

Appendix: Parameters of the Review

“Other than use of physical restraints or prescription of medications, what interventions, strategies, and/or practices have proven effective in preventing and managing agitation and aggression in long-term care residents with dementia?”

A. Research Design & Publication Dates

Our synthesis includes two types of research articles:

1. Systematic reviews, meta-analyses or health technology assessments published between February 2009 and March 2014, inclusive. To be considered “systematic,” a given review had to provide three things:
 - i. a documented search strategy for identifying relevant primary studies;
 - ii. citation info for all included studies; and
 - iii. an aggregate description of included study characteristics that included participants, setting, intervention, outcomes.
2. Randomized controlled trials (RCTs) published between December 31, 2012 (date limit for studies included in Testad, 2014), and March 31, 2014.

B. Selection Criteria

The research team collectively agreed on the following inclusion criteria for selection of articles:

Intervention:

1. RCTs/systematic reviews were selected if they attempted to assess the effectiveness of an intervention or set of interventions designed to prevent or manage the incidence of one or both of the following symptoms of dementia: agitation and aggression.
2. Articles on particular medications or categories of medications were not included. However, articles on prescription medication review and/or modification *were* eligible for inclusion.

Setting:

3. An RCT was selected if
 - a. both the intervention(s) *and* evaluation/measurement/observation were carried out in a long-term care (LTC) setting, defined as an institution where LTC is provided by professional care workers for residents requiring nursing care, i.e., mostly frail elderly people. Examples include:
 - nursing homes
 - long-term hospital units
 - complex continuing care settings
 - protective care settings
 - supervised care settings
 - group dwelling units or personal care homes that serve *only* patients with moderate-to-severe dementia
 - OR**
 - b. in the case of a multi-site study, interventions delivered in LTC were analyzed and evaluated separately from the others, such that we could discern a finding or findings specific to interventions delivered in LTC
4. A systematic review was selected if
 - a. at least 66% of its included studies satisfied criterion #3, **OR**
 - b. included studies that satisfied condition #3 were analyzed separately from the others, such that we could discern a finding or findings specific to interventions delivered in LTC – e.g., subgroup analysis in the case of meta-analyses.

Population:

5. An RCT was selected if
 - a. 100% of study participants were ≥ 60 years old, **OR**
 - b. the mean age of study participants was ≥ 65 years old, **OR**
 - c. in the case of a multi-site study, interventions delivered exclusively to a patient population such as those described in #5 a & b were analyzed and evaluated separately from the others, such that we could discern a finding or findings specific to interventions for older patients

6. A systematic review was selected if
 - a. at least 66% of its included studies satisfied condition #5, **OR**
 - b. included studies that satisfied condition #5 were analyzed separately from the others, such that we could discern a finding or findings specific to interventions for older patients— e.g., subgroup analysis in the case of meta-analyses.

Outcome

7. RCTs/systematic reviews were selected if they employed any measure or set of measures that enabled them to assess the effect of an intervention or set of interventions on the incidence of one or both of the following symptoms of dementia: agitation and aggression.

C. Search Strategy & Article Selection

To identify relevant articles we searched PubMed, CINAHL and EMBASE. Our search was limited to articles published in English. The following tables illustrate how the searches were constructed and provide the detailed search strings with the number of results obtained for each search.

PubMed Search Strategy

Systematic Reviews	
Limits	Abstract available; Publication date from 2009/02/28 to 2014/03/31; English
Search string	((intervention*[Title] OR therap*[Title] OR manag*[Title] or treat*[Title] OR strateg*[Title]) AND ("dementia"[Title] OR ((restraint*[Title] OR antipsychotic*[Title]) AND ("long-term care"[Title] OR "long term care"[Title] OR "long-term geriatric"[Title] OR "long term geriatric"[Title] OR "care home"[Title] OR "care homes"[Title] OR "nursing home"[Title] OR "nursing homes"[Title]))) OR (("Restraint, Physical"[Majr] OR "Antipsychotic Agents"[Majr]) AND ("Homes for the Aged"[Majr] OR "Nursing Homes"[Majr] OR "Long-Term Care"[Majr])) OR ("Dementia"[Majr] AND ("Therapeutics"[Majr] OR "Psychotherapy"[Majr])) OR ("Dementia/diet therapy"[Majr] OR "Dementia/nursing"[Majr] OR "Dementia/psychology"[Majr] OR "Dementia/rehabilitation"[Majr] OR "Dementia/therapy"[Majr])) AND (meta analysis[Publication Type] OR meta analysis[Title/Abstract] OR meta analysis[MeSH Terms] OR review[Publication Type] OR search*[Title/Abstract] OR "systematic review"[Title] OR systematic [sb])
Results	1602 on April 2, 2014
Development	<ol style="list-style-type: none"> 7. Search (#6 AND #1) Filters: Abstract available; Publication date from 2009/02/28 to 2014/03/31; English 6. Search (#2 OR #3 OR #4 OR #5) 5. Search (intervention*[Title] OR therap*[Title] OR manag*[Title] or treat*[Title] OR strateg*[Title]) AND ("dementia"[Title] OR ((restraint*[Title] OR antipsychotic*[Title]) AND ("long-term care"[Title] OR "long term care"[Title] OR "long-term geriatric"[Title] OR "long term geriatric"[Title] OR "care home"[Title] OR "care homes"[Title] OR "nursing home"[Title] OR "nursing homes"[Title]))) 4. Search ("Restraint, Physical"[Majr] OR "Antipsychotic Agents"[Majr]) AND ("Homes for the Aged"[Majr] OR "Nursing Homes"[Majr] OR "Long-Term Care"[Majr]) 3. Search "Dementia"[Majr] AND ("Therapeutics"[Majr] OR "Psychotherapy"[Majr]) 2. Search "Dementia/diet therapy"[Majr] OR "Dementia/nursing"[Majr] OR "Dementia/psychology"[Majr] OR "Dementia/rehabilitation"[Majr] OR "Dementia/therapy"[Majr] 1. Search meta analysis[Publication Type] OR meta analysis[Title/Abstract] OR meta analysis[MeSH Terms] OR review[Publication Type] OR search*[Title/Abstract] OR "systematic review"[Title] OR systematic [sb]

Primary studies	
Limits	Abstract available; Publication date from 2012/12/31 to 2014/03/31; English
Therapy filter	((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])
Results	557 on April 2, 2014

CINAHL Search Strategy

Systematic Reviews	
Limits	Abstract Available; Published Date: 20090201-20140331; English Language; Exclude MEDLINE records; Clinical Queries: Review - Best Balance
Results	58 on April 2, 2014
Development	<ol style="list-style-type: none"> 5. S1 OR S2 OR S3 OR S4 4. (TI intervention* OR TI therap* OR TI manag* or TI treat* OR TI strateg*) AND (TI "dementia" OR ((TI restraint* OR TI antipsychotic*) AND (TI "long-term care" OR TI "long term care" OR TI "care home" OR TI "care homes" OR TI "nursing home" OR TI "nursing homes" OR TI "long-term geriatric" OR TI "long term geriatric"))) 3. (MM "Restraint, Physical" OR MM "Antipsychotic Agents") AND (MM "Nursing Homes" OR MM "Long Term Care") 2. MM "Dementia" AND (MM "Therapeutics" OR MM "Psychotherapy") 1. (MM "Dementia+/DH/NU/RH/TH/PF")
Primary studies	
Limits	Abstract Available; Published Date: 20121201-20140331; English Language; Exclude MEDLINE records; Clinical Queries: Therapy - High Sensitivity
Results	31 on April 3, 2013

EMBASE Search Strategy

Systematic Reviews	
Limits	([cochrane review]/lim OR [meta analysis]/lim OR [systematic review]/lim) AND [english]/lim AND [abstracts]/lim AND [embase]/lim AND [28-2-2009]/sd NOT [31-3-2014]/sd
Results	188 on April 3, 2014
Development	<ol style="list-style-type: none"> 5. #1 OR #2 OR #3 OR #4 4. intervention*:ti OR therap*:ti OR manag*:ti or treat*:ti OR strateg*:ti AND ('dementia':ti OR (restraint*:ti OR antipsychotic*:ti AND ('long-term care':ti OR 'long term care':ti OR 'long-term geriatric':ti OR 'long term geriatric':ti OR 'nursing home':ti OR 'nursing homes':ti OR 'care home':ti OR 'care homes':ti))) 3. 'neuroleptic agent'/exp/mj AND ('long term care'/exp/mj OR 'nursing home'/exp/mj OR 'home for the aged'/exp/mj) 2. 'dementia'/exp/mj AND ('therapy'/exp/mj OR 'psychotherapy'/exp/mj) 1. 'dementia'/exp/mj/dm_th,dm_rh
Primary studies	
Limits	([controlled clinical trial]/lim OR [randomized controlled trial]/lim) AND [english]/lim AND [abstracts]/lim AND [embase]/lim AND [31-12-2012]/sd NOT [31-3-2014]/sd
Results	84 on April 3, 2014

A search of grey literature websites was also conducted in April 2014 in an attempt to identify any relevant articles:

I. Canada

CADTH (<http://www.cadth.ca/en/products>): search for “dementia” in “All Products”, 26 results, none selected

Evidence-Informed Healthcare Renewal Portal (www.eihrportal.org): search for “dementia,” 41 results, none selected

healthvidence.org (<http://www.healthvidence.org/search.aspx>): search for “dementia,” 48 results, none selected

PATH (<http://www.path-hta.ca/Publications-Presentations/Publications/Al.aspx>): manual search, selected: none

CHEPA (<http://www.chepa.org/research-products/search-for-documents>): search for “dementia” in publications database, results: 5, selected: none

AETMIS (<http://www.inesss.qc.ca/index.php?id=49>): manual search, selected: none

TAU of the MUHC (<http://www.mcgill.ca/tau/publications>): manual search, selected: none

MCHP (<http://mchp-appserv.cpe.umanitoba.ca/deliverablesList.html>): manual search, selected: none

IHE (<http://www.ihe.ca/publications/library/>): manual search, selected: none

ARCHE (<http://www.ualberta.ca/ARCHE/publications.htm>): manual search, selected: none

CHSPR (<http://chspr.ubc.ca/pubs/pub-search>): manual search, selected: none

II. U.K.

National Health Service Evidence (<http://www.evidence.nhs.uk/>): search for “dementia AND (aggress* OR agitat*)” (note: this was a keyword search) limited to clinical, last 3 years, systematic reviews/HTAs/primary research, 324 results, selected: Forrester, 2014; Konno, 2013 (doc delivery request pending); Blythe, 2009 (doc delivery request pending)

TRIP Database (<http://www.tripdatabase.com/index.html>): search for (title:dementia) (title:intervention* or therap* or strateg* or treat* or manag*) from:2009 to:2014 in ‘Systematic Reviews’ (50 results) and from:2013 to:2014 in ‘Key Primary Research’ (4), ‘Controlled Trials’ (147), and ‘Extended Primary Research’ (100), selected: Basu, 2010; Houser, 2014; Husebo, 2013; Ridder, 2013; Rosvik, 2014; Vink, 2013.

III. U.S.

CTAF (<http://www.ctaf.org/assessments>): manual search, selected: none

AHRQ (<http://www.ahrq.gov/research/findings/index.html>): manual search of EPC Evidence-based Reports, selected: 0; manual search of Full Research Reports, selected: 0; manual search of Technology Assessments, selected: 0

NY Academy of Medicine Library Catalog (<http://nyam.waldo.kohalibrary.com/cgi-bin/koha/opac-search.pl>): search for “dementia” keywords, English, 2009-2014, results: 34, selected: 0

IV. Australia/New Zealand

National Health and Medical Research Council (<http://www.nhmrc.gov.au/guidelines-publications>): manual search, selected: none

Medical Services Advisory Committee (Gov of Australia)

(<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/completed-assessments>): manual search of Completed Assessments and Reviews, selected: 0

D. Excluded Articles

Articles excluded on the basis of a full-text review are listed below.

- (1) Azermai M, Petrovic M, Engelborghs S, Elseviers MM, Van der Mussele S, Debruyne H, et al. The effects of abrupt antipsychotic discontinuation in cognitively impaired older persons: a pilot study. *Aging Ment.Health.* 2013;17(1):125-132.
- (2) Eggenberger E, Heimerl K, Bennett MI. Communication skills training in dementia care: a systematic review of effectiveness, training content, and didactic methods in different care settings. *Int.Psychogeriatr.* 2013 Mar;25(3):345-358.
- (3) Fossey J, Masson S, Stafford J, Lawrence V, Corbett A, Ballard C. The disconnect between evidence and practice: a systematic review of person-centred interventions and training manuals for care home staff working with people with dementia. *Int.J.Geriatr.Psychiatry* 2014 Feb 18.
- (4) Majic T, Gutzmann H, Heinz A, Lang UE, Rapp MA. Animal-assisted therapy and agitation and depression in nursing home residents with dementia: a matched case-control trial. *Am.J.Geriatr.Psychiatry* 2013 Nov;21(11):1052-1059.
- (5) Mowrey C, Parikh PJ, Bharwani G, Bharwani M. Application of behavior-based ergonomics therapies to improve quality of life and reduce medication usage for Alzheimer's/dementia residents. *Am.J.Alzheimers Dis.Other Demen.* 2013 Feb;28(1):35-41.
- (6) Seitz DP, Brisbin S, Herrmann N, Rapoport MJ, Wilson K, Gill SS, et al. Efficacy and feasibility of nonpharmacological interventions for neuropsychiatric symptoms of dementia in long term care: a systematic review. *J.Am.Med.Dir.Assoc.* 2012 Jul;13(6):503-506.e2.
- (7) Vasionyte I, Madison G. Musical intervention for patients with dementia: a meta-analysis. *J.Clin.Nurs.* 2013 May;22(9-10):1203-1216.
- (8) Wall M, Duffy A. The effects of music therapy for older people with dementia. *Br.J.Nurs.* 2010 Jan 28-Feb 10;19(2):108-113.

E. Critical Appraisal

As stated in the main report, our critical appraisal methodology for systematic reviews employs AMSTAR¹, a validated measurement tool for evaluating the methodological quality of systematic reviews. AMSTAR scores range from 0 to 11. Higher scores can be taken as an indicator that the various stages of the review – e.g., literature searching, pooling of data, critical appraisal, etc. – were conducted appropriately. Each included systematic review was scored independently by both Rob Kean and Sarah Mackey using the AMSTAR tool. Rob and Sarah then met and compared their appraisals, review by review, and resolved any discrepancies in score via a consensus procedure. Below we provide a blank version of the AMSTAR scoring sheet, a table that illustrates how each review was scored, and the data extraction tables.

Rob and Sarah also conducted Cochrane Risk of Bias assessments² for each of the five RCTs discussed in the reports. They assessed each study independently and subsequently compared their appraisals, study by study, and resolved any discrepancies via a consensus procedure. These assessments are presented below.

¹ See: Shea, B.J., Bouter, L.M., Peterson, J., Boers, M., Andersson, N., et al. 2007. External Validation of a Measurement Tool to Assess Systematic Reviews (AMSTAR). *PLoS ONE* 2(12): e1350. doi:10.1371/journal.pone.0001350

² See: Higgins, J.P.T., Altman, D.G.; Sterne, J.A.C. 2011. "Chapter 8: Assessing risk of bias in included studies," in Higgins, J.P.T. and Green, S., eds., *Cochrane Handbook for Systematic Reviews of Interventions* 5.1.0.

REFERENCE:

AMSTAR Item	Answer
<p>1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>7. Was the scientific quality of the included studies assessed and documented? 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I²). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?)</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
<p>11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable

Review	AMSTAR Item											Total
	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	
Declercq 2013	1	1	1	1	1	1	1	1	1	1	0	10/11 (91%)
Richter 2012	1	1	1	1	1	1	1	1	1	1	0	10/11 (91%)
Mohler 2012	1	1	1	0	1	1	1	1	1	1	0	9/11 (82%)
Basu 2010	1	1	1	0	1	1	1	1	1	0	0	8/11 (73%)
Forbes 2014	1	1	1	0	1	1	1	1	1	0	0	8/11 (73%)
Forrester 2013	1	0	1	0	1	1	1	1	1	1	0	8/11 (73%)
Lai 2009	1	0	1	0	1	1	1	1	1	1	0	8/11 (73%)
Vink 2011	1	1	1	0	1	1	1	1	1	0	0	8/11 (73%)
Whear 2014	1	1	1	1	0	1	1	1	1	0	0	8/11 (73%)
Moniz Cook 2012	1	0	1	0	1	1	1	1	1	0	0	7/11 (64%)
Zimmerman 2013	1	1	1	0	0	1	1	1	1	0	0	7/11 (64%)
Kong 2009	0	1	1	0	0	1	1	1	1	0	0	6/11 (55%)
Konno 2013	0	0	1	0	1	1	1	1	1	0	0	6/11 (55%)
Liu 2014	0	1	1	0	0	1	1	1	1	0	0	6/11 (55%)
Guzman-Garcia 2012	0	0	1	0	0	1	1	1	1	0	0	5/11 (45%)
O'Connor 2009	0	0	1	0	0	1	1	1	1	0	0	5/11 (45%)
Pieper 2013	0	0	1	0	0	1	1	1	1	0	0	5/11 (45%)
Reuther 2012	0	0	1	0	0	1	1	1	1	0	0	5/11 (45%)
Enmarker 2011	0	1	1	0	0	1	0	0	1	0	0	4/11 (36%)
Fung 2012	0	0	0	0	0	1	1	1	1	0	0	4/11 (36%)
Husebo 2011	0	0	1	0	0	1	0	0	1	1	0	4/11 (36%)
Kverno 2009	0	0	0	0	0	1	1	1	1	0	0	4/11 (36%)
O'Neil 2011	0	0	1	0	0	1	0	0	1	1	0	4/11 (36%)
Testad 2014	0	0	0	0	0	1	1	1	1	0	0	4/11 (36%)
Bernabei 2013	0	0	1	0	0	1	0	0	1	0	0	3/11 (27%)
Skingley 2010	0	0	1	0	0	1	0	0	1	0	0	3/11 (27%)

Narme 2014

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"A total of 48 patients were randomly assigned to either the music or cooking group" (p361). Comment: How?
Allocation concealment (selection bias)	Unclear risk	See quote & comment above.
Blinding of participants and personnel (performance bias)	Low risk	Comment: Blinding of P&P was not possible, but it does not seem likely that the lack of blinding would have influenced the outcome. Participants all had a diagnosis of dementia, and researchers took special pains to prevent methodological bias related to the therapist effect (see p367).
Blinding of outcome assessment (detection bias)	High risk	"Agitated behaviors and their frequency were rated using the CMAI, with higher scores corresponding to greater occurrence of agitated behaviors (total score out of 203). The NPI is a brief interview filled out by professional caregivers..." (p362). Comment: Behavioral assessments seemed to have been carried out by caregivers, who would very likely have been aware of intervention assignments and the purpose of the study
Incomplete outcome data (attrition bias)	Unclear risk	"Eleven (23% of the participants did not complete the whole intervention due to refusal (n=3), health problems (n=6), or death (n=2). The remaining 37 patients (music group: n=18; cooking group: n=19) underwent a multi-domain evaluation..." (p361). Comment: Not enough information about reasons for attrition within each group.
Selective reporting (reporting bias)	Unclear risk	Protocol unavailable
Other bias	Low risk	Comment: No significant baseline imbalance between groups

Ridder 2013

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"The randomization was carried out immediately after baseline data collection, using a concealed sequence procedure. This was done by the researchers (HMOR in Denmark and LGQ in Norway), and witnessed and signed by a third party (a university secretary or a colleague not involved in the study)" (p669). Comment: Not exactly clear what a "concealed sequence procedure" is
Allocation concealment (selection bias)	Unclear risk	Comment: See quote above. Because we can't be sure that the sequence was random, we can't be sure that it was concealed
Blinding of participants and personnel (performance bias)	Low risk	Comment: Blinding of participants and personnel was not possible, but it does not seem likely that the lack of blinding would have influenced the outcome. Participants all had a diagnosis of dementia and personnel at all sites had a vested interest in preventing or managing BPSD
Blinding of outcome assessment (detection bias)	High risk	"It was a limitation of the study that interviewers and proxy respondents were not blinded to the treatment allocation..." (p675).
Incomplete outcome data (attrition bias)	Low risk	"Collecting data by proxy interviews ensured a high response rate and few missing data" (p675). Comment: Attrition balanced across intervention groups with similar reasons across groups
Selective reporting (reporting bias)	Unclear risk	Comment: Article mentions a protocol, but we couldn't find it
Other bias	Low risk	Comment: Little significant baseline imbalance, cross-over design appropriate, carry-over effects unlikely, & order of receiving treatments was randomized.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Before randomization, the 15 nursing homes were divided into three blocks according to their size defined as small (30-49 patients; 6 nursing homes), medium (50-59 patients; 6 nursing homes) or large (70-95 patients; 3 nursing homes)... Block randomization was done by drawing lots, and each of the three intervention groups then consisted of two small, two medium and one large nursing home" (p342). Comment: The mash of sequence generation steps is confusing
Allocation concealment (selection bias)	Unclear risk	Comment: No indication from the article that steps taken to ensure recruiters were unaware of whether their particular site was in the intervention clusters or the control cluster.
Blinding of participants and personnel (performance bias)	Low risk	Comment: Blinding of P&P not possible, but does not seem likely that this would have influenced the outcome.
Blinding of outcome assessment (detection bias)	High risk	"[RAs] collected data from the patients' records and interviewed the patients' primary nurse" (p342). Comment: The primary nurse and those nurses responsible for maintaining patients' records would likely have had knowledge of assignments
Incomplete outcome data (attrition bias)	Low risk	"We included a total of 446 patients in the efficacy analysis as 178 (29%) were lost to follow-up assessments, most of them because of death. There were no significant differences between the groups in neither the number nor the causes of droupouts" (p346). Comment: Attrition balanced across intervention groups with similar reasons across groups
Selective reporting (reporting bias)	Unclear risk	Comment: Psychotropic drugs mentioned as 2ndary outcome measure in protocol but not in article
Other bias	Low risk	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	PI "generated the random allocation sequence using Excel Random Number Generator" (pp566-7).
Allocation concealment (selection bias)	Unclear risk	Comment: See quote above. No info provided about steps taken to conceal allocation sequence
Blinding of participants and personnel (performance bias)	Low risk	Comment: Blinding of P&P not possible, but it does not seem likely that this would have influenced the outcome.
Blinding of outcome assessment (detection bias)	High risk	"Because of the nature of the activities, it was not possible to blind observers to the Montessori or the control conditions..." (pp569-70).
Incomplete outcome data (attrition bias)	Low risk	"In 25 of 352 sessions (7%), some data points were missing for an average of 7.6 out of the total of 90 minutes of observations... If less than half of an observation period was missing, we imputed data by carrying forward previous observations. If data were missing for over half of a period, we imputed data by calculating the average across the other Montessori or control sessions" (p568). Also: "...dismissal was equally spread across conditions, with two individuals refusing the Montessori intervention and two refusing during the control phase (p570). Comment: Attrition balanced across intervention groups with similar reasons across groups, proportion of missing data points likely too small to bias the outcome
Selective reporting (reporting bias)	Low risk	Comment: Researchers have reported on all the outcomes mentioned in the protocol
Other bias	Low risk	"...participants were randomized to Montessori or control blocks for two weeks then switched to the other condition" (p567). Comment: Cross-over design is appropriate, carry-over effects unlikely, & order of receiving treatments was randomized.

Vink 2013

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"To ensure randomised allocation, sealed envelopes were used, with at least two persons present to ensure appropriate randomisation" (p1032). Comment: Unclear <i>how</i> sealed envelopes were used.
Allocation concealment (selection bias)	Unclear risk	Comment: See above. Unclear whether the envelopes were opaque and sequentially numbered.
Blinding of participants and personnel (performance bias)	Low risk	Comment: Blinding of P&P not possible, but unlikely that this would have influenced the outcome
Blinding of outcome assessment (detection bias)	High risk	"Some of the nurse carers who rated the modified CMAI scores were at occasion responsible for taking the residents to either the activity or music therapy room. Complete blinding for some of the nurse carers could therefore not be guaranteed" (p1033).
Incomplete outcome data (attrition bias)	Unclear risk	"Seven residents (all randomised to general activities) were excluded because of missing data at baseline. Three other residents (one randomised to music therapy and two to general activities) were excluded because CMAI data at 4 h after the session were missing" (pp1034-5)" Overall: "...nine residents in the general activities group versus only one in the music therapy group were excluded from analysis because of missing data" (p1037). Comment: There is a sizeable difference in the proportions of missing outcomes between intervention groups, and the reason for that difference is unclear.
Selective reporting (reporting bias)	Unclear risk	Protocol unavailable
Other bias	Low risk	Comment: Baseline imbalance between groups in terms of GDS scores taken into account during analysis

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessors (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Namæ 2014	?	?	+	+	?	?	+
Fiddri 2013	?	?	+	+	+	?	+
Roksta 2013	?	?	+	+	+	?	+
van der Floot 2013	+	?	+	+	+	+	+
Vink 2013	?	?	+	+	?	?	+

Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

E. Data Extraction – Systematic Reviews

The information contained in the “Review authors’ assessment...” and “Main Findings” columns below consist mainly of direct quotations from the review articles included in our synthesis.

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors’ assessment of review limitations/included study quality	Main Findings
<p>Basu 2010</p> <p>8/11 (73%)</p> <p>N=30* – 4 systematic reviews (Bharani, 2005; Landreville, 2006; Perkins, 2008; Livingston, 2005), 11 RCTs, 15 before & after/case series</p> <p>*includes only those articles with a specific finding on either agitation or aggression</p>	<p>Residential care facilities and specialized dementia care facilities</p>	<ul style="list-style-type: none"> • Training programs for carers, staff, family • Individually tailored behavioural management programs • Music therapy • Physical activity based treatment programs • Aromatherapy • Animal-assisted therapy • Bright light therapy and Snoezelen (multi-sensory stimulation) 	<p><u>From p110-1:</u></p> <p>“In interpreting these results, several limitations imposed by the nature of the evidence warrant discussion: including, ‘attention effects’, the ‘Hawthorne effect’, halo effects, small sample sizes (resulting in a failure to detect a true difference), nonblinding of outcome assessments, selection biases, other observational and measurement biases, inadequate follow-up and other confounders (known and unknown)...” [see p110-1 for a discussion of these]</p>	<p>“Notwithstanding these limitations, and based on a synthesis of the body of evidence pertaining to the effectiveness of different interventions related to the management of BPSD in aged care residents....” (pp111-2):</p> <ul style="list-style-type: none"> • Training – “Training programmes directed at carers and/or staff of residential care facilities and those that incorporated some aspects of communication and behavioural management training and/or monitoring/supervision were found to be beneficial in general, when compared to ‘usual care’ that did not contain any of these elements (Chenoweth, et al., 2009; Landreville, et al., 2006; Livingston, et al., 2005)” (p112) [note: the table of included studies on pp63-82 includes 9 studies that measured the effect of staff training interventions on agitation and/or aggression]. • Music therapy – “The use of music, either in the form of individual-preferred music or music played in common areas for groups was found to be effective in reducing aggression and agitation (Choi, et al., 2009; S.L Hicks-Moore, 2005; S.L. Hicks-Moore & Robinson, 2008; Ziv, et al., 2007)” (p112) [note: the table of included studies on pp63-82 includes 10 studies that measured the effect of musical interventions on agitation and/or aggression]. • Aromatherapy – “Some evidence suggests that lavender, lemon balm, or marjoram extracts used in aromatherapy might be beneficial in reducing agitation.... [However], there is limited evidence to justify the therapeutic role of aromatherapy. While the findings are equivocal, there have been few randomised trials adequately powered to detect even a large treatment effect” (p113). • Animal-assisted therapy – “There was limited evidence to suggest that the use of dogs (pet or therapy) in residential care facilities is associated with a beneficial effect [on the agitation profile scores of residents]” (p113 – based on Perkins 2008 and Churchill 1999). • Bright light therapy and Snoezelen – “...there is insufficient evidence in support of the effectiveness of either BLT or Snoezelen for the management of [any] BPSD” (p114).

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Bernabei 2013</p> <p>3/11 (27%)</p> <p>N=10* – 3 case-control, 7 repeated measures</p> <p>*includes only those articles that measured the effects of intervention on BPSD</p>	<p>3 studies set in psychiatric hospital units, 2 in Special Care Units, 4 in nursing homes, 1 in Alzheimer day care centre</p>	<ul style="list-style-type: none"> Animal Assisted Intervention Animal assisted interventions with robots used as a substitute pet 	<p><i>From pp769 & 771:</i></p> <p>“One limit to the present review, however, pertains to the large differences in study design of the selected papers, type of intervention, and duration, which made comparison between studies particularly difficult.”</p> <p>“The fact that the assessment scales and matching procedures used also differed, presented a further source of bias. Another complication in the results comparison was due to researchers subjectively evaluating participants' quality and frequency of social interaction.”</p> <p>“The studies were frequently limited by small sample size which can, of course, reduce statistical power for detecting statistically significant associations. In addition to sample size, lack of homogeneity in the study samples also confounded the results.”</p>	<p>There appear to have been only six studies that measured agitation and/or aggression specifically: Walsh 1995, Kanamori 2001, Churchill 1999, Richeson 2003, Sellers 2005, and Libin 2004.</p> <p>“Despite the above described difficulties in comparing AAI procedures (in terms of duration, frequency of intervention, assessment scales, sample size and homogeneity, and duration), the following positive influences emerged in studies carried out among demented patients: calming of agitated behaviour and positive effects on quality of social interaction and mood disturbances, although no effect was observed for cognitive performance” (p771).</p>
<p>Declercq 2013</p> <p>10/11 (91%) (Cochrane)</p> <p>N=9 RCTs</p>	<p>7 studies set in nursing homes, 1 in outpatient setting (Devanand 2011), 1 in mixture of the two (Devanand ADAD 2012)</p>	<p>Abrupt or tapered withdrawal of antipsychotics</p>	<p><i>From pp 20-1:</i></p> <p>“We found few studies on this topic with good overall methodological quality.... All included studies had problems including enough frail older people (a group with high mortality) and as a result the statistical power of the studies was low and very few outcomes showed statistically significant differences between the groups.... Therefore, data on the effect of withdrawal of antipsychotics in older people with dementia and NPS remain very sparse and conclusions should be interpreted with caution, especially regarding people with more severe types of dementia and regarding people with psychosis or agitation that responded well to prolonged antipsychotic therapy.”</p>	<p>“Outcome measures were very different across included studies and therefore difficult to compare,” (p11) though 5 of the 7 included studies conducted in nursing homes used specific measures of agitation and/or aggression (the NPI or NPI-Q agitation sub-scores, the PAB scale, the CMAI, or the ROAS), and the other 2 used composite measures of NPSD.</p> <p>In these 7 trials, “antipsychotics could be withdrawn in older people with dementia and NPS without a significant effect on most outcomes. In particular, behavioural symptoms measured by the NPI or NPI-Q were not influenced by withdrawing antipsychotic medication” (p20).</p> <p>“Older people with dementia and NPS using long-term antipsychotics can be withdrawn without detrimental effects on their behaviour. However, there is some evidence suggesting that people with more severe NPS (total NPI > 14) could benefit from continuing antipsychotic treatment. We also found that a subgroup of people with dementia and psychosis or agitation who responded well to antipsychotic medication before may relapse after discontinuation of their antipsychotic medication” (p21).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Enmarker 2011</p> <p>4/11 (36%)</p> <p>N=21 – 1 RCT, 17 prospective studies, 3 qualitative</p>	<p>Nursing home units.</p>	<p>Alternative approaches to aggression management other than physical or chemical restraint in patients with dementia.</p> <p>Themes:</p> <ol style="list-style-type: none"> 1) Resident's personal care 2) Activities decreasing violent behavior 3) Environmental features 4) Person Centred education programs for staff 	<p>Studies whose scientific quality was judged to be poor were excluded from the review.</p>	<p>"...person-centred approach reduces residents' aggression. If nursing home staff use a traditional symptom-focused approach, cues of pain often become ignored since they do not manage to see or understand residents' cues. These clues [<i>sic</i>] include facial grimacing, stiffened posture, guarding actions and increased irritability and, when apparent, there is a greater risk of violence. According to Sloane et al. (2007), the amount of touch during a morning care session could be more than four times per minute. If the staff ignore the residents' cues of pain and do not see them as legitimate human emotion and meaningful expressions or forms of communication, it is logical to assume that residents' use violence as a last resort" (p159).</p>
<p>Forbes 2014</p> <p>8/11 (73%) (Cochrane)</p> <p>N= 6 RCTs*</p> <p>*Only includes those studies that measured agitation</p>	<p>All but one study set in LTC facilities</p>	<p>Light therapy (any intervention involving the use of bright light)</p>	<p>The quality problems identified by the reviewers would have served to exaggerate estimates of intervention effects.</p>	<p>Only 6 of the included studies measured agitation, & the reviewers pooled data from 4 of these (these are the "four included trials" referred to below).</p> <p>"No significant evidence was found that light therapy decreased... challenging behaviours, or improved psychiatric symptoms including depression. Indeed, the four included trials that examined challenging behaviours (that is agitation) revealed that light therapy was not effective when administered in the morning, afternoon, evening, or all day at from 10 days to 10 weeks and with treatment lasting up to two years" (p18).</p> <p>From the abstract: "There is insufficient evidence to justify the use of bright light therapy in dementia."</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Forrester 2013</p> <p>8/11 (73%) (Cochrane)</p> <p>N=7 RCTs</p>	<p>5 studies set in nursing homes, 1 in general hospital ward, 1 not reported</p>	<p>Aromatherapy</p>	<p><u>From p17:</u></p> <p>"The overall quality of the evidence, based on GRADE, is very low. Four out of the seven studies did not report any data that we could use in the analysis, and the three studies that did report data were small with short follow-ups. Ballard 2002 was a cluster-randomised trial and there might have been variation between the eight nursing homes included in the study that was not accounted for in the adjusted analysis, which could have confounded the results from this trial."</p>	<p>"Five trials measured agitation on three scales. Participants were less agitated in the aromatherapy group in two studies, Ballard 2002 and Lin 2007; the latter was a cross-over study only reporting overall data. Three other studies (Burns 2011; Cameron 2011; Fu 2013) found no difference in participants' levels of agitation, although Cameron 2011 did not report any actual data and Fu 2013 did not report data separately for each treatment group" (p17 – results described as "equivocal" in table on p3).</p> <p>In addition: "Fung 2012 reports that there is some evidence that aromatherapy has a positive effect on cognitive functioning and reducing BPSDs. However, although the review stated that they included only RCTs, six of the 11 included studies were not randomised and one was not testing aromatherapy, and so we have not included these studies in our review; accounting for the differences in our results" (p17).</p>
<p>Fung 2012</p> <p>4/11 (36%)</p> <p>N=11 RCTs (but see commentary in Forrester 2013, above)</p>	<p>Only 6 of 11 included studies (55%) set in LTC, but pooled results from 2 of these studies.</p>	<p>Aromatherapy</p>	<p>"Each study was assessed using the Jadad score. The highest score was five and the lowest was zero.... Six out of 11 studies had a Jadad score of two or less [Lin's was 3 and Ballard's was 5]. Sample sizes were less than 30 in seven out of the 11 studies" (p379).</p> <p><u>From Forrester, 2013:</u></p> <p>"Ballard 2002... and Lin 2007 measured agitation on [the CMAI], but analysis was only possible for Ballard 2002.... Lin 2007 was a randomised cross-over trial.... However, the data for each phase of the trial were not presented separately" (pp15-16 – see also these reviewers' commentary under 'Main Findings,' above and on p17 of their review).</p>	<p>"Meta-analysis on the CMAI variables was carried out on Ballard et al.'s and Lin et al.'s studies.... The meta-analysis showed a significant result for the treatment effect of the treatment groups ($X^2 = 0.12$, d.f. = 1, $I^2 = 0\%$).... Based on the results of the present review, aromatherapy might be regarded a potentially effective treatment for BPSD.... Nevertheless, available evidence in the literature is not sufficient to make a conclusive claim" (p380).</p>
<p>Guzman-Garcia 2012</p> <p>5/11 (45%)</p> <p>N=10 – 1 RCT, 4 uncontrolled pilot studies, 1 controlled pilot study, 2 exploratory, 1 descriptive</p>	<p>Studies were conducted in long-term care homes.</p>	<p>Dance therapy</p>	<p>"There are substantial methodological problems in the selected studies. All studies were small" (p917).</p>	<p>Evidence for decrease in agitation from only two qualitative studies (Duignan 2009, Guzmán-García 2012).</p> <p>"In summary, the evidence-base revealed by this review is small; however, results have linked dancing with positive mood, such as reducing stress and diminishing problematic behaviour for the participants such as agitation. The potential benefits of dance work are inconclusive..." (p923).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Husebo 2011</p> <p>4/11 (36%)</p> <p>N=3 RCTs</p>	<p>Nursing Homes</p>	<p>Pain treatment</p>	<p>“The studies have several methodological limitations which make the interpretation of the findings difficult and preclude the conclusion that pain management does not reduce agitation. Although using cross-over design provides a larger statistical power than a parallel-group design, limitations with this design include the risk of carry-over effects. In addition, the placebo-active order was fixed in one study, suggesting that confounding factors might influence the results, including regression to the mean and spontaneous fluctuations. The small sample sizes severely reduce the statistical power to detect smaller differences, leading to an increased risk for false-negative findings, and thus the lack of difference between the groups might not be valid” (p1015).</p>	<p>“Only three randomized controlled trials (RCT) of the effect of analgesics on agitation and related behavioral changes in people with dementia were identified [Manfredi 2003, Chibnall 2005, Kovach 2005]. Two studies were cross-over trials, including only 25 and 47 patients, and only one study recruited subjects with agitation at baseline. The third study was larger, but only a small proportion received analgesics. The findings were inconsistent, and none of the studies reported unequivocal reduction of agitation after pain management” (p1015).</p>
<p>Kong 2009</p> <p>6/11 (55%)</p> <p>N=14 RCTs</p>	<p>All but one study set in nursing homes or other care facilities</p>	<p>7 categories:</p> <p><i>Sensory</i></p> <ul style="list-style-type: none"> • aromatherapy • calming music & hand massage • thermal bath <p><i>Social contact</i></p> <ul style="list-style-type: none"> • simulated presence • pet therapy <p><i>Activities</i></p> <ul style="list-style-type: none"> • rocking chair therapy • therapeutic recreational activities <p><i>Caregiver training</i></p> <p><i>Combination therapy</i></p>	<p>“[T]he results should be interpreted with caution because of several factors including the small number of studies in each category, small sample sizes in respective studies, variability in the nature and duration of the intervention programs, inconsistent definition of agitation across studies, and variability in the measuring instrument and time” (p519).</p>	<p>“The systematic review indicated that only sensory interventions (aromatherapy, thermal bath, and calming music and hand massage) had moderate efficacy in reducing agitation of elders with dementia.* No other type of nonpharmacological interventions (social contact,** activities, environmental, caregiver training, combination therapy, and behavioral therapy) showed efficacy in reducing agitation among the elders with dementia” (p519).</p> <p>*Result was based on pooled data from three studies on different interventions: Ballard 2002 (aromatherapy), Dunn 2002 (thermal bath), Remington 2002 (calming music and hand massage)</p> <p>**Result was based on pooled data from two studies on different interventions: Camberg 1999 (simulated presence) & Churchill 1999 (pet therapy).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
		<ul style="list-style-type: none"> stimulation-retreat program <p><i>Environmental modification</i></p> <ul style="list-style-type: none"> morning bright light therapy <p><i>Behavioral therapy</i></p> <ul style="list-style-type: none"> activities of daily living interventions 		
<p>Konno 2013</p> <p>6/11 (55%)</p> <p>N=7 – 2 RCTs, 1 quasi-experimental, 2 pre-post, 2 qualitative studies</p>	<p>All but 1 study set in LTC</p>	<p>Assisted bathing/showering of older adults with dementia and related educational or supportive interventions</p>	<p>“Methodological quality of included quantitative studies ranged from moderate to poor and the qualitative studies ranged from moderate to high quality” (p125).</p>	<p>Sloane 2004, Dunn 2002, Mickus 2002, Clark 1998, and Miller 1997 evaluated effect of intervention on agitation/aggression in LTC.</p> <p>“The identified quantitative evidence supports using the person-centred showering approach, towel bath/thermal bath and preferred music of older adults. The qualitative evidence emphasised concepts including safety and retaining a sense of dignity and control of patients, and relevant assessment skills of caregivers” (p125).</p>
<p>Kverno 2009</p> <p>4/11 (36%)</p> <p>N=21 – 13 experimental studies/RCTs, 8 pre/quasi-experimental studies lacking either randomization or control</p>	<p>2 studies set in day hospitals, rest set in nursing homes, LTC, Special Care Units, or long-stay geriatric hospital units</p>	<p>3 categories:</p> <p>Emotion-oriented treatments</p> <ul style="list-style-type: none"> verbal and non-verbal emotion-focused care simulated presence <p>Behavioral and environmental treatments</p> <ul style="list-style-type: none"> special care units environmental modifications 	<p>See next column</p>	<ul style="list-style-type: none"> “...studies provide limited high quality evidence that simulated presence can be effective in reducing agitation and withdrawn behavior <i>during (and shortly after)</i> the time that it is provided [emphasis mine]” (p6). Based on 2 studies: Camberg 1999 (level I study/“high” quality) & Garland 2007 (level I study/“high” quality). “[L]imited moderate to high quality evidence suggests that lavender- and lemon balm-based aromatherapies may be effective in reducing agitation and apathy during the time that they are administered” (p8). Based on 4 studies: Holmes 2002 (level II study/“moderate” quality), Lin 2007 (level I study/“moderate” quality), Snow 2004 (level II study/“low” quality), Ballard 2002 (level I study/“high” quality). “Overall there is limited but good quality evidence supporting the use of music therapy for the short-term reduction of agitation and apathy. Interactive live music and preferred music appear to be more beneficial than pre-recorded music for individuals with advanced dementia” (p9). Based on 3 studies: Svansdottir 2006 (level I study/“moderate” quality), Holmes 2006 (level I study/“moderate” quality), Garland 2007 (level I study/“high” quality).

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
		Sensory stimulation-oriented approaches <ul style="list-style-type: none"> • aromatherapy • bright light therapy • preferred or live music • multi-sensory stimulation • movement therapy • touch • balancing arousal controls excesses 		<ul style="list-style-type: none"> • “[Kovach 2004] provides moderate quality evidence supporting interventions that balance arousal states for the treatment of agitation in advanced dementia” (p10). <p>“For [individuals with severe cognitive impairment] non-demanding, non-verbal, sensory-based treatments for NPS (music, aromatherapy, and multisensory stimulation) appear the most efficacious. Other potentially promising non-verbally based interventions involving hands-on (touch) therapies, movement therapies, and personal care approaches need to be further explored” (p12).</p>
<p>Lai 2009</p> <p>8/11 (73%) (Cochrane)</p> <p>N=8 controlled before-and-after studies (only 4 had recoverable quantitative data)</p>	<p>The majority of studies were set in Special Care Units with traditional nursing homes care as the comparison.</p>	<p>Specialized Care Units (set of related interventions including features such as a unique staffing pattern, special programming, or environmental designs)</p> <p>Components include:</p> <ol style="list-style-type: none"> 1.admission of residents with dementia and most often with AD, 2.special selection, training, and supervision of staff 	<p>From the abstract: “Differences between comparator groups in these nonRCTs – for example in severity of dementia - were not adequately adjusted for and were common in the trial which accounted for almost all of the positive outcomes of SCUs (Nobili, 2006).”</p> <p>“The practical challenge of randomizing patients, the nonequivalence of groups at baseline, the heterogeneity of SCUs in the controlled trials being reviewed, the diversity in context (studies were conducted in different countries) and the limited studies available do not permit a definitive reply as to which of the two settings is more suitable for the treatment and care of a person with dementia” (p13).</p>	<p>Study results were reported sequentially – data were pooled for only one outcome (physical restraint use at 6 months, 2 studies).</p> <p>“There were no significant changes in [agitation] outcomes at three months. There were some small but significant improvements that favoured the SCU group over time... measured at the time points at 6, 12, and 18 months respectively” (p11).</p> <p>“Small but significant differences [in use of physical restraints] favouring SCU care were observed at 6 and 12 months” (p12).</p> <p>“The effectiveness of SCU care for people with dementia lacks substantial evidence.... If a somewhat more expensive programme was only capable of increasing positive time use and counteracting detriment in positive affect, but unable to diminish negative behaviours, would the investment be justified? The result of this review is unable to answer this question.... There is no simple conclusion in terms of recommending practice in SCU care. To come back to the review question, the assumption that the SCU can better manage behavioural problems lacks substantial grounds. It seems that it is more important to implement best practice than to provide a specialized care environment (pp13-14).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
		members, 3.specially designed activity programming, 4.family involvement, and 5.a specially designed physical environment that is segregated from other areas		
<p>Liu 2014</p> <p>6/11 (55%)</p> <p>N=22 – 9 RCTs, 5 controlled clinical trials, 6 interrupted time series and 2 cohort studies</p>	All studies set in LTC facilities	Various interventions, but only studies of environmental modification – i.e., music – evaluated effects on agitation (n=3)	<p>Of the three studies on agitation, Richeson 2004 & Hicks-Moore 2005 were described as weak and Ho 2011 as moderate in quality.</p> <p>“Methodologically, the body of literature in this review had some common limitations across studies. These limitations included lack of randomization and/or control group, small sample size without power analysis, lack of theory-based interventions, lack of blinding during data collection, inadequate statistical analysis and plausible confounding bias” (pp22 & 24).</p>	<p>“Three ‘environment/routine modification’ studies (ORCT) reported agitation at 4 day to 4 week. Agitation was consistently measured by the Cohen-Mansfield Agitation Inventory. There was insufficient evidence in relaxing or soothing music to decrease incidence of agitated behaviors” (p24).</p>
<p>Mohler 2012</p> <p>9/11 (82%) (Cochrane)</p> <p>N= 5 cluster-RCTs</p>	4 studies examined nursing home residents and 1 study was set in group dwelling units.	All five included studies (Evans 1997, Huizing 2009a, Pellfolk 2010, Testad 2005 & 2010) assessed the effect of staff educational programmes addressing dementia, aggression, and challenging behavior on use of physical restraints.	<p>“Overall methodological quality of the studies was low to moderate.</p> <p>Three out of five studies were especially prone to bias since the study groups included only one or two nursing homes. The cluster design of the studies was consistently disregarded. Thus, a unit of analysis bias would have emerged. It remains unclear to what extent centre effects have influenced the results. Two studies (Evans 1997; Testad 2010) indicated heterogeneity among study centres due to statistically significant differences in baseline PR prevalence” (p13).</p>	<p>“In summary, the reviewed evidence is inconsistent. Studies of weak methodological quality indicate an effect whereas one study of good quality did not find a reduction in PR. There is insufficient evidence supporting the effectiveness of educational interventions targeting nursing staff for preventing or reducing the use of PR in long-term geriatric care. Further high quality research is needed” (p13).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Moniz Cook 2012</p> <p>7/11 (64%) (Cochrane)</p> <p>N=5 RCTs*</p> <p>Only includes studies conducted in LTC or hospital settings</p>	<p>Studies conducted in LTC/hospital settings were analyzed separately from the rest</p>	<p>Functional Analysis based interventions</p> <p>“Person-Centred Care and Dementia Care Mapping originate from theories of person-centred care in dementia (Kitwood 1997) and were underlying constructs used to develop these respective interventions (Chenoweth 2009; Fossey 2006). The latter (Chenoweth 2009) also drew heavily on the theory of behaviour as a function of ‘unmet need’ (Cohen-Mansfield 2007), a notion that is also understood within functional analysis models of behaviour” (p14-15 – see also pp96-7).</p>	<p>“Overall the quality of combined studies included in this review was judged as low to moderate...” (p9), though it was not clear how many of the general limitations noted by the reviewers were present the studies by Chenoweth et al. and Fossey et al.</p>	<p>“There was a significant reduction in the frequency of challenging behaviours at post-intervention for... two residential studies (N = 505)” (pp10-11, Chenoweth 2009 & Fossey 2006: SMD -0.21, 95% CI -0.39 to -0.03 CI, P = 0.02 – both studies used the CMAI).</p> <p>“Data for all studies incorporating FA showed beneficial effects on both the reported frequency of challenging behaviors... at post-intervention. No significant effects were found at any follow-up periods” (p14).</p> <p>“The evidence of functional analysis-based interventions in the management and resolution of challenging behaviour in dementia is promising but.... It is too early to provide indication of the true effectiveness of functional analysis-based intervention in comparison to other psychosocial interventions for the management and resolution of challenging behaviour in dementia. However, as a component part of psychosocial intervention programmes, including those that focus on training and supporting caregivers, it remains a promising intervention” (p16).</p>
<p>O’Connor 2009</p> <p>5/11 (45%)</p> <p>N=25 – 10 RCTS, 15 before-and-after designs</p>	<p>19 set solely in nursing homes or long stay hospital wards</p>	<p>Psychosocial Interventions</p> <ul style="list-style-type: none"> • Music • Carer education • Sensory enrichment • Simulated 	<p>“[M]ost of the studies considered here were relatively robust with clear inclusion criteria; detailed accounts of methods and participants; structured behavioral observations, and proven inter rater reliability. Only three were graded as ‘weak,’ in two cases because follow-up periods were ambitiously long and large numbers of participants dropped out” (p235).</p>	<p>Treatments that produced greater reductions in agitation and/or aggression than control conditions:</p> <ul style="list-style-type: none"> • aromatherapy – based on Ballard 2002 & Holmes 2002 • bed baths, person-centred bathing – based on Dunn 2002 & Sloane 2004 • individualized music – based on Clark 1998, Gerdner 2000, and Thomas 1997 • simulated family presence – based on Camberg 1999 & Garland 2007

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
		family presence <ul style="list-style-type: none"> • Novel bathing techniques • Aromatherapy • Recreation • Relaxation • Validation therapy 		<p>Aromatherapy, bed baths, and individualized music, in particular, “are supported by studies with robust designs (RCTs or RXTs), that rated as ‘moderate’ or ‘strong’ on the Forbes quality scale and had moderate or high statistical precision (p<0.01)” (p237).</p> <p>By contrast, “We expected to find that boosting carers’ knowledge, empathy and communication skills would lead to significant falls in agitation and aggression. While there were trends in this direction (Wells <i>et al.</i>, 2000; Gormley <i>et al.</i>, 2001; Sloane <i>et al.</i>, 2004), the outcomes were not striking.... Training programs can certainly change family and professional caregivers’ attitudes, knowledge and skills and are valuable for this reason. What impact they have on behavior over a shorter time frame remains to be seen” (p236).</p> <p>“Most treatments entailed some measure of human contact, either directly or indirectly. Positive interaction between the person with dementia on the one hand, and a family member or care attendant on the other, might form the common basis of many of these interventions... Treatments tailored to individuals’ backgrounds and preferences, whether in the form of music, activity or conversation, seem especially beneficial” (pp237-8).</p>
<p>O’Neil 2011</p> <p>4/11 (36%)</p> <p>N=9* – 3 quasi-experimental, 6 repeated measures</p> <p>*This number excludes the systematic reviews included in the synthesis – authors failed to provide a list and description of included reviews</p>	<p>All long term-care facilities/nursing homes</p>	<p>Animal Assisted Therapies</p>	<p>“Most studies were not experimental, did not have adequate control groups, had small sample sizes, and lacked methodological rigor. There were no RCTs” (p24).</p>	<p>Only three studies appear to have measured agitation and/or aggression specifically: Libin 2004, Richeson 2003, & Churchill 1999.</p> <p>“Nine non-randomized studies demonstrated decreases in agitated and disrupted behaviors, increases in social and verbal interactions, decreases in passivity, and increases in nutritional intake” (p4).</p> <p>“Though some benefit of AAT on behavioral symptoms is suggested by the authors of these studies, this is a very limited body of evidence” (p24).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Pieper 2013</p> <p>5/11 (45%)</p> <p>N=16 – 8 RCTs, 1 single case design, 1 placebo controlled cross-over trial, 1 case report, 1 quasi-experimental, 2 cohort, 1 experimental, 1 case series</p>	<p>13/16 studies were conducted in nursing homes or in long-term care facilities</p>	<ul style="list-style-type: none"> • Pain intervention targeting behavior • Behavioural intervention targeting pain • Intervention targeting both pain and behavior 	<p>“Because of the limited number of studies, the often, small sample sizes, and the moderate methodological quality; a limitation of this study is the modest strength of the encountered evidence. Research to assess efficacy of interventions becomes even more challenging, when patients start at a low frequency of behavioural symptoms at baseline, for example seen in the study performed by Chibnall et al. (2005). Therefore, the results have to be interpreted with caution, even though all of the findings are pointing in the same direction” (p1053).</p>	<p>5 studies evaluated the effect of pain treatment on specific measures of agitation and/or aggression in LTC settings (Chibnall 2005, Husebo 2011, Manfredi 2003, Passmore 2011, Chapman 2007).</p> <p>“Overall, our results indicate that pain interventions targeting behaviour and behavioural interventions targeting pain are effective in reducing pain or discomfort and behavioural symptoms such as depression, agitation/aggression and anxiety in dementia” (p1052).</p> <p>“Both fixed and individual dosages of pain medications were effective in reducing challenging or disruptive behaviour in dementia. However, a fixed dosage of analgesics may be less effective, compared to an individually tailored and stepwise approach (Chapman 2007, Husebo 2011, Kovach 2006, 1999)” (p1052).</p> <p>“We found that interventions, such as rocking chair therapy [Watson 1998]... [and] person-centred showering or bathing [Dunn 2002, Sloane 2004]... can be effective in reducing pain, discomfort and behavioural disturbances such as agitation...” (p1052).</p>
<p>Reuther 2012</p> <p>5/11 (45%)</p> <p>N=7 – 4 cluster-randomized, 2 quasi-experimental, 1 pre-post design</p>	<p>All studies set in nursing homes.</p>	<p>Staff case conferences on people with dementia with challenging behavior.</p>	<p>“The quality of the included studies varied between 5 (middle-range quality) and 8 (good quality). Only one cluster randomized trial was of good quality (8 points). The other three cluster-randomized trials were of middle-range quality. The two studies with a quasi-experimental design and the study with a pre– post test design were also of middle-range quality” (p1893).</p> <p>From the abstract: “...due to the middle-range quality of several studies, the methodological heterogeneity and differences in the interventions, the results must be interpreted with caution.”</p>	<p>Three studies applied the CMAI (Opie 2002, Davison 2007, Visser 2008), the remainder measured various other outcomes related to residents' challenging behaviors, e.g., amount of prescribed antipsychotics (Crotty 2004, Bartholomeyczik 2010), caregiver stress, etc.</p> <p>“The study with the highest rated quality was not able to determine any differences in challenging behavior when comparing the control group and the intervention group Crotty <i>et al.</i>, 2004). The authors noticed a significant reduction in the number of antipsychotic drugs administered to the residents, but they did not report the length of the case conferences. The studies with middle-range quality showed various results.” (p1895).</p> <p>“The body of evidence regarding the effect of case conferences is weak, and high-quality studies with longer intervention periods are needed” (p1902).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Richter 2012</p> <p>10/11 (91%) (Cochrane)</p> <p>N=4 cluster RCTs</p>	<p>All studies set in care homes (defined as institutions where long-term care is provided by professional care workers for residents requiring nursing care).</p>	<p>Psychosocial intervention aimed at reducing antipsychotic medication (main component in all studies was a staff educational program).</p>	<p>“One study showed sufficient internal validity (Fossey 2006). Three of four studies (Avorn 1992, Meador 1997, Schmidt 1998) showed weaknesses in at least half or more of the assessed methodological quality indicators. In two studies the method of analysis was adequate for cluster RCT. In Schmidt 1998, it is highly likely that a unit of analysis bias led to ‘over-precise results’ (i.e. to P values that are artificially small); in Meador 1997, this remains unclear. All four included studies showed some differences between groups regarding baseline data with unclear clinical relevance” (p15).</p>	<p>“In summary, the reviewed evidence consistently showed reductions in antipsychotic medication prescription rates as a result of the different interventions, although magnitudes of effects differed between studies. The study with the most complex intervention according to the underlying concept, educational content, number of target groups, and absolute time spent on the intervention as well as the greatest methodological rigor (Fossey 2006) showed an absolute difference between groups of residents with antipsychotic medication of 19.1 percentage points at the end of follow-up after 12 months. As both the IG and CG received a structured medication review every three months, the reported effect may be mainly ascribed to the psychosocial components of the intervention” (p14 – see pp8-10).</p>
<p>Skingley 2010</p> <p>3/11 (27%)</p> <p>N=6*</p> <p>*Includes only those studies related to music or singing and people with dementia</p>	<p>4 of 6 studies in LTC or hospital settings</p>	<p>Music and singing</p>	<p>Reviewers provide little info on study quality</p>	<p>“All studies reported less agitated behavior and greater interaction and cooperation. Where music was compared with other interventions, for example hand massage, touch and object presentation, there appears to be no greater benefit in combining the interventions. Caregiver singing was found to be particularly beneficial in the analysis by Götell <i>et al</i> (2002)” (p37).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Testad 2014</p> <p>4/11 (36%)</p> <p>N=40 – 26 RCTs & 14 quasi-experimental</p>	<p>All studies conducted in nursing homes or care homes</p>	<p>Studies fall into six categories:</p> <ul style="list-style-type: none"> • Reminiscence • Personalized music • Personalized pleasant activities with or without social interaction • Validation therapy • Personalized exercise/physical activities • Person-centered care training and practice development 	<p>“A quality assessment was undertaken for each of the 40 included studies, 9 were rated as <i>green</i>, 8 studies as <i>amber</i>, and 23 were rated as <i>red</i>” (p4).</p> <p>“It should be noted that the study limited the period of inclusion to studies published since 2000. This decision was made as the overall quality and consistency of interventions, study design and outcome measures have dramatically improved over that period, and there has been an increased focus on personalized interventions” (p13).</p>	<p>“Personalized music [i.e., group music therapy] was examined in seven RCTs or studies with a control condition (Sung <i>et al.</i>, 2006; Ledger and Baker, 2007; Raglio <i>et al.</i>, 2008; Choi <i>et al.</i>, 2009; Lin <i>et al.</i>, 2010; Sung <i>et al.</i>, 2010; Sung <i>et al.</i>, 2012) [reviewers graded all of these studies as “red”] (p11)... Evidence regarding personalized music was inconsistent... The large range in effect size on agitation varying from 0.43 in favor of control to 0.66 in favor of active treatment also makes interpretation difficult and further work is needed to understand the differences between individual studies.” (p13).</p> <p>“There was also strong evidence to support the benefit of personalized pleasant activities with and without social interaction as a treatment for agitation, where four of the six studies reported a significant benefit compared to the control condition, with a median standardized effect size of 0.46 (Kovach <i>et al.</i>, 2004; Cohen-Mansfield <i>et al.</i>, 2007; 2010; 2012) [‘red,’ ‘amber,’ ‘amber,’ & ‘green,’ respectively]” (p13).</p> <p>“Only three RCTs were identified which evaluated person-centered care training interventions (Fossey <i>et al.</i>, 2006; Chenoweth <i>et al.</i>, 2009; Brooker <i>et al.</i>, 2011) [‘green,’ ‘green,’ & ‘amber,’ respectively] . Although all three of the studies reported benefit in at least one key outcome, the benefits were inconsistent between studies. One reported a reduction in antipsychotic use (Fossey <i>et al.</i>, 2006), one reported an improvement in agitation (Chenoweth <i>et al.</i>, 2009) and the other study reported an improvement in mood (Brooker <i>et al.</i>, 2011). Further work is needed to optimize these interventions in order to confer more consistent benefits” (p13).</p>
<p>Vink 2011</p> <p>8/11 (73%) (Cochrane)</p> <p>N=10 RCTs – 7 parallel design, 3 cross over design</p>	<p>All studies conducted in LTC settings</p>	<p>Music Therapy</p> <ul style="list-style-type: none"> • Individually based Receptive Music therapy • Active Group Music Therapy 	<p>“Due to poor reporting we were uncertain of the methodological quality of the included studies. Most of the studies describe positive effects which however cannot be warranted due to methodological problems making interpretation of the results difficult. Little information was provided on randomization methods and overall the studies consisted of small sample sizes and short intervention periods, increasing the risk of bias which may have led to an overestimation of the ‘true’ effect of the intervention” (p12).</p>	<p>“Despite ten studies [Groene 1993; Guétin 2009; Lord 1993; Raglio 2008; Raglio n.d.; Sung 2006; Svansdottir 2006; Brotons 2000; Clark 1998; Gerdner 2000] claiming a favourable effect of music therapy in reducing problems in the behavioural, social, emotional, and cognitive domains in older people with dementia we cannot endorse these claims nor refute any positive effect of music therapy” (p12).</p>

Citation, AMSTAR score, type & number of included studies	Setting(s)	Intervention(s)	Review authors' assessment of review limitations/included study quality	Main Findings
<p>Whear 2014</p> <p>8/11 (73%)</p> <p>N=11- 1 controlled trial, 3 before and after studies, 7 repeated-measure- time series</p>	<p>All studies conducted in LTC settings</p>	<p>Mealtimes interventions:</p> <ul style="list-style-type: none"> • Music • Changes to food service • Dining environment alteration • Group conversation 	<p>“Most studies (n = 9) described outcome data and accounted for all participants. However, power calculations were not reported for any of the studies and the blinding of participants or of the outcome assessment was not possible for these studies. Eligibility criteria were described in only half the studies, compliance with the intervention as rarely reported, and the validity and reliability of data collection tools was rarely discussed even though in most circumstances the tools had known validity and reliability. Reassuringly, few studies appeared to show any selectivity in reporting their outcomes. In general, the standard of reporting was too poor to make an informed judgment on the quality of the study; however, 2 studies [Chang 2010, Goddaer 1994] stand out as being better-quality studies according to their reporting, as they met more of the appropriate quality appraisal criteria” (p188).</p>	<p>“Six studies [Chang 2010, Goddaer 1994, Denney 1997, Hicks-Moore 2005, Ho 2011, Richeson 2004] used the Cohen-Mansfield Agitation Inventory (CMAI), or a version of it, to measure aggressive and agitated behaviors” (p188).</p> <p>All seven of the studies on music interventions – including Chang 2010 and Goddaer 1994 – “reported positive effects from mealtime music on behavioral symptoms, including physical aggressive and nonaggressive behaviors, verbal agitated behaviors, hiding/hoarding behaviors, and total CMAI scores” (p189).</p> <p>Most of the studies were small and the reporting was of poor quality. However, all studies demonstrate some positive influence of the mealtime intervention on dementia-related behaviors. The greatest amount of evidence exists for music interventions. The studies in this area demonstrated consistently positive effects of the intervention on physically aggressive behaviors, verbally aggressive behaviors, verbally agitated behaviors, and total CMAI score.... The positive effect of the music interventions in our review should be taken into account alongside the wider Cochrane review of music therapy for people with dementia [Vink 2004] and another recent review [Ueda 2013, excluded], both of which also report positive effects. These reviews highlight the existing evidence for music as a form of therapy to help people with dementia; this reflects something different to music at mealtimes but may work on a similar basis” (p191).</p>
<p>Zimmerman 2013</p> <p>7/11 (64%)</p> <p>N=14 - 4 prospective cohort studies, 9 RCTs, 1 nonrandomized controlled trial</p>	<p>Nursing homes and other residential long-term care settings</p>	<p>Nursing home care:</p> <ul style="list-style-type: none"> • organizational characteristics • structures of care • processes of care 	<p>“[P]erhaps the most noteworthy finding of this evidence-based review is the lack of high-quality evidence regarding which organizational characteristics... other structures of care... or processes of care result in better outcomes for people with dementia who reside in NHs and other residential long-term care settings.... [F]ew rigorous, high quality, comparative effectiveness studies have focused on this population despite being conducted in NHs and other settings.... [Of the 14 included studies] only two... provided evidence with a moderate [strength of evidence], related to the benefits of pleasant sensory stimulation to reduce agitation...” (p1408).</p>	<p>Only 4 studies measured agitation and/or aggression [Toseland 1997, Whall 1997, Remington 2002, Sloane 2004 – quality listed as ‘fair’ in all cases, strength of evidence as ‘low,’ ‘moderate,’ ‘moderate,’ & ‘low,’ respectively]. Toseland also measured psychoactive drug use.</p> <p>“Important findings include the following:</p> <ul style="list-style-type: none"> • Behavioral symptoms [agitation and/or aggression] were... better after pleasant sensory stimulation [Whall 1997 & Remington 2002]... and person-centered protocols for showering and bathing [Sloane 2004]. • Results related to validation therapy were mixed [Toseland 1997]” (p1405).

Data Extraction – Primary Research

The information contained in the “Main Findings” column below consists mainly of direct quotations from the primary research articles included in our synthesis.

Citation, research design, sample size	Setting	Intervention	Quality assessment	Main Findings
<p>Houser 2014</p> <p>Cluster RCT</p> <p>n=20</p>	<p>Continuing care retirement community</p>	<p>“TimeSlips” Creative Expression Program</p>		<p>“When comparing intervention with control groups with respect to the two primary outcomes of mood and behavior, there were no statistically significant results.... With regard to the psychotropic drug data, although there was some flux in dosages and number of prescriptions, no statistically significant differences were noted within or between groups.” (p340).</p>
<p>Narme 2014</p> <p>RCT</p> <p>n=48</p>	<p>Nursing home</p>	<p>Musical intervention & cooking intervention</p> <p>“During the music sessions.... Participants were asked to listen and to participate by singing and/or by using percussion instruments to accompany the musical track. The same playlist was used in the same order for each music session. During the cooking sessions, participants were asked to make a different recipe for each session (e.g., chocolate cake; French pancakes). Each session commenced with a game about ingredients where participants were asked to collectively prepare a given recipe. Roles were distributed according to patients’ abilities (e.g., cutting, peeling, measuring</p>		<p>“[T]he current study suggests benefits of interventions on the severity of behavioral disorders. Agitation (assessed with CMAI) decreased at all evaluations shortly after cooking interventions... and at follow up evaluations in comparison to baseline. In the music group, decreased agitation was only evident after the 4th session” (p66).</p> <p>“[T]he present findings argue against music specificity. Although music sessions elicited stronger effects on the behavioral disturbances and the related caregivers’ distress, the improvement of agitation and mood was stronger following cooking sessions. Thus, it is possible that music does not have a greater therapeutic effect than other hedonic activities and that positive influence was mainly explained by socialization...” (p367).</p>

Citation, research design, sample size	Setting	Intervention	Quality assessment	Main Findings
		quantities, mixing, or cooking)” (p361).		
Ridder 2013 Crossover RCT n=42	14 different nursing homes	Individual music therapy delivered by a trained professional		“This study shows that six weeks of music therapy significantly reduced average agitation disruptiveness [i.e., severity] scores in persons with dementia, compared to standard care. Moreover, during music therapy the prescriptions of psychotropic medication were not increased, whereas they were increased for seven participants during the standard care period.... With a small effect size a decrease in the frequency of agitated behaviors was seen, however, non-significant [<i>sic</i>]” (p675).
Rokstad 2013 Cluster RCT n=446	15 different nursing homes	<p>Person-centred care:</p> <ul style="list-style-type: none"> • Dementia Care Mapping (described on pp342 & 344) • VIPS Practice Model – “valuing people with dementia (V), individualized care (I) understanding the world from the patient’s perspective (P) and providing a social environment that supports the needs of the patient (S)” (p341 – described on pp344-5) 		<p>“We found no significant differences between the intervention groups and the control group regarding the change in the primary efficacy measure (the BARS sum score). However, the NPI-Q sum score, the NPI agitation subscore and the NPI psychosis subscore for the patients of both intervention groups were reduced compared with the patients of the control group” (p349).</p> <p>“In the two comparable previous studies by Fossey et al. and Chenoweth et al., the intervention groups received substantially more supervision (weekly supervision or regular telephone contact) than any of the intervention groups in our study. However, with the available resources, we consider the methods used in the present study to implement PCC as more realistic in daily practice. In contrast to the interventions called ‘PCC’ in the previous studies, the VPM, like DCM, is standardized and replicable. The duration of the study (10 months) strengthens the probability that, in most nursing homes, the effects can be obtained by implementing the models. In our view, both methods are feasible methods to implement PCC in nursing homes” (p350).</p>
van der Ploeg 2013 Crossover RCT n=44	9 residential facilities	Personalized, one-to-one interaction using Montessori-based activities		<p>“The Montessori and control conditions resulted in 50% and 42% reductions, respectively, in agitated behavior counts compared to baseline. Montessori activities were more successful than the control condition in generating positive affect and constructive engagement and, by corollary, in reducing neutral affect and negative engagement” (p569).</p> <p>“Our findings replicate previous studies in the following respects: social contact <i>per se</i> reduced agitation compared to baseline situations (Cohen-Mansfield <i>et al.</i>, 2007; 2010; Gitlin <i>et al.</i>, 2009) and personalized activities elicited more positive mood and engagement than both baseline and control conditions (Orsulic-Jeras <i>et al.</i>, 2000; Cohen Mansfield <i>et al.</i>, 2007; Gitlin <i>et al.</i>, 2009; Lin <i>et al.</i>, 2009) [<i>note</i>: Cohen-Mansfield 2007 & 2010 were reviewed in Testad 2014 under the heading ‘personalized pleasant activities’].... [T]he 50% reduction in agitation is significantly higher than the 1%–30% reduction in agitation reported in other studies (Gerdner, 2000; Garland <i>et al.</i>, 2007; Lin <i>et al.</i>, 2009). This larger reduction may be due to the selection of participants with high frequency behaviors targeted at peak times as</p>

Citation, research design, sample size	Setting	Intervention	Quality assessment	Main Findings
				<p>well as the use of direct observations of behavior as compared to the staff-rated scales used in some of the other studies. However, we also found a similar reduction in agitation with the non-personalized control condition. This is an important finding, as it shows that even a simple social contact intervention of keeping someone company, that requires no additional training or resources, can assist in settling individuals with high-frequency agitation. It may also be a reflection of how in current care there is ample opportunity for improvements in stimulation, diversity, and social contact" (p573).</p>
<p>Vink 2013 RCT n=77</p>	<p>6 nursing homes</p>	<p>Music therapy offered twice weekly during 4 months</p>		<p>"Music therapy offered twice weekly during 4 months to demented older persons with severe cognitive decline had no additional beneficial short-term effect on reducing agitation when compared with general activities. These results are in contrast with other studies that found a positive effect of music therapy.... In the current study, data of 77 residents with dementia were included. Most previous studies [including Groene 1993, Svansdottir 2006 and a 1996 study by Brotons] used smaller sample sizes" (p1036).... Most studies that found a positive effect of music therapy used usual care as control condition. In contrast, the present study used an active control condition providing similar amounts of attention and group contact for both groups. Therefore, the positive findings from the previous studies may have been due to the extra attention or group contact rather than the music.... [On the other hand] we used a modified version [of the CMAI]... [which] may not have been sensitive enough to detect any reductions in agitation" (pp1036-7).</p> <p>"The therapists who participated in this study all reported, on the basis of clinical expertise, that the group size of five participants is far too large for the treatment of severe disruptive behaviours by one single therapist and too large to be able to achieve therapeutic goals. In addition, the preferred frequency and length of the music intervention should be addressed in future studies. The length and frequency of the music therapy intervention in the present study may have been insufficient to reduce agitation. The lack of efficacy of music therapy observed in this study may suggest that the residents were understimulated rather than that music therapy was ineffective. Furthermore, more insight is needed whether music therapy may only be effective in reducing agitation in certain subgroups of patients according to dementia stage or type" (p1037).</p>