

Behavioral problems in nursing residents with dementia.

Gepubliceerd: 11-12-2009 Laatste bijgewerkt: 18-08-2022

Of major concern in dementia are accompanying behavioral problems. Clinically relevant behavioral problems (aggression, agitation, apathy) occur frequently and are mostly chronic. They result in considerable distress and workload for nursing staff...

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

Samenvatting

ID

NL-OMON27234

Bron

Nationaal Trial Register

Aandoening

behavioral problems, dementia
gedragsproblemen, probleemgedrag, dementie

Ondersteuning

Primaire sponsor: VU University Medical Center, EMGO Institute for Health and Care Research, Department of Nursing Home Medicine

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prevalence of behavioral problems (CMAI).

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

To quantify cost-effectiveness of a multidisciplinary, guideline based, care program 'managing behavior problems (BPs) in nursing home (NH) residents with dementia'.

Study design:

A longitudinal controlled study on 14 dementia special care units in the Netherlands that, in a stepped wedge design, all will implement the program.

Study population: all patients on participating units.

Intervention: evidence based standardization of the management of BP in NH residents with dementia, including standardized use of measurement instruments, a standardized method of analysis, and individually tailored psychosocial, psychological and pharmacological treatment according to protocol.

Primary outcomes:

Prevalence of behavioral problems (CMAI); quality of life (EQ-5D).

Sample size calculation/data analysis:

Sample size: 6 measurements on 14 dementia special care units (each with 20 residents on average) are needed (assumptions: BP prevalence 80%, effect 10 points decrease CMAI-score, almost no attrition, alpha 0.05, power 0.80, ICC 0.1).

Data analysis: primary effects will be calculated using multilevel linear and logistic regression analyses. Prescription rate of antipsychotics and the EQ5D will be used in the primary analysis. Secondary analyses will include: prescription rate of antipsychotics; workload (burnout) and job satisfaction of nursing staff; use of restraints.

Economic evaluation: From a healthcare perspective, two ICERs will be calculated for costs per: 1 one point decrease in CMAI-score; 2) one QALY increase.

Time schedule: 48 months (21 months data collection).

Doel van het onderzoek

Of major concern in dementia are accompanying behavioral problems. Clinically relevant behavioral problems (aggression, agitation, apathy) occur frequently and are mostly chronic. They result in considerable distress and workload for nursing staff, are associated with high costs and with a diminished quality of life.

This study investigates the cost effectiveness of an evidence and practice based care program for multidisciplinary teams to detect, analyze and treat behavior problems in nursing home residents with dementia and to evaluate treatment effects.

It is hypothesized that the care program will result in less behavioral problems, less distress for care personnel and less costs and also will improve quality of life.

Onderzoeksopzet

1. Behavioral problems: measured at 0, 4, 8, 12, 16 and 20 months: total score on CMAI;
2. Quality of life: score on EQ-5D by proxy version, measured at 0, 4, 8, 12, 16 and 20 months;
3. Prescription rate of antipsychotics: % of residents using an antipsychotic measured at 0, 4, 8, 12, 16 and 20 months;
4. Use of restraints: % of residents using a restraint measured at 0, 4, 8, 12, 16 and 20 months;
5. Workload nursing staff: score on Utrecht Burnout scale, measured at 0, 12 and 20 months;
6. Jobsatisfaction nursing staff: score on Leiden Quality of Work Questionnaire, measured at 0, 12 and 20 months.

Onderzoeksproduct en/of interventie

Intervention:

Evidence and practice based care program for management of behavioral problems in nursing home residents with dementia.

(the care program includes an evidence based standardisation of the phases in the management of BP: detection, analysis, treatment and evaluation. Cooperation between disciplines is prearranged.

A general training of nursing staff about all phases of management of behavioral problems is the starting point. The care program itself is directed at specific behavioral problems of individual nursing home residents with specific analysis and specific interventions, followed by a close monitoring of treatment effects.)

Control intervention:

Usual care for behavioral problems in nursing home residents with dementia.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Nursing home residents with dementia residing on dementia special care units.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Refusal to participate.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	280
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-12-2009
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	NL2024

Register

NTR-old

Ander register

ISRCTN

ID

NTR2141

ZonMW : 171002212

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A