

# Focussen bij mensen met de gedragsvariant van frontotemporale dementie

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Other
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27059

### Source

NTR

### Brief title

Focussen

### Health condition

Disinhibited behavior in the behavioral variant of frontotemporal dementia

## Sponsors and support

**Primary sponsor:** Radboud University Medical Center (RadboudUMC), Nijmegen

**Source(s) of monetary or material Support:** ZonMw, Alzheimer Nederland

## Intervention

## Outcome measures

### Primary outcome

- Specific disinhibited behavior, scored on a list developed for the specific disinhibited behavior of a resident by an observer
- Well-being, scored on an adjusted version of the EQ-5D thermometer

- Intervention moments by health care professionals, established in advance to the multiple case study during a visitation meeting, behavioral visit or multidisciplinary consultation and scored by an observer
- Current use of psychotropic drugs (in advance to and at the end of the multiple case study), identified by a (retrospective) view of the electronic prescription systems

## **Secondary outcome**

Descriptive measures:

- Relevant medical history (prior to and during admission) with specific attention for the disinhibited behavior. This will be identified using patient records. Eventually, health care professionals and/or family members will be consulted.
- Dementia severity with the Global Deterioration Scale (GDS)
- Cognitive functions with the Mini Mental State Examination (MMSE), Severe Impairment Battery Short Version (SIB-S) and Frontal Assessment Battery (FAB)
- Neuropsychiatric symptoms with the Neuropsychiatric Inventory Nursing Home Version (NPI-NH)
- Disinhibition and related behaviors with the Frontal Behavioral Inventory (FBI) and Middelheim Frontality Score (MFS)

## **Study description**

### **Background summary**

The aim of this study is to tailor and pilot an existing intervention for the management of disinhibited behavior in people with the behavioral variant of frontotemporal dementia. This behavior has a negative impact on the well-being of the affected person and is experienced as an important challenge by those involved in their care as well. In daily practice the intervention seems to have a positive impact on these outcomes. However, the underlying mechanisms are still unknown. In part I of this study the theoretical underpinnings of the intervention are explored by using observations, a systematic search of the literature and a panel discussion with frontotemporal dementia-experts. In part II of the study these findings are used to improve the intervention and to develop a manual and training program for health care professionals. Subsequently, the intervention will be implemented in 2 young-onset dementia special care units (YOD SCU's) and a multiple case study will be carried out to evaluate the intervention. Also, a process evaluation will be carried out and an implementation guideline will be developed.

### **Study objective**

The prevalence of disinhibited behavior is high in institutionalized people with the behavioral variant of frontotemporal dementia. Disinhibited behavior is associated with reduced well-being of residents and is experienced as an important challenge by those involved in the care for these residents. The intervention Focussen will be adapted, a manual and training

program will be developed and the intervention will be applied. We assume that there is a positive effect of the intervention on: 1) specific disinhibited behaviors (established in advance to the multiple case study during a visitation meeting, behavioral visit or multidisciplinary consultation), 2) the well-being of residents with the behavioral variant of frontotemporal dementia, 3) the moments of intervention by health care professionals and 4) psychotropic drug use and the use of pro re nata medication in particular.

## **Study design**

T0:

- Relevant medical history, dementia severity, cognitive functions, neuropsychiatric symptoms, disinhibition and use of psychotropic drugs

T1-T5:

- Specific disinhibited behavior, well-being, intervention moments by health care professionals

T6:

- Use of psychiatric drugs

## **Intervention**

In this intervention study, the adapted intervention 'Focusing in the behavioral variant of frontotemporal dementia' will be implemented at two YOD SCU's. As a part of the intervention health care professionals will be trained in the use of the intervention method. The main elements of the method are the principles 'volgen' and 'sturen' (monitoring and guiding) the behavior of the affected resident. 'Volgen' means you do not intervene but monitor the behavior of the resident in order to get an impression of his/her current condition. When you notice someone is able to focus his/her attention on you, you can start to guide the residents' behavior ('sturen'). Several ways of 'sturen' can be applied, among these are focusing on achieving a daily rhythm, focusing on specific sensory information, focusing on one activity, filtering unwanted sensory information and adhering to agreements. 'Volgen' and 'sturen' are used alternately and attuned to the current situation of the resident. In advance to the multiple case study health care professionals will establish the specific disinhibited behaviors of a resident and how to best intervene according to the principles of the method Focusing. These agreements will be registered in a personal treatment plan. Subsequently six residents will receive their personal approach ('the intervention') intermittently at several time points during a period of five days.

## **Contacts**

### **Public**

Radboudumc

MSc, PhD Christian Bakker

N/A

**Scientific**

Radboudumc

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N/A

## Eligibility criteria

### Inclusion criteria

Residents of young-onset dementia special care units (YOD SCU's); a) diagnosed with the behavioral variant of frontotemporal dementia, b) who show disinhibited behavior and c) have been admitted at the YOD SCU for at least 6 weeks

### Exclusion criteria

- Lack of informed consent
- Advanced dementia

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-04-2021
Enrollment:	6

Type: Unknown

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

Date: 18-03-2021

Application type: First submission

## 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
NTR-new	NL9348
Other	ZonMW : 733050861 ZonMw

## Study results