is based on the conventional GMT, part of the cognitive rehabilitation intervention that now is mostly used for ABI patients with executive problems. The investigational treatment will have an additional errorless learning approach meaning that both learning and applying the algorithm of GMT will be learned errorless. This means that the multiple steps of the GMT as well as the actual performance of the IADL-tasks will be learned without the occurrence of errors under guidance of a therapist. In conventional GMT (comparator) errors do occur. Patients will learn to use an algorithm and the performance of the tasks using trial and error. The therapist is in this group not responsible for preventing errors during learning and applying GMT.
Both types of GMT will consist of 8 sessions (max. 60 minutes) and will be given twice a week.

Main study parameters/endpoints: The main study parameter is a standardized scale measuring performance of IADL tasks before (baseline), after treatment (post treatment) and at follow-up. IADL tasks will be divided into multiple steps using the GMT method. These step will be assessed using three categories: 1) competent; 2) questionable/ineffective 3) deficit, using task-specific assessment forms.
Secondary study parameters are the Goal Attainment Scale (GAS). Moreover, questionnaires and neuropsychological tests will be administered. Measurements will be administered at baseline, post treatment and at follow-up.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All tests and methods that are used are non-invasive and not stressful for the patient. All tests and tasks will be widely-used validated and reliable paper-pencil or computerized tasks. The participant can work in his/her work pace, and if desired additional breaks will be taken. Treatment is also non-invasive and scarcely stressful: a therapist will always be present and assess the patient’s burden and eventually take appropriate measures such as inserting a resting break.

Study objective

Our hypothesis is that combining errorless learning and Goal management training will contribute to a more effective (re)learning of IADL tasks and thus to a better treatment of executive deficits in cognitive rehabilitation for people with Parkinson’s disease.

Study design

T0 (baseline part 1), T1 (baseline part 2), T2 (post-treatment), T3 (4-month follow-up)

Intervention

Goal Management Training and Errorless learning. The investigational treatment is based on the conventional GMT, part of the cognitive rehabilitation intervention that now is mostly used for ABI patients with executive problems. In consultation with the therapist, each participant will select two individual IADL-tasks to be learned during the training. The investigational treatment will include GMT in combination with an errorless learning approach, meaning that both learning and applying the algorithm of GMT will be learned errorless. This means that the multiple steps of the GMT as well as the actual performance of the IADL- tasks will be learned without the occurrence of errors under guidance of a therapist. In conventional GMT (comparator) errors do occur. Patients will learn to use an algorithm and the performance of the tasks using trial and error learning. The therapist is not responsible for preventing errors during learning and applying GMT in this group. Both types of GMT will consist of 8 sessions (max. 60 minutes) and will be given twice a week.

Contacts

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Eligibility criteria

Inclusion criteria

- Parkinson’s disease diagnosed according to the UK Brain Bank criteria.
- Age between 35-80 years
- Experience of cognitive complaint / Cognitive deficits (neuropsychological assessment or questionnaire)
- Living independently at home
- Hoehn & Yahr (H&Y) symptoms of Parkinson's disease ≤ 3 (i.e. patients have to be mobile in order to visit the
participating center)

Exclusion criteria

- Inability to speak/understand the Dutch language
- Severe language or perceptual impairment
- Low premorbid level of intellectual functioning (IQ < 80)
- Severe psychiatric problems (history)
- Substance abuse
- Severe cognitive comorbidity (i.e. dementia; MMSE or MoCA ≤ 24)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	52
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion
Date: 28-06-2021
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55102
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9573
CCMO	NL74970.091.21
OMON	NL-OMON55102

Study results

Summary results
N/A