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Nonpharmacological intervention for agitation in dementia: A systematic review and meta-analysis

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Objective: The purpose of this study was to systematically review the literature regarding the effectiveness of nonpharmacological interventions for agitation in older adults with dementia.

Methods: Seven electronic databases (to 2004) were searched, and randomized clinical trials employing nonpharmacologic interventions for agitation in dementia published in English or Korean were selected. In addition, the reference lists from relevant review articles and all eligible studies were searched to identify other trials. Interventions were categorized into seven types: sensory intervention, social contact, activities, environmental modification, caregiver training, combination therapy, and behavioral therapy. Studies were abstracted, and data were pooled by intervention category.

Results: Fourteen studies ($n = 586$) were included. Sensory interventions were statistically significantly effective in reducing agitation (standardized mean difference: SMD -1.07 ; 95% confidence interval (CI) -1.76 to -0.38 , $p = 0.002$), while social contact (SMD -0.19 ; CI -0.71 to 0.33), activities (SMD -0.20 ; CI -0.71 to 0.31), environmental modification (weighted mean difference: WMD 1.90 ; CI -2.82 to 6.62), caregiver training (SMD 0.21 ; CI -0.15 to 0.57), combination therapy (WMD 1.85 ; CI -1.78 to 5.48), and behavioral therapy interventions (SMD -0.27 ; CI -0.72 to 0.19) were not significantly effective in reducing agitation. These results were consistent among higher quality studies.

Conclusion: This systematic review indicated that among the seven types of nonpharmacological interventions available for agitation in older adults with dementia, only sensory interventions had efficacy in reducing agitation. More trials are needed to confirm this finding and future research should use more rigorous methods.

Keywords: Alzheimer's disease; Psychological and behavioral symptom; psychosocial intervention

Introduction

Dementia in the form of Alzheimer's disease is estimated to affect approximately 5.2 million Americans (AA, 2008). The United States spends over \$148 billion a year on the care of Alzheimer's disease (AA, 2008). Dementia is associated with behavioral symptoms as well as cognitive impairment. Agitation is the most commonly exhibited behavioral symptom in older adults with dementia (Ballard et al., 2001; Everitt, Fields, Soumerai, & Avorn, 1991), with prevalence reported in 48–82% of elders with dementia in nursing homes (Zuidema, Koopmans, & Verhey, 2007).

Agitation has been defined as an inappropriate verbal, vocal, or motor activity that is not explained by needs or confusion *per se* (Cohen-Mansfield & Billig, 1986). Agitation is caused by neurological, physical, psychological, functional, interpersonal relation, environmental, and restraint factors (Kong, 2005). Pharmacological interventions are commonly provided to decrease the agitation of older adults with dementia. Some pharmacological interventions, however, are reported to precipitate agitation in this population (Nasr & Osterweil, 1999; Ryden et al., 1999; Spore, Horgas, Smyer, & Marks, 1992; Talerico, Evans, &

Strumpf, 2002). In addition, pharmacological interventions are reported to have adverse effects such as worsening of cognitive function, somnolence, urinary tract infection, extra-pyramidal symptoms, and abnormal gait (Schneider, Dagerman, & Insel, 2006). Therefore, increased attention has been paid to nonpharmacological interventions which are associated with fewer risks (Livingston, Johnston, Katona, Paton, & Lyketsos, 2005). Many researchers have explored the effects of nonpharmacological interventions on decreasing agitation in dementia. The results, however, are contradictory and the effectiveness of interventions among these studies has varied. Thus, nursing staff encounter difficulties in selecting and employing effective nonpharmacological interventions for agitation. As a result, older adults with agitation are too often inappropriately restrained physically or chemically.

There are a few reviews that have focused on nonpharmacological interventions for agitation in dementia (Cohen-Mansfield, 2001; McGonigal-Kenney & Schutte, 2006; Nasr & Osterweil, 1999). The reviews reported only consensus or the synthesis of nonpharmacological interventions of agitation without the systematic analysis of the effects of

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the interventions. To our knowledge, this is the first systematic review using meta-analysis to assess the effects of nonpharmacological interventions for agitation in dementia. The research will provide valuable practical information in the reduction of the agitation and contribute to improvement of the quality of care for older adults with dementia.

Methods

Study design

The study is a systematic review and meta-analysis. The procedures for this systematic review were based on the eight steps suggested by Egger and Smith (2001, p. 25): (1) formulate review question; (2) define inclusion and exclusion criteria; (3) locate studies; (4) select studies; (5) assess study quality; (6) extract data; (7) analyze and present results; and (8) interpret results.

Inclusion criteria

Studies were included if they met the following criteria: (a) used randomized controlled parallel or randomized crossover study design; (b) enrolled subjects with dementia; (c) included nonpharmacological interventions for agitation; (d) published study in English or Korean; (e) included a published scale measuring agitation as outcome variable; and (f) included sufficient information to determine the effect of nonpharmacological intervention.

Literature search and selection of studies

Literature searches were performed with the key words of 'agitation', or 'agitated'; and 'dementia', or 'demented', or 'Alzheimer' using the following electronic databases: MEDLINE (June 1966, 2004), CINAHL (June 1982, 2004), PsycINFO (June 1894, 2004), AARP Ageline (June 1978, 2004), EBM Reviews-Cochrane Central Register of Controlled Trials (3rd Quarter 2004), ACP Journal Club (June 1991, 2004), and ISI index (June 1945, 2004). The database searches were limited to articles published in English or Korean. Abstracts of potentially eligible studies were reviewed and full text papers were pulled to determine eligibility. All randomized clinical trials employing nonpharmacological interventions for agitation in dementia were selected. The reference lists from relevant review articles and all potentially eligible studies were also searched. Two independent reviewers evaluated appropriateness of inclusion independently. In case of disagreement regarding the appropriateness of inclusion, all three reviewers discussed and came to consensus. As necessary, authors of included studies were contacted by Email in order to obtain missing data in the methods and/or results sections.

Methodological quality assessment

Methodological quality was assessed by two reviewers in terms of characteristics of the allocation concealment and withdrawals and dropouts: (1) allocation concealment was assessed using Cochrane criteria (Cochrane Handbook, 2008): 0 = inadequate, 1 = unclear, 2 = adequate; (2) withdrawals and dropouts: 0 = no description, 1 = described but need more information, 2 = clearly described. Score 0 or 1 was regarded as low score; 2 as high score. The same two independent reviewers assessed methodological quality. If there was disagreement, the third reviewer was consulted and all the three reviewers discussed and made consensus.

Data extraction

Two reviewers independently extracted data using a data extraction form which was developed for this review. The extracted data included the following: (a) type of design (randomized clinical trial, randomized cross-over design study); (b) allocation concealment; (c) withdrawals and dropouts; (d) details of study quality; (e) participants (sample size, age, and gender); (f) setting; (g) dementia severity; (h) inclusion and exclusion criteria; (i) details of the intervention; (j) definition of outcome; (k) outcome measures; (l) details of results (mean and standard deviation); and (m) possible biases (selection, performance, exclusion, and detection bias). In the case of inconsistent data or missing data, the study authors were contacted by Email.

The main outcome was the study-specific measure of agitation. If the included study examined the effects of more than one nonpharmacological intervention, the most effective intervention was selected by the two reviewers. If the effect of nonpharmacological intervention on agitation was measured more than one time, the time immediately after intervention or the time closest to the endpoint of the intervention was selected. We allowed for different measures of agitation, provided the studies reported scale validity. The main comparison was nonpharmacologic interventions compared to usual care. Interventions were categorized into seven types based on the categorization and definition of previous studies (Cohen-Mansfield, 2001; McGonigal-Kenney & Schutte, 2006): sensory (interventions to stimulate senses and to induce relaxation), social contact (interventions to increase social interaction), activities (interventions to increase structured physical activity and to decrease boredom), environmental modification (interventions to reduce unnecessary stimulation, to maintain safety, to protect autonomy, and to support normal circadian rhythm), caregiver training (interventions to increase caregiver knowledge and strategy), combination therapy (interventions combining more than one intervention), and behavioral therapy interventions (interventions to improve specific behavior and function)

(McGonigal-Kenney & Schutte, 2006). We examined separate comparisons for each type of intervention.

Heterogeneity and sensitivity analysis

Two independent reviewers investigated potential sources of clinical heterogeneity and statistical heterogeneity across the included studies. Statistical heterogeneity was explored using both Chi-squared statistic and *I*-squared statistic. Unless heterogeneity was high ($I^2 \geq 75\%$) (Cochrane Handbook, 2008), data were pooled and heterogeneity was explored. Within categories, sensitivity analyses were performed to test the effects of excluded studies with lower methodological quality in terms of allocation concealment and withdrawal.

Data analysis

Meta-analyses were performed using Review Manager Software (RevMan version 4.2). The main outcome was calculated as an effect size for each of the individual studies. We estimated separate pooled estimates for each type of intervention. Because outcome variables were measured by different scales or time intervals, we used the standardized mean difference (SMD) with 95% confidence interval (CI) to estimate a pooled effect size. However, if the category included only one study, weighted mean difference (WMD) with 95% CI was used to estimate effect size. All meta-analyses were conducted using random effects model.

Results

About 14 of 317 articles were identified as eligible and included in this systematic review. The characteristics of the included studies are summarized in Table 1. Among the 14 included studies, 7 were randomized controlled parallel trials and other 7 were randomized crossover design trials. Sample sizes ranged from 8 to 118, and the total sample size was 586. In majority of the studies, enrolled subjects were predominantly female and residents of nursing homes or other care facilities. The duration of the intervention program ranged from 10 minutes to 1 year. In terms of theoretical model, eight studies did not employ theoretical models and six studies employed theoretical models such as the progressively lowered stress threshold model (Remington, 2002), the need-driven dementia-compromised behavior model (Fitzsimmons & Buettner, 2002; Kolanowski, Buettner, Costa, & Litaker, 2001), the stimulation-retreat model (Lawton et al., 1998), Lawton's theory (Beck et al., 2002), or the competence environmental press framework (McGilton, Rivera, & Dawson, 2003). In order to measure agitation, 10 studies used CMAI (The Cohen-Mansfield Agitation Inventory) or ABMI (The Agitation Behavior Mapping Instrument) which were

developed based on the Cohen-Mansfield's definition of agitation. The remaining four studies used Behave-AD (The Behavioral Pathology in Alzheimer's Disease Rating Scale), ABID (The Agitated Behavior Inventory for Dementia), PAS (The Pittsburgh Agitation Scale), or DBS (The Disruptive Behavior Scale) to measure agitation. Four studies examined the long-term effects of interventions at longer than 2-month follow-up (Beck et al., 2002; Lawton et al., 1998; McGilton et al., 2003; Wells, Dawson, Sidani, Craig, & Pringle, 2000).

The nonpharmacological interventions of the studies included aromatherapy (Ballard, O'Brien, Reichelt, & Perry, 2002), thermal bath (Dunn, Thiruchelvam, & Beck, 2002), calming music and hand massage (Remington, 2002), simulated presence (Camberg et al., 1999), pet therapy (Churchill, Safaoui, McCabe, & Baun, 1999), rocking chair therapy (Watson, Wells, & Cox, 1998), therapeutic recreational activities (Fitzsimmons & Buettner, 2002; Kolanowski et al., 2001), morning bright light therapy (Lyketsos, Veiel, Baker, & Steele, 1999), behavior management techniques (Teri et al., 2000), abilities focused morning care (Wells et al., 2000), stimulation-retreat program (Lawton et al., 1998), activities of daily living intervention (Beck et al., 2002), and way finding intervention (McGilton et al., 2003). The nonpharmacological interventions were clustered into seven types: sensory intervention (aromatherapy, thermal bath, and calming music and hand massage); social contact (simulated presence and pet therapy); activities (rocking chair therapy and therapeutic recreational activities); environmental modification (morning bright light therapy); caregiver training (behavior management techniques and abilities-focused morning care); combination therapy (stimulation-retreat program); and behavior therapy (activities of daily living intervention and way finding intervention) (Table 2).

After pooling, the meta-analysis of the 14 included studies showed the following findings. In the three studies ($n=120$) of sensory interventions, there were statistically significant differences in agitation between treatment groups and control groups (SMD -1.07 ; 95% CI -1.76 to -0.38) (Figure 1), indicating moderate beneficial effects of sensory interventions on agitation. In the two studies ($n=82$) of social contact, there were no significant differences in agitation between treatments and control cares (SMD -0.19 ; CI -0.71 to 0.33) (Figure 2). In the activity interventions ($n=65$), there were no significant differences in agitation between treatments and control cares (SMD -0.20 ; CI -0.71 to 0.31) (Figure 3), although one study (Fitzsimmons & Buettner, 2002) of the activity interventions showed a significant difference in agitation (SMD -0.57 ; CI -1.09 to -0.05). In one study ($n=8$) of environmental modification, there was no significant difference in agitation between treatment and control care (WMD 1.90 ; CI -2.82 to 6.62) (Figure 4). In two studies ($n=117$) of caregiver training, there were no significant differences in

Table 1. Included studies.

Author (Year)	Design Sample size Female: % Cognitive status (SD) Site	Duration of type of intervention	Theoretical model	Outcome scale	Results
Ballard et al. (2002)	RCT <i>n</i> = 71 Female: 60 CDR: stage 3 Nursing home RCO	Twice daily for 4 week E – Aromatherapy with Melissa essential oil C – Sunflower oil 8 week (four consecutive sessions in each of the two methods) E – Thermal bath C – Conventional tub bath	No model	CMAI	Significant overall improvement in agitation with 35% reduction in E and 11% reduction in C, ($Z = 4.1, p < 0.0001$).
Dunn et al. (2002)	<i>n</i> = 15 Female: 40 BCRS: 3.8–7 Special care unit & Dementia unit RCT	10 min exposure E – Calming music (CM) E – Hand massage (HM) E – CM + HM C – No intervention	No model	14 items from CMAI & RAS	Summed frequencies of all agitated behaviors was significantly less for the thermal bath than the tub bath ($t = 4.18, p < 0.001$).
Remington (2002)	<i>n</i> = 68 Female: 87 Cognitive status: moderate or severe (96%) Nursing home RCO	17 days for 4 week E – Simulated presence C – Placebo audiotape C – Usual care	PLST model	Modified CMAI	Each of the three experimental interventions had significantly greater reduction in agitation than no intervention.
Camberg et al. (1999)	<i>n</i> = 54 Female: 77 MMSE: 5.1 (4.4) TSI: 13.1(6.9) Nursing home RCO	Two 30 min sessions E – With the dog present C – Without the dog present	No model	OAS AVAS SOAPD SOL SCMAI ABMI	SOL indicated that SimPres reduced agitation 67% of the time and was significantly better in reducing agitation than usual care (59%; $p < 0.001$), and placebo (46%; $p < 0.001$). No significant differences among interventions on SOAPD and SCMAI ($p > 0.05$). The main effect of the presence of the dog was significant.
Churchill et al. (1999)	<i>n</i> = 28 Female: 75 BDBRS: 22.2 (8.3) Care facility RCO	6 weeks E – Rocking chair therapy C – Nonrocking treatment	No model	SCMAI	No significant differences
Watson et al. (1998)	<i>n</i> = 25 Female: 76 CPS: \geq level 2 Special care unit RCO	20 min at 12 days	NDB model	CMAI	No significant differences
Kolanowski et al. (2001)	<i>n</i> = 10 Female: 60 MMSE: 10.2 (7.1) Nursing home RCO	E – Therapeutic recreation activities C – Control activities 2 weeks of daily	NDB model	CMAI	Significant differences ($p = 0.029$)
Fitzsimmons and Buettner (2002)	<i>n</i> = 29 Female: 65 MMSE: 12.93 GDS: 5.28 Community	E – Individualized therapeutic recreational intervention C – Usual homecare	NDB model	CMAI	Significant differences ($p = 0.029$)

(Continued)

Table 1. Continued.

Author (Year)	Design Sample size Female: % Cognitive status (SD) Site	Duration of type of intervention	Theoretical model	Outcome scale	Results
Lyketsoos et al. (1999)	RCO $n = 8$ Female: 93 MMSE: 6.4 (6.8) Chronic care setting RCT	1 h per day for 4 weeks E – Morning bright light C – Dim light	No model	Behave-AD	No significant differences
Teri et al. (2000)	$n = 77$ (BMT + Placebo) Female: 60 (BMT + Placebo) MMSE(E): 12(7) MMSE(C): 13(8) ADCS sites RCT	E – 8 weekly and 3 biweekly structured sessions of BMT E – Haloperidol E – Trazodone C – Placebo treatment for 16 weeks	No model	CMAI ABID	No significant differences
Wells et al. (2000)	$n = 40$ Female: 84 MMSE(E): 6(6.3) MMSE(C): 2.9(4.8) Nursing home level cognitive supports units RCT	Five sessions and reinforcement sessions E-Abilities-focused morning care C-Usual morning care	No model	PAS	No significant difference between the groups at 3 m; Significant differences between the two groups at 6 m follow-up ($p = 0.041$).
Lawton et al. (1998)	$n = 118$ (at 6 m) Female: ND GDS: 5.53 Special care nursing home units RCT	1 year E-Stimulation-retreat program C-ND	Stimulation-retreat model	CMAI	No significant differences between groups at 6 and 12 m follow-up.
Beck et al. (2002)	$n = 127$ (total), 28(ADL), 19 (NI) Female: 84 (ADL + NI) MMSE(E): 11.44, MMSE(C): 11.47 Nursing home RCT	12 weeks E – Activities of daily living E – Psychosocial activity E – Combination C – No intervention C – Placebo 30 min, three times a week for four weeks	Lawton's theory	DBS	No significant differences between groups at post-intervention, 1 m follow-up, and 2 m follow-up.
McGilton et al. (2003)	$n = 29$ Female: 80 GDS: 5.1 Nursing home RCT	E – Way-finding intervention C – Usual care	CEPF	PAS	Experimental group had greater reduction in agitation than control group at 1w. Agitation in experimental group increased at 3 m follow-up while agitation in control group stayed same as 1w.

Notes: ABID = The Agitated Behavior Inventory for Dementia; ABMI = The Agitation Behavior Mapping Instrument; ADCS = The Alzheimer's Disease Cooperative Study; ADL = Activities of daily living; AVAS = The Agitation Visual Analog Scale; BDBRS = The Burke Dementia Behavioral Rating Scale; Behave-AD = The Behavioral Pathology in Alzheimer's Disease Rating Scale; BMT = Behavior Management Techniques; C = Control group; CDR = The Clinical Dementia Rating Scale; CEPF = Competence Environmental Press Framework; CMAI = The Cohen-Mansfield Agitation Inventory; CPS = Cognitive Performance Scale; DBS = The Disruptive Behavior Scale; E = Experimental group; GDS = The Global Deterioration Scale; m = Month; min = Minute; MMSE = The Mini-Mental State Examination; ND = Not described; NDB = The Need-Driven Dementia-Compromised Behavior Model; NI = No Intervention; PAS = The Pittsburgh Agitation Scale; PLST model = The Progressively Lowered Stress Threshold model; OAS = Observed Agitation Scale; RAS = The Ryden Aggression Scale; RCO = Randomized Cross-Over Design; RCT = Randomized Clinical Trial; SCMAI = The Short Form of the Cohen-Mansfield Agitation Inventory; SD = Standard Deviation; SOAPD = The Scale for the Observation of Agitation in Persons with Dementia; SOL = Staff Observation Log; w = Week.

Table 2. Categorization of included nonpharmacological interventions.

Category	Intervention (Author, Year)
Sensory intervention	Aromatherapy (Ballard et al., 2002); Thermal bath (Dunn et al., 2002); Calming music and hand massage (Remington, 2002)
Social contact	Simulated presence (Camberg et al., 1999); Pet therapy (Churchill et al., 1999)
Activities	Rocking chair therapy (Watson et al., 1998); Therapeutic recreational activities (Kolanowski et al., 2001; Fitzsimmons & Buettner, 2002)
Environmental modification	Morning bright light therapy (Lyketsos et al., 1999)
Caregiver training	Behavior management techniques (Teri et al., 2000); Abilities focused program of morning care (Wells et al., 2000)
Combination therapy	Stimulation-retreat program (Lawton et al., 1998)
Behavioral therapy	Activities of daily living intervention (Beck et al., 2002); Way finding intervention (McGilton et al., 2003)

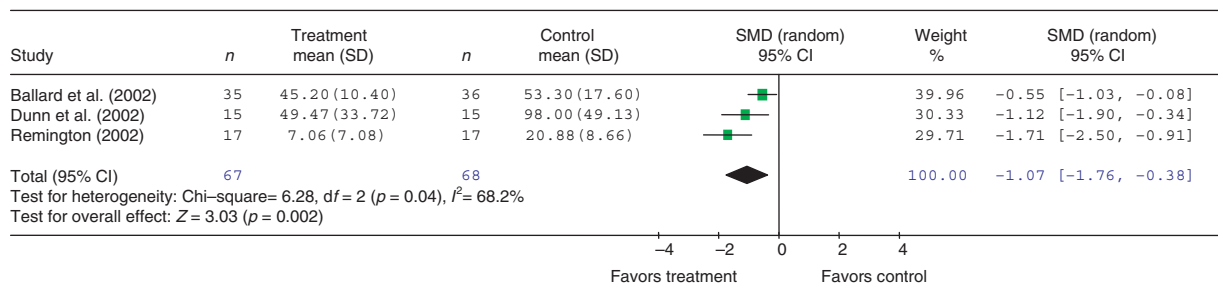


Figure 1. Comparison: Sensory intervention vs. usual care.

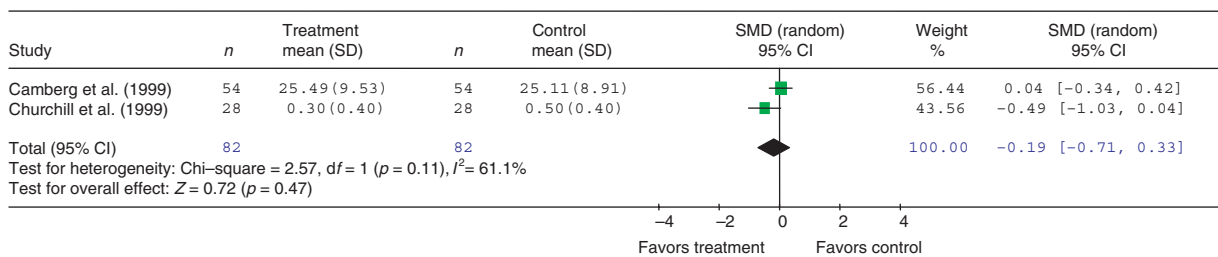


Figure 2. Comparison: Social contact vs. usual care.

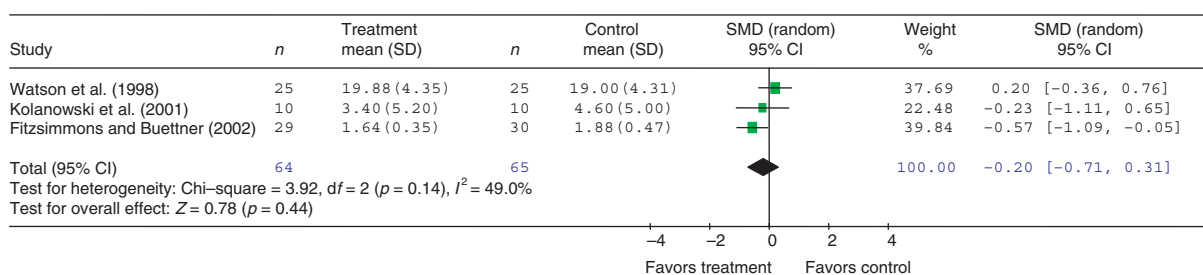


Figure 3. Comparison: Activities vs. usual care.

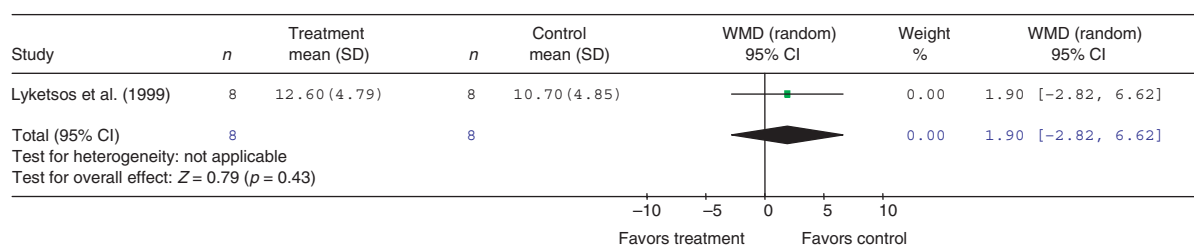


Figure 4. Comparison: Environmental modification vs. usual care.

agitation between treatment groups and control groups (SMD 0.21; CI -0.15 to 0.57) (Figure 5). In one study ($n=118$) of combination therapy, there was no significant difference in agitation between treatment group and control group (WMD 1.85; CI -1.78 to 5.48) (Figure 6). In two studies ($n=76$) of behavioral therapy, there were no significant differences in agitation between treatment groups and control groups (SMD -0.27; CI -0.72 to 0.19) (Figure 7). Thus, among the seven types of interventions, only sensory interventions showed a statistically significant beneficial effects on agitation ($p=0.002$). In addition, in the four studies which tested long-term effects of interventions, there were no significant differences in agitation between treatment groups and control groups at long-term follow-up: caregiver training (SMD -0.12; CI -0.77 to 0.52); combination therapy (WMD 1.72; CI -1.03 to 4.47); and behavioral therapy (SMD 0.22; CI -0.86 to 1.30).

Heterogeneity was found among sensory intervention studies ($\chi^2=6.28$, $df=2$, $p=0.04$, 68.2%). Sensitivity analyses were conducted, excluding studies of lower methodological quality in terms of allocation concealment and withdrawal. Quality scores ranged from 0 to 2 (Table 3). Studies of 0 or 1 quality rating were excluded. Regarding allocation concealment, two studies with adequate allocation concealment

(Ballard et al., 2002; Remington, 2002) were included in the category of sensory intervention, and the result of sensory intervention *versus* usual care was similar to the results of the overall three studies (SMD -1.08; CI -2.21 to 0.04). In terms of withdrawal, 13 studies with clear description were included and one study of

Table 3. Assessment of quality.

Author (Year)	Allocation (0-2)	Withdrawals (0-2)
Ballard et al. (2002)	2	2
Dunn et al. (2002)	1	2
Remington (2002)	2	0
Camberg et al. (1999)	1	2
Churchill et al. (1999)	1	2
Watson et al. (1998)	1	2
Kolanowski et al. (2001)	0	2
Fitzsimmons and Buettner (2002)	1	2
Lyketsos et al. (1999)	2	2
Teri et al. (2000)	1	2
Wells et al. (2000)	1	2
Lawton et al. (1998)	2	2
Beck et al. (2002)	0	2
McGilton et al. (2003)	1	2

Notes: Allocation concealment (0 = Inadequate, 1 = Unclear, 2 = Adequate); Withdrawals (0 = No description, 1 = Described but need more information, 2 = Clearly described).

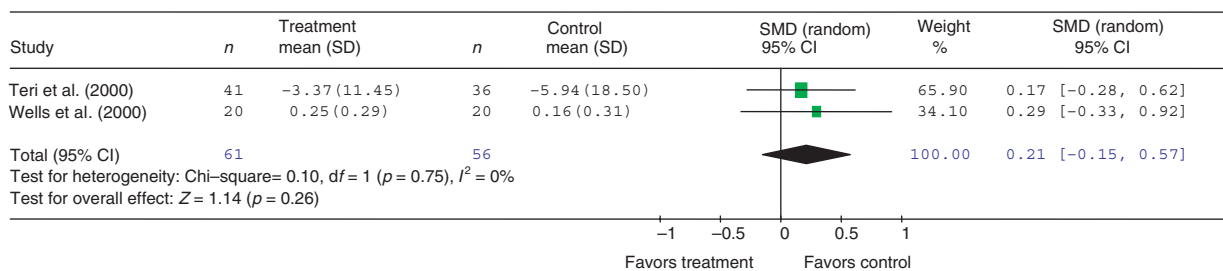


Figure 5. Comparison: Caregiver training vs. usual care.

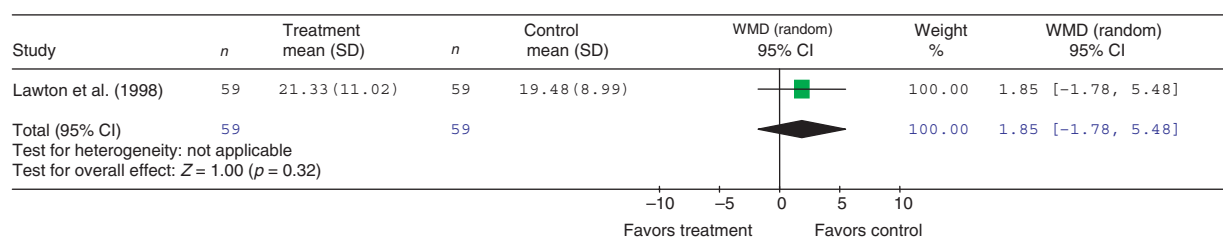


Figure 6. Comparison: Combination therapy vs. usual care.

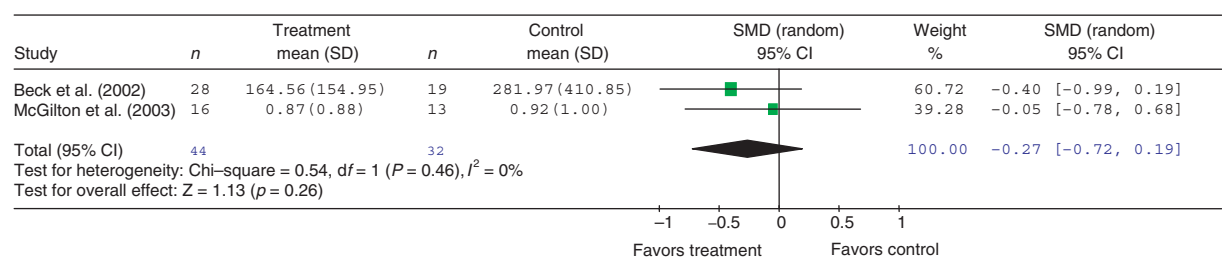


Figure 7. Comparison: Behavioral therapy vs. usual care.

sensory intervention was excluded (Remington, 2002). The result of sensory intervention *versus* usual care showed a slightly smaller effect size than the result of three overall studies (SMD -0.75 ; CI -1.28 to -0.22). Excluding studies with lower methodological quality did not change substantially the results.

Discussion

The systematic review indicated that only sensory interventions (aromatherapy, thermal bath, and calming music and hand massage) had moderate efficacy in reducing agitation of elders with dementia. No other type of nonpharmacological interventions (social contact, activities, environmental, caregiver training, combination therapy, and behavioral therapy) showed efficacy in reducing agitation among the elders with dementia. However, the results should be interpreted with caution because of several factors including the small number of studies in each category, small sample sizes in respective studies, variability in the nature and duration of the intervention programs, inconsistent definition of agitation across studies, and variability in the measuring instrument and time.

In regard to practice, this systematic review suggested sensory interventions might be important practical interventions for agitation in older adults with dementia in terms of significant effect, ease of performance, low cost, and safety. Given that agitation is the most frequently manifested behavioral symptom of elders with dementia and increases with the progress of dementia, effective nonpharmacological interventions may contribute to the improvement of the quality of life of these elders and their caregivers. In addition, employing effective nonpharmacological interventions may delay the nursing home placement of community-dwelling older adults with agitation and decrease the use of pharmacological or physical restraints in the nursing home.

This systematic review has important implications for future research. More research is needed to confirm the findings of this review with attention to methodological quality. Despite the large number of intervention studies regarding agitation in dementia, many could not be included in this review due to methodological inadequacies such as an experimental design study (a descriptive study and a case report), methodologically weak quasi-experimental study design, uncontrolled study, inadequate randomization, no reliable and valid scale of agitation, and insufficient information. Future study should use more rigorous methods including randomized parallel designs, adequate allocation concealment, and an instrument with high reliability and validity. Future studies should also strive for better reporting of methods. For example, many articles described only random generation of allocation sequences without mentioning the method of allocation concealment. Some authors' responses to our queries indicated that they did not understand

concealment of allocation sequences or they confused allocation concealment with blinding. In addition, future study should employ adequate sample sizes based on appropriate power analysis, clear theoretical or operational definition of agitation, and appropriate theoretical model.

Future research is also required to determine adequate duration of nonpharmacological interventions to achieve clinically meaningful reduction of agitation in dementia. In addition, future study is needed to test the effects of nonpharmacological interventions over long-term periods. Only four out of the 14 included studies examined the long-term effects of the interventions. Thus, future study should examine the long-term benefits of the interventions with adequate follow-up periods because agitation is a continuous problem in dementia. Comparative studies of nonpharmacological and pharmacological interventions in terms of effectiveness, cost, side effect, and caregivers' performance are also needed.

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