Effective Health Care Program

Comparative Effectiveness Review
Number 79

Comparison of Characteristics of Nursing Homes and Other Residential Long-Term Care Settings for People With Dementia

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting comparative effectiveness reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input from are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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The investigators deeply appreciate the considerable support, commitment, and contributions of the EPC team staff at RTI International–University of North Carolina Evidence-based Practice Center. We express our gratitude to the following individuals for their contributions to this project: Carol Woodell, B.S.P.H., our Project Manager; Megan Van Noord, M.S.L.S., our EPC Librarian; Jennifer Drolet and Carol Offen, our copy editors; Cheryl Miller, MSG; and Loraine Monroe, our EPC publications specialist.

Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform health care decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism

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Technical Experts comprise a multidisciplinary group of clinical, content, and methodologic experts who provide input in defining populations, interventions, comparisons, or outcomes as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

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Peer Reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer Reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer Reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

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Comparison of Characteristics of Nursing Homes and Other Residential Long-Term Care Settings for People With Dementia

Structured Abstract

Objectives. To compare characteristics and related outcomes of nursing homes (NHs) and other residential long-term care settings for people with dementia so as to reduce uncertainty when choosing a setting of care for someone with dementia.

Data Sources. We searched MEDLINE®, Embase®, the Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL®), AgeLine®, and PsycINFO® from 1990 through March 23, 2012. We identified additional studies from reference lists and experts.

Review methods. Two people independently selected, abstracted data from, and rated the quality of relevant studies. Given that quantitative analyses were inappropriate because of clinical heterogeneity, insufficient numbers of similar studies, or insufficient or variation in outcome reporting, we synthesized the data qualitatively. Two reviewers graded the strength of evidence (SOE) using established criteria.

Results. We identified 14 studies meeting our inclusion criteria. Generally, studies examined characteristics, structures, and process of care for populations with mild to severe dementia. Ten studies addressed health outcomes (Key Question [KQ] 1), and 10 examined psychosocial outcomes (KQ 2) for people with dementia. No eligible studies examined health or psychosocial outcomes for informal caregivers (KQ 3 and KQ 4, respectively). The studies included four prospective cohort studies, nine randomized controlled trials (RCTs), and one non-RCT. Two studies showed that the use of pleasant sensory stimulation reduces agitation. We found limited evidence on a number of interventions, including protocols for individualized care to reduce pain/discomfort and agitation/aggression and functional skill training to improve function. We found largely no differences across outcomes including function, cognition, depressive symptoms, pain, morbidity, behavioral symptoms, engagement, and quality of life based on residence in an NH or residential care/assisted living (RC/AL), other than increased hospitalization for people with mild dementia in RC/AL compared with NHs and increased restraint use in NHs compared with RC/AL for imminently dying residents.

Conclusions. Overall, we found low or insufficient SOE regarding the effect of organizational characteristics, structures, and processes of care on health and psychosocial outcomes for people with dementia and no evidence for informal caregivers. Findings of moderate SOE indicate that pleasant sensory stimulation reduces agitation. Also, although the SOE is low, protocols for individualized care and to improve function result in better outcomes. Finally, outcomes do not differ between NHs and RC/AL except when medical care is indicated. Additional research is needed to develop a sufficient evidence base to support decisionmaking.

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Executive Summary

Background

Dementia is a group of neurological conditions that lead to gradual decline in mental function. It is the most common reason for entry into long-term care settings such as nursing homes (NHs) and residential care/assisted living (RC/AL).[1] The majority of care for people with dementia is provided in the community by family members; however, increasing care needs in later stages of the illness often lead to placement in a long-term care setting. Because long-term care settings are highly varied, people with dementia and their families, who must make a decision regarding placement, would benefit from evidence-based guidance on what to choose from the available options.

Definition of Dementia

Dementia is a syndrome with multiple causes characterized by a decline in mental function, marked most commonly by memory impairment and a reduction in at least one other area of cognitive function, such as reasoning, judgment, abstract thought, registration, comprehension, learning, task execution, and use of language.[2] The most common type of dementia is Alzheimer's disease; other types include vascular dementia, mixed dementia, dementia with Lewy bodies, and frontotemporal dementia.

Prevalence of Dementia

More than 5 million Americans—as many as one in every eight individuals age 65 years or older—have dementia.[2] This number may rise to as high as 13 million by 2050.[1] Dementia increases dramatically with age; the frequency of dementia is approximately 2 percent among people ages 65 to 70 and more than 30 percent for people over 85.[3] The prevalence of dementia differs according to stage, such that by 2050 approximately 7 million people will have mild dementia, and 6 million will have moderate to severe dementia.[1] The impact of dementia relates to its stage.

Impact of Dementia

Dementia causes significant morbidity and mortality and creates a substantial burden on the people affected, as well as on caregivers, health systems, and society.[2] Dementia gradually erodes the individual's ability to make decisions; manage personal affairs; and eventually do even simple tasks such as dressing, toileting, and eating. Late stages of dementia are characterized by weight loss, limited mobility, and frequent infections so that, unless some other illness is fatal sooner, dementia will lead to death. The course of dementia from diagnosis to death is variable but typically 8 to 12 years. Costs of dementia care, including both medical care and informal caregiver time, are estimated at more than $148 billion in the United States annually.[4]

Characteristics of Long-Term Care Settings

One relevant question to ask is whether one type of long-term care setting is superior to another for dementia overall or for certain subgroups of people with dementia, such as those with

mild, moderate, or severe dementia. However, long-term care settings are complex and vary widely within licensure categories, as was highlighted in the 2001 report of the Institute of Medicine Committee on Improving the Quality of Long-Term Care.[5] Therefore, an especially relevant question is whether certain characteristics are critical in providing quality care.

Key characteristics of long-term care settings can be conceptualized in three categories: organizational characteristics, structures of care, and processes of care. Conceptually, good characteristics and structures increase the likelihood of good processes, which increase the likelihood of good outcomes.[6] Organizational characteristics are demographic, community, and licensure characteristics of long-term care settings; they include proprietary status, affiliation (e.g., chain, hospital, continuing care retirement community), location (urban vs. rural), size, cost, and resident case-mix (e.g., dementia, Medicaid, race/ethnicity), as well as the overall model of care (e.g., NH, RC/AL, Alzheimer's/dementia special care units [SCUs]). Structures of care are attributes of the setting, including physical characteristics ("bricks and mortar"); these can involve material resources (e.g., private rooms, familiar homelike components, access to outdoors), human resources (e.g., level of staffing, expertise of staff), and their operation (e.g., hours of care per resident per day by type of worker, consistency of assignment, universal worker perspective). Processes of care refer to what is actually done in giving and receiving care, and include programs and services implemented at the system/setting level in the context of care provision (e.g., assistance with activities of daily living [ADLs], involvement of informal caregivers, activity programs). For additional examples, see Table 2 in the full report.

Scope and Key Questions

Considering the central role of family caregivers in deciding which NH or other residential long-term care setting to choose when home care is no longer feasible, information on which components of these settings relate to better outcomes would be very helpful. Different long-term care settings offer different care and services, and no comprehensive evidence-based guidance exists that identifies which characteristics or settings are best for which type of person based on age, symptom severity, or other characteristics. Further, settings that are better for the person with dementia may also be better for the family caregiver, such as by bringing the family peace of mind. The objective of this review is to provide information that would help families who are trying to decide where to place a family member who has dementia and who can no longer be cared for at home.

This review sought to address the following Key Questions (KQs):

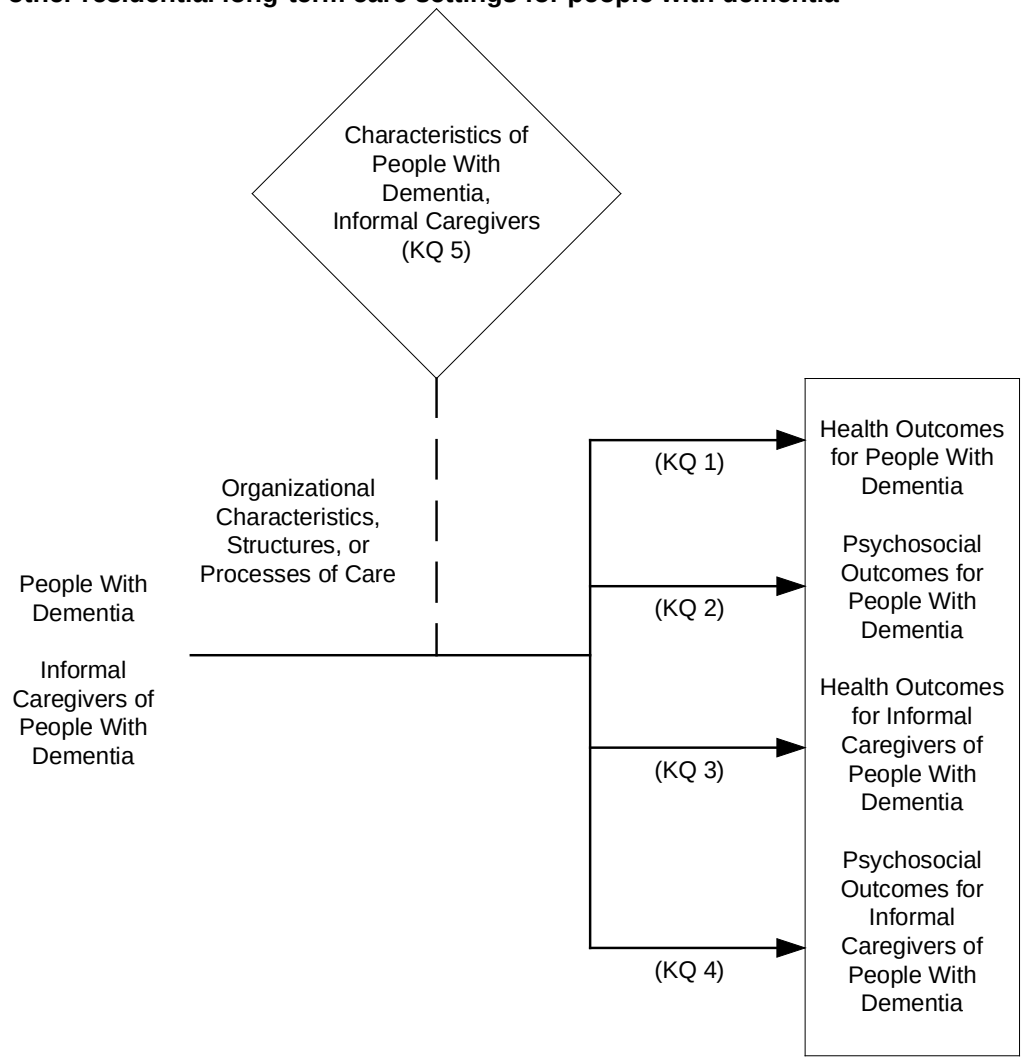
- KQ 1. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving health outcomes for people with dementia?
- KQ 2. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving psychosocial outcomes for people with dementia?
- KQ 3. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving health outcomes for informal caregivers of people with dementia?
- KQ 4. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving psychosocial outcomes for informal caregivers of people with dementia?

- KQ 5. Does the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes vary by the characteristics of the person with dementia (e.g., severity of dementia, functional status) or of the informal caregiver (e.g., age, relationship, health status)?

Wording KQ 1 and KQ 2 in terms of "improving" outcomes for people with dementia recognizes that improvement may be relative; it includes change to a better state of well-being, maintenance of the current state of well-being rather than decline, and also less decline, as opposed to more, in the current state of well-being.

We developed an analytic framework to guide the systematic review process (Figure A).

Figure A. Analytic framework for comparisons of characteristics of nursing homes and other residential long-term care settings for people with dementia



KQ = Key Question

Methods

Literature Search Strategy

Search Strategy

We searched MEDLINE®, Embase®, the Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL®), AgeLine®, and PsycINFO®. We focused our search on long-term care settings, dementia, and informal caregivers by using a variety of terms, medical subject headings (MeSH®), and key words. We reviewed our search strategy with the Technical Expert Panel and incorporated the panel's input into our search strategy.

We limited the electronic searches to English language (consistent with our focus on characteristics, structures, and processes in the United States) and humans. Sources were searched for articles published from 1990 through March 23, 2012, to reflect the changing nature and evolution of NHs and other residential long-term care settings, especially after the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Public Law 100-203), which established new regulatory standards of NH care.

We manually searched reference lists of reviews, including trials and background articles, to look for relevant citations that our searches might have missed and that addressed our KQs. We imported all citations into an electronic database (EndNote® X4).

Inclusion and Exclusion Criteria

We developed inclusion and exclusion criteria with respect to the PICOTS (populations, interventions/exposures, comparators, outcomes, timing, settings) framework. Because many studies have not required a formal diagnosis of dementia for subject inclusion, we did not require that the dementia be specified as formally diagnosed dementia. Instead, dementia could be determined by formal diagnosis, signs or symptoms (e.g., cognitive status assessment), or report by staff or an informal caregiver.

We required that a study must have explicitly stated that at least 80 percent of the population had dementia or that some analyses were specific to the subgroup of those with dementia. The rationale for this decision was to ensure that the findings were relevant and applicable to the population of interest. In addition, we examined informal caregivers as a population of interest (in KQs 3 and 4). Informal caregivers are unpaid individuals who provide care to relatives or friends.[7]

Interventions/exposures of interest included organizational characteristics, structures of care, or processes of care as defined earlier. Organizational characteristics, structures, and processes of care could either be those inherent to the setting to which people were exposed (e.g., NH vs. RC/AL) or new interventions being implemented.

We sought to compare the effectiveness of elements of interventions/exposures with one another and combinations of interventions/exposures. Comparators included various types and amounts (e.g., consistent vs. rotating staffing) of the elements or combinations of certain elements as exhibited in particular models (e.g., the Green House[8] model). We excluded studies without a comparator. We excluded studies judged to be of poor quality.

Outcomes of interest were quite broad:

- Health outcomes for people with dementia, such as pain or discomfort; depressive symptoms; sleep quality; health decline/morbidities, including skin ulcers; decline in

functioning, self-care, or maintenance; decline in cognitive functioning; falls; mortality; and hospitalizations.
- Psychosocial outcomes for people with dementia, such as positive and negative affect, including pleasure and anxiety; behavioral symptoms; engagement, quality of life; quality of dying; spiritual well-being; control, autonomy, choice; satisfaction; use of psychoactive medications; and use of restraints.
- Health outcomes for informal caregivers of people with dementia, such as depressive symptoms; sleep quality; and morbidities such as cardiovascular disease.
- Psychosocial outcomes for informal caregivers of people with dementia, such as anxiety; quality of life; caregiver burden; emotional stress, psychosocial stress; quality of relationship with person who has dementia; self-efficacy; guilt; grief reactions; perception of suffering; satisfaction; financial burden; and family conflict.

The time period of interest in choosing studies was any duration of time beginning after admission to a residential long-term care setting until either permanent transfer to another setting or death.

Settings include NHs, RC/AL, Green House homes, other small NHs, Alzheimer's/dementia SCUs, residential long-term hospice care, and continuing care retirement communities.

We confined our review to studies done in the United States so the evidence examined would be relevant to care in this country.

Study Selection

Two people independently reviewed article abstracts using the inclusion/exclusion criteria. If the reviewers agreed that the study did *not* meet eligibility criteria, we excluded it; otherwise, the two reviewers then independently reviewed the full-text article. If the reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a third member of the team. A reviewer who was also an author of a specific study was not permitted to make the final determination as to whether the study was included.

Data Abstraction

For studies that met our inclusion criteria, we abstracted important information into evidence tables. We designed and used structured data abstraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions/exposures, comparators, study designs, methods, and results. Trained reviewers abstracted the relevant data from each included article into the evidence tables. A second member of the team reviewed all data abstractions against original articles for completeness and accuracy. We recorded intention-to-treat results if available. All data abstraction was performed using Microsoft Excel® software.

Quality Assessment of Individual Studies

To assess the quality (internal validity) of studies, we used predefined criteria based on those developed by the U.S. Preventive Services Task Force (USPSTF) (ratings: good, fair, poor)[9] and the University of York Centre for Reviews and Dissemination.[10] Two independent reviewers assigned quality ratings to each study. Disagreements between the reviewers were resolved by discussion and consensus or by consulting a third member of the team. We gave poor-quality ratings to studies that had a fatal flaw (defined as a methodological shortcoming that leads to a

very high risk of bias) in one or more categories. We excluded poor-quality studies from our analyses, which could in turn affect the strength of the body of evidence.

Data Synthesis

To determine whether quantitative analyses were appropriate, we assessed the clinical and methodological heterogeneity of the studies following established guidance.[11] We examined the PICOTS, looking for similarities and differences. Because we determined that quantitative analyses were not appropriate (owing to clinical heterogeneity, insufficient numbers of similar studies, or insufficient or variation in outcome reporting), we synthesized the data qualitatively. All syntheses were evaluated by multiple coauthors.

Strength of the Body of Evidence

We graded the strength of evidence (SOE) based on the guidance established for the Evidence-based Practice Center Program.[12] This approach incorporates four key domains: risk of bias (including study design and aggregate quality), consistency, directness, and precision of the evidence. A grade of high SOE indicates we have high confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect. Moderate SOE implies we have moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of the effect and may change the estimate. Low SOE suggests we have low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate. Insufficient SOE signifies either that evidence is completely unavailable or that it does not permit estimation of an effect.

We graded the SOE for health and psychosocial outcomes for all included studies. Two reviewers assessed each domain for each key outcome; differences were resolved by consensus. Given that most outcomes had only a single study to provide evidence, consistency would be considered not applicable; when the study had estimates of effects that were not statistically significant or had wide confidence intervals, we rated that domain as imprecise. For outcomes with a single study with imprecise results and for which power was not ensured, we generally graded the SOE as insufficient; for a single study with precise results, we graded it as low. Therefore, although effectiveness is neither synonymous with precision nor with SOE, individual studies that showed an effect generally merited a rating of low SOE.

Applicability

We assessed the applicability of the evidence following guidance from AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[13] We used the PICOTS framework to explore factors that affect applicability.

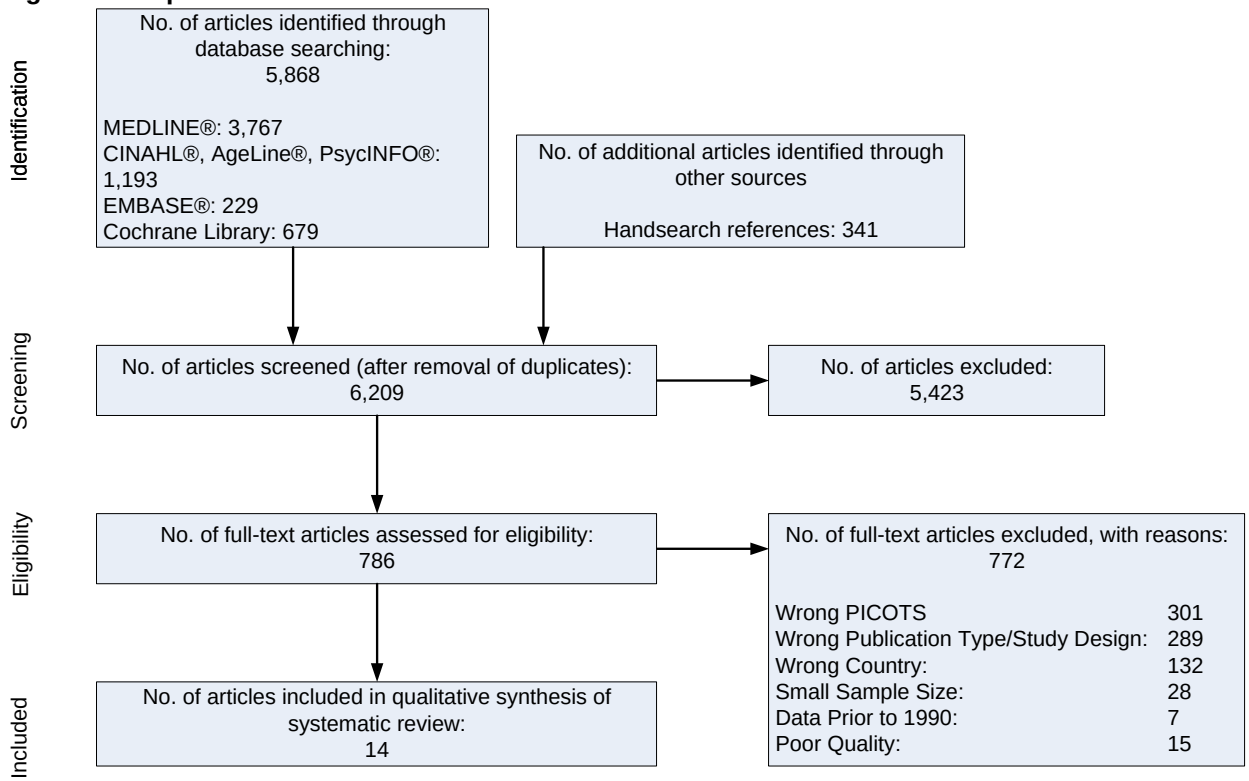
Results

This section is organized by KQ, and results are then grouped by intervention/exposure category. Summary tables and evidence tables of included studies can be found in the full report.

Results of Literature Searches

A total of 6,209 articles were identified through our database searches and hand searches of relevant articles. Results of our literature searches appear in Figure B.

Figure B. Disposition of articles



CINAHL = Cumulative Index to Nursing and Allied Health Literature; No. = number; PICOTS = populations, interventions/exposures, comparators, outcomes, timing, settings

We included 14 published articles: 9 randomized controlled trials (RCTs), 1 nonrandomized controlled trial, and 4 prospective cohort studies. We recorded the reason that each excluded full-text publication did not satisfy the eligibility criteria and compiled a comprehensive list of such studies (Appendix B of the full report).

KQ 1. Health Outcomes for People With Dementia

Of the 10 studies reviewed, 8 interventions showed statistically significant effects on health outcomes, with either insufficient or low SOE. Process of care interventions provided more evidence than did interventions focusing on organizational characteristics or structures of care.

Organizational Characteristics

Two studies addressed organizational attributes but found few differences between RC/AL settings and NH settings on a range of health outcomes; we found some differences between dementia SCUs and non-SCUs located within either RC/AL settings or NH settings (either insufficient or low SOE).

Mortality rates for residents in RC/AL compared with those in NHs did not differ in one study (low SOE).

Some evidence suggested higher hospitalization rates (low SOE) in RC/AL settings than in NH settings but little difference in new or worsening morbidity (low SOE). Among four other morbidity measures the evidence was insufficient.

Evidence on dementia SCUs was inconsistent. Residents of dementia SCUs, when compared with those not in SCUs, had greater decline in functioning over time (low SOE) and lower rates of both hospitalization and new or worsening morbidity (low SOE).

Structures of Care

One RCT found no effect for lighting interventions on sleep quality, and another RCT found no effect on depressive symptoms for the overall populations studied; both trials reported some effects for some subgroups. However, evidence was insufficient regarding the effects of lighting interventions on these outcomes and for subgroup analyses; these were single studies with imprecise results for which power was not ensured.

Processes of Care

Evidence for group activity interventions was mixed. A functional skills training intervention produced modest effect sizes for improving ADLs, with effect sizes being equivalent to moving from major to moderate or from moderate to minor assistance in performing the ADLs (low SOE). A storytelling intervention improved cognitive alertness by about three percentage points (low SOE). Two interventions had no benefits: validation group therapy intervention did not improve functional self-care or depressive symptoms, and an attention-focusing intervention did not improve cognitive impairment. However, evidence was insufficient for these two single studies regarding these specific outcomes due to imprecise results and no reported power calculations to justify sample size.

Evidence for personalized care interventions was modest. A personalized assessment and treatment intervention reduced resident discomfort with an effect size of 0.89 (low SOE). Both personalized showering and towel bath interventions reduced resident discomfort on an Alzheimer's discomfort scale by 0.32 and 0.57 points, respectively, compared with a control group score of 2.14.

KQ 2. Psychosocial Outcomes for People With Dementia

Ten studies (five RCTs) addressed psychosocial outcomes. Almost all showed some statistically significant effects on outcomes (either low or moderate SOE).

Organizational Characteristics

With one exception (restraint use), psychosocial outcomes did not differ between NH settings and RC/AL settings. Behavioral symptoms and engagement did not differ by setting (low SOE).Quality of dying, quality of life, and psychoactive medication use also did not differ by setting although evidence is insufficient in these single studies that had imprecise results and no power calculations. Restraints were used more often in imminently dying residents in NH settings than in RC/AL settings (any restraints, 92% vs. 66%; any restraints other than partial bedrails, 68% vs. 46%; low SOE).

Quality of life did not differ based on proprietary status, chain affiliation, size, age, percentage of dementia beds, and resident case-mix. Evidence was insufficient on the effect of these organizational characteristics on quality of life in this single study that had imprecise results and no reported power calculations.

Behavioral symptoms and engagement did not differ based on residence in an SCU (low SOE).

Structures of Care

With one exception, quality of life did not differ based on many structures of care: RN, LPN, and aide full-time equivalents and number of contract staff per type; administrator, RN, LPN, and aide turnover; environmental quality; consistent staffing; or use of universal workers. Evidence was insufficient on the effect of these structures of care on quality of life in this single study that had imprecise results and no reported power calculations. Quality of life was statistically, but not clinically, better in settings that used specialized care workers (mean raw change over 6 months was 1.7 points worse when specialized workers were not used; low SOE).

Processes of Care

A creative expression storytelling group resulted in more challenging behaviors, anxiety, and sadness (low SOE) and also less disengagement, neutral affect, and more engagement (low SOE).

A validation therapy group was superior to a social control group and/or usual care control group in regard to nurse-reported (but not observer-reported) physically and verbally aggressive behavior at 1 year (low SOE); it also resulted in more physically nonaggressive behaviors (low SOE). Validation therapy did not produce significant changes in engagement, irritability, restraint use, psychoactive medication use, or positive behaviors. Evidence was insufficient for the effect of validation group therapy on these outcomes due to imprecise results in this single study that did not reported power calculations.

More frequent encouragement of activity participation resulted in statistically, but not clinically, better quality of life (mean raw change over 6 months was 0.9 times worse when activities were encouraged less than once a day; low SOE).

Pleasant sensory stimulation (evaluated in two studies) produced a clinically significant decrease in agitation (75% to 83% compared with controls in one study; moderate SOE).

Individualized assessment and management of discomfort and behavioral symptoms did not result in behavioral change but did increase return of behavior to baseline levels (70% vs. 40% in the control group; low SOE).

Person-centered protocols for showering and bathing reduced behavioral symptoms (agitation and aggression) more in the intervention group than the control group (mean time agitated or aggressive 24% and 26% in the intervention groups vs. 36% in the control group; low SOE).

In one prospective cohort study, various processes of care (including policies and practices; staff involvement in care planning; assessments; treatment; use of medications; and use of stimuli such as craft or household items) did not improve quality of life. However, evidence was insufficient for the effects of these processes of care in this single study that had imprecise results and no reported power calculations.

KQ 3. Health Outcomes for Informal Caregivers of People With Dementia

No studies met inclusion criteria for KQ 3 about the impact of organizational characteristics, structures of care, or processes of care on caregiver health outcomes.

KQ 4. Psychosocial Outcomes for Informal Caregivers of People With Dementia

No studies met inclusion criteria for KQ 4 about the impact of organizational characteristics, structures of care, or processes of care on caregiver psychosocial outcomes.

KQ 5. Dementia Severity and Other Characteristics of the Person With Dementia

Two studies examined outcomes of residents with dementia in terms of dementia severity or sociodemographic variables. In one, hospitalization (but not other outcomes) for people in RC/AL settings was more likely for those with mild dementia than for those with moderate to severe dementia. Hospitalization rates did not differ by dementia severity for NH residents. In a second study, a lighting intervention produced better depressive symptoms outcomes for women exposed to morning bright light compared with all-day light, but worse outcomes for men exposed to morning bright light compared with standard light.

Discussion

Key Findings and Strength of Evidence

KQ 1. Health Outcomes for People With Dementia

Table A summarizes the SOE for health outcomes for people with dementia. Regarding organizational characteristics reviewed, NHs and RC/AL differed little on a range of health outcomes. Residents with mild dementia in RC/AL settings, when compared with those in NH settings, had moderately higher hospitalization rates (low SOE); residents differed little in morbidity rates regardless of dementia level (low SOE). Evidence on SCUs within these settings was inconsistent. Residents of SCUs in RC/AL settings, when compared with those in non-SCUs in those settings, had a modestly greater decline in functioning over time (low SOE). By contrast, residents of dementia SCUs in NHs, when compared with those in non-SCUs in NHs, had moderately lower rates of both hospitalization and new or worsening morbidity (low SOE).

Only two studies focused on structures of care. Those two studies reported no effect in the overall populations studied for lighting interventions on either sleep quality or depressive symptoms. Both studies found benefits for certain subgroups (women for depressive symptoms and those with aberrant sleep-cycle timing for sleep quality).Although these studies suggest that lighting interventions may have more benefit on a person-by-person level as opposed to being a structural intervention throughout a setting, we judge the current evidence as insufficient based on these single studies with imprecise results that did not report power calculations.

Regarding processes of care, evidence for group activity interventions was mixed. A functional skills training intervention produced moderate effect sizes for improving ADLs; effect sizes were equivalent to moving from major to moderate or from moderate to minor assistance in performing ADLs (low SOE). A storytelling intervention modestly improved cognitive alertness (low SOE). A single study of validation therapy groups did not find improvement of functional self-care or depressive symptoms. A single study of attention focusing did not find any improvement of cognitive impairment or cognitive function. However, the evidence was insufficient regarding the effects of validation group therapy for self-care and depressive symptoms and of an attention-focusing intervention for cognitive impairment and cognitive

function due to imprecise results in these single studies that did not report power calculations to justify sample size. A personalized assessment and treatment intervention moderately reduced resident discomfort (low SOE). Finally, personalized showering and towel bath interventions reduced resident discomfort (low SOE).

No studies examined the outcome of falls (insufficient SOE).

Table A. Strength of evidence for the effect of organizational characteristics, structures, or processes of care on health outcomes for people with dementia

Outcome	Summary of Results	Strength of Evidence
Functional impairment/decline (including self-care/maintenance)	Functional impairment/decline was worse in RC/AL settings for residents living in a dementia SCU (1 study; 1,252 subjects).	Low
	Function was clinically significantly better (equivalent to moving from major to moderate or moderate to minor need for assistance) after functional skill training (1 study; 63 subjects).	Low
Cognitive impairment/decline	Alertness was modestly better (3 percentage points) after creative expression storytelling (1 study; number of subjects not reported).	Low
Depressive symptoms	Depressive symptoms were better for women but worse for men after a bright morning-light intervention (1 study; 155 subjects).	Low
Pain/discomfort	Pain/discomfort was better after individualized assessment and management of discomfort (1 study; 114 subjects) and person-centered protocols for showering and bathing (1 study; 73 subjects).	Low
Sleep quality	Sleep quality was better for only those with aberrant sleep-cycle timing following morning bright light (1 study; 46 subjects).	Low
New/worsening morbidity and various discrete measures	Morbidity across multiple measures differed little in RC/AL settings compared with NH settings, but was lower in SCUs than in non-SCUs in NHs (1 study; 1,252 subjects).	Low
Hospitalization	Hospitalization occurred more often for residents with mild dementia living in RC/AL settings than for residents in NH settings (1 study; 1,252 subjects).	Low
	Hospitalization occurred more often for NH residents (but not RC/AL residents) not living in dementia SCUs (1 study; 1,252 subjects).	Low
Mortality	Evidence did not support a difference based on residence in an NH setting vs. RC/AL setting or in an SCU vs. non-SCU (1 study; 1,252 subjects).	Low

NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit; SOE = strength of evidence; vs. = versus
Note: No study examined the outcome of falls (insufficient SOE), and not all of the eight outcomes listed above were examined in every one of the 10 studies. Only findings with low or better SOE are reported.

KQ 2. Psychosocial Outcomes for People With Dementia

Table B summarizes the SOE for psychosocial outcomes for people with dementia. Regarding organizational characteristics, NHs and RC/AL differed little on a range of psychosocial outcomes. Behavioral symptoms and engagement did not differ by setting (low SOE).Quality of dying, quality of life, and psychoactive medication use also did not differ by setting although evidence was insufficient in these single studies that had imprecise results and no reported power calculations. Restraints were used more often in imminently dying residents in NHs than in RC/AL (low SOE). The authors suggested additional study of this finding considering that the use of physical restraints in NHs has been strongly discouraged following the Nursing Home Reform Act of 1987, and there is evidence that overall use of restraints is low.[14] Behavioral symptoms and engagement did not differ based on residence in an SCU (low SOE), although the two studies reviewed were prospective cohort studies in which risk adjustment potentially may not have been sufficient.

Regarding structures of care, quality of life was statistically, but not clinically, significantly better when specialized workers were used (low SOE). It did not differ based on many structures

although the evidence was insufficient in this single study that had imprecise results and no reported power calculations.

Regarding processes of care, evidence for group activity interventions was mixed. A storytelling intervention resulted in more challenging behaviors, anxiety, and sadness (low SOE), and also more engagement (low SOE). An intervention involving validation therapy groups resulted in less physical and verbal aggression and also more physically nonaggressive behaviors (e.g., restlessness, repetitious mannerisms, pacing), although these findings were not consistent across raters (low SOE). More frequent encouragement of activity participation resulted in statistically, but not clinically, better quality of life (low SOE). Pleasant sensory stimulation, such as calm music and hand massage, produced a clinically significant decrease in agitation (moderate SOE). A personalized assessment and treatment intervention of behavioral symptoms increased return of behavior to baseline levels (low SOE). Finally, both personalized showering and towel bath interventions reduced behavioral symptoms (agitation and aggression) more in the intervention group than the control group (low SOE).

No studies examined the outcomes of spiritual well-being, control, autonomy, choice, or satisfaction (insufficient SOE).

Table B. Strength of evidence for the effect of organizational characteristics, structures, or processes of care on psychosocial outcomes for people with dementia

Outcome	Summary of Results	Strength of Evidence
Behavioral symptoms	Behavioral symptoms were worse after creative expression storytelling (1 study; number of subjects not reported).	Low
	Physical and verbal aggression were better, and physical nonaggression was worse, after validation therapy (based on nurse report). Verbal aggression was worse after validation therapy (based on observer report) (1 study; 88 subjects).	Low
	Agitation was clinically significantly better after pleasant sensory stimulation (2 studies; 99 subjects; agitation decreased 75% to 83% in one study).	Moderate
	Behavioral symptoms were better after individualized assessment and management of behavioral symptoms (70% vs. 40% return to baseline) (1 study; 114 subjects).	Low
	Agitation and aggression were better after person-centered protocols for showering and bathing (mean time agitated/aggressive 24% to 26% vs. 36% for control group) (1 study; 73 subjects).	Low
Affect	Anxiety and sadness were worse after creative expression storytelling (1 study; number of subjects not reported).	Low
Engagement	Engagement was better after creative expression storytelling (1 study; number of subjects not reported).	Low
Quality of life	Quality of life over 6 months was statistically, but not clinically, significantly better when specialized workers were used and activities were encouraged (1 study; 421 subjects).	Low
Quality of dying	One study did not find a difference based on residence in an NH setting vs. RC/AL setting (1 study; 422 subjects).	Insufficient[a]
Psychoactive medication use	One study did not find a difference based on residence in an NH setting vs. RC/AL setting (1 study; 422 subjects) or after validation therapy (1 study; 88 subjects) studies; 510 subjects).	Insufficient[a]
Restraint use	Restraint use in imminently dying residents occurred more often in NH settings than in RC/AL settings (66% vs. 92%) (1 study; 422 subjects).	Low

NH = nursing home; RC/AL = residential care/assisted living; SOE = strength of evidence; vs. = versus

Note: No study examined the outcomes of spiritual well-being, control, autonomy, choice, or satisfaction (insufficient SOE). Not all of the outcome categories in this table were examined in every one of the 10 studies. Except where indicated, only findings with low or better SOE are reported.

[a]Evidence was from a single study with imprecise estimates.

Table C summarizes the SOE for statistically significant differences in health and psychosocial outcomes according to organizational characteristics, structures, and process of care.

Table C. Strength of evidence for the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes for people with dementia

Characteristics	Intervention/Exposure	Summary of Results	Strength of Evidence
Organizational	NH vs. RC/AL	Morbidity across multiple measures differed little in RC/AL settings compared with NH settings (1 study; 1,252 subjects).	Low
	NH vs. RC/AL	Hospitalization occurred more often for residents with mild dementia living in RC/AL settings than for residents in NH settings (1 study; 1,252 subjects).	Low
	NH vs. RC/AL	Restraint use in imminently dying residents occurred more often in NH settings than in RC/AL settings (66% vs. 92%) (1 study; 422 subjects).	Low
	SCU in NH vs. no SCU	Morbidity was lower in SCUs than in non-SCUs in NHs (1 study; 1,252 subjects).	Low
	SCU in NH vs. no SCU	Hospitalization occurred more often for NH residents not living in SCUs (1 study; 1,252 subjects).	Low
	SCU in RC/AL vs. no SCU	Functional impairment/decline was worse in RC/AL settings for residents in SCUs (1 study; 1,252 subjects).	Low
Structures of Care	Morning bright light vs. all-day light/control	Depression/depressive symptoms were better for women but worse for men after bright morning light (1 study; 155 subjects).	Low
	Morning bright light vs. all-day light/control	Sleep quality was better only for those with aberrant sleep-cycle timing following morning bright light (1 study; 46 subjects).	Low
	Specialized workers vs. not	Quality of life over 6 months was statistically, but not clinically, significantly better when specialized workers were used (1 study; 421 subjects).	Low
Processes of Care	Functional skill training vs. no such training	Function was clinically significantly better (equivalent to moving from major to moderate or moderate to minor need for assistance) after functional skill training (1 study; 63 subjects).	Low
	Creative expression storytelling vs. no such activity	Alertness was modestly better (3 percentage points) after creative expression storytelling (1 study; number of subjects not reported).	Low
	Creative expression storytelling vs. no such activity	Behavioral symptoms, anxiety, and sadness were worse after creative expression storytelling (1 study; number of subjects not reported).	Low
	Validation therapy vs. no such activity	Physical and verbal aggression were better, and physical nonaggression was worse, after validation therapy (based on nurse report). Verbal aggression was worse after validation therapy (based on observer report) (1 study; 88 subjects).	Low
	Encouraging activities more vs. less	Quality of life over 6 months was statistically, but not clinically, significantly better when activities were encouraged (1 study; 421 subjects).	Low

Table C. Strength of evidence for the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes for people with dementia (continued)

Characteristics	Intervention/Exposure	Summary of Results	Strength of Evidence
Processes of Care (continued)	Pleasant sensory stimulation vs. no such stimulation	Agitation was clinically significantly better after pleasant sensory stimulation (2 studies; 99 subjects; agitation decreased 75% to 83% in 1 study).	Moderate
	Individualized assessment and management of discomfort and behavioral symptoms vs. no such protocols	Pain/discomfort was better after individualized assessment and management of discomfort (1 study; 114 subjects; discomfort score 0.89 times lower than control).	Low
	Individualized assessment and management of discomfort and behavioral symptoms vs. no such protocols	Behavioral symptoms were better after individualized assessment and management of behavioral symptoms (1 study; 114 subjects; 70% vs. 40% return to baseline).	Low
	Person-centered protocols for showering and bathing vs. no special protocols	Pain/discomfort was better after person-centered protocols for showering and bathing (1 study; 73 subjects; reduced discomfort by 26% for towel bath and 14% for person-centered showering).	Low
	Person-centered protocols for showering and bathing vs. no special protocols	Agitation and aggression were better after person-centered protocols for showering and bathing (1 study; 73 subjects; mean time agitated/aggressive 24% to 26% vs. 36% for control group).	Low

NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit; SOE = strength of evidence; vs. = versus
Note: No study examined the outcomes of falls, spiritual well-being, control, autonomy, choice, or satisfaction (insufficient SOE). Not all of the interventions in this table were examined in relation to all outcomes. Only findings with low or better SOE are reported.

KQs 3 and 4: Outcomes for Informal Caregivers

No studies met inclusion criteria for either of these KQs about the impact of organizational characteristics, structures of care, or processes of care on caregiver health or psychosocial outcomes. Thus, evidence is insufficient for these topics.

Three potential studies[15-17] were identified in this review, each addressing encouragement of family involvement in care as a means to promote improved family/staff relationships and thus improve resident care. While these studies were excluded for methodological shortcomings (e.g., selection bias, high attrition, inadequate randomization), this literature is evolving and represents an increasingly important aspect of NH and residential care for residents with and without dementia.

KQ 5: Variation by Characteristics of People With Dementia

Two studies examined outcomes of residents with dementia in terms of dementia severity or sociodemographic variables. In one, hospitalization (but not other outcomes) for people in RC/AL settings was more likely for those with mild dementia than for those with moderate to severe dementia. Hospitalization rates did not differ by dementia severity for NH residents. In a second study, a lighting intervention produced better depressive symptoms outcomes for women exposed to morning bright light compared with all-day light, but worse outcomes for men exposed to morning bright light compared with standard light.

Applicability

This review was intended to apply to all people with dementia regardless of their level of dementia. It also was intended to examine differences in outcomes related to the extent of dementia and other characteristics, because people with mild, moderate, or severe dementia differ in the extent to which they are able to respond to interventions.

Studies varied in regard to the level of dementia represented, and some did not specify the level. Two included only residents with severe dementia, making those findings applicable to that subgroup. Only one study considered the evidence in relation to the level of dementia severity. In regard to the other studies, the evidence is insufficient regarding whether effects would have differed for subgroups. This is a serious omission, as what may be helpful at one time (such as to reduce wandering) may not be needed at a later time (if the person becomes bedridden), and what is needed at a later time may not be necessary earlier.

The interventions/exposures included a broad range of organizational characteristics, structures, and processes of care. We had envisioned special interest in exposure to organizational characteristics, such as NH settings compared with RC/AL settings, small NHs with large NHs, and SCUs with no SCU. These are often the level at which families first make their decision regarding a setting of care. However, only four prospective cohort studies provided evidence about these options.

The outcomes examined across the 14 studies included 8 broad categories of health outcomes and 7 categories of psychosocial outcomes. In some cases, a given intervention had both desired and undesired outcomes. In such instances, families are advised to consider which outcomes are most relevant and which they and the person with dementia most value and make their decision accordingly.

The SOE for all findings reported in this review, except one, was low or insufficient. Further, although we found statistically significant effects for some organizational characteristics, structures, and processes of care, for many we found none. In addition, some statistically significant results were relatively small, meaning their clinical importance is limited or unclear.

Finally, we found no evidence related to health or psychosocial outcomes for informal caregivers. Although understanding the benefits or harms of various organizational characteristics, structures, or processes of care for people with dementia may well promote better outcomes for informal caregivers, far more evidence is required on this topic.

Research Gaps

Assuming the overriding question for stakeholders is whether an individual with dementia is best served in an NH setting or RC/AL setting or in an SCU, we found no RCTs to answer these questions and only sparse evidence from nonexperimental studies. RCTs would not be expected to inform the matter of NHs versus RC/AL, given that they would be hard to justify in ethical or feasibility terms. Trials of placement in SCUs might be possible, however. All things considered, additional high-quality prospective cohort studies would be beneficial in this area, especially because the majority of RC/AL residents have dementia,[18] and the number of RC/AL beds has almost doubled in the past 20 years.[19]

The wide array of structural variables and process interventions that surfaced in this work reflects impressive thinking about factors that might improve outcomes. However, this diversity made it impossible for us to improve estimates of effect sizes by pooling data. We are not convinced that “one-off” studies are the best possible use of research resources. Instead,

concerted emphasis on key variables may be warranted so findings can be combined in quantitative analyses to yield stronger evidence for decisionmaking. Two examples of this type of effort include the National Institute on Aging studies examining SCUs, and the Robert Wood Johnson Foundation collaborative of projects examining Green House NHs. Related to this strategy is the suggestion that all studies conducted in NHs and other residential long-term care settings indicate the number and percentage of residents with dementia who composed the sample, and analyze data specific to these individuals.

Another consideration about future research involves the types of outcomes to be studied. As noted, no evidence surfaced on falls or on several aspects of psychosocial well-being, including spiritual well-being, control, autonomy, choice, and satisfaction. Some research effort to clarify care related to these outcomes is warranted, although they may be less salient for decisionmaking than matters such as depressive symptoms, hospitalization, and quality of life.

A related matter is encouraging investigators to use established outcome measures to enhance the possibility of quantitative pooling of studies or qualitative interpretations of the same outcome information. Many studies in this review used the CMAI (the Cohen Mansfield Agitation Inventory, a measure of behavioral symptoms),[20-23] and other established measures are available for other outcomes of interest.

Cutting across the matter of care and outcomes is the question of methods. Of the 14 studies included, we could rate the quality as good for only 4 studies. We excluded 15 studies because of substantial flaws that yielded quality ratings of poor, reflecting important threats to internal validity. Future research should attempt to overcome the risk of bias, such as by attending more closely to masking raters and maintaining consistent raters over time, ensuring similar representation of subjects across arms, focusing on fidelity, and accounting for missing data in analyses. Also, studies with larger samples would provide more precise estimates of differential effects. Finally, more attention to the heterogeneity of people with dementia will better inform the matter of applicability.

To summarize, we suggest the following guidance for future research:

- Examine differences between NH settings versus RC/AL settings, and between SCUs and settings without SCUs as related to outcomes for people with dementia and their caregivers.
- Conduct studies with concerted emphasis on key organizational characteristics, structures, and processes of care as opposed to one-of studies.
- Indicate the number and percentage of residents with dementia who composed the sample, and analyze data specific to these individuals.
- Examine how results differ according to characteristics of the person with dementia, especially the degree of dementia.
- Continue studying outcomes of depressive symptoms, hospitalization, and quality of life, but also consider the relevance of outcomes including falls, spiritual well-being, control, autonomy, choice, and satisfaction.
- Use established outcome measures to enable the pooling of data or qualitative interpretations.
- Employ rigorous methodologies that overcome bias, and use samples of sufficient size to provide precise estimates.

Conclusions

Overall, we generally found low or insufficient SOE about the effectiveness of organizational characteristics, structures, and processes of care for people with dementia. This is true about both their health and their psychosocial outcomes. Virtually no good or fair evidence meeting our inclusion criteria exists about outcomes for informal caregivers of people with dementia.

Even with those caveats, we can state some conclusions. Findings of moderate SOE indicate that pleasant sensory stimulation reduces resident agitation. Even though the SOE was low, protocols for individualized care can reduce pain/discomfort and agitation/aggression, and functional skill training can improve function. Further, if people with dementia and their families are choosing between NH settings and RC/AL settings, considering the individual's current medical needs and health stability is important, because these settings do not differ much in outcomes other than those relating to people for whom medical care is indicated or for whom NHs may be better suited on other grounds.

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Introduction

Background

Dementia is a group of neurological conditions that lead to gradual decline in mental function. It is the most common reason for entry into long-term care settings such as nursing homes (NHs) and residential care/assisted living (RC/AL).[1] The majority of care for people with dementia is provided in the community by family members; however, increasing care needs in later stages of the illness often lead to placement in a long-term care setting. Because long-term care settings are highly varied, people with dementia and their families who must make a decision regarding placement would benefit from evidence-based guidance on what to choose from the available options. The purpose of this review is to identify and summarize the current evidence regarding which long-term care setting characteristics, structures, or processes are effective for improving health and psychosocial outcomes both for people with dementia and for their family caregivers, so as to provide better guidance to families making placement decisions.

Definition of Dementia

Dementia is a syndrome with multiple causes characterized by a decline in mental function, marked most commonly by memory impairment and a reduction in at least one other area of cognitive function, such as reasoning, judgment, abstract thought, registration, comprehension, learning, task execution, and use of language.[2] The most common type of dementia is Alzheimer's disease; other types include vascular dementia, mixed dementia, dementia with Lewy bodies, and frontotemporal dementia. The Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR) provides a commonly accepted definition of dementia (Table 1).

Table 1. Definitions relating to dementia

Term	Definition
Dementia	"The development of multiple cognitive deficits that include memory impairment and at least one of the following cognitive disturbances: aphasia, apraxia, agnosia, or a disturbance in executive functioning. The cognitive deficits must be sufficiently severe to cause impairment in occupational or social functioning and must represent a decline from a previously higher level of functioning." (http://dsm.psychiatryonline.org/content.aspx?bookid=22&sectionid=1889063#8455)[3]
Apraxia	The "impaired ability to execute motor activities despite intact motor abilities, sensory function, and comprehension of the required task."[3]
Agnosia	The "failure to recognize or identify objects despite intact sensory function."[3]
Executive functioning	"Involves the ability to think abstractly and to plan, initiate, sequence, monitor, and stop complex behavior."[3]

Prevalence of Dementia

More than 5 million Americans—as many as one in every eight individuals ages 65 years or older—have dementia.[2] This number may rise to as high as 13 million by 2050.[1] Dementia increases dramatically with age; the frequency of dementia among people ages 65 to 70 is approximately 2 percent, whereas for people older than 85 it is more than 30 percent.[4] The prevalence of dementia differs according to stage of dementia, such that by 2050 approximately 7 million people will have mild dementia, and 6 million will have moderate/severe dementia.[1] The impact of dementia relates to its stage.

Impact of Dementia

Dementia causes significant morbidity and mortality and creates a substantial burden on the people affected, as well as caregivers, health systems, and society.[2] Dementia gradually takes away the individual's ability to make decisions, manage personal affairs, and eventually to do even simple tasks such as dressing, toileting, and eating. Late stages are characterized by weight loss, limited mobility, and frequent infections, so that, unless some other illness is fatal sooner, dementia will lead to death. The course from diagnosis to death is variable but is typically from 8 to 12 years. This longevity places a tremendous burden on family caregivers, on personal savings, and on the health care system.[2] Costs of dementia care, including both medical care and informal caregiver time, are estimated at more than $148 billion in the United States annually.[5]

Dementia in Long-Term Care Settings

Although about 70 percent of people with dementia are cared for at home, the duration and intensity of care needs cause many families to place people affected with dementia into residential long-term care settings as care needs increase.[2] Residential settings that provide care for people with dementia are numerous and differ in their organizational characteristics, structures, and processes of care. The four principal categories of setting include the following:[2, 6]

- Nursing homes. NH settings are federally licensed and regulated settings that provide room, board, 24-hour oversight, health monitoring, assistance with activities of daily living (ADLs), health services, recreational activities, and skilled nursing services. In June 2008, 47 percent of all NH residents had a diagnosis of dementia in their NH record;[2] however, many more have dementia without a recorded diagnosis, so the true proportion of residents with dementia may be as high as 80 percent.
- Residential care/assisted living. RC/AL settings are residences that provide room, board, 24-hour oversight, and assistance with ADLs. They vary widely in size, structure, and services, and are licensed by the States under various names, including sheltered housing, domiciliary care, intermediate care housing, adult foster care, assisted living, congregate care, and other labels. Estimates indicate that, depending on the type of RC/AL setting, between 45 percent and 67 percent of residents have dementia.[7]
- Alzheimer's (or dementia) special care units (SCUs) in RC/AL settings and NH settings. During the past 2 decades, specialized dementia care units have become increasingly common in NH settings and RC/AL settings. As of June 2008, NHs had a total of 86,669 beds in SCUs, accounting for 5 percent of all NH beds. More recently, the growth in SCUs has been largely in RC/AL settings; however, as of 2010 only 11 percent of RC/AL settings had a distinct dementia unit, wing, or floor; of these, the majority had less than 40 percent of their residents in the dementia unit.[8] Given that more than 50 percent of residents in both settings have dementia, the majority of NH and RC/AL residents with dementia are clearly not in SCUs.[9]
- Continuing care retirement communities (CCRCs). CCRCs are retirement communities with different housing and level-of-care options. The area in which a person lives depends on the level of care that he or she needs at a given time. Residents may move from one area to another depending on care needs but stay within the same CCRC. Most CCRCs have both NH and RC/AL beds.

Nationally, 2.36 million older adults reside in long-term care settings. Almost two-thirds (1.5 million) are in one of the country's 16,100 NHs (based on an occupancy rate of 86%), and the remainder (855,000) are in one of 31,100 RC/AL residences (based on an occupancy rate of 88%).[10-12] More than one million of these are people with dementia.[13]

Critical Role of Family Caregivers in Dementia

People with dementia typically need an increasing amount of assistance as progression occurs, and these care needs extend over many years. Families, not long-term care settings, provide the majority of care to individuals with Alzheimer's disease and related dementias (www.caregiver.org).[14] Relatives or friends who provide unpaid care are known as informal caregivers.[15]

When someone with dementia enters a long-term care setting, family caregivers tend to be intimately involved in the placement decision and remain active after placement.[16-18] Families visit long-term care residents an average of 1.9 times a week, for approximately 4.0 to 4.2 hours a week. They are important to the resident to maintain emotional connectedness and psychosocial health. Also, they constitute an important resource to staff because they have knowledge of the resident's history and provide support for ADLs, thereby augmenting the care provided by staff.[16-18] Indeed, family presence improves resident psychological and psychosocial well-being, the accuracy of diagnosis, and the resultant care.[19] Family members are called on to make decisions regarding care for cognitively impaired residents and to provide continuity that may otherwise be lacking because of staff turnover.[20, 21]

Need for Evidence-Based Guidance for Consumers Who Wish To Select a Long-Term Care Setting

Numerous consumer/patient guides are available to help the public choose the type of long-term care setting that may be best for their family member. However, it is unclear whether any of these guides are based on evidence. Instead, most guides focus on geographic factors (such as proximity to family), regulatory criteria (such as level of care needed), financial issues (such as whether a long-term care setting accepts Medicaid, or the overall cost per month for residents who pay privately), or some combination of these considerations. Furthermore, many guides have been developed by one or more organizations with a financial interest in a certain long-term care product.

In addition to these guides, other sources such as quality of care ratings on the Web site of the Centers for Medicare and Medicaid Services offer publicly available information to help families choose among NHs, most notably quality of care ratings on the Web site of the Centers for Medicare and Medicaid Services.[22]

Despite the potential value of these sources, and inspired by a consumer request, the Agency for Healthcare Research and Quality (AHRQ) identified a need for an unbiased, evidence-based review on factors in long-term care settings themselves that affect the quality of care for individuals with dementia. The topic of our review—the comparison of characteristics of NHs and other residential long-term care settings for people with dementia—addresses this issue, with the goal of reducing the uncertainty of families who are trying to make the best decision regarding a setting of care for a family member with dementia.

Characteristics of Long-Term Care Settings

One relevant question to ask is whether one type of long-term care setting is superior to another for dementia overall or for certain subgroups of people with dementia, such as those with mild, moderate, or severe dementia. Long-term care settings are complex and vary widely within licensure categories, as was highlighted in the 2001 report of the Institute of Medicine Committee on Improving the Quality of Long-Term Care.[23] Therefore, an especially relevant question for family members seeking to select a site is whether certain characteristics are critical in providing quality care for all people with dementia or certain subgroups.

Key characteristics of long-term care settings can be conceptualized in three categories: organizational characteristics, structures of care, and processes of care. Models of health care quality posit that good characteristics and structures increase the likelihood of good processes, which increase the likelihood of good outcomes.[24] Table 2 displays definitions and provides examples of each of these key categories of setting characteristics.

Table 2. Organizational characteristics, structures of care, and processes of care

Characteristics	Definitions and Examples
Organizational	Demographic, community, and licensure characteristics of long-term care settings. Includes proprietary status, affiliation (e.g., chain, hospital, CCRC), location (urban vs. rural), size of setting or unit, cost, and resident case-mix (e.g., dementia, Medicaid, race/ethnicity), as well as the overall model of care (e.g., NH, assisted living, Alzheimer's/dementia special care units).
Structures of Care	Attributes of the setting. Includes material resources (e.g., private rooms, familiar homelike components, access to outdoors), human resources (e.g., level of staffing, expertise of staff), and their operation (e.g., hours of care per resident per day by type of worker, consistency of assignment, universal worker perspective).
Processes of Care	What is actually done in giving and receiving care. Includes programs and services implemented at the system/setting level in the context of care provision (e.g., assistance with ADLs, involvement of informal caregivers, activity programs).

ADL = activities of daily living; CCRC = continuing care retirement center; NH = nursing home

Numerous organizational characteristics, structures, and processes of care have been identified as potentially affecting quality of life of people in residential long-term care settings.[25] Among those most commonly suggested are the following:

- Organizational characteristics: residence type, age, profit status, affiliation with another level of care, number of beds, presence of a dementia SCU, and resident case-mix (related to dementia diagnosis).
- Structures of care: aspects of staffing (stability of care provider-resident assignment, universal worker perspective [where staff fill multiple roles] vs. specialized worker perspective [where staff have specialized roles], number of nurses and nursing or personal care aides, staff turnover, previous experience in dementia care) and physical structure (lighting, cleanliness).
- Processes of care: care planning (professional staff involvement and aide involvement), policies and practices (admission, discharge, acceptance of behavioral symptoms, policy choice), assessments and treatments conducted, and activities.

Scope and Key Questions

Scope of This Review

Considering the central role of family caregivers in deciding which NH or other residential long-term care setting to choose when home care is no longer feasible, information on which components of these settings relate to better outcomes would be very helpful. The above settings offer different levels of care and different services, and to date no comprehensive evidence-based guidance exists that identifies which characteristics or settings are best for which type of resident based on age, severity, or other characteristics. Further, settings that are better for the person with dementia may also be better for the family caregiver, such as by bringing the family peace of mind. The objective of this review, therefore, is to provide information that would help families who are trying to decide where to place a family member who has dementia and who can no longer be cared for at home.

Key Questions

This review sought to address the following five Key Questions (KQs):

- KQ 1. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving health outcomes for people with dementia?
- KQ 2. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving psychosocial outcomes for people with dementia?
- KQ 3. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving health outcomes for informal caregivers of people with dementia?
- KQ 4. What is the effectiveness of organizational characteristics, structures, or processes of care in nursing homes and other residential long-term care settings for improving psychosocial outcomes for informal caregivers of people with dementia?
- KQ 5. Does the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes vary by the characteristics of the person with dementia (e.g., severity of dementia, functional status) or of the informal caregiver (e.g., age, relationship, health status)?

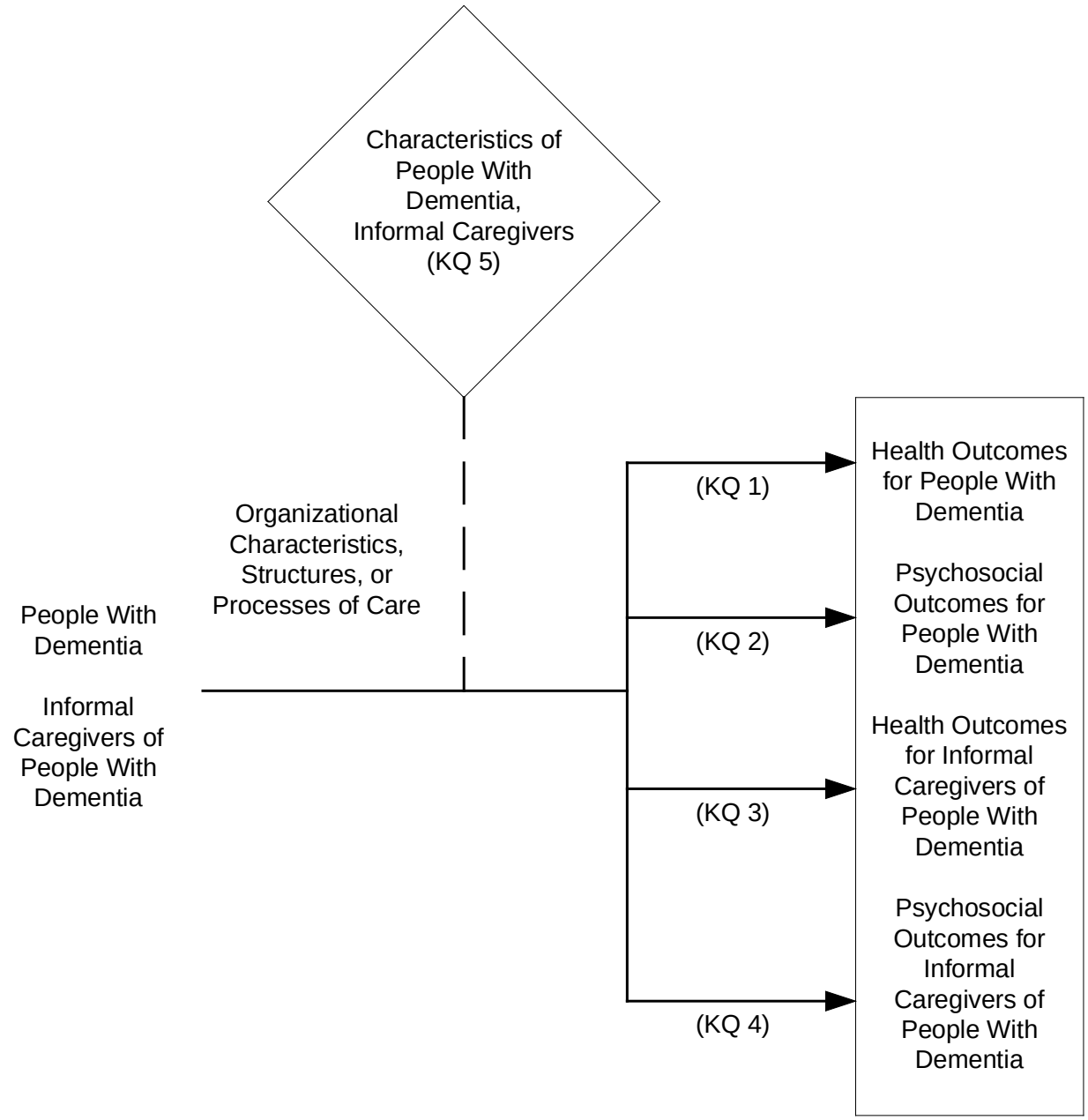
The population of interest for KQs 1, 2, and 5 included people with dementia (i.e., Alzheimer's disease or a related disorder). Wording KQ 1 and KQ 2 in terms of "improving" outcomes for people with dementia recognizes that improvement may be relative; it includes change to a better state of well-being, maintenance of the current state of well-being rather than decline, and also less as opposed to more decline in the current state of well-being. The population of interest for KQs 3, 4, and 5 included informal caregivers of people with dementia of any age, sex, or relationship to the person with dementia. Intervention/exposure elements of interest included organizational characteristics, structures, and processes of care in NHs and other residential long-term care settings for people with dementia. In addition, combinations of certain organizational characteristics, structures, and processes of care as exhibited in particular models of care (e.g., traditional NHs, "Green House" NHs,[26] RC/AL settings) were also of interest. Some examples of comparisons of organizational characteristics, structures, and processes of care include not-for-profit versus for-profit, smaller size versus larger size (setting

or unit), consistent staffing versus rotating staffing, larger proportion of care paid by Medicaid versus private pay, urban versus rural location, specialized dementia care versus nondementia care, more versus fewer hours of care per resident per day by type of worker, private versus nonprivate rooms and bathrooms, neighborhood versus non-neighborhood designs, centralized versus noncentralized nursing desk, and access to outdoors versus no access to outdoors. Examples of comparisons of combinations of organizational characteristics, structures, and processes of care with other combinations include NH settings versus RC/AL settings, and Green House NHs versus traditional NHs.

We developed an analytic framework to guide the systematic review process (Figure 1).

Outcome measures for each KQ included health and psychosocial outcomes for people with dementia (KQ 1 and KQ 2, respectively) and informal caregivers (KQ 3 and KQ 4, respectively). KQ 5 assessed whether the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes varied by the characteristics of the person with dementia (e.g., severity of dementia, functional status) or of the informal caregiver (e.g., age relationship, health status). This review focused on residential long-term care—that is, settings that provide room and board, 24-hour oversight, health monitoring, and support for ADLs and are licensed by the Federal government and the States as NHs, RC/AL settings, or other similar names that are subsumed within these categories.

Figure 1. Analytic framework for comparisons of characteristics of nursing homes and other residential long-term care settings for people with dementia



KQ = Key Question

Methods

The methods for this comparative effectiveness review (CER) follow the methods suggested in the ARHQ Methods Guide for Effectiveness and Comparative Effectiveness Reviews (www.effectivehealthcare.ahrq.gov/methodsguide.cfm). The main sections in this chapter reflect the elements of the protocol established for the CER; certain methods map to the PRISMA checklist.[27] All methods and analyses were determined a priori.

Topic Refinement and Review Protocol

The topic of this report arose through a public process involving the public, the Scientific Resource Center (SRC), and various stakeholder groups (http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/what-is-the-research-process/). Investigators from the RTI-UNC Evidence-based Practice Center then generated an analytic framework, preliminary Key Questions (KQs), and preliminary inclusion/exclusion criteria in the form of PICOTS (populations, interventions/exposures, comparators, outcomes, timing, settings) framework and study design. The processes were guided by the information provided by the topic nominator, a scan of the literature, methods and content experts, and Key Informants. We worked with 8 Key Informants during the topic refinement, and 10 additional individuals participated in the Technical Expert Panel (TEP) (listed in the front matter of this report). Key Informants and TEP members participated in conference calls and discussions through email to review the analytic framework, KQs, and PICOTS at the beginning of the project. Disciplines represented by the Key Informants and TEP included clinicians and researchers in long-term care settings, policy, caregiver advocacy, health care provision, palliative and end-of-life care, minority health issues, dementia care, and consumer advocacy.

TEP members suggested including sleep quality, activity engagement, positive and negative effect, pleasure, use of psychoactive medications, and use of restraints as outcomes of interest for people with dementia. They also suggested including emotional stress, psychosocial stress, family conflict, and self-efficacy as outcomes for informal caregivers. TEP members also provided input on the inclusion and exclusion criteria for the report.

Our KQs were posted for public comment on AHRQ's Effective Health Care Web site from June 27, 2011, to July 25, 2011; the EPC put them into final form after review of the comments and discussion with the TEP.

Literature Search Strategy

Search Strategy

To identify articles relevant to each KQ, we searched MEDLINE,® Embase,® the Cochrane Library, the Cumulative Index to Nursing and Allied Health Literature (CINAHL®), AgeLine,® and PsycINFO.® We focused our search on long-term care settings, dementia, and informal caregivers by using a variety of terms, medical subject headings (MeSH®), and key words. The full search strategy is presented in Appendix A. We reviewed our search strategy with the TEP and incorporated their input into our search strategy.

We limited the electronic searches to English language (consistent with our focus on characteristics, structures, and processes in the United States) and humans. Sources were searched for articles published from 1990 through March 23, 2012, to reflect the changing nature

and evolution of nursing homes (NHs) and other residential long-term care settings, especially after the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Public Law 100-203), which established new regulatory standards of NH care. The landmark Nursing Home Reform Act (amendment to Public Law 100-203), which introduced sweeping change in the way NHs were operated and regulated, was passed by the U.S. Congress as part of OBRA 1987; most of its provisions were implemented under regulations promulgated in 1991-1992 (www.access.gpo.gov/nara/cfr/waisidx_02/42cfr483_02.html). Therefore, the investigative team chose 1990 as the beginning date for its literature review, because publications before that date would reflect pre-OBRA status and be of limited relevance to today's long-term care settings.

We manually searched reference lists of reviews, including trials and background articles on this topic, to look for any relevant citations that our searches might have missed and that addressed our KQs. We imported all citations into an electronic database (EndNote® X4).

We conducted an updated literature search (of the same databases searched initially) concurrently with the peer review process. Any literature suggested by peer reviewers or the public was investigated and, if appropriate, incorporated into the final review. We determined the appropriateness of all additional literature by the same methods described in this chapter.

Inclusion and Exclusion Criteria

We developed eligibility (inclusion and exclusion) criteria with respect to the PICOTS framework (Table 3). Because many studies have not required a formal diagnosis of dementia for subject inclusion, we did not require that the dementia be specified as formally diagnosed dementia. Instead, dementia could be determined by formal diagnosis, signs or symptoms (e.g., cognitive status assessment), or report by staff or an informal caregiver.

Through an iterative process, we determined that a study must have explicitly stated that at least 80 percent of the population had dementia or that some analyses were specific to the subgroup of those with dementia. The rationale for this decision was to ensure that the findings were relevant and applicable to the population of interest. Of note, no excluded studies reached even a 70 percent cut-point. In addition, we examined informal caregivers as a population of interest (in KQs 3 and 4).

Interventions/exposures of interest included organizational characteristics, structures of care, or processes of care as defined in the Introduction. Organizational characteristics, structures, and processes of care could either be those inherent to the setting to which people were exposed (e.g., NH vs. RC/AL) or new interventions being implemented. Staff training interventions are not included in this review because they are a proxy for and a presumed indicator of care. Level of training in the context of staff role (i.e., certified nursing assistant, registered nurse, licensed practical nurse, licensed vocational nurse, medical technologist, and other direct-care workers) was considered in this review.

We sought to compare the effectiveness of elements of interventions/exposures with one another and combinations of interventions/exposures. Comparators included various types and amounts (e.g., consistent vs. rotating staffing) of the elements or combinations of certain elements, as exhibited in particular models (e.g., the Green House model). Studies without a comparator were not included in this review. We excluded studies judged to be of poor quality.

Table 3. Study eligibility criteria

Category	Inclusion Criteria	Exclusion Criteria
Population	People with dementia residing within a long-term residential setting with or without coexisting disease Informal caregivers of people with dementia	• No indication of dementia • People with mild cognitive impairment • Studies in which the case-mix proportion of the population with dementia is unspecified or <80% or in which analyses have not been conducted specific to the subgroup of people with dementia
Interventions/ exposures (described in the Introduction)	Organizational characteristics Structures of care Processes of care	• Interventions/exposures delivered at the person level[a] • Prescribed therapies (e.g., medication trials, nutritional supplements) • Staff training interventions • In-home care • Community services • Interventions/exposures that require the individual to leave the long-term care setting to receive the intervention
Comparators	Various types or amounts of the intervention/exposure element Combination of certain intervention/exposure elements	• Studies with no comparator
Outcomes	Health outcomes for people with dementia: Pain or discomfort; symptoms of depression; sleep quality; health decline/morbidities (including skin ulcers); decline in functioning, self-care or maintenance; decline in cognitive functioning; falls; mortality; hospitalizations Psychosocial outcomes for people with dementia: Positive and negative affect (e.g., pleasure, anxiety); behavioral symptoms; engagement; quality of life; quality of dying; spiritual well-being; control, autonomy, choice; satisfaction; use of psychoactive medications; use of restraints Health outcomes for informal caregivers of people with dementia: Symptoms of depression; sleep quality; morbidities (e.g., cardiovascular disease) Psychosocial outcomes for informal caregivers of people with dementia: Anxiety; quality of life; caregiver burden; emotional stress; psychosocial stress; quality of relationship with person who has dementia; self-efficacy; guilt; grief reactions; perception of suffering; satisfaction; financial burden; family conflict	• Biomarkers
Timing	No minimum study duration limit	Not applicable

Table 3. Study eligibility criteria (continued)

Category	Inclusion Criteria	Exclusion Criteria
Settings	Nursing homes Residential care / assisted living (and similar settings with a different name, such as board and care homes) Green House homes Alzheimer's special care units Residential long-term hospice care Continuing care retirement communities	• Adult day centers • PACE • In-home • Accessory dwelling units • Hospitals
Geography	United States	• All other countries
Sample size	Trials with an N≥30 Observational studies with an N≥100	• Trials with an N<30 • Observational studies with an N<100
Time period	1990 to March 23, 2012	• Articles published before 1990
Publication language	English	• All other languages
Admissible evidence (study design and other criteria)	• Eligible study designs include the following: • Randomized controlled trials • Nonrandomized controlled trials with concurrent eligible controls • Systematic reviews with or without meta-analyses • Subgroup and post hoc analyses of data from relevant controlled trials • Case-control studies • Prospective-cohort studies	• Case series • Case reports • Nonsystematic/narrative reviews • Editorials • Letters to the editor • Pre/post designs without a comparison group • Focus groups • Qualitative interviews • Cross-sectional designs • Articles rated as poor quality (a high risk of bias)

N = number; PACE = Program of All-Inclusive Care for the Elderly

[a]Given the intent of this comparison to inform the selection of a setting for individuals with dementia based on organizational characteristics, structures, and processes of care, we restricted interventions to those at the setting/system level (e.g., dementia care unit, something to which all people are exposed) rather than at the person level (e.g., tube feeding, something to which not everyone is exposed).

In categorizing outcomes, we considered symptoms of depression as health outcomes but other components of affect (e.g., anxiety, pleasure) as psychosocial outcomes. Quality of life could be considered as either a psychosocial outcome or a health outcome. For the purpose of this review, we have categorized it within the psychosocial outcomes (KQ 2 and KQ 4). Caregiver burden, a psychosocial outcome, is defined as "the strain or load borne by a person who cares for an elderly, chronically ill, or disabled family member or other person. It is a multidimensional response to physical, psychological, emotional, social, and financial stressors associated with the caregiving experience."[28]

The time period of interest in choosing studies to review was any duration of time beginning after the admission of the person with dementia to a residential long-term care setting until permanent transfer to another setting or death.

We confined our review to studies done in the United States so that the evidence examined would be relevant to care in this country. The health care systems and approaches to long-term care in other countries differ substantially from those here (and from each other), so that research from other countries will be less applicable to the United States than studies done in this country.

Study Selection

Two people independently reviewed article abstracts using the inclusion/exclusion criteria presented in Table 3. If both reviewers agreed that the study did *not* meet eligibility criteria, we excluded it; otherwise, two reviewers then independently reviewed the full-text article. If the reviewers disagreed, they resolved conflicts by discussion and consensus or by consulting a third member of the review team. A reviewer who was also an author of a specific study was not permitted to make the final determination as to whether the study was included or excluded. Studies excluded at the full-text stage, along with reasons for exclusion, are listed in Appendix B.

Data Abstraction

For studies that met our inclusion criteria, we abstracted important information into evidence tables. We designed and used structured data abstraction forms to gather pertinent information from each article, including characteristics of study populations, settings, interventions/ exposures, comparators, study designs, methods, and results. Trained reviewers abstracted the relevant data from each included article into the evidence tables. A second member of the team reviewed all data abstractions against original articles for completeness and accuracy. We recorded intention-to-treat results if available. All data abstraction was performed using Microsoft Excel® software. Evidence tables containing all abstracted data of included studies are presented in Appendix C. Evidence tables are organized by study characteristics, study population characteristics, intervention/exposure components, and outcomes.

Quality Assessment of Individual Studies

To assess the quality (internal validity) of studies, we used predefined criteria based on those developed by the U.S. Preventive Services Task Force (USPSTF) (ratings: good, fair, poor)[29] and the University of York Centre for Reviews and Dissemination.[30] In general terms, a "good" study has the least risk of bias and its results are considered to be valid. To be rated "good" for the purpose of this review, a trial must have fulfilled all of the following criteria: adequate randomization of patients; adequate allocation concealment; blinded outcome assessors; similar baseline characteristics across treatment arms; overall attrition less than 20 percent; differential attrition less than 15 percent (i.e., there is less than a 15 percentage point difference between attrition in one group and attrition in another); intention-to-treat analysis; and use of equal (across comparison groups), valid, and reliable outcome measures. An observational study receiving the quality rating of "good" must have fulfilled all of the following criteria: prospective design; recruitment from the same source population and during the same time period for the control and intervention subjects; similar inclusion and exclusion criteria across treatment arms; similar length of follow-up; adequate accounting for confounding in statistical analyses or study design; overall attrition less than 20 percent; differential attrition less than 15 percent; and the use of equal, valid, and reliable outcome measures. A "fair" study is susceptible to some bias but probably not sufficient to invalidate its results. A "poor" study has significant risk of bias (e.g., stemming from serious errors in design or analysis) that may invalidate its results.

Two independent reviewers assigned quality ratings for each study. Disagreements between the two reviewers were resolved by discussion and consensus or by consulting a third member of the team. We gave poor-quality ratings to studies that had a fatal flaw (defined as a methodological shortcoming that leads to a very high risk of bias) in one or more categories. We

excluded poor-quality studies from our analyses which could in turn affect the strength of the evidence of the body of literature. Appendix D details the criteria used for evaluating the quality of all included studies. Articles excluded because of a quality rating of poor can be found in Appendix D along with an explanation for the poor-quality rating. A reviewer who was also an author on an included study was not permitted to rate the quality of the study in question.

Data Synthesis

To determine whether quantitative analyses were appropriate, we assessed the clinical and methodological heterogeneity of the studies under consideration following established guidance.[31] We examined the PICOTS of the included studies, looking for similarities and differences. Because we determined that quantitative analyses were not appropriate (because of clinical heterogeneity, insufficient numbers of similar studies, or insufficiency or variation in outcome reporting), we synthesized the data qualitatively. All syntheses were evaluated by multiple coauthors of this report. A list of outcome measures, their acronyms, and their descriptions can be found in Appendix E.

More specifically, we individually reviewed all articles of good or fair quality to articulate clearly whether the intervention/exposure under study was an organizational characteristic, structure of care, and/or process of care; whether the population under study was people with dementia and/or their informal caregivers; and whether the intervention/exposure was examined in the context of health and/or psychosocial outcomes. Then, the research team evaluated articles in terms of their bias, design, quality, directness, precision, and strength of evidence.

Strength of the Body of Evidence

We graded the strength of evidence (SOE) based on the guidance established for the Evidence-based Practice Center Program.[32] Developed to grade the overall strength of a body of evidence, this approach incorporates four key domains: risk of bias (includes study design and aggregate quality), consistency, directness, and precision of the evidence. It also considers other optional domains that may be relevant for some scenarios, such as a dose-response association, plausible confounding that would decrease the observed effect, strength of association (magnitude of effect), and publication bias.

Table 4 describes the grades of evidence that can be assigned. We graded the SOE for a wide array of outcomes relating to KQ 1 and KQ 2:

- Health outcomes for people with dementia, such as pain or discomfort; depressive symptoms; sleep quality; health decline/morbidities including skin ulcers; decline in functioning, self-care, or maintenance; decline in cognitive functioning; falls; mortality; and hospitalizations;
- Psychosocial outcomes for people with dementia, such as positive and negative affect including pleasure and anxiety; behavioral symptoms; engagement; quality of life; quality of dying; spiritual well-being; control; autonomy; choice; satisfaction; use of psychoactive medications; and use of restraints.

Table 4. Definitions of the grades of overall strength of evidence

Grade	Definition*
High	High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of the effect and may change the estimate.
Low	Low confidence that the evidence reflects the true effect. Further research is likely to change our confidence in the estimate of the effect and is likely to change the estimate.
Insufficient	Evidence either is unavailable or does not permit estimation of an effect.

*Owens et al., 2010[32]

At a minimum, two reviewers assessed each domain for each key outcome and resolved any differences by consensus. We used a qualitative process, considering each of the domains, to determine the overall SOE grade for each relevant outcome. Differences in overall SOE grades were resolved by discussion with the research team until reaching consensus. Given that most outcomes had only a single study to provide evidence, consistency would be considered not applicable; when the study had estimates of effects that were not statistically significant or had wide confidence intervals, we rated that domain as imprecise. For outcomes with a single study with imprecise results and for which power was not ensured, we generally graded the SOE as insufficient; for a single study with precise results, we graded it as low. Therefore, although effectiveness is not synonymous with precision nor with SOE, individual studies that showed an effect generally merited a rating of low SOE.

Applicability

We assessed the applicability of the evidence following guidance from the Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[33] We used the PICOTS framework to explore factors that affect applicability. Some factors identified a priori that may limit the applicability of evidence included the following: differences between study resident populations and general resident populations with respect to race, ethnicity, sex, comorbidity, extent of cognitive impairment, and functional status; intensity and delivery of interventions; years in which the studies were performed; and standards of care that differ markedly from settings of interest (e.g., practice standards that vary from State to State).

Peer Review and Public Commentary

Experts in the field and individuals representing stakeholder and user communities were invited to provide external peer review of this CER. They were charged with commenting on the content, structure, and format of the evidence report, providing additional relevant citations, and pointing out issues related to how we conceptualized the topic and analyzed the evidence. Our peer reviewers (listed in the front matter) gave us permission to acknowledge their review of the draft. AHRQ staff and an associate editor also provided comments. In addition, the Scientific Resource Center posted the draft report on the AHRQ Web site (http://effectivehealthcare.ahrq.gov/) for 4 weeks to elicit public comment. We addressed all peer reviewer and TEP comments, revising the text as appropriate, and documented everything in a "disposition of comments report" that will be made available 3 months after the Agency posts the final CER on the AHRQ Web site. No public comments were received for this report.

Results

Introduction

This chapter is organized by Key Question (KQ) and then grouped by intervention/exposure category. Briefly, we wanted to compare the effectiveness of organizational characteristics, structures, and processes of care in nursing homes (NHs) and other residential long-term care settings on four types of outcomes: health outcomes for people with dementia (KQ 1), psychosocial outcomes for people with dementia (KQ 2), health outcomes for informal caregivers of people with dementia (KQ 3), and psychosocial outcomes for informal caregivers of people with dementia (KQ 4). KQ 5 assessed whether the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes varied by the characteristics of the person with dementia (e.g., severity of dementia, functional status) or of the informal caregiver (e.g., age, relationship, health status); we report on relevant KQ 5 studies only in the context of KQs 1 to 4.

People who reside in long-term care settings are often referred to as residents; generally speaking, the term "residents" refers to people who do and do not have dementia. For ease of reading, we refer to people with dementia as residents; unless otherwise noted, however, our comments are relevant only to those residents who have dementia.

Results of Literature Searches

Results of our literature searches appear in Figure 2. We ultimately included 14 published articles: 9 randomized controlled trials (RCTs), 1 nonrandomized controlled trial, and 4 prospective cohort studies. We recorded the reason that each excluded full-text publication did not satisfy the eligibility criteria and compiled a comprehensive list of such studies (Appendix B). Evidence tables for included studies can be found in Appendix C.

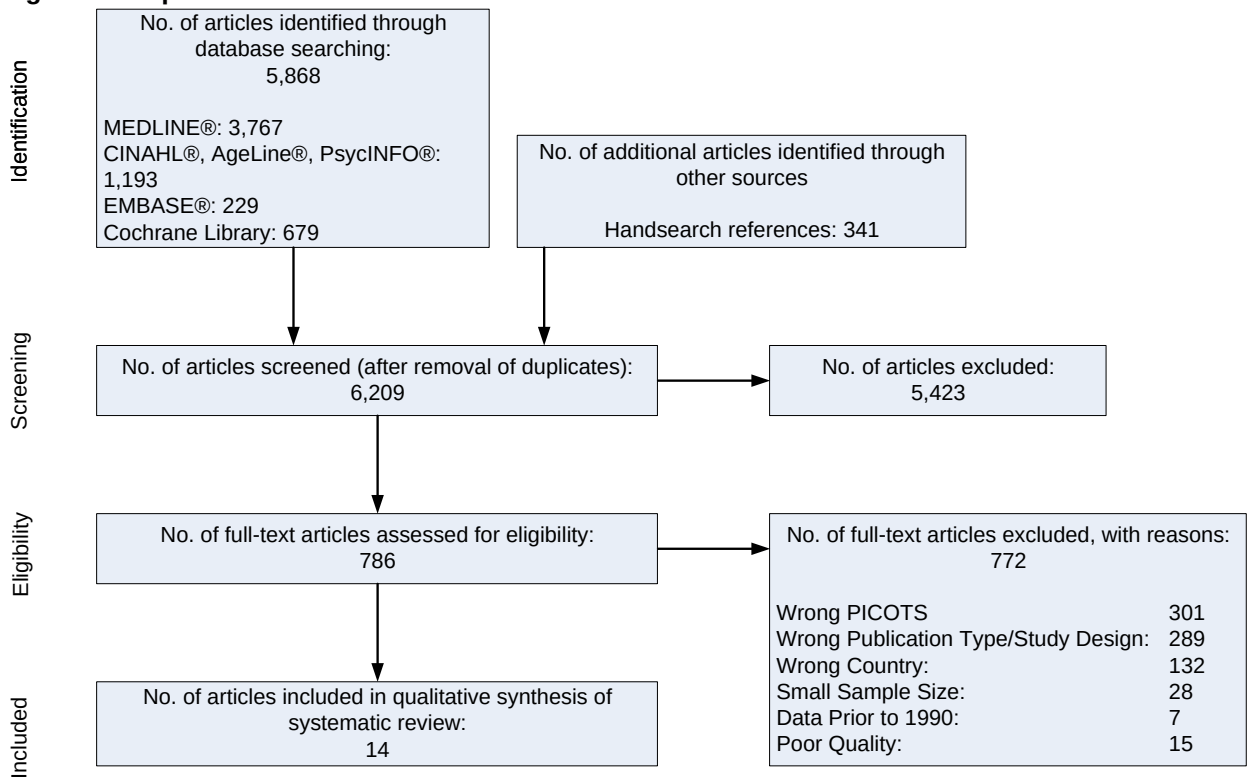
Description of Included Studies

Table 5 outlines the characteristics of the 14 included studies. Half the studies examined the effectiveness of an intervention/exposure among a population ranging in dementia severity from mild to severe.[25, 34-39] One study included a population with moderate to severe dementia severity[40] and two studies focused on populations with severe dementia.[41, 42] A few studies did not report enough information (e.g., range on the Mini-Mental State Examination, Minimum Data Set Cognition Scale, or Global Deterioration Scale) to determine the extent of cognitive impairment or dementia severity of the population.[43-46]

Ten studies addressed health outcomes for people with dementia (KQ 1);[34, 35, 38-41, 43-46] 10 studies examined psychosocial outcomes for people with dementia (KQ 2).[25, 36, 37, 39-44, 46] No eligible studies of fair or better quality examined either health or psychosocial outcomes (respectively, KQ 3 and KQ 4) for informal caregivers of people with dementia. One study addressed whether effects of organizational characteristics differed by dementia severity but not by other characteristics (KQ 5),[39] and one study examined whether effects of a structure of care differed by sociodemographic characteristics (i.e., sex).[35]

One study took place in multiple special care units.[36]Two studies took place in a dementia care unit within an NH.[35, 43] Three additional studies occurred in RC/AL settings and NHs.[25, 39, 44] The remaining eight studies examined characteristics within NHs.[34, 37, 38, 40-42, 45, 46]

Figure 2. Disposition of articles



CINAHL = Cumulative Index to Nursing and Allied Health Literature; No. = number; PICOTS = populations, interventions/exposures, comparators, outcomes, timing, settings

Four prospective cohort studies examined the effectiveness of organizational characteristics.[25, 36, 39, 44] Two RCTs and one prospective cohort study assessed the effectiveness of structures of care.[25, 34, 35] The remaining studies examined processes of care. Five of these process of care studies (four RCTs and one prospective cohort) assessed group activity interventions;[25, 38, 43, 45, 46] two trials related to pleasant sensory stimulation;[37, 42] and two RCTs were protocols for individualized care.[40, 41]

We rated 4 studies as good quality[38, 39, 41, 44] and the remaining 10 studies as fair quality.[25, 34-37, 40, 42, 43, 45, 46] We excluded studies that we rated poor quality from further analyses; they are listed in Appendix D.

Table 5. Characteristics of all included studies

Characteristics	Author, Year, Design Duration Quality	Dementia Severity[a]	Baseline Cognitive Impairment	Sample Size	Setting	Interventions/Exposures
Organizational	Leon and Ory, 1999[36] Prospective cohort 6 months Fair	Mild to severe	MDS-COGS Overall: 6.03 G1: 6.23 G2: 5.49	G1: 495 G2: 200	SCU, Non-SCU	G1: SCU within NH G2: Non-SCU within NH
	Sloane et al., 2005[39] Prospective cohort 12 months Good	Mild to severe	MDS-COGS G1: 5.3 G2: 5.7	G1: 773 G2: 479 G3: 164 G4: 607 G5: 94 G6: 385	RC/AL, NH	G1: RC/AL G2: NH G3: SCU within RC/AL G4: Non-SCU within RC/AL G5: SCU within NH G6: Non-SCU within NH
	Sloane et al., 2008[44] Prospective cohort 1 month Good	NR	NR	G1: 175 G2: 247	RC/AL, NH	G1: RC/AL G2: NH
	Zimmerman et al., 2005[25b] Prospective cohort 6 months Fair	Mild to severe	MMSE or MDS-COGS Mild to moderate: 152 Severe to very severe: 259	G1: 48 G2: 101 G3: 135 G4: 137	RC/AL, NH	G1: RC/AL – settings with <16 beds G2: RC/AL traditional – settings with ≥16 beds, not meeting new-model criteria G3: New-Model: RC/AL settings with ≥16 beds of the “new-model” type G4: NH

Table 5. Characteristics of all included studies (continued)

Intervention/ Exposure Category	Author, Year, Design Duration Quality	Dementia Severity[a]	Baseline Cognitive Impairment	Sample Size	Setting	Interventions/Exposures
Structures of Care	Dowling et al., 2005[34] RCT 10 weeks Fair	Mild to severe	MMSE Overall: 6.7; range 0 to 23	G1: 29 G2: 17	NH	G1: Morning bright light exposure (9:30–10:30 a.m., >2,500 lux in gaze direction) G2: Control - Usual indoor light levels (150–200 lux)
	Hickman et al., 2007[35] RCT 3 weeks Fair	Mild to very severe	MDS-COGS[c] Mild to Moderate Men: 34.3% Women: 29.0% Severe Men: 42.9% Women: 51.6% Very Severe Men: 22.9% Women: 19.4%	G1: 32 G2: 46 G3: 47 G4: 48	Geriatric unit and SCU	G1: Morning bright light (7 a.m.–11 a.m.) G2: Evening bright light (4 p.m.–8 p.m.) G3: All-day bright light (7 a.m.–8 p. m.) G4: Standard light (7 a.m.–8 p. m.)
	Zimmerman et al., 2005[25b] Prospective cohort 6 months Fair	Mild to severe	MMSE or MDS-COGS Mild to moderate: 152 Severe to very severe: 259	G5: NR G6: NR	RC/AL, NH	G5: Use of specialized workers (staff fill specialized roles) G6: No use of specialized workers
Processes of Care	Fritsch et al., 2009[43] RCT 10 weeks Fair	NR	NR	G1: 10 SCUs G2: 10 SCUs	SCU in NHs	G1: TimeSlips – group storytelling program that encourages creative expression among people with dementia G2: Control – no intervention
	Kovach et al., 2006[41] RCT 4 weeks Good	Severe	MMSE G1: 7.35 G2: 8.26 Overall: 7.81	G1: 57 G2: 57	NH	G1: Serial trial intervention – multistep clinical protocol for assessment and management of unmet needs in people with late-stage dementia G2: Control – curricula included common misconceptions about aging, reversible and irreversible causes of dementia, stages of AD, approaches to treating behaviors, and physical conditions associated with dementia
	Remington, 2002[37] RCT 10 minutes Fair	Mild to severe	NR	G1: 17 G2: 17 G3: 17 G4: 17	NH	G1: Calm music (10 minutes) G2: Hand massage (10 minutes) G3: Calm music and hand massage (10 minutes simultaneously) G4: Control – no intervention

Table 5. Characteristics of all included studies (continued)

Intervention/ Exposure Category	Author, Year, Design Duration Quality	Dementia Severity[a]	Baseline Cognitive Impairment	Sample Size	Setting	Interventions/Exposures
Processes of Care (continued)	Rosswurm, 1990[38] RCT 3 weeks Good	Mild to severe	MMSE G1: 9.86 G2: 11.1	G1: 15 G2: 15	NH	G1: Attention-focusing group – welcoming and relaxation exercises; perceptual-matching exercises; reinforcement with refreshments G2: Control – refreshments and the opportunity for social interaction
	Sloane et al., 2004[40] RCT 2 weeks Fair	Moderate to severe	MDS-COGS G1 and G2: 7.7 G3: 6.5	G1: 24 G2: 25 G3: 24	NH	G1: Patient-centered showering – patient-centered techniques: providing choices, covering with towels to maintain warmth, distracting attention, using family- or staff-recommended bathing products, using no-rinse soap, modifying shower spray G2: Towel bath – patient-centered techniques: using two bath blankets, two bath towels, a no-rinse soap, and 2 quarts of warm water; keeping the resident covered at all times; cleansing the body using gentle massage G3: Control – showering without patient-centered training
	Tappen, 1994[45] RCT 20 weeks Fair	NR	MMSE Overall: 6.4	G1: 21 G2: 21 G3: 21	NH	G1: Functional skill training – regain function in basic activities of daily living through repeated practice in group setting 5 days/week for 2.5 hours per day G2: General stimulation – recreationally oriented group activities provided for dementia patients in therapeutically oriented settings 5 days/week for 2.5 hours per day G3: Control – regular care
	Toseland et al., 1997[46] RCT 52 weeks Fair	NR	SPMSQ G1: 7.43 G2: 7.46 G3: 7.15	G1: 31 G2: 29 G3: 28	NH	G1: Validation group therapy – encourage residents with dementia to continue communicating using memory fragments and other aspects of cognitive, affective, and motoric functioning G2: Social contact – one activity each meeting in the 8 categories of music, art, literature and writing, dance/exercise, games/trivia, holiday and event planning, discussion, and other activities G3: Usual care – participation in regular social and recreational programming offered by each NH

Table 5. Characteristics of all included studies (continued)

Intervention/ Exposure Category	Author, Year, Design Duration Quality	Dementia Severity[a]	Baseline Cognitive Impairment	Sample Size	Setting	Interventions/Exposures
Processes of Care (continued)	Whall et al., 1997[42] Non-RCT 1 week Fair	Severe	NR	G1: 15 G2: 16	NH	G1: Shower room – recorded songs of birds, sounds of babbling brooks, and sounds of other small animals; large bright pictures coordinated with audio; offering foods such as banana pudding or soda G2: Usual care
	Zimmerman et al., 2005[25b] Prospective cohort 6 months Fair	Mild to severe	MMSE or MDS-COGS Mild to moderate: 152 Severe to very severe: 259	G7: NR G8: NR	RC/AL, NH	G7: Encourage activities[d] ≥ once a day G8: Encourage activities[d]<once a day

AD = Alzheimer's disease; G = group; MDS-COGS = Minimum Data Set Cognition Scale; MMSE = Mini-Mental State Examination; NH = nursing home; NR = not reported; RC/AL = residential care/assisted living; RCT = randomized controlled trial; SCU = special care unit; SPMSQ = Short Portable Mental Status Questionnaire

[a]Investigators used the following scales and measurement to determine the level of dementia severity: mild, scores of 17-23 on the MMSE, 0-1 on the MDS-COGS, or stage 4 on the Global Deterioration Scale; moderate, scores of 11-16 on the MMSE, 2-4 on the MDS-COGS, or stage 5 on the Global Deterioration Scale; and severe, scores of ≤ 10 on the MMSE, ≥ 5 on the MDS-COGS, or stage 6 and stage 7 on the Global Deterioration Scale.

[b]Zimmerman et al.[25] examined interventions/exposures within all three categories – organizational characteristics, structures of care, and processes of care. It has thus been listed 3 times in Table 5.

[c]For four residents missing MDS-COGS scores, dementia severity was based on MMSE, education, and activities of daily living score.

[d]Activities included exercise, personal care, social activities, housekeeping, meal preparation, crafts/handiwork, special event, sensory activities, and intellectual activities.

KQ 1. Health Outcomes for People With Dementia

KQ 1 compares the effectiveness of organizational characteristics, structures, or processes of care in NHs and other residential long-term care settings for improving health outcomes for people with dementia. Health outcomes measured in at least one included study include discomfort from pain, functional decline, cognitive decline, symptoms of depression, morbidities (e.g., skin ulcers), hospitalization, mortality, and sleep quality. Another health outcome on which we sought but did not identify evidence from included studies was falls. We also assessed whether effects differed by dementia severity and other characteristics of the person with dementia.

Of the 10 studies reviewed, 8 interventions showed statistically significant effects on health outcomes, with insufficient to low SOE. Process of care interventions provided more evidence than did interventions focusing on organizational characteristics or structures of care. Only one study addressed whether effects differed by dementia severity (but not by other characteristics) and found hospitalization was more likely in RC/AL settings than in NH settings for residents with mild dementia (low SOE). Another found the effects of a lighting intervention differed by sex.

Key Points of Organizational Characteristics

- Two studies addressed organizational attributes but found few differences between RC/AL settings and NH settings on a range of health outcomes, with some differences occurring between dementia special care units (SCUs) and non-SCUs located within either RC/AL settings or NH settings, with insufficient to low SOE.
- Evidence from one study did not show a difference in mortality rates for residents in RC/AL compared with those in NHs (low SOE).
- Some evidence suggested higher hospitalization rates (low SOE) but little difference in multiple morbidity measures (insufficient to low SOE) in RC/AL settings than in NH settings.
- Evidence on dementia SCUs was inconsistent. Residents of dementia SCUs, when compared with no SCU, had greater decline in functioning over time (low SOE), and lower rates of both hospitalization and new or worsening morbidity (low SOE).

Key Points of Structures of Care

- One RCT found no effect for lighting interventions on sleep quality and another RCT found no effect on depressive symptoms for the overall populations studied, but benefit in both trials for some subgroups (insufficient SOE; single studies with imprecise results and no power calculations).

Key Points of Processes of Care

Evidence for group activity interventions was mixed:

- A functional skills training intervention produced modest effect sizes for improving ADLs, with effect sizes being equivalent to moving from major to moderate or from moderate to minor assistance in performing the ADLs (low SOE).

- A storytelling intervention improved cognitive alertness by about 3 percentage points (low SOE).
- Two interventions had no benefits. A validation group therapy intervention did not improve functional self-care or depressive symptoms. An attention-focusing intervention did not improve cognitive impairment (insufficient SOE; single studies with imprecise results and no power calculations).

Evidence for personalized care interventions was modest:

- A personalized assessment and treatment intervention reduced resident discomfort with an effect size of 0.89 (low SOE).
- Both personalized showering and towel bath interventions reduced resident discomfort on an Alzheimer's discomfort scale by 0.32 and 0.57 points, respectively, compared with a control group score of 2.14 (low SOE).

Detailed Synthesis of Organizational Characteristics

Two studies considered organizational characteristics and their effects on health outcomes (Tables 6 and 7).[39, 44] Both studies[39, 44] evaluated the effects of care in RC/AL settings versus NH settings. The first study also analyzed a second exposure of interest, separately testing whether dementia SCUs within each setting improved health outcomes when compared with no SCU within each setting.[39] These results from this one study are provided separately. The second study focused on outcomes for people who died.

Both cohort studies reported few differences between RC/AL settings versus NH settings on a range of outcomes for which study authors controlled for differences in resident baseline demographic, health and cognitive characteristics. In the first study, RC/AL settings had a slightly higher hospitalization rate than NH settings for residents with mild dementia.[39] In addition, residents on dementia SCUs versus no SCU within each setting differed on some measures. First, residents of dementia SCUs within RC/AL settings had more decline in ADL functioning over time than residents who were not in SCUs.

Second, residents in dementia SCUs within NHs had lower rates of hospitalization and new or worsening morbidity than those who were not in SCUs. All differences reported were small in magnitude. This study found no differences across either settings or dementia SCUs on outcome measures for discomfort, depressive symptoms, cognitive impairment, or mortality.

In the second study, morbidity differed little between RC/AL settings and NH settings.[44] When compared with NH settings on five different morbidity measures, RC/AL settings differed only by having a much larger proportion of residents who experienced a series of ups and downs in resident health compared with a steady decline in the last months of life. The rate of hospitalization did not differ between settings.

Taken together, these two studies suggest that residents in RC/AL settings and NH settings differ little on the health outcomes measured (low to insufficient SOE; Table 8). However, the findings of no difference concerning RC/AL and NHs on life-sustaining hospitalization in the last month of life, stable health, steady decline in health, and skin ulcers was insufficient. This was a single study that had imprecise results and no power calculations provided to justify sample size. No studies considering organizational characteristics provided evidence on falls and sleep quality, thus the evidence was insufficient.

For KQ 5, only one study[39] addressed whether effects differed by dementia severity (but not by other characteristics) and found no differences in health outcomes based on residence in an NH versus RC/AL (low SOE).

Table 6. Effect of organizational characteristics on functioning, discomfort, depressive symptoms, cognitive impairment, mortality, and hospitalization

Author, Year Design	Interventions/ Exposures	Change in ADL Functioning[a]	Discomfort	Increase in Depressive Symptoms[b]	Cognitive Impairment	Mortality[c]	Hospitalization[c]	Life-Sustaining Hospitalization in Last Month of Life
Sloane et al., 2005[39] Prospective cohort	G1: RC/AL G2: NH	**Mild dementia** G1: 4.29 G2: 5.80 p=0.059 **Moderate to severe dementia** G1: 0.87 G2: 1.13 p=0.807	**Pain not effectively treated during last month of life**[d] G1: 10.2% G2: 5.5% p= 0.186	**Mild dementia** G1: 1.33 G2: 1.53 p=0.753 **Moderate to severe dementia** G1: 1.52 G2: 0.85 p=0.409	**Mild dementia** G1: 0.41 G2: 0.71 p=0.181 **Moderate to severe dementia** G1: -0.13 G2: 0.45 p=0.93	**Mild dementia** G1: 3.2 G2: 4.2 p=0.409 **Moderate or severe dementia** G1: 3.7 G2: 4.2 p=0.682	**Mild dementia** G1: 14.2 G2: 8.4 p=0.009 **Moderate or severe dementia** G1: 14.2 G2: 10.0 p=0.115	NR
	G3: SCU in RC/AL G4: Non-SCU in RC/AL G5: SCU in NH G6: Non-SCU in NH	**Any dementia** G3: 5.64 G4: 2.91 G5: 3.00 G6: 3.19 G3 vs. G4: p=0.029 G5 vs. G6: p=0.886	NR	**Any dementia** G3: 1.59 G4: 1.32 G5: 0.89 G6: 1.25 G3 vs. G4: p=0.823 G5 vs. G6: p=0.630	**Any dementia** G3: 0.33 G4: 0.30 G5: 0.58 G6: 0.61 G3 vs. G4: p=0.943 G5 vs. G6: p=0.903	**Any dementia** G3: 7.0 G4: 4.0 G5: 3.4 G6: 4.0 G3 vs. G4: p =0.116 G5 vs. G6: p= 0.540	**Any dementia** G3: 17.3 G4: 14.4 G5: 3.9 G6: 9.6 G3 vs. G4: p=0.430 G5 vs. G6: p=0.006	NR
Sloane et al., 2008[44] Prospective cohort	G1: RC/AL G2: NH	NR	NR	NR	NR	NR	NR	**Any dementia** G1: 39.7% G2: 23.6% p=0.149

ADL = activities of daily living, CSDD = Cornell Scale for Depression in Dementia; G = group; MDS-ADL = Minimum Data Set – Activities of Daily Living; NH = nursing home; NR = not reported; RC/AL = residential care/assisted living; SCU = special care unit

[a]Mean change in ADL dependency per 12 months using the MDS-ADL scale.

[b]Measured by Cornell Scale for Depression in Dementia (CSDD) scale.

[c]Incidence rate per 100 participants per quarter.

[d]Study also reported pain never an issue during the last month of life, G1: 48.5% vs. G2: 38.7%, p = 0.249.

Table 7. Effect of organizational characteristics on morbidity

Author, Year Design	Interventions/ Exposures	New or Worsening Morbidity[a,b]	Stable Health[c]	Steady Decline in Health[c]	Series of Ups and Downs in Health[c]	One or More Skin Ulcers[c]
Sloane et al., 2005[39] Prospective cohort	G1: RC/AL G2: NH	**Mild dementia** G1: 23.5 G2: 21.8 p=0.574 **Moderate to severe dementia** G1: 21.1 G2: 21.7 p=0.865	NR	NR	NR	NR
	G3: SCU in RC/AL G4: Non-SCU in RC/AL G5: SCU in NH G6: Non-SCU in NH	**Any dementia** G3: 26.7 G4: 25.3 G5: 15.0 G6: 22.0 G3 vs. G4: p=0.772 G5 vs. G6: p=0.043	NR	NR	NR	NR
Sloane et al., 2008[44] Prospective cohort	G1: RC/AL G2: NH	NR	**Any dementia, %** G1: 12.6 G2: 8.1 p=0.136	**Any dementia, %** G1: 53.4 G2: 71.7 p=NR	**Any dementia, %** G1: 33.9 G2: 20.2 p<0.001	**Any dementia, %** G1: 26.9 G2: 22.6 p=0.566

G = group; NH = nursing home; NR = not reported; RC/AL = residential care/assisted living; SCU = special care unit

[a]Incidence rate per 100 participants per quarter.

[b]New or worsening morbidity defined as the incidence or worsening of fracture, infection, stroke or paralysis, bleeding from the stomach or bowel, diabetes, heart condition, or skin ulcer.

[c]Health change in last 12 months of life.

Table 8. Effect of organizational characteristics comparing residential care/assisted living settings versus nursing homes on health outcomes: strength of evidence

Outcomes	Number of Studies; Number of Subjects	Risk of Bias; Design; Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Change in ADL functioning	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	Favors non-SCU vs. SCU in RC/AL	Low
Discomfort	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	RC/AL vs. NH no difference	Low
Change in depressive symptoms	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	RC/AL vs. NH and SCU vs. non-SCU no difference	Low
Cognitive impairment	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	RC/AL vs. NH and SCU vs. non-SCU no difference	Low
Mortality	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	RC/AL vs. NH and SCU vs. non-SCU no difference	Low
Hospitalization	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	Favors NH vs. RC/AL; favors NH SCU vs. NH non-SCU	Low
Life-sustaining hospitalization in last month of life	1; 422	Low; Prospective cohort; Good	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]
New or worsening morbidity	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	Favors NH SCU vs. NH non-SCU	Low
Stable health	1; 422	Low; Prospective cohort; Good	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]

Table 8. Effect of organizational characteristics comparing residential care/assisted living settings versus nursing homes on health outcomes: strength of evidence (continued)

Outcomes	Number of Studies; Number of Subjects	Risk of Bias; Design; Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Steady decline in health	1; 422	Low; Prospective cohort; Good	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]
Series of ups and downs in health	1; 422	Low; Prospective cohort; Good	NA	Direct	Precise	Favors NH vs. RC/AL	Low
One or more skin ulcers	1; 422	Low; Prospective cohort; Good	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]

ADL = activities of daily living; NA = not applicable; NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit

[a]No power calculations provided to justify sample size.

Detailed Synthesis of Structures of Care

Two RCTs considered structures of care, specifically lighting interventions, and their effects on two health outcomes (sleep quality and depressive symptoms) (Table 9).[34, 35] One intervention was conducted in NHs either outdoors or in an indoor space with expansive surrounding windows.[34]

Table 9. Effect of lighting interventions on depressive symptoms and sleep quality

Author, Year Design	Interventions	Depressive Symptoms[a]	Sleep Time	Awake Time
Dowling et al., 2005[34] RCT	G1: Morning bright light exposure G2: Control - Usual indoor light levels	NR	Proportion of night asleep,% G1: 66.64 G2: 71.14 p=NR[b] Sleep time, hours: minutes G1: 7:59 G2: 8:32 p=NR[b]	Night wake time, hours: minutes G1: 3:59 G2: 3:27 p=NR[b] Number of awakenings at night when asleep G1: 42.88 G2: 37.99 p=NR[b] Day wake time, hours: minutes G1 6:24 G2: 6:34 p=NR[b]
Hickman et al., 2007[35] RCT	G1: Morning bright light G2: Evening bright light G3: Standard light G4: All-day light	Subanalyses by men G1 vs.G3: 2.62, p=0.007 G2 vs.G3: 1.13, p=0.23 G4 vs.G3: 1.64, p=0.08 G1 vs.G2: 1.50, p= 0.16 G1 vs.G4: 0.98, p=0.33 G2 vs. G4: –0.52, p=0.60 Subanalyses by women G1 vs.G3: –1.61, p=0.09 G2 vs.G3: 0.09, p=0.94 G4 vs. G3: 1.41, p=0.16 G1 vs. G2: –1.70, p=0.08 G1 vs. G4: –3.02, p=0.01 G2 vs. G4: –1.32, p=0.24	NR	NR

G = group; NR = not reported; RCT = randomized controlled trial

[a]Cornell Scale for Depression in Dementia (negative change scores mean less depressed).

[b]Analysis of Variance was not significant.

The other intervention was conducted in a State-operated psychiatric hospital or a dementia-specific residential care setting in both the activity and dining areas of both sites.[35]

These trials did not find an overall effect of either morning bright light on sleep[34] or morning, evening, or all-day light on depressive symptoms.[35] One trial found that bright morning light improved the start of the sleep and wake cycles of those people with aberrant cycle timing; it found no effect on residents with nonaberrant sleep/wake cycle timing. No other effects were found on people with aberrant sleep/wake cycle timing. Subgroup analyses in the other trial found better depressive symptom scores for women for morning bright light compared with all-day light. Neither study assessed measures for functioning, discomfort, cognitive impairment, morbidity, mortality, or hospitalization.

Taken together, these studies provide insufficient SOE that lighting interventions improve sleep quality and depressive symptoms due to imprecise results and no power calculations provided to justify sample size (Table 10).

Table 10. Effect of lighting interventions on health outcomes: strength of evidence

Outcome	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Sleep Quality	1; 46	Medium; RCT; Fair	NA	Direct	Imprecise	No difference	Insufficient[a]
Depressive Symptoms	1; 155	Medium; RCT; Fair	NA	Direct	Imprecise	No difference	Insufficient[a]

NA = not applicable; RCT = randomized controlled trial
[a]No power calculations provided to justify sample size.

For KQ 5, one study on structures of care related to health outcomes for people with dementia differentiated findings by dementia severity or other characteristics of the person with dementia.[35] This study found that the lighting intervention produced better depressive symptom outcomes for women exposed to morning bright light compared with all-day light but worse outcomes for men exposed to morning bright light compared with standard light. However, the evidence was insufficient regarding the effectiveness of lighting interventions for these subgroups. This was a single study that had imprecise results and no reported power calculation.

Detailed Synthesis of Processes of Care

Six RCTs evaluated the effects of process of care interventions on five health outcomes. Four studies evaluated the effects of various group activity interventions on functioning, self-care, depressive symptoms, and cognitive impairment.[38, 43, 45, 46] Two studies assessed effects of personalized care interventions on discomfort.[40, 41] The interventions in these studies were dissimilar so evidence on each intervention is graded separately. All trials were conducted in NHs, although one was conducted on a dementia SCU within an NH.[43]

Group Activity Interventions

Four trials employed group activity interventions. Tappen[45] used functional skill training to improve basic ADLs; Toseland et al.[46] used validation group therapy to improve self-care and depressive symptoms (Table 11). Fritsch et al.[43] employed a storytelling intervention designed to improve cognition, while Rosswurm[38] sought to improve cognition through an attention-focusing intervention (Table 12).

Table 11. Effect of group activity interventions on ADL functioning, self-care, and depressive symptoms

Author, Year Design	Interventions	ADL Goal Attainment[a]	ADL Test[b]	Self-Care[c]	Depressive Symptoms[c]
Tappen, 1994[45] RCT	G1: Functional skill training G2: General stimulation G3: Control group	**Adjusted post-test means score** G1: 26.17 G2: 24.10 G3: 22.63 G1 vs. G3 p=0.01 G2 vs. G1 or G3: p=NS **Mean achieved score** G1: 1.75 G2: 1.43 G3: 1.10 G1 vs. G3, p=0.05 G2 vs. G1 or G3: p=NS	**Within-group mean change** G1: -3.01 G2: -0.86 G3: +1.14 p=0.12	NR	NR
Toseland et al., 1997[46] RCT	G1: Validation group therapy G2: Social contact G3: Usual care	NR	NR	**Change at endpoint** G1: 0.02 G2: -0.59 G3: -1.07	**Change at endpoint** G1: 1.45 G2: -2.56 G3: 0.6 p=NR, stated difference NS

ADL = activities of daily living; G = group; NR = not reported; NS = not significant; RCT = randomized controlled trial
[a] Physical Self Maintenance Scale (higher scores show greater goal attainment)
[b] Performance Test of Activities of Daily Living
[c] Multidimensional Observation Scale for Elderly Subjects Self-Care Subscale

Table 12. Effect of group activity interventions on cognitive impairment

Author, Year	Interventions	Cognitive Alertness[a]	Cognitive Improvement[b]	Cognitive Function[b]
Fritsch et al., 2009[43] RCT	G1: TimeSlips G2: Control	G1: 1512/1647 G2:1111/1245 G1 vs. G2: 1.028 times greater number of general alertness events p<0.05	NR	NR
Rosswurm, 1990[38] RCT	G1: Attention-focusing group G2: Control group	NR	**Mean gain score at endpoint** G1: 1.33 G2: -0.33 t value=1.36, NS	**Mean gain score at endpoint** G1: 0.33 G2: -0.33 t value=0.32, NS

G = group; NR = not reported; NS = not significant; RCT = randomized controlled trial
[a]General Alertness Subscale.
[b]Mini Mental State Examination.

These four RCTs produced mixed results (Table 13). A functional skills training intervention comprising repeated practice of five ADLs in a group setting 5 days per week for 2.5 hours per day over 20 weeks versus a control group providing usual nursing care produced a strong effect on both a scale measure of functional performance and a personal goal attainment measure.[45] The effect size was reported to be the equivalent of moving from major to moderate or from moderate to minor assistance in performing ADLs. A third group participating in recreationally oriented group activities in a therapeutic setting with the same intensity and performance period experienced no effect (low SOE).

Table 13. Effect of processes of care on health outcomes: strength of evidence

Process of Care	Outcome	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Functional Skill Training	Goal attainment	1; 63	Low; RCT; Fair	NA	Direct	Precise	Favors functional skill training	Low
	Activities of daily living	1; 63	Low; RCT; Fair	NA	Direct	Imprecise	No difference	Insufficient[a]
Validation Group Therapy	Self-care	1; 88	Medium; RCT; Fair	NA	Direct	Imprecise	No difference	Insufficient[a]
	Depressive symptoms	1; 88	Medium; RCT; Fair	NA	Direct	Imprecise	No difference	Insufficient[a]
Storytelling Intervention	Cognitive alertness	1; NR; 20 NHs	Medium; RCT; Fair	NA	Direct	Precise	Favors storytelling	Low
Attention-focusing Group	Cognitive improvement	1; 30	Low; RCT; Good	NA	Direct	Imprecise	No difference	Insufficient[a]
	Cognitive function	1; 30	Low; RCT; Good	NA	Direct	Imprecise	No difference	Insufficient[a]

NA = not applicable; NH = nursing home, NR = not reported; RCT = randomized controlled trial
[a]No power calculations provided to justify sample size.

Another trial found a modest (approximately 3 percentage point) effect of a 10-week storytelling intervention designed to improve general alertness as a measure of cognitive impairment.[43] Residents were asked to comment on a picture, and staff then wove resident contributions into a story that was retold frequently. The intervention group was more alert in a larger proportion of events than the control group receiving usual care (low SOE).

Two other interventions found no effect. An attention-focusing group using perceptual-matching exercises for 30 minutes 3 times weekly over 4 weeks produced no improvement on two measures of cognitive status.[38] The evidence of the effect of the attention-focusing group was insufficient for both outcomes. This was a single study that had imprecise results and did not report power calculations. A validation group therapy intervention versus a social interaction intervention for four 30-minute weekly sessions over 1 year versus usual care yielded no effect on measures of functioning and depressive symptoms.[46] The evidence of the effect of validation group therapy on functioning and depressive symptoms is also insufficient. This was a single study that had imprecise results and provided no power calculations.

Half of the RCTs assessed yielded some benefits across a variety of outcomes. For all interventions/exposures, we found no evidence for the following health outcomes: falls, discomfort, hospitalization, morbidity, mortality, and sleep quality. We found no evidence for depressive symptoms except for validation group therapy, no evidence for functional decline except for functional skill training, and no evidence for cognitive impairment measures except for a storytelling intervention and an attention-focusing intervention. We graded SOE for interventions that did not measure or report on the outcomes below as insufficient.

For KQ 5, none of the four studies on group activity interventions related to health outcomes for people with dementia differentiated findings by dementia severity or other characteristics of the person with dementia (insufficient SOE).

Personalized Care Interventions

Two trials designed to reduce discomfort were individualized to each resident (Table 14). Kovach et al.[41] provided assessment and treatment customized to each resident in the experimental group. Sloane et al.[40] used a patient-centered showering protocol for one intervention group and a towel bath protocol for a second intervention group.

Table 14. Effect of personalized care interventions on discomfort

Author, Year Design	Interventions	Change in Discomfort[a]
Kovach et al., 2006[41] RCT	G1: Serial Trial Intervention G2: Control	Change at endpoint G1: 40.74 G2: -39.53 G1 vs. G2: p<0.001
Sloane et al., 2004[40] RCT	G1: Patient-centered showering G2: Towel bath G3: Showering without patient-centeredness	Change at endpoint G1: 0.32 G2: 0.57 G3: -0.02 G1 vs. G3: p<0.001 G2 vs. G3: p=0.001 G1 vs. G2: p=0.003

G = group; RCT = randomized controlled trial; vs. = versus

[a]Modified Discomfort Scale for dementia of the Alzheimer type. Possible scores ranged from 0 to 900, with higher scores indicating more discomfort.

Kovach et al.[41] evaluated a clinical protocol called the Serial Trial Intervention for assessment and management of unmet needs over a 4-week period designed to create a customized care plan for each resident. Intervention group members were compared with residents whose care staff received general instruction on how to care for all residents but not an individualized care plan for each resident. Residents receiving Serial Trial Intervention had 0.89 times lower discomfort score than the control group.

Sloane et al.[40] evaluated two different showering/bathing interventions to reduce discomfort. The first intervention employed person-centered showering using a wide variety of techniques to calm residents. The second intervention used a towel bath, which encloses and covers the resident while care staff used massage and a no-rinse soap to bathe the resident. A third group received non-person-centered showering. The towel bath and person-centered showering intervention reduced resident discomfort by 26 percent and 14 percent, respectively.

These two trials showed substantial improvements on measures of discomfort (Table 15; low SOE). We found no evidence for the following health outcomes: falls, functioning, pain, depressive symptoms, hospitalization, morbidity, mortality, and sleep quality. We graded SOE for interventions that did not measure or report on these outcomes as insufficient.

Table 15. Effect of personalized care interventions on health outcomes: strength of evidence

Process of Care	Outcome	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Serial Trial Intervention	Change in discomfort	1;114	Low; RCT; Good	NA	Direct	Precise	Favors STI	Low
Bathing	Change in discomfort	1;73	Low; RCT; Fair	NA	Direct	Precise	Favors both showering and towel bath	Low

NA = not applicable; RCT = randomized controlled trial; STI = Serial Trial Intervention

For KQ 5, neither study using personalized care interventions differentiated findings by dementia severity or other characteristics of the person with dementia (insufficient SOE).

KQ 2. Psychosocial Outcomes for People With Dementia

KQ 2 compares the effectiveness of organizational characteristics, structures, or processes of care in NHs and other residential long-term care settings for improving psychosocial outcomes for people with dementia. Psychosocial outcomes measured in at least one included study include behavioral symptoms (e.g., agitation, aggression), engagement (e.g., social function, withdrawal), affect other than depressive symptoms (e.g., anxiety, pleasure), quality of life in Alzheimer's disease, quality of dying, use of restraints, and use of psychoactive medications. Other psychosocial outcomes on which we sought but did not identify evidence from included studies were spiritual well-being, control, autonomy, choice, and satisfaction. We also assessed whether effects differed by dementia severity and other characteristics of the person with dementia.

Ten studies (five RCTs) addressed psychosocial outcomes, with almost all showing some statistically significant effects on outcomes (low to moderate SOE). Only one study addressed whether effects differed by dementia severity (but not by other characteristics) and found no differences in behavioral symptoms or engagement based on residence in an NH versus RC/AL (low SOE).

Key Points of Organizational Characteristics

- Two studies found that, with one exception (restraint use), psychosocial outcomes did not differ between NH settings and RC/AL settings.
    - Behavioral symptoms and engagement did not differ by setting (low SOE).
    - Quality of dying, quality of life, and psychoactive medication use did not differ by setting (insufficient SOE; single studies with imprecise results and no power calculations).
    - Restraints were used more often in imminently dying residents in NH settings than in RC/AL settings (any restraints, 92% vs. 66%; any restraints other than partial bedrails, 68% vs. 46%; low SOE).

- One study found that quality of life did not differ based on proprietary status, chain affiliation, size, age, percentage of dementia beds, or resident case-mix (insufficient SOE; one study with imprecise results and no power calculation).
- Two studies found that behavioral symptoms did not differ based on residence in an SCU (low SOE).
- One study found that engagement did not differ based on residence in an SCU (low SOE).

Key Points of Structures of Care

- Based on one study, with one exception, quality of life did not differ based on many structures of care.
    - Quality of life did not differ based on the following structures: registered nurse (RN), licensed practical nurse (LPN), and aide full-time equivalents (FTEs) and number of contract staff per type; administrator, RN, LPN, and aide turnover; environmental quality; consistent staffing; or use of universal workers (insufficient SOE; one study with imprecise results and no power calculation).
    - Quality of life was statistically but not clinically better in settings that used specialized care workers (mean raw change over 6 months was 1.7 points worse when specialized workers were not used; low SOE).

Key Points of Processes of Care

- Group activity:
    - A creative expression storytelling group resulted in more challenging behaviors, anxiety, and sadness, and also less disengagement, neutral affect, and more engagement (low SOE).
    - A validation therapy group was superior to social control and usual care control groups in regard to nurse-reported (but not observer-reported) physically and verbally aggressive behavior at 1 year, and also resulted in more physically nonaggressive behaviors (low SOE). Validation therapy did not produce significant changes in engagement, irritability, restraint use, psychoactive medication use, or positive behaviors (insufficient SOE; one study with imprecise results and no power calculation).
    - More frequent encouragement of activity participation resulted in statistically but not clinically better quality of life (mean raw change over 6 months was 0.9 times worse when activities were encouraged less than once a day; low SOE).
- Based on two studies, pleasant sensory stimulation produced a clinically significant decrease in agitation (75% to 83% compared with control in one study; moderate SOE).
- Protocols for individualized care:
    - Individualized assessment and management of discomfort and behavioral symptoms did not result in behavioral change but did increase return of behavior to baseline levels (70% vs. 40% in the control group; low SOE).
    - Person-centered protocols for showering and bathing reduced behavioral symptoms (agitation and aggression) more in the intervention group than control group (mean time agitated or aggressive 24% and 26% in the intervention groups vs. 36% in the control group; low SOE).

- In one prospective cohort study, various processes of care (including policies and practices; staff involvement in care planning; assessments; treatment; use of medications; and use of stimuli such as craft or household items) did not improve quality of life (insufficient SOE; one study with imprecise results and no power calculation).

Detailed Synthesis of Organizational Characteristics

Three prospective cohort studies examined organizational characteristics and their effect on psychosocial outcomes, comparing NHs with RC/AL.[25, 39, 44] One study[39] (1,252 residents across 146 settings) differentiated 1-year outcomes by degree of dementia severity and residence on an SCU (Table 16);[39] it examined the effect of these organizational characteristics on behavioral symptoms and engagement, using standardized measures administered by interview to nursing staff. Another study, of 422 residents who died in 230 settings, investigated whether four components of the death experience (appeared to be at peace, received compassionate touch daily, maintained dignity, and had close attachment to staff) and the use of restraints and sedative medications differed by residence in an NH or RC/AL based on interviews with staff (Table 17).[44] The third study[25] focused on change in quality of life over 6 months (Table 17), examining outcomes for 421 residents across 45 NH settings and RC/AL settings using a standardized measure of quality of life in Alzheimer's disease administered to staff; it additionally examined proprietary status and chain affiliation in relation to change in quality of life.[25]

With one exception for one outcome, none of the three studies found differences in outcomes (i.e., behavioral symptoms, engagement [low SOE], quality of dying, quality of life, psychoactive medication use [insufficient SOE]) according to residence in an NH or RC/AL (Table 18). Evidence was insufficient for the effect of residence in an NH or RC/AL on quality of dying, quality of life, and psychoactive medication use. These were single studies that had imprecise results and no reported power calculations to justify sample sizes.

However, use of restraints in imminently dying residents was more frequent in NHs than in RC/AL (any restraints used, 92% vs. 66%, $p<0.001$; any restraints other than partial bedrails, 68% vs. 46%, $p=0.031$; low SOE).[44]

Quality of life over 6 months also did not differ by different types of RC/AL settings (smaller, traditional, new-model) or by other variables (not shown in Table 17 because no statistics were provided) including proprietary status, chain affiliation, size, age, percentage of dementia beds, and resident case-mix.[25] Because no statistics were provided, we graded the SOE for the effect of these structures on quality of life as insufficient. This was a single study that had imprecise results and no reported power calculation.

Behavior and engagement outcomes did not differ by residence on an SCU within an NH or RC/AL (low SOE).[36, 39]

Taken together, most residents' outcomes did not differ by organizational characteristics of settings, except for use of restraints (low SOE). However, evidence concerning the effects of organizational characteristics on quality of dying, quality of life, or psychoactive medication use was insufficient. These are single studies that had imprecise results; no power calculations were provided to justify the sample size. Evidence about effects of organizational characteristics was insufficient on numerous other outcomes not included in the studies (e.g., affect, spiritual well-being, control, autonomy, choice, satisfaction).

Table 16. Effect of organizational characteristics on behavioral symptoms and engagement

Author, Year, Design	Intervention /Exposures	CMAI Mild Dementia	CMAI Moderate or Severe Dementia	CMAI	Decrease in Social Function Mild Dementia	Decrease in Social Function Moderate or Severe Dementia	Decrease in Social Function	MOSES Increased Withdrawal From Activities Mild Dementia	MOSES Increased Withdrawal From Activities Moderate or Severe Dementia	MOSES Increased Withdrawal From Activities
Leon and Ory, 1999[36] Prospective cohort	G1: SCU in NH G2: Non-SCU in NH	NR	NR	**Physically aggressive behaviors Baseline (unadjusted)** G1: 4.84 G2: 4.10 p=NS **Adjusted Beta Coefficient** SCU placement=0.31 p=NS	NR	NR	NR	NR	NR	NR
Sloane[a] et al., 2005[39] Prospective cohort	G1: RC/AL G2: NH G3: SCU in RC/AL G4: Non-SCU in RC/AL G5: SCU in NH G6: Non-SCU in NH	G1: 1.08 G2: 0.69 p=0.604	G1: 1.72 G2: 1.49 p=0.809	G3: -1.53 G4: -1.14 p=0.763 G5: -2.18 G6: -0.72 p=0.168	G1: 1.55 G2:1.76 p=0.568	G1: 0.91 G2: 1.44 p=0.110	G3: 1.58 G4: 1.34 p=0.681 G5: 1.88 G6: 1.46 p=0.303	G1: 2.84 G2: 2.24 p=0.364	G1: 2.55 G2: 1.78 p=0.307	G3: 3.48 G4: 2.58 p=0.409 G5: 2.22 G6: 1.77 p=0.604

CMAI = Cohen-Mansfield Agitation Inventory; G = group; MOSES = Multidimensional Observation Scale for Elderly Subjects; NH = nursing home; NR = not reported; NS = not significant; RC/AL = residential care/assisted living; SCU = special care unit

[a]Outcomes are adjusted for baseline age, gender, race, education, marital status, length of stay, cognition, and number of comorbid conditions.

Table 17. Effect of organizational characteristics on quality of dying, quality of life, restraint use, and psychoactive medication use

Author, Year, Design	Interventions/ Exposures	Appeared To Be at Peace[a]	Received Compassionate Touch Daily[a]	Dignity Maintained[a]	One Staff Had Close Attachment to Resident[a]	QOL-AD Adjusted Change	Any Restraints Used	Any Restraints Other Than Partial Bed Rails	Sedative Used Frequently	Sedative Used at Least Sometime
Sloane et al., 2008[44] Prospective cohort	G1: RC/AL G2: NH	G1: 70.1% G2: 64.2% p=0.304	G1: 96.6% G2: 95.1% p=0.399	G1: 90.2% G2: 89.4% p=0.847	G1: 82.8% G2: 72.1% p=0.528	NR	G1: 65.7% G2: 91.5% p<0.001	G1: 46.3% G2: 67.6% p=0.031	G1: 21.0% G2: 29.2% p=0.592	G1: 29.9% G2: 37.3% p=0.792
Zimmerman et al., 2005[25] Prospective cohort	G1: RC/AL: <16 Beds G2: RC/AL traditional: ≥ 16 beds G3: RC/AL new model: ≥ 16 beds G4: NH	NR	NR	NR	NR	G1: +0.54 G2: +0.48 G3: -0.38 G4: -0.18 p=0.206	NR	NR	NR	NR

G = group; NH = nursing home; NR = not reported; QOL-AD = Quality of Life in Alzheimer's disease; RC/AL = residential care/assisted living

[a] The outcome is a variable related to quality of dying during the last month of life.

Table 18. Effect of organizational characteristics on psychosocial outcomes: strength of evidence

Outcomes	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Behavioral Symptoms	2; 1,848	Low; Prospective cohort; Good (1 study); Fair (1 study)	NA	Direct	Precise	RC/AL vs. NH no difference (1 study) SCU vs. non-SCU no difference (2 studies)	Low
Engagement	1; 1,252	Low; Prospective cohort; Good	NA	Direct	Precise	RC/AL vs. NH no difference SCU vs. non-SCU no difference	Low
Quality of Dying	1; 422	Low; Prospective cohort; Good	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]
Quality of Life	1; 421	Low; Prospective cohort; Fair	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]
Restraint Use (before death)	1; 422	Low; Prospective cohort; Good	NA	Direct	Precise	Favors RC/AL vs. NH	Low
Psychoactive Medication Use	1; 422	Low; Prospective cohort; Good	NA	Direct	Imprecise	RC/AL vs. NH no difference	Insufficient[a]

NA = not applicable; NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit
[a]No power calculations provided to justify sample size.

For KQ 5, only one study[39] addressed whether effects differed by dementia severity (but not by other characteristics); it found no differences in behavioral symptoms or engagement based on residence in an NH versus RC/AL (low SOE).

Detailed Synthesis of Structures of Care

One prospective cohort study described above examined change in quality of life over 6 months for 421 residents across 45 NH and RC/AL settings in relation to the following structures of care: FTEs for RNs, LPNs, and aides; number of contract staff per type; administrator, RN, LPN, and aide turnover; environmental quality; and use of universal and specialized workers (i.e., staff who fill specialized roles; Table 19).[25]

Table 19. Effect of structures of care on quality of life

Author, Year Design	Interventions	QOL-AD Mean Raw Change
Zimmerman et al., 2005[25] Prospective cohort	G5: Use specialized workers (staff fill specialized roles) G6: No use of specialized workers	G5: -1.3 G6: -3.0 p=0.036

G = group; QOL-AD = Quality of Life in Alzheimer's Disease

The mean raw change in quality of life over 6 months was 1.7 points worse when specialized workers were not used (adjusted change $p<0.05$; low SOE) (Tables 19 and 20),[25] a difference not considered to be clinically significant.[47] Other than use of specialized workers, the structure of

care variables and change in quality of life were not related. Because the authors did not provide the related data, we graded the strength of evidence of this single study as insufficient. This information is not shown in Table 19. Also, evidence about effects of structures of care was insufficient for numerous other outcomes not included in the studies (e.g., behavioral symptoms, engagement, affect, quality of dying, spiritual well-being, control, autonomy, choice, satisfaction, use of restraints, use of psychoactive medications).

Table 20. Effect of structures of care on psychosocial outcomes: strength of evidence

Outcomes	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Quality of Life	1; 421	Medium; Prospective cohort; Fair	NA	Direct	Precise	Favors specialized workers vs. not	Low

NA = not applicable

For KQ 5, one study conducted of structures of care related to psychosocial outcomes for people with dementia did not differentiate findings by dementia severity or other characteristics of the person with dementia (insufficient SOE).

Detailed Synthesis of Processes of Care

Seven studies examined processes of care and their effect on psychosocial outcomes. Three studies related to group activity interventions, two studied pleasant sensory stimulation, and two studied individualized care. One of the seven additionally examined other processes of care.

Group Activity Interventions

Three studies examined group activity interventions. Two were RCTs that examined behavioral symptoms and engagement (Table 21). One trial (in dementia care units) employed a creative expression storytelling intervention;[43] the other trial examined the effects of validation group therapy in NHs compared with a social contact comparison group and a usual care group.[46] In the first trial, research staff coded outcomes for 2,088 10-minute observations of staff-resident interactions. In the second, behavior was assessed through a standardized measure completed by blinded nursing staff and nonparticipant observers (the Cohen-Mansfield Agitation Inventory-Nursing Staff Derived [CMAI-N] and the Cohen-Mansfield Agitation Inventory-Observer Derived [CMAI-O]), respectively, in Table 21), and engagement was assessed through interviews with nursing staff using a standardized measure.

These two RCTs also examined results related to affect (Table 22). One used observations coded according to an established affect rating scale,[43] and the other used nurse interview with a standardized measure.[46] The latter trial additionally examined restraint and psychoactive medication use.

Table 21. Effect of group activity interventions on behavioral symptoms and engagement

Author, Year, Design	Interventions	Challenging Behaviors # of Observations	CMAI-N	CMAI-O	Types of Engagement # of Observations	MOSES Withdrawal Subscale
Fritsch et al., 2009[43] RCT	G1: TimeSlips G2: Control	G1: 9/1,651 G2: 1/1,250 6.80 times more for G1 p=0.034	NR	NR	Disengaged G1: 68/1,651 G2:107/1,250 0.481 times less disengaged for G1 p<0.001 Nonsocial engagement G1: 174/1,651 G2:135/1,250 0.976 times less nonsocial engagement for G1 p=0.822 Engagement G1: 1,400/1,651 G2:1,007/1,250 1.053 times more engaged for G1 p=0.003	NR

Table 21. Effect of group activity interventions on behavioral symptoms and engagement (continued)

Author, Year, Design	Interventions	Challenging Behaviors # of Observations	CMAI-N	CMAI-O	Types of Engagement # of Observations	MOSES Withdrawal Subscale
Toseland et al., 1997[46] RCT	G1: Validation group therapy G2: Social contact group G3: Usual care	NR	Physically Aggressive Behavior χ^2=14.90 p=0.001 G1 vs. G2 and G3 showed significant reduction in physically aggressive behaviors Verbally Aggressive Behavior χ^2=5.88 p=0.053 G1 and G2 vs. G3 showed significant reduction in verbally aggressive behaviors Physically Nonaggressive Behaviors χ^2=6.76 p=0.034 G2 and G3 reduced	Physically Aggressive Behavior χ^2=1.41 p=0.590 Verbally Aggressive Behavior χ^2=12.46 p=0.002 G2 vs. G1 and G3 showed significantly lower scores in verbally aggressive behaviors Physically Nonaggressive Behaviors χ^2 =1.52 p=0.47	NR	Baseline[a] G1: 14.05 G2:13.05 G3:14.43 Endpoint G1: 13.95 G2: 13.67 G3: 14.91

CMAI-N = Nurse-derived Cohen-Mansfield Agitation Inventory; CMAI-O = Observer-derived Cohen-Mansfield Agitation Inventory score; G = group; MOSES = Multidimensional Observation Scale for Elderly Subjects; NR = not reported; RCT = randomized controlled trial; X^2 = chi-square statistic

Note: Toseland, 1997[46] found among the Geriatric Indices of Positive Behavior— no significant changes in positive social interactions with family, staff, or other residents.

[a]No effect by Condition X Time.

Table 22. Effect of group activity interventions on affect, quality of life, restraint use, and psychoactive medication use

Author, Year, Design	Interventions	PGCARS Other Subscale (Neutral Affect)	PGCARS Anxiety Subscale # of Observations	PGCARS Anger Subscale # of Observations	PGCARS Sadness Subscale # of Observations	PGCARS Pleasure Subscale # of Observations	MOSES Irritability Subscale	QOL-AD Mean Raw Change	Restraint Use	Psychoactive Medication Use
Fritsch et al., 2009[43] RCT	G1:Time-Slips G2: Control	G1: 30/1,647 G2: 75/1,245 0.302 times less neutral for G1 p=0.001	G1: 39/1,647 G2: 11/1,245 2.68 times more events for G1 p=0.002	G1: 6/1,647 G2: 1/1,245 4.54 times more events for G1 p=0.124	G1: 7/1,647 G2: 0/1,245 >7 times more events for G1 p=0.021	G1: 54/1,647 G2: 47/1,245 0.869 times less pleasure for G1 p=0.472	NR	NR	NR	NR
Toseland et al., 1997[46] RCT	G1: Validation group therapy G2: Social contact group G3: Usual care	NR	NR	NR	NR	NR	Baseline[a] G1: 5.36 G2: 5.64 G3: 5.22 Endpoint G1: 4.81 G2: 6.10 G3: 5.36	NR	No significant changes in frequency of restraint use in the 3 groups	No significant differences in the 3 groups with regard to use of antipsychotic, antianxiety, or antidepressant medications
Zimmerman et al., 2005[25] Prospective cohort	G7: Encourage activities ≥ once a day G8: Encourage activities <once a day	NR	NR	NR	NR	NR	NR	G1: -1.9 G2: -2.6 p=0.043	NR	NR

G = group; MOSES = Multidimensional Observation Scale for Elderly Subjects; NR = not reported; PGCARS = Philadelphia Geriatric Center Affect Rating Scale; QOL-AD = Quality of Life in Alzheimer's Disease; RCT = randomized controlled trial

[a]No effect by condition X time.

Finally, one prospective cohort study examined the extent to which encouraging participation in activities related to quality of life.[25] It also investigated numerous other processes of care, including policies and practices, professional and paraprofessional involvement in care planning, assessments conducted (professional or standardized), treatment provided (professional or informal), use of antipsychotic or sedative hypnotic medications, and use of stimuli such as craft or household items.

The creative expression group activity[43] resulted in more challenging behaviors (9 vs. 1 event in more than 1,000 observations per group, p=0.034), anxiety (39 vs. 11 events, p=0.002), and sadness (7 vs. 0 events, p=0.021);[43] it also produced less disengagement (68 vs. 107 events, p<0.001), more engagement (1,400 vs. 1,007 events, p=0.003), and less neutral affect (30 vs. 75 events, p<0.001) (low SOE) (Table 23). Effects related to nonsocial engagement, anger, or pleasure were not statistically significant.

A validation therapy group[46] was superior to social control and usual care control groups in regard to blinded nurse report of physically aggressive behavior (p<0.001) and verbally aggressive behavior (p<0.01) at 1 year, but it resulted in more physically nonaggressive behaviors (p=0.034) (low SOE; Table 23).[46]

Blinded observers did not favor validation therapy, and rated social contact as superior in relation to verbally aggressive behavior (low SOE). Validation group therapy did not produce significant changes in engagement or positive social interactions, irritability, restraint use, or psychoactive medication use. However, the evidence was insufficient regarding the effects of validation therapy on these outcomes. This was a single study that had imprecise results and no reported power calculation.

In the prospective cohort study, the mean raw change in quality of life over 6 months was 0.9 points worse when activities were encouraged less than once a day (p=.043; adjusted change p<0.05)[25] (low SOE), a difference not considered to be clinically significant.[47] No other processes of care (policies and practices, staff involvement in care planning, assessments, treatment, medications, and use of stimuli) had a statistically significant relationship to change in quality of life (data not reported by authors and so not included in Table 22).

These studies indicate that group activity interventions may have both positive and negative effects on psychosocial outcomes (low SOE). Evidence about effects of group activity interventions was insufficient on numerous other outcomes not included in the studies (e.g., spiritual well-being, control, autonomy, choice, quality of dying, or satisfaction).

For KQ 5, the three studies of group activity interventions related to psychosocial outcomes for people with dementia did not differentiate findings by dementia severity or other characteristics of the person with dementia (insufficient SOE).

Table 23. Effect of group activity interventions on psychosocial outcomes: strength of evidence

Process of Care	Outcomes	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Creative Expression Storytelling Intervention	Behavioral symptoms	1; NR	Medium; RCT; Fair	NA	Direct	Precise	Favors control vs. storytelling	Low
	Engagement	1; NR	Medium; RCT; Fair	NA	Direct	Precise	Favors storytelling vs. control for engagement Storytelling vs. control no difference for nonsocial engagement	Low
	Affect	1; NR	Medium; RCT; Fair	NA	Direct	Precise	Favors control vs. storytelling for anxiety and sadness; Storytelling vs. control no difference for anger or pleasure	Low
Validation Group Therapy	Behavioral symptoms	1; 88	Medium; RCT; Fair	NA	Direct	Precise	Nurse rating: Favors validation vs. control for physical and verbal aggression; favors control vs. validation for physical nonaggression Observer rating: Favors comparison vs. validation for verbal aggression; validation vs. control no difference for physical aggression or physical nonaggression	Low
	Engagement	1; 88	Medium; RCT; Fair	NA	Direct	Imprecise	Validation vs. control no difference	Insufficient[a]
	Affect	1; 88	Medium; RCT; Fair	NA	Direct	Imprecise	Validation vs. control no difference	Insufficient[a]
	Restraint use	1; 88	Medium; RCT; Fair	NA	Direct	Imprecise	Validation vs. control no difference	Insufficient[a]
	Psychoactive medication use	1; 88	Medium; RCT; Fair	NA	Direct	Imprecise	Validation vs. control no difference	Insufficient[a]
Encouragement of Activities	Quality of life	1; 421	Medium; Prospective cohort; Fair	NA	Direct	Precise	Favors encouragement vs. not	Low

NA = not applicable; NR = not reported; RCT = randomized controlled trial; vs. = versus

[a]No power calculations provided to justify sample size.

Pleasant Sensory Stimulation Interventions

Two studies were related to the use of pleasant sensory stimulation to reduce agitation and aggression in NH residents who displayed agitated behavior (Table 24). One RCT compared outcomes of calm music, hand massage, and a combination of the two with those of a control group in terms of agitated behavior displayed over 1 hour.[37] The other, a nonrandomized controlled trial, administered pleasant sensory stimulation during shower-bath time and measured agitation over 1 and 2 weeks (i.e., time one and time two).[42] Both sets of investigators measured agitation using an existing observational instrument completed by research staff.

Table 24. Effect of pleasant sensory stimulation interventions on behavioral symptoms

Author, Year, Design	Interventions	CMAI–Agitation (Mean Difference in Score)	CMAI–Aggression
Remington, 2002[37] RCT	G1: Calm music G2: Hand massage G3: Calm music and hand massage G4: Control	G1: 13.76 (75% change)[a] G2: 13.41 (81% change)[a] G3: 18.24 (83% change)[a] G4:1.29 (0.06% change)[a] p<0.01[b]	Physically aggressive behaviors: G1: NR G2: NR G3: NR G4: NR p=0.09[c]
Whall et al., 1997[42] Non-RCT	G1: Pleasant sensory stimulation shower room G2: Usual care	Mean baseline to time two: -6.73[d] p<0.004	Mean baseline to time two: -1.47 p<0.19

CMAI = Cohen-Mansfield Agitation Inventory; G = group; NR = not reported; RCT = randomized controlled trial

[a]These are measures of the within-group mean reduction in score. Mean baseline scores: G1: 18.41; G2: 16.47; G3: 22.00; G4: 21.76.

[b]Repeated measures analysis of variance yielded significant difference among the four groups.

[c]Repeated measures ANOVA yielded no significant differences in physically aggressive behavior among the four groups.

[d]T-test mean difference scores between G1 and G2.

Both pleasant sensory stimulation interventions resulted in a decrease in agitation. Specifically, the study of music and hand massage found a decrease in agitation 1 hour after the intervention to be between 12.12 points (hand massage) and 16.95 (music plus hand massage) greater than the control group ($p<0.01$);[37] compared with their own baseline values, the decrease in agitation for the three intervention groups ranged from 75 percent to 83 percent. The pleasant sensory stimulation during the shower-bath found a decrease in agitation over 2 weeks to be 6.73 points greater in the intervention group.[42] Because a 30 percent reduction in agitation has been determined to be of clinical significance,[48] we graded the SOE that pleasant sensory stimulation interventions may reduce agitation as moderate (Table 25).

Table 25. Effect of pleasant sensory stimulation interventions on psychosocial outcomes: strength of evidence

Outcome	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Behavioral Symptoms: Agitation	2;99	Medium; 1 RCT, 1 non-RCT; both fair	Consistent	Direct	Precise	Favors stimulation vs. control	Moderate
Behavioral Symptoms: Aggression	2;99	Medium; 1 RCT, 1 non-RCT; both fair	Consistent	Direct	Imprecise	Stimulation vs. control no difference	Insufficient[a]

RCT = randomized controlled trial; vs. = versus

[a]No power calculations provided to justify sample size.

Neither of the pleasant sensory stimulation interventions resulted in a statistically significant decrease in physical aggression. However, evidence was insufficient regarding the effects of these processes of care on this outcome. Neither of these single studies provided power calculations to justify sample size nor were their results precise. The authors of both studies commented that the lack of significance was likely the result of either measurement error or low levels of aggressive behaviors overall. Also, evidence about effects of pleasant sensory stimulation was insufficient on numerous other outcomes not included in the studies (e.g., engagement, affect, quality of life, quality of dying, spiritual well-being, control, autonomy, choice, satisfaction, use of restraints, use of psychoactive medications).

For KQ 5, the two studies of pleasant sensory stimulation related to psychosocial outcomes for people with dementia did not differentiate findings by dementia severity or other characteristics of the person with dementia (insufficient SOE). One study commented on the distribution of residents by level of dementia (mild, 4 %; moderate, 43%; severe, 53%); the other noted that all residents had late-stage Alzheimer's disease or Alzheimer's disease with multi-infarct dementia.

Protocols for Individualized Care Interventions

Two trials tested protocols for individualized care (Table 26). One focused on assessment and management of discomfort and behavioral symptoms for NH residents with late-stage dementia; staff used a standardized scale of behavioral symptoms at baseline and over 4 weeks and also recorded return of behavioral symptoms to baseline by marking a visual analog scale.[41] The other trial focused on agitation and aggression during bathing for NH residents with moderate or severe cognitive impairment who demonstrated these types of behaviors during bathing.[40] Research staff masked to the intervention coded behavioral observations 2 weeks after the intervention and noted the percentage of time residents displayed agitation or aggression using a coding tool (the Care Recipient Behavior Assessment) based on the CMAI.[40]

Table 26. Effect of protocols for individualized care interventions on behavioral symptoms

Author, Year Design	Interventions	BEHAVE-AD (Within-Group Mean Change)[a]	Return of Behavior to Baseline: Number of Subjects (%)	CAREBA (Endpoint Scores, Percent Time)
Kovach et al., 2006[41] RCT	G1: Serial Trial Intervention G2: Control	G1: 2.75 G2: 1.84 p=0.50[b]	G1: 40/57 (70%) G2: 23/57 (40%) p=0.002	NR
Sloane et al., 2004[40] RCT	G1: Person-centered showering G2: Towel bath G3: Control	NR	NR	G1: 25.84 G2: 23.51 G3: 35.65 G1 vs.G3: p=0.02 G2 vs.G3: p=0.01 G1 vs.G2 change from baseline: p=0.4

BEHAVE-AD = Behavioral Pathology in Alzheimer's Disease Rating Scale; CAREBA = Care Recipient Behavior Assessment; G = group; NR = not reported; RCT = randomized controlled trial
[a]Baseline scores were as follows, G1:7.43, G2:6.80.
[b]Measures the Time X Group Interaction.

The trial that individualized assessment and management of discomfort and behavioral symptoms found no change in behaviors compared with those for the control group using the standardized measure of behavioral symptoms, but found a significant difference in return of behavior to baseline levels (a good outcome) for residents in the intervention group (70% vs. 40% in the control group, p=0.002) (low SOE; Table 27).[41] This apparent contradiction may relate to a difference in measurement.

Table 27. Effect of protocols for individualized care interventions on psychosocial outcomes: strength of evidence

Process of Care	Outcome	Number of Studies; Number of Subjects	Risk of Bias; Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Serial Trial Intervention	Behavioral symptoms	1;114	Medium; RCT; Good	NA	Direct	Precise	Individualized care vs. control no difference	Low
	Behavioral symptoms: Return to baseline	1;114	Medium; RCT; Good	NA	Direct	Precise	Favors individualized care vs. control	Low
Bathing	Behavioral symptoms	1;73	Medium; RCT: Fair	NA	Direct	Precise	Favors individualized care vs. control	Low

NA = not applicable; RCT = randomized controlled trial

The trial of protocols for showering and bathing found a significant reduction in overall agitation and aggression for both groups compared with outcomes in the control group condition (mean time agitated or aggressive 24 to 26% in the intervention groups compared with 36% in the control group, p=0.01 and p=0.02, respectively; low SOE).[40]

Evidence about effects of protocols for individualized care interventions was insufficient on numerous other outcomes not included in the studies (e.g., engagement, affect, quality of life, quality of dying, spiritual well-being, control, autonomy, choice, satisfaction, use of restraints, use of psychoactive medications).

For KQ 5, the two studies of protocols for individualized care related to psychosocial outcomes for people with dementia did not differentiate findings by dementia severity or other characteristics of the person with dementia (insufficient SOE).

KQ 3. Health Outcomes for Informal Caregivers of People With Dementia

No studies met inclusion criteria for KQ 3 about the impact of organizational characteristics, structures of care, or processes of care on caregiver health outcomes.

KQ 4. Psychosocial Outcomes for Informal Caregivers of People With Dementia

No studies met inclusion criteria for KQ 4 about the impact of organizational characteristics, structures of care, or processes of care on caregiver psychosocial outcomes.

KQ 5. Dementia Severity and Other Characteristics of the Person With Dementia

KQ 5 assessed whether the effect of organizational characteristics, structures, or processes of care on health and psychosocial outcomes varied by the characteristics of the person with dementia (e.g., severity of dementia, functional status) or of the informal caregiver (e.g., age, relationship, health status); we report on relevant KQ 5 studies in the context of KQs 1 to 4.

Discussion

This report addressed a question commonly posed when an older adult with dementia requires long-term care beyond what can be provided by the family: What is the best care setting for an older adult with dementia who can no longer be cared for at home? Numerous options are available when this need arises, including traditional nursing homes (NHs), specific models of NHs (e.g., Green House homes), and residential care/assisted living (RC/AL). Because these options differ considerably in various attributes (e.g., settings are of different sizes, have different policies, and offer different services), we assembled and reviewed evidence on specific components of the organizational structure and care and their effects on a range of outcomes for residents who live in such settings. We sought similar information about the effects of interventions on informal caregivers (i.e., family members of long-term care residents), but we identified no eligible studies.

We broadly defined the scope of our review to include all organizational characteristics, structures, and processes of care as they exist in the United States; the substantial differences in health care systems and approaches to long-term care in other countries make studies from other countries less applicable to the United States. Also, we focused on articles published after 1990 to reflect the changing nature and evolution of NH and other residential long-term care settings, especially after the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Public Law 100-203), which established new regulatory standards for NH care (www.access.gpo.gov/nara/cfr/waisidx_02/42cfr483_02.html).

Our review focused on four Key Questions (KQs), differentiated by two types of outcomes relevant to people with dementia and their informal caregivers: health outcomes (KQ 1 and KQ 3, respectively) and psychosocial outcomes (KQ 2 and KQ 4, respectively). We also examined the extent to which outcomes differed according to dementia severity and other characteristics of the person with dementia (KQ 5); these findings are subsumed under KQ 1 and KQ 2.

Below we summarize the main findings and strength of evidence (SOE) for each KQ. In the summary section that follows, we first present findings on outcomes by specific organizational characteristics, structures of care, or processes of care that the included studies had examined.

Key Findings and Strength of Evidence: Outcomes

KQ 1: Health Outcomes for People With Dementia

Ten studies examined organizational characteristics (2 prospective cohort studies), structures of care (2 randomized controlled trials [RCTs]), or processes of care (6 RCTs) related to health outcomes for people with dementia. Table 28 presents key findings and the related SOE grades. Across these 10 studies, the health outcomes assessed included functional impairment or decline (including self-care/maintenance), cognitive impairment or decline, depressive symptoms, pain or discomfort, sleep quality, morbidities (e.g., skin ulcers), hospitalization, and mortality. SOE grades are given for all major outcomes and comparisons. For many outcomes such as falls, no evidence was available at all, so SOE was insufficient (these are not noted in the table).

Table 28. Strength of evidence for the effect of organizational characteristics, structures, or processes of care for people with dementia on health outcomes

Outcome	Summary of Results	Strength of Evidence
Functional impairment/decline (including self-care/maintenance)	Functional impairment/decline was worse in RC/AL settings for residents living in a dementia SCU (1 study; 1,252 subjects).	Low
	Function was clinically significantly better (equivalent to moving from major to moderate or moderate to minor need for assistance) after functional skill training (1 study; 63 subjects).	Low
Cognitive impairment/decline	Alertness was modestly better (3 percentage points) after creative expression storytelling (1 study; number of subjects not reported).	Low
Depressive symptoms	Depressive symptoms were better for women but worse for men after a bright morning light intervention (1 study; 155 subjects).	Low
Pain/discomfort	Pain/discomfort was better after individualized assessment and management of discomfort (1 study; 114 subjects) and person-centered protocols for showering and bathing (1 study; 73 subjects).	Low
Sleep quality	Sleep quality was better for only those with aberrant sleep cycle timing following morning bright light (1 study; 46 subjects).	Low
New/worsening morbidity and various discrete measures	Morbidity across multiple measures differed little in RC/AL settings compared with NH settings, but was lower in SCUs than in non-SCUs in NHs (1 study; 1,252 subjects).	Low
Hospitalization	Hospitalization occurred more often for residents with mild dementia living in RC/AL settings than for residents in NH settings (1 study; 1,252 subjects).	Low
	Hospitalization occurred more often for NH residents (but not RC/AL residents) not living in dementia SCUs (1 study; 1,252 subjects).	Low
Mortality	Evidence did not support a difference based on residence in an NH setting vs. RC/AL setting or in an SCU vs. non-SCU (1 study; 1,252 subjects).	Low

Note: No study examined the outcomes of falls (insufficient SOE). Not all of the outcome categories in this table were examined in every one of the 10 studies. Only findings with low or better SOE are reported.
NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit

Regarding organizational characteristics reviewed, NHs and RC/AL differed little on a range of health outcomes. The evidence of the effect of organizational characteristics on these outcomes ranged from insufficient to low. Generally, single studies with no power calculations provided and with imprecise results merited insufficient SOE. Residents with mild dementia in RC/AL, when compared with NHs, had moderately higher hospitalization rates (low SOE) but little difference in morbidity rates regardless of dementia level (low to insufficient SOE). Evidence on SCUs within these settings was inconsistent. Residents of SCUs in RC/AL, when compared with non-SCUs in those settings, had a modestly greater decline in functioning over time (low SOE). On the other hand, residents of dementia SCUs in NHs, when compared with non-SCUs in those settings, had moderately lower rates of both hospitalization and new or worsening morbidity (low SOE).

Only two studies focused on structures of care, finding no effect in the overall populations studied for lighting interventions on sleep quality and depressive symptoms. Both studies found benefits for certain subgroups (women for depressive symptoms and those with aberrant sleep cycle timing for sleep quality). Although these studies suggest that lighting interventions may have more benefit on a person-by-person level as opposed to being a structural intervention throughout a setting, we judge the current evidence as insufficient based on these single studies with imprecise results which did not provide power calculations to justify sample size.

Regarding processes of care, evidence for group activity interventions was mixed. A functional skills training intervention produced moderate effect sizes for improving activities of

daily living (ADLs), with effect sizes being equivalent to moving from major to moderate or from moderate to minor assistance in performing ADLs (low SOE). A storytelling intervention modestly improved cognitive alertness (low SOE). A single study of validation therapy groups did not find improvement in functional self-care or depressive symptoms, and a single study of attention-focusing did not find any improvement in cognitive impairment or dementia behavior. However, the evidence was insufficient in these two studies due to imprecise results which did not report power calculations to justify sample size. A personalized assessment and treatment intervention moderately reduced resident discomfort. Finally, personalized showering and towel bath interventions reduced resident discomfort.

KQ 2: Psychosocial Outcomes for People With Dementia

Ten studies examined organizational characteristics (4 prospective cohort studies), structures of care (1 prospective cohort study), and/or processes of care (5 RCTs, 1 non-RCT, and 1 prospective cohort study) related to psychosocial outcomes for people with dementia. Table 29 presents key findings and the related SOE grades. Across these 10 studies, the psychosocial outcomes assessed included behavioral symptoms (e.g., agitation, aggression), engagement (e.g., social function, withdrawal), affect other than depressive symptoms (e.g., anxiety, pleasure), quality of life in Alzheimer's disease, quality of dying, use of restraints, and use of psychoactive medications. SOE grades are given for all major outcomes and comparisons. For many outcomes such as spiritual well-being, control, autonomy, choice, or satisfaction, no evidence was available at all, so the strength of evidence was insufficient (these are not noted in the table).

Table 29. Strength of evidence for the effect of organizational characteristics, structures, or processes of care for people with dementia on psychosocial outcomes

Outcome	Summary of Results	Strength of Evidence
Behavioral symptoms	Behavioral symptoms were worse after creative expression storytelling (1 study; number of subjects not reported).	Low
	Physical and verbal aggression were better, and physical nonaggression was worse, after validation therapy (based on nurse report). Verbal aggression was worse after validation therapy (based on observer report) (1 study; 88 subjects).	Low
	Agitation was clinically significantly better after pleasant sensory stimulation (2 studies; 99 subjects; decreased 75% to 83% in 1 study).	Moderate
	Behavioral symptoms were better after individualized assessment and management of behavioral symptoms (70% vs. 40% return to baseline) (1 study; 114 subjects).	Low
	Agitation and aggression were better after person-centered protocols for showering and bathing (mean time agitated/aggressive 24% to 26% vs. 36% for control group) (1 study; 73 subjects).	Low
Affect	Anxiety and sadness were worse after creative expression storytelling (1 study; number of subjects not reported).	Low
Engagement	Engagement was better after creative expression storytelling (1 study; number of subjects not reported).	Low
Quality of life	Quality of life over 6 months was statistically, but not clinically, significantly better when specialized workers were used and activities were encouraged (1 study; 421 subjects).	Low
Quality of dying	One study did not find a difference based on residence in an NH setting vs. RC/AL setting (1 study; 422 subjects).	Insufficient [a]
Psychoactive medication use	One study did not find a difference based on residence in an NH setting vs. RC/AL setting (1 study; 422 subjects) or after validation therapy (1 study; 88 subjects).	Insufficient [a]
Restraint use	Restraint use in imminently dying residents occurred more often in NH settings than in RC/AL settings (66% vs. 92%) (1 study; 422 subjects).	Low

Note: No study examined the outcomes of spiritual well-being, control, autonomy, choice, or satisfaction (insufficient SOE). Not all of the outcome categories in this table were examined in every one of the 10 studies. Except where indicated, only findings with low or better SOE are reported.
NH = nursing home; RC/AL = residential care/assisted living; vs.= versus
[a]Evidence was from a single study with imprecise estimates

Regarding organizational characteristics, NHs and RC/AL differed little on behavioral symptoms and engagement (low SOE). Quality of dying, quality of life, and psychoactive medication use also did not differ by setting. However evidence was insufficient concerning the effect of these organizational characteristics in these single studies that had imprecise results and no reported power calculations. Restraints were used more often in imminently dying residents in NHs than in RC/AL (low SOE). The authors suggested additional study of this finding considering that the use of physical restraints in NHs has been strongly discouraged following the Nursing Home Reform Act of 1987 and there is evidence that overall use of restraints is low.[44] Behavioral symptoms and engagement did not differ based on residence in an SCU (low SOE), although the two studies reviewed were prospective cohort studies where risk adjustment potentially may not have been sufficient.

Regarding structures of care, quality of life did not differ based on many structures. However, evidence was insufficient concerning the effect of these structures on quality of life in this single study with imprecise results and no reported power calculations. Quality of life was statistically but not clinically significantly better when specialized workers were used (low SOE).

Regarding processes of care, evidence for group activity interventions was again mixed. A storytelling intervention resulted in more challenging behaviors, anxiety, and sadness, and also more engagement (low SOE). An intervention involving validation therapy groups resulted in

less physical and verbal aggression, and also more physically nonaggressive behaviors (e.g., restlessness, repetitious mannerisms, pacing), although these findings were not consistent across raters (low SOE). More frequent encouragement of activity participation resulted in statistically but not clinically better quality of life (low SOE). Pleasant sensory stimulation, such as calm music and hand massage, produced a clinically significant decrease in agitation (moderate SOE). A personalized assessment and treatment intervention of behavioral symptoms increased return of behavior to baseline levels (low SOE). Finally, both personalized showering and towel bath interventions reduced behavioral symptoms (agitation and aggression) more in the intervention than control group (low SOE).

KQs 3 and 4: Outcomes for Informal Caregivers

No studies met inclusion criteria for either of these KQs about the impact of organizational characteristics, structures of care, or processes of care on caregiver health or psychosocial outcomes. Thus, evidence is insufficient for these topics.

Three potential studies [49-51] were identified in this review, each addressing encouragement of family involvement in care as a means to promote improved family/staff relationships and thus improve resident care. While these studies were excluded for methodological shortcomings (e.g. selection bias, high attrition, inadequate randomization), this literature is evolving and represents an increasingly important aspect of NH and residential care for residents with and without dementia.

KQ 5: Variation by Characteristics of People With Dementia

Two studies examined outcomes of residents with dementia in terms of dementia severity or sociodemographic variables. In one, hospitalization (but not other outcomes) for people in RC/AL settings was more likely for those with mild dementia than for those with moderate to severe dementia. Hospitalization rates did not differ by dementia severity for NH residents. In a second study, a lighting intervention produced better depressive symptoms outcomes for women exposed to morning bright light compared with all-day light, but worse outcomes for men exposed to morning bright light compared with standard light.

Key Findings and Strength of Evidence: Organizational Characteristics, Structures of Care, and Processes of Care

Table 30 summarizes the SOE we found for statistically significant differences in health and psychosocial outcomes according to organizational characteristics, structures, and process of care.

Table 30. Strength of evidence for the effect of organizational characteristics, structures, or processes of care for people with dementia on health and psychosocial outcomes

Characteristics	Intervention/ Exposure	Summary of Results	Strength of Evidence
Organizational	NH vs. RC/AL	Morbidity across multiple measures differed little in RC/AL settings compared with NH settings (1 study; 1,252 subjects).	Low
	NH vs. RC/AL	Hospitalization occurred more often for residents with mild dementia living in RC/AL settings than for residents in NH settings (1 study; 1,252 subjects).	Low
	NH vs. RC/AL	Restraint use in imminently dying residents occurred more often in NH settings than in RC/AL settings (66% vs. 92%) (1 study; 422 subjects).	Low
	SCU in NH vs. no SCU	Morbidity was lower in SCUs than in non-SCUs in NHs (1 study; 1,252 subjects).	Low
	SCU in NH vs. no SCU	Hospitalization occurred more often for NH residents not living in SCUs (1 study; 1,252 subjects).	Low
	SCU in RC/AL vs. no SCU	Functional impairment/decline was worse in RC/AL settings for residents in SCUs (1 study; 1,252 subjects).	Low
Structures of Care	Morning bright light vs. all-day light/control	Depressive symptoms were better for women but worse for men after bright morning light (1 study; 155 subjects).	Low
	Morning bright light vs. all-day light/control	Sleep quality was better for only those with aberrant sleep cycle timing following morning bright light (1 study; 46 subjects).	Low
	Specialized workers vs. not	Quality of life over 6 months was statistically, but not clinically, significantly better when specialized workers were used (1 study; 421 subjects).	Low

Table 30. Strength of evidence for the effect of organizational characteristics, structures, or processes of care for people with dementia on health and psychosocial outcomes (continued)

Characteristics	Intervention/ Exposure	Summary of Results	Strength of Evidence
Processes of Care	Functional skill training vs. no such training	Function was clinically significantly better (equivalent to moving from major to moderate or moderate to minor need for assistance) after functional skill training (1 study; 63 subjects).	Low
	Creative expression storytelling vs. no such activity	Alertness was modestly better (3 percentage points) after creative expression storytelling (1 study; number of subjects not reported).	Low
	Creative expression storytelling vs. no such activity	Behavioral symptoms, anxiety, and sadness were worse after creative expression storytelling (1 study; number of subjects not reported).	Low
	Validation therapy vs. no such activity	Physical and verbal aggression were better, and physical nonaggression was worse, after validation therapy (based on nurse report). Verbal aggression was worse after validation therapy (based on observer report) (1 study; 88 subjects).	Low
	Encourage activities more vs. less	Quality of life over 6 months was statistically, but not clinically, significantly better when activities were encouraged (1 study; 421 subjects).	Low
	Pleasant sensory stimulation vs. no such stimulation	Agitation was clinically significantly better after pleasant sensory stimulation (2 studies; 99 subjects; decreased 75% to 83% in 1 study).	Moderate
	Individualized assessment and management of discomfort and behavioral symptoms vs. no such protocols	Pain/discomfort was better after individualized assessment and management of discomfort (1 study; 114 subjects; discomfort score 0.89 times lower than control).	Low
	Individualized assessment and management of discomfort and behavioral symptoms vs. no such protocols	Behavioral symptoms were better after individualized assessment and management of behavioral symptoms (1 study; 114 subjects; 70% vs. 40% return to baseline).	Low
	Person-centered protocols for showering and bathing vs. no special protocols	Pain/discomfort was better after person-centered protocols for showering and bathing (1 study; 73 subjects; reduced discomfort by 26% for towel bath, and 14% for person-centered showering).	Low
	Person-centered protocols for showering and bathing vs. no special protocols	Agitation and aggression were better after person-centered protocols for showering and bathing (1 study; 73 subjects; mean time agitated/aggressive 24% to 26% vs. 36% for control group).	Low

NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit, vs.= versus
Note: No study examined the outcomes of falls, spiritual well-being, control, autonomy, choice, or satisfaction (insufficient SOE). Not all of the interventions/exposures in this table were examined in relation to all outcomes. Only findings with low or better SOE are reported.

Findings in Relation to What Is Already Known

This systematic review is the first to examine these specific questions in this way. Therefore, we could not compare evidence reported here with any established knowledge base.

Applicability

This review was intended to apply to all people with dementia regardless of their level of dementia. It also was intended to examine differences in outcomes related to the extent of

dementia and other characteristics of the person with dementia, because people with mild, moderate, or severe dementia vary in the extent to which they are able to respond to interventions.

Studies varied in regard to the level of dementia represented. Some included residents only with severe dementia,[41, 42] one with moderate to severe dementia,[40] some with mild through severe dementia,[25, 34-39] and some did not specify the level of dementia.[43-46] Those that included only residents with severe dementia were one of the pleasant sensory stimulation studies and the study of individualized assessment and management of discomfort and behavioral symptoms; the findings from these studies are generally applicable to residents with severe dementia. Only one study considered the evidence in relation to the level of dementia severity, examining differences between NH settings and RC/AL settings based on dementia severity for several outcomes: mortality, hospitalization, new or worsening morbidity, and changes in function, cognition, depressive symptoms, behavioral problems, and engagement. It found no differences except an increased risk of hospitalization for residents with mild dementia in RC/AL.[39] These findings, which generally did not favor either NHs or RC/AL and were of either insufficient or low SOE, nevertheless are broadly applicable to people with all levels of dementia severity. There is no evidence whether findings from the other studies differed in relation to the level of dementia severity. This is an important omission because needs vary as dementia progresses. Thus, what may be helpful at one point in time (such as to reduce wandering) may not be needed at a later time (if the person becomes bedridden), and what is needed at a later time may not be necessary earlier.

Only one other characteristic of the person with dementia was examined in any study. It found (with low SOE) that the effects of a lighting intervention differed for women and men, with depressive symptoms improved for women but worsened for men, making its implications specific to those subgroups.[35] No studies examined differences by characteristics such as race or ethnicity, perhaps because no studies had samples with sufficient variability, especially in regard to ethnicity, to test such differences.

The evidence is therefore insufficient regarding whether the effects of some of the interventions/exposures under study would have been different for different subgroups of the populations. Other than for the small number of findings noted above, we cannot say whether they are the same or different for people at different stages of dementia severity or by other characteristics. This is a serious omission in the literature and our knowledge base.

The interventions/exposures under study included a broad range of organizational characteristics, structures, and processes of care. We had envisioned special interest in exposure to organizational characteristics, such as NH versus RC/AL, small NH versus large NH, and SCU versus no SCU. These are often the level at which families first make their decision regarding a setting of care. However, only four prospective cohort studies (one focused on care for imminently dying residents) provided evidence about these options. Thus, although the evidence is informative, our confidence in whether these effects will hold up over time is low, and future research could either confirm or change them.

The outcomes examined across these 14 studies included eight broad categories of health outcomes and seven categories of psychosocial outcomes. Not all were examined in all studies, and in some cases, a given intervention had both desired and undesired outcomes. For example, creative expression storytelling resulted in better alertness and more engagement but worse behavioral symptoms, anxiety, and sadness. In such instances, families are advised to consider

which outcomes are most relevant and which they and the person with dementia most value, and make their decision accordingly.

The SOE for all findings reported in this review, except one, was either low or insufficient. Furthermore, although we found statistically significant effects for some organizational characteristics, structures, and processes of care, for many we found no significant effects. In addition, some statistically significant results were relatively small, meaning that their clinical importance is limited or unclear. Also, it is important to note that not all outcomes were examined in these studies, including falls, spiritual well-being, control, autonomy, choice, and satisfaction. Thus, even though these studies covered a wide array of outcomes, a substantial set of outcomes of interest was never examined. Issues of control, autonomy, choice, and satisfaction remain relevant until late in dementia, and merit better recognition.

Finally, we found no evidence related to health or psychosocial outcomes for informal caregivers of people with dementia. Thus, this review is not directly applicable to such family members or other caregivers, although understanding the benefits or harms of various organizational characteristics, structures, or processes of care for people with dementia may well promote better outcomes for informal caregivers; still, far more evidence is required on this point.

Implications for Clinical and Policy Decisionmaking

Few studies met the evidence criteria; those that did provided information with only generally low SOE. We found limited evidence related to health and psychosocial outcomes for people with dementia, and none for informal caregivers. Additional research is needed to develop a sufficient evidence base to support family decisionmaking.

As documented in the preceding discussion and tables, the SOE was low for any impact of all but one of the organizational characteristics, structures, and processes of care we examined. The one exception is that SOE was moderate for use of pleasant sensory stimulation to reduce agitation, and we found no evidence that pleasant sensory stimulation resulted in negative outcomes. Therefore, families, providers, policy makers, advocates, and educators may want to promote the use of pleasant sensory stimulation, and researchers may want to study further the use of pleasant sensory stimulation to strengthen the available evidence.

In addition, we found evidence of positive impacts (all low SOE) and no evidence of any negative impacts for a limited number of outcomes in SCUs in NHs (but not RC/AL settings); protocols for individualized care including person-centered showering/bathing and assessment/management of discomfort and behavioral symptoms; functional skill training, use of specialized workers, and encouraging activities.

Apart from our review, other reviews focused on SCUs have shown mixed results on various outcomes. A Cochrane review identified no RCTs investigating the effects of SCUs on behavioral symptoms in dementia; in addition, it found no strong evidence of benefit from available non-RCTs.[52] The Cochrane study authors suggested that implementing "best practices" may be more important for resident outcomes than providing a specialized care environment.[52] Other specific studies (not included in our review) provide some evidence that SCU residents are at lower risk for hospitalization and more often receive better care, but also that they have greater use of antipsychotic medications.[53-55] Conflicting results may in part reflect the fact that SCU residents may have different baseline characteristics from those not residing in SCUs.[56] One study reviewed suggested that SCUs might be good for helping segregate populations with different needs.[36]

Personalized care protocols may have potential effectiveness in that they can be more accurately targeted and possibly have more of a direct effect on outcomes than group activity interventions. In particular, the person-centered showering and bathing intervention protocol that we examined in this review [40] has been widely adopted by practitioners; it is broadly considered an example of culture change that strives to deinstitutionalize NHs and individualize care.[57] More generally, both in the United States and overseas, person-centered care has received broad support.[58, 59] A wide range of personalized care interventions related to organizational characteristics, structures, and processes of care fit within this broader effort, including care provision in smaller, home-like settings.[57] Further, the one study we reviewed that found both positive and negative outcomes related to the use of morning bright light (decreased depressive symptoms for women, increased depressive symptoms for men)[35] suggests that lighting interventions may best be applied at the person level rather than the setting level.

Functional skill training in ADLs has also had mixed effects, including short-term but not long-term functional benefits.[60] The functional skill training examined in this review,[45] as well as a behavioral rehabilitation intervention for improving the performance of morning care activities[61] both found some success. Given the challenges of improving function in this population and the limited research available, additional study is needed to test new interventions. This point is especially important because the functional skill training studied was conducted 5 days per week for 2.5 hours per day over 20 weeks, which limits its feasibility for wide-spread adoption.

Studies found both positive and negative evidence for a limited number of outcomes for residents of NH settings as compared with residents of RC/AL settings. Residents with mild dementia were less likely to be hospitalized if they resided in NHs, and residents in NHs were more likely to have stable health before death. The explanation may be that NH settings, as contrasted with RC/AL settings, can provide more medical care and have more nursing staff. However, we found no evidence regarding differences across these setting types in relation to behavioral symptoms, engagement, quality of life, quality of dying, and for imminently dying residents, psychoactive medication use. If people with dementia and their families are choosing between NH settings and RC/AL settings, considering the individual's current medical needs and health stability will be helpful. In addition, taking into account the difference in costs between these two settings (annual 2011 rate $78,000 to $87,000 in NHs and $42,000 in RC/AL settings)[62] and the availability of Medicaid (should it be necessary) may also be important.

Limitations of the Comparative Effectiveness Review Process

This comparative effectiveness review evaluated outcome differences examined over time. Thus, cross-sectional studies were considered as not as directly pertinent or appropriate to include. Many cross-sectional studies that have adjusted for confounders have been conducted over the years, and some might inform the research questions with respect to effectiveness.

We found almost 30 cross-sectional studies with potential relevance.[53-55, 63-90] For example, evidence from cross-sectional studies has indicated that hospitalization is less likely in NH SCUs (compared with NHs with no SCU), when more residents with dementia are present in the NH, and when Medicaid payment rates are relatively higher. In addition, depressive symptoms and pain were higher in for-profit settings than nonprofit settings.[54, 75, 89] This type of information may be helpful for family members when determining the optimal setting of care for relatives

with dementia, but such studies might well have higher risks of bias than the studies we included and, therefore, would not produce findings of materially higher SOE.

In addition, we dropped from our analyses any study for which our quality rating was poor; we retained only trials or prospective cohort studies assessed as either good or fair. Given the fact that the SOE was principally low (if not insufficient), we do not believe that adding poor-quality studies, which may have involved yet other organizational characteristics, structures of care, or processes of care, would have improved the overall robustness or applicability of this body of evidence.

Limitations of the Evidence Base

We excluded numerous studies of potential relevance conducted in NH settings and RC/AL settings for a variety of reasons determined a priori. Particularly relevant were two criteria: that the studies did not specify that at least 80 percent of the study population had dementia and that analyses had not been conducted specific to the subgroup of those with dementia. A total of 136 studies were excluded because they did not meet these criteria; some might have been excluded for other reasons as well and in none did at least 70 percent of the population have dementia. Despite the fact that a large proportion of residents in NH settings and RC/AL settings have dementia,[25] we still had to ensure that the populations analyzed in the included studies were specific to this review.

Research Gaps

Assuming that the overriding (or first) question for stakeholders is whether an individual with dementia is best served in an NH or RC/AL setting, or in an SCU, we reiterate that we found no RCTs to answer these questions and only quite sparse evidence from nonexperimental studies. RCTs would not be expected to inform the matter of NH settings versus RC/AL settings, given that they would be hard to justify in ethical or feasibility terms. Trials of placement in SCUs might be possible, however. All things considered, additional high-quality prospective cohort studies would be beneficial in clarifying the advantages and disadvantages of residence in different types of settings, especially because the majority of RC/AL residents have dementia[7] and the number of RC/AL beds almost doubled in the last 20 years.[91]

The wide array of structural variables and process interventions/exposures that surfaced in this work reflects impressive thinking about all the factors that either experience or theory suggests might improve the quality of life and outcomes of people with dementia. This diversity did, however, make it impossible for us to improve estimates of effect sizes of any one characteristic, structure, or process by pooling data. We are not convinced that continued "one-off" studies are the best possible use of research resources. Instead, concerted emphasis on key structural variables or types of specialized services may be warranted in coming years, so that findings can be combined in quantitative analyses to yield stronger evidence for decisionmaking by all stakeholders. Two examples of this type of effort include the National Institute on Aging studies examining SCUs (launched in 1991), and the Robert Wood Johnson Foundation collaborative of research projects examining Green House NHs (launched in 2011). Related to this strategy is the suggestion that all studies conducted in NHs and other residential long-term care settings indicate the number and percentage of residents with dementia who composed the sample, and analyze data specific to these individuals.

Of special concern might be efforts to maintain or improve physical function and to decrease pain/discomfort and behavioral symptoms in this population. Thus, we emphasize that additional

studies are warranted to test interventions that show some promise, including functional skill training,[45] pleasant sensory stimulation,[37, 42] and individualized protocols for care,[40, 41] in addition to exploring the impact of enhanced or completely new interventions in this area. Of particular importance is to build on the existing empirical work and also on robust conceptual frameworks and clinical or behavioral theories about what might "work best" for these individuals.

Another consideration about future research involves the types of outcomes to be studied. As noted, we identified a considerable array of health and psychosocial outcomes about which we believed clinicians, people with dementia and their families, and other interested parties would want to know more. Of these, no evidence at all surfaced on several important matters, including falls and several aspects of psychosocial well-being including spiritual well-being, control, autonomy, choice, and satisfaction. Some research effort to clarify care related to these outcomes is warranted, although they may be less salient for decisionmaking than matters such as depressive symptoms, hospitalization, and quality of life. Falls are especially important insofar as they constitute a significant threat to safety and cost to the health care system, which is a matter of concern for residents and families, staff, administrators, and policymakers.

A related matter may be encouraging investigators to use established outcome measures that have proven reliability and validity. Consolidation on some types of measures might enhance the possibility of quantitative pooling of studies (other things equal) or at least of some qualitative interpretations of the same (or very similar) outcome information. Many studies in this review used the Cohen-Mansfield Agitation Inventory (CMAI, a measure of behavioral symptoms),[37, 39, 42, 46] and other established measures are available for numerous other outcomes of interest.

Cutting across components of care and outcomes is the question of methods. As noted, of the 14 studies finally included, we could rate the quality of the investigation as good for only 4 studies. We excluded 15 studies because of substantial flaws that yielded quality ratings of poor (Appendix D). The principal problems of these studies, which hinge on threats to internal validity (substantial risks of bias), were performance bias (e.g., care providers provided care in both arms of the study),[92-94] selection bias (e.g., groups were not similar at baseline),[49, 51, 95-98] detection bias (e.g., raters were not blind to the group to which the resident belonged),[99, 100] and attrition bias (e.g., greater than 20%).[50, 101-103] Thus, we conclude that future research should attempt to overcome at least the primary deficits of this entire body of work. For example, investigators should attend more closely to masking raters and maintaining consistent raters over time, assuring similar representation of subjects across arms, focusing on fidelity, and accounting for missing data in their analyses.

Moreover, most studies were relatively small. Larger sample sizes might allow investigators to gain more precision in estimates of differential effects or changes over time. Then, they will be in a better position to say more about the superiority (or inferiority) of various organizational characteristics and interventions. Admittedly, larger studies are more costly to conduct, again highlighting the benefit of conducting studies with a concerted emphasis in one area, such as a program project or other collaborative studies wherein separate studies designed to inform different areas include similar subjects and use common measures. Similarity, more attention to the heterogeneity of people with dementia, and examining how different levels of dementia and other differences (measured in consistent ways) relate to outcomes, will better inform the matter of applicability.

Finally, the number of people with dementia who reside in traditional and emerging settings can only rise in the future. Finding answers to the numerous questions and concerns that people today might have about dementia care (for themselves and for family members) is crucial.

Focusing on *truly* critical choices and questions, and improving the quality of studies, are crucial steps for providing actionable information for such difficult decisions.

To summarize, we suggest the following guidance for future research:

- Examine differences between NH settings versus RC/AL settings, and between SCUs and settings without SCUs as related to outcomes for people with dementia and their caregivers.
- Conduct studies with concerted emphasis on key organizational characteristics, structures, and processes of care as opposed to one-of studies.
- Indicate the number and percentage of residents with dementia who composed the sample, and analyze data specific to these individuals.
- Examine how results differ according to characteristics of the person with dementia, especially the degree of dementia.
- Continue studying outcomes of depressive symptoms, hospitalization, and quality of life, but also consider the relevance of other outcomes including falls, spiritual well-being, control, autonomy, choice, and satisfaction.
- Use established outcome measures to enable the pooling of data or qualitative interpretations.
- Employ rigorous methodologies that overcome bias, and use samples of sufficient size to provide precise estimates.

Conclusions

Overall, we generally found either low or insufficient SOE about the effectiveness or comparative effectiveness of organizational characteristics, structures, and processes of care for people with dementia. This is true about both their health and their psychosocial outcomes. Virtually no good or fair evidence meeting our inclusion criteria exists about health and psychosocial outcomes for informal caregivers of people with dementia.

Even with those caveats, we can state some conclusions about interventions. In particular, findings of moderate SOE indicate that pleasant sensory stimulation reduces resident agitation. In addition, even though the SOE was only low, protocols for individualized care can reduce resident pain/discomfort and agitation/aggression, and functional skill training of people with dementia can improve their functioning. Further, if people with dementia and their families are making a choice between NH settings and RC/AL settings, considering the individual's current medical needs and health stability is important because these settings do not differ much in outcomes other than those relating to people for whom medical care is indicated or for whom NHs may be better suited on other grounds.

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Appendix A. Search Strategy

We outline our search strategies by database below.

Initial Search

We performed the initial searches on July 15, 2011.

Table A-1. MEDLINE®

Search	Queries	Result
#1	Search "dementia"[MeSH Terms] OR "dementia"[All Fields] OR "alzheimer disease"[MeSH Terms] OR "alzheimer"[All Fields] OR "alzheimer disease"[All Fields]	124861
#2	Search #1 Limits: Humans, English	96335
#3	Search "Assisted Living Facilities"[MeSH Terms]	653
#4	Search #2 AND #3	126
#5	Search "Nursing Homes"[MeSH Terms]	28793
#6	Search #2 AND #5	2508
#7	Search "Long-Term Care"[MeSH Terms]	19577
#8	Search #2 AND #7	892
#9	Search "Group Homes"[MeSH Terms]	746
#10	Search #2 AND #9	56
#11	Search "Homes for the Aged"[MeSH Terms]	9773
#12	Search #2 AND #11	1099
#13	Search "Housing for the Elderly"[MeSH Terms]	1336
#14	Search #2 AND #13	72
#15	Search "Institutionalization"[MeSH Terms]	7326
#16	Search #2 AND #15	545
#17	Search "long term care"[tiab]	12016
#18	Search #2 AND #17	862
#19	Search "residential care"[tiab]	1588
#20	Search #2 AND #19	196
#21	Search "institutional care"[tiab]	1252
#22	Search #2 AND #21	142
#23	Search skilled nursing facilit*	3995
#24	Search #2 AND #23	162
#25	Search group home*	1122
#26	Search #2 AND #25	69
#27	Search nursing home*	32683
#28	Search #2 AND #27	3181
#29	Search assist* living	27313
#30	Search #2 AND #29	782
#31	Search "Wellspring"	38
#32	Search #2 AND #31	1
#33	Search Eden alternative*	18
#34	Search #2 AND #33	0
#35	Search green house*	173
#36	Search #2 AND #35	1
#37	Search green home*	7
#38	Search #2 AND #37	0
#39	Search #4 OR #6 OR #8 OR #10 OR #12 OR #14 OR #16 OR #18 OR #20 OR #22 OR #24 OR #26 OR #28 OR #30 OR #32 OR #34 OR #36 OR #38	5250
#40	Search #39 Limits: Editorial, Letter, Addresses, Autobiography, Bibliography, Biography, Case Reports, Comment, Congresses, Consensus Development Conference, Consensus Development Conference, NIH, Dictionary, Directory, Festschrift, In Vitro, Interactive Tutorial, Interview, Lectures, Legal Cases, Legislation, Patient Education Handout, Periodical Index, Portraits, Scientific Integrity Review, Video-Audio Media, Webcasts	477

Table A-1. MEDLINE® (continued)

Search	Queries	Result
#41	Search #39 NOT #40	4773
#42	Search #41 Limits: Middle Aged: 45-64 years, Middle Aged + Aged: 45+ years, Aged: 65+ years, 80 and over: 80+ years	4128
#43	Search ((#42) AND "1990/01/01"[Publication Date] : "3000"[Publication Date]) AND "0"[Publication Date] : "3000"[Publication Date] Sort by: Author	3646

Table A-2. Cochrane Database

ID	Search	Hits
#1	"dementia"[MeSH Terms] OR "dementia"[All Fields] OR "alzheimer disease"[MeSH Terms] OR "alzheimer"[All Fields] OR "alzheimer disease"[All Fields]	9351
#2	"Assisted Living Facilities"[MeSH Terms]	38
#3	"Nursing Homes"[MeSH Terms]	1217
#4	"Long-Term Care"[MeSH Terms]	2229
#5	"Group Homes"[MeSH Terms]	64
#6	"Homes for the Aged"[MeSH Terms]	415
#7	"Housing for the Elderly"[MeSH Terms]	34
#8	"Institutionalization"[MeSH Terms]	308
#9	"long term care"[tiab]	2229
#10	"residential care"[tiab]	281
#11	"institutional care"[tiab]	193
#12	skilled nursing facilit*	191
#13	group home*	16569
#14	nursing home*	4813
#15	assist* living	2258
#16	Wellspring	1
#17	Eden alternative*	30
#18	green house*	87
#19	green home*	217
#20	(#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)	20704
#21	(#1 AND #20)	1263
#22	(#21), from 1990 to 2011	1220
#23	"Humans"[Mesh]	412650
#24	(#22 AND #23)	921
#25	(#24)	916

Table A-3. CINAHL, AgeLine, PsycINFO

#	Query	Limiters/Expanders	Last Run Via	Results
S29	S27 and S28	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	1890
S28	DE "United States"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	238126
S27	S25 and S26	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	2786
S26	DE "Older Adults"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	102053
S25	S4 and S23	Limiters - English Language; Exclude MEDLINE records; Human; Language: English; Publication Year from: 1990-2011; Publication Type: Journal article; Publication Year from: 1990-2011; English; Language: English; Population Group: Human; Exclude Dissertations Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	6791
S24	S4 and S23	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	11975
S23	S5 or S6 or S7 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	94213
S22	green home*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	80
S21	green house*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	87

Table A-3. CINAHL, AgeLine, PsycINFO (continued)

#	Query	Limiters/Expanders	Last Run Via	Results
S20	Eden alternative*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	100
S19	"Wellspring"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	115
S18	assist* living	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	5359
S17	nursing home*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	48507
S16	group home*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	5106
S15	skilled nursing facilit*	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	3417
S14	"institutional care"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	4684
S13	"residential care"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	16659
S12	"long term care"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	34904

Table A-3. CINAHL, AgeLine, PsycINFO (continued)

#	Query	Limiters/Expanders	Last Run Via	Results
S11	"Institutionalization"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	9680
S10	"Housing for the Elderly"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text;AgeLine;PsycINFO	2288

Table A-4. EMBASE Database Search

ID	Search	Results
2	'dementia'/exp/mj	119986
3	'alzheimer disease'/exp/mj	60262
4	#2 OR #3	119986
6	'nursing home'/exp/mj OR 'long term care'/exp/mj OR 'residential home'/exp/mj OR 'home for the aged'/exp/mj OR 'institutionalization'/exp/mj OR 'residential care'/exp/mj OR 'institutional care'/exp/mj OR 'skilled nursing facility' OR 'assisted living facility'/exp	60593
7	#4 AND #6	1684
8	#4 AND #6 AND ('article'/it OR 'article in press'/it OR 'conference abstract'/it OR 'conference paper'/it OR 'review'/it)	1514
9	#8 AND [humans]/lim AND [english]/lim AND ([embase]/lim OR [embase classic]/lim) AND [1990-2012]/py	543

Total number of records identified: 5,589

Update Search

We performed update searches from March 21 - 23, 2012.

PubMed: 21 March 2012

Search	Query	Items found
#1	Search "dementia"[MeSH Terms] OR "dementia"[All Fields] OR "alzheimer disease"[MeSH Terms] OR "alzheimer"[All Fields] OR "alzheimer disease"[All Fields]	130527
#2	Search #1 Limits: Humans, English	100658
#3	Search "Assisted Living Facilities"[MeSH Terms]	694
#4	Search #2 AND #3	132
#5	Search "Nursing Homes"[MeSH Terms]	29462
#6	Search #2 AND #5	2622
#7	Search "Long-Term Care"[MeSH Terms]	20040
#8	Search #2 AND #7	931
#9	Search "Group Homes"[MeSH Terms]	772
#10	Search #2 AND #9	60
#11	Search "Homes for the Aged"[MeSH Terms]	10039
#12	Search #2 AND #11	1144
#13	Search "Housing for the Elderly"[MeSH Terms]	1361
#14	Search #2 AND #13	74
#15	Search "Institutionalization"[MeSH Terms]	7436
#16	Search #2 AND #15	558
#17	Search "long term care"[tiab]	12478
#18	Search #2 AND #17	919
#19	Search "residential care"[tiab]	1679
#20	Search #2 AND #19	209
#21	Search "institutional care"[tiab]	1301
#22	Search #2 AND #21	147
#23	Search skilled nursing facilit*	4094
#24	Search #2 AND #23	164
#25	Search group home*	1159
#26	Search #2 AND #25	73
#27	Search nursing home*	33580
#28	Search #2 AND #27	3336
#29	Search assist* living	29200
#30	Search #2 AND #29	831
#31	Search "Wellspring"	40
#32	Search #2 AND #31	1
#33	Search Eden alternative*	19
#34	Search #2 AND #33	0
#35	Search green house*	182
#36	Search #2 AND #35	1
#37	Search green home*	7
#38	Search #2 AND #37	0
#39	Search #4 OR #6 OR #8 OR #10 OR #12 OR #14 OR #16 OR #18 OR #20 OR #22 OR #24 OR #26 OR #28 OR #30 OR #32 OR #34 OR #36 OR #38	5503
#40	Search #39 Limits: Editorial, Letter, Addresses, Autobiography, Bibliography, Biography, Case Reports, Comment, Congresses, Consensus Development Conference, Consensus Development Conference, NIH, Dictionary, Directory, Festschrift, In Vitro, Interactive Tutorial, Interview, Lectures, Legal Cases, Legislation, Patient Education Handout, Periodical Index, Portraits, Scientific Integrity Review, Video-Audio Media, Webcasts	492
#41	Search #39 NOT #40	5011
#42	Search #41 Limits: Middle Aged: 45-64 years, Middle Aged + Aged: 45+ years, Aged: 65+ years, 80 and over: 80+ years	4326
#43	Search (#42) AND ("2011/04/01"[Date - Entrez] : "3000"[Date - Entrez])	142

Cochrane: 21 March 2012

ID	Search	Hits
#1	"dementia"[MeSH Terms] OR "dementia"[All Fields] OR "alzheimer disease"[MeSH Terms] OR "alzheimer"[All Fields] OR "alzheimer disease"[All Fields]	9771
#2	"Assisted Living Facilities"[MeSH Terms]	45
#3	"Nursing Homes"[MeSH Terms]	1328
#4	"Long-Term Care"[MeSH Terms]	2445
#5	"Group Homes"[MeSH Terms]	68
#6	"Homes for the Aged"[MeSH Terms]	436
#7	"Housing for the Elderly"[MeSH Terms]	37
#8	"Institutionalization"[MeSH Terms]	334
#9	"long term care"[tiab]	2445
#10	"residential care"[tiab]	330
#11	"institutional care"[tiab]	210
#12	skilled nursing facilit*	254
#13	group home*	17986
#14	nursing home*	5656
#15	assist* living	2978
#16	Wellspring	1
#17	Eden alternative*	57
#18	green house*	679
#19	green home*	1714
#20	(#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)	22643
#21	(#1 AND #20)	1529
#22	(#21), from 2011 to 2012	191
#23	"Humans"[Mesh]	429201
#24	(#22 AND #23)	171

CINAHL, AgeLine, PsycINFO: 23 March 2012

#	Query	Results
S28	S27 Limiters - Published Date from: 20110701-20120431; English Language; Human; Language: English; Age Groups: All Adult; Publication Year from: 2011-2012; Publication Type: Journal Article; Publication Year from: 2011-2012; English; Age Groups: Adulthood (18 yrs & older); Population Group: Human; Exclude Dissertations Search modes - Boolean/Phrase	10
S27	S23 and S26	1995
S26	S24 or S25	416805
S25	DE "United States"	245288
S24	(MH "United States+")	332536
S23	S20 and S21 and S22	5348
S22	S18 or S19	692901
S21	S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17	113110
S20	S1 or S2 or S3 or S4	83188
S19	DE "Older Adults"	102212
S18	(MH "Adult+") OR (MH "Frail Elderly")	590689
S17	DE "Long Term Care"	25056
S16	(MH "Residential Care+")	4106
S15	(MH "Institutionalization+")	57237
S14	DE "Institutionalization"	5718
S13	(MH "Housing for the Elderly")	1593
S12	DE "Homes for the Elderly"	670
S11	(MH "Long Term Care")	14191
S10	DE "Nursing Homes"	27470
S9	(MH "Nursing Homes+")	14695
S8	DE "Assisted Living Facilities"	1492
S7	DE "Assisted Living"	1919
S6	"assisted living"	4760
S5	(MH "Assisted Living")	1518
S4	DE "Dementia"	44708
S3	(DE "Dementia" OR DE "AIDS Dementia Complex" OR DE "Dementia with Lewy Bodies" OR DE "Presenile Dementia" OR DE "Semantic Dementia" OR DE "Senile Dementia" OR DE "Vascular Dementia")	48489
S2	(MH "Dementia+")	28434
S1	Dementia	73994

EMBASE: 23 March 2012

ID	Search	Results
1	'dementia'/exp/mj	**128,476**
2	'alzheimer disease'/exp/mj	**64,758**
3	#1 OR #2	**128,476**
4	'nursing home'/exp/mj OR 'long term care'/exp/mj OR 'residential home'/exp/mj OR home for the aged'/exp/mj OR 'institutionalization'/exp/mj OR 'residential care'/exp/mj OR 'institutional care'/exp/mj OR 'skilled nursing facility' OR 'assisted living facility'/exp	**64,845**
5	#3 AND #4	**1,823**
6	#5 AND ([adult]/lim OR [aged]/lim) AND [humans]/lim AND [english]/lim AND [1-7-2011]/sd NOT [31-3-2012]/sd	**71**

Total number of records identified: 353

Handsearches

Handsearches of the following references yielded 341 additional records.

Alessi CA, Schnelle JF. Approach to sleep disorders in the nursing home setting. REVIEW ARTICLE. Sleep Med Rev. 2000 Feb;4(1):45-56. PMID: 12531160.

Allen-Burge R, Stevens AB, Burgio LD. Effective behavioral interventions for decreasing dementia-related challenging behavior in nursing homes. Int J Geriatr Psychiatry. 1999 Mar;14(3):213-28; discussion 28-32. PMID: 10202663.

Aoyama L, Weintraub N, Reuben DB. Is weight loss in the nursing home a reversible problem? Journal of the American Medical Directors Association. 2005;6(4):250-6.

Blasi ZV, Hurley AC, Volicer L. End-of-life care in dementia: a review of problems, prospects, and solutions in practice. Journal of the American Medical Directors Association. 2002;3(2):57-65.

Cunje A, Molloy DW, Standish TI, et al. Alternate forms of logical memory and verbal fluency tasks for repeated testing in early cognitive changes. Int Psychogeriatr. 2007 Feb;19(1):65-75. PMID: 16684396.

Day K, Carreon D, Stump C. The therapeutic design of environments for people with dementia: a review of the empirical research. Gerontologist. 2000 Aug;40(4):397-416. PMID: 10961029.

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Doyle CJP. Social interventions to manage mental disorders of the elderly in long-term care. Australian Psychologist. 1993;28(1):25-30.

Finkel SI. Behavioral and psychological signs and symptoms of dementia: implications for research and treatment. Int Psychogeriatr. 1996;8(Suppl. 3):215-542.

Finnema E, Droes RM, Ribbe M, et al. The effects of emotion-oriented approaches in the care for persons suffering from dementia: a review of the literature (Structured abstract). Int J Geriatr Psychiatry; 2000. p. 141-61.

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Gaugler JE, Kane RL. Families and Assisted Living. Gerontologist. 2007;47:83-99.

Hall S, Kolliakou A, Petkova H, et al. Interventions for improving palliative care for older people living in nursing care homes. Cochrane Database Syst Rev. 2011(3):CD007132. PMID: 21412898.

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Konetzka RT, Spector W, Limcangco MR. Reducing hospitalizations from long-term care settings. Med Care Res Rev. 2008 Feb;65(1):40-66. PMID: 17895516.

Kong EH, Evans LK, Guevara JP. Nonpharmacological intervention for agitation in dementia: a systematic review and meta-analysis (Structured abstract). Aging and Mental Health; 2009. p. 512-20.

Lai CK, Yeung JH, Mok V, et al. Special care units for dementia individuals with behavioural problems. Cochrane Database Syst Rev. 2009(4):CD006470. PMID: 19821370.

Livingston G, Johnston K, Katona C, et al. Systematic review of psychological approaches to the management of neuropsychiatric symptoms of dementia. Am J Psychiatry. 2005 Nov;162(11):1996-2021. PMID: 16263837.

Lum TY, Kane RA, Cutler LJ, et al. Effects of Green House nursing homes on residents' families. Health Care Financ Rev. 2008 Winter;30(2):35-51. PMID: 19361115.

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Opie J, Rosewarne R, O'Connor DW. The efficacy of psychosocial approaches to behaviour disorders in dementia: a systematic literature review (Structured abstract). Aust N Z J Psychiatry; 1999. p. 789-99.

Ostaszkiewicz J, Johnston L, Roe B. Timed voiding for the management of urinary incontinence in adults. Cochrane Database of Systematic Reviews. Chichester, UK: John Wiley & Sons, Ltd; 2004.

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Verkaik R, van Weert JC, Francke AL. The effects of psychosocial methods on depressed, aggressive and apathetic behaviors of people with dementia: a systematic review. Int J Geriatr Psychiatry. 2005 Apr;20(4):301-14. PMID: 15799081.

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Total references from initial and update search and handsearches after duplicates removed=6,209.

Appendix B. Excluded Studies

Excluded for Wrong PICOTS Element

Some demented patients are still able to execute advance directives. Geriatrics. 1996 Jul;51(7):23. PMID: 11644794.

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Appendix C. Evidence Tables

Evidence Table 1. Characteristics of included studies

Author, Year Trial Name Funding Source	Overall Sample Population Size	Overall Setting Sample Size	Group Sample Sizes	# of Beds	% for Profit	Study Design	Models of Care
Dowling, 2005[1] NA Government	46	2	G1: 29 G2: 17	NR	NR	RCT	NH
Fritsch, 2009[2] NA Foundation or non-Profit	NR	20	NR	NR	0%	RCT	SCU in NH
Hickman, 2007[3] NA Government	66	2	G1: 32 G2: 46 G3: 47 G4: 48	NR	NR	RCT	Geriatric units in a state-operated psychiatric hospital and SCU
Kovach, 2006[4] NA Government	127	14	G1: 57 G2: 57	Average # of beds: 115.2 Ranged from 60-187 per facility	57.14%	RCT	NH
Leon and Ory, 1999 [5] NA Government	695	153	G1: 495 G2: 200	68% of the settings had > 150 beds	NR	Prospective Cohort	SCU, non-SCU
Remington, 2002[6] NA Other	68	4	G1: 17 G2: 17 G3: 17 G4: 17	NR	NR	RCT	NH
Rosswurm, 1990[7] NA Other	30	3	G1: 15 G2: 15	NR	NR	RCT	NH
Sloane, 2004[8] NA Government	73	15	G1: 24 G2: 25 G3: 24	G1: 128.0 G2: 119.6	G1: 80% G2: 80%	RCT	NH
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	1,252	146	G1: 773 G2: 479 G3: 164 G4: 607 G5: 94 G6: 385	Mean bed size G1: 30 G2:116	G1: 83% G2: 58%	Prospective Cohort	RC/AL, NH

Evidence Table 1. Characteristics of included studies (continued)

Author, Year Trial Name Funding Source	Overall Sample Population Size	Overall Setting Sample Size	Group Sample Sizes	# of Beds	% for Profit	Study Design	Models of Care
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	422	230	G1: 175 G2: 247	NR	NR	Prospective Cohort	RC/AL, NH
Tappen, 1994[11] NA Foundation or non-profit	63	1	G1: 21 G2: 21 G3: 21	NR	NR	RCT	NH
Toseland, 1997[12] NA Government	88	4	G1: 31 G2: 29 G3: 28	464 total beds across all 4 nursing homes	NR	RCT	NH
Whall, 1997[13] NA Other	31	5	G1: 15 (2 homes) G2: 16 (3 homes)	NR	NR	Non-randomized controlled trial	NH
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	421	45	G1: 48 G2: 101 G3: 135 G4: 137	Mean Overall: 61.8 G1: <16 beds G2: >/= 16 beds G3: >/= 16 beds G4: NR	Overall: 75.6%	Prospective Cohort	RC/AL, NH

Abbreviations: G = group; NA = not applicable; NH = nursing home; NR = not reported; RC/AL = residential care/assisted living; RCT = randomized controlled trial; SCU = special care unit.

Evidence Table 2. Characteristics of study populations

Author, Year Trial Name Funding Source	Dementia Severity	Mean Baseline Level of Cognitive Impairment	Range Baseline Level of Cognitive Impairment	Mean Functional Status	Range of Functional Status	Baseline Age - Mean	Baseline % Female	Baseline % Non-White or by Minority Group
Dowling, 2005[1] NA Government	Mild to severe	MMSE Overall: 6.7 G1: NR G2: NR	MMSE Range Overall: 0-23 G1: NR G2: NR	NR	NR	Overall: 84 G1: NR G2: NR	Overall: 78% G1: NR G2: NR	African-American Overall: 13.0% G1: NR G2: NR Hispanic: Overall: 4.4% G1: NR G2: NR Asian Overall: 2.2% G1: NR G2: NR
Fritsch, 2009[2] NA Foundation or non-profit	NR	NR	NR	NR	NR	NR	NR	NR
Hickman, 2007[3] NA Government	Mild to severe	MDS-COGS Mild to Moderate Men: 34.3% Women: 29.0 % Severe Men: 42.9% Women: 51.6% Very Severe: Men: 22.9% Women: 19.4%	NR	Need assistance Bathing Men: 60% Women: 76.7% Need assistance in locomotion Men: 14.3% Women: 22.6%, Need assistance eating Men: 25.7% Women: 22.6 % Urinary incontinence Men: 51.4%, Women: 29.0%	NR	<65 years Men: 14.3% Women: 3.2% 65-79 years Men: 51.4% Women: 32.3% ≥ 80 Men: 34.3% Women: 64.5%	Overall: 47% G1: NR G2: NR G3: NR G4: NR	Overall: 25.76% G1: NR G2: NR G3: NR G4: NR Overall Men: 25.7%, African American Overall Women: 25.8%, African American

Evidence Table 2. Characteristics of study populations (continued)

Author, Year Trial Name Funding Source	Dementia Severity	Mean Baseline Level of Cognitive Impairment	Range Baseline Level of Cognitive Impairment	Mean Functional Status	Range of Functional Status	Baseline Age - Mean	Baseline % Female	Baseline % Non-White or by Minority Group
Kovach, 2006[4] NA Government	Severe	MMSE Overall: 7.81 G1: 7.35 G2: 8.26	NR	FAST function Stage 4 G1:3 G2:2 Stage 5 G1: 1 G2: 0 Stage 6 G1: 33 G2:29 Stage 7 G1: 20 G2: 26	NR	Overall: 86.55 G1: 86.58 G2:86.53	Overall: 75% G1: 73.68% G2:77.19%	NR
Leon and Ory, 1999[5] NA Government	Mild to severe	MDS-COGS Overall: 6.03 G1: 6.23 G2: 5.49 G1 vs. G2: p <0.001	NR	ADL impairment Overall: 4.21 G1: 4.26 G2:4.09	NR	Overall: 81.55 G1: 80.43 G2: 84.48 G1 vs. G2: p<0.001	Overall: 71% G1: 69% G2: 77% G1 vs. G2: p<0.05	NR
Remington, 2002[6] NA Other	Mild to severe	Overall: 4% Mild, 43% moderate, 53% severe G1: NR G2: NR G3: NR G4: NR	NR	NR	NR	Overall: 82.4 G1: NR G2: NR G3: NR G4: NR	Overall: 87% G1: NR G2: NR G3: NR G4: NR	Overall: 6% non-white G1: NR G2: NR G3: NR G4: NR
Rosswurm, 1990[7] NA Other	Mild to severe	MMSE Overall: NR G1: 9.86 G2: 11.1	NR	DBS Overall: NR G1: 26.0 G2: 24.0	NR	Overall: 84 G1: NR G2: NR	Overall: 60% G1: NR G2: NR	Overall: 10% Black G1: NR G2: NR

Evidence Table 2. Characteristics of study populations (continued)

Author, Year Trial Name Funding Source	Dementia Severity	Mean Baseline Level of Cognitive Impairment	Range Baseline Level of Cognitive Impairment	Mean Functional Status	Range of Functional Status	Baseline Age - Mean	Baseline % Female	Baseline % Non-White or by Minority Group
Sloane, 2004[8] NA Government	Moderate to severe	MDS-COGS Overall: NR G1: 7.7 G2: 6.5 MMSE Overall: NR G1: 2.2 G2: 2.1	NR	ADL Overall: NR G1: 2.9 G2: 2.5	NR	Overall: NR G1:86.0 G2:86.9	Overall: NR G1: 73.9 % G2:95.7%	Overall: NR Non-white G1:10.9% G2:13.0%
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	Mild to severe	MDS-COGS Overall: NR G1: 5.3 G2: 5.7	NR	MDS-ADL Overall: NR G1: 7.6 G2: 11.9	NR	Overall: NR G1: 84.4 G2: 84.9	Overall: NR G1: 78.1% G2: 76.2%	Overall: NR African American G1: 5.2% G2: 17.8% Other G1: 2.6% G2: 1.5%
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	NR	NR	NR	NR	NR	NR	NR	NR
Tappen, 1994[11] NA Foundation or non-profit	NR	MMSE Overall: 6.4 G1: NR G2: NR	NR	NR	NR	Overall: 84 G1: NR G2: NR	Overall: 75% G1: NR G2: NR	NR
Toseland, 1997[12] NA Government	NR	SPMSQ Overall: NR G1: 7.43 G2: 7.46 G3: 7.15	NR	Need for ADL assistance Overall: NR G1: 20.41 G2: 21.21 G3: 21.74	NR	Overall: 88 G1: 87.79 G2: 87.29 G3: 87.78	Overall: 75% G1: 86% G2: 69% G2: 68%	Overall: 4.55% African American G1: 6% G2: 3% G3: 4%
Whall, 1997[13] NA Other	Severe	NR	NR	NR	NR	NR	Overall: 87.1% G1: NR G2:NR	NR

Evidence Table 2. Characteristics of study populations (continued)

Author, Year Trial Name Funding Source	Dementia Severity	Mean Baseline Level of Cognitive Impairment	Range Baseline Level of Cognitive Impairment	Mean Functional Status	Range of Functional Status	Baseline Age - Mean	Baseline % Female	Baseline % Non-White or by Minority Group
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	Mild to severe	MMSE/ MDS-COGS Overall: Mild to moderate: 152 Severe to very severe: 259	NR	MDS-ADL Overall: 0-4 ADLs: 198 5-7 ADLs: 164	NR	Overall: ≥ 85 years: 206	Overall: 79.1%	Overall: Non-white: 8.3% White: 80.3%

Abbreviations: ADL = activities of daily life; DBS = Dementia Behavior Scale; FAST = Functional Assessment Staging; G = group; MDS-COGS = Minimum Data Set Cognition Scale; MMSE = Mini-Mental State Examination; NA = not applicable; NR = not reported; SPMSQ = Short Portable Mental Status Questionnaire; vs. = versus.

Evidence Table 3. Intervention/Exposure components

Author, Year Trial Name Funding Source	Intervention/Exposure Components by Group
Dowling, 2005[1] NA Government	G1: Morning bright light exposure (9:30-10:30 a.m., >2,500 lux in gaze direction) G2: Control - Usual indoor light levels (150-200 lux)
Fritsch, 2009[2] NA Foundation or non-profit	G1: TS storytelling groups, met for 10 weeks. Facilitators handed out a playful theatrical picture to serve as the basis for the story. Facilitators asked open-ended questions about the picture and recorded residents' responses on pads of paper, making it clear that there were no correct answers. Facilitators then wove the responses into a story, periodically reading it back to the participants as it progressed. Staff participated in a 9-week training in order to implement the program. G2: Control Setting – No Intervention
Hickman, 2007[3] NA Government	G1: Morning bright light (7 a.m.–11 a.m.) G2: Evening bright light (4 p.m.–8 p.m.) G3: All-day bright light (7 a.m.–8 p.m.) G4: Standard light (7 a.m.–8 p.m.)
Leon and Ory, 1999 [5] NA Government	G1: SCU G2: Non-SCU
Kovach, 2006[4] NA Government	G1: Nurses were taught to use STI. STI was developed for comfort assessment and management. Multiple levels of assessment and treatment are used, including both nonpharmacological treatments and analgesics. STI allows a standardized treatment to be customized to the individual's specific need. G2: Control nurses were taught common misconceptions about aging, the physical effects of aging, reversible and irreversible causes of dementia, stages of Alzheimer's disease, and various approaches to treating behaviors and physical conditions associated with dementia.
Remington, 2002[6] NA Other	G1: Calm Music (10-minutes) G2: HM (10 minutes) G3: Calm Music and Hand Massage (ten minutes simultaneously) G4: Control - no intervention
Rosswurm, 1990[7] NA Other	G1: AFG consisting of 1) welcoming and relaxation exercises; 2) perceptual-matching exercises; 3) reinforcement with refreshments. G2: Control group had refreshments and the opportunity for social interaction but no planned program.
Sloane, 2004[8] NA Government	G1: Person-centered showering individualize the experience for the resident by using a wide variety of techniques, such as providing choices, covering with towels to maintain resident warmth, distracting attention (e.g., by providing food), using bathing products recommended by family and staff, using no-rinse soap, and modifying the shower spray. G2: Caregiver uses two bath blankets, two bath towels, a no-rinse soap, and 2 quarts of warm water; keeps the resident covered at all times; and cleanses the body using gentle massage. G3: Showering (without person-centered training) was used as the control.

Evidence Table 3. Intervention/Exposure components (continued)

Author, Year Trial Name Funding Source	Intervention/Exposure Components by Group
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	G1: Residential Care/Assisted Living G2: NH G3: Special Care Unit with in RC/AL G4: Non-Special Care Unit within RC/AL G5: Special Care Unit within NH G6: Non-Special Care Unit within NH
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	G1: Residential Care/Assisted Living G2: Nursing Home
Tappen, 1994[11] NA Foundation or non-profit	G1: Regain function in basic activities of daily living through repeated practice; Group setting 5 days/wk. for 2.5 hrs. per day; G2: Recreationally oriented group activities provided for dementia patients in therapeutically oriented settings; 5 days/wk. for 2.5 hrs. per day G3: No additional treatment; regular nursing care
Toseland, 1997[12] NA Government	G1: Developed to encourage residents with dementia to continue communicating by using memory fragments and any other aspects of their cognitive, affective, and motoric functioning that remain intact. VT is highly interactive and relatively structured and can include (a) the use of nonthreatening, simple, concrete words; (b) speaking in a clear, low, empathic tone of voice; (c) rephrasing and paraphrasing unclear verbal communications; (d) responding to the meanings explicit and implicit in verbal and nonverbal communications; and (e) mirroring verbal and nonverbal communications. G2: Group leaders conducted one activity each meeting, following a manual that contained 54 activities in the eight categories of music, art, literature and writing, dance/exercise, games/trivia, holiday and event planning, discussion, and other activities. Group leaders were not trained in the use of VT and were not informed about the content of the other group intervention. G3: Participation in regular social and recreational programming offered by each nursing facility
Whall, 1997[13] NA Other	G1: Bathed in a shower room with recorded songs of birds, sounds of babbling brooks, and the sounds of other small animals such as ducks, kittens, and chickens. Large bright pictures were coordinated with audio. Offering of foods such as banana pudding and/or soda. G2: Usual Care
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	G1: Facilities with < 16 beds G2: Facilities with >/= 16 beds, not meeting new-model criteria G3: Facilities with >/= 16 beds of the ‘‘new-model’’ type G4: Reference or control G5: Encourage activities ≥ once a day G6: Encourage activities < once a day G7: Use specialized workers (staff fill specialized roles) G8: No use of specialized workers

Abbreviations: AFG = Attention-focusing group; G = group; HM = hand massage; hrs = hours; NA = not applicable; NH = nursing home; RC/AL = residential care/assisted living; SCU = special care unit; STI – serial trial intervention; TS = time slips; VT = Validation Therapy; wk = week.

Evidence Table 4. Health outcomes for people with dementia: cognitive decline, functional decline, and pain

Author, Year Trial Name Funding Source	Cognitive Decline	Functional Decline	Pain
Dowling, 2005[1] NA Government	NR	NR	NR
Fritsch, 2009[2] NA Foundation or non-profit	General Alertness Subscale G1: 1512/1647 G2:1111/1245 G1 vs. G2: 1.028 times greater number of alertness events p<0.05	NR	NR
Hickman, 2007[3] NA Government	NR	NR	NR
Kovach, 2006[4] NA Government	NR	NR	Discomfort-DAT Baseline G1:162.91 G2:158.39, End Point: G1: 122.17 G2: 197.92 Within Group Mean Change G1: 40.74 G2: -39.53 G1 vs. G2: 95% CI, 43.26 to 113.26 p<0.001 Effect size: 0.89
Remington, 2002[6] NA Other	NR	NR	NR
Rosswurm, 1990[7] NA Other	MMSE Mean Gain Scores G1: 1.33 G2: -0.33 t value = 1.36, NS	DBS Mean Gain Score G1: 0.33 G2: -0.33 t value = 0.32, NS	NR

Evidence Table 4. Health outcomes for people with dementia: cognitive decline, functional decline, and pain (continued)

Author, Year Trial Name Funding Source	Cognitive Decline	Functional Decline	Pain
Sloane, 2004[8] NA Government	NR	NR	Modified Discomfort -DAT Endpoint G1: 1.82 G2: 1.57 G3: 2.14 G1 vs. G2: p=0.001 G2 vs.G3: p<0.001 Change in Modified Discomfort-DAT G1: 0.29 G2: 0.54 G3: -0.02 G1 vs. G3 p<0.001 G2 vs. G3 p=0.001 G1 vs. G2: p=0 .003

Evidence Table 4. Health outcomes for people with dementia: cognitive decline, functional decline, and pain (continued)

Author, Year Trial Name Funding Source	Cognitive Decline	Functional Decline	Pain
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	MDS-COGS Increase in cognitive impairment, Mean Change per 12 months Mild Dementia G1: 0.41 G2: 0.71 p=0.181 Moderate or Severe Dementia G1: -0.13 G2: 0.45 p=0.93 MDS-COGS Increase in cognitive impairment, Mean Change per 12 months G3: 0.33 G4: 0.30 G3 vs. G4 p=0.943 G5: 0.58 G6:: 0.61 G5 vs. G6: p=0.903	MDS-ADL Mean Change in ADL dependency per 12 months, MDS-ADL scale Mild Dementia G1: 4.29 G2: 5.80 p=0.059 Moderate or Severe Dementia G1: 0.87 G2: 1.13 p=0.807 MDS-ADL Mean Change in ADL dependency per 12 months, MDS-ADL scale G3: 5.64 G4: 2.91 G3 vs. G4: p=0.029 G5: 3.00 G6: 3.19 G5 vs. G6: p=0.886	Pain, not effectively treated during last month of life, % G1: 10.2 G2: 5.5 p=0.186 No Pain, never an issue during the last month of life, % G1: 48.5 G2: 38.7 p=0.249
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	NR	NR	NR

Evidence Table 4. Health outcomes for people with dementia: cognitive decline, functional decline, and pain (continued)

Author, Year Trial Name Funding Source	Cognitive Decline	Functional Decline	Pain
Tappen, 1994[11] NA Foundation or non-profit	NR	Physical Self Maintenance Scale Within group mean change G1: -3.33 G2: -0.82 G3: +0.74 G1 vs. G2 and G3, p=0.04 Adjusted Endpoint Means G1: 26.17 G2: 24.10 G3: 22.63 G1 vs. G3, p=0.01 G2 vs. G1 or G3, p=NS Performance Test of ADL Within group mean change G1: -3.01 G2: -0.86 G3: +1.14 p=0.12 Physical Self Maintenance Scale Goal Attainment Endpoint Mean G1: 1.75 G2: 1.43 G3: 1.10 G1 vs. G2 vs. G3, p=0.0023 G1 vs. G3, p=0.05 G2 vs. G1 or G3, p=NS	NR

Evidence Table 4. Health outcomes for people with dementia: cognitive decline, functional decline, and pain (continued)

Author, Year Trial Name Funding Source	Cognitive Decline	Functional Decline	Pain
Toseland, 1997[12] NA Government	NR	MOSES Self-care Subscale at baseline G1: 16.54 G2: 16.09 G3: 15.70 MOSES Self-care Subscale at endpoint G1: 16.52 G2: 16.68 G3: 16.77 MOSES Self-care Subscale change at endpoint G1: 0.02 G2: -0.59 G3: -1.07 MOSES Disorientation Subscale at Baseline G1: 15.68, G2: 16.09 G3: 17.91 MOSES Disorientation Subscale at Endpoint G1: 17.90 G2: 17.43 G3: 17.09	NR
Whall, 1997[13] NA Other	NR	NR	NR
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	NR	NR	NR

Abbreviations: ADL = Activities of Daily Living; DAT = Dementia of the Alzheimer's Type; G = group; MDS-ADL = Minimum Data Set Activities of Daily Living Scale; MDS-COGS = Minimum Data Set Cognition Scale; MMSE = Mini-Mental State Examination; MOSES = Multidimensional Observation Scale for Elderly Subjects; NA = not applicable; NR = not reported; NS = not sufficient.

Evidence Table 5. Health outcomes for people with dementia: sleep quality and depressive symptoms

Author, Year Trial Name Funding Source	Sleep Quality	Symptoms of Depression
Dowling, 2005[1] NA Government	Proportion of night asleep, % End point Mean G1: 66.64 G2: 71.14 Within Group Mean Change G1: -3.62 G2: -4.26 p=NR, ANOVA non-significant Sleep Time (hours: minutes) End point Mean G1: 7:59 G2: 8.32 Within Group Mean Change G1: -0:26 G2: -0:31 p=NR, ANOVA non-significant Night wake time (hours: minutes) End Point Mean G1: 3:59 G2: 3.27 Within Group Mean Change G1:+0:66 G2: +0:31 p=NR, ANOVA non-significant Number of awakenings End point Mean G1: 42.88 G2: 37.99 Within Group Mean Change G1: -1.32 G2 : -3.11 p=NR, ANOVA non-significant	NR

Evidence Table 5. Health outcomes for people with dementia: sleep quality and depressive symptoms (continued)

Author, Year Trial Name Funding Source	Sleep Quality	Symptoms of Depression
Dowling, 2005[1] (continued)	Day wake time (hours: minutes) End point mean: G1: 6.24 G2: 6.34 Within Group Mean Change: G1: +0.12 G2: +0.87 p=NR, ANOVA non-significant	
Fritsch, 2009[2] NA Foundation or non-profit	NR	NR
Hickman, 2007[3] NA Government	NR	CSDD Subanalyses by men G1 vs. G3: 2.62, p=0.007 G2 vs. G3: 1.13, p=0.23 G4 vs. G3: 1.64, p=0.08 G1 vs. G4: 1.50, p=0.16 G1 vs. G4: 0.98, p=0.33 G2 vs. G4: 0.52, p=0.60 Subanalyses by women G1 vs. G3: - 1.61, p=0.09 G2 vs. G3: 0.09, p=0.94 G4 vs. G3: 1.41, p=0.16 G1 vs. G2: –1.70, p=0.08 G1 vs. G4: –3.02, p=0.01 G2 vs. G4: –1.32, p=0.24
Kovach, 2006[4] NA Government	NR	NR
Remington, 2002[6] NA Other	NR	NR
Rosswurm, 1990[7] NA Other	NR	NR
Sloane, 2004[8] NA Government	NR	NR

Evidence Table 5. Health outcomes for people with dementia: sleep quality and depressive symptoms (continued)

Author, Year Trial Name Funding Source	Sleep Quality	Symptoms of Depression
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	NR	CSDD, Increase in depressive symptoms Mild Dementia G1: 1.33 G2: 1.53 p=0.753 Moderate or Severe Dementia G1: 1.52 G2: 0.85 p=0.409 CSDD, Increase in depressive symptoms G3: 1.59 G4: 1.32 G3 vs. G4: p=0.823 G5: 0.89 G6: 1.25 G5 vs. G6: p=0.630
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	NR	NR
Tappen, 1994[11] NA Foundation or non-profit	NR	NR
Toseland, 1997[12] NA Government	NR	MOSES Subscale at baseline G1: 10.64 G2: 7.73 G3: 8.78 MOSES Subscale at endpoint G1: 9.19 G2: 10.29 G3: 8.18 MOSES Subscale change at endpoint G1: 1.45 G2: -2.56 G3: 0.6 p=NR, stated difference NS

Evidence Table 5. Health outcomes for people with dementia: sleep quality and depressive symptoms (continued)

Author, Year Trial Name Funding Source	Sleep Quality	Symptoms of Depression
Whall, 1997[13] NA Other	NR	NR
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	NR	NR

Abbreviations: ANOVA = analysis of variance; CSDD = Cornell Scale for Depression in Dementia; G = group; MOSES = Multidimensional Observation Scale for Elderly Subjects; NA = not applicable; NR = not reported; vs. = versus.

Evidence Table 6. Health outcomes for people with dementia: morbidity, mortality, hospitalizations, and falls

Author, Year Trial Name Funding Source	Morbidity	Mortality	Hospitalizations	Falls
Dowling, 2005[1] NA Government	NR	NR	NR	NR
Fritsch, 2009[2] NA Foundation or non-profit	NR	NR	NR	NR
Hickman, 2007[3] NA Government	NR	NR	NR	NR
Kovach, 2006[4] NA Government	NR	NR	NR	NR
Remington, 2002[6] NA Other	NR	NR	NR	NR
Rosswurm, 1990[7] NA Other	NR	NR	NR	NR
Sloane, 2004[8] NA Government	Hardy Skin Condition Data Form Baseline: 2.97 Endpoint G1: 2.61 G2: 2.48 Mean Debris Score Baseline: 1.46 Endpoint G1: 0.75 G2: 0.49 Baseline vs. G1, p=0.001 Baseline vs. G2, p=0.003 G1 vs. G2 change: 0.56, NS Baseline vs. G1, p<0.001 Baseline vs. G2, p<0.001 G1 vs. G2 change p=0.08	NR	NR	NR

Evidence Table 6. Health outcomes for people with dementia: morbidity, mortality, hospitalizations, and falls (continued)

Author, Year Trial Name Funding Source	Morbidity	Mortality	Hospitalizations	Falls
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	New or worsening morbidity (Incidence rate per 100 participants per quarter) Mild Dementia G1: 23.5 G2: 21.8 p=0.574 Moderate or Severe Dementia G1: 21.1 G2: 21.7 p=0.865 New or worsening morbidity, incidence rate per 100 participants per quarter G3: 26.7 G4: 25.3 G3 vs. G4: p=0.772 G5: 15.0 G6: 22.0 G5 vs. G6: p=0.043	Mortality (Incidence rate per 100 participants per quarter) Mild Dementia G1: 3.2 G2: 4.2 p=0.409 Moderate or Severe Dementia G1: 3.7 G2: 4.2 p=0.682 Mortality (Incidence rate per 100 participants per quarter) G3: 7.0 G4: 4.0 G3 vs. G4: p=0.116 G5: 3.4 G6: 4.0 G5 vs. G6: p=0.540	Hospitalization (Incidence rate per 100 participants per quarter) Mild Dementia G1: 14.2 G2: 8.4 p=0.009 Moderate or Severe Dementia G1: 14.2 G2: 10.0 p=0.115 Hospitalization (Incidence rate per 100 participants per quarter) G3: 17.3 G4: 14.4 G3 vs. G4: p=0.430 G5: 3.9 G6: 9.6 G3 vs. G4: p=0.006	NR
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	Stable Health during last months of life G1: 12.6% G2: 8.1% p=0.136 Steady decline in health during last months of life G1: 53.4% G2: 71.7% p=NR	NR	Life-sustaining interventions during the last month of life Hospitalized G1: 39.7% G2: 23.6% p=0.149	NR

Evidence Table 6. Health outcomes for people with dementia: morbidity, mortality, hospitalizations, and falls (continued)

Author, Year Trial Name Funding Source	Morbidity	Mortality	Hospitalizations	Falls
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other (continued)	Series of up's and downs in health during last months of life G1: 33.9% G2: 20.2% p<0.001 One or more skin ulcers during last months of life G1: 26.9% G2: 22.6% p=0.566			
Tappen, 1994[11] NA Foundation or non-profit	NR	NR	NR	NR
Toseland, 1997[12] NA Government	NR	NR	NR	NR
Whall, 1997[13] NA Other	NR	NR	NR	NR
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	NR	NR	NR	NR

Abbreviations: G = group; NA = not applicable; NR = not reported; NS = not sufficient; vs. = versus.

Evidence Table 7. Psychosocial outcomes for people with dementia: anxiety, affect, quality of life, use of psychoactive medications, use of restraints, and behavior

Author, Year Trial Name Funding Source	Anxiety	Affect	Quality of Life	Use of Psychoactive Medications	Use of Restraints	Behavior
Dowling, 2005[1] NA Government	NR	NR	NR	NR	NR	NR
Fritsch, 2009[2] NA Foundation or non-profit	PGCARS Anxiety Subscale G1: 39/1647 G2: 11/1245 2.68 times more anxiety events for G1 p=<0.002	PGCARS Anger Subscale G1: 6/1647 G2: 1/1245 4.54 times more anger events for G1 p<0.124 PGCARS Sadness Subscale G1: 7/1647 G2: 0/1245 >7 times more sadness events for G1 p<0.021 PGCARS Other (Neutral Affect) G1: 30/1647 G2: 75/1245 p=0.001	NR	NR	NR	Challenging behavior G1: 9/1651 G2: 1/1250 6.80 times more challenged for G1 p=0.034
Hickman, 2007[3] NA Government	NR	NR	NR	NR	NR	NR

Evidence Table 7. Psychosocial outcomes for people with dementia: anxiety, affect, quality of life, use of psychoactive medications, use of restraints, and behavior (continued)

Author, Year Trial Name Funding Source	Anxiety	Affect	Quality of Life	Use of Psychoactive Medications	Use of Restraints	Behavior
Kovach, 2006[4] NA Government	NR	NR	NR	NR	NR	BEHAVE-AD Baseline G1: 7.43 G2: 6.80 Endpoint G1: 4.68 G2: 4.96 Within Group Mean Change G1: 2.75 G2: 1.84 p=0.50, measuring the Time X Group interaction Return of behavior to baseline G1: 40 (70%) G2: 23 (40%) p=0 .002
Remington, 2002[6] NA Other	NR	NR	NR	NR	NR	NR
Rosswurm, 1990[7] NA Other	NR	NR	NR	NR	NR	NR
Sloane, 2004[8] NA Government	NR	NR	NR	NR	NR	NR
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	NR	NR	NR	NR	NR	NR

Evidence Table 7. Psychosocial outcomes for people with dementia: anxiety, affect, quality of life, use of psychoactive medications, use of restraints, and behavior (continued)

Author, Year Trial Name Funding Source	Anxiety	Affect	Quality of Life	Use of Psychoactive Medications	Use of Restraints	Behavior
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	NR	NR		Sedative Used Frequently G1: 21.0% G2: 29.2% p=0.592 Sedative Used At Least Sometimes G1: 29.9% G2: 37.3% p=0.792	Any Restraints Used G1: 65.7% G2: 91.5% p<0.001 Any Restraints Other than partial bed rails used G1: 46.3% G2: 67.6% p=0.031	NR
Tappen, 1994[11] NA Foundation or non-profit	NR	NR	NR	NR	NR	NR
Toseland, 1997[12] NA Government	NR	MOSES Irritation Subscale Baseline G1: 5.36 G2: 5.64 Endpoint G1: 4.81 G2: 6.10 G3:5.36 No effect by Condition X Time	NR	No significant differences among residents in the three intervention conditions with regard to use of antipsychotic, antianxiety, or antidepressant medications.	No changes in frequency of restraint use among residents in the three intervention conditions.	GIPB - no significant changes in Positive social interactions with family, staff, or other residents
Whall, 1997[13] NA Other	NR	NR	NR	NR	NR	NR

Evidence Table 7. Psychosocial outcomes for people with dementia: anxiety, affect, quality of life, use of psychoactive medications, use of restraints, and behavior (continued)

Author, Year Trial Name Funding Source	Anxiety	Affect	Quality of Life	Use of Psychoactive Medications	Use of Restraints	Behavior
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	NR	NR	QOL-AD Adjusted Change G1: +0.54 G2: +0.48 G3: -0.38 G4: -0.18 p=0.206 G5: -1.9 G6: -2.6 p=0.043 G7: -1.3 G8: -3.0 p=0.036	NR	NR	NR

Abbreviations: GIPB = Geriatric Indices of Positive Behavior; MOSES = Multidimensional Observation Scale for Elderly Subjects; NR = not applicable; NR = not reported; PGCARS = The Philadelphia Geriatric Center Affect Rating Scale; QOL-AD = Quality of Life scale in Alzheimer's Disease.

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Dowling, 2005[1] NA Government	NR	NR	NR	NR	NR
Fritsch, 2009[2] NA Foundation or non-profit	NR	Disengaged G1: 68/1651 G2:107/1250 0.481 times less disengaged for G1 p<0.001 Nonsocial engagement G1:174/1651 G2:135/1250 0.976 times less nonsocial engagement for the G1 p=0.822 Engagement G1: 1400/1651 G2:1007/1250 1.053 times more engaged for G1 p=0.003	NR	NR	NR
Hickman, 2007[3] NA Government	NR	NR	NR	NR	NR
Kovach, 2006[4] NA Government	NR	NR	NR	NR	NR

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering (continued)

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Leon and Ory, 1999 [5] NA Government	NR	NR	CMAI – Physically Aggressive Behavior Baseline (Unadjusted) G1: 4.84 G2: 4.10 p=NS Beta Coefficients (adjusted)[c] SCU Placement = 0.31, p=NS Religious Facility = 1.80, p=NS Large facility = -0.90, p=NS Gender of resident =2.05, p=NS Age of resident = -0.18, p<0.001 Disruptive behavior=1.65, p<0.001 Level of ADL=0.20, p=NS Level of Cognitive Status = -0.27, p=NS	NR	NR

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering (continued)

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Remington, 2002[6] NA Other	NR	NR	CMAI, Mean Baseline G1: 18.41 G2: 16.47 G3: 22.00 G4: 21.76 Endpoint G1 : 4.65 G2: 3.06 G3: 3.76 G4: 20.47 Within Group Reduction in Score G1:13.76 G2: 13.41 G3: 18.24 G4: 1.29 Significant difference found in level of agitation among four groups in repeated measures analysis of variance, p<0.01 Significant difference found between groups on physically nonaggressive behaviors, p<0.01	NR	NR
Rosswurm, 1990[7] NA Other	NR	NR	NR	NR	NR

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering (continued)

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Sloane, 2004[8] NA Government	NR	NR	CAREBA Endpoint G1: 25.84 G2: vs..51 G3: 35.65 G1 vs. G3 p=0.02 G2 vs. G3 p=0.01 G1 vs. G2 Change from Baseline, p=0.43	NR	NR
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	Decrease in Social Function (Adjusted Rates) Mild Dementia G1: 1.55 G2: 1.76 p=0.568 Moderate or Severe Dementia G1: 0.91 G2: 1.44 p=0.110 Decrease in Social Function (Adjusted Rates) G3: 1.58 G4: 1.34 p=0.681 G5: 1.88 G6: 1.46 p=0.303	MOSES subscale; Increased withdrawal from activities (Adjusted Rates) Mild Dementia G1: 2.84 G2: 2.24 p=0.364 Moderate or Severe Dementia G1: 2.55 G2: 1.78 p=0.307 MOSES subscale; Increased withdrawal from activities (Adjusted Rates) G3: 3.48 G4: 2.58 p=0.409 G5: 2.22 G6: 1.77 p=0.604	CMAI, Increase in Behavior Problems (Adjusted Rates) Mild Dementia G1: 1.08 G2: 0.69 p=0.604 Moderate or Severe Dementia G1: 1.72 G2: 1.49 p=0.809 CMAI, Increase in Behavior Problems (Adjusted Rates) G3: -1.53 G4: -1.14 p=0.763 G5: -2.18 G6: -0.72 p=0.168	NR	NR

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering (continued)

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	NR	NR	NR	NR	NR
Tappen, 1994[11] NA Foundation or non-profit	NR	NR	NR	NR	NR
Toseland, 1997[12] NA Government	NR	MOSES Withdrawal Subscale Baseline G1: 14.05 G2:13.05 G3:14.43 Endpoint G1: 13.95 G2: 13.67 G3: 14.91 No effect by Condition X Time	CMAI-N Physically Aggressive Behavior χ^2=14.90 p=0.001 G1 vs. G2 and G3 showed significant reduction in Physically aggressive behaviors Verbally Aggressive Behavior – χ^2=5.88 p=0.053 G1 and G2 vs. G3 showed significant reduction in verbally aggressive behaviors	NR	NR

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering (continued)

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Toseland, 1997[12] NA Government (continued)			Physically Nonaggressive Behaviors – χ^2=6.76 p=0.034 G2 and G3 reduced CMAI-O Physically Aggressive Behavior χ^2=1.41 p=0.590 Verbally Aggressive Behavior – χ^2=12.46 p=0.002 G2 vs. G1 and G3 showed significantly lower scores in verbally aggressive behaviors Physically Nonaggressive Behaviors χ^2=1.52 p=0.47		

Evidence Table 8. Psychosocial outcomes for people with dementia: activity engagement, social engagement, agitation, satisfaction, wandering (continued)

Author, Year Trial Name Funding Source	Activity Engagement	Social Engagement	Agitation	Satisfaction	Wandering
Whall, 1997[13] NA Other	NR	NR	CMAI Agitation T-test of mean difference scores Mean Baseline to T2 - 6.73; t=3.13, p<0.004 Mean Baseline to T1 - 5.08; p<0.02 Aggression (7-items from CMAI) T-test of mean difference scores Mean Baseline to T2 t=-1.47; p<0.19	NR	NR
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	NR	NR	NR	NR	NR

[a]Model 3 independent variables = SCU placement, religious setting, large setting, gender of resident, age of resident at admission, level of disruptive behavior at admission, level of ADL limitations at admission, and level of cognitive status at admission.

Abbreviations: ADL = activities of daily life; CAREBA = Care Recipient Behavior Assessment; CMAI = Cohen-Mansfield Agitation Inventory; CMAI-N = Nurse-derived Cohen-Mansfield Agitation Inventory; CMAI-O = Observer-derived Cohen Mansfield Agitation Inventory; G = group; MOSES = Multidimensional Observation Scale for Elderly Subjects; NA = not applicable; NR = not reported; NS = not sufficient; SCU = special care unit.

Evidence Table 9. Psychosocial outcomes for people with dementia: autonomy, choice, control, pleasure, quality of dying, spiritual well-being

Author, Year Trial Name Funding Source	Autonomy	Choice	Control	Pleasure	Quality of Dying	Spiritual Well-being
Dowling, 2005[1] NA Government	NR	NR	NR	NR	NR	NR
Fritsch, 2009[2] NA Foundation or non-profit	NR	NR	NR	PGCARS Pleasure Subscale G1: 54/1647 G2: 47/1245 0.869 times less pleasure for G1 p<0.472	NR	NR
Hickman, 2007[3] NA Government	NA	NA	NA	NA	NA	NA
Kovach, 2006[4] NA Government	NR	NR	NR	NR	NR	NR
Remington, 2002[6] NA Other	NR	NR	NR	NR	NR	NR
Rosswurm, 1990[7] NA Other	NR	NR	NR	NR	NR	NR
Sloane, 2004[8] NA Government	NR	NR	NR	NR	NR	NR
Sloane, 2005[9] Collaborative Studies of Long-Term Care Government	NR	NR	NR	NR	NR	NR

Evidence Table 9. Psychosocial outcomes for people with dementia: autonomy, choice, control, pleasure, quality of dying, spiritual well-being

Author, Year Trial Name Funding Source	Autonomy	Choice	Control	Pleasure	Quality of Dying	Spiritual Well-being
Sloane, 2008[10] Collaborative Studies of Long-Term Care Other	NR	NR	NR	NR	Psychosocial status during last month of life Resident Appeared to be at peace G1: 70.1% G2: 64.2% p=0.304 Received a compassionate touch daily G1: 96.6% G2: 95.1% p=0.399 Dignity Maintained G1: 90.2% G2: 89.4% p=0.847 At least one staff had close attachment to resident G1: 82.8% G2: 72.1% p=0.528	NR
Tappen, 1994[11] NA Foundation or non-profit	NR	NR	NR	NR	NR	NR
Toseland, 1997[12] NA Government	NR	NR	NR	NR	NR	NR
Whall, 1997[13] NA Other	NR	NR	NR	NR	NR	NR
Zimmerman, 2005[14] Dementia Care Project Foundation or non-profit	NR	NR	NR	NR	NR	NR

Abbreviations: G = group; NA = not applicable; NR = not reported; PGCARS = The Philadelphia Geriatric Center Affect Rating Scale.

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Appendix D. Quality Assessment

This appendix describes the criteria relating to internal validity and the procedures that topic teams follow for all updates and new assessments in making these judgments.

All topic teams use initial "filters" to select studies for review that deal most directly with the question at issue and that are applicable to the population at issue. Thus, studies of any design that use outdated technology or that use technology that is not feasible for long-term residential care may be filtered out before the abstraction stage, depending on the topic and the decisions of the topic team. The teams justify such exclusion decisions if there could be reasonable disagreement about this step. The criteria below are meant for those studies that pass this initial filter.

Presented below are a set of minimal criteria for each study design and then a general definition of three categories: "good," "fair," and "poor," based on those criteria. These specifications are not meant to be rigid rules but rather are intended to be general guidelines, and individual exceptions, when explicitly explained and justified, can be made. In general, a "good" study is one that meets all criteria well. A "fair" study is one that does not meet (or it is not clear that it meets) at least one criterion but has no known "fatal flaw." "Poor" studies have at least one fatal flaw.

Systematic Reviews

Criteria:

Comprehensiveness of sources considered/search strategy used
Standard appraisal of included studies
Validity of conclusions
Recency and relevance are especially important for systematic reviews

Definition of Ratings From Above Criteria:

Good: Recent, relevant review with comprehensive sources and search strategies; explicit and relevant selection criteria; standard appraisal of included studies; and valid conclusions.

Fair: Recent, relevant review that is not clearly biased but lacks comprehensive sources and search strategies.

Poor: Outdated, irrelevant, or biased review without systematic search for studies, explicit selection criteria, or standard appraisal of studies.

Case-Control Studies

Criteria:

Accurate ascertainment of cases
Nonbiased selection of cases/controls with exclusion criteria applied equally to both
Response rate
Diagnostic testing procedures applied equally to each group
Measurement of exposure accurate and applied equally to each group
Appropriate attention to potential confounding variables

Definition of Ratings Based on Criteria Above:

Good: Appropriate ascertainment of cases and nonbiased selection of case and control participants; exclusion criteria applied equally to cases and controls; response rate equal to or greater than 80 percent; diagnostic procedures and measurements accurate and applied equally to cases and controls; and appropriate attention to confounding variables.

Fair: Recent, relevant, without major apparent selection or diagnostic work-up bias but with response rate less than 80 percent or attention to some but not all important confounding variables.

Poor: Major selection or diagnostic work-up biases, response rates less than 50 percent, or inattention to confounding variables.

Randomized Controlled Trials and Cohort Studies

Criteria:

- Initial assembly of comparable groups: for RCTs: adequate randomization, including first concealment and whether potential confounders were distributed equally among groups; for cohort studies: consideration of potential confounders with either restriction or measurement for adjustment in the analysis; consideration of inception cohorts
- Maintenance of comparable groups (includes attrition, cross-overs, adherence, contamination)
- Important differential loss to follow-up or overall high loss to follow-up
- Measurements: equal, reliable, and valid (includes masking of outcome assessment)
- Clear definition of interventions
- All important outcomes considered
- Analysis: adjustment for potential confounders for cohort studies, or intention to treat analysis for RCTs.

Definition of Ratings Based on Above Criteria:

Good: Meets all criteria: Comparable groups are assembled initially and maintained throughout the study (follow-up at least 80 percent); reliable and valid measurement instruments are used and applied equally to the groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention to confounders in analysis. In addition, for RCTs, intention to treat analysis is used.

Fair: Studies will be graded "fair" if any or all of the following problems occur, without the fatal flaws noted in the "poor" category below: Generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention to treat analysis is done for RCTs.

Poor: Studies will be graded "poor" if any of the following fatal flaws exists: Groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied at all equally among groups (including not masking outcome assessment); and key confounders are given little or no attention. For RCTs, intention to treat analysis is lacking.

Criteria for Assessing External Validity (Generalizability) of Individual Studies

Each study that is identified as one that provides evidence to answer a KQ is assessed by according to its external validity (generalizability) using the following criteria.

Study Population:

The degree to which the people who were involved as subjects in the study constitute a special population because they were selected from a larger eligible population or were for other reasons unrepresentative of people who are likely to seek or be candidates for the preventive service. The selection has the potential to affect the following:

- absolute risk: The background rate of outcomes in the study could be greater or less than what might be expected in asymptomatic people because of the inclusion/exclusion criteria, because of non-participation, or for other reasons.
- harms: The harms observed in the study could be greater or less than what might be expected in asymptomatic people.

The following are features of the study population and the study design that may cause experience in the study to be different from what would be observed in the US long-term residential care population:

- demographics (age, gender, ethnicity, education, income): The criteria for inclusion/exclusion or non-participation do not encompass the range of people likely to be candidates for the preventive services in the US long-term residential care population.
- co-morbidities: the frequency of co-morbid conditions in the study population does not represent of the frequency likely to be encountered in people who seek the preventive service in the U.S. long-term residential care population.
- special inclusion/exclusion criteria: There are other special inclusion/exclusion criteria that make the study population unrepresentative.
- refusal rate (ratio of included to not-included but eligible participants): The refusal rate among eligible study subjects is high, making the enrollees in the study unrepresentative even of the people eligible for the study.
- adherence (run-in phase, frequent contact to monitor adherence): The design of the study has features that may make the effect of the intervention in the study greater than it would be in a clinically observed population.
- stage in natural history of dementia; severity of dementia: the selection of subjects for the study includes people with at a stage that is earlier or later than would be found in people who are candidates for the preventive service.
- source, intensity of recruitment: The sources for recruiting subjects for the study and/or the effort and intensity of recruitment may distort the characteristics of the study subjects in ways that could increase the effect of the intervention as it is observed in the study.

Situation:

The degree to which the clinical experience in the situation in which the study was conducted is likely to be reproduced in other settings

- healthcare system: The clinical experience in the system in which the study was conducted is not likely to be the same as experience in other systems because, for

example, the system provides essential services for free when these services are only available at a high cost in other systems.

- country: The clinical experience in the country in which the study was conducted is not likely to be the same as in the U.S. because, for example, services available in the U.S. are not widely available in the other country of study conduct or vice versa.
- selection of participating centers: The clinical experience in which the study was conducted is not likely to be same as in other settings in which the service will be delivered to the U.S. long-term care population because, for example, the centers have ancillary services not available generally.
- time, effort, and system cost for the intervention: The time, effort, and cost to develop the service in the study is more than would be available outside the study setting.

Providers:

The degree to which the providers in the study have the skills and expertise likely to be available in general settings

- training to implement the intervention: The intervention in the study was done after giving providers special training not likely to be available or required in U.S. long-term residential care settings
- expertise, skill to implement intervention: The providers included in the study had expertise and/or skills at a level that is higher than the level likely to be encountered in typical settings.
- ancillary providers: The study intervention relied on ancillary providers who are not likely to be available in typical settings.

Global Rating of External Validity (Generalizability):

External validity is rated “good” if the study differs minimally from the US long-term residential care population/ situation/ providers and only in ways that are unlikely to affect the outcome; it is highly probable (>90%) that the clinical experience with the intervention observed in the study will be attained in the US primary care setting.

External validity is rated “fair” if the study differs from the US long-term residential care population/ situation/ providers in a few ways that have the potential to affect the outcome in a clinically important way; it is only moderately probable (50%-89%) that the clinical experience with the intervention in the study will be attained in the US primary care setting.

External validity is rated “poor” if the study differs from the US long-term residential care population/ situation/ providers in many way that have a high likelihood of affecting the clinical outcomes; the probability is low (<50%) that the clinical experience with the intervention observed in the study will be attained in the US primary care setting.

Table D-1. Quality ratings for trials

Author, Year Trial Name	Was randomization adequate?	Was allocation concealment adequate?	Were groups similar at baseline?	Were outcome assessors masked?	Were care providers masked?	Were patients masked?	Was overall attrition ≥20%?	Was differential attrition ≥15%?	Did the study use ITT analyses?	Were outcome measures equal, valid and reliable?	Quality Rating[a]
Chapman, 2007[1] NA	Yes	Yes	No	No	No	No	NR	NR	NR	Yes	Poor
Cohen, 1999[2] NA	NA	NA	No	Yes	NR	No	Yes	No	NR	Yes	Poor
Cohen, 2003[3] NA	NA	NA	No	NR	No	NR	No	Yes	NR	NR	Poor
Dowling, 2005[4] NA	Yes	No	NR	Yes	No	No	NR	NR	Yes	Yes	Fair
Dowling, 2007[5] NA	Yes	No	NR	No	No	No	NR	NR	NR	No	Poor
Fritsch, 2009[6] NA	Yes	NR	Yes	No	No	No	NR	NR	No	Yes	Fair
Hickman, 2007[7] NA	Yes	No	Yes	No	No	No	No	No	No	Yes	Fair
Holmes, 2007[8] NA	No	No	No	No	NA	No	No	No	No	Yes	Poor
Jablonski, 2005[9] Family Involvement in Care	NR	NR	No	NR	No	No	Yes	No	No	Yes	Poor
Kovach, 2006[10] NA	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Good
Lawton, 1998[11] NA	No	NR	NR	No	No	NR	Yes	No	No	NR	Poor
Lord, et al. 1993{#7197	NR	NR	Yes	No	No	No	NR	NR	NR	No	Poor
Maas, 2004[12] NA	Yes	No	Yes	NR	No	No	Yes	NR	No	Yes	Poor
McCallion, 1999[13] NA	NR	NR	No	No	Yes	No	No	NR	Yes	Yes	Poor
Moyer, 1996[14] NA	No.	No	No	yes	Yes	Yes	NR	NR	NR	Mixed	Poor
Reichenbach, 1991[15] NA	Yes	NR	Yes	NR	NA	NA	No	No	No	No	Poor
Remington, 2002[16] NA	Yes	Yes	Yes	No	No	No	No	No	No	Yes	Fair

Table D-1. Quality ratings for trials (continued)

Author, Year Trial Name	Was randomization adequate?	Was allocation concealment adequate?	Were groups similar at baseline?	Were outcome assessors masked?	Were care providers masked?	Were patients masked?	Was overall attrition ≥20%?	Was differential attrition ≥15%?	Did the study use ITT analyses?	Were outcome measures equal, valid and reliable?	Quality Rating[a]
Robison, 2007[17] Partners in Care	NR	NR	No	NR	No	No	No	No	No	Yes	Poor
Rosswurm, 1990[18] NA	NR	Yes	Yes	Yes	No	NR	No	No	Yes	Yes	Good
Schnelle, 1995 [19]	NR	NR	NR	No	No	Yes	No	No	No	Yes	Poor
Sloane, 2004[20] NA	NR	NR	Yes	Yes	No	No	No	No	Unclear /NR	Yes	Fair
Tappen, 1994[21] NA	NR	NR	NR	Yes	No	NA	NR	NR	No	Yes	Fair
Tosleand, 1997[22] NA	NR	NR	Yes	Yes	No	No	Yes	No	Unclear /NR	Yes	Fair
Whall, 1997[23] NA	NA	No	NR	NR	NR	NR	No	No	No	Yes	Fair

[a]Rationale for poor quality studies can be found in Table 3.

Abbreviations: NA, not applicable; NR, not reported

Table D-2. Quality ratings for prospective cohort studies

Author, Year Trial Name	Were groups recruited from the same source population?	Were subject in both groups recruited over the same time period?	Were inclusion and exclusion criteria equally applied in both groups?	Was an attempt made to blind the outcome assessors?	Was the time of follow-up equal in both groups?	Were differences between groups taken into account in the statistical analysis?	Was confounding adequately accounted for either through study design or statistical analysis?	Was overall attrition ≥20%?	Was differential attrition ≥15%?	Were any participants who started the trial excluded from the analysis?	Were outcome measures equal, valid and reliable?	Quality Rating[a]
Leon, 1999[24] NA	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Fair
Sloane, 1991[25] NA	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Good
Sloane, 2005[26] Collaborative Studies of Long-Term Care	Yes	Yes	Yes	No	Yes	Yes	Yes	NA	NA	No	Yes	Good
Sloane, 2008[27] Collaborative Studies of Long-Term Care	Yes	No	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Good
Volicer, 1994[28] NA	No	Yes	Yes	No	Yes	NR	Yes	NR	NR	NR	Mixed	Poor
Zimmerman, 2005[29] Dementia Care Project	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	No	Yes	Fair

[a]Rationale for poor quality studies can be found in Table 3.

Abbreviations: NA, not applicable; NR, not reported

Table D-3. Rationale for Poor Quality Rating

Author, Year Trial Name	Primary Reasons for Poor Quality Rating
Chapman, 2007[1] NA	High potential for performance bias. Care providers were providing care in both arms of the study. High potential for selection bias. Differences between groups in baseline characteristics. Potential for attrition bias. Study did not report attrition statistic.
Cohen, 1999[2] NA	High potential for selection bias. Baseline groups not similar, study not randomized and differences not controlled for. High potential for performance bias as care providers were not masked. High potential for attrition bias. Study attrition ≥ 20%. Not clear as to whether ITT analysis was used.
Cohen, 2003[3] NA	High potential for selection bias. The study had different eligibility criteria for group 1 and group 2. High potential for attrition bias. Differential attrition equaled 28% between groups. Potential for performance bias. Changes in treatment which were not monitored were noted as confounder.
Dowling, 2007[5] NA	High potential for detection bias. The raters were not blind and they changed over time; also, inter-rater reliability was not tested. High potential for selection bias. Allocation concealment was not adequate. Unequal sized groups with no report of block size or rationale for differences in size. Differences in baseline characteristics not tested for significance.
Holmes, 2007[8] NA	High potential for performance bias. Study reports that the less worse affect scores may have been the result of more direct care hours. Also poor fidelity to the intervention. High potential for selection bias. Covariates for cognition and functional status did not strongly control enough for case mix differences at baseline. Continued direct care intervention at even higher pre-intervention levels may have caused the less worse affect in the intervention group.
Jablonski, 2005[9] Family Involvement in Care	High potential for attrition bias. Attrition rate was >20%. Did not account for missing data in the analysis. Reported differences between those lost to attrition. High potential for selection bias. Groups dissimilar at baseline. High potential for performance bias. Differences in the "dose' of the intervention per person.
Lawton, 1998[11] NA	High potential for attrition bias. Attrition was 44%-49%, and ITT analyses were not done. High potential for performance bias. The study makes explicit mention related to poor fidelity. High potential for detection bias. Raters aware of the identity of control and experiment groups as well as the hypotheses of the intervention's impact.
Lord, 1993[30]	High potential for selection bias. Randomization and allocation not adequate. Does not report on similarities or differences among groups at baseline. High potential for attrition bias. No attrition statistic reported. High potential for detection bias. Outcome measures not assessed for reliability or validity.
Maas, 2004[12] NA	High potential for attrition bias. Overall attrition equaled 55%.
McCallion, 1999[13] NA	High potential for selection bias. Randomization scheme not reported. Significant difference in baseline characteristics High potential of detection bias. Contamination by inadequate blinding.
Moyer, 1996[14] NA	High potential for performance bias. Unclear that the interventions were different from each other at all. High potential for reporting bias. The abstract and body of the text differed in which group was experimental and which was control. Limited data are presented. High potential for selection bias. Study utilized convenience sample; residents of one larger facility were compared with 3 smaller ones.
Reichenbach, 1991[15] NA	High potential for detection bias. Lack of assessor blinding, with consequent observer bias is strongly suspected based on statistically significant findings in all measures. High potential for selection bias. Lack of information on whether randomization occurred, and whether the experimental and control groups were within separate facilities or within both of the study facilities.
Robison, 2007[17] Partners in Care	High potential for selection bias. Study does not report baseline statistics. High potential for reporting bias. Selective outcome reporting. High potential for attrition bias. Completer analysis used. When examining ITT analysis, most of the significant effects go away.

Table D-3. Rationale for Poor Quality Rating

Author, Year Trial Name	Primary Reasons for Poor Quality Rating
Schnelle, 1995[19] NA	High potential for selection bias. Unclear if there are significant differences between groups at baseline due to lack of reporting. High potential for Attrition bias. Study report a loss of 51% of study participants and do not account for this in their analysis. High potential for detection bias. Assessors for the intervention group were not blinded. High potential for reporting bias. Investigators use different units of measurement between groups.

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Appendix E. Outcome Scales Commonly Used in Dementia Studies

Table E-1. Outcome scales commonly used in dementia studies

Abbreviated Name	Complete Name of Measure or Instrument	Description	Range or Mean of Scores	Improvement Denoted by
BEHAVE-AD	Behavioral Pathology in Alzheimer's Disease	• Measures behavioral and psychological symptoms of dementia in persons with Alzheimer's disease. • Based on interview with the participant.	0-42	Decrease
CAREBA	Care Recipient Behavior Assessment	• Modification of the CMAI. • Based on observations of the participant.	NR	Decrease
CMAI	Cohen Mansfield Agitation Inventory	• Assess manifestations of agitated behaviors in elderly people with cognitive impairment • Based on caregiver report.	Varies	Decrease
CMAI-N	Nurse-derived Cohen-Mansfield Agitation Inventory	• Assess manifestations of agitated behaviors in elderly people with cognitive impairment • Based on nursing staff report	Varies	Decrease
CMAI-O	Observer-derived Cohen-Mansfield Agitation Inventory	• Assess manifestations of agitated behaviors in elderly people with cognitive impairment • Based on non-participant observations of video-tapes	Varies	Decrease
CSDD	Cornell Scale for Depression in Dementia	• Identification of depressive symptoms and sign in people with Alzheimer's Disease and other dementias. • Based on participant and caregiver report and clinical observation.	0-38	Decrease
DBS	Dementia Behavior Scale	• Evaluate function deficits in cognitive and psychomotor areas. • Based on observations of the participant	0-48	Decrease
Discomfort-DAT	Discomfort – Dementia of the Alzheimer's Type	• Measures overall discomfort by vocalizations, breathing, facial expressions, and body movement • Based on observations of the participant	0-900	Decrease
FAST	Functional Assessment Staging	• Stages severity of dementia via a measurement of functional deficits, mental age, and MMSE score. • Based on observations of the participant	Stages 1-7	Decrease
GIPB	Geriatric Indices of Positive Behavior	• Measures the occurrence of verbal, nonverbal, and noninteractive, positive behaviors • Base on observations of the participant	NR	Decrease
MDS-ADL	Minimum Data Set Activities of Daily Living Scale	• Used to measure activities of daily living	0-21	Decrease
MDS-COGS	Minimum Data Set Cognition Scale	• Assess the presence and severity of cognitive impairment.	0-10	Decrease

Table E-1. Outcome scales commonly used in dementia studies (continued)

Abbreviated Name	Complete Name of Measure or Instrument	Description	Range or Mean of Scores	Improvement Denoted by
MMSE	Mini-Mental State Examination	• Measures global cognitive status in older people • Based on interviews with the participant	0-30	Increase
MOSES	Multidimensional Observation Scale for Elderly Subjects	• Assess participants' psychosocial function • Based on informant report	Varies	Decrease
PGCARS	The Philadelphia Geriatric Center Affect Rating Scale	• Assess positive and negative affect • Based on observations of the participant	0-100	Decrease
QOL-AD	Quality of Life scale in Alzheimer's Disease	• Assess the quality of life of persons with dementia • Based on self and caregiver report	13-52	Increase
SPMSQ	Short Portable Mental Status Questionnaire	• Assess the mental status of an elderly person • Based on interview with the participant	0-10	Decrease