

# A behavioral intervention for agitation of people with dementia living at home.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Dementia and amnestic conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON41421

### Source

ToetsingOnline

### Brief title

Impact of a behavioral intervention for agitation of people with dementia

### Condition

- Dementia and amnestic conditions

### Synonym

agitation, challenging behavior, restlessness

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Trimbos Instituut

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

## Intervention

**Keyword:** agitation, case managers, people with dementia, structured intervention

## Outcome measures

### Primary outcome

Person with dementia: frequency of the agitated behaviors of the person with dementia, frequency of the targeted agitated behaviors, desired behavior.

Informal Caregiver: perceived disruptiveness of the agitated behaviors by the caregiver, perceived disruptiveness of the targeted agitated behavior.

### Secondary outcome

Person with dementia: quality of life of the person with dementia, frequency and severity of behavioral problems, use of psychotropic medication, movement to long term care facility.

Informal Caregiver: the current mental health, the level of perceived caregiver burden due to informal caregiving and self-efficacy.

The person with dementia and the informal caregiver together: the relationship quality

## Study description

### Background summary

Of major concern in dementia is the challenging behavior that may accompany the disease, like agitation, aggression, and apathy. The prevalence of challenging

behavior among non-institutionalized people with dementia is high, in the Netherlands as in other countries. For example, agitation and irritability is present in 30-40% of the people with dementia living in the community and hyperactivity in 60% of the cases (de Vugt, 2004). the consequences of agitation are often far-reaching: reduced quality of life of people with dementia themselves, increased burden of the informal caregivers, and acceleration of nursing home placement with a substantial impact on the already high costs of long term care (Pot, 1996; de Vugt, 2004; Gaugler et al., 2009).

All current dementia guidelines (APA, IPA, NICE, CBO) recommend psychosocial (or non-pharmacological) interventions as the preferred treatment for challenging behavior. However, most psychosocial interventions are provided to people with dementia who are already receiving daycare or who are placed in Long Term Care Facilities, facilities with multi-disciplinary teams including a psychologist. There are less psychosocial interventions for people with dementia living in the community, cared for by an informal caregiver. Furthermore, there is a lack of individualized interventions. Most psychosocial interventions are not tailored to the needs, abilities and background of the people with dementia. Ignorance of individual sources of variability by testing an \*one size fits all\* intervention may be a reason for the ambiguous results of studies on psychosocial interventions for people with dementia thus far (for an overview Livingstone et al., 2005).

For the development of psychosocial interventions for people with dementia and their caregivers, it is important to take the behavior of the people with dementia and their caregivers as a starting point (de Lange, 2004; Pot, 2009b). Challenging behavior of a specific person with dementia interacting with a specific caregiver needs to be analyzed and an individualized plan to prevent the challenging behavior need to be formulated. In addition, two approaches described in the literature seem to be promising: Applied Behavioral Analysis and the unmet needs model. The reason to chose for agitation rather than the broad variety of challenging behavior is to simplify the behavioral analysis because every behavior might have a broad spectrum of different causes.

## **Study objective**

The objective of this study is to develop an evidence-based individualized intervention and to compare the effectiveness of this individualized approach with care as usual to reduce or prevent the increase of agitation (frequency or caregiver perceived disruptiveness) among people with dementia living at home cared for by an informal caregiver.

Research questions that will be answered:

Effect evaluation

What is the impact of the intervention on the agitated behavior of the person with dementia and the perceived disruptiveness of the behavior by the caregiver

over time?

#### Process evaluation

1. Which factors contribute to the feasibility and acceptability of the intervention (a.o. characteristics dyad, competences case manager, advice from the psychologist)?
2. How can the intervention be adjusted to enhance the acceptability and feasibility?
3. What is the usual care when agitated behavior occurs in a person with dementia living at home with his caregiver?

### **Study design**

The study proposed is a process- and effect evaluation with an intervention period of 15 weeks and four measurements for all caregivers: a pre- (T0), amid (T1) post- (T2) and a follow-up measurement (T3) after 3 months. All the people with dementia will receive three measurements: a pre- (T0) post- (T2) and follow-up measurement (T3).

Before providing the intervention to all dyads, a small pilot study will be carried out with 2-4 case managers of two dementia chains that participate in the process- and effect evaluation. The objective of this small pilot study is to establish the feasibility of the study and intervention.

### **Intervention**

The focus of the intervention will be the agitation of people with dementia living in the community cared for by an informal caregiver. because the intervention is tailor-made the goals and treatment plan is different for every dyad. Not only reduction of the agitated behavior could be a goal of the intervention, but also the acceptance of the perceived disruptiveness of the agitation by the caregiver or the prevention of the increase of the agitation. The treatment plan will be tailored to the person's past identity, preferences and abilities. The intervention consists of a cycle of analyzing the behavior of the person with dementia and formulating and evaluating a treatment program.

The case manager plays an important role in detecting the presence of disruptive agitated behaviors. During a first home visit of the case manager the agitation will be described in more precise terms of observable behavior and the case manager and the dyad will decide which agitated behavior is the focus of the intervention. The case manager will make a behavioral analysis of the targeted agitated behavior. The analysis will give insight in starting points for the treatment plan. To make a good analysis it is necessary to know what happens in the situations the agitation occurs. Therefore the caregiver will be asked to observe the situation with the help of standardized forms and if necessary to give a precise description of the situation. It could be

difficult for the caregiver to put in words what happens, therefore the caregiver will be given the opportunity to video-tape the situation (obvious, only when the person with dementia agrees to it). The case manager and the caregiver will discuss and look at the observations (second home visit). Next, the case manager will analyze the agitated behavior. An Applied Behavioral Analysis (ABA) will be used to determine how the agitation of the person with dementia relates to the environment, with special attention to the interactions with the caregiver. To identify the stimulus or stimuli (S) and the characteristics of the person with dementia (O), special attention to the unmet needs of the person with dementia will be paid. Based on this analysis a individualized treatment plan will be formulated. When needed, the case manager can contact the psychologist of the dementia chain for advice.

During the third home visit the case manager will discuss the concept analysis and treatment plan with the informal caregiver and if possible also with the person with dementia. A final analysis and plan to reduce the agitation will be formulated together (consensus-based). The caregiver will bring the proposed intervention into practice, the case manager will be in contact by phone every two weeks to discuss the progress of the intervention.

During a fourth home visit the executed treatment plan will be evaluated. This first cycle will take 7 weeks. The cycle can be repeated two times, and will take a maximum of 8 weeks together. A cycle will start with evaluation of the behavior, next the case manager and dyad will decide where the cycle will start. A cycle can start at different points, such as continuing the treatment plan, formulating a new treatment plan, setting new goals or changing the GAS, making a new behavior analysis, making new video-recordings or description on paper, the focus of the intervention is different or new agitated behavior occurred.

When the agitation is reduced to a level that is acceptable for the dyads, the home visits will stop. With the GAS the attainment of the goals will be evaluated en registered.

## **Study burden and risks**

The duration of the intervention period is 15 weeks and four measurements for all caregivers: a pre- (T0), amid (T1) post- (T2) and a follow-up measurement (T3) after 3 months. All the people with dementia will receive three measurements: a pre- (T0) post- (T2) and follow-up measurement (T3). The duration of these measurements are approximately 30 minutes. The intervention consists of a maximum of 3 cycles. The first cycle will take 7 weeks, the repetition of these cycles will take a maximum of 8 weeks together. The duration of the home visits is approximately 30 to 60 minutes. When the caregiver brings the treatment plan into practice, the case manager will be in contact by phone every two weeks to discuss the progress of the intervention. For each person with dementia participating in this study, a tailor-made treatment will be formulated, with their strengths and limitations taken into account.

We expect that the intervention will result in a reduction or prevention of

agitation among the people with dementia and that this will have positive effects on the people with dementia as well as their caregivers. All this taken into consideration we expect that the occurrence of risk to the dyads is small and the expected burden will be in proportion to the potential value.

## Contacts

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

The inclusion criteria for regional dementia chains are:

1. The job of case managers in the chain includes treatment. We want to include case managers who not only, coordinate the care, but also provide treatment to the dyads. With treatment we mean the activities of the case manager that are methodical performed with the purpose to influence or improve the disease, symptoms and limitations of the person with dementia and the caregiver;

2. A psychologist is available for consultation;
3. The case manager is in contact with the general practitioners.;The inclusion criterium for case managers is:
  1. Working as a casemanager for at least 16 hours per week.;The inclusion criteria for the people with dementia are:
    1. Living in the community;
    2. Having a diagnosis of dementia according to the file of the general practitioner;
    3. Having at least a positive score on one item of the questionnaire measuring several types of agitation (CMAI; see measurements).

## Exclusion criteria

N/A

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 04-06-2014

Enrollment: 80

Type: Actual

## Ethics review

Approved WMO

Date: 24-04-2014

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO  
Date: 25-11-2015  
Application type: Amendment  
Review commission: METC Amsterdam UMC

## 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	NL43715.029.13