PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Cognitive stimulation in patients with Parkinson's Disease with cognitive impairment living in long-term care

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Parkinson's disease is mainly characterized by motor symptoms. In addition, dementia is frequent, e.g. with symptoms such as memory, executive or attention dysfunctions. These cognitive impairments lead to impariments of activities of daily living. Patients with dementia living in long-term care are typically in a more advanced stage of dementia compared to patients who live at home.
For the treatment of cognitive impairment, non-pharmacological interventions, including cognitive therapies, are increasingly considered in addition to pharmacotherapy. A positive influence of cognitive therapy methods has already been demonstrated in patients with other types of dementia. This study will be realized in a specific long-term care department - unique in the Netherlands and worldwide - specialized in dealing with Parkinson patients with cognitive impairment in Kerkrade (Netherlands). We will examine the effect of cognitive stimulation - a specific form of cognitive therapy - in a group of 20 patients with Parkinson´s disease and cognitive impairment/ dementia living in this specific long-term care facility. The therapy is offered in small groups including 3 to 5 persons over a period of 8 weeks twice a week for 60 minutes. We will investigate short-term effects of this intervention at the end of the therapy as well as long-term effects after 6 weeks. Neuropsychological tests and questionnaires will be used. The study is carried out in cooperation with the Universities of Maastricht, Nijmegen, and Groningen.

Brief Summary in Scientific Language

The efficacy of cognitive training in PD patients without cognitive impairment, mild cognitive impairment (MCI) and (non-PD) dementia patients has already been demonstrated in several studies. However,there is no study that investigates the effectiveness of cognition-based interventions, especially cognitive stimulation, in patients with Parkinson's disease with cognitive impairment living in long-term care.
For the first time, we investigate the effect of a cognitive stimulation program in Parkinson patients with cognitive impairment.
The study has a randomized, controlled study with a cross-over design. In

cooperation with the Universities of Maastricht, Nijmegen and Groningen, the University Hospital of Cologne will recruit Parkinson patients with cognitive impairment at the Medical Center in Kerkrade (NL). Patients are divided randomly into intervention group A and intervention group B. The patients receive a 60 minute cognitive stimulation twice a week in the first or second 8 week Intervention period. Before and after the intervention, as well as 6 weeks after the end of the intervention, a neuropsychological test battery is performed with the patients. The nursing staff is also consulted to give information about psychiatric symptoms, quality of life, depression and basic daily functions.
We main aim is to investigate for the first time the short-term and long-term effects of a cognitive stimulation program in patients with Parkinson's disease and cognitive impairment.
The primary outcome is cognitive performance. Secondary outcomes include quality of life, depression, behavioral and psychiatric symptoms, and activities of daily living (ADL). Paper and pencil tests as well as questionnaires will be used to measure the aforementioned outcomes.
We hypothesize that cognitive stimulation has a short-term and long-term effect on cognitive performance as well as on quality of life, depressive symptoms, behavioral and psychiatric symptoms and ADLs.

Organizational Data

- DRKS-ID: **DRKS00011776**
- Date of Registration in DRKS: **2017/09/05**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **01/2017 , Ethikkommission Lückerheide (Meander Wonen met Zorg), Kerkrade, NL**

Secondary IDs

Health condition or Problem studied

- ICD10: **G20 - Parkinson disease**

Interventions/Observational Groups

- Arm 1: **The study has a cross-over design. The patients are randomized into two groups (A and B) including max.10 patients. Group A receives the cognitive stimulation during the first phase (0 - 8 weeks) of the study, Group B after a waiting time of 8 weeks. The program takes place in small groups (3 - 5 individuals). The cognitive Stimulation program NEUROvitalis sinnreich, translated into Dutch, is used. The intervention extends over a period of eight weeks, twice a week (16 exercise units) for 60 minutes. In addition to**

**cognitively stimulating exercises, the program also includes fine motor skills training as well as multisensory stimulation.
Neuropsychological testing takes place before and after the intervention period as well as a six-week follow-up.**

- Arm 2: **Group B receives no intervention ("usual care") during the first phase (week 0 - 8) and the Dutch version of the cognitive stimulation NEUROvitalis sinnreich, during the second phase (week 9 - 16). Neuropsychological testing takes place before and after the first phase (week 0 - 8, cross over design), after the intervention (week 16), and at six-week follow-up.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Cognition: times of measurement: Baseline, Posttest, Follow up (after 6 weeks) CERAD (+ Trail Making A+B, letter fluency), Clock Drawing Test

Secondary Outcome

Patient-Related Endpoints:

Quality of life: measuring instruments: EQ-5D-5L (self-administered), EQ-5D-5L (proxy-administered) Quality of Life in Dementia (Qualidem, proxy-administered)

Depression; Measuring instruments: geriatric depression scale (GDS, self-administered), Cornell depression scale (CDS, proxy-administered);

Behavioral and psychiatric symptoms; Measuring instrument: neuropsychiatric inventory (NPI, proxy-administered);

Activities of daily life (ADLs); Measuring instrument: Barthel Index (proxy-administered);

All endpoints are collected at the time of pre- and post-testing (short-term effect) and after 6 weeks (long-term effect)

Countries of recruitment

- NL **Netherlands**

Locations of Recruitment

- other **Pflegeheim, Kerkrade**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/17**
- Target Sample Size: **12**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **50 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

Clinical diagnosis conducted by neurologist or psychiatrist, mild to moderate dementia; Age: 50 years or older, mother tongue Dutch or very good skills in Dutch language; Good or sufficiently corrected vision and hearing

Exclusion criteria

MMSE overall score below 10 points; Major depression (operationalized by the CDS >12) (Rasmus, 2009); Alcohol and drug abuse in the last three years; Acute suicidal tendencies, acute psychotic symptoms, other serious / life-threatening comorbidities that oppose study participation

Addresses

- **Primary Sponsor**

  Universitätsklinik Köln, Medizinische Psychologie |Neuropsychologie und Gender Studies
  Ms. Prof. Dr. Elke Kalbe
  Kerpenerstraße 62

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/06/30**

Trial Publications, Results and other documents

- Paper **Folkerts, Dorn et al. (2018). Cognitive Stimulation for Individuals with Parkinson's Disease Dementia Living in Long-Term Care: Preliminary Data from a Randomized Crossover Pilot Study.**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*