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The Impact of a Stepwise Method Involving Family Caregivers in Managing Challenging Behavior and Pain in Nursing Home Residents With Dementia

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ABSTRACT

Objectives: Challenging behavior and pain are common in nursing home residents with dementia. STA OP! *with family* is a multidisciplinary stepwise method that involves family in addressing challenging behavior and pain. This study examines the impact of STA OP! *with family* on residents, family, and nursing staff.

Methods: Pre-post-test study with multilevel analyses of impact of the method at 3 and 6 months following implementation. Challenging behavior was assessed with the Neuropsychiatric Inventory Questionnaire Nursing Home version as primary outcome. Secondary outcomes included observed pain, quality of life, medication use, and family caregivers' experience of involvement in the method and caregiver burden. In addition, we assessed emotional burden of challenging behavior on nursing staff.

Results: Ten wards in a Dutch nursing home implemented STA OP! *with family*. 77 residents and their family caregivers were included. Challenging behavior decreased 3 months (standardized coefficient −0.2; 95%CI −0.3 to −0.04) and 6 months after implementation (−0.2; 95%CI −0.3 to −0.03). Observed pain in residents (3 months: −0.01 95%CI −0.2 to 0.2; 6 months: −0.2; 95%CI −0.3 to −0.004) and emotional burden on nursing staff also decreased (3 months: −0.3; 95%CI −0.4 to −0.1; 6 months: −0.3; 95%CI −0.4 to −0.1). No change was seen in residents' quality of life and medication use, or in family caregivers' involvement, burden, and positive caregiving experiences.

Conclusions: STA OP! *with family* improved challenging behavior and some of the secondary resident and nursing staff outcomes. Further research is needed to optimize family involvement in the method.

Trial Registration: The study protocol was registered at OSF on May 18, 2022: https://osf.io/5ghnx

Miharu Nakanishi and Jenny T. van der Steen Shared last authorship.

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Key Points

- STA OP! *with family*, a multidisciplinary stepwise method that actively involves family caregivers in the assessment and management of challenging behavior and pain, was associated with a significant reduction in challenging behavior among nursing home residents with dementia.
- Residents with dementia showed a reduction in observed pain 6 months after implementation, while quality of life and psychotropic medication use remained unchanged.
- Nursing staff reported a decrease in the emotional burden associated with residents' challenging behavior, suggesting benefits beyond symptom reduction alone.
- Despite efforts to involve family caregivers, no measurable changes were found in family caregivers' involvement, burden, and positive caregiving experiences, highlighting the need for further research on optimizing family involvement in dementia care interventions.

1 | Introduction

Challenging behavior, such as aggression, agitation, wandering, and repetitive actions, is present in more than 80% of nursing home residents with dementia [1]. Cognitive and communicative impairment put residents with advanced dementia at risk for unmet physical, psychological, social, or spiritual [2, 3] needs. These unmet needs may contribute challenging behavior [3]. Healthcare professionals often face difficulties identifying and addressing these needs.

Challenging behavior is burdensome for professional and family caregivers [4] and negatively affects residents' quality of life (QoL) [5]. Nursing staff may also experience emotional distress when managing challenging behavior [6]. Although several effective non-pharmacological interventions are available [7], psychotropic medications are still frequently prescribed, despite their potential adverse effects on residents' QoL due to undesirable side effects [8].

Pain is a common unmet physical need among nursing home residents with dementia [9], and may be expressed through challenging behavior [10]. Pain assessment can be difficult, especially when communication abilities are impaired [11]. As a result, pain may remain untreated [12], leading to increased challenging behavior [13] and reduced in QoL [9].

Family caregivers play a crucial role in person-centered dementia care [14, 15]. They provide emotional support, knowledge of the resident's personal history, and a familiar presence.[14] [15] Their involvement can help tailor care to the individual needs of the resident [16, 17]. Although family caregivers frequently remain involved after nursing home admission, their role may become more distant than when their relative with dementia still lived at home [18]. Therefore, interventions should support meaningful family involvement and address family caregivers' needs and potential barriers to participation [14].

Several interventions have been shown to reduce challenging behavior and pain in nursing home residents with dementia [7, 19]. One such interventions is STA OP!, a stepwise multicomponent method has been implemented in Dutch nursing homes [20]. STA OP! has been associated with reductions in challenging behavior [19] and pain [21], as well as improvements in the QoL domains restless tense behavior and social isolation [22]. However, the STA OP! method does not explicitly involve family caregivers. The stepwise multicomponent aspect may align with actively involving family caregivers. To explore how family could be effectively involved in the method, the Cared-4 study was conducted. In the first part of the study, STA OP! [20] was adapted in cooperation with family and professionals to actively involve the family, which resulted in the modified version, STA OP! *with family* [23].

The aim of the second part of the Cared-4 study is to examine the impact of STA OP! *with family* on residents, family caregivers, and staff, with challenging behavior as primary outcome. More specifically, we hypothesize that STA OP! *with family* will reduce challenging behavior, pain, and psychotropic medication use, and increase analgesic medication use and residents' QoL. We also expected STA OP! *with family* to improve family caregiver experiences in caring for their relative, caregiver burden, and family caregiver involvement. Finally, we expected STA OP! *with family* to reduce the emotional burden of challenging behavior on staff.

2 | Methods

2.1 | Study Design

We employed a pre-posttest design with a baseline measurement and follow-ups at 3 and 6 months after implementation of STA OP! *with family* [24]. Data were collected between November 2022 and September 2023.

3 | Ethical Approval

The *Medical Ethics Committee Leiden Den Haag Delft* provided a waiver of the need for approval under the Medical Research Involving Human Subjects Act (WMO) (protocol number: N21.158). The study protocol was registered at OSF on May 18, 2022: https://osf.io/5ghnx [24].

3.1 | Training and Implementation

STA OP! provides an organized, stepwise multi-component method for managing challenging behavior and pain in nursing home residents with dementia [23]. The method focuses on the systematic identification, observation, and treatment of potential causes of pain and challenging behavior by the care team using six steps. Table 1 describes the steps of the original STA OP! method. If a step does not lead to improvements, staff move to the next step. We have modified STA OP! by adding suggestions to each step to actively involve family caregivers, resulting in STA OP! *with family* [23]. More details about the development of STA OP! *with family* are described elsewhere [23]. Figure 1 presents the steps of the adjusted method, including family involvement at each step.

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TABLE 1 | Steps of the original STA OP! (before adding family caregivers' involvement).

Step 0[a]	Assessment of basic needs; does someone need to go to the toilet, is someone hungry, is someone uncomfortable? Nursing staff have an important role in discovering the underlying need and fulfilling the needs
Step 1	Pain observation using a pain assessment tool and physical examination by the physician or nurse practitioner; is there a physical cause for the behavior, such as an infection or constipation?
Step 2	Affective needs assessment: Mapping activities, environmental factors causing the behavior together with the psychologist.
Step 3	Deploy comfort interventions, such as massage, aromatherapy, music therapy, slide projector that projects soft colors on the wall, etc.
Step 4	Test treatment with analgesic medication, even if it is unclear whether the cause is pain (i.e., "blind" use of pain medication).
Step 5	Trial treatment with medication (psychopharmaceuticals) or consultation of a psychiatrist, only after all other steps have been completed.

Note: From: Pieper MJ, Achterberg WP, Francke AL, van der Steen JT, Scherder EJ, Kovach CR. The implementation of the serial trial intervention for pain and challenging behavior in advanced dementia patients (STA OP!): a clustered randomized controlled trial. BMC Geriatr. 2011 Mar 24; 11:12. doi: 10.1186/1471-2318-11-12.

[a]If a step is unsuccessful, the team can proceed to the next step.

The nursing staff received five 3-h training sessions to introduce them to STA OP! *with family*, with other multidisciplinary team members (e.g., psychologists, physicians, occupational therapists, and physiotherapists) attending one or two sessions depending on their area of focus. The training was delivered by a psychologist, a nurse practitioner (PT), or an experienced STA OP! trainer. The physicians specialized in long-term care for older people (called 'elderly' care medicine in the Netherlands) and nurse practitioners received an additional 2-h session on pain treatment delivered by a professor in Elderly Care Medicine and pain management expert (WA). Training sessions consisted of lectures, group discussions, case-based learning, and practical exercises.

Topics discussed in the training included the course of dementia, possible causes of the behavior highlighted in the various steps of the method, communication with family caregivers, and their role in the method. Particular attention was given to strategies for involving family caregivers throughout the six steps of the method. In groups, participants applied STA OP! *with family* to help them manage challenging behaviors in a resident of their choice who was participating in the study. To maximize the learning process, participants were asked to select as their case a resident participating in the study whom they found particularly challenging in daily practice. No additional inclusion criteria were established for case selection, allowing participants to choose a resident whose behavior they considered most challenging and therefore most relevant to their learning needs. Following the training, participants were expected to apply the method in their daily practice.

3.2 | Participants and Recruitment

The nurse practitioner at a nursing home organization in the center of the Netherlands, which provides care to approximately 350 residents with dementia, initiated Cared-4 and was assigned as one of the researchers. Figure 2 presents the study flowchart. Nursing home wards providing care for residents with dementia within the participating organization were invited to participate. Next, members of the nursing staff who knew the residents well, completed the Neuropsychiatric Inventory Questionnaire (NPI-NH) [25] for all residents, to identify those who met the inclusion criteria. The care team selected the staff members based on their familiarity with the residents' behavior and functioning through regular involvement in daily care. Inclusion criteria were a diagnosis of dementia and an NPI-NH score > 4 (frequency x severity sum score). Exclusion criteria were young-onset dementia, Korsakov syndrome, and a life expectancy of < 2 weeks. Legal representatives of the residents who met the inclusion criteria were then invited to participate in the study together with their relative with dementia and provided consent on behalf of both themselves and the resident. With mutual agreement, another family member could assume this role.

3.3 | Instruments

3.3.1 | *Resident Assessment*

Resident characteristics were collected through a paper-based questionnaire completed at baseline by nursing staff (age, sex, type of dementia) and family caregivers (religion, living situation prior to admission, education level, country of birth).

The Bedford Alzheimer Nursing Severity-Scale (BANS-S) [26] was completed by nursing staff at baseline to measure the severity of dementia. This scale consists of 7 items. A score of 17 or higher indicates severe dementia [27].

3.3.1.1 | *Challenging Behavior.* Challenging behavior was the primary outcome in this study, measured by the Frequency x Severity total score of the NPI-NH [25], which comprises 12 neuropsychiatric symptoms [28]. Each item is scored from 0 to 12, with higher scores indicating more frequent or more severe challenging behavior.

3.3.1.2 | *Pain Assessment.* Symptoms of pain or pain-related behavior were measured using the Pain Assessment in Impaired Cognition (PAIC15) [29]. The PAIC15 contains 15 items that are scored on a scale of 0–3. A sum score of ≥ 4 indicates the presence of pain [29]. Each observation took 3–5 minutes and was performed at rest and during the daily care activities.

3.3.1.3 | *Quality of Life.* Quality of life was measured using the QoL in late-stage dementia scale (QUALID) [30] for an overall measure of QoL, while the QUALIDEM [31] subscales 'Social isolation' and 'Social relationships' were used to assess the resident's social functioning and social engagement.

The subscales 'Social isolation' and 'Social relationships' of the QUALIDEM contain 3 and 6 items, respectively. Items are

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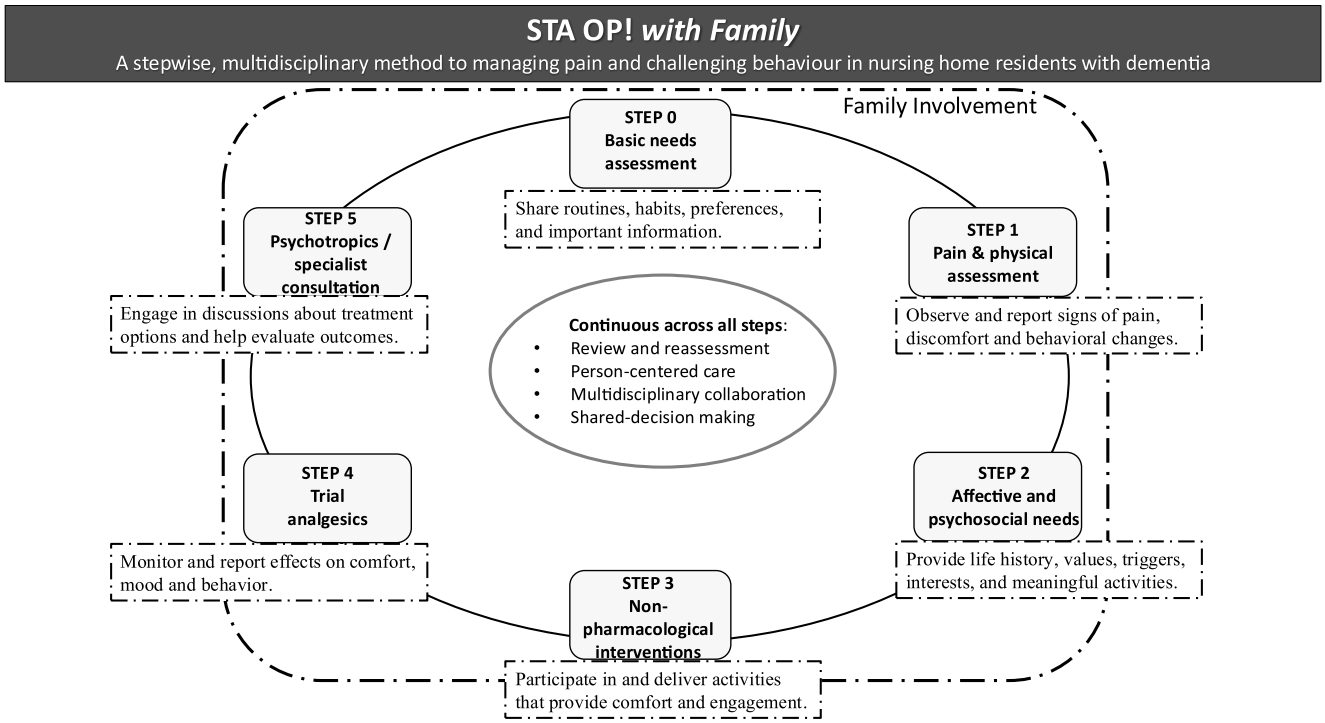

FIGURE 1 | Overview of the steps of STA OP! *with Family*.

scored on a 4-point scale, with higher scores indicating better QoL. The QUALID contains 11 items and provides an overall assessment of the resident's well-being based on observed behavior. Each item has 5 response options with different descriptors. Scores range from 11 to 55, with lower scores indicating higher QoL.

Medication Each medication is associated with an Anatomical Therapeutic Chemical Code (ATC), a unique code assigned according to the World Health Organization (WHO) classification system. The sum of Daily Defined Doses (DDD) of opioids (N02A), other analgesics and antipyretics (N02B), antidepressants (N06A), antipsychotics (N05A), anxiolytics (N05B), hypnotics and sedatives (N05C) were compared between baseline and the 3- and at 6-month assessments to detect possible changes over time after implementation of STA OP! *with family*. Prescription data was extracted from the electronic health record.

3.3.2 | *Family Caregiver Assessment*

Family caregivers provided their characteristics at baseline. Family caregivers were also asked to rate the extent to which they felt supported in participating in their relative's care by healthcare professionals using a visual analogue scale with endpoints 0, not supported, and 10, very supported.

3.3.2.1 | *Frequency of Involvement.* The frequency of family caregiver involvement in the steps in the STA OP! *with family* was assessed with 12 questions. Family caregivers were asked how frequently they had been involved in activities, with the following response options: 3 (1 or more times a week), 2 (once a month), 1 (less than once a month), and 0 (not involved).

3.3.2.2 | *Family Caregiver's Experience With Care.* Positive family caregiver experiences were measured using the Gain in Alzheimer care INstrument (GAIN) [32]. The GAIN includes 10 items measured on a five-point scale. The sum score ranges from 0 to 40, with higher scores indicating higher gains.

3.3.2.3 | *Caregiver Burden.* The Zarit Burden Interview [33] measures the burden experienced by family caregivers with 7 questions scored on a five-point scale. Total scores range from 0 to 28.

3.3.3 | *Professional Caregivers' Assessment*

3.3.3.1 | *Emotional Burden.* The emotional burden of challenging behavior on nursing staff was measured using the NPI-NH [28]. For each symptom present, staff were asked "How much does this behavior upset you and/or create more work for you?". The 12 symptoms are rated on a 6-point Likert scale from 'not at all' to 'very severely', with the total sum score ranging from 0 to 60.

3.3.4 | *Procedure*

Psychology students and the first author conducted the pain observations at baseline, and at 3- and 6-month assessments after completing the PAIC15 e-learning [34]. For quality purposes, 11% of the observations were performed independently by two observers. They then discussed discrepancies in their scores until reaching consensus.

Nursing staff completed questionnaires about the resident's challenging behavior, the emotional burden of the challenging behavior on nursing staff, and QoL at baseline, and at the 3- and 6-month assessments. At the same time points, family caregivers completed questionnaires with five sections: frequency of

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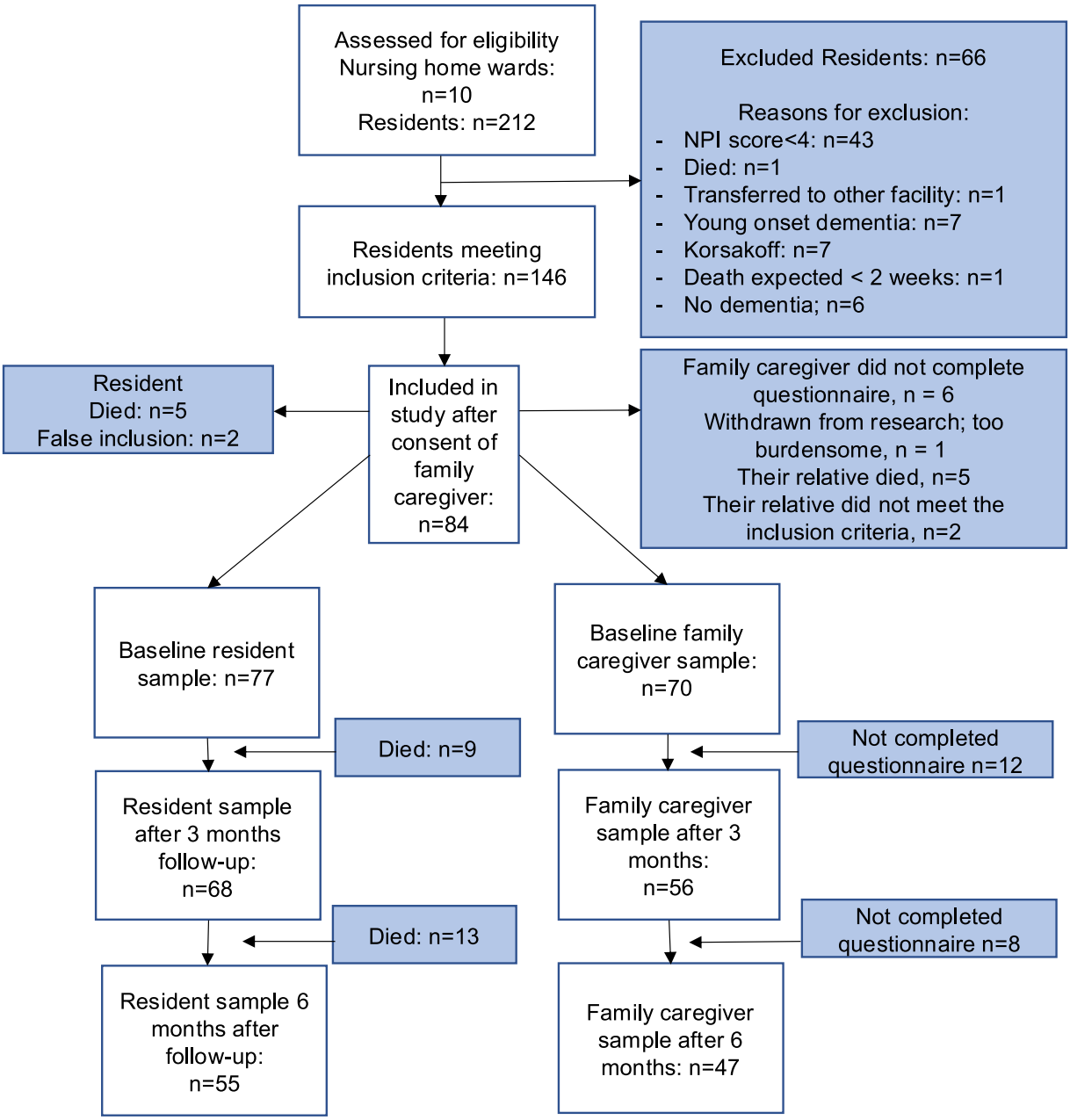

FIGURE 2 | Flowchart Cared-4 study. NPI, Neuropsychiatric Inventory Questionnaire.

involvement in care, positive aspects of being a family caregiver, caregiver burden, satisfaction with care, and experience with care. Questionnaires could be completed online or on paper.

3.3.4.1 | *Statistical Analysis.* Based on previous research [19], we calculated the number of residents needed to detect differences in the primary outcome NPI-NH [25] between the three measurements. Using G*Power software [35], a repeated-measures ANOVA power calculation (within-subjects design, single group, correlation between repeated measures = 0.5, effect size = 0.2, power = 80%, alpha = 0.05) indicated a minimum sample size of 42 residents. Multiplied by a design effect of 1.2, a minimum of 50 residents is needed for the analysis.

We conducted multilevel analyses to assess differences between multiple assessments modeled at the within-person level [19, 36]. Controlling for clustering of participants within wards was not necessary. Intraclass correlations (ICC) were calculated as the proportion of variance of the between-ward variance over the total variance in a null model of multilevel regression. The ICC was 0.040 and was considered negligible. We calculated Cohen's *d* effect sizes, where 0.2 is considered a small effect and 0.5 a moderate effect [37].

Covariates for resident outcomes were age, sex, and type of dementia. For family outcomes, age, sex, and relationship with the resident were included. We adjusted for medication use by including medication variables in analyses for NPI and PAIC scores to examine whether this altered the associations. Furthermore, we explored whether effects on emotional burden were explained by changes in symptom levels by including NPI-scores as a covariate. Mplus, version 8.10 was used for multilevel

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modeling with Full Information Maximum Likelihood method (FIML) [38]. FIML manages missing data over time. It does not perform estimation for missing data but includes these cases in the regression analyses based on data from the full dataset. STATA18 was used for statistical analysis [39]. Standardized coefficients and 95% confidence intervals (CIs) were estimated in multilevel analyses unadjusted and adjusted for covariates.

4 | Results

A total of 214 residents were assessed for eligibility, of whom 143 met the inclusion criteria. Ultimately, 77 residents and their family caregivers were enrolled in the study (Figure 2). Table 2 shows the characteristics of residents and family caregivers at baseline. Of the 224 nursing staff members invited to the STA OP! *with family* training, 159 attended at least one session (response rate 71.0%). Additionally, 3 managers (representing 5 of the 10 wards), and 4 multidisciplinary professionals participated in at least one session. All training sessions were delivered across participating wards.

4.1 | Residents

Table 3 shows that the overall adjusted mean difference in challenging behavior over time was −0.2 (95% CIs −0.3,−0.04, $p = 0.015$) at 3 months and −0.2 (−0.3,−0.03, $p = 0.018$) at 6 months. Observed pain also decreased significantly at 6 months by −0.2 (−0.3,−0.0.01 $p = 0.041$). QoL did not change over time. The ratio of Daily Defined Doses and number of prescriptions for psychopharmaceutics, sedatives, and antidepressants did not change over time (Table 4). Adjusted coefficients did not differ appreciably from unadjusted coefficients (Supplement A). Supplement B shows the small to moderate effect sizes of resident's outcomes.

4.2 | Nursing Staff

The overall adjusted mean difference in the emotional burden associated with the resident's behavior on nursing staff decreased significantly by −0.3 points (−0.4, −0.1, $p < 0.001$) at 3 months, and by −0.3 points (−0.4,−0.1, $p < 0.001$) at 6 months (Table 3). The association remained similar after adjustment for resident challenging behavior. Effect sizes were small to moderate (Supplement B).

4.3 | Family Caregivers

Table 3 shows adjusted associations with the family caregivers' outcomes. There was no significant change over time in the frequency of family caregivers' involvement in the different steps of the method. Family caregivers' positive caregiving experiences and burden did not change. Effect sizes were small to moderate (Supplement B).

TABLE 2 | Characteristics of residents ($n = 77$) and family caregivers ($n = 71$) at baseline.

Residents	Mean (SD) or %	*n*
Age, years	85.2 (6.2)	75
Missing		2
Sex		
Male	27	21
Female	73	56
Type of dementia		
Alzheimer's disease	42	30
Vascular dementia	13	9
Lewy body dementia	3	2
Parkinson's Dementia	1	1
Frontotemporal dementia	3	2
Dementia not otherwise specified	11	8
Mixed Alzheimer's disease and vascular dementia	10	7
Other[a]	17	12
Missing		6
Severity of dementia (BANS-S)	12.6 (3.9)	72
Missing		5
Family caregivers		
Age, years		
Missing	59.5 (9.7)	68 3
Sex		
Male	40	28
Female	60	42
Relationship with the resident		
Daughter or son	70	46
Spouse	17	11
Daughter or son-ln-aw	2	1
Niece or nephew	2	1
Sister or brother	3	2
Legal representative other than family	3	2
Other (i.e., friend, step-granddaughter)	5	3
Missing		5

Abbreviation: BANS-S, Bedford Alzheimer Nursing Severity scale.
[a]non-congenital brain injury, Parkinson's disease, cognitive impairment, intellectual disability.

5 | Discussion

This study examined the impact of STA OP! *with family* on residents, family caregivers, and nursing staff. For residents, challenging behavior and observed pain decreased. No effect was found on QoL and daily defined dosages of medication. Family caregivers' positive caregiving experiences, burden, and involvement did not change over time. For nursing staff, the emotional burden related to residents' challenging behavior decreased.

In line with our hypothesis and the previous STA OP! randomized controlled trial [19], STA OP! *with family* reduced residents' challenging behavior. The emotional burden of

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TABLE 3 | Change from pretest to post-test for resident and family caregiver outcomes and nursing staff's emotional burden adjusted for clustering and covariates.

	T1 (at 3 months) Standardized coefficient (95% CI)	*p*-value	T2 (at 6 months) Standardized coefficient (95% CI)	*p*-value
Resident[a]				
Neuropsychiatric symptoms, NPI, range 0–144	−0.2 (−0.3, −0.04)*	0.015	−0.2 (−0.3, −0.03)*	0.018
Pain, PAIC15, range 0–45	−0.01 (−0.2, 0.1)	0.860	−0.2 (−0.3, −0.01)*	0.041
Quality of life, QUALID, range 11–55	0.1 (−0.05, 0.3)	0.169	0.2 (−0.01, 0.3)	0.058
Quality of life subscale social relationships, QUALIDEM, range 0–9	0.1 (−0.1, 0.2)	0.514	−0.04 (−0.2, 0.1)	0.639
Quality of life subscale social isolation, QUALIDEM, range 0–18	−0.1 (−0.3, 0.1)	0.240	−0.1 (−0.3, 0.02)	0.089
Family caregiver[b]				
Supported by nursing staff to be involved in the care for their relative, range 0–10	−0.2 (−0.3, 0.01)	0.066	−0.2 (−0.3, 0.02)	0.077
Positive caregiving experiences (GAIN), range 0–40	0.1 (−0.1, 0.2)	0.452	0.1 (−0.1, 0.2)	0.563
Caregiver burden (Zarit burden interview), range 0–28	−0.1 (−0.2, 0.1)	0.537	−0.1 (−0.2, 0.1)	0.542
Frequency of involvement in the care for their relative, range 0–3	0.002 (−0.2, 0.2)	0.983	−0.1 (−0.3, 0.03)	0.097
Nursing staff				
Nursing staff's emotional burden regarding neuropsychiatric symptoms, NPI, range 0–60	−0.3 (−0.4, −0.1)**	< 0.001	−0.3 (−0.4, −0.1)**	< 0.001

Abbreviations: CI, confidence interval; NPI, Neuropsychiatric Inventory Questionnaire; PAIC15, Pain Assessment in Impaired Cognition; QUALID, Quality of Life in Late-Stage Dementia Scale; T1, first measurement; T2, second measurement; "QUALIDEM" = "QUALIDEM, a dementia-specific quality of life instrument".
[a]$N = 209$ observations (77 nursing home residents with dementia) Full information maximum likelihood method was used to handle missing data. Covariates included age, sex, and type of dementia at between-person level.
[b]$N = 195$ observations (71 participants) Full information maximum likelihood method was used to handle missing data. Covariates included family caregiver's age and sex, resident's age, sex and type of dementia, and relationship between family and resident.
*$p < 0.001$.
**$p < 0.05$.

TABLE 4 | Change from pretest to post-test for resident's daily defined dosages adjusted for clustering and covariates.

Daily defined dosages	T1 Standardized coefficient (95% CI)	*p*-value	T2 Standardized coefficient (95% CI)	*p*-value
Opioids [N02A]	0.02 (−0.1, 0.2)	0.805	0.1 (−0.1, 0.2)	0.454
Other analgesics and antipyretics [N02B]	−0.03 (−0.2, 0.1)	0.672	0.04 (−0.1, 0.2)	0.630
Antipsychotics [N05A]	0.1 (−0.1, 0.2)	0.318	0.1 (−0.1, 0.2)	0.309
Anxiolytic [N05B]	0.1 (−0.1, 0.3)	0.249	−0.01 (−0.2, 0.2)	0.951
Hypnotics and sedatives [N05C]	−0.03 (−0.2, 0.1)	0.677	−0.1 (−0.3, 0.1)	0.244
Anti-depressants [N06A]	0.2 (−0.001, 0.3)	0.052	0.1 (−0.1, 0.2)	0.421

Note: Full information maximum likelihood method was used to handle missing data. Time in-variant covariates included age, sex, and type of dementia.
Abbreviations: CI, confidence interval; *N*, 209 observations (77 nursing home residents with dementia); T1, first measurement; T2, second measurement.

challenging behavior on nursing staff also declined. Previous research on STA OP! did not examine the effect on staff's emotional burden. Two studies on similar interventions have addressed the impact on job satisfaction and demands for nursing staff, but not specifically emotional distress related to the NPI [40, 41]. One program showed no significant effects on perceived job stress, job satisfaction, or stress reactions among staff, while another program demonstrated positive effects on job satisfaction. Our analysis showed that emotional burden decreased independently from the decrease in challenging behavior. Therefore, more factors than decreased frequency and intensity of challenging behavior alone lead to less emotional burden on staff, while managing challenging behavior is known to be very stressful for staff [6]. Possibly, the method helps them to cope better with the behavior and makes it less stressful, regardless of whether the behavior decreases.

Consistent with other studies [12, 42], the decrease in observed pain may be explained by the method's focus on pain observation and pain management, including instruction in the use

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of a pain observation scale in the training, which may have increased awareness of the importance of pain management. Incorporating pain management into a multidisciplinary model that has a good balance between the use of non-pharmacological interventions, pain observation tools, and prescription of pain medication promotes good pain assessment and treatment [43].

Contrary to our expectations, the frequency of family involvement, positive caregiving experiences, and caregiver burden did not change over time, whereas several resident outcomes and staff outcomes improved. This may suggest that the observed benefits were primarily driven by components of the method such as staff training, systematic assessment, and the structured stepwise approach to pain and behavioral management. Because this study did not include a comparison group receiving the original STA OP! without the family component, the specific contribution of family involvement cannot be determined. Another consideration is that the outcome measures may not have fully captured the type of family involvement targeted by STA OP! *with family*. The intervention aims not only to increase the frequency of involvement, but also to improve collaboration, communication, and recognition of family caregivers' expertise. Such changes may not necessarily be reflected in measures of involvement frequency, burden, or positive caregiving experiences. Therefore, the absence of measurable changes in family caregiver outcomes does not exclude the possibility that family involvement contributed to the intervention's effects.

Also, contrary to what we expected, QoL did not increase. Although challenging behavior and pain decreased, these improvements may not have been sufficiently large to translate into measurable changes in QoL. Klapwijk et al. [22] found that after implementation of the original STA OP!, QoL improved only on the two subscales Restless tense behavior and Social isolation [22]. Husebø et al. [44] examined the effect of a multicomponent intervention aimed at improving the QoL of nursing home residents with dementia and also found no improvement in QoL, whereas other outcomes such as activities of daily living (ADL) improved, and medication use among residents and stress among staff decreased. Because QoL in the intervention group temporarily decreased after the start of the implementation, but increased again significantly after follow-up, it was hypothesized that nursing staff may have felt overwhelmed by the work the intervention generated [44]. Further, it is known that QoL may decline progressively as the disease progresses [45, 46]. Many factors commonly known to influence QoL, such as mood and cognitive impairment [46], as well as understaffing (especially activity staff) and the mix of residents [47], may also have affected the results of this study. QoL of people with dementia must be viewed as a multidimensional construct that is very complex to study as an outcome for an intervention [22].

Our small to moderate effect sizes were in line with findings from studies of non-pharmacological interventions [7, 37]. Although this may initially seem to limit the value for daily practice, many studies on medication show similarly small effect sizes [7].

Contrary to our hypotheses, no change in pharmacological prescriptions was found. Despite the availability of various nonpharmacological interventions, psychotropic medication is still frequently prescribed [48, 49]. The absence of changes in medication use may indicate that the observed improvements in challenging behavior and pain were achieved primarily through non-pharmacological management rather than through changes in prescribing practices.

5.1 | Limitations and Strengths

The sample size of 77 residents was adequate compared to the predefined minimum of 50. The lack of a control group warrants caution when drawing conclusions. Although STA OP! *with family* was not applied to all residents, all residents on the ward may benefit from more effective management of challenging behavior in other residents by healthcare professionals.

5.2 | Conclusions and Implications for Daily Practice

STA OP! *with family* has a positive impact on residents' behavior and pain, and on the emotional burden on nursing staff. Although effects on residents and staff in this study are consistent with previous studies of STA OP!, additional effort to involve family caregivers in the method did not result in measurable improvements in family caregiver outcomes. Continuous support and good communication about STA OP! *with family* and its positive impact on residents' behavior can help staff maintain use of the method. Further research is needed on how family involvement in the method is implemented and used in daily practice, as family involvement is not yet integrated into daily care. A process evaluation with lessons learned about what supports or limits the implementation is a necessary next step.

Author Contributions

P.E.M.T.-D., H.J.A.S., W.P.A. and J.T.v.d.S. contributed to the study concept and design. P.E.M.T.-D and H.J.A.S. were responsible for data acquisition. Data analysis and interpretation of data were conducted by P.E.M.T.-D, H.J.A.S., M.N. and J.T.v.d.S., P.E.M.T.-D drafted the manuscript, while H.J.A.S., W.P.A., J.T.v.d.S. and M.N. critically revised it for important intellectual content.

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Ethics Statement

The Medical Ethics Committee Leiden Den Haag Delft provided a waiver of the need for approval under the Medical Research Involving Human Subjects Act (WMO) (protocol number: N21.158).

Consent

Legal representatives of the residents gave consent for themselves and the resident to participate in the study. This could also be adopted by another family member by mutual agreement.

Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be perceived as a potential conflict of interest. P.E.M.T.-D is employed at the participating nursing home as nurse practitioner. However, the organization had no influence on the study design or reporting.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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