

To improve early recognition and tailored treatment of behavioral changes in patients with Alzheimer's disease and Mild Cognitive Impairment visiting the memory clinic

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Neuropsychiatric symptoms (e.g. apathy, depression, anxiety, agitation) are very common in patients with Mild Cognitive Impairment (MCI) and Alzheimer's disease (AD) and are negatively related to various clinical outcomes. However, despite growing...

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| Ethische beoordeling | Positief advies |
| Status | Werving nog niet gestart |
| Type aandoening | - |
| Onderzoekstype | Interventie onderzoek |

Samenvatting

ID

NL-OMON28628

Bron

NTR

Verkorte titel

BEAT-IT

Aandoening

Alzheimer's disease, Mild Cognitive Impairment, dementia

De ziekte van Alzheimer, Milde Cognitieve Stoornissen, dementie

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: Alzheimer Nederland and Memorabel ZonMw Grant 733050823 (Deltaplan Dementie)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life of patient and their caregiver

Toelichting onderzoek

Achtergrond van het onderzoek

Neuropsychiatric symptoms (NPS) are very common in patients with Mild Cognitive Impairment (MCI) and Alzheimer's disease (AD) and are negatively related to various clinical outcomes. However, despite growing evidence on the efficacy of (non)pharmacological interventions to reduce these symptoms, NPS remain underrecognized and undertreated in memory clinics. The DICE method aims to structure and standardize the assessment and management of NPS to improve early recognition and personalized treatment. The objective of the BEhavioural symptoms in Alzheimer's disease Towards early identification and Treatment (BEAT-IT) study is to examine the effectiveness and feasibility of the DICE approach in the memory clinic. We aim to enroll a total of 150 community-dwelling patients with MCI or AD and their caregivers in two cohorts. First, we will build a historical control group that will receive care as usual. Consequently, a second cohort of participants will undergo the DICE method. This approach consists of the following steps: Describe the context in which NPS occur, Investigate possible causes, Create and implement a treatment plan, and Evaluate whether interventions were implemented and effective. Primary outcomes include quality of life of patients and their caregivers. Secondary outcomes include NPS, caregiver burden, confidence managing NPS, psychotropic medication use, and the feasibility and cost-effectiveness of the intervention. The BEAT-IT study is a project that aims to improve the early recognition and treatment of NPS in AD in memory clinics.

Doel van het onderzoek

Neuropsychiatric symptoms (e.g. apathy, depression, anxiety, agitation) are very common in patients with Mild Cognitive Impairment (MCI) and Alzheimer's disease (AD) and are negatively related to various clinical outcomes. However, despite growing evidence on the efficacy of (non)pharmacological interventions to reduce these symptoms, NPS remain underrecognized and undertreated in memory clinics.

The objective of BEAT-IT study is to examine the effectiveness and feasibility of the DICE method to structure and standardize the assessment and management of neuropsychiatric symptoms in the memory clinic. By doing so, we aim to improve the quality of life of both caregivers and patients with early stage AD.

Onderzoeksopzet

- Baseline
- T1 after 3 months
- T2 after 6 months

Onderzoeksproduct en/of interventie

In the first part of the study, a historical control group will be recruited that will receive care as usual.

After one year, we will enroll a second cohort of participants that will receive a structured and standardized assessment and treatment of NPS by the use of the DICE method (Describe, Investigate, Create, Evaluate). Neuropsychiatric symptoms will be established by a psychiatrist. Then, a multidisciplinary treatment advice will be formulated and adjusted to the needs of the patient and caregiver. Treatments will be carried out according to the current guidelines. Treatment progression will be monitored and evaluated.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical diagnosis of Alzheimer's disease or Mild Cognitive Impairment. Based on patient history, neuropsychological assessment, and neuro-imaging
- Presence of neuropsychiatric symptoms (score >1 on NPI-Q)
- Mini-Mental State Examination score > 15
- Patients need to live at their home and be outpatient
- Until 2 years after diagnosis
- Reliable informant needs to be available

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Legally incapable and unable to give written consent to participate
- Severe (premorbid) psychiatric disorders such as schizophrenia or bipolar disorder, or current abuse of alcohol or drugs
- Evidence of current delirium or previous delirium in the past six months
- Patients meet criteria for dementia with Lewy bodies, behavioral variant of Frontotemporal Dementia, or vascular dementia
- Currently participating in a clinical trial

Onderzoeksopzet

Opzet

Type: Interventie onderzoek
Onderzoeksmodel: Factorieel

| | |
|-------------|-------------------------|
| Toewijzing: | Niet-gerandomiseerd |
| Blinding: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

Deelname

| | |
|-------------------------|--------------------------|
| Nederland | |
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2018 |
| Aantal proefpersonen: | 150 |
| Type: | Verwachte startdatum |

Ethische beoordeling

| | |
|-----------------|------------------|
| Positief advies | |
| Datum: | 06-09-2018 |
| Soort: | Eerste indiening |

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

| Register | ID |
|----------------|-----------------------------|
| NTR-new | NL7252 |
| NTR-old | NTR7459 |
| Ander register | : Memorabel ZonMw 733050823 |

Resultaten