Trauma and Dementia

Published: 02-03-2021
Last updated: 19-04-2025

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52695

Source
ToetsingOnline

Brief title
TRADE-study

Condition

- Other condition
- Dementia and amnestic conditions

Synonym
Post Traumatic Stress Disorder; PTSD in dementia

Health condition

Psychiatric disorders and behavioral problems

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Mondriaan - Cicero-

zorggroep;Meandergroep;Sevagram;Envida;Zuyderland en andere derde geldstromen zijn aangevraagd. EMDR-europe heeft een gedeelte gesponsord. Crowdfunding via SWOL

Intervention

Keyword: Trauma Dementia PTSD EMDR

Outcome measures

Primary outcome

study A:

PTSS: TRADE-interview.

BPSD:The Neuropsychiatric Inventory (NPI-NH), Cornell Depression Scale(CDSS).

Functioning: frailty (Groningen Frailty Indicator (GFI) and physical: sqeezing

force, walking speed)

Physiological stress measures: bloodpressure, hearth rate (variability),

Electrodermal skin conduction (EDA)(measured with Empatica E4 wristband).

Quality of Life: Utility-Weighted Dementia Quality of Life (DEMQOL-U-PROXY) en

EuroQol 5D (EQ5D).

Disease burden: Ervaren Druk Door Informele Zorg (EDIZ)

study B:

PTSS: TRADE-interview.

BPSD:The Neuropsychiatric Inventory (NPI-NH), Cornell Depression Scale (CDSS).

Functioning: frailty (Groningen Frailty Indicator (GFI) and physical: sqeezing

force, walking speed)

Physiological stress measures: bloodpressure, hearth rate (variability),

Electrodermal skin conduction (EDA)(measured with Empatica E4 wristband).

Quality of Life: Utility-Weighted Dementia Quality of Life (DEMQOL-U-PROXY) en EuroQol 5D (EQ5D).

Disease burden: Ervaren Druk Door Informele Zorg (EDIZ), Resource Use in Dementia (RUD), medical care use in financial costs (indications, diagnostics, consultations, procedures, medication

Demographic variables: ethnicity, age, gender, (neuro)psychiatric history (including comorbid disorders), somatic disorders, marital status, children, education and employment history, social network, weight, length, use of alcohol, smoking.

Secondary outcome

Study A & B:

Cognition:Mini Mental State Examination (MMSE), the Frontal Assessment Battery (FAB).

Personality: (Gerontological Personality Scale (GPS), Heteroanamnestische persoonlijkheidsvragenlijst (tegenwoordige tijd (HAP(-t)).

Epigenetics: Methylation of FKBP5, SERT and genome-broad DNA (saliva)

`Study B:

Amendement: Persoonlijkheidsfunctioneren : LPFS-BF 2.0 The Level of Personality Functioning Scale - Brief Form 2.0 Informant version Dutch, PID5BF+ M The

Personality Inventory for DSM-5 and ICD-11-Brief Form Modified - informant

version

Study description

Background summary

Traumatic life events can result in severe psychiatric symptoms of which Post Traumatic
Stress Disorder (PTSD) is the most prevalent. PTSD is associated with chronic stress and
cognitive dysfunctions and has been described as an independent risk factor for cognitive decline and dementia (Qureshi, Kimbrell et al. 2010, Yaffe, Vittinghoff et al. 2010, Wang, Wei et al. 2016, Flatt, Gilsanz et al. 2018).
In other studies such an association has not been found (Sundstrom, Ronnlund et al. 2014).Qualitative good studies on PTSD in patients with dementia are missing due to lack of a valid diagnostic tool for PTSD in this subgroup.

PTSD may be difficult to recognize in patients with dementia due to its complicated presentation.As anamnesis is often compromised in patients diagnosing PTSD requires expertise. Despite, there is no golden standard available for trauma screening and measurements of PTSD symptoms in this patient group. Concisely, recognition of PTSD in patients with dementia is a conceded issue.
Neuropsychiatric symptoms, such as sleeping disorders, psychotic symptoms, apathy and impulsivity are described as behavior problems in dementia (BPSD: behavioral and Psychological Symptoms of Dementia). There is clinical evidence that traumatic life events and PTSD are risk factors for BPSD.Recognition of PTSD in patients with dementia is essential to tailor personalized treatment, i.e. behavior counseling and psychological treatment.

In this study we develop a standardized method (a semi-structured interview: TRADE-interview) to screen for PTSD in patients with dementia.
Next we will investigate the effects of trauma focused therapy : EMDR

Study objective

The overall aim of the current study is to improve quality of life in patients with cognitive disorders. First, by improving diagnosis of PTSD symptoms in these patients. Second, we will estimate comorbidity rate of PTSD in clinical populations of patients with dementia. The association with BPSD, autonomic stress measures, frailty, quality of life and perceived disease burden of caregivers will be investigated. Thereafter, effects of standard care (EMDR

treatment) will be studied and compared with a wait list control group (WLC).

In this study, we have the following hypotheses:
1) The TRADE-interview is reliable, valid and feasible for PTSD in patients with dementia.
2) PTSD is associated with increased BPSD and physiologic measures of the sympathetic autonomic nervous system, alterations in epigenetic profiles, decreased quality of life and increased frailty in patients, increased perceived disease burden on caregivers with dementia. Personality and cognition will be taken as co variables.
3) Eye Movement Desensitisation and Reprocessing (EMDR) treatment of PTSD results in improvement of PTSD the measures mentioned under 2) and in the amendement : personality functioning.

Study design

The current study compromises 2 major parts:
The first part (study A) concerns a literature review and a Delphi-design to develop the TRADE-interview (Nov 2019- July 2020). Second, the feasibility and interrater reliability will be investigated in an observational study design. Third, we will investigate criterion validity and correlating factors in an observational study. Convenience sampling will be used.
The second part (study B) is an observational study according to regular psychological care. EMDR treatment will be allocated at random and compared with a WLC control group.

Intervention

THE TRADE interview is a questionnaire which may potentially give psychological distress

Study burden and risks

Nature of burden of participation for the participants (patients and caregivers) consists of periodic interviews and questionnaires of PTSD, BPSD, personality functioning and quality of life. There will be some addition cognitive tests and some physical measurements. The short interviews and questionnaires do not pose any burden or risk for the participating subjects.

Talking about traumatic life events may be seen as a burden. Though, not talking about traumatic life events is a shortcoming in old age care. There will be a psychologist available to provide professional support if necessary. In study B, patients receive clinical treatment conform (inter)national practice guidelines for psychiatric hospitals and nursing homes. As clinical practise shows benefits from EMDR treatment in this patient group - it is not expected that the treatment will harm patients. Even staying in the WLC group

will not harm, but will only delay the possible positive effects of treatment (unfortunately, we suggest that most patients with cognitive disorders do not receive trauma treatment at all nowadays). Saliva samples will be collected for epigenetic parameters.

Thus the research concerns some additional non-invasive measurements related to care as usual (diagnostics and treatment) in patients with dementia and comorbid PTSD

Amendement: some extra time to fill in the questionnaires 5 minutes

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Study A:
To investigate, feasibility, reliability and validity (sensitivity and specificity) of the TRADE-interview, we include all patients with dementia (major neurocognitive disorder according to DSM-5 : Alzheimer*s disease, vascular dementia, frontotemporal dementia, lewy-body dementia, other specified dementia) receiving care from Mondriaan or Cicero-zorggroep, Meandergroep Envida or Sevagram, Zuyderland. Patients and legal representative have to give informed consent.

Study B:
In order to be eligible to participate in this study, a subject must meet all of the following criteria:
-Clinical diagnoses according to DSM-5 with: major neurocognitive disorder, dementia (Alzheimer*s disease, vascular dementia, frontotemporal dementia, lewy-body dementia, other specified dementia).
-Patients with a positive life report of traumatic life events and symptoms of PTSD and eligible for psychiatric treatment according to routine clinical standards (according to clinical psychiatric evaluation by a psychiatrist or psychologist).
-Intention to be treated and participate with treatment (including legal representative).
-Written informed consent (including legal representative and informant).

Exclusion criteria

Study A:
- Subjects who do not have a family member or concerned caregiver who can deliver informant information are excluded from the study.
- Subjects who are severely demented and impaired in their verbal communication: Based on the model of Verdult & van der Kooij on experience-based care, subjects in phase 3 and 4 will be excluded (Finnema 2015).
- Subject who are expected to give resistance, based on their daily care experience.
-Major medical or psychiatric conditions that may interfere with the study procedures, e.g. deafness, severe psychotic conditions.
-Any other condition which in the opinion of the (co-) investigator might interfere with the evaluation of the study objectives: unpredictable aggressive outbursts which may threaten the investigator*s safety, serious physical condition that makes it estimated that participation will be too burdened.
- Language barrier.

Study B:
A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Subjects who do not have a family member or concerned caregiver who can deliver informant information are excluded from the study.
- Subjects who are severely demented and impaired in their verbal communication: Based on the model of Verdult & van der Kooij on experience-based care, subjects in phase 3 and 4 will be excluded (Finnema 2015).
- Subject who are expected to give resistance, based on their daily care experience.
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- Language barrier.
- Active drug abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-05-2022
Enrollment:	148
Type:	Actual

Ethics review

Approved WMO Date:	02-03-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-09-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL70479.068.20