Original Study

Coming to Grips With Challenging Behavior: A Cluster Randomized Controlled Trial on the Effects of a Multidisciplinary Care Program for Challenging Behavior in Dementia

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ABSTRACT

Objectives: The Grip on Challenging Behavior care program was developed using the current guidelines and models on managing challenging behavior in dementia in nursing homes. It was hypothesized that the use of the care program would lead to a decrease in challenging behavior and in the prescription of psychoactive drugs without increase in use of restraints.

Design: A randomized controlled trial was undertaken using a stepped-wedge design to implement the care program and to evaluate the effects. An assessment of challenging behavior and psychoactive medication was undertaken every 4 months on all participating units followed by the introduction of the care program in a group of 3 to 4 units. A total of 6 time assessments took place over 20 months.

Setting: Seventeen dementia special care units of different nursing homes.

Participants: A total of 659 residents of dementia special care units. All residents with dementia on the unit were included. Units were assigned by random allocation software to 1 of 5 groups with different starting points for the implementation of the care program.

Intervention: A care program consisting of various assessment procedures and tools, which ensure a multidisciplinary approach and which structure the process of managing challenging behavior in dementia.

Measurements: Challenging behavior was measured using the Cohen-Mansfield Agitation Inventory (CMAI) and the Neuropsychiatric Inventory. Research assistants (blinded for intervention status of the unit) interviewed nurses on the units about challenging behavior. Data on psychoactive drugs and restraints were retrieved from resident charts.

Results: A total of 22,922 assessments took place involving 659 residents (1,126 control measurements, 1,166 intervention measurements). The group of residents who remained in the intervention condition compared with the group in the control condition differed significantly in the CMAI change scores between successive assessments [2.4 CMAI points, 95% confidence interval (CI) -4.3 to -0.6]. No significant effects were found for the control-to-intervention group compared with the group who remained in the control group (0.0 CMAI points, 95% CI -2.3 to 2.4). Significant effects were found on 5 of the 12 Neuropsychiatric

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Challenging behavior is very common in nursing homes; over 80% of nursing home residents with dementia show 1 or more forms of challenging behavior. The presence of challenging behavior in nursing homes diminishes quality of life of residents, is associated with the use of physical restraints, and results in higher costs.2–4

Although several effective psychosocial interventions have been developed,5–7 the prescription of psychoactive drugs currently dominates the treatment of challenging behavior.8,9 The effects of drugs on behavior, however, are limited.10 What is more, the adverse effects of this type of intervention can be very serious,11–14 which underlines the need for other, more effective, and less harmful methods of managing challenging behavior.

Even though prescribing psychoactive drugs or using restraints to control challenging behavior is a relatively straightforward treatment, many current models emphasize that the management of challenging behavior requires an analysis of the meaning of behavior. In line with the work of Kitwood15 on the concept of person-centered care, Cohen-Mansfield proposed the model of unmet needs to explain the challenging behavior of people with dementia.16 A thorough analysis of those needs (which may have various causes such as physical illness, cognitive impairments, psychological needs, or personality features) is needed to understand and diminish challenging behavior. Other models place more emphasis on the influence of (environmental) stimuli. In the model of progressive lowered stress threshold, for example, it is assumed that people with dementia have more difficulty with processing environmental stimuli than healthy people, which makes them experience more stress than healthy elderly. When there are too many environmental stimuli, the stress threshold is exceeded and symptoms of challenging behavior may appear. To prevent challenging behavior, the amount of stimuli should, therefore, be adjusted to the processing capabilities of the person with dementia.17 There has also been attention for explaining challenging behavior as a result of the way in which people with dementia cope with the complex changes in life they experience.18–21

Understanding challenging behavior as a symptom of underlying problems implies analysis, and treatment should be focused on the biological, psychological, or social factors that can help explain the challenging behavior, instead of the behavior itself.22 To achieve this, several professional disciplines (ie, physician, psychologist, nursing staff, recreational therapist) should work together in determining the type of treatment needed and the goals to be reached, based on the underlying causes of the behavior or on better techniques for care staff to cope with the behavior. Current international and Dutch guidelines follow this view and state that the management of challenging behavior in nursing homes should be undertaken as a multidisciplinary venture by using an individually tailored care plan that is based on thorough analyses of the behavior and that consists of 1 or more psychosocial interventions combined with limited and nonpermanent use of psychoactive drugs when indicated.23–28

The Grip on Challenging Behavior care program was developed using the current guidelines and models on challenging behavior in dementia.26–28 It structures the process of detection, analysis, treatment, and evaluation of the treatment of challenging behavior and pre-arranges multidisciplinary consultation. The care program provides tools for multidisciplinary care teams that help them in taking the right steps and asking the right questions to identify and, if possible, treat the underlying problem of the challenging behavior.29 The aim of this study was to determine the effects of the Grip on Challenging Behavior care program.

This article reports on the effects that using the care program has on challenging behavior and on the use of psychoactive drugs and restraints.

Methods

Ethics

The full trial protocol has been published elsewhere.29 The study protocol is in accordance with the declaration of Helsinki and with the Dutch legislation on medical research; it is in agreement with the Conduct Health Research of the Dutch federation of Biomedical Scientific Societies. The study protocol was approved by the Medical Ethics Review Committee of the VU University Medical Centre. The committee stated that, in accordance with Dutch legislation, the study can be performed without a review procedure by the committee because in the study, only observational data gathered by nursing staff as part of their daily work were used.

Setting

In The Netherlands, nursing home care is divided into units for people with predominantly physical disorders (somatic units) and units for people with dementia [dementia special care units (DSCUs)]. For this study, only DSCUs were included. In these units, a psychologist and an elderly care physician usually have a permanent position and work with care staff in a multidisciplinary team.

The care program was introduced in 17 DSCUs of 17 different nursing homes in The Netherlands. The main hypothesis was that the use of the care program would diminish challenging behavior and the use of antipsychotics without a concomitant increase in the use of other psychoactive drugs and restraints. The study was registered in The Netherlands National Trial register, under number NTR 2141.

Design

A stepped-wedge design was used, which is considered appropriate when an intervention will probably do more good than harm and when there are practical and logistic constraints to implementing the intervention simultaneously to all participants,30 which is applicable to the Grip on Challenging Behavior care program. Practical and logistic considerations (training and support of implementation of the units on different time points instead of all at once) also influenced the decision, but more importantly, the stepped-wedge design is far more efficient in terms of sample size than a traditional parallel analysis of covariance design.31

The participating care units were randomly divided into 5 groups by using random allocation software.32 Challenging behavior was assessed every 4 months for 20 months (February 2010-October 2012), resulting in 6 time assessments. The first group was trained in using the care program after the baseline assessment. The second group was trained after the next assessment point, and so on, resulting in all care units using the care program at the time of the last assessment.

Sample Size

The following assumptions were used in calculating the sample size. DSCUs house 20 residents on average, the prevalence of challenging behavior is 80%, and the mean Cohen-Mansfield Agitation

Inventory items and on the use of antipsychotics (odds ratio 0.54, 95% CI 0.37–0.80) and antidepressants (odds ratio 0.65, 95% CI 0.44–0.94). No effect on use of restraints was observed.

Conclusions: The Grip on Challenging behavior program was able to diminish some forms of challenging behavior and the use of psychoactive drugs.
Inventory (CMAI) score is 47.7.1 It was expected that 5% of the residents’ (legal) representatives would not agree with the resident being enrolled in the research project. In the event a resident died or moved away from the unit, the new resident who was admitted instead was enrolled in the study so no further attrition was expected.

The CMAI,23 as the primary outcome, was used to calculate the sample size. Based on an earlier study of Chenoweth in which training and support on person centered care was compared with dementia care mapping and usual care, it was expected that the Grip on Challenging Behavior care program would lead to a 10-point decrease on the CMAI.24 Based on a recent Dutch study in nursing home residents,35 a mean intraclass correlation coefficient of 0.1 was assumed for clustering of challenging behavior within a DSCU.

Based on these assumptions and a significance level (α) of 0.05 (2-sided) and a power (β) of 0.80, at least 14 dementia DSCUs with 6 time measurements were needed in a stepped-wedge design. Recruiting more than 14 DSCUs was preferred as the timeframe of the project (20 months) might have led to some DSCUs dropping out because of unforeseen circumstances, such as staffing problems or renovations.

**Intervention**

Grip on Challenging behavior is an evidence- and practice-based care program that consists of 4 steps: detection, analysis, treatment, and evaluation (Figure 1). The most recent scientific knowledge and evidence-based guidelines were incorporated into the care program. Expert meetings with nurses, psychologists, and elderly care physicians were held to ensure fit between science and practice. Representatives of the professional associations of nurses, psychologists, and elderly care physicians were consulted in the development process of the care program.

Care staff detected challenging behavior in daily care after which they commenced using the structured analysis form (as described below). To ensure that no signs of challenging behavior were missed during daily observations, every 6 months (prior to the standard multidisciplinary meeting about the resident, which is compulsory in The Netherlands) the units’ care staff filled in a screening tool to detect signs of challenging behavior that they did not already address spontaneously. If signs of challenging behavior were detected (either in daily care or by using the screening tool), a structured analysis form was used by the care staff. This form could also be used whenever signs of challenging behavior were detected in daily care. Following this, the unit psychologist or the unit elderly care physician was called in to undertake further analysis. Both the physician and the psychologist had their own analysis form, based on and structured by the explanatory models of challenging behavior and national guidelines. After the analysis was completed, the treatment goal, the outline of the treatment plan, and an evaluation date—all defined in a multidisciplinary meeting with the involved disciplines—were filled-in on the treatment form. At the predetermined evaluation date, a multidisciplinary evaluation took place by using a flowchart on the evaluation form.

A full day of training was organized on the unit before the Grip on Challenging Behavior care program was implemented on a DSCU. The training was split-up into 2 sessions: 1 kick-off meeting in which the care program was introduced and 1 follow-up meeting 2 weeks after the care program was implemented on the unit. In the training session, several models regarding challenging behavior were discussed and used to explain different forms of behavior, such as the unmet-needs model, the model of progressive lowered stress threshold, and the adaptation-coping model. Care teams were encouraged to think about their own residents and the behavior of their residents in light of these models. Part of the training was also focused on the negative consequences of using psychoactive medication and on the alternatives to medication, in particular psychosocial interventions.

**Participating DSCUs**

Care organizations were approached by the University Network of Organizations for Care for the Elderly of the VU University Medical Center and the University Nursing Home Network of the Radboud University Medical Center to allow 1 of their DSCUs to take part in the study. In addition, convenient sampling was used by 1 of the researchers (MS) to further invite nursing homes that were not affiliated with universities. The participating organizations were free to select which one of their DSCUs would take part in the research project; however, units for special target groups (Korsakov patients, Huntingdon patients, etc.) were excluded. All residents with a diagnosis of dementia were included in the study.

**Measurements**

**Primary outcome**

The primary outcome for this study was challenging behavior. There are different ways to define and measure challenging behavior, but for this research project, every form of behavior that may challenge the person with dementia or the people living with and/or caring for the
person with dementia is considered ‘challenging behavior’." This means that both externalized behavior such as aggression or calling out as well as more silent behavior such as apathetic or depressive behavior was considered as challenging behavior.

As agitation and agitation-related behaviors are the most prevalent and persistent form of challenging behavior, causing diminished quality of life and high caregiver burden, an instrument specifically focused on these behaviors was used (ie, CMAI). The CMAI is a questionnaire containing 29 items regarding agitation behavior. Each item may be scored from 1 (this behavior never occurs) to 7 (behavior occurring multiple times per hour).

To determine effects on other forms of challenging behavior than agitation, the Neuropsychiatric Inventory for Nursing Homes (NPI-NH) was used. The NPI-NH is a structured interview concerning 12 different domains of challenging behavior. For each domain the severity and the frequency of the behavior can be scored. The total score is the product of the severity and frequency score and ranges from 0–12. A total score of at least 4 is considered clinically relevant.

Both the CMAI and the NPI-NH have been translated into Dutch and have been found to be reliable and valid in Dutch settings.

The questionnaires were administered by interviewing the care staff member who was most involved in the daily care of the resident. The research assistants conducting the interviews were trained in administering the CMAI and NPI-NH questionnaires. The interview assistants were blinded for intervention or control status of the DSCUs. Neither the care staff members nor the psychologist or physician were informed about the CMAI and NPI-NH scores.

Secondary outcomes

Data on psychoactive drug use were retrieved from patient charts and classified according to the Anatomical Therapeutic Chemical (ATC) classification system. The drugs were categorized into antipsychotics (ATC code N05A), antidepressants (ATC code N06A), anxiolytics/hypnotics (ATC code N05B and N05C), anti-epileptics (ATC code N03), and anti-dementia drugs (ATC code N06D). The interview assistant also collected an up-to-date overview of physical restraints that were used on the unit. For analyses, the restraints were divided into 4 categories: bedrails, other night-time restraints (belts in bed, restraining blanket), and daytime restraints (table-top, fixation in chair or wheelchair, geriatric chair, separation). Because of the ongoing debate on the ethical, legal, and practical aspects of using surveillance technology in long-term dementia care, the use of surveillance technology (movement sensor, bed exit alarm, chips in clothing) was also analyzed as a separate ‘restraints’ category.

Other measurements

Characteristics of the residents (sex, age, and time of institutionalization) were retrieved from the patient’s charts. The units’ elderly care physicians classified the type of dementia according to the DSM-IV and they determined the severity of the dementia, using the Global Deterioration Scale (GDS). This is a 7-point scale that describes 7 stages from ‘no global impairment’ (1) to ‘very severe global impairment’ (7).

After the last assessment, a questionnaire about the degree of implementation of the care program was distributed amongst the unit leader, the psychologist, and the physician of the DSCUs. These key persons rated the percentage of cases with challenging behavior they were currently treating by means of the care program. The questionnaire contained 4 questions to determine what percentage of the cases concerned challenging behavior. They are (1) the analysis form for care staff used; (2) the analysis form for psychologist or physician used; (3) the treatment form used; and (4) the evaluation form used. Response categories were never, <25 %, 25%–50%, 50%–75%, and 75%–100%. A score for the degree of implementation of the care program was assigned to each DSCU based on the questionnaire. When a DSCU consistently scored above average compared with the other DSCUs, they were categorized as ‘good implementation (score = 3),’ and when a DSCU consistently scored below average they were categorized as ‘poor implementation (score = 1).’ DSCUs scoring variably were categorized as ‘moderate implementation (score = 2).’

The interviewed care staff were obviously aware whether their DSCU was in the intervention condition, which could potentially introduce information bias. It was assumed that determining whether the attitude toward the care program is associated with CMAI scoring and determining whether the effect of participation in the training about the care program is associated with CMAI scoring, could both provide an indication of the importance of this bias.

To determine whether the effect of participation in the training about the care program is associated with CMAI scoring, differences between the CMAI scoring of the same residents scored by a care staff member who participated in the training session and was actively involved in the care program vs care staff members who did not participate in the training were investigated.

Analyses

SPSS 20.0 (IBM Corp., Armonk, NY) was used for the descriptive analyses. For all other analyses, MLwin v. 2.26 (University of Bristol, Bristol, UK) was used. Mixed models were used to adjust for dependency of the repeated measures over time within the individual residents and for dependency of the residents within the DSCU when necessary (eg, when intercorrelations were significant; P < .05). No missing CMAI or NPI data were imputed.

Although the stepped-wedge design has advantages in practical and logistic ways which were crucial for the realization of the implementation of the care program on 17 DSCUs, there are several viewpoints on the correct way to analyze data from stepped-wedge designs. For the current study, differences in changes of CMAI scores were analyzed between 3 different groups: (1) the change in CMAI score when remaining in the control condition; (2) the change in CMAI score after changing from control to intervention; and (3) the change in CMAI score when remaining in the intervention condition. The difference in change of CMAI scores were analyzed using linear mixed models. Because change scores might be influenced by the initial baseline score of the CMAI (higher baseline scores increase the probability of finding larger changes scores), it was tested whether the baseline CMAI scores of the 5 separate intervention groups differed from the baseline score to the rest of the group, using independent t tests.

Because the NPI-NH measures quite heterogeneous areas of behavior, the 12 individual symptoms were dichotomized into clinically relevant symptoms (NPI-NH score per item ≥4). Analyses were undertaken on the total amount of clinically relevant symptoms (range 0–12) and on the presence of each individual symptom before and after the intervention. The NPI-NH analyses were undertaken using binomial logistic mixed models with a second order penalized quasi-likelihood (PQL) estimation procedure. Medication data and data on (physical) restraints were dichotomized for each category (antipsychotics, anxiolytics, antidepressants,
anti-epileptics, antidementia drugs; bedrails, other night-time physical restraints, daytime physical restraints, surveillance technology) and analyzed with binomial logistic mixed models using a second order PQL estimation procedure. Data were dichotomized because almost none of the residents were prescribed more than 1 restraint or drug of one category. Because of logistic reasons, for 1 DSCU data on antidepressants and anxiolytics was not available for the first measurement. Data were imputed from the second measurement for these 32 residents, as this unit was still in the control group during the second assessment.

Following the initial analyses, adjusted analyses were performed correcting for the confounding variables age, sex, GDS stage, type of dementia, and length of stay on DSCUs. Finally, if prevalence rates allowed it, interaction of the intervention with these variables and with degree of implementation and duration of the intervention were performed.

For the analyses on information bias, an independent t test was performed between the CMAI scores of care staff that trusted the care program to be beneficial and the CMAI scores of care staff who did not think the care program would make a difference.

The difference between CMAI scores obtained from the care staff member actively involved in the care program and from the care staff member who did not participate in the training on the care program was analyzed by paired t tests and by calculating Pearson correlation coefficients. For all analyses, a cut off score of P < .05 was used for statistical significance.

Results

Of the 22 organizations that originally showed interest in participation, 5 decided not to take part. Four of these organizations declined because of organizational changes in the near future, and 1 organization had planned to introduce their own new approach for the management of behavioral problems. One unit that did participate moved to another location after T3. Only data from T0–T3 were used in this study for this DSCU.

Of the 17 participating organizations, 9 were affiliated with 1 of the university networks. Nine of the participating units were located in the densely populated Randstad area of The Netherlands; the other 8 were situated in less densely populated areas (Noord-Brabant, Gelderland, and Friesland). All units were organized into several shared living rooms in which a set group of residents resided. The mean size of the unit was 29 residents (range 18–43) and a mean number of 11 (range 6–19) residents resided in 1 living room.

In total, 659 unique residents participated in this study, with a mean age of 84 (standard deviation 7.3), and 69.7 % was female (Table 1). One hundred seventy-eight residents participated in all assessments, other residents either enrolled at a later moment, or they had died, been discharged, or moved away to another unit before the end of the study (Figure 2). The mean scores for challenging behavior and the mean percentages of the use of psychoactive medication are shown in Table 2.

Five of the units consistently scored above average on the implementation questionnaire (good implementation; score = 3). Eight units scored moderately on the implementation (score = 2). Three units scored consistently below average (bad implementation; score = 1). The unit, which moved to another location after T3, had not as yet implemented the care program.

### Primary Outcome

None of the analyses showed significant differences in CMAI scores at baseline. Table 3 shows the results of the analyses of the changes in CMAI score between subsequent measurements. These analyses yielded significant effects in the group that maintained in the intervention condition compared to the group that maintained in the control condition [−2.4, 95% confidence interval (CI) −4.3 to −0.6]. The analyses were corrected for age, sex, severity of dementia, type of dementia, length of stay on the DSCU, and for prescription of psychoactive medication. The effect of the degree of implementation was examined by analyzing the interaction between the intervention and the degree of implementation. The effect of the program on the differences of CMAI scores was −3.2 (95% CI −6.4 to 0.0) between the intervention-intervention and the control-control group when implementation was good.

Figure 3 shows the results of the analyses of the number of clinically relevant neuropsychiatric symptoms in the measurements before and after the implementation of the care program. An odds ratio (OR) of 0.83 (95% CI 0.67–1.04) was found between the control and intervention measurements.

The analysis of the number of clinically relevant NPI-NH symptoms revealed an interaction effect for severity of dementia (GDS stage). No effects were found for less severe stages of dementia (GDS <6) (OR 0.99; 95% CI 0.77–1.26), whereas significant effects were found (OR 0.79; 95% CI 0.63–0.99) for the severe stages of dementia (GDS ≥6). An interaction effect was also found for degree of implementation. When the implementation of the care program was good, the OR for the number of clinically relevant NPI-NH symptoms was 0.59 (95% CI 0.42–0.83).

Figure 3 and Table 4 show the results of the analyses of the 12 separate symptoms of the NPI-NH. A significant decrease in clinically relevant symptoms of delusions, depression, apathy, disinhibition, and aberrant motor behavior was found. A trend toward a decrease of the prevalence of clinically relevant symptoms was found for all other symptoms except for irritability. Because of the prevalence rates of the symptoms, these analyses were undertaken with smaller group sizes. As a consequence, models for adjusted analyses did not converge; therefore, only the initial analyses can be reported.

### Secondary Outcomes

Figure 3 also shows the effects of the care program on the prescription of psychoactive drugs. Analyses on antiepileptic drugs and antidepressants drugs could not be performed because of low prevalence rates (5.1% and 9.6%, respectively). For the other categories except anxiolytics, the odds of being prescribed psychoactive drugs were significantly lower after the introduction of the care program (antipsychotics: OR 0.54; 95% CI 0.37–0.80; antidepressants: OR 0.65;
Fig. 2. Flowchart for the primary outcome analysis. A total of 2292 measurements of the total CMAI score were conducted on 659 unique residents. Data were missing when 1 or more CMAI items were missing or a resident was absent (eg, admission into hospital). Residents without dementia were excluded. Residents could drop out of the study because of dying, discharge to home, or transfer to another unit or nursing home. CMAI, Cohen-Mansfield Agitation Inventory.
Table 2
Overview of the Measurement Data

<table>
<thead>
<tr>
<th></th>
<th>T0</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
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<tbody>
<tr>
<td>Mean CMAI (SD) C</td>
<td>51 (18)</td>
<td>55 (19)</td>
<td>53 (20)</td>
<td>53 (20)</td>
<td>56 (22)</td>
<td></td>
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<tr>
<td>Mean CMAI (SD) I</td>
<td>47 (18)</td>
<td>52 (19)</td>
<td>51 (18)</td>
<td>50 (17)</td>
<td>51 (19)</td>
<td></td>
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<tr>
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<td>3.0 (2.5)</td>
<td>3.0 (2.5)</td>
<td>2.3 (2.3)</td>
<td>3.3 (2.8)</td>
<td></td>
</tr>
<tr>
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<td>2.4 (2.2)</td>
<td>2.4 (2.3)</td>
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<td>2.4 (2.4)</td>
<td></td>
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<tr>
<td>% Antipsychotics C</td>
<td>27.9</td>
<td>28.1</td>
<td>27.4</td>
<td>26.0</td>
<td>20.0</td>
<td></td>
</tr>
<tr>
<td>% Antipsychotics I</td>
<td>23.3</td>
<td>23.3</td>
<td>25.9</td>
<td>24.3</td>
<td>23.0</td>
<td>22.6</td>
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<tr>
<td>% Anxiolytics C</td>
<td>23.5</td>
<td>21.3</td>
<td>25.1</td>
<td>27.6</td>
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<td>% Anxiolytics I</td>
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<td>17.3</td>
<td>17.6</td>
<td>18.4</td>
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<td>% Antidepressants C</td>
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<td>33.0</td>
<td>30.1</td>
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<td>% Antidepressants I</td>
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<td>27.0</td>
<td>25.7</td>
<td>28.5</td>
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</table>

C, control; clin.rel., clinically relevant; CMAI, Cohen-Mansfield Agitation Inventory; I, intervention; NPI, Neuropsychiatric Inventory; SD, standard deviation.

95% CI (0.44–0.94). Models for adjusted analyses did not converge because of low prevalence rates.

No significant effects were found in any of the restraint categories (bedrails, night-time restraints, daytime restraints, and surveillance technology). Both before and after the introduction of the care program, 31.7% of the residents were being restrained or monitored by surveillance technology. Most of these residents had bedrails (±85%).

Analyses of Information Bias

All but 1 care staff member (N = 16) believed the introduction of the care program was necessary and judged the design of the care program to be good, and, therefore, no analyses were possible on these data. There were differences in the care staff rating as to whether they believed the care program would be able to decrease challenging behavior on the unit. Twelve care staff members scored a rate of 6 or higher on this question (range 1–10; 12 care staff members scoring the CMAI of 45 residents) and 4 care staff members rated 5 or lower (4 care staff members scoring the CMAI of 22 residents). No significant differences were found in the CMAI scoring between these 2 groups (mean difference = 3 points, t(65) = 0.55, P = .59).

The analyses of CMAI scoring by staff care members actively involved in the care program and by care staff members who did not participate in the training of the care program, (N = 240 residents; 56 actively involved care staff members, 33 care staff members not involved) showed high correlation between raters (r > 0.70) and on both time points a nonsignificant difference of 1 point between raters (t(69) = −0.446, P = .657, on T1 and t(169) = 1213, P = .227 on T2).

Discussion

The aim of this study was to determine the effect of using the Grip on Challenging Behavior care program on the prevalence of challenging behavior and on the use of psychoactive medication and restraints. The care program was implemented in 17 DSCUs and challenging behavior and the use of psychoactive medication and restraints was measured over a 20-month period. A significant decrease of challenging behavior, measured as differences in total CMAI score between subsequent measurements, was found in the group of DSCUs that were using the care program for over 8 months compared with the control group, but this difference was smaller than expected. No significant effects were found on differences in CMAI score on the first assessment, 4 months after the care program was introduced. The frequency of the use of the detection tool, which was administered semi-annually, might have resulted in this delayed effect. A decrease of the odds for several individual NPI items was found but for the total number of clinically relevant neuropsychiatric symptoms a decrease was only found for residents with severe dementia. For the secondary outcomes, a decrease in prescribed psychoactive drugs (antipsychotics and antidepressants) was found after the care program was introduced. Although it is regularly supposed that a decrease in use of psychoactive drugs might lead to an increase in use of restraints (and vice versa), no such effect was found in our study.

Even though not all effects were statistically significant, analyses of individual clinically relevant behavioral symptoms consistently show the benefit of the use of the care program. A significant decrease of delusions, depression, apathy, disinhibition, and aberrant motor behavior was found. The significant effects on depression and apathy are promising, as these ‘quiet’ symptoms are easily overlooked. Care staff have to be really vigilant for signs of depression and apathy, particularly in the more severe stages of dementia, as they are more difficult to detect than in the less severe stages. The introduction of a detection tool and the emphasis in the training sessions on detecting these symptoms probably raised more awareness about these symptoms, including in the more severe stages of dementia. The interaction effect that was found for severity of dementia on the effect on total number of clinically relevant NPI symptoms might be explained by the additional attentiveness to depression and apathy in severe stages of dementia.

In spite of growing awareness regarding negative side effects and limited effectiveness, the prescription rates of psychoactive drugs remain high. It is quite remarkable that up until now, medication has had such a significant place in the approach to challenging behavior. Although in general, the focus in care-giving for people with dementia has gradually evolved from a pure disease-oriented view to a more person-centered and tailored approach, it seems that the treatment of challenging behavior has not fully benefited from this progression. In Dutch nursing homes, every resident has his/her own individual care plan; there are protocols for pressure ulcers, feeding problems, the use of antibiotics, and so on. In contrast, there is no protocol that assures a structured and tailored approach when challenging behavior occurs. Corneé-Blokland et al concluded in earlier research that better implementation of guidelines would help bringing down inappropriate prescription rates and that as long as alternative approaches to challenging behavior are not adequately implemented, physicians will more often feel that they have run out of other options and prescribe psychoactive drugs. However, a structure of communication and collaboration between different disciplines is necessary to apply the guidelines.
CMAI are, however, relatively small. It is, of course, no surprise that several aspects of agitation. The effects that were found on the measure subtle changes, the CMAI was especially developed to measure the effects of the Care Program on Individual Clinically Relevant NPI-NH Symptoms.

**Table 4**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>OR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delusions</td>
<td>0.67</td>
<td>0.47–0.96</td>
<td>.03</td>
</tr>
<tr>
<td>Hallucinations</td>
<td>DNC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agitation</td>
<td>0.82</td>
<td>0.48–1.39</td>
<td>.47</td>
</tr>
<tr>
<td>Depression</td>
<td>0.42</td>
<td>0.29–0.60</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Anxiety</td>
<td>0.81</td>
<td>0.50–1.32</td>
<td>.41</td>
</tr>
<tr>
<td>Euphoria</td>
<td>DNC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apathy</td>
<td>0.76</td>
<td>0.60–0.97</td>
<td>.03</td>
</tr>
<tr>
<td>Disinhibition</td>
<td>0.63</td>
<td>0.45–0.89</td>
<td>.01</td>
</tr>
<tr>
<td>Irritability</td>
<td>1.03</td>
<td>0.59–1.83</td>
<td>.91</td>
</tr>
<tr>
<td>Aberrant motor behavior</td>
<td>0.65</td>
<td>0.48–0.86</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Night-time behavior disturbance</td>
<td>0.91</td>
<td>0.68–1.24</td>
<td>.57</td>
</tr>
<tr>
<td>Eating abnormalities</td>
<td>0.76</td>
<td>0.54–1.06</td>
<td>.10</td>
</tr>
</tbody>
</table>

CI, confidence interval; DNC, did not converge; NPI-NH, Neuropsychiatric Inventory for Nursing Homes; OR, odds ratio.

The evident effects on prescription of psychoactive drugs, especially on antipsychotics, are thus an important finding of this study. The Grip on Challenging behavior care program provides a tool that structures the multidisciplinary process of analyzing behavior and developing a treatment plan. It is likely that the structured analysis and the more explicit involvement of a psychologist have led to the use of more psychosocial treatments. Furthermore, the trainings sessions and the use of the care program probably made care staff and clinicians reflect on the negative side effects of psychoactive drugs use and gave physicians a feeling of support in trying other treatment options and not revert to medication. Hence, the care program had more effects on (prescribing) behavior of clinicians and care staff than on the actual challenging behavior of the residents, in particular agitation, on which only small effects were found. Even though the assessment of agitation with 1 NPI-NH item might have been too broad and unspecified to measure subtle changes, the CMAI was especially developed to measure several aspects of agitation. The effects that were found on the CMAI are, however, relatively small. It is, of course, no surprise that behavior of clinicians is more easily influenced than the behavior of residents with dementia. It might be that more fundamental changes in (the environment of) long-term dementia care are needed to diminish agitation in dementia residents. Moreover, into the effects of, for example, small scale living and home-like facilities would, therefore, be very welcome. Nevertheless, the effects on challenging behavior found in this study are also smaller than those of earlier multidisciplinary interventions. However, there are significant differences between these studies and ours that can explain these discrepancies. Most of these studies made a preselection of residents with severe forms of challenging behavior, either selected by facility managers or by a cut-off score for frequency of the behavior. The Grip on Challenging Behavior care program, on the other hand, does not use a cut-off score for inclusion. This means that all of the residents of the DSCU were included in (analysis of) the care program, including residents without challenging behavior, which mutates the effect size of the study. The only study known to us that did analyze all residents is the study of Fossey et al, in which the effects of a training and support package for managing agitated behavior in dementia were analyzed. Similar to the current study, Fossey et al found effects on the use of psychoactive drugs, but in their study, no effects on challenging behavior were found. In addition, in the Grip on Challenging Behavior study, the DSCUs stemmed from 17 different care organizations, which all had their own care system and culture, whereas other studies limited the inclusion of residents to 1 facility or to multiple facilities with the same care and management structure. Although including several different kinds of organizations does improve generalizability of the results, it also meant that the way in which the care program was implemented had to be adjusted to the daily routine of each separate DSCU, which increased the risk of implementation problems. Problems with implementation indeed did arise during the study and adjusted analyses for CMAI scores showed larger effects for the DSCUs in which implementation was good, which supports the idea that larger effects would have been possible with better implementation. Finally, 1 of the strengths of the Grip on Challenging Behavior study is the fact that once the care program is implemented, the team of the DSCU is able to use it without involvement of external parties. In contrast, earlier studies involved an external expert team, which...
carried out the intervention.58–60 The effects that were measured in the Grip on Challenging Behavior study, however, cannot be attributed to extra staffing or availability of extra expertise on a unit. Furthermore, the effects found in the Grip on Challenging Behavior study can be obtained without the investment of external parties once the training sessions are finished, which is of great relevance to nursing home practice.

There are some limitations to this study which should be considered when interpreting the results. First, the participating nursing homes were not randomly selected and one-half of them were part of university networks of long-term care. Although the variety in participating nursing homes represents the Dutch situation, the nursing homes that were part of university networks are obviously eager to participate in scientific research projects and are more used to research circumstances, which by definition, distinguishes them from nursing homes that do not collaborate with universities. The participating units from these nursing homes, however, did not differ in implementation rates from the other involved DSCUs. Second, the care program is aimed at improving the structure and multidisciplinarity of the process of managing challenging behavior. Therefore, outcomes of working according to the care program instead of measuring the effects of different interventions that were used were measured. The success rate of different intervention methods could nevertheless be important for the overall effects. Further research into the effectiveness of the separate parts of the care program and the use of different (psychosocial) interventions in the treatment phase would, therefore, be useful. Finally, the Grip on Challenging Behavior care program was developed for use in Dutch nursing home care practice, which has unique characteristics such as the availability of a specialized physician and a psychologist. To transfer the results to long-term care in other countries, adaptations are probably needed.

There are also some methodological considerations. First, the choice for using a stepped-wedge design was based on both practical and statistical benefits. By using this design, the research team was able to guide the implementation on all units. Also, fewer participants are needed to achieve enough power over a limited period of time, which makes it a particularly strong design that is very suitable for this specific type of complex intervention studies. Because this is a relatively new design, however, there is no consensus yet over how to analyze the data. Moreover, because of clustering on unit level and switching from control to intervention status at different time points, and because of possible collinearity between time of intervention and unit, the analysis for this specific study was very complicated and the best possible solution, in our view, was to analyze change scores. Nevertheless, the interpretation of the effects on change scores is not as straightforward as one might hope. Second, the interviewed nursing staff were obviously not blinded for the intervention, although the interview assistants were. When performing intervention research in a population of people in the more severe stages of dementia living in long-term care facilities, nursing staff are an essential source of information. In this type of intervention study they are, however, also usually the people who perform (parts of) the intervention, which could potentially introduce information bias. Therefore, a bias analysis was conducted in this study, which, as reported in the results section, did not show any signs of influence of information bias. In our view, this is the best way to deal with the area of tension between conducting complex intervention studies in nursing home care and performing methodologically sound research.

Conclusions

A small but significant decrease in prevalence of challenging behavior was found after implementation of the Grip on Challenging Behavior program. The program considerably diminished the use of psychoactive drugs, especially antipsychotics and antidepressants, whereas no difference in restraint use was found.

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Supplementary Data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jamda.2014.04.007.

References
