Effects of a behavioral intervention for agitation of people with dementia

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

Samenvatting

ID

NL-OMON21356

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: Netherlands institute for mental health and addiction (Trimbos-institute)
Overige ondersteuning: Alzheimer nederland (Dutch Alzheimer organization)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Research associate
Postbus 725 - 3500 AS Utrecht
B. Willemse
Da Costakade 45 - 3521 VS Utrecht

Utrecht

The Netherlands
030 29 59 210

Wetenschappelijk

Research associate
Postbus 725 - 3500 AS Utrecht
B. Willemse
Da Costakade 45 - 3521 VS Utrecht

Utrecht
The Netherlands
030 29 59 210

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

N/A

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2012
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-10-2014

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	NL4663
NTR-old	NTR4815
Ander register	METC : 2013/362

Resultaten