# Health Care Team Interventions for Older Adults With Distress Behaviors

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### **PREFACE**

The VA Evidence Synthesis Program (ESP) was established in 2007 to conduct timely, rigorous, and independent systematic reviews to support VA clinicians, program leadership, and policymakers to improve the health of Veterans. ESP reviews have been used to develop evidence-informed clinical policies, practice guidelines, and performance measures; to guide implementation of programs and services that improve Veterans' health and wellbeing; and to set the direction of research to close important evidence gaps. Four ESP Centers are located across the US. Centers are led by recognized experts in evidence synthesis, often with roles as practicing VA clinicians. The Coordinating Center, located in Portland, Oregon, manages program operations, ensures methodological consistency and quality of products, engages with stakeholders, and addresses urgent evidence synthesis needs.

Nominations of review topics are solicited several times each year and submitted via the <u>ESP website</u>. Topics are selected based on the availability of relevant evidence and the likelihood that a review on the topic would be feasible and have broad utility across the VA system. If selected, topics are refined with input from Operational Partners (below), ESP staff, and additional subject matter experts. Draft ESP reviews undergo external peer review to ensure they are methodologically sound, unbiased, and include all important evidence on the topic. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. In seeking broad expertise and perspectives during review development, conflicting viewpoints are common and often result in productive scientific discourse that improves the relevance and rigor of the review. The ESP works to balance divergent views and to manage or mitigate potential conflicts of interest.

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### **Operational Partners**

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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### Technical Expert Panel

To ensure robust, scientifically relevant work, the technical expert panel (TEP) guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members included:

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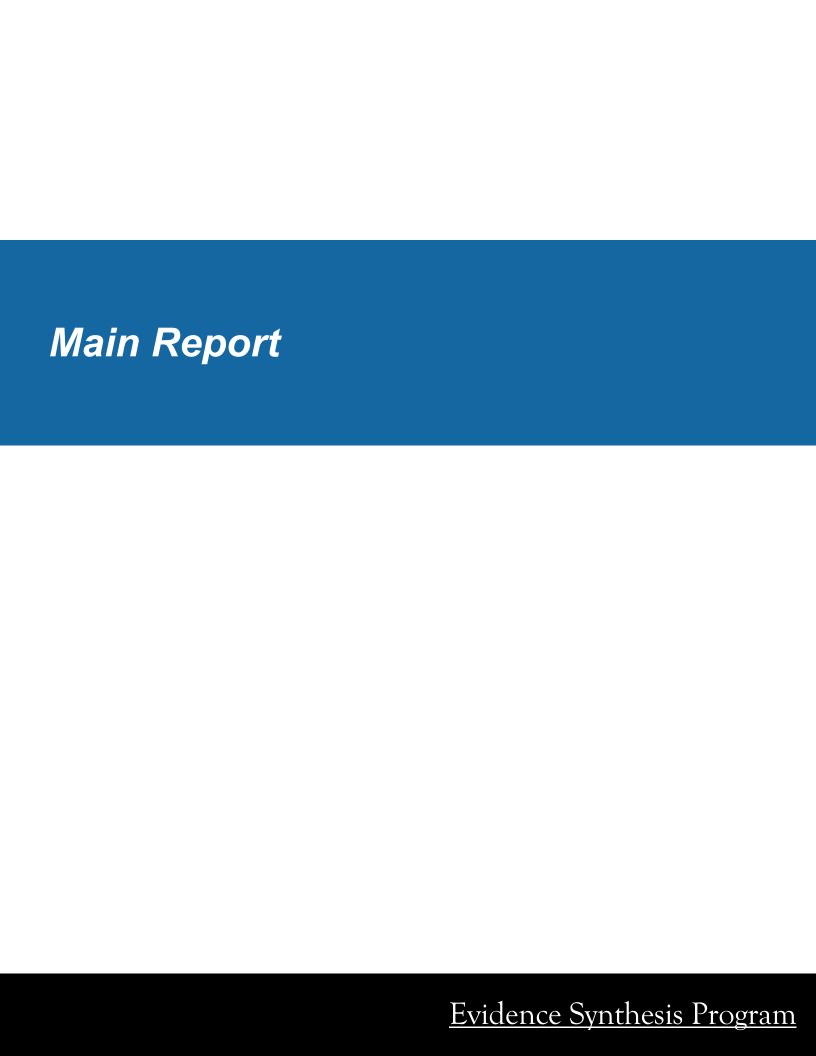
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### Disclosures

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The findings and conclusions in this document are those of the author(s) who are responsible for its contents and do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. The final research questions, methodology, and/or conclusions may not necessarily represent the views of contributing operational and content experts. No investigators have affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.



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# **ABBREVIATIONS TABLE**

Abbreviation	Definition
ABMI	Agitation behavior mapping instrument
AICT	Advanced illness care team
BC	Behavioral coordinator
CBS	Challenging Behavior Scale
CI	Confidence interval
CLC	Community living centers
CMAI	Cohen-Mansfield Agitation Inventory
DCM	Dementia care mapping
EPOC	Effective Practice and Organisation of Care
FBFC-CI	Function and Behavior Focused Care for the Cognitively Impaired
FFC-AL-EIT	Function Focused Care for Assisted Living Using the Evidence Integration Triangle
FFC-CI	Function Focused Care Intervention for the Cognitively Impaired
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCW	Health care worker
HR	Hazard ratio
ICC	Intraclass correlation coefficient
ICU	Intensive care unit
IDD	Intellectual and developmental disabilities
KQ	Key question
MBI	Maslach Burnout Inventory
MD	Mean difference
NPI	Neuropsychiatric Inventory
OECD	Organization for Economic Co-operation and Development
OPAL	Optimizing Prescribing of Antipsychotics in Long-Term Care
OR	Odds ratio
PCC	Person-centered care
PTSD	Posttraumatic stress disorder
QOL	Quality of life
QUALID	Quality of Life in Late-Stage Dementia
RAI-MDS	Resident Assessment Instrument-Minimum Dataset
RCT	Randomized controlled trial
RN	Registered nurse
ROB	Risk of bias
SD	Standard deviation
SE	Standard error
SMD	Standardized mean difference
SMI	Serious mental illness
STAR	Staff Training in Assisted Living Residences



Abbreviation	Definition
STI	Serial Trial Intervention
SUD	Substance use disorder
TREA	Treatment Routes for Exploring Agitation
UC	Usual care
WHELD	Well-being and Health for People Living with Dementia



### **BACKGROUND**

Older adults with comorbid medical disorders (*eg*, dementia, serious mental illness, multiple chronic medical conditions) may experience an increased prevalence of behavioral and psychological symptoms. Exacerbation of these symptoms is likely due to vulnerability to environmental factors such as under- or over-stimulation, or unmet medical, physical, emotional, and social needs that may unintentionally be reinforced by staff or care routines. These behavioral and psychological symptoms, in the context of receiving care across health care settings, can be considered as manifestations of patient distress and may be uncomfortable for both patients and their paid caregivers. Patient distress and associated behaviors can affect patient quality of life, care provision, cost of care, or transition to community-based care settings.<sup>1-3</sup>

Among patients with dementia, 75% exhibit at least 1 neuropsychiatric symptom.<sup>4</sup> While mental illness and other cognitive disorders among older adults, including serious mental illness (SMI), substance use disorders (SUD), and intellectual and developmental disabilities (IDD), are less well researched, distress behaviors are also prevalent with these conditions. For example, in 2004, among nursing home residents in the VA health care system, 66% of Veterans with SMI expressed verbal "disruption," nearly 30% expressed physical aggression, and 58% expressed inappropriate behavior.<sup>5</sup> Distress behaviors can cause significant challenges to the ability of health care systems generally and for clinical providers in particular to deliver care using traditional, clinician-focused strategies (*eg*, close monitoring, new treatment plans),<sup>6</sup> as these strategies tend to prioritize diagnostic procedures, close monitoring, and delivery treatments within the context of short stays.<sup>7</sup> These challenges can lead to staff burnout.<sup>8,9</sup> In order to better address the patient needs underlying recognized patient distress behaviors and better prepare health care teams to meet these patient needs in a productive and safe work environment, it is imperative that health systems develop high-quality approaches for patients with these complex needs.<sup>10</sup>

Existing strategies to manage distress behaviors are largely ineffective and considered not patient centered. For example, antipsychotic medications have been used to manage behaviors perceived as disruptive by health care teams. 11,12 Between 2011 and 2019, 80% of publicly funded long-stay nursing home residents in the United States received an antipsychotic prescription. However, reliance on these medications is off-label and not always effective to address behavioral disturbances, and some medications are known to have substantial adverse effects, including an increased risk of death. Historically, restraints are another ineffective approach used to prevent wandering and falls among older adults in institutional settings. However, the use of restraints is still relatively high, especially for older adults with dementia. Given ethical concerns about restricting individual autonomy and the potential harms, advocates increasingly view physical restraints as an untenable approach to manage distress behaviors. For example, the Joint Commission and the Alzheimer's Association recently announced a collaboration to improve quality and safety in skilled nursing facilities through evidenced-based practice recommendations. 19,20

Effective, patient-centered nonpharmacologic approaches are critically needed to better support patients who are at increased risk for distress and related behaviors through centering care provision and accommodation on the patient. Interventions primarily focused on changing health care worker (HCW) skills, patient interactions, and team roles are particularly compelling to promote safe, personcentered, and positive systemic change. For example, Staff Training in Assisted Living Residences (STAR-VA) is a training program for staff working in VA Community Living Centers that aims to support teams in understanding and managing distress behaviors among residents with dementia via a

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team-based, behavioral, problem-solving approach. STAR-VA helps teams have realistic expectations of individuals with dementia, communicate effectively, and use the ABC model (identify and change activators and consequences to specific behaviors, and integrate person-centered pleasant events into daily care).<sup>21</sup>

Despite integration of individual patient-level nonpharmacologic approaches into recent guidelines for the care of older adults with dementia, interventions primarily focused on HCWs (eg, improving HCW skills and knowledge or adjusting workflow patterns or team roles) have received limitation attention. In addition, while patients with SMI and other psychiatric disorders are overrepresented in residential long-term care settings, <sup>22-24</sup> little is known about the use of these strategies among this high-risk population. The goal of this systematic review is to evaluate the effect of interventions designed to address patient distress behaviors, focusing on HCW-focused interventions (eg, optimal staffing, staffing education/training). For this review, we focus on interventions to ameliorate patient distress leading to behaviors such as physical or verbal aggression, repeated vocalizations, yelling, pacing, wandering, hoarding, handling objects unsafely, sexual disinhibition, psychosis, disengagement, or apathy.

This review was nominated by the VA Office of Mental Health and Suicide Prevention to inform work being done by the VHA Interoffice of Care for Patients with Complex Problems Steering Committee to support health care delivery for Veterans with distress behaviors.



### **METHODS**

### REGISTRATION AND REVIEW

A preregistered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews (<u>CRD42023402760</u>). A draft version of this report was reviewed by external peer reviewers; their comments and author responses are located in the <u>Appendix</u>.

### **KEY QUESTIONS AND ELIGIBILITY CRITERIA**

The following key questions were the focus of this review:

Key Question 1	What is the effect of health care team-focused interventions designed to manage persistent or recurrent distress behaviors among older adults in long-term residential or inpatient health care settings on patient, staff, and utilization outcomes?
Key Question 2	What is the effect of health care team-focused interventions designed to manage persistent or recurrent distress behaviors among older adults during transitions between health care settings on patient, staff, and utilization outcomes?
Key Question 3	What is the effect of health care team-focused interventions designed to manage persistent or recurrent distress behaviors among older adults in the context of inpatient mental health settings on patient, staff, and utilization outcomes?

Study eligibility criteria are shown in the table below. Overall, we focused on interventions intended to improve health care staff knowledge and behaviors related to distress behavior management. We did not include patient-directed interventions (*eg*, providing patient-tailored background music). An analytic framework that illustrates the relationship between key questions and eligible interventions and outcomes is provided in the Appendix.

Eligibility Crite		
	Inclusion	Exclusion
Population	Older adults (≥ 50 years of age) in residential, long-term, inpatient health care settings or who are transitioning between hospital to these settings or to home and who are at elevated risk of persistent or recurrent distress behaviors in health care settings associated with underlying conditions such as neurocognitive disorders (eg, dementia), mental health disorders (eg, serious mental illness, psychosis, PTSD, substance use disorders), and/or other chronic medical illnesses  Eligible studies must include at least 75% of participants aged ≥ 50 years  Patients could be those identified to be at-risk OR those already displaying disruptive behaviors	Patients not currently in residential or inpatient settings (eg, home-based care, outpatient) Peri-operative or ICU patients Studies with populations < 75% aged ≥ 50 years Patients with primary diagnosis of delirium Intoxicated patients or patients in acute substance withdrawal Pediatric population or populations with < 75% patients < 50 years



Eligibility Criteria		
	Inclusion	Exclusion
Intervention	Staff- or health care unit-focused approaches to build capacity, knowledge, behaviors, or skills intended to reduce or prevent distressed and/or disruptive behaviors among a population of older adults in indicated health care settings Intervention could involve staff or clinic-facing interventions that focus on optimizing facility staffing, staff training, and education, and/or developing and strengthening staff competencies as they relate to managing disruptive behaviors Intervention must be primarily targeted at the health care providers or unit (eg, team, clinical service) as the primary point of deployment that involves a change in the way care is delivered Interventions must specify a primary intent to reduce disruptive and/or distressed behaviors (or have such behaviors as a primary outcome) Interventions could include electronic health record components that involve staff interaction or recognition of at-risk patients	Interventions that target the patient as the level of deployment only and do not involve staff or the health care unit employed by a health care system Interventions that only involve staff for training of the delivery of an individual patient-level therapy for symptom management (eg, pet therapy, music therapy) Interventions focused on management of symptoms of chronic condition only or which mention disruptive behavior as a minor focus of the intervention Pharmacologic interventions
Comparator	Any or none	NA
Outcomes	Patient outcomes: Mental and/or medical symptom improvement, improvement or management of disruptive behavior (to include neuropsychiatric symptoms such as agitation, aggression), patient safety, quality of life Staff outcomes: Morale, provider/staff satisfaction, provider/staff safety, turnover, staff competencies/skills, or staff self-efficacy as they relate to handling disruptive behaviors  Utilization outcomes: Length of stay in acute care hospital or nursing home settings, timeliness of discharge, hospital readmissions, overall costs of care	Studies that do not explicitly state the primary intent to be the improvement of disruptive behaviors must have disruptive behaviors as primary outcome (though data were collected on other secondary outcomes of interest)  Neuropsychiatric symptoms such as apathy, depression, delusions, hallucinations, delirium
Timing	Any	NA
Setting	Inpatient medicine, inpatient mental health, residential care/nursing homes, and transitional care, including from hospital or nursing home to community-based or family caregiving	Outpatient, home-based care settings, nonclinical group home settings, emergency departments
Study Design	Randomized trials, nonrandomized trials, controlled before-after studies, interrupted time-series studies or repeated measures studies, retrospective/prospective cohort studies, case-control studies, program evaluations	Patient-level case studies/series, systematic reviews, organizational case studies





Eligibility Criteria		
	Inclusion	Exclusion
Publication Types	Full publication in a peer-reviewed journal	Letters, opinion pieces, editorials, reviews, dissertations, meeting abstracts, and protocols without results Pilot studies (for KQ1 only)
Years	December 2002-present	
Language	No limits	NA
Country	Organization for Economic Co-operation and Development countries (Australia, Austria, Belgium, Canada, Chile, Colombia, Costa Rica, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States)	Non-OECD countries

Abbreviations. ICU=intensive care unit; PTSD=posttraumatic stress disorder.

### SEARCHING AND SCREENING

To identify articles relevant to the key questions (KQs), a research librarian searched Ovid MEDLINE, Elsevier Embase, and Ovid PsycInfo from December 2002 through December 2022 using terms for setting (residential, transition of care), inpatients with mental illness, older adults, older adult inpatients with mental illness, distressed or disruptive behavior (see Appendix for complete search strategies). Additional citations were identified from hand-searching reference lists and consultation with content experts. We limited the search to published and indexed articles involving human subjects and OECD countries. Study selection was based on the eligibility criteria described above. Titles, abstracts, and full-text articles were reviewed by 2 investigators. All disagreements were resolved by consensus or discussion with a third reviewer.

### DATA ABSTRACTION AND ASSESSMENT

We approached the abstraction and synthesis of each KQ separately, as each KQ focuses on distinct health care settings with different staffing and team dynamics. We expected KQ1 to yield the largest number of available studies based on a recent systematic review conducted by AHRQ<sup>25</sup> that included 19 randomized controlled trials (RCTs) and was focused solely on patients with dementia living in nursing home and assisted living settings.

We synthesized available studies following a best-evidence approach. Specifically, we prioritized synthesis of studies with more rigorous designs (eg, randomized trials, nonrandomized trials, controlled before-after, interrupted time series) over less rigorous designs (eg, retrospective or prospective cohort studies, program evaluations). If we identified a sufficient number of randomized trials, we prioritized these over all other designs. Because this project is intended to inform VA policy and decision-making, we also included all VA-specific studies regardless of design for contextualization and comparison. If VA studies used less rigorous designs, we included them descriptively but did not conduct a formal risk of bias assessments or incorporate them into certainty of



evidence assessments. In addition, given the existence of a prior high-quality systematic review relevant to this topic, <sup>25</sup> we abstracted descriptive information about primary studies from those reviews with up to 20% over-reading to verify accuracy of data.

Effect information and population, intervention, and comparator characteristics were abstracted for all prioritized studies. From these studies, we also abstracted key intervention characteristics and evaluated intervention complexity using a modified iCAT-SR tool to inform future intervention implementation.<sup>26</sup> We report intervention labels such as "person-centered" based on author description in published papers. To group the prioritized studies conceptually for analysis, we considered multiple approaches and sought input from our technical expert panel and operational partner to identify a meaningful approach that aligns with the way that people caring for patients with distress behaviors group and label patient care activities. Given the complexity and multi-component nature of the interventions, we were unable to group for analysis by any 1 specific intervention activity (eg, antipsychotic medication review). Instead, we grouped studies by current clinical practice approaches adapted from the Alzheimer's Association Dementia Care Practice Recommendations.<sup>27</sup> The Association developed these recommendations to define quality of care across all care settings for patients with dementia. Of the 10 total Association recommendations, we identified 8 that we determined were most relevant to the care of older adults experiencing distress to categorize interventions. For each of these 8, we developed tailored definitions for operationalization and mapped each adapted recommendation to the level at its intended impact (ie, patient, staff, environment/setting) (listed and defined in Appendix). Given the complexity of interventions in the included studies, many interventions targeted more than 1 level. Therefore, our final grouping categories included HCWfocused-only, patient-only (interventions designed to change HCW behaviors and interactions with patients), HCW-/patient-focused, and patient-, HCW-, and environment-focused interventions. We did not include any environment-only studies as these would not meet our eligibility criteria of requiring a health care team or HCW focus. We then abstracted intervention characteristics for all studies.

Information abstracted included a description of the intervention, setting, target patient population, components of the intervention, dose, who delivered the intervention, the disciplines of staff receiving the intervention, the intervention delivery mode, and the underpinning theories. Then, descriptions of interventions were reviewed across included studies and key intervention activities were identified. Intervention activities were mapped to the adapted Alzheimer's Association practice recommendation categories by 1 reviewer who referenced the original study as needed. A second reviewer corroborated these decisions. Discrepancies were resolved through discussion and consensus between the 2 reviewers (MSB, KMG).

The internal validity (*ie*, risk of bias) of each prioritized study was rated using Cochrane risk of bias tools for randomized trials<sup>28</sup> or other intervention study designs.<sup>29</sup> All data abstraction was first completed by 1 reviewer and then checked by another; disagreements were resolved by consensus or discussion with a third reviewer (see <u>Appendix</u> for risk of bias ratings). Risk of bias assessment was completed independently by 2 reviewers and disagreements were resolved by consensus.

### **SYNTHESIS**

When synthesizing evidence for KQ1, we prioritized studies judged as moderate or low risk of bias. When at least 3 studies with the same outcome were available, we synthesized results using 3-level random-effects models that accounted for clustering of observations within studies as well as clustering of comparisons within studies in the case of 3 or more treatment groups. For analyses with



fewer than 20 studies, we used the Knapp-Hartung adjustment to better account for uncertainty in heterogeneity estimates. If meta-analysis was not feasible, we summarized available evidence narratively.

When meta-analysis was possible, bias-adjusted standardized mean differences (SMDs) were used for continuous outcomes and odds ratios (ORs) for binary outcomes. The random effects model used to estimate the overall/pooled effect accounted for shared variance of samples within studies and shared variance among multiple comparisons within studies where applicable. For cluster-randomized trials and stepped-wedge designs, we incorporated a design effect into effect size calculation using intraclass correlation coefficients (ICCs).<sup>30</sup> If ICCs were not reported, we used the average of ICCs reported by other studies of the same outcome; if no ICCs were available, an ICC of 0.10 was assumed. If measured constructs were considered not sufficiently conceptually similar, outcome data were synthesized separately.

Heterogeneity was assessed using visual inspection and 95% prediction intervals. Publication bias was assessed using funnel plots (when there were > 10 studies) and Begg's or Egger's regression statistics. Meta-analyses were conducted using the *metafor* package<sup>31</sup> for R (R Foundation for Statistical Computing, Vienna, Austria).

### Strength of Evidence

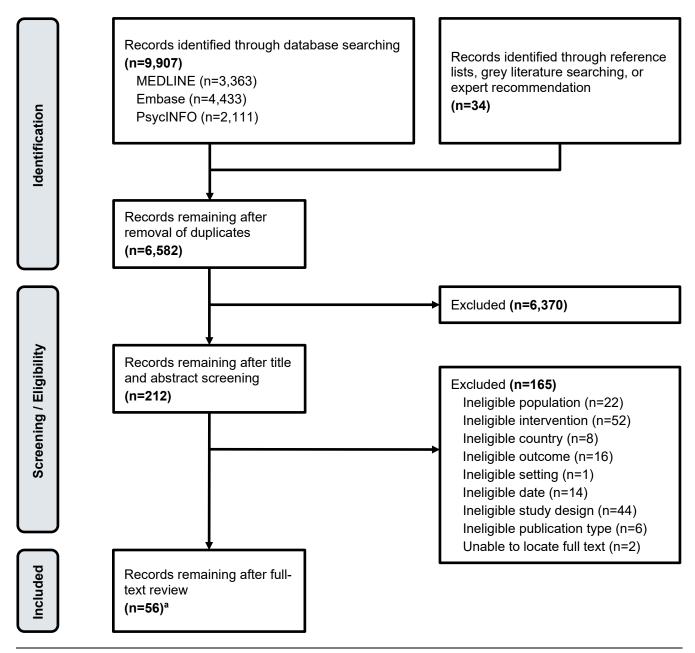
After synthesizing available evidence, we rated the strength of evidence for prioritized outcomes (those outcomes identified by the stakeholders as critical to decision-making with sufficient data for synthesis). Assessment of strength of evidence was guided by the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach,<sup>32</sup> which requires assessment of 4 domains: risk of bias, consistency, directness, and precision. Additional domains to be used when appropriate are dose-response association, impact of plausible residual confounders, strength of association (magnitude of effect), and publication bias. Domains were considered qualitatively, and a summary rating was assigned after discussion by 3 investigators (high, moderate, or low). When high, moderate, or low ratings were impossible or imprudent to make, evidence was considered insufficient to draw conclusions.



### **RESULTS**

### LITERATURE FLOW DIAGRAM

The literature flow diagram summarizes the results of the study selection process. A full list of excluded studies is provided in the <u>Appendix</u>.



Notes. a 56 records including 48 unique studies.





### **OVERVIEW OF INCLUDED STUDIES**

We identified 9,907 publications through database searching and an additional 34 articles through hand-searching citations of earlier systematic reviews. After deduplication and title and abstract screening, 212 articles remained for full-text review. 56 publications met eligibility criteria. Among these, there were 43 unique studies included for KQ1,<sup>33-75</sup> 2 studies for KQ2,<sup>76,77</sup> and 3 studies for KQ3.<sup>78-80</sup> Studies were conducted in the US, Canada, Austria, Finland, France, Germany, Netherlands, Norway, Japan, Australia, and the United Kingdom. Table 1 provides an overview of included studies; additional study and intervention characteristics can be found in the <u>Appendices</u>).

Of the 43 unique studies in KQ1, 42 used more rigorous designs, and 1 program with 4 publications was implemented in the VA. These studies consisted of 1 interrupted time series study, 1 cluster nonrandomized controlled trial, 1 nonrandomized controlled before-after study, and 39 randomized controlled trials. The 39 randomized trials were assessed for risk of bias. The 29 studies determined to have low-to-moderate risk of bias were retained for data abstraction. Among these were 26 cluster-randomized trials, 1 factorial cluster-randomized trial, and 2 stepped-wedge randomized trials.

The 2 studies relevant to KQ2 consisted of 1 interrupted time series study and 1 other study. The 3 studies in KQ3 consisted of 1 cluster-randomized trial, 1 cross-sectional program evaluation, and 1 other. All 5 were retained for data abstraction.

**Table 1. Evidence Profile** 

Number of Studies	48 unique studies (56 articles)
Key Question	KQ1 (N = 43); KQ2 (N = 2); KQ3 (N = 3)
Study Designs	Cluster randomized controlled trial ( $N = 37$ ); randomized controlled trial ( $N = 3$ ); cluster nonrandomized trial ( $N = 1$ ); controlled before-after ( $N = 1$ ); interrupted time series ( $N = 1$ ); non-EPOC interrupted time series ( $N = 1$ ); program evaluation ( $N = 3$ )
ROBINS I Risk of Bias	Low $(N = 0)$ ; moderate $(N = 1)$ ; serious $(N = 3)$ ; critical $(N = 0)$
ROB 2 Risk of Bias	Low (N = 2); Some concerns (N = 27); high (N = 10)
Prioritized for Analysis	KQ1 low/moderate risk of bias randomized studies ( $N = 29$ ); KQ1 non-EPOC VA studies ( $N = 1$ ); KQ2 ( $N = 2$ ); KQ3 ( $N = 3$ )
Study Year Range	2005 to 2022
Number of Participants	13,784 (N prioritized for analysis = 9,668)
Mean Age Range	63.86 to 89.8 (NR = 4)
Countries	USA ( $N$ = 10); Europe ( $N$ = 18); Australia and New Zealand ( $N$ = 4); Japan ( $N$ = 1); Canada ( $N$ = 2)
Intervention Categories (KQ1)	Health care worker (HCW) only ( $N = 6$ ); patient only ( $N = 3$ ); patient and HCW ( $N = 17$ ); patient and HCW and environment ( $N = 3$ )
Outcome Levels <sup>a</sup>	Patient outcomes ( $N = 32$ ); staff outcomes ( $N = 8$ ); utilization outcomes ( $N = 0$ )

Notes. <sup>a</sup> Eight studies reported more than 1 outcome type.

Abbreviations. EPOC=Effective Practice and Organisation of Care.



# **KEY QUESTION 1: LONG-TERM RESIDENTIAL OR INPATIENT HEALTH CARE SETTINGS**

### **Key Points**

- Many interventions included more than 1 active component and most often were directed at changing more than 1 HCW behavior; many interventions included a high level of interaction between intervention activities.
- The 3 interventions focusing on patient-facing aspects of the HCW role had mixed results on agitation. Only 1 study measured the impact on quality of life and found no significant effect.
- The 6 studies including HCW-focused intervention activities only suggest distress behaviors may be reduced when measured by the Neuropsychiatric Inventory (NPI) in the short term (ie, 30 days, > 8 weeks), but there is no evidence of an effect in the longer term (ie, 7 months, 8 months) or when measured by the Cohen-Mansfield Agitation Inventory (CMAI). There is no evidence of improvement in quality of life or reduction in antipsychotic use in the few studies reporting these outcomes.
- Seventeen interventions included both HCW-/patient-focused activities. A summary effect estimate from meta-analysis of 7 studies (9 interventions) did not show a significant reduction in agitation as measured by CMAI (SMD = -0.31, 95% CI [-0.78, 0.16]) or NPI (SMD = -0.47, 95% CI [-1.18, 0.24]) Effects varied substantially across studies. However, interventions were associated with a significant reduction in odds of antipsychotic use (OR = 0.79, 95% CI [0.69, 0.91]), and a medium to large improvement in quality of life as measured by DEMQOL-Proxy, EQ-5D index, or the QUALID (SMD = 0.71, 95% CI [0.39, 1.04]).
- Of the 3 interventions addressing health care teams, patients, and environment activities, only 1 showed an improvement in agitation, though only with short-term (*ie*, 4 months) but not longer-term follow-up (*ie*, 12 months). Antipsychotic use was not reduced.
- Six studies across multiple intervention types examined staff-level outcomes and none demonstrated a beneficial effect.
- Harms were measured using differing definitions at various time points across studies, making it difficult to draw conclusions.
- There were no health care utilization outcomes reported by the abstracted studies.

### Patient-Focused Intervention Activities Only

### Intervention Characteristics

Three studies tested interventions that focused only on structured patient care activities delivered by HCWs, including a mechanism to detect or diagnose distress behaviors, assessment and care planning, ongoing support for distress behaviors, and/or medical management (Table 2).<sup>50,54,59</sup> All studies took place in residential facilities and focused on care for patients with dementia. Two studies took place in the United States and described results from the Treatment Routes for Exploring Agitation (TREA) intervention, <sup>50,54</sup> and 1 study took place in Canada.<sup>59</sup> The TREA intervention applied a decision tree protocol to detect and diagnose distress behaviors and create tailored care plans for patients.<sup>50,54</sup> The third study used a patient-centered care theoretical approach to create patient life histories for staff to review and use to inform care and their connections with the residents.<sup>59</sup> Training for both



interventions was delivered by members of the research team to nursing home staff.<sup>50,59</sup> Staff training content, strategies, and dose were not clearly described.

### Patient-Level Outcomes

#### Distress behaviors

Agitation (CMAI). The trial that randomized patients to patient life histories versus a medical history control arm<sup>59</sup> included 73 patients and reported patient agitation using the CMAI. Results were reported at 2 time points that were from baseline to post intervention (which occurred at 20 days), and then follow-up at 46 days. No significant intervention effects were found as measured by CMAI. With the inclusion of cognitive impairment as a covariate in the model to assess differences between groups over time, the 2 groups did not have statistically different changes.

Other measures of agitation. The same life history study also measured agitation using the aggression behavior scale (ABS),<sup>59</sup> while the other 2 studies examining the TREA intervention measured agitation using the agitation behavior mapping instrument (ABMI).<sup>50,54</sup> For the life history study,<sup>59</sup> analysis of ABS change scores from post intervention to follow-up was nonsignificant. Over the 10-day intervention of TREA<sup>54</sup> during a 4-hour period of greatest agitation compared to the control group, there was a significant decrease in overall agitation from baseline (p = 0.002). In a second TREA study,<sup>50</sup> overall, verbal, and nonaggressive physical agitation scores were significantly reduced compared with a control group during a 2-week observation period.

### Quality of life

The life history study<sup>59</sup> also examined changes in quality of life. Although unadjusted analyses found a significant difference favoring the intervention (p < 0.01), the finding was no longer significant after accounting for baseline characteristics including cognitive impairment.

Table 2. Summary of Evidence for Patient-Focused Intervention Activities

Number of Studies	3 studies
ROB 2 Risk of Bias	Some concerns (N = 3)
Study Year Range	2007 to 2016
Number of Participants	365
Outcome Measured	
CMAI	1 intervention (1 inadequate data)
Quality of Life	1 intervention (1 significant beneficial effect)

Abbreviations. CMAI=Cohen-Mansfield Agitation Index.

### Health Care Worker-Focused Intervention Activities Only

### Intervention Characteristics

Six studies tested interventions activities focused solely on improving HCW skills and knowledge or altered HCW responsibilities or team roles (Table 3). These interventions primarily centered on 2 areas: (1) providing general education about dementia and/or (2) building staff skills to cope with distressed behaviors or implementing a tool, such as an assessment to identify the underlying causes of distress. These studies all took place in nursing homes or assisted living facilities and tested the interventions among individuals with dementia.

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Five of the 6 studies included a general education activity that provided information to HCWs about dementia and the basic principles of distressed behavior. Five of 6 studies provided training in skills and intervention implementation. These studies tested skills-based interventions related to adopting methods of verbal and motor stimulation, directly addressing the distress behaviors, improving communication with residents, developing care plans, and using skills to reduce restraint and medication use.

Reported training strategies included coaching,<sup>51,61</sup> supervision,<sup>38</sup> role play,<sup>56</sup> case vignettes,<sup>56</sup> and guidance groups to apply skills.<sup>43</sup> All interventions were delivered in person. Interventions were generally delivered to all HCWs employed at the nursing home or assisted living facility.<sup>38,41,43,51,56</sup> Intervention dose ranged from a single 2-hour session<sup>41</sup> to a 2-day seminar followed by 6 monthly group meetings.<sup>43</sup> The majority of studies delivered the intervention through multiple sessions,<sup>38,43,51,56,61</sup> and 4 included supervision or coaching after the education intervention.<sup>38,43,51,56</sup> While most studies did not report the training and credentials of the interventionist, 1 study did report that the training was provided by a clinical psychologist with geriatric mental health experience.<sup>56</sup> The studies in this section did not refer to a theoretical model used to guide the intervention.

All but 1 study were found to have some concerns for risk of bias (ROB) with 1 low ROB. Common sources of concern for ROB for these studies include issues with randomization, missing patient data, deviations from the intended intervention, and outcome measurement.

#### Patient-Level Outcomes

#### Distress behaviors

Agitation (CMAI). Three studies reported patient agitation using the CMAI and none found a significant improvement. One French study of 16 nursing homes provided education on dementia and distress behaviors, as well as pocket training cards offering practical advice on how to handle such behaviors followed by ongoing feedback sessions over 2 months. The study found no significant difference in total CMAI score at 8 or 20 weeks compared to baseline (Appendix). A second study of 24 Norwegian care homes delivered an education program (MEDCED)<sup>43</sup> intended to identify alternative interventions to restraints to manage distress behavior followed by guidance groups over 5 months also did not find a significant different in CMAI between groups at 7 months. Of note, this study reported a statistically significant reduction in restraint use across both intervention and control groups. The third study evaluated a 6-session manual-based intervention (MARQUE) followed by monthly supervision meetings and did not find a significant reduction in agitation at 8 months (adjusted mean difference [MD] = -0.40, 95% CI [-3.89, 3.09]). A fourth study evaluated a 2-day workshop of a dementia-specific training program (STAR)<sup>56</sup> followed by 4 individual follow-up sessions over 2 months in 15 assisted living residences. This study reported a significant reduction in distress behaviors at 8 weeks using the agitated behavior in dementia scale (MD = -3.8 vs -0.5; p <0.001).

Neuropsychiatric Inventory (NPI). Four studies assessed intervention effect on patient distress behaviors using the NPI total score. Two studies with longer-term outcomes found no intervention effect, while 2 with shorter-term outcomes found that the intervention reduced patient distress behaviors in the short run. An evaluation of a 120-minute staff training on behavioral and psychological symptoms of dementia at 17 residential care facilities in Japan significantly reduced total NPI score at 30 days compared to standard care (p = 0.029), though the method used for calculating the total NPI score appears atypical. The STAR study found a significant reduction in total





NPI at 8 weeks (p = 0.031). The longer-term MEDCED study found a nonsignificant difference from baseline to 7 months between arms (5.7 vs 1.8; p = 0.207). Similarly, the MARQUE study<sup>38</sup> reported a nonsignificant adjusted mean difference of -0.84 (95% CI [-5.51, 3.84]) at 8 months. Finally, 2 studies reported NPI subscales other than agitation without a total score.

### Quality of life

Two studies reported patient quality of life and neither found an intervention effect. The 2-month French study provided dementia education, pocket training cards, and ongoing feedback sessions and found no difference at 20 weeks. The MARQUE intervention found no improvement in quality of life at 8 months either as rated by staff (MD = 0.09, 95% CI [-3.87, 4.05]) or by a family carer (MD = -0.03; 95% CI [-2.87, 2.82]).

### Antipsychotic use

Two studies reported changes in medication use and neither found an intervention effect. The 2-month French study reported no change in mean number of psychotropic drugs (which included anticholinergics, memantine, antipsychotics, anxiolytics, and antidepressants) at baseline and at 20 weeks for intervention and control groups. The MEDCED intervention designed to reduce restraint use led to a small, nonsignificant increase in use of antipsychotics from 14.1% to 17.1% in both groups at 7 months.

Table 3. Summary of Evidence for Health Care Worker-Focused Intervention Activities

Number of Studies	6 studies			
ROB 2 Risk of Bias	Low (N = 1); some concerns (N = 5)			
Study Year Range	2005 to 2019			
Number of Participants	1,689			
Outcome Measured				
CMAI	3 interventions (1 inadequate data; 2 no significant effect)			
NPI	4 interventions (1 inadequate data; 2 no significant effect; 1 significant benefit)			
Antipsychotic Use	3 interventions (2 inadequate data; 1 no significant effect)			
Quality of Life	2 intervention (2 no significant effect)			

Abbreviations. CMAI=Cohen-Mansfield Agitation Index; NPI=Neuropsychiatric Inventory; ROB=risk of bias.

#### Staff Outcomes

Two of the 3 studies that assessed HCW-focused-only interventions used subscales of the caregiver burnout instrument (Maslach Burnout Inventory, MBI).<sup>38,41</sup> The MBI has 3 subscales (emotional exhaustion, personal accomplishment, depersonalization). The 2 studies measured differences in scores at 30 days and 8 months, respectively, but neither found a difference between the intervention and control groups. The third study<sup>56</sup> evaluated the STAR intervention (*eg*, workshops and follow-up sessions on activators and consequences of behavioral distress) in assisted living facilities and measured "sense of competence and satisfaction with patient care" and supervision and coworker relations over an 8 week follow-up period, but also did not find a difference in mean scores.

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#### **Utilization Outcomes**

No included studies examined utilization outcomes.

### Health Care Worker and Patient-Focused Intervention Activities

#### Intervention Characteristics

Seventeen studies examined interventions directed at both direct patient care activities delivered by HCWs and HCW-focused trainings and role changes (Table 4). 34,37,39,40,42,45,48,49,53,55,58,62,81-83 Two of the 17 examined this combination of strategies across multiple study arms. 49,60,84 Studies were conducted in the Netherlands, 39,45,48,83 UK 40,55,62,81 USA, 53,58 Australia, 82,84 Canada, 37 Germany, 49 and Norway. 34,42,60

Five studies examined different outcomes among different patient populations using similar principles inspired by WHELD, <sup>40,81</sup> and dementia care mapping. <sup>84</sup> All interventions took place in nursing home settings and, with the exception of 1 study, <sup>34</sup> all examined outcomes exclusively in patients with dementia.

All studies implemented at least 2 distinct intervention activities, and 2 studies implemented 5 activities. <sup>39,42</sup> The most common intervention activity across studies was assessing resident dementia and behaviors to inform individualized care plans. <sup>34,37,39,40,42,45,48,49,53,58,62,81-83</sup> Other intervention activities that targeted patients included detection of distressed behaviors, <sup>34,39,42,45,84</sup> medical management, <sup>37,39,40,42,48,53,55,58,81,83</sup> and ongoing care for distressed behaviors through symptom monitoring, and, in some cases, monitoring how well the care plan was working. <sup>39,40,42,48,53,58,83</sup> Most medical management activities focused on a review of resident medications, primarily antipsychotics.

The most common intervention activity focused directly on HCWs was education about a specific intervention or approach to reduce distressed behaviors. <sup>34,37,40,42,45,48,49,51,55,58,60,62,81,82,84</sup> Topics ranged from how to implement a specific care program (*eg*, Coming to Grips with Challenging Behavior Care Program, <sup>45</sup> dementia care mapping, <sup>48,60,84</sup> and patient-centered care <sup>40,55</sup>) to how to perform case conferences, <sup>34</sup> how to develop an individualized care plan, <sup>62</sup> how to assess distressed behaviors using a specific tool, <sup>37,49</sup> and how to improve communication skills with residents (social interaction arm). <sup>81</sup> Several studies also tested the effect of general education for staff focused on dementia and distressed behaviors. <sup>34,37,39,45,49,51,84</sup> Six studies also incorporated changes to how staff functioned as a team. For example, several studies implemented multidisciplinary case conferences or care meetings. <sup>34,42,45,60</sup> Another study developed a process to create care plans that included input from nurse's aides and other staff. <sup>53</sup> Two studies trained staff to take on new roles. <sup>34,60</sup>

Among studies that reported intervention delivery mode, all but 1 had an in-person component, \$^{34,37,39,42,45,49,53,55,58,60,81-84}\$ several had a telephone or teleconference component, \$^{37,82,84}\$ and 1 was internet based. \$^{62}\$ In 1 study, trainings were delivered by a multidisciplinary team comprised of nurses, physicians, and psychologists \$^{39,49}\$; other interventions were delivered by trained (though credentials were unspecified) "therapists," \$^{40,62,81}\$ clinical social workers, \$^{53}\$ patient-centered care experts, \$^{82}\$ trained members of the research team, \$^{34,37,55,60,84}\$ nurses, \$^{34,58}\$ and dementia care mapping experts. \$^{48,60}\$ Generally a multidisciplinary team of nursing home staff were trained in each study, including physicians, \$^{37,39,42,45,53,81,83}\$ psychologists, \$^{39,45,53}\$ social workers, \$^{53}\$ nurses, \$^{34,37,39,42,45,53,58,60,82-84}\$ care managers, \$^{40,82,84}\$ nursing home staff, \$^{40,45,48,49,55,60,81-84}\$ residents, \$^{40}\$ and other staff (\$eg\$, physical)



therapists, occupational therapists, nutritionists, pharmacists<sup>37,53,82</sup>). Targeted professionals were most frequently nurses, nursing home staff, and physicians.

Training approaches and duration differed between studies. The most intensive training lasted 2 days a week for 10 months,<sup>55</sup> and the study that offered the least amount of training provided a 3-hour lecture.<sup>60</sup> Many studies used a combination of an initial training activity and follow-up supervision, coaching, or case conferences conducted in-person or via telephone.<sup>34,37,40,42,55,58,82,84</sup> Some studies also offered different tiers of training to staff. For example, several studies provided a baseline training for multiple staff and additional training in the intervention methodology to onsite champions or intervention teams.<sup>40,42,49,60</sup> In a few studies, only champions or site implementers received any training.<sup>34,48,53,81,84</sup> Several studies mentioned theoretical underpinnings for the intervention, including person-centered care, <sup>40,42,48,81</sup> normalization process theory, <sup>62</sup> DICE models, <sup>37</sup> cognitive behavioral theory, <sup>42</sup> and the VIPs framework.<sup>60</sup>

### Patient-Level Outcomes

#### Distress behaviors

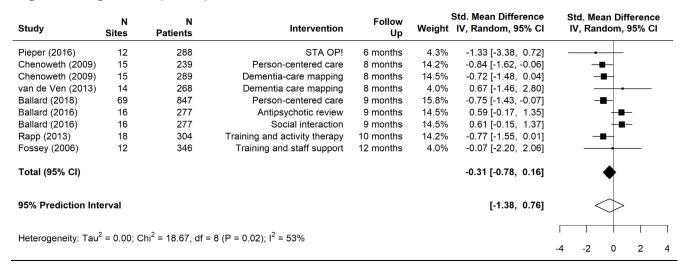
Agitation (CMAI). Eleven studies (Table 4 and Appendix) assessed reductions in agitation using the CMAI. 40,42,45,48,49,55,62,81-84 Of these, 5 reported reductions in agitation. 40,42,45,49,84 Specifically, the WHELD intervention, 40 which combined staff training, social interaction, and guidance on the use of antipsychotic medications in 69 UK care homes across a 9-month period, found significant reduction in agitation compared to treatment as usual (MD = -4.27, 95% CI [-7.39, -1.15]). In the CADRES study, 84 which compared dementia care mapping and a person-centered care intervention to usual care, CMAI scores were lower in both intervention conditions over an 8-month period (dementia care: MD = 10.9, 95% CI [0.7 to 21.1]; person-centered care: MD = 13.6, 95% CI [3.3, 23.9]). Across a 10month period, patients with dementia enrolled in the VIDEANT intervention<sup>49</sup> (consisting of staff training, support, and activity therapy) exhibited significantly less agitation (aMD = 6.24, 95% CI [2.03, 14.14]) than patients in a usual care group. For dementia residents in the Grip on Challenging Behavior care program, 45 their CMAI change scores were significantly improved compared to the preintervention control period (stepped-wedge design) between successive assessments (-2.5 points, 95% CI [-4.3, -0.6]). However, no significant effects were found for the control-to-intervention group compared with those who remained in the control group (0.0 points, 95% CI [-2.3, 2.4]). Last, in a stepwise multicomponent intervention (STA OP!) delivered to nursing home patients with advanced dementia, an overall reduction in agitation was observed compared to usual care from baseline to 6 months (MD = -4.07; 95% CI [-7.9, -0.24]). Finally, the Targeted Interdisciplinary Model for Evaluation and Treatment of Neuropsychiatric Symptoms (TIME) study reported significantly reduced agitation at 8 weeks (SMD = 0.23, p = 0.026) and 12 weeks (SMD = 0.29, p = 0.006) compared with usual care.<sup>42</sup>

Interventions in the remaining 6 studies did not significantly reduce agitation<sup>48,55,62,81-83</sup> and 2 showed a nonsignificant reduction in agitation.<sup>81,82</sup>

In a meta-analysis of 7 studies (including 9 intervention conditions), health care worker- and patient-focused interventions did not lead to a significant reduction in patient agitation (SMD = -0.31, 95% CI [-0.78, 0.16]). This result may be attributable to substantial variation in effects across studies (95% PI [-1.38, 0.76]), including across studies of the same specific intervention (Figure 1).



Figure 1. Agitation (CMAI) Results



Four studies assessed reductions in agitation using CMAI subscales.  $^{39,53,60,62}$  The subscales examined included aggressive,  $^{39,53}$  agitation,  $^{60}$  physical,  $^{53,62}$  and verbal  $^{39,53,62}$  domains. Only 1 study of the 4 indicated significant reductions in physically nonaggressive behaviors. Specifically, this study  $^{53}$  examined the effectiveness of an advanced illness care team (AICTs) intervention for nursing home residents living with advanced dementia. The AICTs intervention focused on medical, meaningful activities, psychological, and behavioral domains. Compared to usual care, nursing home residents experienced a significant decrease in physically nonaggressive behaviors across an 8-week period (p < .05).

Neuropsychiatric symptoms (NPI). Nine studies examined intervention effects in reducing overall neuropsychiatric behaviors and symptoms using the NPI total scores.  $^{34,42,45,48,60,62,81,83,84}$  Three studies  $^{60,81,83}$  found significant intervention effects. An evaluation of the impact of antipsychotic review, social interaction, and exercise interventions on neuropsychiatric symptoms at 9-month follow-up indicated significant symptom improvement favoring antipsychotic review (MD = 7.37, 95% CI [1.53, 13.22]) and a social interaction intervention (SMD = 5.45, 95% CI [0.12, 10.77]). The STA OP! study also reported an improvement from baseline to 6 months (adjusted MD = -3.57 (95% CI [-6.30, -0.84]). The effects of a person-centered dementia intervention and the VIPS practice model (VPM) compared to education of the nursing home staff about dementia only were significant at 10 months (SMD = -2.7, 95% CI [-4.6, -0.7], SMD = -2.4, 95% CI [-4.1, -0.6], respectively). In addition, 1 evaluation of a dementia care mapping intervention found that NPI scores decreased in the usual care arm but not in the intervention arm (p = 0.022).

Of the other 5 intervention arms from 4 studies, 1 found a non-significant reduction in NPI score with delivery of an interdisciplinary model (TIME; SMD = -0.25, p = 0.053). Three found no intervention effects.  $^{34,45,62}$  The fifth study did not report a direct statistical comparison, but mean scores over follow-up showed a clinically significant reduction in NPI in the patient-centered care arm but not in the dementia-care mapping arm. For 3 of these, the NPI was the primary outcome for the study.  $^{34,42,62}$  Overall, the time period of these interventions ranged between 4 and 20 months.

Eight interventions from 5 studies were included in a meta-analysis that indicated a moderate, though nonsignificant, reduction in neuropsychiatric behaviors (SMD = -0.47, 95% CI [-1.18, 0.24]) at 6-11

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months following HCW and patient-focused interventions. The prediction interval for this estimate was -2.40 to 1.46 (Figure 2), suggesting notable heterogeneity across studies.

Figure 2. Neuropsychiatric Symptoms (NPI) Results

Study	N Sites	N Patients	Intervention	Follow Up	Weight	Std. Mean Difference IV, Random, 95% CI		ean Diffe ndom, 95		
Pieper (2016)	12	288	STA OP!	6 months	6.7%	-2.94 [-5.01, -0.87]				
Moniz-Cook (2017)	63	832	Staff e-learning	7 months	13.0%	0.01 [-0.79, 0.81]		_	•	
Chenoweth (2009)	15	239	Person-centered care	8 months	13.2%	-0.53 [-1.31, 0.25]		-	-	
Chenoweth (2009)	15	239	Dementia-care mapping	8 months	13.2%	0.18 [-0.60, 0.96]		-	-	
Ballard (2016)	16	277	Antipsychotic review	9 months	13.2%	0.80 [ 0.03, 1.57]			-	_
Ballard (2016)	16	277	Social interaction	9 months	13.3%	0.65 [-0.12, 1.42]			-	_
Mork Rokstad (2013)	15	624	Dementia-care mapping	11 months	13.7%	-1.54 [-2.23, -0.85]		-		
Mork Rokstad (2013)	15	624	VIPS practice model	11 months	13.7%	-1.53 [-2.22, -0.84]		-		
Total (95% CI)						-0.47 [-1.18, 0.24]		•		
95% Prediction Interv	/al					[-2.40, 1.46]		<		>
Heterogeneity: Tau <sup>2</sup> =	0.00: Chi <sup>2</sup>	= 46.65. df = 7	7 (P = 0.00): I <sup>2</sup> = 84%							$\neg$
<b>3,</b>	,	.,	,,				-6 -4	-2	0	2

A total of 6 studies examined reduction in neuropsychiatric symptoms using NPI subscales.  $^{34,39,42,48,58,62}$  The subscales covered affective,  $^{34}$  agitation,  $^{34,39,48}$  agitation/aggression,  $^{39,42}$  apathy,  $^{34}$  distress, frequency, and incidence,  $^{62}$  psychosis,  $^{34}$  and severity  $^{62}$  domains. Only 2 studies  $^{34,42}$  reduced agitation/aggression and apathy, respectively. In 1 Norwegian study of 33 nursing homes from 20 municipalities,  $^{42}$  the TIME intervention was implemented to target moderate-to-severe agitation compared to a control group. A significant between-group difference was evidenced in reducing agitation/aggression at 8 weeks (SMD = 0.32, p = 0.03) and at 12 weeks (SMD = 0.47, p = 0.002). In a secondary Norwegian study,  $^{34}$  the implementation of a modified comprehensive geriatric assessment alongside regular case conferencing reduced apathy symptoms among nursing home residents at 3 months (SMD = -0.5, 95% CI [-0.9, -0.05]).

The 4 studies that found no or nearly zero intervention effects (compared to usual care, control, or a brief education arm) on reducing NPI agitation subscale scores included a multidisciplinary intervention focused on education and management of neuropsychiatric symptoms, <sup>39</sup> dementia care mapping, <sup>48</sup> e-learning, <sup>62</sup> and modified comprehensive geriatric assessment and case conferences. <sup>34</sup>

### Other distress behaviors

Three studies reported other challenging behaviors  $^{37,58,62}$  and none found an intervention effect. The behaviors examined included aggression/wandering behavior as assessed by worsening behavioral symptoms using the Resident Assessment Instrument-Minimum Dataset v 2.0 (RAI-MDS),  $^{37}$  severity, frequency, and increase of resident behavior using the Challenging Behavior Scale (CBS),  $^{62}$  and the BEHAVE-Alzheimer's Disease scale.  $^{58}$  An educational in-service intervention consisting of evidence-based tools to assess and monitor neuropsychiatric symptoms in dementia with monthly interprofessional team meetings found no effect at 12 months (OR = 0.96, 95% CI [0.8, 1.14]). An elearning intervention found no effects to reduce the incidence of difficult, frequent, or behavioral symptoms in dementia from baseline to 4 and 7 months. The Serial Trial Intervention (STI) study focused on the assessment and management of people with late-stage dementia. Compared to control, no significant group differences were found in reducing wandering behaviors at 4 weeks (p = 0.50).



### Quality of life

A total of 9 studies examined intervention effects to improve quality of life among patient- and health care worker-level interventions.  $^{33,40,42,48,55,60,62,82,84}$  Of these studies, 4 improved either overall quality of life using the DEMQOL-Proxy, EQ-5D index (self-report), the Quality of Life in Late-stage Dementia, the QUALID,  $^{40,42,60}$  or a facet of quality of life like restless tense behavior as assessed by the QUALIDEM observation tool.  $^{33}$  The WHELD (staff training and in person-centered care) intervention  $^{40}$  compared to treatment as usual found a significant mean difference in improving participant quality of life (MD = 2.54, 95% CI [0.81, 4.28]). The TIME intervention compared to a brief education intervention at 12 weeks (and not at 8 weeks) found a between-group difference in quality of life among those with late-stage dementia (SMD = 0.17, p = 0.044). Last, in a dementia care mapping (DCM) or a VIPS practice model (VPM) compared to control at 10 months, quality of life scores favored the DCM versus control arm (SMD = -3.0, 95% CI [-5.5, -0.6]). In the STA OP! intervention study  $^{33}$  compared to usual care, restless tense behavior symptoms (ie, facets of quality of life) improved at 3 months (95% CI [0.36, 1.54]). However, at 6 months the usual care group fared better in restless tense behavior symptoms (95% CI [-1.60, -0.36]).

Seven interventions from 5 studies were included in a meta-analysis measuring quality of life at 7 to 11 months after baseline and found a significant medium to large beneficial effect after HCW-/patient-focused interventions with an SMD of 0.71 (95% CI [0.39, 1.04]; Figure 3). Of note, the prediction interval for this effect estimate suggests marked heterogeneity of treatment effect, ranging from a small to large effect.

Figure 3. Quality of Life Results

Study	N Sites	N Patients	Intervention	Follow Up		d. Mean Difference /, Random, 95% CI	Std. Mean Difference IV, Random, 95% CI
Moniz-Cook (2017)	63	832	Staff e-learning	7 months	13.8%	0.29 [-0.51, 1.09]	-
Chenoweth (2009)	15	289	Person-centered care	8 months	15.4%	0.77 [ 0.02, 1.52]	<b></b>
Chenoweth (2009)	15	289	Dementia-care mapping	8 months	15.4%	0.05 [-0.70, 0.80]	<b>-</b>
van de Ven (2013)	14	268	Dementia-care mapping	8 months	2.3%	2.00 [-0.14, 4.14]	<b>—</b>
Ballard (2018)	69	847	Person-centered care	9 months	17.6%	0.81 [ 0.12, 1.50]	<b></b>
Mork Rokstad (2013)	15	624	Dementia-care mapping	11 months	17.7%	1.36 [ 0.67, 2.05]	<b></b>
Mork Rokstad (2013)	15	624	VIPS practice model	11 months	17.8%	0.67 [-0.01, 1.35]	-
Total (95% CI)						0.71 [0.39, 1.04]	•
95% Prediction Interva	al					[0.21, 1.22]	$\Diamond$
Heterogeneity: Tau <sup>2</sup> = 0	0.00; Chi <sup>2</sup> = 8	.97. df = 6 (P = 0	0.18); I <sup>2</sup> = 19%				
,			,,				-1 0 1 2 3 4 5

### Antipsychotic use

Eight studies assessed effects on antipsychotic medication use (Figure 4). $^{37,39,40,45,62,81,83,84}$  Trials used a cluster-randomized design,  $^{62,81,83}$  stepped-wedge design,  $^{37,39,45}$  or RCT design. $^{40,84}$  Four of the 8 studies reported changes in reducing antipsychotic medication use. $^{37,45,62,81}$  Seven interventions from 6 studies were included in a meta-analysis and found a reduced odds of antipsychotic use at 6 to 12 months with HCW-/patient-focused interventions (OR = 0.79, 95% CI [0.69, 0.91]).

In a 9-month study<sup>81</sup> that randomized patients to antipsychotic review, social interaction, or exercise alone or in combination, results suggest that antipsychotic review versus no antipsychotic review significantly reduced antipsychotic medication use (OR = 0.17, 95% CI [0.05, 0.59]). None of the other interventions (*eg*, social interaction vs no antipsychotic review; OR = 0.6, 95% CI [0.19, 1.91])





had a significant impact on medication use. The DEMCare e-learning intervention<sup>62</sup> based on a functional analysis of dementia behaviors was compared to usual care, revealing a small nonsignificant reduction in medication use (chi square > 0.999) from baseline to 7-month follow-up. A multi-component intervention<sup>37</sup> that included education in-service, monthly interprofessional team meetings, and evidence-based tools to address neuropsychiatric symptoms reported a reduction in odds of inappropriate antipsychotic prescribing from baseline to 12-month follow-up (OR = 0.73, 95% CI [0.58, 0.94]). In a 20-month study examining the Grip on Challenging Behavior care program,<sup>45</sup> odds of antipsychotic prescribing were significantly lower compared with control (OR = 0.54, 95% CI [0.37, 0.80]). Similarly, in an enhanced psychosocial care intervention offering training and staff support in the care of patients with dementia,<sup>55</sup> there was a significant 19.1% reduction in neuroleptic prescription use in the intervention group compared with control (95% CI [0.5%, 37.70%]). Finally, a trial of the VIDEANT intervention (consisting of staff training, support, and activity therapy) found that nursing home residents with dementia in the intervention group compared to controls received fewer neuroleptics (OR 0.79, [95% CI 0.64, 0.98]) within a 10-month period.<sup>49</sup>

Figure 4. Antipsychotic Use Results

Study	N Sites	N Patients	Intervention	Follow Up	Weight IV	Odds Ratio 7, Random, 95% CI	Odds Ratio IV, Random, 95%	CI
Appelhof (2019	) 13	274	Grip on neuropsychiatric symptoms	6 months	22.1%	0.99 [0.74, 1.33]	+	
Pieper (2016)	12	288	STA OP!	6 months	2.0%	0.87 [0.33, 2.30]		
Ballard (2016)	16	277	Antipsychotic review	9 months	1.2%	0.17 [0.05, 0.59]		
Ballard (2016)	16	277	Social interaction	9 months	1.4%	0.60 [0.19, 1.91]		
Rapp (2013)	18	304	Training and activity therapy	10 months	39.9%	0.79 [0.64, 0.98]	=	
Fossey (2006)	12	346	Training and staff support	12 months	1.0%	0.41 [0.10, 1.63]		
Kirkham (2020)	) 10	1745	OPAL	12 months	32.4%	0.73 [0.58, 0.94]	=	
Total (95% CI)						0.79 [0.69, 0.91]	•	
95% Prediction	n Interval	I				[0.69, 0.91]	$\Diamond$	
11-4	T2 - 0	00: 0b <sup>2</sup> - 0.04	$df = 6 (P = 0.14); I^2 = 0\%$					
Heterogeneity:	rau = 0.	.00; Cni = 9.64, (	at = 6 (P = 0.14); T = 0%				0.05 0.5 2	8
							Favors Intervention	Favors Contro

#### Other medication use

In addition to the above, reductions in other medications such as anxiolytics, psychotropics, neuroleptics, and ChEI were examined in 4 studies.<sup>39,45,49,55</sup> The BEYOND-II trial<sup>39</sup> found no evidence of reduced use of anxiolytics (regression coefficient = -0.033, 95% CI [-0.095, 0.029]) nor any psychotropic medication (regression coefficient = -0.023, 95% CI [-0.09, 0.044]) from baseline to 6 months. Similarly, in an enhanced psychosocial care intervention offering training and health care teams support in the care of patients with dementia,<sup>55</sup> reductions in psychotropics were nonsignificant with a weighted mean difference of -5.9 (95% CI [-27.2, 15.5]). No support for reduction in prescribed anxiolytics was found (*ie*, odds ratios were not significantly lower) after introducing the Grip on Challenging Behavior care program<sup>45</sup> compared to control. Table 4 presents results for the HCW- and patient-focused interventions.

Table 4. Summary of Evidence for Health Care Worker and Patient-Focused Intervention Activities

Number of Studies	17 studies
ROB 2 Risk of Bias	Low $(N = 1)$ ; some concerns $(N = 15)$ , high $(N = 1)$
Study Year Range	2006 to 2022
Number of Participants	6,377
Outcome Measured	
CMAI	11 interventions (2 inadequate data; 5 no significant effect; 4 significant benefit)
NPI	10 interventions (1 inadequate data; 4 no significant effect; 3 significant benefit; 2 significant detrimental effect)
Antipsychotic Use	9 interventions (1 inadequate data; 6 no significant effect; 2 significant benefit)
Quality of Life	9 interventions (7 no significant effect; 4 significant benefit)

Abbreviations. CMAI=Cohen-Mansfield Agitation Index; NPI=Neuropsychiatric Inventory; ROB=risk of bias.

#### Staff Outcomes

Two studies<sup>48,62</sup> measured staff outcomes; there were no common measures (measures included quality of life as measured by the EQ-5D, attitudes toward people with dementia, and perceived self-efficacy in caring for people with dementia, MBI, stress symptomology, staff job satisfaction). Neither study demonstrated an improvement in staff outcomes at 4 to 8 months.

### **Utilization Outcomes**

No included studies examined utilization outcomes.

### Health Care Worker, Patient, and Environment-Focused Intervention Activities

#### Intervention Characteristics

Three studies conducted in the United States tested similar interventions targeting patients, staff, and environment<sup>35,36,44</sup> which were based on the social ecological model and social cognitive theory (Table 5). Intervention activities focused on HCWs included skills and implementation training that focused on providing proactive, function-focused care. All 3 interventions also targeted patient behaviors by training staff to develop tailored care plans for residents. One intervention also provided ongoing care to address resident distress by evaluating the effect of the care plan and instituted multidisciplinary team meetings.<sup>36</sup> The interventions also included assessments of the physical settings and a review of residential care policies to inform modifications to the environment that would optimize function and physical activity for residents. All interventions were provided to staff in person by a trained nurse. Staff targeted by the training included nurses, social workers, and activity staff.<sup>35,36,44</sup> One study also included families and residents in the training.<sup>44</sup> Training was fairly intensive, ranging from 10 hours per week for 12<sup>35</sup> or 6 months<sup>44</sup> to 2 hours per month for 12 months.<sup>36</sup>



#### Patient-Level Outcomes

#### Distress behaviors

Agitation (CMAI). Three studies reported patient agitation using the CMAI; 2 of these studies did not find a significant improvement. One cluster-randomized trial consisted of 4 assisted living facilities, 96 patients, and 76 nursing staff delivering the Function Focused Care Intervention for the Cognitively Impaired (FFC-CI). 44 The FFC-CI intervention is a 4-component intervention that teaches staff how to engage with patients with dementia in activities that improve function with the aim to reduce behavioral symptoms. Compared to a control group at 3 and at 6 months, no significant reductions in agitation were found as measured by CMAI (p = 0.18 and p = 0.49, respectively). A second study of 12 US-based nursing homes delivered a Function and Behavior Focused Care for the Cognitively Impaired (FBFC-CI) intervention compared to an educational control arm.<sup>35</sup> The FBFC-CI is similar to the FFC-CI, with a joint focus on function and behavior care goals. There were no significant differences in agitation from baseline to 12 months, with a mean difference of -0.06 (95% CI [-2.41, 1.69]). The third study<sup>36</sup> evaluated a 12-month, 4-component intervention facilitated by a research nurse who meets with a facility team champion and stakeholder for 2 hours per month, Function Focused Care for Assisted Living Using the Evidence Integration Triangle (FFC-AL-EIT), compared to an education-only arm. Between baseline and 4 months, there was a statistically, though likely not clinically, significant decrease in agitation in the FFC-AL-EIT group compared to the control (treatment group baseline of 14.79 decreased to 14.64 and the control group increased from 14.55 to 14.88, p = 0.045). At 12 months this difference was no longer significant (p = 0.17).

### Antipsychotic use

One study that focused on the delivery of a FBFC-CI intervention compared to an educational control found no decrease in antipsychotic use at 12 months, mean difference -0.44 (95% CI [-2.27, .64)]).<sup>35</sup>

### Staff Outcomes

The single study that examined an intervention with HCW, patient, and environment activities used staff-level outcomes related to self-efficacy and job satisfaction.<sup>44</sup> There was no difference in scores at 3 or 6 months.

### **Utilization Outcomes**

No included studies examined utilization outcomes.

Table 5. Summary of Evidence for Health Care Worker, Patient, and Environment-Focused Intervention Activities

Number of Studies	3 studies	
ROB 2 Risk of Bias	Some concerns (N = 3)	
Study Year Range	2015 to 2021	
Number of Participants	491	
Outcome Measured		
CMAI	3 interventions (3 no significant effect)	
Antipsychotic Use	1 intervention (1 no significant effect)	

Abbreviations. CMAI=Cohen-Mansfield Agitation Index; ROB=risk of bias.



### Harms (All Intervention Types)

Seven studies reported on patient harms in long-term residential or inpatient health care settings (Table 6). 37,52,55,57,62 Studies included a range of adverse events, such as falls, hospitalizations, death, and composite endpoints of multiple incidents. Across studies, falls were the most commonly reported adverse event. In a randomized controlled trial of neuroleptic prescription reduction among British nursing home patients, there was no significant difference in the number of patients experiencing falls in the intervention group (91/175, 52%) versus the usual care group at 12 months (90/165, 54%), with a weighted mean difference of 2.6 (95% CI [18.7, 23.8]). A stepped-wedge trial to reduce inappropriate prescribing of antipsychotics in long-term care found no significant difference in the baseline (15.1; SD = 1.3) and 12-month (15.2; SD = 0.8) mean number of falls in the prior month (OR = 1.00, 95% CI [0.83, 1.21]). In an Australian pragmatic cluster-randomized trial of person-centered care, dementia care mapping, and usual care, the proportion of patients with falls decreased with dementia care mapping (change from baseline = -7%) but increased somewhat with person-centered care (change from baseline = 2%). At follow-up, 10% fewer falls were reported among patients receiving dementia care mapping compared with usual care (p = 0.02). Reported proportions were adjusted for clinical and demographic characteristics, but importantly, the baseline proportion of patients with falls was much lower in the usual care group than in the intervention groups. This may have attenuated the difference in fall rates between dementia care mapping and usual care groups.

Death was an adverse event or secondary outcome in 2 studies. The first was a cluster-randomized factorial controlled trial evaluating social interaction and/or a review of antipsychotic medication use that was conducted in people with dementia in 16 nursing homes across the United Kingdom and reported death as a secondary outcome. Patients who received the medication review had reduced mortality compared to those who did not receive a review, though this reduction was not statistically significant (OR = 0.67, 95% CI [0.39, 1.14]). An increase in social interaction was associated with significantly reduced mortality (OR = 0.26, 95% CI [0.13, 0.51]). A clustered, randomized implementation trial in 18 nursing homes in Berlin, Germany, implemented guidelines to reduce agitation and review medication use. During the study, 17 residents in the intervention group and 12 residents in the control group died (p = 0.57).

Hospitalization was also reported as an adverse event in the German study. 24 intervention group patients and 22 control group patients were hospitalized (p = 0.97). In a nonpharmacologic intervention in French nursing homes, a statistically significant difference in mean baseline hospitalizations was observed between the intervention (40, SD = 23) and control (49, SD = 37.1) groups (p < 0.05), but there was no significant difference noted at 8 or 20 weeks.

Finally, 2 studies used composite measures to assess adverse events. First, a cluster-randomized trial in the United Kingdom of a staff education and decision support system intervention in care homes used the composite outcome of serious adverse events (eg, death, life-threatening event, hospitalization, significant disability or incapacity, medically significant event, alleged or suspected abuse or neglect). Eighty participants in the e-learning intervention experienced a serious adverse event (80/420, 19%), compared to 55 out of 412 (13%) usual care patients. The authors did not perform a statistical analysis between the groups. Second, the Australian trial of person-centered care, dementia care mapping, and usual care also reported a composite endpoint of incidents, capturing falls, injuries, drug errors, and behavioral events. There was no statistically significant difference (p = 0.89) when comparing over time across the 3 arms: baseline (PCC 0.43%; DCM 0.40%; UC 0.25%), 4 months (PCC 0.53%; DCM 0.49%; UC 0.37%), and 8 months (PCC 0.44%; DCM 0.46%; UC 0.37%). The authors also separated



the components of the composite endpoint to look at hospitalizations due to falls; however, they determined there were so few incidents that they did not report the number of incidents or complete statistical analysis.

Table 6. Results of Studies Reporting Harms

Study N Clusters N Patients Primary Outcome	Outcome Direction Time Point	Results
Ballard, 2016 <sup>81</sup> 16 nursing homes 277 patients randomized	Death Lower = better 9 months	Antipsychotic review vs no antipsychotic review OR = 0.67 (95% CI [0.39, 1.14]) p value: 0.15
Primary outcome: CMAI		Social interaction vs no social interaction OR = 0.26 (95% CI [0.13, 0.51]) p value: <0.001
Chenoweth, 2009 <sup>84</sup>	Incidents (falls, injuries, drug errors,	Baseline
15 care sites	and behavioral events)	Person-centered care: 0.43%
289 patients randomized	Lower = better	Dementia care mapping: 0.40%
Primary outcome: CMAI	4 months 8 months	Usual care: 0.25%
		4 months
		Person-centered care: 0.53%
		Dementia care mapping: 0.49%
		Usual care: 0.37%
		8 months
		Person-centered care: 0.44%
		Dementia care mapping: 0.46% Usual care: 0.37%
		Arm x time <i>p</i> value: 0.89
Chenoweth, 200984	Falls	Baseline
15 care sites	Lower = better	Person-centered care: 0.32%
289 patients randomized Primary outcome: CMAI	4 months 8 months	Dementia care mapping: 0.27% Usual care 0.13%
		4 months
		Person-centered care: 0.37%
		Dementia care mapping: 0.24%
		Usual care 0.27%
		8 months
		Person-centered care: 0.34%
		Dementia care mapping: 0.20% Usual care: 0.30%



Study N Clusters N Patients Primary Outcome	Outcome Direction Time Point	Results
		Mean difference between person-centered care and usual care: 0.15 (95% CI [0.02, 0.28]), <i>p</i> value: 0.03
		Mean difference between dementia-care mapping and usual care: 0.24 (95% CI [0.08, 0.4]), <i>p</i> value: 0.02
		3 arms x time p value: 0.13
Fossey, 2006 <sup>55</sup> 12 nursing homes 346 patients randomized	Falls Lower = better 12 months	Training and staff support intervention: 19/175
Primary outcome: neuroleptic use	12 monuis	Usual care: 90/165
·		Weighted mean difference between training and staff support and usual care: 2.6 (95% CI [-18.7, 23.8]), <i>p</i> value: 0.27
Kirkham, 2020 <sup>37</sup> 10 long-term care facilities	Falls in the last 30 days Lower = better	OPAL intervention baseline mean: 15.1 (SD = 1.3)
Primary outcome: antipsychotic use	12 months	OPAL intervention at 12-month follow-up mean: 15.2 (SD = 0.8)
		OR = 1.00 (95% CI [0.83, 1.21]), <i>p</i> value: 0.98
Moniz-Cook, 2017 <sup>62</sup>	Serious adverse events (eg, death, life-threatening event, hospitalization,	e-learning intervention: 80/420
63 care homes 832 patients randomized Primary outcome: NPI	significant disability or incapacity, medically significant event, alleged or suspected abuse or neglect)  Lower = better  4 months  7 months	Usual care: 55/412

### Intervention Complexity Across KQ1 (iCAT\_SR)

In addition to categorizing the intervention characteristics by intervention activity target, we also rated intervention complexity across intervention types (*eg*, staff only, patient and staff only) (Table 7). As a reminder, our team assessed studies using iCAT domains that were most relevant to the purpose of this systematic review.<sup>26</sup> The domains that we used to assess intervention complexity included number of activities, number of actions, number of organization categories, degree of tailoring, degrees of interactions, and nature of the causal pathway. Broadly, across all KQ1 studies, many interventions included more than 1 active component with intervention actions directed at changing more than 1 HCW behavior. For example, Appelhof et al<sup>39</sup> tested the BEYOND-II study for young-onset dementia that included 2 active components: staff education and a 5-step care program to manage distress behaviors. The BEYOND-II intervention aimed to (1) increase HCW ability to work in





multidisciplinary teams, (2) train HCWs to design, implement, and evaluate tailored treatment plans for residents, and (3) reduce resident distress behaviors.

In addition, many interventions included a high level of interaction between intervention activities. The Appelhof et al study is an example of a study judged to have a high level of interaction between activities because the steps in the care program to reduce resident distress behaviors were interdependent. As part of the care program, staff observed residents to detect distress behaviors, nurses analyzed these observations to identify unmet needs, and then nurses, physicians, and psychologists met in a multidisciplinary case conference to develop a tailored treatment plan for each resident. Staff then evaluated whether the care plan reduced distress behaviors; if distress behaviors were not reduced, the process was repeated until the team developed a treatment plan that mitigated distress behaviors.

Tested interventions were also fairly flexible indicated by moderate to high degrees of tailoring, often through individualized treatment plans (*eg*, Appelhof, 2019<sup>39</sup>). Generally, we assessed studies with more intervention targets to also have higher degrees of tailoring. Interventions displayed the least amount of complexity in the nature of the causal pathways. Specifically, most interventions acted on a clear and short-term causal pathway between the intervention and outcome; only 2 interventions were rated as having a causal pathway that included 3 or more steps. For example, the BEYOND-II intervention was assessed to have a short, linear causal pathway because the treatment plans were hypothesized to have a direct impact on reducing distress behaviors by addressing unmet needs.<sup>39</sup> On the other hand, the social interaction intervention arm examined in a study by Ballard et al<sup>57</sup> was judged to have a more variable, longer causal pathway because staff received education about how to implement social activities to enhance resident interactions with staff, family, and volunteers in an effort to reduce distress behaviors. The causal pathway between staff education about social activities and impacts on distress was determined to be somewhat variable because social interactions do not directly address all unmet needs of residents displaying distress behaviors.

The intended intervention target and the number of targets influenced how complex the interventions were. Among patient-only interventions, levels of complexity were lower across all domains, except for degree of tailoring and degree of interaction. For interventions focused only at the staff level, interventions were slightly more complex than patient-only interventions, but less complex than interventions with more than 1 target. One notable exception to this observation was degree of tailoring, which was lower generally among staff-only interventions than interventions in other component areas, including patient-only interventions. Interventions in the patient and staff and the patient and staff and environment groups were fairly complex across all domains. We observed the most complexity in the domains of number of actions, degree of tailoring, and degree of interactions. Compared with single-target interventions, the multi-target interventions were slightly more complex in the nature of the causal pathway.



Table 7. Intervention Complexity (Assessed by iCAT\_SR)

Study	Study Design	Number of Activities	Number of Actions	Number of Organization Categories	Degree of Tailoring	Degree of Interactions	Nature of the Causal Pathway
Patients Only							
Cohen-Mansfield 2007 <sup>54</sup>	Cluster-randomized trial						
Cohen-Mansfield 2012 <sup>50</sup>	Cluster-randomized trial						
Eritz 2016 <sup>59</sup>	Cluster-randomized trial						
Health Care Workers Only	,	•					
Deudon 2009 <sup>51</sup>	Cluster-randomized trial						
Fukuda 2018 <sup>41</sup>	Cluster-randomized trial						
Leone 2012 <sup>61</sup>	Cluster-randomized trial						
Livingston 2019 <sup>38</sup>	Cluster-randomized trial						
Teri 2005 <sup>56</sup>	Cluster-randomized trial						
Testad 2016 <sup>43</sup>	Cluster-randomized trial						
Health Care Workers and	Patients	•					
Appelhof 2019 <sup>39</sup>	Stepped-wedge randomized trial						
Ballard 2018 <sup>40</sup>	Cluster-randomized trial						
Ballard 2016 <sup>57</sup>	Cluster-randomized trial (factorial)						
Chapman 2007 <sup>53</sup>	Cluster-randomized trial						
Chenoweth 2014-PCC <sup>46</sup>	Cluster-randomized trial						
Chenoweth 2009 <sup>52</sup>	Cluster-randomized trial						
Fossey 2006 <sup>55</sup>	Cluster-randomized trial						
Moniz-Cook 2017 <sup>62</sup>	Cluster-randomized trial						
Kirkham 2020 <sup>37</sup>	Stepped-wedge randomized trial						
Klapwijk 2018 <sup>33</sup>	Cluster-randomized trial						
Kovach 2006 <sup>58</sup>	Cluster-randomized trial						
Lichtwarck 2018 <sup>42</sup>	Cluster-randomized trial						



Study	Study Design	Number of Activities	Number of Actions	Number of Organization Categories	Degree of Tailoring	Degree of Interactions	Nature of the Causal Pathway
Mork Rokstad 2013- DBM <sup>60</sup>	Cluster-randomized trial						
Mork Rokstad 2013- PCC <sup>60</sup>	Cluster-randomized trial						
Rapp 2013 <sup>49</sup>	Cluster-randomized trial						
Stensvik 2022 <sup>34</sup>	Cluster-randomized trial						
Van de Ven 2013 <sup>48</sup>	Cluster-randomized trial						
Zwijsen 2014 <sup>45</sup>	Cluster-randomized trial						
Health Care Workers, Patients, and Environment							
Galik 2015 <sup>44</sup>	Cluster-randomized trial						
Galik 2021 <sup>35</sup>	Cluster-randomized trial						
Resnick 2021 <sup>36</sup>	Cluster-randomized trial						

*Notes*. Grey = unable to assess; darker blue = more complex.

Number of activities = # of active, independent components, *eg*, staff training & patient assessment; number of actions = # of actions/behaviors performed by intervention recipients which the intervention is trying to change, *eg*, multidisciplinary case conferences & medication reviews; number of organization categories = # of organization categories directly engaged by the intervention, *eg*, providers, nurses, administrative staff; degree of tailoring = amount of tailoring allowed across sites or individuals in applying the intervention, *eg*, choice of assessment tools, menu of training topics; degree of interactions = interdependency between intervention activities, *eg*, earlier intervention activities necessary to complete later ones; nature of causal pathway = relationship of steps between intervention and outcome, *eg*, duration from intervention to expected outcomes.

## VA-Specific Studies

We identified 5 articles that addressed VA-specific interventions. <sup>47,85-88</sup> All 4 were program evaluations of the Staff Training in Assisted Living Residences (STAR)-VA program that had been implemented in VA Community Living Centers (CLCs). <sup>56</sup> Two articles reported on patient outcomes and staff feedback on the program after implementation with 71 Veterans, <sup>47,56,86</sup> 1 reported outcomes from 302 Veterans from 71 CLCs, <sup>85</sup> 1 compared use of as-needed psychotropic medications between 229 STAR-VA cases and 1,163 matched comparison cases from CLCs that did not implement STAR-VA, <sup>88</sup> and 1 evaluated staff injury after STAR-VA training. <sup>87</sup>

In response to limited use of evidence-based nonpharmacologic interventions to address behavioral symptoms impacting the quality of life of Veterans living with dementia, the VA's Office of Mental Health and Suicide Prevention (OMHSP) adapted the STAR program for implementation in Community Living Centers (CLC) to create STAR-VA.<sup>89</sup> STAR-VA is a manualized, interdisciplinary psychosocial intervention led by a behavioral coordinator (BC) and registered nurse (RN) champion team. BCs are either psychologists, psychiatric mental health nurse practitioners, or psychiatrists. After





attending a 3-day intensive workshop, followed by a 6-month case-focused, competency-based mentorship period to ensure fidelity to the intervention, the BC-RN team assists CLC staff to operationalize 4 inter-related components: (1) develop realistic expectations of a Veteran's needs, based on understanding of how major neurocognitive disorders influence communication and behavior; (2) engage in effective communication approaches, including a technique known as listen with respect, comfort, and re-direct; (3) identify and change activators to and consequences of targeted challenging behaviors; and (4) increase frequency of personally relevant and meaningful pleasant events consistent with the person's current preferences.

The process of delivering these components is highly individualized to each Veteran by using a structured assessment, individualized goal setting, and care planning approach to operationalize the core components. The intervention uses the theory of person-environment fit<sup>90</sup> and social learning theory. Importantly, these reductions in frequency and severity of targeted behaviors were clinically significant. For example, in 1 analysis (N = 302 Veterans), the average target frequency of behavior was reduced from 3-6 times per week to 1-2 times per week. This same analysis found a reduction in agitation as measured by the CMAI of -2.6 (-10.2% change; p < 0.001). Similarly, an earlier analysis of data from 71 Veterans noted a 27.3% reduction in CMAI from 28.5 (SD = 6.6) to 20.8 (SD = 4.8) with a p < 0.0001. Moreover, implementation of STAR-VA resulted in an average reduction in "as needed" psychotropic medication use of 0.92 doses per month (95% CI [-1.82, -0.02]) compared to no reduction in matched CLC controls. Staff feedback on the program in these evaluations was generally positive. In the evaluation of the STAR-VA on staff injury due to assault, a reduction was noted in the year after training (p = 0.04), but rose again in the subsequent year.

Considering the key components of STAR-VA, we see a similar intervention complexity to other identified multi-level interventions (*eg*, those that target both HCW and patient management). Specifically, it features multiple intervention components requiring multiple actions of the involved health care team with significant tailoring to individual patients. Moreover, the interaction between the described components is significant (*eg*, using effective communication approaches could contribute to increasing frequency of personally relevant and pleasant events).



# **KEY QUESTION 2: TRANSITIONS AMONG HEALTH CARE SETTINGS**

## **Key Points**

- Two studies evaluated patient distress behaviors during or around a transition from 1 residential setting to another residential setting that was engineered to provide a more supportive environment and which required changes in HCW responsibilities and/or workflow patterns.
- One study of 116 patients relocated to a newly built facility with improved features (eg, improving lighting, access to indoor ambulation) found a significant reduction in distress behaviors as measured by NPI among the 14 residing in special care units for patients with advanced dementia and no change in the other 112 patients. The second study found no change in "negative affect or inappropriately engaged."
- We did not identify any eligible studies that evaluated interventions focused on transitions from 1 health care setting to another (*eg*, hospital to home).

#### Intervention Characteristics

We identified 2 studies that met inclusion criteria to address patient distress behaviors during or around a transition in location. To both studies, patients were transitioned from 1 residential setting to another residential setting that was engineered to provide a more supportive environment. We found no studies addressing distress behavior management during transitions from inpatient settings to long-term care or inpatient/long-term care to home.

Neither study referenced an underlying theory, and only the Australian study included a component of intervention fidelity through the mention of a manualized approach. Using the definitions for iCAT criteria, these interventions were relatively simple compared with interventions in KQ1, including only 1 activity (move to a different setting), a single target (the patient), and with no<sup>76</sup> to moderate<sup>77</sup> levels of tailoring. However, in the Australian study, the intervention was directed to both patients and home care staff who were expected to change how they engaged with the patients.

### **Patient-Level Outcomes**

The first relevant study<sup>76</sup> was conducted in France and evaluated behavioral and psychiatric symptoms changes among 116 residents with dementia who were relocated to a newly built facility featuring improving lighting, access to indoor ambulation, and outdoor spaces for ambulation and leisure. Of the 116 patients, 102 resided in regular units and 14 in special care units that were dedicated to patients with Alzheimer's disease. Distressed behaviors, as measured by the NPI-NH, were significantly reduced among residents in the special care units at 4 weeks (MD = -10.8, p < 0.001) and 12 weeks (MD = -14.08, SE = 2.9, p < 0.001). In contrast, there was no decrease in symptoms for those in regular units (MD at 12 weeks = -0.8, p = 0.45). The interaction between time and unit type was significant at week 4 (95% CI [-15.6, -3.1]) and week 12 (95% CI [-19.5, -6.8]). This study was considered at moderate risk of bias due to lack of information about dropouts and missing data.

A second study<sup>77</sup> based in Australia measured behaviors of 55 nursing home residents with moderate-to-severe dementia before and after they were relocated from an outdated facility to a newly built setting made of 5 cottages designed specifically for the needs of 15 patients with dementia per cottage and intended to be "home-like." In addition to the location change, staff working with residents also received a 1-week training workshop focused on engaging residents with life-skill activities. Resident



distress measured by observer determination of "negative affect or inappropriately engaged" was analyzed for 43 residents with complete data and no significant difference was found in distress over 3 time points (before the transition, after the transition but before the training, and after the training). This study was considered at high risk of bias due to imbalance in disease burden between intervention and control groups, high dropout rate, new replacement participants added after study initiation, and intervention deviations.



# **KEY QUESTION 3: INPATIENT MENTAL HEALTH SETTINGS**

## **Key Points**

- Two primarily staff-focused interventions were evaluated across 3 articles.
- A theoretically driven, multifaceted intervention with 10 packaged activities (eg, Safewards) was found to reduce the rate of conflicts per shift by 15% (risk ratio [RR] = 0.85, 95% CI [0.76, 0.94]) and the rate of containment events by 26.4% (RR = 0.77, 95% CI [0.66, 0.90]). A second evaluation of a single-site staff education program with ongoing monitoring reduced the average number of aggressive incidents towards peers or objections by 6 to 2.

#### Intervention Characteristics

Two interventions (3 studies) focused on staff-facing activities in the inpatient mental health treatment setting. <sup>78-80</sup> In both interventions, staff education was a key component. In a randomized trial of 31 acute inpatient mental health wards from 15 British hospitals, a theoretically driven (eg, Safewards), multifaceted intervention with 10 packaged activities (eg, de-escalation model, access to distraction and sensory tools for patients, standards of behavior for staff) aimed at staff training was evaluated with respect to the impact on staff-patient conflict and containment. <sup>78</sup> Both interventions were fairly complex per iCAT standards. They were staff-focused, multi-component interventions that were moderately tailored to address resident and staff behavior.

#### Patient-Level Outcomes

Conflict was measured by charge nurse observation per shift using a checklist and included 22 types of conflict events including verbal aggression, substance use, and self-harm attempts; containment was similarly measured and accounted for 8 types of containment (*eg*, coerced medication, restraints). At 16 weeks, rate of conflicts was reduced by 15% in the intervention arm per shift (RR = 0.85, 95% CI [0.76, 0.94]) and rate of containment events was reduced by 26.4% (RR = 0.77, 95% CI [0.66, 0.90]). Notably, data collection for the primary outcomes was low due to <50% of data collection forms being submitted; sensitivity analyses showed that missingness was slightly greater in the control group (OR = 0.87, 95% CI [0.74, 1.03]). A later program evaluation<sup>79</sup> conducted a cross-sectional survey of staff after the government-funded implementation of Safewards across 7 self-selected health services in Australia. After 9-12 months of implementation, 76 staff reported a positive impact of the intervention on verbal conflicts (42% usually or always) and physical conflicts (34% usually or always). Fifty-four percent of staff reported usually or always feeling "positive about being on the unit," and 38% reported feeling safer. This program evaluation was considered at serious risk of bias largely due to the optional nature of the staff survey.

A second study evaluated the effect of a staff education program that emphasized communication skills, environmental changes, incident reporting, medication management, and resident activities in a community-based, long-term 170 bed neurobehavioral rehabilitation program setting. <sup>80</sup> Staff received skills assessments, a day-long training, in-service training, and ongoing monitoring to improve staff self-efficacy. At 15 months among 267 patients with a minimum stay of 5 days, the average number of aggressive incidents toward peers or objects per month per quarter had been reduced by 77%, from 6 to 2. This study was considered at serious risk of bias largely due to high turnover of patients, lack of blinded outcomes assessment, and lack of consideration of confounding.



# DISCUSSION

Across 43 studies evaluating the impact of health care team-focused interventions on the management of distress behaviors among older adults, the majority of the available literature focused on the evaluation of interventions in the long-term residential health care setting among patients with dementia. Most interventions were fairly complex with multiple active components. Activities were intended to address multiple HCW behaviors and relied on a high level of interaction between intervention activities. Interventions incorporating activities focused only on HCWs through education or skills development may have some short-term benefit on distress behaviors, but there is no evidence supporting longer-term reductions in distress behavior or benefit on patient quality of life. Interventions that included both HCW education and training, as well as structured patient care activities, were found to improve quality of life and reduce the odds of antipsychotic use; while results were inconclusive about reducing patient distress, these intervention effects were generally in the direction of being beneficial. The few studies that examined staff-level outcomes of long-term health care setting interventions did not observe beneficial effects. There were few studies that examined interventions involving transitions in locations of care or that evaluated multi-faceted interventions from inpatient mental health settings.

The certainty of evidence (COE) ranged from very low to high certainty (Table 8). Within the patient-only intervention category, only 1 study was eligible for GRADE given the few studies in this category and inconsistent effect estimate reporting. This study showed moderate COE of no effect of patient-only interventions on quality of life. Studies in the HCW-only intervention category were graded as low or very low COE due to risk of bias, inconsistency, and serious imprecision. Specifically, 3 studies showed low COE of no effect of HCW interventions on CMAI; 4 studies showed very low COE of no effect on NPI; and 2 studies showed low COE of no effect on quality-of-life outcomes. Eight studies in the HCW-/patient-focused intervention category were rated as high COE for the reduction in antipsychotic use. Eleven showed moderate COE that the health care teams and patient interventions reduced distress behaviors using the CMAI, and 9 showed moderate COE of a reduction using the NPI measure. We also found moderate COE of an increase in quality of life in 8 studies evaluating health care teams and patient interventions. One study in the health care teams and patient and environment intervention category showed moderate COE of no effect of the intervention on antipsychotic use. In the same category, 3 studies showed moderate COE of no effect of the interventions on CMAI outcomes.

Our findings build on those of prior reviews. In particular, a 2016 AHRQ review of nonpharmacologic interventions on agitation and aggression in patients with dementia evaluated a variety of interventions for community settings, nursing homes, or assisted living facilities. They grouped long-term setting care models based on underlying theory and approach, specifically dementia care mapping, personcentered care, emotion-oriented care, and interventions to reduce antipsychotics. They found low strength of evidence that the effects of the first 2 are no different from usual care and insufficient evidence to draw conclusions on the latter 2. We included 15 of the studies found in the AHRQ review but grouped studies differently for analysis to capture the multi-level nature of identified interventions and overlapping approaches.



**Table 8. Certainty of Evidence** 

Outcome	Number of Studies	Findings	Certainty of Evidence (Rationale)	
Patient Only				
CMAI	1 RCT (73 patients)	Effect estimate NR	Not possible to assess	
Quality of life	1 RCT (73 patients)	Effect estimate for the adjusted analysis NR	Moderate (Downgraded for serious imprecision)	
Health Care Wo	rker Only			
Antipsychotics	1 RCT (274 patients)	Effect estimate NR	Not possible to assess	
CMAI	3 RCTs (898 patients)	Mean difference for 1 study was -0.4, <i>p</i> values ranged from 0.078 to 0.8226 in 2 studies, 1 study showed a decrease compared to control arm.	Low (Downgraded for serious risk of bias and serious imprecision)	
NPI	4 RCTs (980 patients)	One study reported mean difference of -0.84, 1 reported F statistic of 4.78, 1 reported a z score of -2.15, and 1 didn't report an effect estimate. <i>P</i> values ranged from 0.726 to 0.029 across 4 studies.	Very low (Downgraded for serious risk of bias, serious inconsistency, and serious imprecision)	
Quality of life	2 RCTs (624 patients)	One study reported a mean difference of 0.09 and a <i>p</i> value of 0.9657. One study reported an increase at 8 weeks but not at 20 weeks.	Low (Downgraded for serious inconsistency, and serious imprecision)	
Health Care Wo	rker and Patient			
Antipsychotics	8 RCT (3,476 patients)	SMD = 0.43, 95% CI [0.22, 0.84]	High (Not downgraded)	
CMAI	11 RCT (4,940 patients)	SMD = -0.31, 95% CI [-0.78, 0.16]	Moderate (Downgraded for serious ROB)	
NPI	9 RCTs (3,772 patients)	SMD = -0.47, 95% CI [-1.18, 0.24]	Moderate (Downgraded for serious ROB)	
Quality of life	8 RCTs (4,036 patients)	SMD = 0.71, 95% CI [0.39, 1.04]	Moderate (Downgraded for serious imprecision)	
Health Care Wo	rker, Patient, and Enviro	onment		
Antipsychotics	1 RCT (336 patients)	Difference between groups at 4 Moderate months 0.69 ( <i>p</i> value 0.584) and 0.44 (Downgraded for set imprecision)		
CMAI	3 RCTs (982 patients)	Mean difference in 1 study was -0.12 at 4 months to -0.06 at 12 months. The other studies did not report effect estimates. <i>P</i> values ranged from 0.729 to 0.05.	Moderate (Downgraded for serious imprecision)	

Abbreviations. CMAI=Cohen-Mansfield Agitation Index; NPI=Neuropsychiatric Inventory.





Reducing agitation or neuropsychiatric symptoms was the stated primary objective of most included studies. However, somewhat surprising was the lack of clear impact on patient distress, specifically agitation as measured by the CMAI or multiple neuropsychiatric behaviors and symptoms as measured by the NPI. It is noteworthy that for both instruments, patient distress level was reported by the staff receiving the intervention and not the patients themselves. It is possible that there was an increase in recognition of agitation behaviors due to intervention training or priming effect that balanced out any positive impact by the intervention. Meta-analyses of these outcomes were not statistically significant, which may be driven by a number of factors including heterogeneity of included complex intervention designs, small sample sizes of some included studies, and variation in effects across studies. Because benefits were apparent in some studies, results of these syntheses do not conclusively rule out a beneficial effect of interventions with both patient and HCW activities on patient distress. Instead, findings suggest that there may be contextual and intervention design factors that differ across studies and may contribute to intervention effectiveness. Indeed, the substantial variability in interventions designed to impact the same outcome suggests that results of meta-analysis should be viewed as secondary to findings from the most rigorous individual studies.

Reassuringly, we found evidence of a meaningful improvement in quality of life with interventions acting at both the HCW and patient level, even without a clear pattern of impact on agitation. One explanation is that the impact of these interventions could be felt on overall patient affect rather than distress behaviors. Affect, behavior, and mood are interconnected but distinct concepts in psychology, each contributing to our understanding of emotional and psychological experiences, 92-94 and the link may not be apparent or as strong as anticipated. Given that we found a meaningful improvement in quality of life with interventions acting at both the HCW and patient level, there may be a few mechanisms of action at play that relate to improvements in affect and thereby improve mood over time. One example is that establishing a consistent daily schedule and structured routine can help reduce confusion and anxiety. Another mechanism might relate to social engagement. Promoting social interactions and engagement with health care workers and/or caregivers can reduce feelings of isolation and may enhance opportunities for group activities and companionship. It does not necessarily fully alter agitation, but it may improve quality of life. 54,95 One challenge with this body of literature is the wide array of outcomes and intervention activities, which makes it difficult to evaluate the mechanism of action and related effect. Greater specificity and clarification regarding the intended mechanism of action for each outcome would be beneficial for this field moving forward.

Of note, we found limited data describing the impact of interventions on clinical team members or the potential mechanism of effect on this key group. Available data came from 6 studies and measured a variety of disparate constructs (eg, burnout, self-efficacy in caring for patients with dementia, job satisfaction). Regardless of the intervention components (ie, staff, patient, environment), there was consistency in results, in that there was no effect of these interventions on staff-level outcomes. Understanding the impact on HCWs of interventions designed to improve the management of distress behaviors is critical given the shortage of HCWs in long-term care settings and high rates of burnout and turnover. Some HCW outcomes, such as burnout and job stress, may be hard to impact by the types and duration of interventions included in this review because the determinants of these constructs stem from ever-evolving, system-level challenges and complications that exceed challenging interactions with patients with distress behavior (eg, understaffing, inadequate wages, job culture). Outcomes that measure more proximal experiences and focus on the relationship between staff and the specific person or people with dementia may be more sensitive to intervention-related effects (eg, self-efficacy with managing distress behaviors).



## Clinical Implications

In the context of an aging population, health care systems and long-term care facilities manage increasingly complex patients, many of whom may exhibit behaviors reflecting distress due to unaddressed personal needs and behavioral manifestations of an underlying illness or disease regardless of distress. Such behaviors can be further exacerbated by triggers or a stressful environment. The goal is not necessarily to eradicate challenging behavior but to find optimal ways to curb these behaviors and help staff be more aware of how they can empower themselves and the patient in managing these symptoms. The true goal in dementia care, or any other illness that causes distress behaviors, should transcend the focus on reducing agitation or aggression, and instead should be to improve and address patient needs. However, distress behaviors can also cause distress for HCWs and overwhelm limited resources in long-term care settings, restricting the ability to identify appropriate safe care settings for older individuals and placing tremendous pressure on family members.

Health care systems seeking to better equip health care teams to provide optimal patient-centered management of distress behaviors will need to look beyond interventions that are directed solely at health care team members or that only address patient care management patterns. The findings from this review point to the importance of multi-level interventions with activities that target health care team members, patient evaluation and management, and, likely, environmental or policy structures. This is in keeping with recent trends in care for older adults with cognitive impairment that call to enhance the quality and efficiency of care, caregiver training, and interdisciplinary longitudinal care. <sup>96,97</sup> The necessity for such complexity requires anticipation and attention to real world contextual factors that will require investment of time and resources to ensure successful, high-fidelity adoption especially across community-based long-term care facilities with widely varying resources and contexts. The VA has multiple resources as a national integrated health care system including long-term care as well as extensive implementation science expertise that could be leveraged for future multi-level interventions.

#### Limitations

It is important to note limitations of both the identified literature and our approach to conducting this review. With respect to the identified literature, the majority of included studies focused on care for patients with dementia in long-term care settings. While this field is on the forefront of managing distress behaviors, there are likely strategies and interventions being used in other settings (eg, inpatient general medicine) that could be applied across patient populations that have not made it into the published peer reviewed literature. Moreover, the interventions were almost universally complex in nature, combining components directed at multiple behaviors and clinical practices. Therefore, it was not possible to group studies for analysis based on individual intervention components (eg, antipsychotic medication review or individualized care planning) to determine which were most effective. After much consideration, we grouped studies based on intervention components identified conceptually in alignment with clinical guidance used to care for this patient population in practice. This approach likely explains the important heterogeneity in effects found in our meta-analyses. Other approaches might have led to different results. In addition, we had sought to identify interventions focused on transitions between care settings (eg, inpatient to skilled nursing facilities) and found very little addressing this vulnerable time point. Many studies described interventions with insufficient detail for replication and appropriate fidelity monitoring. We note that staff turnover is often quite high in long-term care settings, and few included studies actually reported the rates of turnover. High turnover of staff could limit the impact of interventions dedicated to skills training and knowledge gain given the need to retrain new staff. Included studies were conducted across multiple countries, which





could introduce local cultural differences and heterogeneity of regulations and clinical settings in a way that impacts how distress behaviors are managed.

There were multiple limitations with respect to the type and detail provided on outcomes reported. First, the specific definition of distress behaviors varied across studies. In addition, there were limited data on adverse events, and it was difficult to compare adverse events across studies because of differing definitions of, and time points for, measuring adverse events. For example, the definition of falls was either not explicit or varied across studies: an observed fall was an adverse event in 1 study, but other study teams did not specify whether the fall was defined as needing medical treatment or was self-reported). Similarly, there was relatively limited detail on clinical staff-level outcomes for these interventions, which is problematic because 1 of the desired outcomes of improved distress behavior management is reducing the stress and burden on staff caregivers. Further, there was no information on how these interventions impact health care utilization. We were frequently unable to pool all identified studies for a given outcome due to heterogeneity of timing of follow-up, approach to measurement, and lack of reporting of an ICC or verification that clustering was incorporated into the analytic model. This final issue is significant in this field of study as a cluster-randomized trial is the most appropriate study design to evaluate interventions delivered at the clinic or care team level, and meta-synthesis is only valid with incorporation of statistical methods to account for the effect of clustering.

In order to focus the scope of the review, we did not include search terms or eligibility criteria that would have allowed inclusion of workplace violence. Nor did we seek to include literature employing trauma-informed care, which could be informative. Literature in this area may offer translatable insights that could apply to our target population of interest. In addition, it is possible we missed studies that evaluated interventions that were not focused specifically on distress behavior management but which could have had a secondary impact. In particular, we excluded studies focused on managing delirium, as we considered the implicit short-term nature of this condition to be a distinct construct from persistent or recurrent distress behaviors with different underlying causes; however, it is possible that interventions designed to address delirium could provide relevant lessons. We purposefully did not limit the sample to studies focused on older adults with dementia in order to identify potentially effective interventions from other patient populations. However, all the studies for KQ1 focused primarily on patients with dementia. Finally, we limited our data abstraction and analysis to studies found to have low or moderate risk of bias, though studies having a higher risk of bias could provide ideas about intervention types to explore for future study.

### **FUTURE RESEARCH**

In Table 9, we make suggestions on how future studies can improve the current evidence base and move the field toward identifying more effective interventions to improve the care for older adults with distress behaviors. Expanding exploration of interventions in older adult populations without dementia will be critical. One specific population of relevance for the VA is aging Veterans with posttraumatic stress disorder (PTSD), a condition that can accelerate cognitive decline and may increase distress behaviors. Multi-level, theory-based interventions with clearly articulated mechanisms of action and alignment with intended effects measured at appropriate time points should be pursued and could provide key data needed to foster appropriate comparisons. When the goal is improving staff outcomes, higher system-level targets could be explored. After effective interventions are identified, it will be critical to develop robust, evidence-based appropriate approaches to the implementation of these complex interventions. To better understand the balance in cluster-randomized trials, greater description of site characteristics including staff turnover and leadership structure would be helpful.



Similarly, more information about who delivered the intervention and the nature of their qualifications would support replication. After effectiveness is established, it will be important to explore how patients with different types of distress behaviors and health histories (*eg*, PTSD) might respond differently to such interventions. Further, implementation-based research and pragmatic trial designs may be useful methodologic approaches to advance this field.

Table 9. Evidence Gaps

PICOTS Domain	Areas for Future Exploration			
Population	Older adults with complex behaviors at increased risk of distress behaviors who do not have dementia			
	Adults with varying stages of illness and comorbidity to explore heterogeneity of treatment effects			
Intervention	Multi-level, theory-based interventions with clearly articulated mechanisms of action and alignment with intended effect			
	Consideration of higher-level components ( <i>eg</i> , health care system culture or administration) for interventions intended to impact staff outcomes			
	Interventions that incorporate environmental changes			
	Interventions that incorporate trauma-informed care principles			
Comparator	Clearly defined usual care (eg, staffing levels, organization factors)			
	Health care staff education only			
Outcomes	Harms ( <i>eg</i> , self-injury, HCW injury)			
	Health care utilization (eg, hospital readmission, ER visits)			
	Proximal HCW outcomes (eg, self-efficacy for managing distress behaviors)			
	Healthcare worker demonstrated competency in patient-centered approaches to distress behavior management			
	Healthcare worker turn-over			
	Studies using cluster-randomized trial designs should report the intraclass correlation coefficient (ICC) or models that account for the effect of clusters			
Timing	Medium (3-6 months) and long-term outcomes (>6 months)			
-	If transitions of care, short-term after transition			
Setting	Health care settings other than nursing homes and long-term care facilities ( <i>eg</i> , inpatient medical/surgical units, ICUs, psychiatric inpatient settings)			
	Transitions of care between health care settings or health care settings and home			

### CONCLUSIONS

Novel interventions to reduce distress behaviors among older adults that feature both HCW education and training along with patient management intervention activities appear to have some beneficial impact on patient quality of life, reduction in antipsychotic use, and possibly distress behaviors. Less complex interventions, for example those focusing solely on HCW-only training, appear less likely to lead to desired effects. While more effective, complex interventions raise important questions about the challenges of high-fidelity implementation across varied long-term care settings for older adults with distress behaviors. Work remains to be done to determine the impact of these interventions on important health care staff outcomes such as burnout and systems-level outcomes such as utilization.



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