Effects of a behavioral intervention for agitation of people with dementia

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21356

Source
Nationaal Trial Register

Health condition

people with dementia
agitation
challenging behavior
BPSD
tailor-made intervention
structured intervention
case managers
familiy caregivers

mensen met dementie
agitatie
onbegrepen gedrag
probleemgedrag
gestructureerde interventie
geindividualiseerde interventie
casemanagers
mantelzorgers

Sponsors and support

Primary sponsor: Netherlands institute for mental health and addiction (Trimbos-institute)
Source(s) of monetary or material Support: Alzheimer nederland (Dutch Alzheimer

organization)

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

The consequences of agitation among people with dementia living in the community 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). In the Netherlands, case managers play an essential role in the care chain for people with dementia living in the community. Because the profession has just been started, there is a lack of evidence-based practice to provide treatment for agitation and other challenging behavior of people with dementia living at home with an informal caregiver.

The objective of this study is to study the effect of an evidence-based individualized intervention to treat or prevent agitation among people with dementia living in the community with the help of an informal caregiver. The individualized intervention consists of a cycles of analyzing the behavior of the person with dementia and formulating and evaluating a treatment program, based on the behavioral analyses, tailored to the person's past identity, preferences and abilities.
The study entails a Randomized Controlled Trial (RCT) on the effectiveness of this individualized and structured approach to reduce or prevent agitation among people with dementia in comparison with care as usual. This RCT has three measurements in the experimental and control group, and a follow-up measurement in the experimental group only. Cluster-randomization of 16 regional dementia chains will be used (8 control; 8 experimental). In total 40 case managers will be included (2-5 case-managers per dementia care chain) and 80 dyads per condition will be included, 160 dyads in total.

Study objective

In the Netherlands, case managers play an essential role in the care chain for people with dementia living in the community. Because the profession has just been started, there is a lack of evidence-based practice to provide treatment for agitation and other challenging behavior of people with dementia living at home with an informal caregiver.

The objective of this study is to develop an evidence-based individualized intervention to treat or prevent agitation among people with dementia living in the community with the help of an informal caregiver and to compare the effectiveness of this individualized approach with care as usual. We expect that the effect on agitation of people with dementia (frequency and/or disruptiveness for the caregiver) is larger in the intervention group than the control group.

Study design

The study proposed is a RCT with an intervention period of 15 weeks and three measurements: pre- (T0), amid- (T1; 7 weeks from baseline) and post-measurement (T2) in the experimental and control group, and a follow-up measurement (T3) after 3 months in the experimental group only.

Intervention

The dyads in the experimental condition will receive the structured and tailor-made intervention that consists of a cycle of analyzing the behavior of the person with dementia and formulating and evaluating a treatment program tailored to the person's past, identity, preferences and abilities. The intervention will be carried out by case managers, professionals specialized in dementia care, in cooperation with the person with dementia and family caregiver. The family caregiver wherever possible together with the person with dementia, will carry out the treatment program.

Contacts

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Eligibility criteria

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 two items of the questionnaire measuring several types of agitation (CMAI; see measurements);

4. Having a caregiver with at least a score of >=4 (very much or extremely) on at least two items of the CMAI disruptiveness scale;

5. Not using psychotropic drugs or being on a stable dose of psychotropic medication. With a stable dose we mean that the dose of psychotropic medication is not changed since 6 weeks before baseline.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2012
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-10-2014
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	NL4663
NTR-old	NTR4815
Other	METC : 2013/362

Study results