

Appendix A. Search Strategy

Database: Ovid MEDLINE(R) <1946 to November Week 1 2014>

Search Strategy:

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- 1 exp *Dementia/
 - 2 dementi*.ti.
 - 3 alzheimer*.ti.
 - 4 1 or 2 or 3
 - 5 neuropsych*.mp.
 - 6 behav*.mp.
 - 7 agitat*.mp.
 - 8 aggress*.mp.
 - 9 exp Behavioral Symptoms/
 - 10 exp Psychomotor Agitation/
 - 11 5 or 6 or 7 or 8 or 9 or 10
 - 12 4 and 11
 - 13 limit 12 to "therapy (maximizes sensitivity)"
 - 14 limit 13 to (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial phase iv or clinical trial or controlled clinical trial or randomized controlled trial)
 - 15 limit 14 to yr="1994-Current"

Embase Search Strategy:

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- 1 dementia/
 - 2 Alzheimer*.ti.
 - 3 dementia.ti.
 - 4 1 or 2 or 3
 - 5 agitation/
 - 6 neuropsych*.mp.
 - 7 agitat*.mp.
 - 8 behav*.mp.
 - 9 exp behavior/
 - 10 aggres*.mp.
 - 11 5 or 6 or 7 or 8 or 9 or 10
 - 12 4 and 11
 - 13 limit 12 to "therapy (maximizes sensitivity)"
 - 14 limit 13 to (article or journal)
 - 15 limit 14 to (randomized controlled trial or multicenter study)
 - 16 limit 15 to yr="1994-Current"

Appendix B. Excluded Studies

(Reason for exclusion appears in italics following each reference)

1. Bourgeois MS, Burgio LD, Schulz R, et al. Modifying repetitive verbalizations of community-dwelling patients with AD. *Gerontologist*. 1997 Feb;37(1):30-9. PMID WOS:A1997WH81800005. *Not randomized controlled trial*
2. Burgio LD, Stevens A, Burgio KL, et al. Teaching and maintaining behavior management skills in the nursing home. *Gerontologist*. 2002 Aug;42(4):487-96. PMID 12145376. *Include- Population not dementia population*
3. Burns R, Nichols LO, Martindale-Adams J, et al. Primary care interventions for dementia caregivers: 2-year outcomes from the REACH study. *Gerontologist*. 2003 Aug;43(4):547-55. PMID WOS:000184967700011. *Not randomized controlled trial*
4. Callahan CM, Boustani MA, Unverzagt FW, et al. Effectiveness of collaborative care for older adults with Alzheimer disease in primary care - A randomized controlled trial. *Jama-Journal of the American Medical Association*. 2006 May 10;295(18):2148-57. PMID WOS:000237391300024. *Not randomized controlled trial*
5. Churchill M, Safaoui J, McCabe BW, et al. Using a therapy dog to alleviate the agitation and desocialization of people with Alzheimer's disease. *Journal of psychosocial nursing and mental health services*. 1999 Apr;37(4):16-22. PMID MEDLINE:10218187. *Not randomized controlled trial*
6. Clark PA, Bass DM, Looman WJ, et al. Outcomes for patients with dementia from the Cleveland Alzheimer's Managed Care Demonstration. *Aging & Mental Health*. 2004 Jan;8(1):40-51. PMID 14690867. *Intervention does not address agitation/aggression*
7. Huang HL, Shyu YIL, Chen MC, et al. A pilot study on a home-based caregiver training program for improving caregiver self-efficacy and decreasing the behavioral problems of elders with dementia in Taiwan. *International Journal of Geriatric Psychiatry*. 2003 Apr;18(4):337-45. PMID WOS:000182353600012. *Not randomized controlled trial*
8. Lyne KJ, Moxon S, Sinclair I, et al. Analysis of a care planning intervention for reducing depression in older people in residential care. *Aging & Mental Health*. 2006 Jul;10(4):394-403. PMID WOS:000238562200009. *Not Dementia Population not dementia population*
9. Moniz-Cook E, Agar S, Silver M, et al. Can staff training reduce behavioural problems in residential care for the elderly mentally ill? *International Journal of Geriatric Psychiatry*. 1998 Mar;13(3):149-58. PMID 9565836. *Not randomized controlled trial*
10. Teri L, Gibbons LE, McCurry SM, et al. Exercise plus behavioral management in patients with Alzheimer disease: a randomized controlled trial. *JAMA*. 2003 Oct 15;290(15):2015-22. PMID 14559955. *Intervention does not address agitation/aggression*
11. Teri L, McCurry SM, Logsdon R, et al. Training community consultants to help family members improve dementia care: A randomized controlled trial. *Gerontologist*. 2005 Dec;45(6):802-11. PMID WOS:000233699500010. *No behavioral outcomes*
12. Testad I, Mikkelsen A, Ballard C, et al. Health and well-being in care staff and their relations to organizational and psychosocial factors, care staff and resident factors in nursing homes. *International Journal of Geriatric Psychiatry*. 2010 Aug;25(8):789-97. PMID WOS:000280538300004. *Not randomized controlled trial*
13. Zanetti O, Frisoni GB, De Leo D, et al. Reality orientation therapy in Alzheimer disease: Useful or not? A controlled study. *Alzheimer Disease and Associated Disorders*. 1995;9(3):132-8. *No behavioral outcomes*
14. Aguirre E, Spector A, Hoe J, et al. Maintenance Cognitive Stimulation Therapy (CST) for dementia: a single-blind, multi-centre, randomized controlled trial of Maintenance CST vs. CST for dementia. *Trials [Electronic Resource]*. 2010;11:46. PMID 20426866. *Intervention does not address agitation/aggression*

15. Anderson K, Bird M, Macpherson S, et al. Findings from a pilot investigation of the effectiveness of a snoezelen room in residential care: should we be engaging with our residents more? *Geriatric Nursing*. 2011 May-Jun;32(3):166-77. PMID 21306798. *Not randomized controlled trial*
16. Avila R, Carvalho IA, Bottino CM, et al. Neuropsychological rehabilitation in mild and moderate Alzheimer's disease patients. *Behavioural Neurology*. 2007;18(4):225-33. PMID 18430980. *Neither arm is a nonpharmacologic intervention for agitation/aggression*
17. Bach D, Bach M, Bohmer F, et al. Reactivating occupational therapy: a method to improve cognitive performance in geriatric patients. *Age & Ageing*. 1995 May;24(3):222-6. PMID 7645443. *No behavioral outcomes*
18. Ballard C, Brown R, Fossey J, et al. Brief psychosocial therapy for the treatment of agitation in Alzheimer disease (the CALM-AD trial). *American Journal of Geriatric Psychiatry*. 2009 Sep;17(9):726-33. PMID 19700946. *Not randomized controlled trial*
19. Bird M, Jones RH, Korten A, et al. A controlled trial of a predominantly psychosocial approach to BPSD: treating causality. *International Psychogeriatrics*. 2007 Oct;19(5):874-91. PMID 17234041. *Not randomized controlled trial*
20. Burgener SC, Yang Y, Gilbert R, et al. The effects of a multimodal intervention on outcomes of persons with early-stage dementia. *American Journal of Alzheimer's Disease & Other Dementias*. 2008 Aug-Sep;23(4):382-94. PMID 18453642. *Intervention does not address agitation/aggression*
21. Camic PM, Williams CM, Meeten F. Does a 'Singing Together Group' improve the quality of life of people with a dementia and their carers? A pilot evaluation study. *Dementia*. 2013 Mar;12(2):157-76. PMID 24336767. *Not randomized controlled trial*
22. Cerga-Pashoja A, Lowery D, Bhattacharya R, et al. Evaluation of exercise on individuals with dementia and their carers: a randomised controlled trial. *Trials [Electronic Resource]*. 2010;11:53. PMID 20465799. *Not randomized controlled trial*
23. Chang FY, Huang HC, Lin KC, et al. The effect of a music programme during lunchtime on the problem behaviour of the older residents with dementia at an institution in Taiwan. *Journal of Clinical Nursing*. 2010 Apr;19(7-8):939-48. PMID 20492038. *Not randomized controlled trial*
24. Cheng ST, Lau RW, Mak EP, et al. A benefit-finding intervention for family caregivers of persons with Alzheimer disease: study protocol of a randomized controlled trial. *Trials [Electronic Resource]*. 2012;13:98. PMID 22747914. *Not randomized controlled trial*
25. Choi AN, Lee MS, Cheong KJ, et al. Effects of group music intervention on behavioral and psychological symptoms in patients with dementia: a pilot-controlled trial. *International Journal of Neuroscience*. 2009;119(4):471-81. PMID 19229716. *Not randomized controlled trial*
26. Clare L, Woods RT, Whitaker R, et al. Development of an awareness-based intervention to enhance quality of life in severe dementia: trial platform. *Trials [Electronic Resource]*. 2010;11:73. PMID 20579370. *Not randomized controlled trial*
27. Cohen-Mansfield J, Marx MS, Thein K, et al. The impact of stimuli on affect in persons with dementia. *Journal of Clinical Psychiatry*. 2011 Apr;72(4):480-6. PMID 21527124. *Not randomized controlled trial*
28. Cyarto EV, Cox KL, Almeida OP, et al. The fitness for the Ageing Brain Study II (FABS II): protocol for a randomized controlled clinical trial evaluating the effect of physical activity on cognitive function in patients with Alzheimer's disease. *Trials [Electronic Resource]*. 2010;11:120. PMID 21143943. *Not randomized controlled trial*
29. Davison TE, Hudgson C, McCabe MP, et al. An individualized psychosocial approach for "treatment resistant" behavioral symptoms of dementia among aged care residents. *International Psychogeriatrics*. 2007 Oct;19(5):859-73. PMID 16973098. *Not randomized controlled trial*
30. Denney A. Quiet music. An intervention for mealtime agitation? *Journal of Gerontological Nursing*. 1997 Jul;23(7):16-23. PMID 9287602. *Not randomized controlled trial*

31. Dias A, Dewey ME, D'Souza J, et al. The effectiveness of a home care program for supporting caregivers of persons with dementia in developing countries: a randomised controlled trial from Goa, India. *PLoS ONE* [Electronic Resource]. 2008;3(6):e2333. PMID 18523642. *Neither arm is a nonpharmacologic intervention for agitation/aggression*
32. Done DJ, Thomas JA. Training in communication skills for informal carers of people suffering from dementia: a cluster randomized clinical trial comparing a therapist led workshop and a booklet. *International Journal of Geriatric Psychiatry*. 2001 Aug;16(8):816-21. PMID 11536349. *Intervention does not address agitation/aggression*
33. Dunn JC, Thiru-Chelvam B, Beck CH. Bathing. Pleasure or pain? *Journal of Gerontological Nursing*. 2002 Nov;28(11):6-13. PMID 12465197. *Not randomized controlled trial*
34. Edberg A, Hallberg IR. Actions seen as demanding in patients with severe dementia during one year of intervention. Comparison with controls. *International Journal of Nursing Studies*. 2001 Jun;38(3):271-85. PMID 11245864. *Not randomized controlled trial*
35. Fan JT, Chen KM. Using silver yoga exercises to promote physical and mental health of elders with dementia in long-term care facilities. *International Psychogeriatrics*. 2011 Oct;23(8):1222-30. PMID 21385519. *Not randomized controlled trial*
36. Farina E, Mantovani F, Fioravanti R, et al. Evaluating two group programmes of cognitive training in mild-to-moderate AD: is there any difference between a 'global' stimulation and a 'cognitive-specific' one? *Aging & Mental Health*. 2006 May;10(3):211-8. PMID 16777648. *Not randomized controlled trial*
37. Farina E, Mantovani F, Fioravanti R, et al. Efficacy of recreational and occupational activities associated to psychological support in mild to moderate Alzheimer disease: a multicenter controlled study. *Alzheimer Disease & Associated Disorders*. 2006 Oct-Dec;20(4):275-82. PMID 17132973. *Not randomized controlled trial*
38. Gitlin LN, Mann WC, Vogel WB, et al. A non-pharmacologic approach to address challenging behaviors of Veterans with dementia: description of the tailored activity program-VA randomized trial. *BMC Geriatrics*. 2013;13:96. PMID 24060106. *Not randomized controlled trial*
39. Gitlin LN, Winter L, Dennis MP, et al. A non-pharmacological intervention to manage behavioral and psychological symptoms of dementia and reduce caregiver distress: design and methods of project ACT3. *Clinical Interventions In Aging*. 2007;2(4):695-703. PMID 18225471. *Not randomized controlled trial*
40. Gray SG, Clair AA. Influence of aromatherapy on medication administration to residential-care residents with dementia and behavioral challenges. *American Journal of Alzheimer's Disease & Other Dementias*. 2002 May-Jun;17(3):169-74. PMID 12083347. *Not randomized controlled trial*
41. Haffmans PM, Sival RC, Lucius SA, et al. Bright light therapy and melatonin in motor restless behaviour in dementia: a placebo-controlled study. *International Journal of Geriatric Psychiatry*. 2001 Jan;16(1):106-10. PMID 11180494. *Intervention does not address agitation/aggression*
42. Halek M, Dichter MN, Quasdorf T, et al. The effects of dementia care mapping on **nursing home residents'** quality of life and staff attitudes: design of the quasi-experimental study *Leben-QD II*. *BMC Geriatrics*. 2013;13:53. PMID 23725292. *Not randomized controlled trial*
43. Hart BD, Wells DL. The effects of language used by caregivers on agitation in residents with dementia. *Clinical Nurse Specialist*. 1997 Jan;11(1):20-3. PMID 9233134. *Intervention does not address agitation/aggression*
44. Haupt M, Karger A, Janner M. Improvement of agitation and anxiety in demented patients after psychoeducative group intervention with their caregivers. *International Journal of Geriatric Psychiatry*. 2000 Dec;15(12):1125-9. PMID 11180469. *Not randomized controlled trial*
45. Hebert R, Levesque L, Vezina J, et al. Efficacy of a psychoeducative group program for caregivers of demented persons living at home: a randomized controlled trial. *Journals of Gerontology Series B-Psychological Sciences & Social Sciences*. 2003 Jan;58(1):S58-67. PMID 12496309. *Intervention does not address agitation/aggression*

46. Herrmann N, Cappell J, Eryavec GM, et al. Changes in nursing burden following memantine for agitation and aggression in long-term care residents with moderate to severe Alzheimer's disease: an open-label pilot study. *CNS Drugs*. 2011 May;25(5):425-33. PMID 21476613. *Neither arm is a nonpharmacologic intervention for agitation/aggression*
47. Ho SY, Lai HL, Jeng SY, et al. The effects of researcher-composed music at mealtime on agitation in nursing home residents with dementia. *Archives of Psychiatric Nursing*. 2011 Dec;25(6):e49-55. PMID 22114806. *Not randomized controlled trial*
48. Hoeffler B, Talerico KA, Rasin J, et al. Assisting cognitively impaired nursing home residents with bathing: effects of two bathing interventions on caregiving. *Gerontologist*. 2006 Aug;46(4):524-32. PMID 16921006. *No behavioral outcomes*
49. Holm A, Michel M, Stern GA, et al. The outcomes of an inpatient treatment program for geriatric patients with dementia and dysfunctional behaviors. *Gerontologist*. 1999 Dec;39(6):668-76. PMID 10650676. *Not randomized controlled trial*
50. Holmes C, Hopkins V, Hensford C, et al. Lavender oil as a treatment for agitated behaviour in severe dementia: a placebo controlled study. *International Journal of Geriatric Psychiatry*. 2002 Apr;17(4):305-8. PMID 11994882. *Not randomized controlled trial*
51. Huey ED, Garcia C, Wassermann EM, et al. Stimulant treatment of frontotemporal dementia in 8 patients. *Journal of Clinical Psychiatry*. 2008 Dec;69(12):1981-2. PMID 19203481. *Intervention does not address agitation/aggression*
52. Ismail Z, Emeremni CA, Houck PR, et al. A comparison of the E-BEHAVE-AD, NBRs, and NPI in quantifying clinical improvement in the treatment of agitation and psychosis associated with dementia. *American Journal of Geriatric Psychiatry*. 2013 Jan;21(1):78-87. PMID 23290205. *Neither arm is a nonpharmacologic intervention for agitation/aggression*
53. Jablonski RA, Kolanowski A, Therrien B, et al. Reducing care-resistant behaviors during oral hygiene in persons with dementia. *BMC Oral Health*. 2011;11:30. PMID 22100010. *Not randomized controlled trial*
54. Kolanowski AM, Fick DM, Clare L, et al. Pilot study of a nonpharmacological intervention for delirium superimposed on dementia. *Research in Gerontological Nursing*. 2011 Jul;4(3):161-7. PMID 21053841. *No behavioral outcomes*
55. Leone E, Deudon A, Bauchet M, et al. Management of apathy in nursing homes using a teaching program for care staff: the STIM-EHPAD study. *International Journal of Geriatric Psychiatry*. 2013 Apr;28(4):383-92. PMID 22700526. *Intervention does not address agitation/aggression*
56. Libin A, Cohen-Mansfield J. Therapeutic robot for nursing home residents with dementia: preliminary inquiry. *American Journal of Alzheimer's Disease & Other Dementias*. 2004 Mar-Apr;19(2):111-6. PMID 15106392. *Not randomized controlled trial*
57. Liddle J, Smith-Conway ER, Baker R, et al. Memory and communication support strategies in dementia: effect of a training program for informal caregivers. *International Psychogeriatrics*. 2012 Dec;24(12):1927-42. PMID 23092595. *Intervention does not address agitation/aggression*
58. Logsdon RG, McCurry SM, Teri L. A home health care approach to exercise for persons with Alzheimer's disease. *Care Management Journals*. 2005;6(2):90-7. PMID 16544870. *Not randomized controlled trial*
59. Logsdon RG, Teri L, Weiner MF, et al. Assessment of agitation in Alzheimer's disease: the agitated behavior in dementia scale. *Alzheimer's Disease Cooperative Study*. *Journal of the American Geriatrics Society*. 1999 Nov;47(11):1354-8. PMID 10573447. *Not randomized controlled trial*
60. Luk KY, Lai KY, Li CC, et al. The effect of horticultural activities on agitation in nursing home residents with dementia. *International Journal of Geriatric Psychiatry*. 2011 Apr;26(4):435-6. PMID 21412848. *Not randomized controlled trial*
61. Mahoney DM, Tarlow B, Jones RN, et al. Factors affecting the use of a telephone-based intervention for caregivers of people with Alzheimer's disease. *Journal of Telemedicine & Telecare*. 2001;7(3):139-48. PMID 11346473. *Not randomized controlled trial*

62. Marques A, Cruz J, Barbosa A, et al. Motor and multisensory care-based approach in dementia: long-term effects of a pilot study. *American Journal of Alzheimer's Disease & Other Dementias*. 2013 Feb;28(1):24-34. PMID 23221028. *Not randomized controlled trial*
63. Martindale-Adams J, Nichols LO, Burns R, et al. A trial of dementia caregiver telephone support. *Canadian Journal of Nursing Research*. 2013 Dec;45(4):30-48. PMID 24617278. *Intervention does not address agitation/aggression*
64. Matteson MA, Linton AD, Cleary BL, et al. Management of problematic behavioral symptoms associated with dementia: a cognitive developmental approach. *Aging-Clinical & Experimental Research*. 1997 Oct;9(5):342-55. PMID 9458995. *Not Dementia Population not dementia population*
65. Matthews EA, Farrell GA, Blackmore AM. Effects of an environmental manipulation emphasizing client-centred care on agitation and sleep in dementia sufferers in a nursing home. *Journal of Advanced Nursing*. 1996 Sep;24(3):439-47. PMID 8876402. *Not randomized controlled trial*
66. McCabe MP, Mellor D, Davison TE, et al. A study protocol to investigate the management of depression and challenging behaviors associated with dementia in aged care settings. *BMC Geriatrics*. 2013;13:95. PMID 24047236. *Not randomized controlled trial*
67. McCurry SM, Logsdon RG, Vitiello MV, et al. Successful behavioral treatment for reported sleep problems in elderly caregivers of dementia patients: a controlled study. *Journals of Gerontology Series B-Psychological Sciences & Social Sciences*. 1998 Mar;53(2):P122-9. PMID 9520929. *Intervention does not address agitation/aggression*
68. Miller S, Vermeersch PE, Bohan K, et al. Audio presence intervention for decreasing agitation in people with dementia. *Geriatric Nursing*. 2001 Mar-Apr;22(2):66-70. PMID 11326212. *Not randomized controlled trial*
69. Mishima K, Okawa M, Hishikawa Y, et al. Morning bright light therapy for sleep and behavior disorders in elderly patients with dementia. *Acta Psychiatrica Scandinavica*. 1994 Jan;89(1):1-7. PMID 8140901. *Not Dementia Population not dementia population*
70. Mossello E, Ridolfi A, Mello AM, et al. Animal-assisted activity and emotional status of patients with Alzheimer's disease in day care. *International Psychogeriatrics*. 2011 Aug;23(6):899-905. PMID 21356158. *Not randomized controlled trial*
71. Mowrey C, Parikh PJ, Bharwani G, et al. Application of behavior-based ergonomics therapies to improve quality of life and reduce medication usage for Alzheimer's/dementia residents. *American Journal of Alzheimer's Disease & Other Dementias*. 2013 Feb;28(1):35-41. PMID 23196404. *Not randomized controlled trial*
72. Nair BK, Heim C, Krishnan C, et al. The effect of Baroque music on behavioural disturbances in patients with dementia. *Australasian Journal on Ageing*. 2011 Mar;30(1):11-5. PMID 21395934. *Not randomized controlled trial*
73. Nichols LO, Martindale-Adams J, Burns R, et al. Translation of a dementia caregiver support program in a health care system--REACH VA. *Archives of Internal Medicine*. 2011 Feb 28;171(4):353-9. PMID 21357811. *Not randomized controlled trial*
74. Nolan BA, Mathews RM. Facilitating resident information seeking regarding meals in a special care unit: an environmental design intervention. *Journal of Gerontological Nursing*. 2004 Oct;30(10):12-6; quiz 55-6. PMID 15515440. *Not randomized controlled trial*
75. Oh H, Hur MH, Eom M. Development and analysis of the effects of caregiver training program on aggressive behavior in elders with cognitive impairment. *Daehan Ganho Haghoeji*. 2005 Jun;35(4):745-53. PMID 16037730. *Not randomized controlled trial*
76. O'Shea E, Devane D, Murphy K, et al. Effectiveness of a structured education reminiscence-based programme for staff on the quality of life of residents with dementia in long-stay units: a study protocol for a cluster randomised trial. *Trials [Electronic Resource]*. 2011;12(1):41. PMID 21320303. *Not randomized controlled trial*
77. Perilli V, Lancioni GE, Hoogeveen F, et al. Video prompting versus other instruction strategies for persons with Alzheimer's disease. *American Journal of Alzheimer's Disease & Other Dementias*. 2013 Jun;28(4):393-402. PMID 23687181. *No behavioral outcomes*

78. Pieper MJ, Achterberg WP, Francke AL, et al. The implementation of the serial trial intervention for pain and challenging behaviour in advanced dementia patients (STA OP!): a clustered randomized controlled trial. *BMC Geriatrics*. 2011;11:12. PMID 21435251. *Not randomized controlled trial*
79. Raggi A, Iannaccone S, Marcone A, et al. The effects of a comprehensive rehabilitation program of Alzheimer's Disease in a hospital setting. *Behavioural Neurology*. 2007;18(1):1-6. PMID 17297213. *Not randomized controlled trial*
80. Raglio A, Bellandi D, Baiardi P, et al. Listening to music and active music therapy in behavioral disturbances in dementia: a crossover study. *Journal of the American Geriatrics Society*. 2013 Apr;61(4):645-7. PMID 23581919. *Not randomized controlled trial*
81. Raglio A, Bellelli G, Traficante D, et al. Efficacy of music therapy in the treatment of behavioral and psychiatric symptoms of dementia. *Alzheimer Disease & Associated Disorders*. 2008 Apr-Jun;22(2):158-62. PMID 18525288. *Not randomized controlled trial*
82. Ragneskog H, Asplund K, Kihlgren M, et al. Individualized music played for agitated patients with dementia: analysis of video-recorded sessions. *International Journal of Nursing Practice*. 2001 Jun;7(3):146-55. PMID 11811810. *Not randomized controlled trial*
83. Ragneskog H, Kihlgren M, Karlsson I, et al. Dinner music for demented patients: analysis of video-recorded observations. *Clinical Nursing Research*. 1996 Aug;5(3):262-77; discussion 78-82. PMID 8850771. *Not randomized controlled trial*
84. Rogers JC, Holm MB, Burgio LD, et al. Improving morning care routines of nursing home residents with dementia. *Journal of the American Geriatrics Society*. 1999 Sep;47(9):1049-57. PMID 10484245. *Not randomized controlled trial*
85. Rovner BW, Steele CD, Shmueli Y, et al. A randomized trial of dementia care in nursing homes. *Journal of the American Geriatrics Society*. 1996 Jan;44(1):7-13. PMID 8537594. *Intervention does not address agitation/aggression*
86. Scherder EJ, Bouma A, Steen LM. Effects of "isolated" transcutaneous electrical nerve stimulation on memory and affective behavior in patients with probable Alzheimer's disease. *Biological Psychiatry*. 1998 Mar 15;43(6):417-24. PMID 9532346. *Intervention does not address agitation/aggression*
87. Schwarz B, Chaudhury H, Tofle RB. Effect of design interventions on a dementia care setting. *American Journal of Alzheimer's Disease & Other Dementias*. 2004 May-Jun;19(3):172-6. PMID 15214204. *Not randomized controlled trial*
88. Skjerve A, Holsten F, Aarsland D, et al. Improvement in behavioral symptoms and advance of activity acrophase after short-term bright light treatment in severe dementia. *Psychiatry & Clinical Neurosciences*. 2004 Aug;58(4):343-7. PMID 15298644. *Not randomized controlled trial*
89. Snow LA, Hovanec L, Brandt J. A controlled trial of aromatherapy for agitation in nursing home patients with dementia. *Journal of Alternative & Complementary Medicine*. 2004 Jun;10(3):431-7. PMID 15253846. *Not randomized controlled trial*
90. Snyder M, Egan EC, Burns KR. Interventions for decreasing agitation behaviors in persons with dementia. *Journal of Gerontological Nursing*. 1995 Jul;21(7):34-40. PMID 7615916. *Not randomized controlled trial*
91. Snyder M, Tseng Y, Brandt C, et al. A glider swing intervention for people with dementia. *Geriatric Nursing*. 2001 Mar-Apr;22(2):86-90. PMID 11326215. *Not randomized controlled trial*
92. Spector A, Orrell M, Lattimer M, et al. Cognitive behavioural therapy (CBT) for anxiety in people with dementia: study protocol for a randomised controlled trial. *Trials* [Electronic Resource]. 2012;13:197. PMID 23092336. *Not randomized controlled trial*
93. Spijker A, Wollersheim H, Teerenstra S, et al. Systematic care for caregivers of patients with dementia: a multicenter, cluster-randomized, controlled trial. *American Journal of Geriatric Psychiatry*. 2011 Jun;19(6):521-31. PMID 21358385. *Intervention does not address agitation/aggression*

94. Stella F, Canonici AP, Gobbi S, et al. Attenuation of neuropsychiatric symptoms and caregiver burden in Alzheimer's disease by motor intervention: a controlled trial. *Clinics (Sao Paulo, Brazil)*. 2011;66(8):1353-60. PMID 21915483. *Not randomized controlled trial*
95. Suzuki M, Kanamori M, Watanabe M, et al. Behavioral and endocrinological evaluation of music therapy for elderly patients with dementia. *Nursing & Health Sciences*. 2004 Mar;6(1):11-8. PMID 14764189. *Not randomized controlled trial*
96. Suzuki M, Tatsumi A, Otsuka T, et al. Physical and psychological effects of 6-week tactile massage on elderly patients with severe dementia. *American Journal of Alzheimer's Disease & Other Dementias*. 2010 Dec;25(8):680-6. PMID 21131675. *Not randomized controlled trial*
97. Thyrian JR, Fis T, Dreier A, et al. Life- and person-centred help in Mecklenburg-Western Pomerania, Germany (DelpHi): study protocol for a randomised controlled trial. *Trials [Electronic Resource]*. 2012;13:56. PMID 22575023. *Not randomized controlled trial*
98. van der Ploeg ES, Camp CJ, Eppingstall B, et al. The study protocol of a cluster-randomised controlled trial of family-mediated personalised activities for nursing home residents with dementia. *BMC Geriatrics*. 2012;12:2. PMID 22236064. *Not randomized controlled trial*
99. van der Ploeg ES, O'Connor DW. Evaluation of personalised, one-to-one interaction using Montessori-type activities as a treatment of challenging behaviours in people with dementia: the study protocol of a crossover trial. *BMC Geriatrics*. 2010;10:3. PMID 20096137. *Not randomized controlled trial*
100. van Dijk AM, van Weert JC, Droes RM. Does theatre improve the quality of life of people with dementia? *International Psychogeriatrics*. 2012 Mar;24(3):367-81. PMID 22040605. *Not randomized controlled trial*
101. van Weert JC, van Dulmen AM, Spreeuwenberg PM, et al. Behavioral and mood effects of snoezelen integrated into 24-hour dementia care. *Journal of the American Geriatrics Society*. 2005 Jan;53(1):24-33. PMID 15667372. *Not randomized controlled trial*
102. Venturelli M, Magalini A, Scarsini R, et al. From Alzheimer's disease retrogenesis: a new care strategy for patients with advanced dementia. *American Journal of Alzheimer's Disease & Other Dementias*. 2012 Nov;27(7):483-9. PMID 22984089. *Not randomized controlled trial*
103. Wang JJ, Yen M, OuYang WC. Group reminiscence intervention in Taiwanese elders with dementia. *Archives of Gerontology & Geriatrics*. 2009 Sep-Oct;49(2):227-32. PMID 18930560. *Not randomized controlled trial*
104. Wang KL, Hermann C. Pilot study to test the effectiveness of Healing Touch on agitation in people with dementia. *Geriatric Nursing*. 2006 Jan-Feb;27(1):34-40. PMID 16483898. *Not randomized controlled trial*
105. Ward-Smith P, Llanque SM, Curran D. The effect of multisensory stimulation on persons residing in an extended care facility. *American Journal of Alzheimer's Disease & Other Dementias*. 2009 Dec-2010 Jan;24(6):450-5. PMID 19846683. *Not randomized controlled trial*
106. Woods DL, Dimond M. The effect of therapeutic touch on agitated behavior and cortisol in persons with Alzheimer's disease. *Biological Research for Nursing*. 2002 Oct;4(2):104-14. PMID 12408216. *Not randomized controlled trial*
107. Yang MH, Wu SC, Lin JG, et al. The efficacy of acupressure for decreasing agitated behaviour in dementia: a pilot study. *Journal of Clinical Nursing*. 2007 Feb;16(2):308-15. PMID 17239066. *Not randomized controlled trial*
108. Van Bogaert P, Van Grinsven R, Tolson D, et al. Effects of SolCos model-based individual reminiscence on older adults with mild to moderate dementia due to Alzheimer disease: a pilot study. *Journal of the American Medical Directors Association*. 2013 Jul;14(7):528.e9-13. PMID 23583001. *Not randomized controlled trial*

Appendix C. Patient-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities

Table C1. Patient-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities: Risk of bias assessments

Study	Risk of Bias Assessment
Ancoli- Israel, 2003 ¹	Moderate - Patient blinding unclear; staff/outcome assessors not blinded, staff reported preconceptions of what each treatment group would do for the patients; analysis methods do not mention attrition, but period is short so possibly little.
Baillon, 2004 ²	High. High performance, detection, and attrition bias.
Baker, 2003 ³	Moderate - Fidelity issues, also different organizational contexts across countries, high attrition.
Ballard, 2002 ⁴	Moderate -Randomization at facility level but study does not account for facility differences.
Beck, 2002 ⁵	Moderate - Attrition not equal in groups.
Burns, 2009 ⁶	Low
Camberg, 1999 ⁷	Moderate - Intervention not implemented as directed, instruments not validated for agitation; staff reporting may introduce bias.
Clark, 1998 ⁸	High - Blinding unclear; Only valid data presented in line graphs; other data combines from crossover groups; attrition and missing data unclear.
Cohen-Mansfield, 2012 ⁹	Moderate - Selection bias, unclear performance bias, potential detection bias.
Cohen-Mansfield, 2007 ¹⁰	High - Partial randomization; baseline characteristics not similar regarding age; no mention of blinding of participants, interventionists, manuals, power analysis, attrition, or handling of missing data; outcome assessors not blinded; co-interventions not similar.
Cooke, 2010 ¹¹	Low
Deponte, 2007 ¹²	High - Selection and randomization unclear; high performance bias; blinding and fidelity unclear; incomplete data not handled appropriately; underpowered.
Dowling, 2007 ¹³	Moderate - Performance and detection bias unclear; high attrition.
Fu, 2013 ¹⁴	Moderate - Mid intervention they had 5 dropouts that withdrew consent because they wanted to be sure they were in experimental group--they were dropped so ITT model not completely used.
Fuji, 2008 ¹⁵	Moderate - Performance bias may be an issue; they did the aroma therapy 3 times a day an hour after meals; no placebo control
Garland, 2007 ¹⁶	High - Unclear randomization method and baseline characteristics, no mention of fidelity checks, manuals, outcome assessors, power and attrition; High risk of reporting bias; Crossover study. Unclear if patients were observed for all outcomes or only those which the patient primarily displayed. Unsure if 2-day washout is appropriately long enough. Assessors not completely blinded (seemed to guess which treatment the participant had). Many excluded participants seemingly after randomization. Not ITT analysis.
Gerdner, 2000 ¹⁷	High - Unclear randomization method, no mention of blinding of participants, interventionists, fidelity checks, manuals and outcome assessors. No mention of power analysis or handling of missing data; Crossover study; Unblinded outcome assessor (RA who did assessment was also there while the music was playing); Possibly unbalanced groups at baseline (no demographic table, but mention 2 of 16 demographic variables significantly different). Low attrition. Not ITT analysis.
Hatakeyama, 2010 ¹⁸	High - Small sample size; selective recruitment unclear randomization, Blinding, Attrition, Fidelity.
Hawranik, 2008 ¹⁹	Moderate - Selection bias, small sample size, diffusion, definition of intervention, fidelity unclear.
Houser, 2014 ²⁰	High - Unclear randomization method, small study sample (no power analysis); no mention of blinding of participants, interventionists, fidelity checks, manuals and outcome assessors. No mention of handling of missing data.
Hozumi, 1996 ²¹	Moderate - Participants seemingly blinded, unclear about outcomes assessors. Attrition unclear. Missing data unclear.
Ito, 2007 ²²	Moderate - Participants and staff not blinded. High attrition and MNAR obvious from group comparisons. Not ITT analysis. High possibility for bias for how data is presented for primary and secondary analysis purposes.
Jablonski, 2005 ²³	High - Selection bias; performance bias (actual implementation of intervention, fidelity checks, hard to know what exactly was done for the intervention.

Study	Risk of Bias Assessment
Kolanowski, 2005 ²⁴	Moderate - Crossover study. Outcome assessors blinded. Only selected certain behaviors by patient, did not assess all behaviors. Fidelity checks appropriate. Study design and analysis very confusing since A, B, and C treatments are individualized. Multiple comparisons correction unclear but unlikely and many comparisons were made. Not ITT analysis.
Kolanowski, 2011 ²⁵	Moderate – Baseline differences among groups.
Kovach, 2004 ²⁶	Moderate – Performance bias; nurses sometimes didn't implement if they were too busy; had to change schedules several times, groups unequal at baseline; high attrition.
Landi, 2004 ²⁷	High - Authors call this a case control study but mention randomization. Blinding unclear. Little description of intervention. No mention of attrition or missingness. Bar graphs only for outcomes.
Lawton, 1998 ²⁸	High - About 50% attrition rate, missing data not appropriately handled, outcome assessors not blinded. Fidelity and Power unclear.
Lichenberg, 2005 ²⁹	Moderate -Assessor not blinded—an outside geriatric neuropsychologist; attrition not reported.
Lin, 2007 ³⁰	Moderate - Non-random sampling, issues with design (assumes no changes in condition), staff were not blinded to outcomes.
Lin, 2009 ³¹	Low
Lin, 2011 ³²	Moderate - Some issues with selection bias and contamination (in the same facility); blinding unclear; low attrition; likely not ITT analysis, but unclear; did not appear to correct for multiple comparisons.
Lyketsos, 1999 ³³	Moderate - High attrition, not clear about how these patients were selected (and small sample size), whether sample was appropriate (did not report concerns with sleep/wake cycles), concerned about diffusion, not clear if staff were trained differently, etc.
McCallion, 1999a ³⁴	Moderate - Unclear regarding method of randomization and study may be under powered, unbalanced on two baseline measures one being length of stay which may mean there are unobserved disease severity variables impacting results.
Milev, 2008 ³⁵	High - No ITT analysis; mostly unblinded; Low attrition, but small population. Unbalanced groups at baseline; selection bias, contamination, power issues, Inadequate randomization. -Incomplete data not handled appropriately; Lack of blinding of outcome assessors.
Narme, 2014 ³⁶	High - Selection bias (only native French speakers, those without musical expertise, etc.); diffusion issues in same NH; attrition issues, small sample size, no usual care control group; very high attrition; assessors blinded; blinding of participants unclear; Not ITT analysis.
Raglio, 2010 ³⁷	Moderate – High attrition issues, differences across experimental and control groups, inadequate controls in statistical models.
Remington, 2002 ³⁸	Moderate - Issues with detection bias, questions about whether this was the right sample (residents all had low scores for agitation).
Ridder, 2013 ³⁹	High - Unblinded. Some baseline differences. Paired RCT. Say ITT analysis but then say they exclude missing data from main analysis.
Robichaud, 1994 ⁴⁰	Moderate - Issues with selection bias, sample size, diffusion across institutions, concerns about fidelity of the program; Some baseline differences between groups. Second assessment unblinded. Participant blinding unclear. ITT analysis. Low attrition.
Rodriguez-Mansilla, 2013 ⁴¹	Moderate – Self designed instruments not validated.
Rolland, 2007 ⁴²	Moderate - Only assessor blinded. Low attrition. Not ITT analysis for outcomes we are interested in here.
Sakamoto, 2013 ⁴³	Moderate - Not enough information about selection of patients, short followup, power issues; Participant blinding unclear. Assessors blinded. Corrected for multiple comparisons. Attrition unclear.
Sloane, 2004 ⁴⁴	High - Group-randomized trial. Participant blinding unclear. Assessors blinded. Analyses combined treatment groups (person-centered vs. towel were separate time periods in two groups, seemingly combined for analysis). Baseline differences for important characteristics. Corrected for multiple comparisons. Attrition unclear.
Smallwood, 2001 ⁴⁵	High - Study does not have enough power to detect a difference. The allocation of subjects is poorly described. Differences between controls and active group; Participant blinding unclear. Outcome assessors and aromatherapist blinded. Attrition unclear. Analysis methods not described.
Staal, 2007 ⁴⁶	High - Selection bias, low sample size, differences between exp. and control groups; Participant blinding unclear. Nurse assessors unblinded. Reported significant group differences at baseline. Attrition unclear.
Sung, 2006 ⁴⁷	High - Low attrition, but not ITT analysis. Researchers blinded, outcome assessors not blinded.

Study	Risk of Bias Assessment
Sung, 2012 ⁴⁸	High - No blinding; single facility; tool for measuring anxiety has poor validity; Low attrition, but not ITT analysis. Not blinded.
Svansdottir, 2006 ⁴⁹	High - Authors refer to it as a case-control study, but it appears to be RCT. Little information about analysis, but not ITT analysis according to tables. Attrition under 20%. Outcome assessors blinded. Blinding of intervention staff and patients unclear.
Van de Winckel, 2004 ⁵⁰	High - Practitioner not blinded. Behavior assessors blinded to treatment. Cognition assessor not blinded (same person who delivered intervention). Low attrition.
Van der Ploegg, 2013 ⁵¹	Moderate – Control intervention same number of one-on-one therapy time; unclear if outcomes assessors blinded; underpowered; odd selection of instruments for agitation trial.
Vink, 2013 ⁵²	Moderate - Nurses who took patients to activities were those who completed outcomes instruments. Not ITT analysis. Attrition okay, but excluded a lot of people from analysis.
Woods, 2005 ⁵³	Moderate - Blinded patients and assessors, not research assistants who performed intervention. Questionable assignment of research assistants to TT and placebo groups.
Woods, 2009 ⁵⁴	High - Blinded. Dropped one participant from the study and analysis due to problem behaviors. Did not correct for multiple comparisons, yet many time points shown. Did not seem to present results for each measure collected.

Patient-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities: Description of Trials Rated High Risk of Bias

Music

Seven studies of music intervention were rated as having high risk of bias.^{8,17,36,39,47-49} Both the Sung studies were participatory with the first involving movement, and the second involving percussion instruments;^{47,48} Narme et al., was a group music therapy intervention.³⁶ The other four studies used individual interventions;^{8,17,39,49} Clark et al. used pre-recorded soothing music for residents with a history of aggression during bathing; Gerdner et al. compared listening to recordings of preferred music rather than recordings of classical music; and Ridder et al. tested the effects of individual in-person music therapy compared with usual care (which often included group music therapy). These studies are briefly summarized below.³⁹

In a cross-over design with 18 subjects, Clark et al. examined the effects of prerecorded music on aggressive behavior among people with severe Alzheimer's type dementia during bath time in a 2-week period, compared with usual care.⁸ Significant decreases were found in hitting behaviors during the intervention, and "discussions with caregivers" was associated with less agitation during the intervention.

Gerdner, et al., in a cross-over design, 39 residents participated in a study comparing 30 minute periods listening to recordings of relaxing classical music versus recordings of preferred music during their lives, as determined by family members completing a preferred music questionnaire on their behalf.¹⁷ Dose was 30 minutes 2 days a week. The outcomes were measured by the Temporal Pattern in Assessment of Agitation (TPAA) scale, which was modified from the CMAI. The study compared the immediate and 30-minute residual effects of the individualized music. Positive findings are reported, but the raters of outcomes were the ones who applied the intervention.

Sung, et al. studied a 1-month study of 30-minute, twice weekly sessions of group music therapy with movement compared with usual care in a single large Taiwanese nursing home.⁴⁷ The authors reported significant decrease in episodes of agitation by week 2 and week 4 using CMAI.

Sung et al. randomized 60 residents from a Taiwanese residential care facility to the intervention (active participation in music therapy with percussion instruments and exercise for 30 minutes twice-weekly for a month versus usual care).⁴⁸ Authors reported no differences in agitation but significantly less anxiety on the RAID measure in the music group compared with the control group.

Narme, et al. randomized 48 residents with dementia in a single nursing home in France to music therapy or a cooking group;³⁶ 37 remained in the study for analysis. Groups lasted for an hour, and were conducted twice weekly for 4 weeks. They found no differences in reduction of agitation between the new groups measured by CMAI and by NPI.

Ridder et al. conducted a cross-over trial in 14 nursing homes in Denmark and Norway.³⁹ Forty-two paired participants were randomized to 6 weeks of individualized music therapy or 6 weeks of usual care, which could include group music therapy. In this nonblinded study, the experimental group experienced a significant reduction in agitation while the control group was reported to have had a significant increase in psychoactive medication prescriptions.

Aromatherapy

Smallwood et al. randomized 21 district general hospital ward patients into three groups: aromatherapy and massage, conversation and aromatherapy, and massage only (seven per group).⁴⁵ The intervention is not well explained, but it appears that the aromatic oil was used for massage in the combined group, conversation occurred during aromatherapy for the second group, and ordinary oil was used for massage in the last group. Each individual received treatment twice weekly, after which the patients' behavior was recorded. Treatment time of day was rotated in each period so that over the course of the study each person received treatment twice in each period of the day. The study used a single-blind design. Frequency of behaviors was based on daily recordings. Findings showed no overall difference in frequency of behavior across groups. Aromatherapy and massage showed a reduction in the frequency of excessive motor behavior (one of the domain on the scale) of all three conditions which reached statistical significance between 3 p.m. to 4 p.m. ($P < 0.05$).

Tailored Interventions

Two studies involving individual assessments and tailored activity interventions to reduce agitation were identified but rated as having a high risk of bias. One is an earlier study of the TREAS model;¹⁰ a later study of TREAS was rated as having lesser risk of bias and is included in our analysis.⁹ The second is a study of that attempts to achieve optimal mix of stimulation and withdrawal tailored to the residents' needs.²⁸ The two studies are briefly described below.

Cohen-Mansfield et al. tested the efficacy of an algorithm for providing individualized nonpharmacological approaches to reduce agitation tailored to individual profiles of each resident's unmet needs, physical, cognitive, and sensory abilities; and with interventions based on residents' lifelong habits and roles and well as abilities: TREA (Treatment Routes for Exploring Agitation).¹⁰ Interventions were applied for 10 days during the 4 hours of the individual's greatest agitation. The study was conducted in 12 Maryland nursing homes, 6 used as experimental and 6 used as controls. The implementation of personalized, nonpharmacological interventions resulted in statistically significant decreases in overall agitation in the intervention group relative to the control group from baseline to treatment and implementation of individualized interventions for agitation resulted in statistically significant increases in pleasure and interest.

Lawton et al. randomized residents from two Dementia Special Care Units in the same nursing home to the condition of receiving a package of care according to individually assessed needs for stimulation or release from stimulation (retreat).²⁸ The study was conducted over 2 years, with considerable difficulty in implementation because of noncooperation of care teams and interference of prescribed the stimulation-retreat cycle with staff duties and resident schedules. Over time most functions worsened for both groups, agitated behavior did not decline more in the experimental unit, and there was marginal improvement in external engagement and lesser declines in positive affect and greater increases in negative affect in the experimental group.

Family Involvement in Care

Jablonski et al. tested family involvement in care using contracts to identify the type, frequency, and duration of involvement and activity that the family agreed to have.²³ The intervention is the Family Involvement in Care (FIC) protocol, whereby a primary family

member is oriented to the facility, educated on potential involvement in resident care, and contracts to participate in a specified number of care activities in nine possible areas of care) for a specified amount of time. The dosage is calculated across all types and amount of activities. The experimental group exhibited less global deterioration but inappropriate behavior remained the same.

Creative Activity Program (TimeSlips)

Houser et al. tested a creative story telling intervention called TimeSlips.²⁰ This small pilot study evaluated the creative story-telling activity known as TimeSlips (wherein residents react to a picture with story ideas that are recorded and then read back to participants as their collective story) for its effect on behavioral symptoms and mood. The intervention group of 10 residents received two 1-hour TimeSlips sessions for 6 weeks and the comparison group of 10 residents received standard activity programming for 6 weeks. In this pilot study no statistically significant differences in mood or behavior were found.

Validation Versus Sensorial Reminiscence Versus No treatment

Deponte et al. compared validation therapy to sensorial reminiscence to no control and measured outcomes with the NPI.¹²

Simulated Presence

Garland et al. tested simulated family presence (15-minute audiotapes by a family member about a positive experience from the past), music preferred by the resident in earlier life, and a placebo condition of reading from a horticultural text, to usual care.¹⁶ The tapes were applied once a day for 3 days a week for 3 weeks. Family presence and preferred music both led to reduced counts of physically agitated behavior, and simulated presence (but not music) resulted in significantly reduced counts of verbally agitated behaviors. The placebo tape also was associated with benefits over usual care

Hatakeyama et al. tested an intervention consisting of modified television watching by screening a person's home-made DVD with favorite pictures and greetings of family members.¹⁸ Patients in a large Japanese long-term care setting who had a dementia diagnosis participated and were assigned to a homemade or comparable length commercial DVD for 2 hours each afternoon, for 4 weeks. Positive results in agitation are reported on the NPI.

Multisensory Stimulation

Staal et al. compared multisensory behavior therapy with a structured activity session.⁴⁶ The study took place on a geriatric psychiatric unit using a single-blinded, between-group study design. Twenty-four participants were randomized to MSBT or structured activity. Outcomes included the Pittsburgh Agitation Scale and the Scale for the Assessment of Negative Symptoms in Alzheimer's Disease. Combination treatment of MSBT and standard psychiatric care reduced agitation and apathy more than standard psychiatric inpatient care alone ($P = 0.05$). Multiple regression analysis predicted that within the multisensory group, apathy and agitation were reduced ($R^2 = 0.42$; $p = 0.03$).

Milev et al. used multisensory stimulation (MSS) study (using a Snoezelen room), in this case a dimly lit room that included many objects pertaining to the five senses: fiber-optic cables, aroma therapy, different music/sounds, water columns of different colors, textured balls to touch,

and screen projectors, among others.³⁵ Subjects were assigned to one of three groups. The control group received no experimental treatment for the entire duration of the study and had only care as usual. The first experimental group had one Snoezelen session per week, and the other experimental group had three Snoezelen sessions per week for 12 weeks. Each session lasted for 30 minutes on a 1:1 basis with a qualified Snoezelen facilitator. At the end of the 12 weeks, all participants received no Snoezelen treatment for another 12 weeks. The 21 participants were randomly assigned to one of three groups. Outcomes included DOS mean scores. Patients who received one and three Snoezelen treatments per week had a consistently lower DOS mean score (i.e., they improved), without much fluctuation when compared with the control group. The effect was sustained even 12 weeks after the cessation of intervention.

Bathing

Sloane et al. randomized residents with dementia and a history of agitation during bathing to person-centered showering, a towel bath (i.e., a person-centered, in-bed, bag-bath with no-rinse soap), or usual care bathing.⁴⁴ The study was done in nine Oregon and six North Carolina facilities using a cross-over design between the two experimental conditions with randomization at the facility level. The Care Recipient Behavior Assessment (CAREBA), a modification of the CMAI, was used to rate behaviors for the videotaped bathing experience. All measures of agitation and aggression declined significantly in both treatment groups but not in the control group, with aggressive incidents declining 53 percent in the person-centered shower group ($P < .001$) and 60 percent in the towel-bath group ($P < .001$). Discomfort scores also declined significantly in both intervention groups ($P < .001$) but not in the control group. The two interventions did not differ in agitation/aggression reduction,

Multisensory Stimulation Versus Reminiscence

Baillon, et al. used Snoezelen versus reminiscence sessions as an attention control.² Each subject was allocated one of three research staff with whom they had all their intervention sessions. This staff member spent time with the resident prior to commencing the interventions. Sessions lasted up to 40 minutes every day for 2 weeks. The study was done at the Bennion Centre, Glenfield General Hospital, at Foxton Grange, which is a charity-run nursing home for older people, and at the Evington Centre, Leicester General Hospital. Subjects were randomized to one of two groups using a sealed envelope technique. Outcomes included the ABMI with reference to 3-minute samples before, immediately after, 15 minutes after, and 30 minutes after each therapy session. No statistically significant differences were seen between Snoezelen and Reminiscence sessions in terms of the change in level of agitation from pre-session to immediately post-session (CI -4.3 to 2.0) or from pre-session to 15 minutes post-session (CI -2.0 to 3.4).

Exercise

Landi et al. studied an exercise program in nursing homes in managing dementia residents' behaviors and use of antipsychotic drugs.²⁷

Therapeutic Touch

Woods et al. studied therapeutic touch on behavior of nursing home residents with dementia.⁵⁴

Table C2. Patient-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities: strength of evidence assessments

Comparison	Outcome (Instrument) # Trials (n)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
Music vs. Passive Control (for sustained reduction in agitation/aggression)	Patient Agitation/Aggression k=4; n=233	Standardized Mean Difference ^{32,43} -0.18 95% CI:-2.41 to 2.05 NPI Agitation Subscale , mean (SD) ³⁷ Baseline: 3.13 (NR) vs. 3.87 (NR) End of treatment: 1.36 (NR) vs. 3.00 (NR) 4 week followup: 1.57 (NR) vs. 2.92 (NR)	Moderate	Direct	Imprecise	Consistent	Undetected	Low
	Patient General Behavior k=2; n=99	Behave-AD Global mean (SD) ⁴³ Baseline: 0.9 (0.5) vs. 1.5 (0.7) vs. 1.3 (0.7) Post: 0.8 (0.4) vs. 0.7 (1.0) vs. 1.5 (0.8) 3 weeks follow-up: 1.1 (0.5) vs. 1.2 (0.6) vs. 2.2 (0.9) NPI ³⁷ results presented graphically; authors report lower scores post-intervention (F1,51=4.84, p<0.05); difference likely not significant at followup	Moderate	Indirect	Imprecise	Inconsistent	Undetected	Insufficient
Music vs. Passive Control (for immediate reduction in agitation/aggression)	Patient Agitation/Aggression k=1; n=34	CMAI mean (SD) ³⁸ Baseline: 18.41 (11.19) vs. 21.76 (9.09) Immediately post: 9.18 (11.11) vs. 21.88 (10.38) 10 min. post: 7.76 (9.55) vs. 20.88 (8.66) 20 min. post: 3.06 (5.44) vs. 20.47 (10.90)	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
Music vs. active control	Patient Agitation/Aggression k=4; n=218	Behave-AD Aggressiveness , mean (SD) ⁴³ Baseline: 1.5 (1.8) vs. 2.5 (2.4) Post-intervention: 1.5 (0.9) vs. 0.7 (1.0) 3 weeks followup: 1.3 (2.0) vs. 2.5 (2.2) CMAI ⁶² means– shown in figures; adjusted mean difference NS(F=2.89; p=0.09) CMAI , mean (95% CI) ¹¹ Baseline: 1.66 (1.42-1.91) vs. 1.54 (1.32-1.77) After first arm:1.67 (1.49-1.85) vs. 1.66 (1.37-1.96) Post crossover:1.65 (1.38-1.91) vs. 1.70 (1.44-1.97)	Low to Moderate	Direct	Imprecise	Consistent	Undetected	Low

Comparison	Outcome (Instrument) # Trials (n)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		CMAI-SF, mean (SD) ³⁸ Baseline: 18.41 (11.19) vs. 16.47 (9.94) vs. 22.00 (11.94) Imm post: 9.18 (11.11) vs. 10.35 (11.20) vs. 8.59 (7.87) 10 min post: 7.76 (9.55) vs. 7.76 (9.55) vs. 7.06 (7.08) 20 min post: 3.06 (5.44) vs. 3.06 (5.44) vs. 3.76 (4.40)						
	Patient General Behavior k=1; n=26	Behave-AD Global, mean (SD) ⁴³ Baseline: 0.9 (0.5) vs. 1.5 (0.7) Post-intervention: 0.8 (0.4) vs. 0.7 (1.0) 3 weeks followup: 1.1 (0.5) vs. 1.2 (0.6)	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Aromatherapy (lavender) vs. passive control	Patient Agitation/Aggression k=2; n=115	CMAI – aggressive behaviors ¹⁴ No overall results reported; no statistically significant difference between groups on individual behaviors reported. C-CMAI, mean (SD) ³⁰ Baseline: 63.17 (17.81) vs. 63.94 (SD 17.67) Post: 58.77 (16.74) vs. 63.90 (17.73)	Moderate	Direct	Imprecise	Consistent	Undetected	Low
	Patient General Behavior k=2; n=98	NPI, mean (SD) ¹⁵ Baseline: 31 (10) vs. 32 (11) 4 weeks: 18 (12) vs. 27 (12) CNPI, mean (SD) ³⁰ Baseline: 24.68 (10.54) vs. 24.33 (10.08) Post: 17.77 (7.52) vs. 24.41 (10.24)	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Aromatherapy (melissa) vs. passive control	Neuroleptic Use k=1; n=72	Prescribed additional psychotropic drugs during the study: ⁴ 6% vs. 8% (SDs not reported)	Moderate	Indirect	Unclear	Unknown	Undetected	Insufficient
	Patient Agitation/Aggression k=1; n=72	CMAI ⁴ Proportion making 30% decrease in score: (60% vs. 14%, $\chi^2=16.3$; $p<.0001$). CMAI, median change ⁴ -22.0 vs. -6.5 Z=4.1; $p<.0001$	Moderate	Direct	Unclear	Unknown	Undetected	Insufficient
Bright Light vs. passive control k=4; n=225	Patient Agitation/Aggression k=4; n=225	Standardized Mean Difference, 95% CI ^{1,6} 0.09 (-0.32 to 0.50) NPI Agitation/aggression, mean (SD) ¹³ Morning bright light vs. evening bright light vs. standard light	Low to Moderate	Direct	Imprecise	Consistent	Undetected	Low

Comparison	Outcome (Instrument) # Trials (n)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		Baseline: 5.3 (3.5) vs. 3.7 (2.4) vs. 5.8 (3.4) Post-intervention mean: 5.5 (3.3) vs. 4.8 (2.6) vs. 4.3 (2.5) Agitation – Behave-AD Aggression subscale ³³ No significant differences, did not present data (p>0.05)						
	Patient General Behavior k=3; n=133	Crichton Royal Behavior Rating , mean (SD) ⁶ Baseline: 34.2 (6.5) vs. 35.6 (7.6) Week 4: 41.3 (2.9) vs. 42.8 (1.4) Week 8: 43.8 (3.4) vs. 44.2 (2.5) MOUSEPAD , mean (SD) ⁶ Baseline: 13.5 (11.6) vs. 13.4 (8.8) Week 4: 7.8 (7.9) vs. 7.8 (SD 4.3) Week 8: 8.0 (7.8) vs. 7.7 (3.7) NPI , mean (SD) ¹³ Baseline: 29.4 (20.7) vs. 27.0 (15.7) vs. 24.1 (15.8) Post-intervention: 26.3 (13.9) vs. 27.5 (16.5) vs. 19.6 (10.8) Behave-AD, mean (SD) ³³ Baseline: 14.9 (3.83) vs. 13.7 (3.49) Week 4: 12.6 (SD 4.79) vs. 10.7 (4.85)	Low to Moderate	Indirect	Imprecise	Consistent	Undetected	Insufficient
Therapeutic Touch vs. passive control	Patient Agitation/Aggression k=1; n=51	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Patient General Behavior k=2; n=108	See Report Text Table 4	Moderate	Indirect	Imprecise	Inconsistent	Undetected	Insufficient
Massage therapy vs. passive control K=2;n=105	Patient Agitation/Aggression k=1; n=34	Baseline: 16.47 (9.94) vs. 21.76 (SD 9.09) Post:10.35 (SD 11.20) vs. 21.88 (SD 10.38) 10 min. post: 7.76 (SD 9.55) vs. 20.88 (SD 8.66) 20 min. post: 3.06 (SD 5.44) vs. 20.47 (SD 10.90)	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Patient	Behavior alterations improvement	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient

Comparison	Outcome (Instrument) # Trials (n)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
	General Behavior k=1; n=71	3 months: 34/36 vs. 0/35 5 months: 28/35 vs. 32/36						
Tailored Activities vs. Nontailored Activities K=3; n=247	Patient Agitation/Aggression k=3; n=247	Mean (SD) ⁵¹ Baseline: 16.7 (9.9) vs. 17.1 (9.8) During intervention: 8.4 (9.9) vs. 10.0 (10.4) After intervention: 17.6 (10.3) vs. 17.0 (9.4) ABMI, mean (SD) ⁹ Baseline: 8.76 (5.61) vs. 7.16 (7.61) Post: 2.08 (2.68) vs. 7.92 (9.09) Visual Analog Scale (0 to 100 based upon observation), mean (SD) ²⁶ Baseline: 38.97 (20.54) vs. 32.59 (21.66) Posttest mean(SD): 30.54 (15.31) vs. 32.25(20.16) (Pretest to Posttest * group: $F_{1,69}=4.26$; $p=0.43$)	Moderate	Direct	Imprecise	Inconsistent	Undetected	Insufficient
Tailored Activities vs. Tailored Activities K=2; n=158	Patient Agitation/Aggression k=2; n=158	CMAI, Least Square means (95%CI) ²⁵ Baseline: 1.62 (0.9-2.4) vs. 2.46 (1.7-3.2) vs. 1.86 (1.1-2.6) vs. 1.88 (1.1-2.6) Post: 1.2 (0.3-2.0) vs. 1.7 (0.9-2.5) vs. 1.5 (0.6-2.3) vs. 1.10 (0.3-1.9) CMAI, mean (CI) ²⁴ Baseline: 2.85 (2.0-3.7) vs. 2.85 (2.0-3.7) vs. 2.85 (2.0-3.7) Post: 1.35 (0.5-2.2) vs. 1.09 (0.3-1.9) vs. 1.14 (0.2-4.0)	Moderate	Direct	Imprecise	Unknown	Undetected	Low
Acupuncture k=1; n=76	Patient General Behavior k=1; n=76	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Massage vs. Ear Acupuncture k=1; n=75	Patient General Behavior k=1; n=75	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Acupressure K=1; n=133	Patient Agitation/Aggression k=1; n=133;	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
Structured	Patient	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient

Comparison	Outcome (Instrument) # Trials (n)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
Activities K=1; n=133	Agitation/ Aggression k=1; n=133;							
Acupressure vs. Structured Activities K=1; n=133	Patient Agitation/ Aggression k=1; n=133;	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
Reminiscence K=1; n=40	Patient General Behavior k=1; n=40	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Exercise K=1; n=134	Patient General Behavior k=1; n=40	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Adverse Effects	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Pleasant Experiences K=1; n=20	Patient General Behavior k=1; n=20	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Multisensory stimulation vs. Recreation K=1; n=40	Patient General Behavior k=1; n=40	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Activities of Daily Living vs. Psychosocial Activity k=1; n=127	Patient General Behavior k=1; n=127	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Simulated presence K=1; n=54	Patient Agitation/ Aggression k=1; n=54;	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
Enhancing Family Visits k=1; n=66	Patient Agitation/ Aggression k=1; n=66	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Patient	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient

Comparison	Outcome (Instrument) # Trials (n)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
	General Behavior k=1; n=66							
Electro stimulation K=1; n=27	Patient Agitation/Aggression k=1; n=27	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
Group Multistimulation vs. Leisure Activities k=1; n=40	Patient Agitation/Aggression k=1; n=40	See Report Text Table 4	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Patient General Behavior k=1; n=40	See Report Text Table 4	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient

Appendix D. Care-Delivery-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities

Table D1. Care-Delivery-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities: Risk of bias assessments

Study	Risk of Bias Assessment
Chapman, 2007 ⁵⁵	Moderate - Risk of contamination across groups; crossover design with incomplete reporting; attrition unclear.
Chenoweth, 2009 ⁵⁶	Moderate - Unclear: not balanced on several facility and patient level variables; low attrition, attrition higher than 20% in the control group at followup.
Clare, 2013 ⁵⁷	Low - slightly underpowered in terms of patients but provided power calculation.
Davison, 2007 ⁵⁸	High - intervention has been described elsewhere in greater detail. As a standalone article difficult to fully understand implementation; no power calculation, small sample, assessors not blinded; high attrition of staff; high detection bias.
Deudon, 2009 ⁵⁹	Moderate - Randomization unclear, groups unbalanced on key outcomes. Even through no power calculation there was a relatively large number of observations in treatment and control.
Finnema, 2005 ⁶⁰	Low - Assessors not blinded but used a validation method to determine if this impacted results and found it did not; patient Attrition >20% and staff attrition = 20%.
Fossey, 2006 ⁶¹	Moderate - The unit of analysis is the NH but patients were not stable in the study and both groups experienced a large amount of turnover in terms of residents.
Gozolo, 2014 ⁶²	High - Potential risk of bias due to detection bias (assessors could easily determine group assignment), attrition bias, and bias in the reporting of outcomes by group assignment).
Kovach, 2006 ⁶³	Moderate - Potential selection bias (method of randomization not clear) and detection bias (assessors not blinded).
Magai, 2002 ⁶⁴	Moderate - Reporting of outcomes is unclear and method of randomization was not adequately explained, unbalanced on race; method of randomization unclear, not balanced on race; unclear if reported CMAI or Behavioral Pathology in Alzheimer Disease Rating Scale; no power calculation.
McCallion, 1999 ⁶⁵	Moderate - Unclear: method of randomization not clear, not balanced on some baseline variables including overall disease severity; no power calculation; only provided attrition info on staff. In control group attrition greater than 20% for staff; unclear regarding selection, detection, and attrition bias.
McGilton, 2003 ⁶⁶	Moderate - No ITT analysis; Unclear if participants blinded. 15% attrition; Groups similar at baseline on demographic characteristics, possibly different on agitation; intervention dose, fidelity issues, small sample size.
Proctor 1999 ⁶⁷	Moderate - Unclear method of randomization; unclear performance bias; unclear blinding.
Rapp, 2013 ⁶⁸	Moderate - Performance bias (unclear application of the intervention) and detection bias (not blinding assessors).
Rokstad, 2013 ⁶⁹	Moderate - Not balanced on secondary outcomes; high attrition but no difference in groups in terms of attrition or reasons for attrition; unbalanced on some baseline measures.
Schrijneamaekers, 2002 ⁷⁰	Moderate – Facility selection unclear; different sources for reporting, risk of contamination; unclear (use of staff for reporting of outcomes); problems with missing data; paired group-randomized trial; unblinded assessors; participant blinding unclear; Appropriate analysis; Low attrition except at 12 months due to deaths.
Teri, 2005 ⁷¹	Moderate - Unbalanced on baseline data, no info on attrition, focus on paper is really on implementation and development of intervention not testing it; method of randomization not clear and not balanced on baseline variables; no power calculation and small sample size; no information regarding attrition.
Testad, 2005 ⁷²	High - Not balanced on key baseline variables; unbalanced at baseline and high attrition; attrition in both groups at 6months and 12 months higher than 20%; very high staff turnover; no power calculation and high attrition led to smaller sample sizes.
Testad, 2010 ⁷³	High -Attrition in both groups at 6 months and 12 months higher than 20%, Also very high staff turnover.
van de Ven, 2013 ⁷⁴	Moderate - Unclear regarding performance and detection bias; unit of analysis is patient and NH but patients lost to followup were replaced with new patients but imputed missing data for resident questionnaires not completed; unclear if assessors blinded to the intervention;

Study	Risk of Bias Assessment
	unclear if fidelity checks conducted.
Visser, 2008 ⁷⁵	High - Unclear regarding method of randomization and high detection bias; High attrition in one group but this group excluded from analysis; no power calculation and had small sample size, outcome assessors not blinded; Not clear regarding fidelity; method of randomization unclear.
Wells, 2000 ⁷⁶	High - Unclear: method of randomization unclear; unclear regarding method of randomization, no power calculation, and high attrition; unclear: no power calculation; attrition was 28.5%, complete reasons for attrition not given, not clear how handled missing or incomplete data.
Wenborn, 2013 ⁷⁷	Moderate - issues related to fidelity and high dropout; not clear if protocol followed exactly some residents could have received more activity; Attrition >20% but similar in both groups, also say use IIT but clear how handled drop outs.

Care-Delivery-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities: Description of Trials Rated High Risk of Bias

Six studies were assessed as having a high risk of bias.^{58,62,72,73,75,76} These studies were not included in our narrative analysis but are described below.

Testad et al. compared a staff-training program designed to reduce restraint use (n = 55) and a control group (n = 96).⁷² The 7-month intervention consisted of educating staff on dementia-related behaviors and alternatives to the use of restraints. Intervention staff members were also provided with an hour of monthly guidance for 6 months. Treatment effects were tested with the Mann-Whitney U-test and Wilcoxon matched pairs signed rank test. At followup, use of restraints was significantly lower in the intervention group than in the control (p = 0.017). The intervention and control groups did not statistically significantly differ on the measure of agitation or use of psychotropic drugs. This study had a high risk of bias due to high detection bias (potentially underpowered given no power calculation [resident N = 151] and unclear if assessor were blinded) and high attrition bias.

Visser et al. compared two interventions, staff education only (n = 21) and staff education with peer support (n = 23), to a control group over a 3-month period (n = 32).⁷⁵ The education-only program trained staff members to manage behaviors with individualized approaches. The education and peer support intervention combined training in individualized approaches to behavior management with support to staff members. Treatment effects were evaluated with a mixed analysis of variance. Neither intervention group nor the control group differed significantly on measures of agitation on the CMAI or CMAI subscales. This study had a high risk of bias due to possible selection bias (unclear method of randomization), high detection bias (potentially underpowered given no power calculation and small sample size), and high performance bias (fidelity inadequately explained).

Wells et al. compared a staff-training program (n = 20) with a control group (n = 20).⁷⁶ Over a 3-month period staff members in the intervention group attended five sessions on providing abilities-focused care. Treatment effects were estimated with repeated measures analysis of variance. Residents in the intervention group improved significantly in agitated behavior (measured by the agitation subscale of the MIBM) compared with the control group (p = 0.021). On the PAS, the intervention group exhibited nonsignificant improvements compared with the control (p = 0.19). Staff outcomes of stress and ease of caregiving did not differ between intervention and control. This study had a high risk of bias due to potential selection bias (unclear regarding method of randomization), potential detection bias (potentially underpowered given no power calculation and small sample size [resident N = 44] and failure to adjust for multiple comparisons), and high attrition bias.

Gozalo et al. compared an intervention designed to reduce agitation during bathing (n = 134) with a wait-list control (n = 106).⁶² Up to five staff members from each intervention home attended a 2-day training session focused on effective communication strategies and interpreting behaviors as an unmet need. These five staff then trained other staff at their home institution. Fixed-effects regressions were estimated to evaluate treatment effects. We could not determine the effect of the intervention compared with the wait-list control group from the results presented. This study had a high risk of bias due to detection bias (assessors could easily determine group assignment), attrition bias, and bias in the reporting of outcomes by group assignment).

Davison et al. compared a staff-training program only (n = 46), a staff training combined with a peer-support program (n = 35), and usual care (n = 32).⁵⁸ Staff training consisted of eight 60 to 90 minute sessions on care for dementia-related behaviors. The peer-support program consisted of facilitated informal group session among staff members to discuss challenging behaviors of residents. Analysis of covariance was used to evaluate treatment effects. Treatment and control groups did not differ significantly on staff emotional exhaustion or resident agitation as measured by CMAI. This study had a high risk of bias due to high performance bias (intervention not adequately described), high detection bias (potentially underpowered given no power calculation and small sample size [resident N = 113] and assessors not blinded), and high attrition bias.

Testad et al. compared a staff-training program designed to reduce the use of restraints (n = 75) with usual care (n = 70).⁷³ All staff in intervention nursing homes were provided a 2-day seminar. In addition, study investigators led six monthly group guidance meetings. Repeated measures analysis of variance was used to evaluate treatment effects. At 6 months the proportion of residents who started, remained unchanged, or stopped interactional restraint differed between the intervention and control (Mann-Whitney test, p = 0.021). However, whether this difference favored the intervention or control is not clear. At 12 months (6 months post intervention) no evidence of treatment effect was observed. The intervention group improved significantly in CMAI scores relative to the control group over a 12-month period (mean difference -5.6 95% CI -10.2 – 1.0). Use of antipsychotic drugs over time did not differ significantly between intervention and control. This study had a high risk of bias due to high selection bias (not balanced on key baseline variables), high detection bias (potentially underpowered given no power calculation (resident N = 145) and attrition bias.

Table D2. Care-Delivery-Level Interventions for Agitation/Aggression in Nursing Home and Assisted Living Facilities: strength of evidence assessments

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
Dementia Care Mapping K=3; n=643	Staff Behavior K=1; n=180	QEAW emotion reactions, baseline Mean(SE)=13.69 (1.51) vs. 9.48(1.40) QEAW emotion reactions, 4 months postintervention Mean(SE)=23.38 (1.67) vs. 25.97(1.59) QEAW emotion reactions, 8 months postintervention Mean(SE)=53.28 (1.20) vs. 53.09(1.12) Linear mixed-effect model p-value for group: 0.719	Moderate	Direct	Precise	Unknown	Undetected	Insufficient
	Neuroleptic Drug Use K=1; n=159	Antipsychotic use adjusted proportion, baseline 0.15% vs. 0.19% Antipsychotic use adjusted proportion, 4 months postintervention 0.19% vs. 0.14% Antipsychotic adjusted proportion, 8 months postintervention Adjusted Proportion=0.15% vs. 0.14% Hierarchical linear model: p-value for group: 0.01	Low	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Patient Agitation/Aggression K=3; n=643	SMD: -0.12 (-0.66 to 0.42)	Moderate	Direct	Imprecise	Consistent	Undetected	Low
	Patient General Behavior K=3; n=643	NPI, baseline ⁵⁶ Adjusted Mean(SE)=12.7(5.1) vs. 16.9(5.3) NPI, 4 months postintervention ⁵⁶ Adjusted Mean(SE)=16.8(5.1) vs. 20.2(5.4)	Moderate	Indirect	Imprecise	Inconsistent	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>NPI, 8 months postintervention⁵⁶ Adjusted Mean(SE)=12.7(5.1) vs. 16.9(5.3)</p> <p>Hierarchical linear model:⁵⁶ p-value for group: 0.68</p> <p>NPI-Q⁶⁹ MC(p-value between group) -0.2 vs. 1.4 (<0.01)</p> <p>NPI-Q⁶⁹ Multivariate regression Coefficient (CI)= -2.7 (-4.6 to -0.7)</p> <p>NPI-NH, baseline⁷⁴ Mean(SE)=5.35(0.94) vs. 6.28(0.88)</p> <p>NPI-NH, 4 months postintervention⁷⁴ Mean(SE)=7.19(0.95) vs. 4.45(0.88)</p> <p>NPI-NH, 8 months postintervention⁷⁴ Mean(SE)=6.28(0.92) vs. 4.13(0.86)</p> <p>Linear mixed-effect model⁷⁴ p-value for group: 0.23</p>						
	Injuries K=1; n=159	<p>Falls, injuries, drug errors, behavioral events, baseline Adjusted Proportion=0.40% vs. 0.25%</p> <p>Falls, injuries, drug errors, behavioral events, 4 months postintervention Adjusted Proportion=0.49% vs. 0.37%</p> <p>Falls, injuries, drug errors, behavioral events, 8 months postintervention Adjusted Proportion=0.46% vs. 0.37%</p> <p>Hierarchical linear model:</p>	Moderate	Indirect	Unclear	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		p-value for group: 0.15						
	Staff Distress, Burden, QoL K=1; n=180	<p>GHQ 12, baseline Mean(SE)=17.48 (0.33) vs. 16.67(0.29)</p> <p>GHQ 12, 4 months postintervention Mean(SE)=15.72 (0.38) vs. 14.89(0.34)</p> <p>GHQ 12, 8 months postintervention Mean(SE)=14.57 (0.37) vs. 14.42(0.32)</p> <p>Linear mixed-effect model: p-value for group: 0.122</p> <p>Linear mixed-effect model p-value for group * time: 0.43</p> <p>MJSS-HC, baseline Mean(SE)=76.98 (1.36) vs. 77.29(1.44)</p> <p>MJSS-HC, 4 months postintervention Mean(SE) =76.40 (1.34) vs. 75.10(1.43)</p> <p>MJSS-HC, 8 months postintervention Mean(SE)=78.08 (1.40) vs. 75.58(1.46)</p> <p>Linear mixed-effect model p-value for group: 0.56</p> <p>Linear mixed-effect model p-value for group * time: 0.069</p>	Moderate	Indirect	Precise	Unknown	Undetected	Insufficient
Person Centered Care K=3; n=775	Neuroleptic Drug Use K=2; n=487	<p>Adjusted proportion, baseline⁵⁶ 0.42% vs. 0.19%</p> <p>Adjusted proportion, 4 months postintervention⁵⁶ 0.30% vs. 0.14%</p> <p>Adjusted proportion, 8 months postintervention⁵⁶ 0.34% vs. 0.14%</p> <p>Hierarchical linear model</p>	Moderate	Indirect	Imprecise	Inconsistent	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>Chenoweth 2009) p-value for group: 0.01 Proportion taking neuroleptics⁶¹ MD(CI)= -19.5% (-47.1% to 3.0%) Dose of neuroleptics⁶¹ AMD(CI)= -4.0% (-29.9% to 22.0%)</p>						
	Patient Agitation/Aggression	Standardized Mean Difference, 95% CI: -0.15 (-0.67 to 0.38)	Moderate	Direct	imprecise	Consistent	Undetected	Insufficient
	Patient General Behavior K=2; n=429	<p>NPI, baseline⁵⁶ Adjusted Mean(SE)=21.3(6.8) vs. 16.9(5.3) NPI, 4 months postintervention⁵⁶ Adjusted Mean(SE)=16.8(5.1) vs. 20.2(5.4) General Behavior NPI, 8 months postintervention⁵⁶ Adjusted Mean(SE)=13.5(5.1) vs. 15.3(5.3) Hierarchical linear model⁵⁶ p-value for group: 0.68 Hierarchical linear model⁵⁶ p-value for group x time: p = 0.30 NPI-Q⁶⁹ MC(p-value between group)= 0.7 vs. 1.4 (<0.01) Multivariate regression⁶⁹ Coefficient (CI)= -2.4 (-4.1 to -0.6)</p>	Low to Moderate	Indirect	Imprecise	inconsistent	Undetected	Insufficient
	Injuries K=1; n=141	<p>Falls, injuries, drug errors, behavioral events, baseline Adjusted Proportion=0.43% vs. 0.25% Falls, injuries, drug errors, behavioral events, 4 months postintervention</p>	Moderate	Indirect	Unclear	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		Adjusted Proportion=0.53% vs. 0.37% Falls, injuries, drug errors, behavioral events, 8 months postintervention Adjusted Proportion=0.44% vs. 0.37% Hierarchical linear model: p-value for group: 0.15						
Protocols to reduce Neuroleptic Use K=2; n=604	Neuroleptic Drug Use K=2; n=604	Daily Dose SMD postintervention: -0.28 (-3.50 to 2.94)	Low to Moderate	Indirect	Imprecise	Inconsistent	Undetected	Insufficient
	Patient Agitation/Aggression K=2; n=604	CMAI postintervention MD: -4.50 (-38.83 to 29.83)	Low to Moderate	Direct	Imprecise	inconsistent	Undetected	Insufficient
Emotion Oriented Care K=2; n=297	Neuroleptic Drug Use K=1; n=151	Psychotropic Use ward unit caregivers linear multilevel model Adjusted MD per month (p-value): 0.00 (NS) Psychotropic use 3-month ward unit caregivers linear multilevel model adjusted MD per month (p-value): 0.00 (NS) Psychotropic use 6-month ward unit caregivers linear multilevel model adjusted MD per month (p-value): 0.07 (NS) Psychotropic use 12-month ward unit caregivers linear multilevel model adjusted MD per month (p-value): 0.02 (NS)	Moderate	Indirect	Unclear	Unknown	Undetected	Insufficient
	Patient Agitation/Aggression K=2; n=297	Combined CMAI, CMAI-physically aggressive, CMAI-verbally aggressive, BIP10-restless behavior⁶⁰ Multivariate Analysis of Variance	Low to Moderate	Direct	Imprecise	Consistent	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>Adjusted Means (F-test, p-value): 3.34 vs. 3.63 (0.43, 0.51)</p> <p>CMAI-verbal aggression Day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.04 (NS)</p> <p>CMAI-verbal aggression 3-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 1.54 (NS)</p> <p>CMAI-verbal aggression 6-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.78 (NS)</p> <p>CMAI-verbal aggression 12-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.41 (NS)</p> <p>CMAI-verbal aggression Ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.14 (NS)</p> <p>CMAI-verbal aggression 3-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.07 (NS)</p> <p>CMAI-verbal aggression 6-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -1.10 (NS)</p>						

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>CMAI-verbal aggression 12-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -1.41 (NS)</p> <p>CMAI aggression Day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.04 (NS)</p> <p>CMAI aggression 3-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.59 (NS)</p> <p>CMAI aggression 6-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.12 (NS)</p> <p>CMAI aggression 12-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.67 (NS)</p> <p>CMAI aggression Ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.13 (NS)</p> <p>CMAI aggression 3-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.87 (NS)</p> <p>CMAI aggression 6-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.83 (NS)</p>						

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>CMAI aggression 12-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -1.18 (NS)</p> <p>CMAI physical nonaggression Day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.03 (NS)</p> <p>CMAI physical nonaggression 3-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.70 (NS)</p> <p>CMAI physical nonaggression 6-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.85 (NS)</p> <p>CMAI physical nonaggression 12-month day-care unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): 0.97 (NS)</p> <p>CMAI physical nonaggression Ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.14 (NS)</p> <p>CMAI physical nonaggression 3-month ward unit caregivers linear multilevel model⁷⁰ adjusted MD per month (p-value): -0.28 (NS)</p> <p>CMAI physical nonaggression 6-month ward unit caregivers linear multilevel model⁷⁰</p>						

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		adjusted MD per month (p-value): -2.26 (<0.01) in favor of control CMAI physical nonaggression 12-month ward unit caregivers linear multilevel model ⁷⁰ adjusted MD per month (p-value): -1.27 (NS)						
	Staff Distress, Burden, QoL K=1; n=146	GHQ 12 Multivariate Analysis of Variance Adjusted Means improved and not improved (F-test, p-value): treatment 15.42 and 20.47 and control 19.14 and 14.19 (9.11, 0.003). QOS Multivariate Analysis of Variance Adjusted Means improved and not improved (F-test, p-value): treatment 23.02 and 24.73 and control 22.59 and 23.70 (1.51, 0.54)	Low	Indirect	Imprecise	Unknown	Undetected	Insufficient
Miscellaneous Deudon 2009) ⁵⁹ K=1; n=306	Patient Agitation/Aggression K=1; n=306	CMAI Linear mixed effect model coefficient for MC(SD) [p-value for difference between intervention and control]: -0.26(0.05) vs. 0.02(0.06) [0.001] CMAI physically nonaggressive behavior Linear mixed effect model coefficient for MC(SD) [p-value for difference between intervention and control]: -0.02(0.002) vs. -0.003(0.03) [<0.0001] CMAI verbally nonaggressive behavior Linear mixed effect model	Low to Moderate	Direct	Precise	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>coefficient for MC(SD) [p-value for difference between intervention and control]: -0.02 (0.003) vs. 0.001(0.004) [<0.001]</p> <p>CMAI physically aggressive behavior Linear mixed effect model coefficient for MC(SD) [p-value for difference between intervention and control]: -0.001(0.002) vs. 0.004(0.002) [0.142]</p> <p>CMAI verbally aggressive behavior Linear mixed effect model coefficient for MC for MC(SD) [p-value for difference between intervention and control]: -0.01(0.004) vs. -0.001 (0.004) [0.571]</p>						
Miscellaneous Proctor 1999 ⁶⁷ K=1; n=120	Patient General Behavior K=1; n=120	CRB AMD(CI)= -0.7 (-3.0 to 1.6)	Low to Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Miscellaneous Clare 2013 ⁵⁷ K=1; n=65	Staff Behavior K=1; n=65	MBI Depersonalization Analysis of Covariance Adjusted Means(SE): 1.32(0.04) vs. 0.53(0.07) Analysis of Covariance F-test (p-value) of group * time: 2.55 (0.12)	Low	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Patient General Behavior K=1; n=65	PRS Analysis of Covariance Adjusted Means(SE): 37.39(2.32) vs. 34.71(2.17) Analysis of Covariance F-test (p-value) of group * time: 0.25 (0.62)	Low	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Staff Distress, Burden, QoL	GHQ Analysis of Covariance	Low	Indirect	Imprecise	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
	K=1; n=65	Adjusted Means(SE): 6.63 (0.82) vs. 7.12(1.05) Analysis of Covariance F-test (p-value) of group * time: 0.22 (0.64) Emotional Exhaustion Analysis of Covariance Adjusted Means(SE):12.36(0.07) vs. 12.38(0.07) Analysis of Covariance F-test (p-value) of group * time: 0.00 (0.99)						
Miscellaneous Wenborn 2013 ⁷⁷ K=1; n=159	Neuroleptic Drug Use K=1; n=159	Total Medications 4-week MD(CI)= 0.10 (-0.53 to 0.34, 0.66) 12-week AMD(CI)= -0.15 (-0.55 to 0.24)	Low to Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Patient Agitation/Aggression K=1; n=159	CBS 4-week MD(CI)= 1.15 (-9.23 to 11.52) 12-week AMD(CI)= 4.13 (-21.10 to 29.36)	Low to Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Patient General Behavior K=1; n=159	CAPE BRS 4-week MD(CI)= 1.08 (-0.18 to 2.34) 12-week AMD(CI)= 0.52 (-1.63 to 2.67)	Low to Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Miscellaneous Kovach 2006 ⁶³ K=1; n=114	Patient General Behavior K=1; n=144	BEHAVE AD, baseline Mean(SD)=7.43(6.75) vs. 6.80(5.47) BEHAVE AD, 2 weeks postintervention Mean(SD)=5.56(5.64) vs. 6.15(5.55) BEHAVE AD, 4 weeks postintervention Mean(SD)=4.68(4.06) vs. 4.96(4.39) Repeated Measures Analysis of Variance F-test (p-value) group	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		x time: 0.70 (0.5)						
Miscellaneous Magai 2002 ⁶⁴ K=1; n=95	Patient Agitation/Aggression K=1; n=95	<p>Aggregate measure incorporating CDS, CMAI, and BEHAVE-AD, baseline Mean(SD)=83.7(51.2) vs. 25.2(5.2) vs. 40.6(7.8)</p> <p>Aggregate measure incorporating CDS, CMAI, and BEHAVE-AD, 3 weeks postintervention Mean(SD)=69.1(36.1) vs. 49.6(27.2) vs. 75.4(41.4)</p> <p>Aggregate measure incorporating CDS, CMAI, and BEHAVE-AD, 6 weeks postintervention Mean(SD)=69.1(36.1) vs. 49.6(27.2) vs. 75.4(41.4)</p> <p>Aggregate measure incorporating CDS, CMAI, and BEHAVE-AD, 9 weeks postintervention Mean(SD)=71.8(37.6) vs. 44.6(23.7) vs. 63.1(42.0)</p> <p>Aggregate measure incorporating CDS, CMAI, and BEHAVE-AD, 12 weeks postintervention Mean(SD)=65.5(37.7) vs. 39.2(15.2) vs. 61.6(31.1)</p> <p>Repeated Measures Analysis of Variance F-test (p-value) for group: 2.28 (NS)</p> <p>Repeated Measures Analysis of Variance F-test (p-value) for group x interaction: 1.15 (NS)</p>	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
Miscellaneous McCallion 1999 ⁶⁵ K=1; n=95	Staff Behavior K=1; n=105	<p>Restraints Use, baseline Mean(SD)=1.20(1.34) vs. 1.82(1.62)</p> <p>Restraints Use, 3 months postintervention</p>	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		Mean(SD)=1.53(1.56) vs. 2.04(1.78) Random effects regression F-test (p-value) 3-month group: 43.99 (NS) F-test (p-value) 3-month group x interaction: 0.00 (NS) Restraints Use, 6 months postintervention Mean(SD)=1.88(1.82) vs. 1.75(1.42) F-test (p-value) 6-month group: 7.20 (NS) F-test (p-value) 6-month group x interaction: 9.54 (<0.01)						
	Neuroleptic Drug Use K=1; n=105	Psychotropic Use, baseline Mean(SD)=0.98(1.41) vs. 1.62(1.70) Psychotropic Use, 3 months postintervention Mean(SD)=0.93(1.39) vs. 1.7(1.82) Random effects regression F-test (p-value) 3-month group: 37.48 (NS) F-test (p-value) 3-month group x interaction: 1.78 (NS) Psychotropic Use, 6 months postintervention Mean(SD)=1.30(2.15) vs. 1.57(1.71) F-test (p-value) 6-month group: 4.99 (NS) F-test (p-value) 6-month group x interaction: 1.61 (NS)	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Patient Agitation/Aggression K=1; n=105	CSDD behavioral disturbance, baseline Mean(SD)=2.00 (1.58) vs. 1.13(1.06) CSDD behavioral disturbance, 3 months	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>postintervention Mean(SD)=1.32 (1.40) vs. 0.98(1.13) Random effects regression F-test (p-value) 3-month group: 49.20 (NS) Random effects regression F-test (p-value) 3-month group x interaction: 7.76 (<0.01)</p> <p>CSDD behavioral disturbance, 6 months postintervention Mean(SD)=1.26 (1.17) vs. 1.29(1.29) F-test (p-value) 6-month group: 23.46 (NS) F-test (p-value) 6-month group x interaction: 18.64 (<0.001)</p> <p>CMAI aggressive behavior, Baseline Mean(SD)=15.16(9.81) vs. 13.25(7.52)</p> <p>CMAI aggressive behavior, 3 months postintervention Mean(SD)=11.00(5.35) vs. 12.46(6.82) Random effects regression F-test (p-value) 3-month group: 0.23 (NS) Random effects regression F-test (p-value) 3-month group x interaction: 8.67 (NS)</p> <p>CMAI aggressive behavior, 6 months postintervention Mean(SD)=12.21(8.31) vs. 12.02(6.22) F-test (p-value) 6-month group: 6.02 (NS) F-test (p-value) 6-month group x interaction: 0.92 (NS)</p> <p>CMAI physically</p>						

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>nonaggressive behavior, baseline Mean(SD)=12.49(6.34) vs. 11.09(5.47)</p> <p>CMAI physically nonaggressive behavior, 3 months postintervention Mean(SD)=10.36(4.72) vs. 11.86(6.54) Random effects regression F-test (p-value) 3-month group: 0.56 (NS) F-test (p-value) 3-month group x interaction: 17.59 (<0.001)</p> <p>CMAI physically nonaggressive behavior, 6 months postintervention Mean(SD)=11.38(5.99) vs. 10.38(6.32) F-test (p-value) 6-month group: 7.78 (NS) F-test (p-value) 6-month group x interaction: 0.26 (NS)</p> <p>CMAI verbally aggressive behavior, baseline Mean(SD)=16.22(10.31) vs. 10.44(6.21)</p> <p>CMAI verbally aggressive behavior, 3 months postintervention Mean(SD)=11.38(7.13) vs. 11.52(6.71) Random effects regression F-test (p-value) 3-month group: 38.65(NS) F-test (p-value) 3-month group x interaction: 32.97 (<0.001)</p> <p>CMAI verbally aggressive behavior, 6 months postintervention Mean(SD)=12.88(8.39) vs.</p>						

Intervention vs. Comparison	Outcome (Instrument)	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		12.05(6.86) F-test (p-value) 6-month group: 38.82 (NS) F-test (p-value) 6-month group x interaction: 14.23 (<0.001)						
Miscellaneous Teri 2005 ⁷¹ K=1; n=31	Patient Agitation/Aggression K=1; n=31	ABID AMC (SD)=-3.8 (4.0) vs. -0.5 (6.7)	Moderate	Direct	Precise	Unknown	Undetected	Insufficient
	Patient General Behavior K=1; n=31	NPI AMC (SD)= -3.5 (8.1) vs. 2.7 (10.0) RMBPC Total Score Frequency AMC (SD)= -1.1 (1.0) vs. 0.2 (0.8) RMBPC Disruption Frequency AMC (SD)= -0.2 (0.2) vs. 0.0 (0.3)	Moderate	Indirect	Precise	Unknown	Undetected	Insufficient
	Staff Distress, Burden, QoL K=1; n=31	NPI (staff impact) AMC (SD)= -1.2 (5.3) vs. 1.6 (4.2) RMBPC (reaction) AMC (SD)= -0.7 (1.0) vs. 0.2 (0.8) RMBPC-disruption (reaction) AMC (SD)= -0.1 (0.3) vs. 0.0 (0.0) Job Satisfaction AMC (SD)= 0.2 (0.4) vs. 0.00 (0.05)	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient

MD=mean difference; NA=not applicable; NR=not reported; RR=risk ratio

Appendix E. Patient-Level Interventions for Agitation/Aggression in Community Dwelling Individuals with Dementia

Table E1. Patient-Level Interventions for Agitation/Aggression in Community Dwelling Individuals with Dementia: Risk of bias assessments

Study	Risk of Bias Assessment
Baker 2001 ⁷⁸	Moderate - Patient blinding unclear. Assessor not blinded. Attrition was low. ITT analyses attempted.
Fitsimmons 2002 ⁷⁹	High -Results not presented in a way consistent with how we will need to analyze it. Pre-/post-test design with participants included in both groups in analyses (to increase their n, probably).
Teri 2000 ⁸⁰	Moderate - Methodological issues since one group randomized to 3 groups (not including behavior therapy) and other to 4 groups, but all data appears combined. Very high attrition. Outcome assessors blinded.

Patient-Level Interventions for Agitation/Aggression in Community Dwelling Individuals with Dementia Descriptions of Trials Rated High Risk of Bias

Fitsimmons et al. studied an at-home recreational therapy for community dwelling individuals with dementia and disturbing behaviors.⁷⁹ Agitation was measured after 2 weeks of daily, individualized recreational therapy interventions.

Table E2. Patient-Level Interventions for Agitation/Aggression in Community Dwelling Individuals with Dementia: strength of evidence assessments

Setting Intervention vs. Comparison	Outcome	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
Multisensory Stimulation vs. attention control	Patient Agitation/Aggression K=1; n=50	REHAB deviant behavior AMD (CI) ^c : -.32 (-.55 to -.09) BRS social disturbance AMD (CI) ^c : -.32 (-.55 to -.09)	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Patients General Behavior K=1; n=50	REHAB general behavior MD (CI): ND BMD MD in MC: ND	Moderate	Indirect	Unclear	Unknown	Undetected	Insufficient

Mod=moderate; MD=mean difference; NA=not applicable; NR=not reported; RR=risk ratio

Appendix F. Caregiver-Level Interventions for Agitation/Aggression in Community Dwelling Individuals with Dementia

Table F1. Caregiver-Level Interventions for Agitation/Aggression in Community Dwelling Individuals with Dementia: Risk of bias assessments

Study	Risk of Bias Assessment
Belle, 2006 ⁸¹	Low - Assessors blinded, unsure about participants. Minor missing data issues as they used only available data.
Burgener, 1998 ⁸²	High - Random assignment only mentioned in abstract; Randomization method unclear; Blinding unclear. No methods section.
Burgio, 2003 ⁸³	High - Minimization randomization technique used; Staff not blinded, unsure about participants. Handling of missing data unclear, possibly used only complete data.
Gerdner, 2002 ⁸⁴	Moderate - Not a crossover study. Extremely high attrition. Outcome assessors blinded. Participant blinding unclear. Only included outcomes from one measure, did not include from another scale used. Nearly ITT analysis (excluded 4 people, only about 1.5% of this study). Unclear randomization method, no mention of blinding of participants, interventionists and fidelity checks. Outcome assessors blinded. No mention of power analysis, high attrition.
Gitlin, 2003 ⁸⁵	Moderate - Blinding unclear. Not corrected for multiple comparisons. High attrition.
Gitlin, 2008 ⁸⁶	Low - Blinding unclear. Not ITT analysis, but low attrition.
Gitlin, 2010a ⁸⁷	Moderate - attrition at 9 months (over 20%), though okay at 4 months. Blinding unclear. Unsure where .5 SD clinical significance comes from (cites Belle, but only says it's consistent with this article, not a reason why it matters). Not ITT analysis. Does not report 9 month results adequately.
Gitlin, 2010b ⁸⁸	Moderate - Blinding unclear. Differential attrition approaching 20% in one group. Call it an ITT analysis, but they do not include those lost to followup in analyses.
Gonyea, 2006 ⁸⁹	High - Participant blinding unclear. Assessors not blinded. Not ITT analysis.
Gormley, 2001	Moderate - Participant blinding unclear. Assessor blinded. No attrition.
Marriott, 2000 ⁹⁰	Moderate. Single-blind (assessors). Very low attrition (only one dyad).
Mittelman, 2004 ⁹¹	Moderate. - Blinding unclear. Extremely high attrition after 4 month follow-up. ITT analysis.
Moniz-Cook, 2008 ⁹²	High - Poor randomization method. Extremely high attrition. Blinding unclear. Not ITT analysis, but data used unless patient died or was institutionalized.
Nobili, 2004 ⁹³	High - Blinding unclear. Extremely high attrition. Last obs carried forward used for missing data, poor method.
Ostwald, 1999 ⁹⁴	Moderate. Blinding unclear. 19.7% attrition. Not ITT analysis.
Teri, 2005b ⁹⁵	Moderate - Very high attrition at 6 months. Outcome assessors blinded, unclear about participants and caregivers. ITT analyses, though using last value carried forward is a biased method.
Tibaldi, 2004 ⁹⁶	High – Selection and detection bias; attrition and blinding unclear.
Ulstein, 2007 ⁹⁷	Moderate. Staff and outcomes assessors not blinded. ITT analyses, though using last value carried forward is a based method. Moderate attrition at 12 months, but lower before that.
Weiner, 2002 ⁹⁸	High - Secondary data analysis. Very high attrition. Possibly not eligible due to no valid control group (placebo pill or medications with behavior therapy only). Most study information unclear. Original study was Teri 2000.
Wright, 2001 ⁹⁹	High - Difference in minority group representation and severity of dementia despite randomization. Outcome assessors not blinded, same providers who delivered intervention. ITT analysis.

Descriptions of Community-Level Intervention Trials Rated High Risk of Bias

The Geriatric Home Hospitalization Service in Torino conducted a randomized controlled trial on 109 elderly, demented patients requiring admission for acute illnesses.⁹⁶ They compared home hospital care to a general medical ward care in reducing behavioral disturbances in elderly individuals with dementia.

Burgener et al. randomized 54 home-dwelling patients with dementia and their caregivers to educational and behavioral intervention or a control group.⁸² There were no group differences in outcomes relevant to our review.

Burgio et al. developed and studied manual-guided, replicable interventions based on common needs and cultural preferences of White and African American family caregivers of community-dwelling individuals with dementia.⁸³ Caregivers (70 white and 48 African American) were randomized to either a skills training condition or a minimal support control condition. Both interventions were delivered, according to protocol and well received by caregivers. Both groups reported decreasing levels of problem behavior and appraisals of behavioral bother.

Gonyea et al. reported on Project CARE, a randomized controlled trial designed to test the effectiveness of a caregiver-based multicomponent behavioral intervention aimed to reduce caregiver burden/distress associated with behavioral symptoms and reduce behavioral symptom severity among individuals with Alzheimer's disease.⁸⁹ The behavioral intervention involved five weekly sessions designed to teach caregivers specific techniques for managing patient behavioral symptoms in the home environment. Eighty caregivers were assigned to either the behavioral intervention group or a psychoeducational control group. Caregivers in the intervention group displayed greater reductions in caregiver distress ($p=.005$). Global caregiver burden, however, did not decrease significantly for caregivers in either group ($p>.05$). Although it was not statistically significant, there was a trend toward greater reductions in care recipients' neuropsychiatric symptom severity in the intervention group ($p=.10$).

Moniz-Cook et al. evaluated the effects of training community health nurses in a systematic psychosocial intervention to help family carers manage behavioural changes in individuals with dementia.⁹² One hundred and thirteen family carers received the intervention or a 'usual practice' Problem behaviour reduced with intervention with some but not all community health nurses. Carer management and mood improved with PSI support. In contrast, by 18 months, families supported by the intervention reported reduced coping resources, increased problem behaviour and their level of depression worsened.

Nobili et al. assessed the effects of a structured intervention on caregiver stress and the institutionalization rate among individuals with dementia and problem behaviors.⁹³ Caregivers were recruited through the Federazione Alzheimer Italia. Eligible caregiver-patient dyads were randomized to intervention or usual care. Mean problem behavior score in the 39 families completed the 12-month followup was significantly lower with intervention than control ($p < 0.03$).

Weiner et al. randomized caregivers to behavior management techniques, trazodone, and haloperidol for the treatment of agitated behaviors in individuals with dementia.⁹⁸ This study reports on the 12-month outcomes, 4 month outcomes were reported in another publication. After 4 months, treatment was allowed with any agent. Nearly half of the individuals with dementia received additional psychotropics between 4 and 12 months. The relative risk of being prescribed any psychotropic drug was similar across groups.

Wright et al. evaluated a 1-year long course education and counseling program with 93 family caregivers of individuals with dementia.⁹⁹ Individuals with dementia received treatment for agitation in an inpatient setting and were subsequently discharged. Caregivers were randomly assigned to intervention (n = 68) or control (n = 25). There were no significant treatment effects for care recipient agitation, caregiver stress and no significant differences between groups in rates of institutionalization. Longitudinal data revealed several important trends. Agitation in individuals with dementia rose steadily with control but declined for intervention.

Table F2. Caregiver-level interventions: strength of evidence assessments

Setting Intervention vs. Comparison	Outcome	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
Standard Education and Training vs. haloperidol	Patient Agitation/Aggression K=1; n=75	Improved (ADCS-CGIC) RR(CI)=1.0 [0.7 to 1.4] BRSD MC(SD): -3.56 (12.85) vs. -5.35 (22.41) RMBPC Total Frequency MC(SD): -0.08 (0.54) vs. -0.17 (0.65) CMAI MC(SD): -3.37 (11.45) vs. -7.26 (22.51) ABID Frequency MC(SD): -3.61 (9.88) vs. -6.74 (16.22)	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Caregiver Burden K=1; n=75	SCB Subjective MC(SD): -2.95 (7.29) vs. -1.88 (8.89) SCB Objective MC(SD): -1.23 (3.32) vs. -0.44 (3.22) ABID Reaction MC(SD): -2.41 (6.71) vs. -3.27 (9.10)	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Tailored Education and Training without psychosocial support	Caregiver Behavior K=1; n=190	Perceived change in ability to manage caregiving AMD (CI): -.12 (-.05 to .30)	Moderate	Direct	Imprecise	Unknown	Undetected	Insufficient
	Neuroleptic Drug Use K=1; n=62	Taking psychotropic drugs RR: 0.87 (0.56 to 1.35)	Low/	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Patient Agitation/Aggression K=2; n=252	RMPBC no. of disruption-related behaviors⁸⁵ AMD (CI): -.07 (-.46 to .33) RAGE, postintervention¹⁰⁰ mean(SD)=6.9 (3.6) vs. 8.6 (4.5)	Moderate	Direct	Imprecise	Consistent	Undetected	Insufficient
	Patient General Behavior K=2; n=118	NPI-Q severity score¹⁰¹ MC(SD): -1.7 (3.3) vs. -1.6 (2.6) BEHAVE-AD, postintervention¹⁰⁰ mean(SD)=6.5 (2.8) vs. 7.8 (3.4)	Moderate	Direct	Imprecise	Consistent	Undetected	Insufficient

Setting Intervention vs. Comparison	Outcome	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
	Patient distress/QoL k=1; n=56	See Report Text Table 8	Moderate	Indirect	Imprecise	Unknown	Undetected	Insufficient
Tailored Education and Training with psychosocial support	Caregiver Behavior k=4; n=694	Confidence using activities ⁸⁷ AMD (CI) ^a : 0.81 (0.30 to 1.32) Confidence managing behavior ⁸⁸ 16 weeks AMD (CI) ^b : 0.33 (0.08 to 0.58) 24 weeks: 71.9% vs 29.1%; $\chi^2=41.1$; $p=.001$ Mastery ⁸⁶ AMD (CI) ^c : .34 (.08 to .60) Confidence using activities ⁸⁶ AMD (CI) ^c : 1.67 (.41 to 2.94) Strategy use ⁸⁶ AMD (CI) ^c : 0.25; (0.04 to 0.46) Perceived change in ability to manage caregiving ⁸⁵ AMD (CI): .12 (-.05 to .30) Mastery ⁸⁵ AMD (CI): .11 (-.05 to .27)	Moderate to Low	Direct	Imprecise	Consistent	Undetected	Low
	Patient Agitation/Aggression k=2; n=265	ABID ⁸⁷ AMD (CI) ^a : -.65 (-3.05 to 1.74) Specific Behaviors-agitated ⁸⁶ AMD (CI) ^c : .06 (.01 to .56) Behavioral Occurrences ⁸⁶ AMD (CI) ^c : -.32 (-.55 to -.09) Number of Behaviors ⁸⁶ AMD (CI) ^c : -.98 (-2.67 to .71)	Moderate to Low	Direct	Imprecise	Inconsistent	Undetected	Insufficient
	Patient General Behavior k=8; n=1,896	Improvement in occurrence of targeted behavior ⁸⁸ 16 weeks 67.5% vs. 45.8%; $p=.002$ Target symptoms worsened/stayed the same, 16 weeks ⁸⁸ 18.4%/14% vs. 31.7%/22.5%; $p>.05$ NPI-S, 4.5 month ⁹⁷ MD in MC(SD)=0.8 (-3.61 to 5.28)	Moderate to Low	Indirect	Imprecise	Inconsistent	Undetected	Insufficient

Setting Intervention vs. Comparison	Outcome	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>NPI-S, 12 month⁹⁷ MD in MC(SD)=-2.2 (-2.65 to 7.06) Problem behavior-Hispanic⁸¹ Change (%) in net improvement (CI): 36.3 (13.2 to 56.7) Problem behavior: White⁸¹ Change (%) in net improvement (CI): 13.6 (-6.3 to 35.3) Problem behavior: Black⁸¹ Change (%) in net improvement (CI): -3.6 (-25.2 to 16.7) MBPC-frequency log growth model⁹¹ Estimate for group (SE): 0.24 (1.23); p=.84</p> <p>RMPBC no. of disruption-related behaviors⁸⁵ AMD (CI): -.07 (-46 to .33)</p> <p>MBPC frequency (hierarchical linear model)⁸⁴ Coefficient (SE) Non-spouse experimental: REF Non-spouse comparison: 0.77 (0.36); p<.001 Spouse experimental: 0.18 (0.26) Spouse comparison: 0.18 (0.26)</p> <p>MOUSE-PAD-Behavioral disturbance⁹⁰ Baseline, mean (SD): 5.1 (2.1) vs. 5.4 (2.5) VS. 5.1 (2.2) Post-treatment, mean (SE): 4.9 (0.2) vs. 5.0 (0.2) vs. 5.6 (0.2) Followup, mean (SD): 5.3 (2.0) vs. 5.5 (2.4) vs. 5.2 (2.0)</p> <p>RMBPC, disruptive behavior subscale⁹⁴ Baseline, mean (SD): 6.75 (5.55) vs. 5.32 (4.10) 3-months, mean (SD): 6.16 (5.26)</p>						

Setting Intervention vs. Comparison	Outcome	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		vs. 4.87 (3.54) 5-months, mean (SD): 6.35 (5.20) vs. 6.68 (4.50)						
	Patient distress/QoL k=1;n=209	Patient QoL-AD⁸⁷ AMD (CI) ^a : 0.10 (0.00 to 0.20)	Moderate to Low	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Patient LTC Admission k=1; n=518	Long term care admission RR (95% CI) Hispanic: 0.17 (0.02 to 1.36) White: 0.51 (0.21 to 1.22) African American: 1.54 (0.45 to 5.31)	Moderate to Low	Indirect	Imprecise	Unknown	Undetected	Insufficient
	Caregiver Burden, distress, QoL k=9; n=2119	Perceived change in well-being⁸⁷ AMD (CI) ^a : 0.22 (0.08 to 0.36) ZBS, 16 weeks⁸⁸ AMD (CI) ^b : -1.37 (-2.75 to 0.01) ZBS, 24 weeks⁸⁸ AMD (CI) ^b : -1.61 (-3.13 to -0.09) Behavior upset overall, 16 weeks⁸⁸ AMD (CI) ^b : -1.07 (-1.57 to -0.56) Behavior upset overall, 24 weeks⁸⁸ AMD (CI) ^b : -0.82 (-1.34 to -0.29) Caregiver Wellbeing⁸⁸ Perceived Change Index, 16 weeks⁸⁸ AMD (CI) ^b : 0.45 (0.29 to 0.62) Perceived Change Index, 24 weeks⁸⁸ AMD (CI) ^b : 0.29 (0.14 to 0.44) ZBS Subjective - Behavior Upset⁸⁶ AMD (CI) ^c : -.01 (-1.21 to 1.18) ZBS Subjective - Burden⁸⁶ AMD (CI) ^c : .75 (-3.36 to 4.85) RSS, 4.5 month⁹⁷ MD in MC(SD)=-0.1 (-2.50 to 2.32) RSS, 12 month⁹⁷	Moderate to Low	Direct	Imprecise	Inconsistent	Undetected	Insufficient

Setting Intervention vs. Comparison	Outcome	Summary Statistics	Risk of Bias	Directness	Precision	Consistency	Reporting Bias	Strength of Evidence
		<p>MD in MC(SD)=-1.2 (-4.23 to 1.79)</p> <p>Change (%) in net improvement – Hispanic⁸¹ (CI): -4.2 (-16.9 to 25.7)</p> <p>Change (%) in net improvement – White⁸¹ (CI): -4.6 (-23.7 to 15.4)</p> <p>Change (%) in net improvement – Black⁸¹ (CI): 23.1 (0.6 to 45.7)</p> <p>MBPC-reaction⁹¹ Estimate for group (SE): -2.90 (1.27) p=.02</p> <p>Upset with disruptive behaviors (RMPBC subscale)⁸⁵ AMD (CI): -.05 (-19 to .09)</p> <p>MBPC reaction hierarchical linear model estimate⁸⁴ -0.39; SE 0.18; p<.01</p> <p>ZBS⁹⁴ Baseline, mean (SD): 56.18 (13.29) vs. 56.54 (15.97) 3-months, mean (SD): 56.82 (11.83) vs. 55.43 (15.91) 5-months, mean (SD): 54.13 (11.29) vs. 59.81 (15.23)</p> <p>Caregiver distress RMBPC, caregiver response to disruptive behavior subscale⁹⁴ Baseline, mean (SD): 6.76 (6.27) vs. 5.20 (5.10) 3-months, mean (SD): 5.00 (5.38) vs. 4.42 (4.23) 5-months, mean (SD): 4.08 (4.44) vs. 5.73 (4.42)</p>						

Mod=moderate; MD=mean difference; NA=not applicable; NR=not reported; RR=risk ratio

References for Appendixes

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