Behavioral problems in nursing residents with dementia.

No registrations found.

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

Summary

ID

NL-OMON27234

Source
NTR

Health condition

behavioral problems, dementia
gedragsproblemen, probleemgedrag, dementie

Sponsors and support

Primary sponsor: VU University Medical Center, EMGO Institute for Health and Care Research, Department of Nursing Home Medicine
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Prevalence of behavioral problems (CMAI).

Secondary outcome

1. Quality of life (EuroQol: EQ5D, by proxy version);

2. Prescription rate of antipsychotics;

3. Use of restraints;

4. Workload nursing staff (Utrecht Burnout Scale);

5. Jobsatisfaction nursing staff (Leiden Quality of Work Questionnaire).

Study description

Background summary

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).

Study objective

Of major concern in dementia are accompanying behavioral problems. Clinically relevant behavioral problems (aggression, agitation, apathy) occur frequently and are mostly chronical. 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.

Study design

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 at 0, 4,8, 12, 16 and 20 months;

4. Use of restraints: % of residents using a restraint measured at 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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Refusal to participate.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: Active

Recruitment

NL

Recruitment status: Pending

Start date (anticipated):   01-02-2011

Enrollment: 280

Type: Anticipated

Ethics review

Positive opinion
Date: 11-12-2009

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	NL2024

Register	ID
NTR-old	NTR2141
Other	ZonMW : 171002212
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A