TITLE: Interventions to Manage Aggressive Behavior in Long-term Care Residents: A Review of the Clinical Effectiveness and Guidelines

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CONTEXT AND POLICY ISSUES:

Aggressive behavior in residents of long-term care facilities is a common occurrence that is distressful to both facility-employed caregivers and residents’ families.\(^1\) Such behavior is frequently demonstrated by patients diagnosed with dementia or other forms of cognitive impairment, and may include kicking, punching, scratching, biting, verbal abuse, refusal of treatment, or other hostile activities.\(^2\) Estimates of the prevalence of aggressive behavior have varied widely, with figures as low as 7% and as high as 91%.\(^1\) Variation in prevalence estimates is likely explained, at least in part, by variations of the distribution of resident diagnoses, the quality of care provision, the extent of physical interaction in care provision, outcome definitions used by investigators, and subjective interpretation of what different individuals may consider to constitute aggressive behavior.\(^1\)

It is hypothesized that aggressive behavior in dementia patients and other elderly residents living in long term care facilities is a multi-causal phenomenon stemming from issues relating to personal history, interactions with care staff, disease progression, unmet needs (and the inability to vocalize them), stress, and environmental factors.\(^2,3\) Given this host of contributory factors, there exist both pharmacologic and non-pharmacologic therapies for management of such behavior. Recently, reviews published in a series of prominent medical journals found that use of atypical and typical antipsychotic drugs lack sufficient evidence of benefit,\(^4\) and had an association with an increased risk of death.\(^5,6\) Use of physical restraints is sometimes employed, though their use may intensify the problem given their negative impact on a patient’s independence and self-esteem; this may instigate additional episodes of aggressive behavior.\(^1,7,8\)

The purpose of this report was to review relevant evidence pertaining to the evaluation of any identified non-pharmacologic, non-restraint interventions for management of aggressive
behavior in long-term care residents, and to provide a summary and critical appraisal of the relevant data.

**RESEARCH QUESTIONS:**

1. What non-pharmacological/non-restraint interventions are available to reduce aggressive or violent behaviors in long-term care residents?

2. What is the clinical effectiveness of non-pharmacological/non-restraint interventions to reduce aggressive or violent behaviors in long-term care residents?

3. What are the guidelines to reduce aggressive or violent behaviors in long-term care residents?

**METHODS:**

A limited literature search was conducted on key health technology assessment resources, including Medline, CINAHL, the Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international health technology agencies, and a focused Internet search. Database results include articles published between 1998 and December 2008, and are limited to English language publications only. No filters were applied to limit the retrieval by study type.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials (RCTs), controlled clinical trials, observational studies, and evidence-based guidelines.

Given the multi-causal model upon which the occurrence of aggressive behavior is hypothesized to arise, as well as the tendency of the set of included systematic reviews to simultaneously describe related outcomes falling into this model, summary of findings from identified reviews includes discussion of outcomes beyond agitation and aggressive behavior as deemed appropriate. This includes cognitive function, depression, environmental needs, nutrition, and other such secondary factors. Discussion of findings from RCTs was limited to measures of agitation and aggressive behavior. Given the wealth of information that was identified in terms of systematic reviews, RCTs and clinical guidelines, controlled clinical trials and observational studies were only described in detail if they presented findings regarding a type of intervention not otherwise discussed elsewhere.

**SUMMARY OF FINDINGS:**

**Available forms of non-pharmacologic/non-restraint interventions:**

A total of thirty relevant articles were identified from the electronic search of databases and grey literature. Details from these articles are reported below stratified by research type, with accompanying study details provided in tables in the appendix of this review. A broad array of interventions that included music therapy, bright light therapy, physical activity programs, touch/massage therapy, staff training exercises, pet/animal assisted therapy, aromatherapy, scheduled toileting programs, modified bathing methods, psychosocial/behavioral therapies and family visit programs was identified.
Health technology assessments

No relevant health technology assessments were identified by our literature search.

Systematic reviews and meta-analyses

A total of 11 relevant systematic reviews/meta-analyses were identified by the electronic literature search. An evidence table summarizing primary characteristics and conclusions of all included reviews is provided in table 1 of the appendix. A discussion of the primary details of target populations, interventions assessed, methodologies used and clinical findings for each review is provided next.

**Bright light therapy:**

Forbes et al. (2008)\(^9\) reported a systematic review of five RCTs encompassing a total of 165 subjects that assessed use of bright light therapy for management of sleep disturbance, mood symptoms, behavioral symptoms, or cognition in dementia patients in long-term care settings. Bright light therapy of any intensity and duration was of interest, and no restrictions were placed on comparator interventions. Studies that enrolled patients with Alzheimer’s disease, dementia with Lewy bodies, vascular dementia, or other forms of dementia were eligible for inclusion. Bright light therapy was administered using a light box placed in the close proximity of the subject in four of the included studies, while the fifth evaluated dawn-dusk simulation that made use of an overhead halogen lamp covered by a diffuse membrane; exposure ranged from 2,500 lux to 10,000 lux. Control interventions across studies included exposure to dim light or low frequency blinking light of less than 300 lux. Treatments were administered for durations from ten days up to four weeks, in 1-2 hour intervals each day. Based on the heterogeneity that existed across studies in terms of both patient populations and interventions evaluated, no meta-analyses were pursued. Three studies reported findings pertaining to changes in agitation: one found no significant differences between dawn-dusk simulation and dim red light groups for measures of the neuropsychiatric index (NPI); one found no significant differences for agitation as measured using the Cohen Mansfield Agitation Inventory (CMAI) and the Agitated Behavior Rating Scale (ABRS); and one found no difference between interventions in agitated behavior as measured by the Behavioral Pathology in Alzheimer’s Disease scale. There was insufficient evidence from the set of included studies that bright light therapy had any clinically important effects on sleep time or depression levels, though the authors did mention that methodologic shortcomings of individual studies, small sample sizes, and the inability to meta-analyze collections of homogeneous patients limited their findings. Further research was recommended.

**Massage/touch therapy:**

Hansen et al. (2006)\(^10\) performed a systematic review evaluating the value of massage and touch therapy in dementia patients, and included two eligible RCTs with total sample sizes of 68 and 42 subjects, respectively. One study evaluated the effects of no intervention, hand massage alone, music therapy alone, and hand massage with music therapy on 68 nursing home residents (only the first two groups were discussed in the systematic review; n=17 per group) with dementia on agitation level (measured using the CMAI score). The randomized therapy was administered once for a ten minute period by trained research assistants, and agitation scores in the no intervention and hand massage groups recorded during treatment (mean±SD - 0.12±3.33 versus 6.12±6.08; p<0.01), immediately following treatment (0.88±4.59 versus...
8.71±5.83; p<0.01), and one hour following treatment (1.29±5.46 versus 13.41±10.3; p<0.01) suggested a significant benefit in the hand massage therapy group. A second study compared the effect of gentle touching of the forearm coupled with verbal encouragement during meals versus encouragement alone in a collection of 42 nursing home residents diagnosed with chronic organic brain syndrome, and observed the effect on the nutritional intake as measured by the extent of food remaining on the resident’s plate. The study was included on the premise that nutritional intake belongs to the class of possible sources of agitated behavior pertaining to unmet needs. Statistically significant increases in the intervention group in both caloric intake (increase from 570 calories per day to 740 calories per day) and protein intake (increase from 32 grams per day to 43 grams per day) were identified. The authors concluded that there was insufficient data regarding the value of massage/touch therapy, and that further rigorous research is needed.

Activity programs:

A review by Forbes et al. (2008) evaluated the use of physical activity programs for persons with dementia to determine their effects on cognition, behavior, depression, and mortality, and identified a total of four relevant RCTs (n=280) for inclusion. In some of the trials, additional inclusion criteria pertaining to basic physical capabilities of potential participants were stipulated to ensure the ability to participate in activities. The frequency (2 to 3 times per week), activity duration (from 20 minutes to one hour), and intervention program duration (from two weeks to one year) varied between studies. Two of the trials exceeded a sample size of 100 patients (120 and 134, respectively), while the remaining pair of studies included totals of 12 and 14 subjects. The content of single activity sessions was also variable; three studies involved sessions where patients were sitting during activities (tasks in these studies made use of bean bags, velcro balls, canes; targeted gross and fine motor skills; and made use of joint and large muscle group movements), while the fourth study involved unassisted walking followed by exercises focused upon strength, flexibility and balance. Given insufficient reporting of data by two of the included trials, the reviewers were able to perform only one meta-analysis, a random effects computation of a weighted standardized mean difference (SMD) of function using data from 7 weeks follow-up in one study and 6 months in another study: SMD -0.09, 95%CI (-0.69, 0.52) was achieved, suggesting no difference between physical activity and usual care approaches for improvement of function. One study, which provided the intervention for a one year period, also reported comparisons of behavioral disturbance frequency and depression in activity and usual care groups at 6 and 12 months, and found no statistically or clinically significant differences. The authors concluded that there was insufficient evidence for the effectiveness of activity programs on measures of cognition, function, depression, and behavior, and that few studies thus far have captured these clinically important outcomes. Given the heterogeneity of patients in the included studies, the varied forms and frequencies of activity and the potentially limiting impact of non-compliance included trials, the reviewers recommended further rigorous research be pursued.

Music therapy:

Vink et al. (2004) reported findings from a systematic review of music therapy in dementia patients (in- or out-patients of any severity of disease) that included a total 5 RCTs (n=173). No limitations on the type of music therapy or the type of comparator were employed, and outcomes of interest were pre-specified as changes in problematic behaviors (including verbal agitation and restlessness), social behaviors, cognition, and emotional well being. Due to a combination of between study methodologic heterogeneity and poor outcome reporting, no meta-analysis was performed by the reviewers. The studies were rated to be of poor quality based on assessment of a set of criteria selected by the reviewers (randomization, allocation
concealment, blinding, patient similarity at baseline, appropriate presentation of results, and use of an intention-to-treat analysis). Music interventions across studies included individualized music selection, music/reading therapy, group music therapy, favorite music during bathing periods, and big band music playing, while corresponding comparators consisted of classical relaxation music, reading/music therapy (compared to music/reading therapy; one group consisted of five music and two reading sessions, while the other consisted of five reading sessions and two music sessions), conversation sessions, no music during bathing, jigsaw puzzles, or no intervention. Four of the five included studies made claims of benefits associated with varying forms of music therapy, but statistical analysis and/or presentation of analytic findings were described as being inappropriate or incomplete by the authors. The remaining study reported only on the extent of wandering exhibited by study subjects and Mini-Mental State Examination (MMSE) scoring, and thus is not relevant to this review. The reviewers claimed that no valid conclusions could be drawn given the limitations of the evidence, and urged that more rigorous studies evaluating the effect of music therapy are needed.

**Animal-assisted therapy:**

Filan and Llewellyn-Jones (2006) evaluated the value of animal assisted therapy (AAT) in dementia patients in a systematic review of published literature, and discussed findings from 11 studies (n=344) that discussed the effect of AAT on anxiety and aggression outcomes, social behavior outcomes, and nutrition outcomes. Included studies enrolled patients with diagnoses of dementia or Alzheimer’s disease, took place in a variety of settings (nursing homes, psychiatric wards, extended care facilities, or private homes), employed varying forms of AAT (visiting dogs, resident dogs, cats, aquariums, and robot pets), were of varying frequencies and durations of AAT (from single sessions to repeated sessions over several months), and used varying forms of observational study design and data collection. No meta-analyses were performed, and the authors provided only a generalized description of findings from individual studies, without mention of supporting quantifying summary data. While all included studies provided evidence of varying extents of improvement in measures pertaining to agitation, cognition, and social functioning, most studies were of minimal sample size, sub-optimal design (often lacking a control group), and heterogeneous in terms of interventions. The authors concluded that while the published evidence suggests potential benefits of AAT for several behavioral issues associated with dementia, issues such as identification of the optimal mode (resident versus visiting animals, dogs versus cats versus others, etc) and duration/ frequency of AAT, dose response for AAT, and the impact of cumulative exposure remain to be addressed by future research. Larger, more rigorous and randomized studies (using a cluster design where feasible) were recommended.

**Psychosocial methods:**

Verkaik et al. (2005) reported findings from a systematic review of thirteen different psychosocial methods used in institutionalized or home dwelling dementia patients suffering from behavioral and psychological symptoms of dementia, which were described as including aggressive, apathetic, or depressed behavior. The authors included both randomized (n=666 subjects) and non-randomized controlled clinical trials (n=336), and sought only studies where observed outcomes pertaining to changes in depression, aggression, or apathy were reported. A set of measures based on components suggested by Jadad et al. and Verhagen et al. assessing 11 criteria for internal validity, 6 descriptive criteria, and 2 statistical criteria was employed to assess methodologic quality of all included studies. No meta-analysis was performed for any intervention type, as the reviewers instead used principles of Best Evidence Synthesis (details shown in the appendix, table 3, and are also available in the review article).
to determine the extent of evidence for each intervention. A total of 19 eligible studies were included in the review process across the thirteen classes of therapy. Quantitative summaries at the study level were not provided. Using the approach to evidence synthesis described in table 3 of the appendix, the authors provided separate recommendations for the outcomes of apathy, depression, and aggression. Snoezelen/multi-sensory stimulation in a multi-sensory room showed some evidence for reduction of apathy, certain forms of behavior therapy showed limited evidence for reduction of depression, and psychomotor therapy group interventions showed some limited value for reduction of aggression. The review paid minimal attention to the timing or duration of benefits of therapies for reduction of these symptoms. Other forms of therapies evaluated were not found to be beneficial for any of these outcome measures.

Bayles et al. (2006)\textsuperscript{17} performed a review of evidence available for the use of simulated presence therapy in dementia patients, and reported findings on the extent to which this approach modified the frequency of agitation and aggressive behavior. Simulated presence therapy refers to the use of audiotapes (often recorded by family members of the patient) that are played when the patient demonstrates undesired aggressive behavior, or when staff believe such an episode might occur. Access to this study report was limited to a structured abstract, but sufficient information regarding methodology and results was available. The authors performed a comprehensive literature search of several databases. No specific inclusion criteria regarding patient population or outcomes were provided, though studies of patients with dementia that evaluated response to simulated presence therapy in terms of resolving agitation or reducing problem behaviors appeared of interest. A total of three studies were identified, one employing a Latin square crossover design (n=54) and two employing before-after study designs (sample sizes of 27 and 9, respectively). A narrative summary of study-specific findings was provided by the authors. The largest study of 54 patients reported significantly greater reductions of agitation with simulated presence therapy than with either usual care or a placebo audio tape, while the two before-after studies also reported improved levels of agitation during the experimental period than in the control period. Numerical estimates of effectiveness were not available from the abstract.

Various strategies:

Landreville et al. (2006)\textsuperscript{18} performed a systematic review of non-pharmacologic strategies for management of aggressive behavior in residents of long-term care facilities. Studies that included patient populations of mean age 60 years or more, reported one or more results related to aggressive behavior, and measured some form of change in behavior (over time or compared to a control group) were retained for inclusion. A total of 41 studies were identified by their systematic search and retained for inclusion. Interventions evaluated by individual studies included care staff training (10 studies), changes to the care environment (10 studies), sensory stimulation programs (8 studies), behavioral management strategies (4 studies), structured activities (3 studies), use of special care units (3 studies), and psychosocial interventions (3 studies). Study designs were predominantly of an observational format, and a large number of included studies were of small sample size (14 studies of between 11-30 patients, 6 studies of between 2-10 patients, 5 single case studies). A total of 26/41=63.4\% of included studies were performed strictly in dementia patients; an additional 8 were performed in populations that consisted of entire units where patients with other diagnoses were also cared for, 5 failed to specify the population under study, and the two remaining studies were single case designs performed in a post-stroke patient and a patient with multiple unspecified comorbidities. The authors reported that 27 of the 41 included studies identified statistically significant differences amongst competing interventions. Interventions that involved incorporation of specialized staff
training and modifications to the facility environment were noted as demonstrating the greatest effectiveness. A need for more robust and rigorous studies was suggested.

Cohen-Mansfield (2001)\textsuperscript{2} performed a systematic review of non-pharmacologic alternatives for treatment and management of inappropriate behaviors in dementia, with studies having been performed in either nursing homes (76\%) or other hospital or residential settings. The review included a total of 83 studies (median sample size \textit{n}=16), including a large number of small case studies (fourteen of sample size <5 subjects, thirteen of which consisted of 5-10 subjects, and twenty of which consisted of 11-20 subjects), a broad array of therapeutic alternatives (music therapy, massage/touch therapy, white noise, staff training, pet therapy, bright light therapy, and other alternatives), and provided narrative summaries of study-specific findings in each class of therapy type; no formal meta-analyses were pursued. The article failed to provide an indication of the study designs of the included studies or an assessment of their quality, but did indicate that most failed to use a control group, and performed only pre-/ post-treatment comparisons. Only brief, narrative elusion to study-specific findings was made, and the author indicated that a considerable number of included studies failed to perform statistical analysis or found statistically insignificant findings. However, despite these findings, 91\% of included studies reported some form of benefit for reducing inappropriate behavior. The review indicated that while a broad array of the types of therapies studies showed signs of potential clinical benefit, more rigorous research and more efforts to elucidate the specifics of each type of intervention are needed. A recommendation was also made that personalization of care is necessary.

Forbes \textit{et al.} (1998)\textsuperscript{19} reported findings of a systematic review that summarized evidence regarding a variety of strategies used to manage symptomatic undesirable behaviors associated with Alzheimer’s dementia. Only access to the structured abstract was available. The authors assessed study quality based on study design, allocation procedures, inclusion/exclusion criteria, the extent of loss to follow-up, control for confounding factors, data collection procedures, and appropriateness of statistical analysis. A total of 45 eligible studies was located, though only seven were scored as being of moderate to strong quality, while 20 were rated as weak and 18 as poor. The poor quality articles were excluded, leaving a total of 27 articles that were discussed in detail. The number of patients in the collection of final studies was not reported, though a total of 190 patients for the seven moderate/high quality reports was provided. A variety of behavioral outcomes were of interest to the reviewers, and totals of 14.8\%, 9.3\%, 7.4\%, and 5.6\% of the included articles were found to report data on agitation, physically violent behavior, vocally disruptive behavior, and day/night disturbances, respectively. The author provided a narrative synthesis of study-specific findings, and no meta-analyses were performed. Discussion of measures of effect of outcomes were not provided in the structured abstract, but the authors indicated that planned walking programs, simulated presence therapy, bright light therapy, and music therapy could be useful for management of aggressive behavior. The authors suggested that more multi-center studies of clinically relevant follow-up are needed, as well as increased consideration of the cost-effectiveness of the many therapeutic options available.

Ayalon \textit{et al.} (2006)\textsuperscript{20} reported findings from a systematic review of non-pharmacological interventions for management of neuropsychiatric symptoms in dementia patients. The review included 3 RCTs and 6 case studies; RCTs evaluated caregiver interventions, while identified case studies evaluated the use of hearing aids, bright light therapy, and a series of three learning and behavioral interventions. One RCT evaluated a family visit education plan versus usual care to determine if improvements in family communication with long term care residents could have a positive effect on measures of agitation and irritability. There was some indication
of benefit for these outcomes at six months of follow-up, but the effect appeared small, and was described as possibly being a consequence of regression to the mean. The remaining pair of RCTs evaluated caregiver training programs in behavior management provided by community consultants versus usual care to determine differences in neuropsychiatric symptoms, behavioral disturbances and depression; no important differences were found. The authors concluded that more funding in this field of research is needed given the paucity of studies that meet the American Psychological Association (APA) guidelines, and suggested that larger, more rigorous studies are needed. It was suggested also that several current non-pharmacologic approaches to management of symptoms are considered gold standards despite a lacking evidence base, an issue that remains to be addressed.

Randomized controlled trials

A total of 13 eligible RCTs were identified from the literature search. Five of these studies were included in one or more of the aforementioned systematic reviews and their study details are summarized in table 2 of the appendix. The eight RCTs that were not included in the systematic review are described, and study details are also included in table 2 of the appendix.

Light therapy:

Two reports by Dowling et al. (2007) (n=70, mean age 84 years) and Riemersma-van der Lek et al. (2008) (n=189, mean age 85.8 years) reported findings of RCTs of bright light therapy in populations of dementia patients. One study employed a 2x2 factorial design that evaluated light therapy (whole day bright light versus dim light) and melatonin use (melatonin 2.5mg in the evening versus placebo) simultaneously using four intervention groups, and one randomized patients to receive either morning or afternoon bright light compared to usual indoor light. Dowling et al. identified statistically significant changes in agitation between groups, but subsequently claimed that these differences were a result of deficiencies with the scale used (the Nursing Home translation of the Neuropsychiatric Inventory) and were not clinically meaningful. Riemersma-van der Lek et al. noted that combined treatment with melatonin and light therapy showed some benefit based on a 9% improvement on the CMAI scale, but provided little to no discussion to this secondary finding or its clinical significance. Two other identified trials of bright light therapy were included in an earlier discussed systematic review, and thus are not discussed in detail here.

Physical activity:

A pilot study conducted by Connell et al. randomized a group of 24 dementia patients of varying disease severities (mean age 79.7 years) from a single nursing home to a program of either structured indoor activities or activities performed in an outdoor setting, thereby increasing daylight exposure. Agitation and behavior disturbance were secondary outcomes of the study, measured using the CMAI scale. The programs were given for approximately an hour per day for 10 days, and were administered by a geriatric nurse practitioner and a nursing assistant. Measurements at baseline and at completion of follow-up were performed. Content of the programs was described as incorporating activities like potting of plants, making decorative ornaments, singing, joke telling, and other activities meeting the interests of participants. The authors reported finding no significantly different changes from baseline to the end of follow-up for outdoor compared to indoor groups for CMAI-based measures of aggression (outdoor: 6.50(2.92) to 5.90(2.23) versus indoor: 6.30(2.91) to 5.40(2.88)), physical agitation (7.70 (3.30) to 7.10 (3.07) versus 6.00(2.31) to 6.50(1.90)) or verbal agitation (9.60 (3.03) to 7.80(3.94)). However, an important within-group reduction in verbal
agitation from baseline to study follow-up after the intervention period in the outdoor group was found (from 9.60±3.03 to 7.10±2.42). There was also an identified benefit of increased sleep duration in the outdoor group, the primary outcome of interest in the study. A second study identified in our literature search also evaluated a physical activity program, but this article was included in one of the above described systematic reviews and thus is not described in detail.

Other therapies evaluated:

A total of 5 RCTs were identified that evaluated other therapies, which included modified approaches to bathing, aromatherapy, music therapy, therapeutic touch, and a staff training program.

Sloane et al. reported findings from a randomized crossover trial of 73 dementia patients with a history of agitation (mean age 86 years) during bathing from a collection of 15 nursing homes in Oregon and North Carolina. Individual nursing homes were randomized to person-centered showering, towel bathing, or a usual care group, with crossover occurring after a six week period. Reduction of agitation and aggression were of primary interest to the investigators and were assessed using the Care Recipient Behavior Assessment tool (a modified version of the CMAI scale) by blinded raters who observed videotapes of all bathing sessions. Person-centered bathing/showering was described as being focused on maximizing resident comfort and preferences by providing choices, distracting attention, using towels to maintain warmth, employing communication techniques targeted to the individual’s disease severity, and modifying shower spray. Towel bathing was described by the authors as an in-bed bathing technique that made use of two bath blankets, two bath towels, no-rinse soap and two quarts of warm water that were used to clean the subject using gentle massage while keeping them covered at all times. Showering without a person-centered approach was used as the control group, and the experimental approaches were first introduced at each participating site by a clinical nurse specialist. Significantly reduced measures of agitation and aggression and a reduced occurrence of aggressive incidents were seen in both intervention groups, but not in the usual care arm. These findings included reductions of 60% and 53% in the shower and towel bath groups in terms of the frequency of hitting, biting, kicking, throwing of objects, or spitting. Measures of discomfort were also greatly reduced in the two intervention groups but not the control group, which may explain this pattern of observed data.

A study by Lin et al. (2007) compared aromatherapy with lavender inhalation for three weeks versus aromatherapy with sunflower inhalation (referred to as a placebo) in 70 Chinese adults of mean age 78.3 years old with dementia and clinically significant agitation in the context of a randomized crossover trial. Patients were residents at care and attention homes in Hong Kong. One group of subjects received lavender for three weeks first, while the second group received sunflower for three weeks first, and a washout period of two weeks was used before administration of the second form of therapy for an additional three-week period. Aromatherapies were administered each night of the treatment period for a minimum of 1 hour using diffusers placed beside subjects’ pillows during sleep. The presence and severity of agitated behavior was measured using Chinese translations of the CMAI scale and the Neuropsychiatric Inventory (NPI) prior to and after completion of each intervention period. Severity of agitation based on these measures was found to be significantly reduced with lavender aromatherapy (NPI total score change from 24.68(10.54) to 17.77 (7.52), p<0.001; CMAI total score change from 63.17(17.81) to 58.77 (16.74, p<0.001), while sunflower aromatherapy showed no such benefit (NPI total score change score from 24.33 (10.08) to 24.41 (10.24), p=0.24; CMAI total score change from 63.94 (17.67) to 63.90 (17.74), p=0.52). The authors concluded that aromatherapy could serve as a valuable adjunctive therapy in
dementia patients to reduce agitation, though acknowledged that pharmacologic and non-pharmacologic co-interventions in their study population could also have had an effect on outcomes.

One recently reported RCT reported by Svansdottir et al. (2006)\(^{32}\) compared a music therapy intervention with a control intervention in a group of 46 nursing home and psychogeriatric ward patients in Iceland diagnosed with moderate to severe Alzheimer’s disease (age range 71-87 years). Eight patients were lost to follow-up due to transfer from the psychogeriatric ward to a nursing home (n=5), deterioration (2), or death (1), reducing the sample size to 38 patients who participated in all sessions. Music therapy was conducted in groups of 3-4, and a total of eighteen 30-minute sessions was provided over a six-week period, while no change in care was provided to the control group. Music therapy consisted of either actively singing selected songs or listening to others sing while following in a songbook; guitar and other instruments were sometimes used, and dancing was also allowed if desired. Patients were assessed at baseline, at the completion of the 6-week intervention period, and again at 10 weeks from baseline using the Behavior Pathology in Alzheimer’s Disease Rating Scale. The authors identified a significant reduction in symptoms described as activity disturbances in the music therapy group but not in the control group, and subsequently observed that this benefit disappeared during the four weeks after the intervention was halted.

Hawranik et al. (2008)\(^{33}\) compared therapeutic touch, simulated therapeutic touch, and usual care in a set of 51 Alzheimer’s disease patients (mean age 82.8 years) in a randomized, multiple time series design carried out at a single long-term care center. Patients were aged 65 years or more and had a history of consistent agitated behavior in the month preceding the study. The authors evaluated changes in measures of physical aggression, physical non-aggression, and verbal aggression using the CMAI scale, and continued follow-up until two weeks after the completion of treatment to estimate the duration of benefits from therapy. Therapeutic touch consisted of daily therapy for 5 days during the evening, administered by a registered nurse with advanced training from a therapeutic touch and healing program. During the five day treatment period, the authors observed a decrease in physical non-aggressive behavior in patients receiving therapeutic touch, but not in those receiving either of the competing interventions; no difference was identified for measures of physical aggression or verbal aggression. During the time frame from the end of intervention administration up to two weeks follow-up, significant differences in all of the three measures of aggression were no longer found.

Magai et al. (2002)\(^{34}\) randomized 91 patients with mid- or late-stage dementia (mean age 86 years) and their associated caregivers from three centers to participation in a study that compared staff training in sensitivity to non-verbal communication, staff training with a “behavioral placebo” in both cognitive and behavioral aspects of dementia, or a waiting list control group. Training provided to staff occurred over a series of ten sessions taught during a two-week span, each an hour in length, which were instructed by a psychologist. Training in sensitivity to non-verbal communication included instruction in both universal and culturally specific aspects of basic emotions, facial, vocal, and body indicators of emotion, cues to identify various emotions, and other related material. The behavioral placebo group was instructed in both cognitive and behavioral aspects of dementia, but attention was not paid to elements of interpreting patient emotions. Patient outcomes of interest included measures of agitation, behavioral symptoms, and depression as reported by caregivers in structured interviews carried out by research assistants, which were measured at baseline, and then every three weeks during a three month span. The Behavioral Pathology in Alzheimer’s Disease Rating Scale and
the CMAI scale were used for data collection pertaining to the former measures. Analysis of the collected data did not show the presence of any important differences between the three intervention groups for measures of agitation, behavioral symptoms, or depression.

**Controlled clinical trials**

One controlled clinical trial describing an intervention not reported in the systematic reviews or RCTs was identified.

Engst et al. (2004) described findings from a study that compared usual care with the implementation of a scheduled toileting program in a long-term care facility. Separate floors in the facility served as the active and control groups (n=50 per group, respectively), and characteristics of participating patients were not reported, but were described as similar in terms of clinical practice. Residents participating in the planned toileting program were selected after an evaluation of continence patterns and the perceived potential benefit for those individuals from a planned regimen of toileting, while residents in the control group were randomly chosen. The increased requirement for patient lifting and maneuvering by care staff in the active group was managed by purchase of mechanical lifts for use. Staff providing care for patients in both groups were additionally provided with training in agitation awareness that provided insight on possible causes of agitation, and also enabled a greater ability to identify early indications of such an episode. Investigators were primarily interested in the effects on the risk of injury to staff caregivers, but also assessed changes in patient agitation (measured using the CMAI scale and a staff questionnaire). Analysis of data collected prior to, in the middle of, and at completion of the study period identified a significant beneficial effect of the toileting regimen on agitation expressed as verbal or emotional behaviors, but no differences were seen in physical behaviors. These findings were supported by replies in the form of staff surveys.

**Observational studies**

One observational study describing an intervention not otherwise identified in the examination of systematic reviews and RCTs is discussed in detail. Observational studies identified that pertained to previously discussed treatments including music therapy, bright light therapy, robotherapy (i.e. robot pets), and therapeutic recreation are not discussed.

Kovach et al. (2004) reported findings of a double-blind, pre-test/post-test study conducted in 78 residents from a group of thirteen long-term care homes diagnosed with moderate to severe dementia (mean age 86.6 years). The study compared use of a Balancing Arousal Controls Excesses (BACE) strategy versus usual care, and assessed the relative impacts that each intervention had on observed agitation levels in study subjects. The BACE intervention was developed based on the premise that external factors or stimuli play a primary role in the appearance of aggressive behavior in dementia patients, and the goal of its implementation was to provide balance to the extent of daily arousal experienced by subjects in order to avoid overstimulation and sensory deprivation. To accomplish this, the intervention sought to re-organize each subject’s daily schedule to avoid periods of daytime awake arousal imbalance (defined by the authors to be a period of more than 1.5 hours without change in activity). All patients receiving the BACE intervention were assessed individually for one day by research staff to determine activity patterns and associated episodes of agitation, and then assigned a new schedule of activities tailored to the subject’s capacity and interests to reduce arousal imbalance. All patients who obeyed one or more of the suggested schedule changes were included in analysis of study data. Levels of arousal were assessed using the Arousal States in Dementia Scale, and patient agitation was measured using a visual analog scale (VAS) scored from 0-100 using a set of a priori established parameters for guidance of scoring based on the
Wisconsin Agitation Intensity Parameters. Analysis of pre-intervention/post-intervention measures of agitation based on VAS assessments saw a significant reduction of agitation in the BACE group (from 38.97±20.54 to 30.54±15.31; p<0.01) compared to the control group (from 32.59±21.66 to 32.25±32.25; p=0.76). Subgroup analysis that stratified each patient’s data into periods of arousal balance and arousal imbalance showed that the BACE intervention decreased agitation during both time periods, but significantly so during periods of imbalance. The authors concluded the notion of individually tailored activity schedules was strongly supported to reduce agitation. Discussion of examples of planned activities was not included in the article.

Recommendations from published guidelines for managing aggressive behavior:

A total of four guidelines were identified that pertained to reducing use of restraints in acute care by implementation of alternative methods and management of neuropsychiatric symptoms of dementia and problematic behavior.

Park et al. (2005) reported guidelines to assist geriatric nursing staff in reducing the use of restraints in patients more than 60 years of age in an acute care setting. Guidelines were developed based on a systematic review of published evidence, and grading was assigned according to criteria outlined in table 4 of the appendix. Recommendations were determined based on expert consensus. The guideline separately discussed and graded evidence for (1) the task of identifying contributing factors to displayed behaviors for each patient; (2) interventions at the institutional level for reduced use of restraints; and (3) alternative interventions of various formats (physical, psychological, environmental) that can be provided at the level of the individual patient. The following recommendations were made:

- **Patient assessment:**
  - Nursing/healthcare staff should perform rigorous evaluations of each patient’s health history (care plan, conditions, incidents, etc; Grade=C), medication usage (Grade=B), functional status (Grade=C), mental status (Grade=C), psychological status (Grade=C) and environment (Grade=C) in order to try and explain the patient’s displayed behavior and identify an appropriate resolution free of restraint use.

- **Changes at the institutional level:**
  - Changes to consider may include development of a restraint elimination committee or taskforce (Grade=D); adoption of a formal policy promoting a restraint free setting (Grade=D); use of expert consultation from advanced practice nurses and/or an interdisciplinary team to improve individualized patient assessment (Grade=C); provision of staff education (Grade=C); planning for an adequate amount of nurse staffing and provision of consistent patient assignments (Grade=C).

- **Interventions at the patient level:**
  - **Physical:** Evaluated approaches included elimination, replacement or modified administration of bothersome treatments (e.g. intravenous versus oral feeding; use of longer gowns to conceal catheter sites) (Grade=C); provision of physical activities that can distract undesirable patient behaviors, including exercise, games, physical or occupational therapy (Grade=C); use of reality orientation or psychosocial interventions (Grade=B); increased companionship and constant observation (Grade=D).
Psychological: Suggested possibilities included an invitation for increased family participation in care (Grade=D) and increased provision of familiar activities, people and personal items (e.g. photos)(Grade=D).

Environmental modification: suggested changes included maximizing accessibility to call light and responding more quickly when summoned; providing an appropriate amount of light based on the patient's specific needs; minimizing excessive noise; developing personalized toileting routines; leaving patient's bedrails down; moving patient within closer proximity to a nursing station for observation (Grade=C).

In 2006, the Scottish Intercollegiate Guidelines Network reported a guideline for management of patients with dementia, and a portion of that document provided recommendations pertaining to the use of non-pharmacologic interventions to appropriately deal with disturbing behaviors. The guideline was developed following an extensive review of the literature and a national open meeting attended by experts from relevant related specialties. The criteria for assignment of evidence grades is described in table 5 of the appendix. Based on the evidence identified and reviewed, the following recommendations were made:

- Behavior management therapy is useful for reduction of depression in dementia patients (Grade B);
- Caregiver intervention programs to educate care staff on appropriate interventions for managing dementia-related behavior are valuable (Grade B);
- Dementia patients should be offered cognitive stimulation (recreational activity, problem solving tasks, memory tasks, or otherwise) (Grade B).
- Environmental design: The evidence regarding modifications to environment in care homes was found to be from weak study designs and was not assigned a grade, but considerations mentioned included the following: separation of non-impaired patients from those with dementia, moderating stimulation levels, improvement of lighting, incorporation of outdoor areas with therapeutic design features, facilities to minimize stress during bathing, and improved accessibility to toilets.
- Multisensory stimulation and combined therapies: Aromatherapy, light therapy, music therapy, and multisensory stimulation were not recommended given insufficient evidence and/or patient intolerability in some cases.
- Physical Activity: The evidence for physical activity programs involving exercise was considered minimal, and thus use of such techniques was only recommended as a point of potential interest in clinical practice.
- Reality Orientation Therapy: Refers to a form of psychosocial intervention that assists in reorientating a patient using continuous stimulation to slow down cognitive decline (Grade D). No benefit pertaining to agitated behavior was noted.
- Recreational Activities: Participating in recreational activities that include self-expression, drawing, music, cooking, games, pet therapy, or other such events has been shown to enhance quality of life and well being (Grade B). No indication of effects on agitated or undesirable behavior were noted.
- Therapies lacking evidence of benefit: Use of memory books, reminiscence therapy, simulated presence therapy and validation therapy were described as having no established evidence of therapeutic value.

In 2006, The National Collaborating Center for Mental health reported a National Institute for Clinical Excellence (NICE) guideline providing recommendations for the care of individuals diagnosed with dementia, as well as their caregivers. A section of this guideline focused on the use of non-pharmacologic interventions for management of non-cognitive symptoms and
challenging behavior including comorbid agitation, aggression, wandering, or other related activities. It was recommended that as early as possible, patients demonstrating problematic behaviors be provided a comprehensive assessment examining physical health, depression, pain levels, medication side effects, perceived problems with living environment and psychosocial factors to identify plausible causes of the problem behavior. A care plan tailored to the patient’s perceived problem, their preferences and their abilities is recommended, given the variable response of individuals to the many treatments available. Some of the suggested approaches were aromatherapy, multi-sensory stimulation, music therapy, animal-assisted therapy, and massage/touch therapy. The authors recommended that further research be pursued to evaluate the effects of staff training on reduction of challenging behavior and use of medication for control of behavior in dementia patients compared to current practice.

Livingston et al. (2005) developed a guideline for a broad set of approaches to management of neuropsychiatric symptoms of dementia based on a systematic review of 162 included studies. The authors sought reports of studies that included quantitative measures of neuropsychiatric symptoms evaluated in a collection of dementia patients. Level of evidence was ranked from 1 to 5 based on study design (lower ranks indicated higher level), and the evidence rating scale proposed by the Oxford Centre for Evidence-Based Medicine was employed as follows: A=consistent level of evidence of Grade 1, D=level of evidence grade of 5 or troublingly inconsistent/inconclusive studies at any level. Table 6 in the appendix provides a detailed summary of all the forms of therapy assessed, the grade of recommendation prescribed by the authors, and the rationale for the various modes of therapy as described by the authors. Amongst the set of 162 included studies, only 9 were considered to be level one evidence. Only one form of intervention (psychoeducation and teaching of caregivers) received a grade of A, while staff training, cognitive stimulation, music therapy, and Snoezelen therapy (multi-sensory therapy rooms with stimuli that appeal to multiple senses) were assigned a grade of B. The authors noted that while the latter two therapies only reduced disruptive behavior during and perhaps shortly after the sessions, approaches to staff training were found to be capable of showing significant reductions in patient aggression at 3 months of follow-up and patient depression at 6 months of follow-up. The duration of benefit of cognitive simulation therapy was unclear given the use of different follow-up durations across studies, but a benefit of a month or more was considered plausible based on the evidence. The authors recommended that further research is needed to elucidate the value of reminiscence therapy, training of caregivers for implementation of behavioral management techniques, use of therapeutic activity programs, simulated presence interventions, and reduced stimulation units. Conversely, reality orientation therapy, validation therapy, and exercise were deemed to be ineffective.

Limitations:

There are several limitations associated with the published evidence identified in this clinical review.

- **Systematic review contents:** Several of the systematic reviews primarily included studies of small sample size that employed observational study designs, and a large number of these reviews used narrative or vote counting procedures to qualitatively synthesize the trends of study findings. Such practice is of minimal value in the context of making decisions for uptake of new interventions in the face of multiple possibilities. In cases where RCTs were identified, meta-analysis was often deemed infeasible for reasons of clinical heterogeneity, and narrative descriptions were provided instead.

- **Outcome measures used to quantify aggressive behavior:** A majority of the evidence used one of several available scales to assess the impact of interventions on outcomes
related to agitation, depression, apathy, or other patient characteristics related to the occurrence of aggressive behavior. The correspondence of these measures to clinical manifestations and clinically important changes in behavior is not entirely clear, and future studies should additionally capture the incidence of significant clinical episodes of aggressive behavior as well.

- **Disparity of long-term data:** For most studies, only immediate and short-term measures of agitation, depression, and other outcomes of interest were assessed. Attention to long-term benefit of therapies remains to be addressed.

- **Heterogeneity amongst patients:** While all of the included systematic reviews, randomized trials and observational studies included in this summary pertained to patients with dementia, the extent of heterogeneity of these patients in terms of disease severity, use of co-interventions and other relevant factors is unclear and difficult to summarize. Most studies sought to include both more severe and less severe cases, but data was not available to quantify the balance of patients. This factor could have an important effect on estimates of effectiveness.

- **Tailored care is needed:** While identification of some primary components (e.g. staff training, institutional policies, or environmental considerations for long term care settings) may assist to reduce the incidence of aggressive behavior, choice of the optimal management approach may still require tailoring to an individual patient’s needs to fully alleviate the cause. A combination of approaches is likely needed.

- **Heterogeneity of interventions identified:** In regard to the use of treatments like pet therapy and massage therapy, intervention-specific components (e.g. frequency of provision, optimal setting, optimal approach to administration) tended to vary across studies, and further work is needed to elucidate the best approach to their use.

- **Relating research to practice:** There is currently a paucity of data indicating what approaches to management of aggressive behavior are being employed in practice in long-term care settings. Thus, there may be a gap in terms of current topics of research in this field and to what extent they are implemented at the level of standard patient care. The extent of availability of expertise to implement some of the psychosocial and behavioral interventions vaguely described by some studies is not known.

**CONCLUSIONS AND IMPLICATIONS FOR POLICY OR DECISION MAKING:**

The extent of evidence available pertaining to assessment of non-pharmacologic, non-restraint alternatives for management of long-term care residents demonstrating aggressive behaviors was considerable, and included a vast array of alternatives at both the level of the long-term care facility and the individual patient. The quality of the included studies was moderate, though it is worth noting that several of the included systematic reviews include a wealth of small observational studies, as is commonplace in this field of research. The included studies described in this review evaluated or summarized previous evaluations of a variety of non-pharmacologic interventions in this patient population, and included use of bright light therapy, music therapy, therapeutic massage, activity training programs, aromatherapy, training programs for care staff, animal assisted therapy, and individual or group counseling psychotherapy approaches. Identified evidence from RCTs, systematic reviews, and clinical guidelines suggested that while facility-level interventions can have an important effect on agitation and aggressive behavior, care tailored to meet the specific needs of individual patients is also required in many or possibly most cases. No health technology assessments were identified, and thus no discussion of economic implications for competing interventions can be described; guidelines from the National Institute for Clinical Excellence suggest that further research into the cost-effectiveness of the many possible treatments is needed. The current gap
that exists in regard to the research of non-pharmacologic alternatives versus the established use of these methods in day-to-day practice may be due in part to the non-reimbursement for such therapies. Further funding to provide more rigorous research of such treatments is also needed to address current shortcomings of existing research, to provide higher quality data upon which decisions regarding care can be made, and upon which modifications to current reimbursement practices can be based.

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Tel: 1-866-898-8439
REFERENCES:


### Table 1: Systematic reviews/meta-analyses included

<table>
<thead>
<tr>
<th>First Author, Year Published</th>
<th>Patient population</th>
<th>Interventions Evaluated</th>
<th># of included studies (# of patients)</th>
<th>Outcomes</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forbes, 2008</td>
<td>Patients with dementia</td>
<td>Bright light therapy of any intensity or duration, placebo or alternative control</td>
<td>5 RCTs (n=165)</td>
<td>Sleep, behavior, cognitive disturbances, mood</td>
<td>Insufficient evidence exists to recommend bright light therapy to manage symptoms in dementia population</td>
</tr>
<tr>
<td>Hansen, 2006</td>
<td>Patients with dementia</td>
<td>Massage/touch therapy</td>
<td>2 RCTs (n=110)</td>
<td>Behavioral disturbances, pain, agitation</td>
<td>Limited data shows promise, but more research is needed; plausible as an adjunctive therapy</td>
</tr>
<tr>
<td>Forbes, 2008</td>
<td>Patients with dementia</td>
<td>Structured activity programs</td>
<td>4 RCTs (n=280)</td>
<td>Function, behavior, mood, cognition</td>
<td>Insufficient evidence for the effectiveness of activity programs on measures of cognition, function, depression and behavior. Further research needed.</td>
</tr>
<tr>
<td>Vink, 2004</td>
<td>In- or out-patients with dementia of any severity</td>
<td>Music therapy</td>
<td>5 RCTs (n=173)</td>
<td>Verbal agitation, wandering, restlessness, cognition, emotional well being, social behaviors</td>
<td>Despite all studies claiming a favorable effect of music therapy, poor methodology and reporting necessitate the performance of more rigorous research studies of music therapy</td>
</tr>
<tr>
<td>Filan, 2006</td>
<td>Patients with dementia or Alzheimer’s in nursing homes, psychiatric wards, extended care facilities or private homes</td>
<td>Animal assisted therapy (varying forms)</td>
<td>11 non-randomized studies (n=344)</td>
<td>Measures of agitation, aggression and social behavior</td>
<td>While evidence of effectiveness of animal therapy in dementia patients exists, further rigorous research is required to address remaining issues</td>
</tr>
<tr>
<td>Verkaik, 2005</td>
<td>Patients with dementia in long term care or living at home with caretaker</td>
<td>Integrated emotion-oriented care, validation/ reality orientation, multi-sensory stimulation, reminiscence, psychomotor therapy, skills training, behavior therapy, art therapy, gentle care</td>
<td>11 RCTs (n=666), 6 controlled clinical trials (n=336)</td>
<td>Measures of apathy, depression and aggression</td>
<td>Multi-sensory stimulation may reduce apathy in later stage dementia; psychomotor therapy group sessions may reduce aggression in nursing home residents with Alzheimer’s disease; some behavior therapies may reduce depression in home dwelling Alzheimer’s patients; there is a limited number of high quality studies of psychosocial methods in dementia care</td>
</tr>
<tr>
<td>Bayles, 2006</td>
<td>Patients with dementia</td>
<td>Simulated presence therapy</td>
<td>1 Latin square design, 2 before-after studies (n=90)</td>
<td>Well being, changes in problem behavior</td>
<td>Data showed promise for reduction of agitation and withdrawn behaviors</td>
</tr>
<tr>
<td>Landreville, 2006</td>
<td>Patients aged 60 or more years living in an institutional setting (26/41 in dementia patients)</td>
<td>Staff training, environmental modification, sensory stimulation, behavioral management, structured activities, special care units, psychosocial interventions, social contact</td>
<td>4 RCTs, 37 non-randomized</td>
<td>Measures of aggressive behavior</td>
<td>Specialized staff training and modifications to environment showed the most promise. More robust and rigorous research required</td>
</tr>
<tr>
<td>Cohen-Mansfield, 2001</td>
<td>Patients with dementia</td>
<td>Massage/ touch, bright light therapy, music, white noise, behavior therapies,</td>
<td>83 studies (n=2,239)</td>
<td>Various measures of inappropriate behaviors</td>
<td>The majority of types of intervention reviewed showed potential clinical benefits, but more rigorous research is needed to clarify benefits and</td>
</tr>
</tbody>
</table>

Interventions to Manage Aggressive Behaviour in Long-Term Care Residents 21
<table>
<thead>
<tr>
<th>First Author, Year Published</th>
<th>Patient population</th>
<th>Interventions Evaluated</th>
<th># of included studies (# of patients)</th>
<th>Outcomes</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forbes, 1998</td>
<td>Patients with dementia</td>
<td>Music, skills training, visual barriers, exercise, bright light therapy, pet therapy, sensory integration, reality orientation, white noise therapy</td>
<td>27 studies (designs, total sample size unavailable from structured abstract)</td>
<td>Agitation, social interaction, violent behavior, vocally disruptive behavior, disturbances, eating problems</td>
<td>Planned walking, pet therapy, attention focusing programs, skills training and music therapy showed promising impacts on agitation, social interaction, disturbing behaviors, wandering</td>
</tr>
<tr>
<td>Ayalon, 2006</td>
<td>Patients with dementia</td>
<td>Classified interventions into classes of unmet needs therapies, behavioral interventions, caregiving interventions and bright light therapy</td>
<td>3 RCTs, 6 single case designs</td>
<td>Measures of neuropsychiatric symptoms</td>
<td>Therapies geared toward targeting behavioral issues and patients’ unmet needs and that include caregivers or BLT showed promise. Further rigorous research needed.</td>
</tr>
</tbody>
</table>

**Table 2: RCTs and Observational Studies Included**

<table>
<thead>
<tr>
<th>First Author, Year Published</th>
<th>Study Design, Participants &amp; Setting</th>
<th>Sample Size</th>
<th>Outcomes</th>
<th>Interventions</th>
<th>Summary of results/ author conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bright Light Therapy</strong></td>
<td>2x2 randomized factorial study</td>
<td>189</td>
<td>Agitation rating, observed disruptive behavior, positive behavior</td>
<td>Melatonin+bright light therapy, melatonin+placebo, bright light therapy+placebo, placebo only (melatonin 2.5mg)</td>
<td>Melatonin+bright light therapy showed a 9% reduction of CMAI score; clinical significance not discussed</td>
</tr>
<tr>
<td>Riemersma-van der Lek, 2008</td>
<td>Residents of 12 Dutch homes for the elderly</td>
<td></td>
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</tr>
<tr>
<td>Dowling, 2007</td>
<td>RCT</td>
<td>70</td>
<td>Presence, frequency, severity, disruptiveness of neuropsychiatric behaviors</td>
<td>Morning/afternoon bright light exposure versus usual indoor light</td>
<td>Statistically significant differences between groups were found for agitation/aggression, depression and motor behavior, but the magnitudes were not considered clinically significant</td>
</tr>
<tr>
<td><strong>Massage/Touch Therapy</strong></td>
<td>RCT</td>
<td>51</td>
<td>Physical aggression, verbal agitation</td>
<td>Therapeutic touch, simulated therapeutic touch, usual care</td>
<td>Therapeutic touch showed reduced physical non-aggression during treatment, but no differences for any aggression measures existed two weeks after therapy ended</td>
</tr>
<tr>
<td>Hawranik, 2008</td>
<td>Alzheimer’s disease patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Activity Programs</strong></td>
<td>RCT</td>
<td>24</td>
<td>Sleep, behavior disturbances (Cohen-Mansfield Agitation Inventory)</td>
<td>Outdoor activity program versus indoor activity program</td>
<td>No significant differences for measures of aggression, physical agitation or verbal agitation were found</td>
</tr>
<tr>
<td>Connell, 2007</td>
<td>Nursing home patients with dementia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Music Therapy</strong></td>
<td>RCT</td>
<td>46</td>
<td>Activity disturbances (Behavior Pathology in Alzheimer’s Disease scale)</td>
<td>Music therapy (6 weeks, 18 half hour sessions) versus usual care</td>
<td>Significant reduction in activity disturbances during the treatment period, but no difference between groups 4 weeks after therapy completed</td>
</tr>
<tr>
<td>Svansdottir, 2006</td>
<td>Patients with moderate to severe Alzheimer’s disease in a nursing home or psychogeriatric ward</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Author, Year Published</td>
<td>Study Design, Participants &amp; Setting</td>
<td>Sample Size</td>
<td>Outcomes</td>
<td>Interventions</td>
<td>Summary of results/ author conclusions</td>
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</tr>
<tr>
<td>Lin, 2007</td>
<td>Cross-over RCT Dementia patients in Hong Kong</td>
<td>70</td>
<td>Cohen-Mansfield Agitation Inventory</td>
<td>Lavender inhalation versus sunflower inhalation</td>
<td>Aromatherapy may serve as a valuable adjunctive therapy to reduce agitation</td>
</tr>
<tr>
<td>Sloane, 2007</td>
<td>Cross-over RCT Dementia patients in nursing home setting</td>
<td>73</td>
<td>Agitation, aggression, discomfort</td>
<td>Person-centered showering, towel bathing, control</td>
<td>Both experimental bathing techniques greatly reduced various measures of aggressive behavior</td>
</tr>
<tr>
<td>Magai, 2002</td>
<td>RCT Patients with mid or late stage dementia</td>
<td>91</td>
<td>agitation, behavioral symptoms and depression</td>
<td>Staff training program for sensitivity to non-verbal communication versus staff training in behavioral and cognitive aspects of dementia or control</td>
<td>No important differences between groups were found for changes in agitation, behavioral symptoms or depression</td>
</tr>
<tr>
<td>Engst, 2004</td>
<td>Non-randomized Long-term care facility setting; patient characteristics not described</td>
<td>100</td>
<td>Risk of caregiver injury, patient agitation (Cohen Mansfield Agitation Inventory and staff questionnaire)</td>
<td>Scheduled toileting program versus usual care; agitation awareness training provided to staff in both groups</td>
<td>Reduced agitation was seen in terms of lesser verbal behavior and emotional upset, but no difference in physical behaviors. Risk of injury to caregivers was reduced</td>
</tr>
<tr>
<td>Kovach, 2004</td>
<td>Blinded pre-test/post-test, Patients with dementia</td>
<td>78</td>
<td>Observed agitation</td>
<td>Balancing Arousal Controls Excesses (BACE) intervention versus usual care</td>
<td>Tailored activity schedules to improve balance of arousal levels reduced agitation</td>
</tr>
</tbody>
</table>

### Identified studies that were included in other systematic reviews

<table>
<thead>
<tr>
<th>First Author, Year Published</th>
<th>Study Design, Participants &amp; Setting</th>
<th>Sample Size</th>
<th>Outcomes</th>
<th>Interventions</th>
<th>Summary of results/ author conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ancoli-Israel, 2003</td>
<td>RCT Patients with severe Alzheimer’s disease</td>
<td>92</td>
<td>Agitation, as rated by research staff</td>
<td>Morning bright light, evening bright light</td>
<td>No important benefits on agitation (measured by Cohen-Mansfield agitation inventory) were found</td>
</tr>
<tr>
<td>Lyketsos, 1999</td>
<td>Crossover RCT Dementia patients in long-term care</td>
<td>15</td>
<td>Sleep behaviors, changes in agitation behavior</td>
<td>Bright light therapy 1 hour per day versus dim light exposure (4 weeks per intervention)</td>
<td>no difference between interventions in agitated behavior as measured by the Behavioral Pathology in Alzheimer’s Disease scale</td>
</tr>
<tr>
<td>Rolland, 2007</td>
<td>RCT Patients with mild to severe Alzheimer’s disease</td>
<td>134</td>
<td>Activities of daily living, physical performance, nutrition status, behavioral disturbances, depression</td>
<td>Exercise program (2 hours per week involving walking, strength and flexibility training) versus routine care</td>
<td>Exercise caused a significant change in rate of decline of Activities of Daily Living score over one year, but no important differences were seen regarding frequency of disturbing behaviors</td>
</tr>
<tr>
<td>McCaillion, 1999</td>
<td>RCT Patients with dementia and their primary caregiver</td>
<td>66</td>
<td>Psychosocial functioning, depression, agitated behavior, social interaction</td>
<td>Family visit education plan versus usual care</td>
<td>Family visit education plans associated with improvement of resident depression, improved levels of verbal agitation, and reduced restraint use</td>
</tr>
<tr>
<td>Burgio, 2002</td>
<td>RCT Nursing home residents with a history of behavior disturbances; 44% Alzheimer’s disease, 22% vascular disease, 19% mixed AD/vascular</td>
<td>88</td>
<td>Aggressive behavior, physically non aggressive behavior, verbally aggressive behavior (Cohen-Mansfield Agitation Inventory)</td>
<td>Formal staff management versus conventional staff management (staff training program)</td>
<td>Reduced agitation levels were found in both intervention groups, with signs of benefit up to 6 months after intervention initiation</td>
</tr>
<tr>
<td>Richeson, 2003</td>
<td>Non-randomized Patients with dementia in a nursing home setting</td>
<td>15</td>
<td>Agitated behavior (Cohen-Mansfield Agitation Inventory), social interaction</td>
<td>Animal assisted therapy for three weeks</td>
<td>Significant decline in agitated behavior and an increase in social interaction</td>
</tr>
</tbody>
</table>
### Table 3: Best Evidence Synthesis Criteria (Verkaik et al.)

<table>
<thead>
<tr>
<th>Evidence Grade</th>
<th>Evidence Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>Statistically significant results in outcome measures which are consistent in two or more high quality RCTs</td>
</tr>
<tr>
<td>Moderate</td>
<td>Statistically significant results in outcome measures that are consistent in one or more high quality RCTs and one or more low quality RCTs or high quality CCTs</td>
</tr>
<tr>
<td>Limited</td>
<td>Statistically significant results in at least one high quality RCT, OR statistically significant results that are consistent in two or more high quality CCTs (if no high quality RCTs are identified)</td>
</tr>
<tr>
<td>Indicative</td>
<td>Statistically significant results in outcome measures in one or more high quality CCTs or low quality RCTs (if there are no high quality RCTs identified)</td>
</tr>
</tbody>
</table>
| Insufficient or none | Various possible criteria:  
  - Less than 50% of the total number of studies found within the same category of methodologic quality and study design show statistically significant findings;  
  - The results of studies fail to meet the criteria for one of the above levels of evidence;  
  - There exists contradictory results among RCTs and CCTs (i.e. significant positive versus significant negative findings);  
  - No eligible studies identified. |

RCT = randomized controlled trial; CCT = controlled clinical trial

### Table 4: Grading Criteria, Park et al.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Evidence from a well-designed meta-analysis</td>
</tr>
<tr>
<td>B</td>
<td>Evidence from randomized or non-randomized controlled trials, with results consistently supporting a specific action</td>
</tr>
<tr>
<td>C</td>
<td>Evidence from observational studies</td>
</tr>
<tr>
<td>D</td>
<td>Evidence from expert opinion or case reports</td>
</tr>
</tbody>
</table>

### Table 5: Grading Criteria, SIGN guidelines

<table>
<thead>
<tr>
<th>Grade</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review of RCTs or RCT rated as 1++ and directly applicable to target population of interest, or a body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; or extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>

**Evidence Levels**

- **1++**
  - High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- **1+**
  - Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with low risk of bias
- **1-**
  - Meta-analyses, systematic reviews of RCTs, or RCTs with high risk of bias
- **2++**
  - High quality systematic reviews of case control or cohort studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability of causal relationship
- **2+**
  - Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability of causal relationship
- **2-**
  - Case control or cohort studies with high risk of confounding or bias and a moderate probability of causal relationship
- **3**
  - Non-analytic studies (case reports, case series)
- **4**
  - Expert opinion
### Table 6: Summary of Evidence Grades by Livingston et al.\(^45\)

<table>
<thead>
<tr>
<th>Class of therapy</th>
<th>Evidence Grade Assigned</th>
<th>Described rationale of therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reminiscence therapy</td>
<td>D</td>
<td>Use of materials (newspapers, other items) to stimulate memories, provoke sharing of experiences</td>
</tr>
<tr>
<td>Validation therapy</td>
<td>D</td>
<td>Provide chance to deal with unresolved conflicts through encouragement of expression of feelings</td>
</tr>
<tr>
<td>Reality orientation therapy</td>
<td>D</td>
<td>Provide reminders of orientating information (date, time, names, weather) to facilitate functioning</td>
</tr>
<tr>
<td>Cognitive stimulation therapy</td>
<td>B</td>
<td>Related to reality orientation therapy; makes use of information processing rather than factual knowledge to address problems in functioning</td>
</tr>
<tr>
<td>Individualized special instruction</td>
<td>C</td>
<td>Participation in 30 minutes of an activity suitable to an individual with attention from another</td>
</tr>
<tr>
<td>Self maintenance therapy</td>
<td>C</td>
<td>Use of techniques from reminiscence, validation, psychotherapy to assist in maintenance of personal identity</td>
</tr>
<tr>
<td>Psychologic interventions with caregivers</td>
<td>D</td>
<td>Included training caregivers to administer behavioral management techniques, sometimes in conjunction with exercise</td>
</tr>
<tr>
<td>Psychoeducation and teaching caregivers to change interactions with patients</td>
<td>A</td>
<td>Included training in stress management &amp; dementia education (for caregivers’ health), individual family interventions, educational program for family carers, psychoeducation on changing interactions, and other variations</td>
</tr>
<tr>
<td>Family counseling</td>
<td>C</td>
<td>Not described</td>
</tr>
<tr>
<td>Music therapy</td>
<td>B</td>
<td>Playing of music or activities involving instruments or movements to music to improve sensory skills</td>
</tr>
<tr>
<td>Snoezelen therapy</td>
<td>B</td>
<td>Improvement of sensory skills through combination of relaxation</td>
</tr>
<tr>
<td>Other sensory stimulation (massage, white noise, others)</td>
<td>C</td>
<td>Combination of other approaches to appeal to sensory skills of dementia patients to improve neuropsychiatric symptoms</td>
</tr>
<tr>
<td>Simulated presence therapy</td>
<td>D</td>
<td>Presentation of positive autobiographical memories to the patient in the form of a continuous-play, audiotaped telephone conversation</td>
</tr>
<tr>
<td>Activity programs</td>
<td>D</td>
<td>Use of puzzles, bicycles, swings, or combination of different activities</td>
</tr>
<tr>
<td>Exercise</td>
<td>D</td>
<td>Use of exercises, movement or walking to alleviate symptoms</td>
</tr>
<tr>
<td>Social interaction</td>
<td>D</td>
<td>Enforced social interaction with nurses for several hours daily for 1-2 months</td>
</tr>
<tr>
<td>Decreased sensory stimulation</td>
<td>D</td>
<td>Lowering of voices, turning off televisions, reduction of fast movements by care staff</td>
</tr>
<tr>
<td>Environmental manipulation</td>
<td>C</td>
<td>Included use of two-dimensional grids on floor surfaces near doors, wall murals, incorporation of more mirrors, use of signs, unlocking of ward doors and allowance of group living arrangements</td>
</tr>
<tr>
<td>Complex environment</td>
<td>D</td>
<td>Training pertaining to communication skills, ability to implement behavioral therapy techniques, dementia education &amp; management strategies, provision of integrity-promoting care (more time spent with residents, efforts to increase environmental resemblance to home) and other concepts</td>
</tr>
</tbody>
</table>

**Interventions to Manage Aggressive Behaviour in Long-Term Care Residents**

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\(^{45}\) Livingston et al. (2019).