

# A systematic review of the literature

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The effectiveness of non-pharmacological interventions for behavioural and psychological symptom management for people with dementia in residential care settings

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## **Review Team**

This review was undertaken by the Health Services Assessment Collaboration (HSAC). HSAC is a collaboration of the Health Sciences Centre of the University of Canterbury, New Zealand and Health Technology Analysts, Sydney, Australia. This report was authored by Arindam Basu, Senior Researcher and David Brinson, Researcher, who jointly developed and undertook the literature search, extracted the data, conducted the critical appraisals, and prepared the report. Sub-editing was performed by Lyn Wright.

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Dr Ray Kirk peer reviewed the final draft. Cecilia Tolan (Administrator) provided document formatting. Franziska Gallrach, Carmel Olsen and staff at the University of Canterbury Libraries assisted with retrieval of documents.

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A working party/steering committee provided advisory input to the review (see **Appendix A** for membership). The systematic review of the evidence will ultimately be used by the working party/steering committee to inform policy decision making in conjunction with other information. The content of the review alone does not constitute clinical advice or policy recommendations.

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## **Executive Summary**

The purpose of this systematic review is to provide a summary of the evidence pertaining to the relative effectiveness and safety of non-pharmacological interventions for the management of behavioural and psychological symptoms of dementia (BPSD) in residential care settings, when compared to 'usual care'.

The review was requested by the Policy and Service Development team (Mental Health Group, Population Health Directorate) in the Ministry of Health (the Ministry). The content of this evidence review alone does not constitute clinical advice or policy recommendations. The review will inform the Ministry's Mental Health and Addiction of Older People and Dementia project. A working party/steering committee has been convened to lead the project (**Appendix A**) and the Health Services Assessment Collaboration (HSAC) has been contracted to conduct the systematic review.

#### Introduction

Dementia is an acquired deficiency in cognition that impairs successful performance of the activities in daily living. About one in 100 elderly individuals in New Zealand are diagnosed with dementia and it is projected that by 2026, the age-adjusted prevalence of dementia will be about 1.5% of the population. It is estimated that about 70% of elderly individuals in New Zealand living in residential care facilities show some form of dementia and as of 2002, the total estimated cost of dementia treatment in New Zealand was about 713 million dollars.

For carers in residential care facilities, management of specific behavioural and psychological symptoms attributed to dementia is important. These symptoms are collectively referred to as BPSD and are defined as patterns of disturbed perception, thought content, mood, and behaviour that frequently occur in people with dementia. The term BPSD was introduced by the International Psychogeriatrics Association Task Force at an international meeting in 1986 in order to relate an appropriate term that could express the complexities of different behavioural and psychological symptoms associated with dementia. While pharmacological interventions have been used extensively to treat BPSD, increasing concerns over their efficacy and significant side-effects have resulted in calls for non-pharmacological approaches to be prioritised as first-line interventions. Further, not all symptoms respond to pharmacological agents, for example, behaviours such as wandering, social withdrawal, pacing, and cognitive deficits, and incontinence. However, the range of non-pharmacological interventions is broad and the evidence base is incomplete. Therefore, the purpose of this review is to summarise the effectiveness of different non-pharmacological treatments for the management of BPSD in individuals who are in residential care facilities.

#### Methods

A systematic review was conducted using the following steps. First, relevant publications and research reports on the effectiveness of different non-pharmacological treatments aimed at individuals with dementia in residential care facilities were identified using specific search algorithms for literature retrieval. The literature was searched using the following bibliographic databases: MEDLINE, EMBASE, PsycINFO, CINAHL, the Cochrane Database of Systematic Reviews

(CDSR), the Database of Abstracts of Reviews of Effects (DARE), and Database of Abstracts of Reviews of Effectiveness, Health Technology Assessment database, and the National Guideline Clearing House database were also searched to help identify existing systematic reviews. In addition, the bibliographies of included papers were examined for relevant studies. Searches were limited to English-language material published from 1999 to August, 2009 inclusive.

The comprehensive search process was followed by the critical appraisal of initially the title and/or abstracts, and subsequently the full texts of the identified publications. The critical appraisal of literature was undertaken following the Australian National Health and Medical Research Council (NHMRC) guidelines using the 'populationintervention-comparator-outcomes' (PICO) framework. Based on initial appraisals of the titles and abstracts, publications were excluded if they did not meet specific inclusion criteria. Inclusion criteria for this review were: publications (primary and secondary research) on the effectiveness of non-pharmacological interventions targeted towards individuals who were in residential care facilities with a diagnosis of dementia; non-pharmacological intervention studies on humans, conducted and reported in the previously specified ten years (1999-2009 July); publications available in English-language (or in the form of a reliable pre-existing translation); and only outcomes specified as belonging to BPSD were considered (ie non-cognitive). These BPSD outcomes included (but were not limited to) agitation, aggression, mood disorders and psychosis, sexual disinhibition, eating problems, abnormal vocalisations, 'sundowning', exiting behaviour, wandering and/or quality of life scores and/or safety-related outcomes. Studies were excluded from the review if either the title or the abstract initially did not indicate the nature of the study and did not meet the inclusion criteria; studies were also not considered for review or further appraisal if full-text articles were not available. Studies that were single participant case studies, opinions, studies published in non-standard non-peer reviewed publications such as letters, opinions, or editorials were also excluded.

Systematic reviews, randomised controlled trials (RCTs), and other epidemiological study designs with appropriate comparison groups were included in the appraisal process. Comparison groups included 'attention control' (placebo) or 'usual care'. In this review, 'usual care' is defined as the care that is normally provided in the study setting, which may or may not include medication for behavioural problems, referral to psychiatric or community mental health services and/or any other programmes or activities (ie the absence of a non-pharmacological intervention aimed specifically at treating BPSD). The less frequently used (and generally more difficult to implement) 'attention control' conditions provide equivalent attention and diversion. Examples of attention controls include a general activity session to control for a specific intervention activity (for example a music therapy activity) or a conventional bath to control for one accompanied by touch, massage or music.

For each article included in the final appraisal and summary process, the key findings were summarised and the quality of the articles, with respect to the rigour with which the study was conducted, was evaluated and possible threats to internal validity were also considered. On the basis of these appraisals, the studies were quality-evaluated, although in the final appraisal, studies were not excluded on the basis of any specified quality criteria cut-off point because of the lack of comparability and diversity of study designs. All study designs except for single case study designs were considered for the evidence generation. Therefore, on the basis of gross heterogeneity inherent in

the review process (incorporating many different study types on the same topic), no formal numerical summary or meta-analysis was conducted. Studies were summarised based on their design and the evidence.

## **Key results**

The search strategy identified a total of 4043 citations of different publication types. These studies included reviews, primary studies, and other forms of publication. Initial review of the title and abstract of these 4043 studies revealed that 3436 (84.9%) were either partial or incomplete records, or duplicates, or not specific to the population or intervention or outcomes relevant to this review, or were publication types that were not appropriate for inclusion in this review (ie they were newsletters, or publications that were neither peer reviewed nor quality assessed, or opinion pieces). These publications were not considered further. A review of the titles and abstracts of the remaining 607 studies revealed that 243 (40%) were ineligible for full-text appraisal because of inappropriate study designs, inappropriate population, or inappropriate outcome. Further, based on full-text appraisal of the remaining 364 studies, 266 (73.1%) were excluded. The majority of studies deemed ineligible for this review were excluded because of inappropriate study designs. Only well-defined systematic reviews and primary studies that utilised appropriate methodologies were accepted for inclusion in this review. To be considered for inclusion, primary research studies had to incorporate appropriate comparison groups and report sufficient detail of the methods used so as to enable an adequate assessment of internal validity and the results. Therefore, narrative reviews, personal experiences, or other forms of research that would not enable data abstraction, appraisal and assessment were excluded. In addition, the reference lists of all the included studies were checked to search for additional studies that may have been missed in the initial retrieval process. No additional study was identified in this process. Thus, in the final count, 98 studies were found to be eligible for data extraction and further appraisal.

The eligible studies included both primary research and ten systematic reviews. With respect to the primary studies, there were many overlaps. That is, many primary research studies were found to be common to one or more of the systematic reviews (in some cases, with three or more previous systematic reviews). Out of the 98 eligible studies, 46 studies were found to be reviewed in detail elsewhere (all 46 studies would otherwise have been eligible for inclusion and full appraisal and data extraction in this review). Therefore, these 46 studies are not separately reviewed here but appraised as part of the systematic review in which they occur. This left 42 eligible and unique primary studies to be appraised and summarised in this review, in addition to the ten eligible systematic reviews as shown in **Figure 1**.

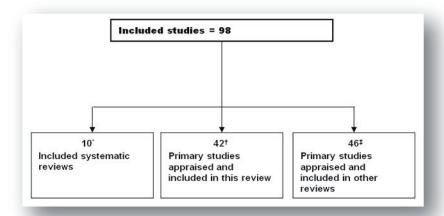


Figure 1: Sub-sets of the 98 included studies

- \* Systematic reviews that have been critically appraised and reported in this review.
- † Primary research studies that have been critically appraised and reported in this review.
- ‡ Primary research studies that have been appraised and reported within one of the ten included reviews.

A total of 22 interventions, and 21 clinical outcomes were identified in the reviewed publications, measured by 62 distinct instruments. Out of the 62 outcomes defined in the 88 primary studies, about one-half were aggression or agitation (n = 45, 51%), followed by non-specific or multiple outcomes listed under generalised BPSD (n = 32, 36%) followed by anxiety, depression, apathy (n = 11, 13%). The ten systematic reviews appraised a total of 434 primary studies. However, only approximately 120 of these studies were relevant for this current review, because of significant differences in scope (eg some reviews also included pharmacological treatments and/or considered carer-related outcomes or studies conducted in 'family home' settings).

#### Limitations

A wide range of interventions have been studied in the context of reducing behavioural and psychological symptoms, reflecting the apparent lack of consensus as to which category or categories of interventions might be generally effective. Although several outcomes and intervention-outcome pairs were considered, no effect size summary estimate could be provided. This is because the heterogeneity in the nature of the primary studies precluded pooling together the results of the individual trials. In interpreting these results, several limitations imposed by the nature of the evidence are discussed, including: 'attention effects' 1, the 'Hawthorne effect' 2, halo effects 3, small sample sizes (resulting in a failure to detect a true difference), non-blinding of outcome assessments, selection biases, other observational and measurement biases, inadequate follow-up, poor participant retention (high drop-out

<sup>2</sup> The phenomenon in which subjects in behavioral studies change their performance in response to being observed.

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<sup>&</sup>lt;sup>1</sup> Stimulating or personal attention of any kind exerting (generally unintentionally) an intervention effect.

<sup>&</sup>lt;sup>3</sup> A cognitive bias in which traits are interpreted, perceived and generalized because of pre-existing expectations.

rates due to death), variable 'stage-specific' efficacy, and other confounders (known and unknown). Numerous scales and instruments have been used to measure a range of outcomes in the different studies, and this further limits the direct comparability between studies.

#### Effectiveness

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 residents' with dementia, the following themes emerged.

TRAINING PROGRAMMES: CARERS, STAFF, FAMILY

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 or supervision were found to be beneficial in general, when compared to 'usual care', which did not contain any of these elements. Further, psycho-education intended to change carers' behaviour is effective, especially if it is provided in individual rather than group settings, and improvements in neuropsychiatric symptoms associated with these interventions may be sustained for months. Also, specific types of staff education lead to reductions in behavioural symptoms (and the use of restraints) and to improved affective states. Staff education in communication skills and enhancement of staff members' knowledge about dementia may improve many outcomes related to neuropsychiatric symptoms. In contrast, staff training programmes aimed at teaching staff emotion-oriented care or programmes aimed at changing staff attitudes or perceptions were not associated with significant changes in outcomes compared to 'usual care'.

#### INDIVIDUALLY TAILORED BEHAVIOURAL MANAGEMENT PROGRAMMES

Individually tailored behavioural management programmes were generally effective for a range of outcomes. Behavioural management techniques centred on individual patients' behaviour are generally successful for the reduction of neuropsychiatric symptoms, and the effects of these interventions can last for months. The exceptions to this general observation were two small studies of individually tailored recreational activities that did not find statistically significant changes in behaviour. Although both reported other favourable changes that were deemed clinically meaningful. Thus, on the whole, individual tailored behavioural management programmes for residents appear to be beneficial.

#### MUSIC THERAPY

The use of music, either in the form of individual-preferred music or music played in common areas for groups was generally found to be effective in reducing aggression and agitation. In addition to vocal music, there was some evidence that non-vocal instrumental music was effective in improving several BPSD. Other studies reported that music therapy is a useful treatment for neuropsychiatric symptoms during the session, but the longer-term effects may be limited. Although some studies failed to demonstrate the effectiveness of music for the reduction of agitation, overall, there is evidence that music, whether personal-preferred music or music therapy in groups or music played in common areas, is beneficial.

#### PHYSICAL ACTIVITY BASED TREATMENT PROGRAMMES

Physical activity based treatment programmes may be beneficial for agitation and/or aggression. In a relatively large meta-analysis of 30 studies, physical activity among

individuals with cognitive impairment and dementia was associated with a reduction in aggression and other cognitive and physical functioning outcomes. Other studies indicate that walking, exercise, or structured daily routines are associated with reduced wandering, or improvement in agitation. In contrast, another (albeit earlier) review did not find appreciable benefits of physical activity therapy.

#### **AROMATHERAPY**

Some evidence suggests that lavender, lemon balm, or marjoram extracts used in aromatherapy might be beneficial in reducing agitation. A systematic review and a pre-post intervention study involving ten individuals found the use of aromatherapy to be beneficial for agitation. However, another larger study did not find sufficient evidence in favour of aromatherapy for reducing agitation but did find aromatherapy to be effective for reducing 'withdrawn social behaviour' and for increasing the time residents spent engaged in constructive activities. In addition, aromatherapy administered via a diffuser during the night was found to effectively reduce agitation in 70 residents participating in a crossover randomised trial. A recent review of 11 randomised trials, on balance, did not find sufficient evidence in favour of aromatherapy for reducing agitation. Thus, while aromatherapy has been investigated in reference to agitation reduction in dementia residents, 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. The aromatherapy oils tested and the methods of delivery, dose, and outcomes measured have varied widely across studies. Aromatherapy is a commonly used 'alternative therapy' but the efficacy and side-effect profiles remain largely unknown.

#### ANIMAL-ASSISTED THERAPY(AAT)

There was limited evidence to suggest that the use of dogs (pet or therapy) in residential care facilities is associated with beneficial effect. Three studies were identified that investigated the use of therapy dogs in residential care units. While each study found that the introduction of pet dogs was associated with significant reductions in the agitation profile scores of the residents, each study was conducted on a small number of individuals and used a 'pre-post' intervention study design that was considerably less rigorous than a RCT. Therefore, while there is some evidence in favour of the use of therapy (pet) dogs, the level of evidence is low.

#### BRIGHT LIGHT THERAPY AND SNOEZELEN

There is insufficient evidence in favour of modification of the immediate environment either in the form of administration of Snoezelen (multi-sensory stimulation (MSS)) or periodic treatment with bright light. None of the three systematic reviews found sufficient evidence of Snoezelen being beneficial for BPSD. However, one study found Snoezelen therapy, compared to usual treatment, to be beneficial in reducing agitation. Despite some physiological/neurological justification for the use of Snoezelen in some circumstances, overall, and in the light of more recent equivocal studies, Snoezelen therapy was not found to be effective in the management of agitation and aggression in dementia (at least for the specific population studied).

One recent systematic review and two randomised trials found no evidence that treatment with bright light therapy (BLT), when compared with 'usual care', was beneficial in the management of depression. However, another randomised trial found that compared to 'usual care', individuals in residential care units treated with BLT had lower rates of aggression, and the difference was statistically significant.

However, the authors cautioned against attaching any clinical significance to the results since the observed changes did not represent clinically meaningful changes in aggression scores. The statistically non-significant results of some studies may have been related to the small sample sizes that contribute to insufficient power to detect a difference, if one is present. There were two notable exceptions, one randomised trial included 92 participants and another included 94 participants. These trials were adequately powered, yet still failed to demonstrate any significant between-group differences. The response to light therapy of individuals with different diagnoses and severity of dementia may differ (eg Alzheimer's disease (AD) versus vascular, 'mild-moderate' versus 'severe'). Small sample sizes and the small number of included trials precluded any analyses. Based on these findings, there is insufficient evidence in support of the effectiveness of either BLT or Snoezelen for the management of BPSD.

#### INTERVENTIONS SPECIFICALLY FOR WANDERING BEHAVIOURS

In a recent 'single outcome' systematic review, 14 empirical studies containing discrete findings about wandering behaviour (published 2003 through 2005) were evaluated. In the main, few intervention studies to manage wandering were sufficiently rigorous, although the evidence for effectiveness of subjective barriers is mounting. Ten studies of interventions such as tape grids placed on the floor, cloth panels over doors, murals painted over exits, and the use of mirrors were evaluated. The quality of the studies varied greatly. However, there are data to support the use of objects that obscure exits and some compelling evidence for the use of tape grids. Other interventions with potential include walking/exercise/activity, behavioural techniques, music (short–term effect), alarms, and electronic tracking.

#### **Economic implications**

The search of the published literature did not identify any relevant economic evaluations that could inform a qualitative discussion of the incremental costs and outcomes likely to be associated with non-pharmacological interventions for behavioural and psychological symptom management for people with dementia in residential care settings, relative to 'usual care'.

The scope of this review encompasses a range of interventions and intervention components (rather than any one 'standard' intervention) and multiple outcomes. The costs of these interventions are not well documented. Estimating resource utilisation and any possible cost off-sets and/or savings to the health care system remains beyond the scope of this report.

#### **Conclusions**

This report systematically reviewed the evidence for the effectiveness of non-pharmacological interventions for behavioural and psychological symptom management, for people with dementia in residential care settings. The methods that have been trialled in residential care settings to reduce agitation and aggression and other BPSDs are diverse.

The main findings from this review suggest that training of staff members associated with the care of the dementia patients in residential facilities, individually tailored behavioural modification programmes, and incorporating physical activities, music therapy, and aromatherapy, might be beneficial for the management of key elements of BPSD, most notably agitation, aggression, and/or several symptoms in combination. On the other hand, while bright light and Snoezelen therapy have been

studied in various different contexts, this review did not identify sufficient evidence to suggest that these were indeed beneficial for people with dementia.

One notable observation is the large number of studies reporting statistically significant benefits in both the intervention group/s and the control group/s. These studies would generally be described as 'negative studies' because of the failure to demonstrate statistically significant *between-group* differences. However, with respect to dementia care, it can be argued that this phenomenon is a potentially important finding in its own right and, at least in part, demonstrates the potential positive effect of simple 'attention'. Based on the body of evidence, it seems reasonable to attest that the potential effects of simple 'attention' should not be overlooked, and any lack of evidence does not necessarily equate to a lack of efficacy, nor be (necessarily) a barrier to implementation. One feature of the dementia research in general is the propensity of individuals with dementia to respond to interventions (or not) in individualised ways. There is no panacea, and arguably, from a practical perspective, simple case-by-case solutions may be as valid as more complex intervention programmes

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## **List of Abbreviations and Acronyms**

AAA Animal-assisted activity
AARS Apparent affect rating scale
AAT Animal-assisted therapy
AB Aggressive behaviours

ABMI Agitated behaviour mapping instrument

ABRS Agitated behaviour rating scale

AD Alzheimer's disease ADL Activities of daily living

ADRQL Alzheimer's disease related quality of life scale

AHRQ Agency for Healthcare Research and Quality (formerly AHCPR)

(USA)

ANCOVA Analyses of covariance ANOVA Analyses of variance ARR Absolute risk reduction

ASD Arousal states in dementia scale
BACE Balancing arousal controls excesses

BAGS Aggression Scale (also known as the QEBAGS system)

BCC Behavioural category code

BEHAVE-AD Behaviour pathology in Alzheimer's disease rating scale

BI Barthel index
BLT Bright light therapy

BPSD Behavioural and psychological symptoms of dementia

BRAD Behaviour rating in Alzheimer's disease scale

BRS Behaviour rating scale
BSI Brief symptom inventory

CANE The Camberwell assessment questionnaire for the needs in elderly

CERAD Consortium to Establish a Registry for Alzheimer's Disease

CGIC Clinical Global Impression of Change

CI Confidence interval

CINAHL Cumulative Index to Nursing and Allied Health Literature CCMAI Chinese version of Cohen-Mansfield agitation inventory

CMAI Cohen-Mansfield agitation inventory

CMAI-SF Cohen-Mansfield agitation inventory - short form

CMMSE Chinese mini-mental state examination

CNA Certified nursing assistant

CNPI Chinese neuropsychiatric inventory

COBRA Caretaker obstreperous behaviour rating assessment

C-RCT Cluster randomised controlled trial

CRAI Copper Ridge activity index

CRBRS Crichton Royal behaviour rating scale
CSDD Cornell scale for depression in dementia
DBDS Dementia behaviour disturbance scale

DBOSPI Dutch behaviour observation scale for psychogeriatric patients

DCM Dementia care mapping
DLB Dementia with Lewy bodies

DSM-IV Diagnostic and Statistical Manual of Mental Disorders (4th Ed.)

ERIC Emotional responses as quality indicators

FACSA Functional assessment of communication skills for adults

FM Favourite music

FTD Frontotemporal dementia

FVEP Family visit education programme
GBS Scandinavian psychiatric scale
GDS Geriatric depression scale

GD-15 Geriatric depression scale (short form 15 questions)

GP General practitioner HCP(s) Health care professional(s)

HM Hand massage

HRSD Hamilton rating scale for depression HTA Health technology assessment

INAHTA International Network of Agencies for Health Technology

Assessment

Lux, a unit of illumination equal to one lumen per square metre.

MCI Mild cognitive impairment

MD Mixed dementia MDS Minimum data set

MMSE Mini-mental state examination MOH Ministry of Health (NZ)

MOUSEPAD Manchester and Oxford Universities scale for the

psychopathological assessment of dementia

MSS Multi-sensory stimulation NEOFFI NEO five factor inventory

NHBPS Nursing home behaviour problem scale

NHMRC National Health and Medical Research Council (Australia)

NHS National Health Service (UK)

NI-ADL Nurse-informant activities of daily living

NPI Neuropsychiatric inventory

NPI-NH Neuropsychiatric inventory – nursing home version

NPS Neuropsychiatric symptoms

NZ New Zealand

PAINAD Pain in advanced dementia PAS Pittsburgh agitation scale PCC Person-centred care PD Personal detraction

PGCARS Philadelphia Geriatric Centre affect rating scale PICO(T) Population, intervention, comparator, outcomes (time

consideration)

**PLST** Progressively lower stress threshold **PSMS** Physical self-maintenance scale Ouality of life in Alzheimer's disease OOL-AD Quality of life in late-stage dementia **QUALID RAID** Rating for anxiety in dementia **RCI** Restorative care intervention **RCT** Randomised controlled trial **RCC** Residential care centres

REPDS Revised elderly persons' disability scale SBOC Social behaviour observation checklist

Rehabilitation evaluation

SCU Special care unit

REHAB

#### xviii

SD Standard deviation SP Simple pleasures

SPT 'Simulated presence' tapes

TT Therapeutic touch

TENS Transcutaneous electrical nerve stimulation TREA Treatment routes for exploring agitation

UC Usual care UK United Kingdom

USA United States of America

VD Vascular dementia VT Validation therapy

WHO World Health Organisation

WIB Well/ill-being value

## Introduction

## **Objective**

The purpose of this systematic review is to provide a summary of the evidence pertaining to the relative effectiveness and safety of non-pharmacological interventions for the management of behavioural and psychological symptoms of dementia (BPSD) in residential care settings, when compared to 'usual care'.

The review was requested by the Policy and Service Development team (Mental Health Group, Population Health Directorate) in the Ministry of Health (the Ministry). The content of this evidence review alone does not constitute clinical advice or policy recommendations. The review will inform the Ministry's Mental Health and Addiction of Older People and Dementia project. A working party/steering committee has been convened to lead the project (**Appendix A**) and the Health Services Assessment Collaboration (HSAC) has been contracted to conduct the systematic review

## **Description of indication/condition**

#### **Definitions**

Dementia has been defined as acquired deficiency in cognition that impairs successful performance of the activities in daily living (Fauci, et al., 2008). The World Health Organisation's International Classification of Disease (ICD-10, 1993) describes dementia as:

"... a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language and judgement. Consciousness is not clouded. The impairments of cognitive function are commonly accompanied, and occasionally preceded by deterioration in emotional control, social behaviour, or motivation. The syndrome occurs in Alzheimer's disease (AD), in cerebrovascular disease, and in other conditions primarily or secondarily affecting the brain" (W.H.O., 2007).

Individuals with dementia have memory and cognitive impairment, and these may manifest in the form of a spectrum of diverse symptoms. Symptoms of dementia may include disturbances in mood, behaviour, thought and perception; these symptoms are referred to as the behavioural and psychological symptoms of dementia (BPSD) (Finkel, 1996, 2003).

The term BPSD was coined by participants at an international consensus conference on behavioural disturbances of dementia, convened by the International Psychogeriatrics Association Task Force on BPSD, March 31 to April 2, 1996, in Lansdowne, Virginia, USA<sup>4</sup>. Previously, clinicians and researchers had used the term 'behavioural disturbances of dementia' but this proved difficult to define and was seen as hampering efforts to reach a better understanding of this aspect of dementia, given the heterogeneity of interpretation it inspired.

<sup>&</sup>lt;sup>4</sup> from: http://www.ipa-online.org/ipaonlinev3/ipaprograms/taskforces/bpsd/intro.asp

For the purposes of this review, BPSD is defined as: patterns of disturbed perception, thought content, mood, and behaviour that frequently occur in people with dementia. **Table 1** provides a brief list of symptoms that BPSD can involve.

Table 1: Symptoms classified as BPSD<sup>5</sup>

| Symptoms assessed by behavioural observation or by patient/relative |
|---|
| Aggression.   |
| Screaming.  |
| Restlessness.   |
| Agitation.  |
| Wandering.  |
| Culturally-inappropriate behaviours.                                |
| Sexual disinhibition.   |
| Hoarding.   |
| Cursing.  |
| Shadowing.  |
|   |

These symptoms have also been described as 'challenging behaviours' as they are perceived to challenge the norms and social rules of the contexts in which they occur (Moniz-Cook, Woods, & Richards, 2001). On the other hand, challenging behaviours can also be seen as an active attempt by a person to express or communicate a need. A person with dementia may communicate through a range of behaviours and it may not necessarily serve the person well for these to be suppressed. Symptoms may well be present without causing concern to the person (Moniz-Cook, et al., 2001).

#### Types of Dementia

**Table 2** overviews the clinical differentiation of the major dementias. Alzheimer's disease (AD) is the most common form (or cause) of dementia and it is estimated to account for 50-70% of all dementias (Fauci, et al., 2008; MOH, 2002). Alzheimer's disease is a primary degenerative cerebral disease with characteristic neuropathological and neurochemical features. As the disease progresses, neurofibrillary tangles and plaques spread throughout the brain. By the final stage, damage is widespread and brain tissue has shrunk significantly. The disorder is usually insidious in onset and develops slowly but steadily over a period of 8-10 years (NIH, 2008). Symptoms include memory problems and a progressive decline in the ability to perform basic activities of daily living (ADL). Apathy, social withdrawal and behavioural disturbances are also common (SIGN, 2006).

Vascular dementia (VD) is the second most common form of dementia and it is estimated to account for 10–20% of all dementias (MOH, 2002). Vascular dementia is a group of symptoms relating to different pathophysiology including hypertensive cerebrovascular disease, multi-infarct disease (transient ischaemic episodes) and stroke. The onset of vascular dementia may be sudden (eg following a stroke) or gradual. People with vascular dementia typically show progressive psycho-motor, cognitive, mood and behavioural changes over a period of 5-10 years with major depression being widely observed (SIGN, 2006; W.H.O., 2007).

<sup>&</sup>lt;sup>5</sup> Adapted from the website of the International Psychogeriatrics Association: retrieved from– http://www.ipa-online.org/ipaonlinev3/ipaprograms/taskforces/bpsd/intro.asp

Mixed dementia (MD) is generally considered to be the coexistence of AD and VD pathology (Bartlett et al., 2007).

Dementia with Lewy Bodies (DLB) is estimated to account for approximately 10% of all dementias. Lewy body disorders exist as a spectrum. The underlying mechanism of Lewy body disorders involves abnormal brain cells (Lewy bodies) forming in parts of the brain. The presence of Lewy bodies is also associated with Parkinson's disease. Common characteristics of DLB are cognitive decline, fluctuation of awareness, hallucinations or delusions, tremors, slowness of movement, and falls (Fauci, et al., 2008).

Frontotemporal dementia (FTD) results from pathology related to the frontal and temporal regions of the cerebral hemispheres and related pathways. This results in a set of clinical symptoms including impaired executive function, lethargy, disinhibition, loss of social awareness, disturbance of mood and speech (Fauci, et al., 2008).

In addition, there are numerous other dementias including dementia secondary to Parkinson's disease and Huntington's disease, dementia in human immunodeficiency virus (HIV) disease, dementia in Pick's disease, dementia in Creutzfeldt-Jakob disease and degeneration of the nervous system due to long-term misuse of alcohol or other drugs Bartlett et al., 2007). Further, mild cognitive impairment (MCI) is a clinical diagnosis that includes aged persons without dementia, but with memory impairment and no significant disability. Individuals with MCI have a significantly accelerated rate of progression to Alzheimer's disease.

With respect to the structure of the review, it is acknowledged that dementia results from diverse underlying causes, and will invariably have differing disease profiles in terms of onset, duration, symptoms, symptom sequencing and tempo of progression for each person. Therefore, this review will be structured with an intervention–outcome based focus (ie the effectiveness of non-pharmacological interventions for the management of BPSD, rather than an underlying disease-based focus).

Table 2: Clinical differentiation of the major dementias

| Disease                                   | First symptom   | Mental status   | Neuropsychiatry   |
|---|---|---|---|
| Alzheimer's disease (AD)                  | Memory loss.  | Episodic memory loss.   | Initially normal.   |
| Front-<br>temporal<br>dementia<br>(FTD).  | Apathy, poor judgement/insight, speech/language, hyperorality.  | Frontal/executive, language, spares drawing.                  | Apathy, disinhibition, hyperorality, euphoria, depression.          |
| Dementia<br>with Lewy<br>Bodies<br>(DLB). | Visual hallucinations, rapid<br>eye movement' sleep<br>(REM) sleep disorder,<br>delirium, Capgras'<br>syndrome, parkinsonism. | Drawing and frontal/executive, spares memory, delirium prone. | Visual hallucinations,<br>depression, sleep disorder,<br>delusions. |
| Vascular<br>dementia                      | Often but not always sudden, variable, apathy, falls, focal weakness.   | Frontal/executive, cognitive slowing, can spare memory.       | Apathy, delusions, anxiety.   |

Source: Fauci et al. (2008).

#### Burden of disease

The burden of dementia in New Zealand is substantial. An economic impact report published in 2008 by Alzheimers New Zealand, estimated that, in 2008, there were over 40,000 people with dementia in New Zealand (NZ), and this number was predicted to nearly double by 2026 (Access Economics, 2008). This represents an increase in prevalence from 1.0% of the population in 2008 to 1.5% by 2026. The total costs of dementia in NZ were estimated as NZ \$712.9 million. It has also been estimated that between 60% and 70% of all people living in residential care in NZ have some form of dementia (MOH, 2002). Thus, the economic and social implications of an increase in the prevalence of dementia are significant.

Not only does dementia result in profound changes that can impair a person's successful performance of ADL, it also brings about profound change for carers, who are often family members. Caring for a person with dementia can have high physical, emotional, and financial costs. The demands of day-to-day care, changing family roles, and difficult decisions about placement in a care facility can be onerous. Up to 50 percent of carers experience significant anxiety and depressive symptoms during the course of their care-giving (Donaldson, Tarrier, & Burns, 1998; Schulz, O'Brien, Bookwala, & Freissner, 1995).

#### Pharmacological treatment of BPSD

Pharmacological interventions include the administration of therapeutic drugs that interact within biological systems to affect function. These therapeutic drugs include antipsychotics, anti-depressants, and mood stabilizers (National Prescribing Service, 2007). While pharmacological interventions have been used extensively to treat BPSD increasing concerns over their efficacy and significant side-effects have resulted in calls for non-pharmacological approaches to be prioritised as first-line interventions (All-Party Parliamentary Group on Dementia, 2008; National Institute for Health and Clinical Excellence-Social Care Institute for Excellence, 2007) Similarly, in New Zealand, a recent Pharmaceutical Management Agency of New Zealand (PHARMAC) funded report (BPACNZ, 2008) on the use of pharmacological interventions in residential care in New Zealand indicates significant misuse of drug therapies in residential care settings.

While there is some evidence that antipsychotics are effective for psychotic symptoms (eg delusions or hallucinations) associated with dementia, or for people who are aggressive or agitated without psychoses, antipsychotics are not effective for all BPSD. The Australian National Prescribing Service practice review (2007), stated that an antipsychotic is only indicated if aggression, agitation or psychotic symptoms cause severe distress or an immediate risk of harm to the person with dementia or others. Symptoms that do not usually respond to an antipsychotic include wandering, social withdrawal, shouting, pacing, touching, cognitive defects and incontinence. However, these symptoms may respond to interventions such as subtle changes to the environment. Other studies have reported that pharmacological therapies are 'not particularly effective' for the management of BPSD. Sink, Holden, and Yaffe (2005) found that generally the effects are modest and further complicated by an increased risk of stroke. In a recent meta-analysis of 15 trials, Schneider et al. (2006) evaluated the effectiveness of atypical antipsychotic drugs in individuals with AD and found that, at best, the effectiveness of antipsychotics for BPSD is modest. Further, cognitive test scores deteriorated amongst those being treated with antipsychotics and there was evidence of serious adverse events, including drowsiness, abnormal gait,

falls, urinary tract infections and a significantly increased risk for cerebrovascular events.

The NICE-SCIE guideline (2007) and SIGN (2006) have suggested that antipsychotic drugs should be used in the first instance only if an individual is severely distressed or if there is an immediate risk of harm to others.

## **Description of intervention/technology**

#### Non-pharmacological treatment of BPSD

Most recommendations for the application of non-pharmacological treatments of BPSD are based on best practice guidelines and institutional experience of what has been shown to work. In fact there is a plethora of non-pharmacological interventions reported in the literature, including: activity therapy; aromatherapy; art therapy; behavioural therapy; bright-light therapy; cognitive behavioural therapy; complementary therapy; interpersonal-therapy; multi-sensory approaches; music therapy; physical activity; reality orientation; reminiscence therapy; validation therapy (VT); carer education and changes to the physical environment in which care is provided.

Several systematic and/or narrative reviews have provided some evidence to support the effectiveness of some non-pharmacological treatments (Ayalon, Gum, Feliciano, & Arean, 2006; Bartlett, Gray, Byrne, Travers, & Lui, 2007; Bates, Boote, & Beverley, 2004; Cohen-Mansfield, 2004; Finnema, Dröes, Ribbe, & Van Tilburg, 2000; Livingston, et al., 2005; O'Connor, Ames, Gardner, & King, 2009; Opie, Rosewarne, & O'Connor, 1999; Sink, et al., 2005; Verkaik, van Weert, & Francke, 2005). However, the evidence base is far from complete. Nevertheless, this lack of evidence regarding many of the therapies is not evidence of lack of efficacy. Behaviour management therapies, specific types of carer and residential care staff education, and cognitive stimulation do appear to have potential for the management of BPSD.

A Ministry of Health report on dementia in New Zealand (MOH, 2002) suggested that many providers of residential care were attempting to manage challenging behaviours in an environment not suited to that type of care. Further, tensions were evident between providing a custodial 'institutional model of care' with a focus on risk minimisation versus a 'person-centred' model that allowed expression of normal risk-taking behaviour.

While guidelines have been developed to improve prescribing of pharmacological interventions (National Institute for Health and Clinical Excellence-Social Care Institute for Excellence, 2007; National Prescribing Service, 2007; Royal Australian and New Zealand College of Psychiatrists, 2006), relatively little has been documented on effective alternatives. Providing health care professionals (HCPs)in New Zealand with guidance for managing BPSD in residential care will assist in meeting the requirement for the development of a trained and skilled workforce and help to ensure the delivery of safe, quality care. If the rationale for a reduced reliance on medication is to be accepted, then healthcare professionals will need to be confident in the use of non-pharmacological alternatives.

## **Structure of report**

This report is divided into sections. The next section describes the review's methods and includes: the research questions; search strategy; inclusion and exclusion criteria; the data extraction, appraisal and synthesis methods; and the methodological limitations of the evidence review. The results section considers the included appraised studies, reporting first on the systematic reviews and meta-analyses, and then on the original primary research. Study characteristics and findings are reported in separate tables and synthesised in the text, and the body of evidence for each research question is reported. The final section summarises results, briefly discusses the limitations of the evidence base and identified gaps in knowledge, and presents key conclusions. A glossary and detailed appendices follow, including the search strategy, all excluded papers annotated by reason for exclusion, and the completed data extraction tables for included papers.

## **Methods**

The review methodology used for all HSAC evidence reviews is broadly based upon guidelines published by the Australian National Health and Medical Research Council (NHMRC, 2000a, 2000b, 2008).

## Research questions

The clinical question to be answered by this review was defined by staff from the MOH's Mental Health Group, Population Health Directorate and the working party on Mental Health and Addiction of Older People and Dementia, in conjunction with the reviewers. In general, the aim of this review was to evaluate the effectiveness of non-pharmacological interventions for treating and managing BPSD.

The primary research question to be addressed by this review was:

What non-pharmacological interventions, in the context of residential care facilities/rest homes in New Zealand, show high-level evidence of effectiveness for treating and managing BPSD?

The secondary research question was:

Based on the evidence, what non-pharmacological interventions could be adapted or matched to individual or group settings and disease stages, and are acceptable to residents and carers?

The review questions are defined according to the PICO (or PICOT) criteria:

- Population
- Intervention
- Comparator (where appropriate)
- Outcomes
- Time consideration (should be considered with regard to all of the above domains)

For inclusion in the current review, the evidence had to fulfil the criteria outlined in **Table 3** and **Table 4**. These criteria were developed a priori and described in the scoping protocol prepared prior to commencement of the review proper.

Table 3: Criteria for determining study eligibility

| Participants/<br>population | Adults of all ages in rest homes (aged residential care facilities not domestic settings) and specialised dementia care facilities who have dementia (including, but not limited to, Alzheimer's disease (AD), vascular dementia (VD), dementia with Lewy Bodies (DLB), frontotemporal dementia (FTD), and mixed dementia) and who experience and/or exhibit behavioural and psychological symptoms of dementia (BPSD). |
|-----------------------------|---|
| Intervention                | Non-pharmacological* interventions that can be used in rest homes (aged residential care facilities) and specialised dementia care facilities to treat/manage/minimise/mitigate BPSD either in individual or group settings and for different disease stages.   |
| Comparator                  | Broadly: 'Usual care'.  In this review, 'usual care' is defined as the care that is normally provided in the study setting, which may include medication for behavioural problems, referral to psychiatric or community mental health services and/or any other programmes or activities (ie the absence of a non-pharmacological intervention aimed specifically at treating BPSD).                                    |
| Outcomes                    | Resident-relevant outcomes: reduction of, or reduction in effect of, BPSD (such as agitation, aggression, mood disorders and psychosis, sexual disinhibition, eating problems, abnormal vocalisations, 'sundowning', exiting behaviour, wandering, lifestyle adaptations, quality of life scores.  Safety-related outcomes: Physical and psychological safety of residents.   |

<sup>\*</sup> Interventions other than recognised drugs and devices.

It is important to note that studies not specifically designed to answer the research questions were excluded. The most common example of such exclusions were studies conducted in populations that differed from 'residential care' (or rest homes or specialised care facilities). For example, adults living in private (family) home settings and/or people who do not have dementia (including studies of people with mild cognitive impairment only, or older people with age-normal cognitive decline).

Table 4: Nature of the evidence

| Publication type | Studies published in the English-language, including primary (original) research published as full original reports and secondary research (systematic reviews and meta-analyses) appearing in the published literature. Papers for which an abstract is not available for review via the bibliographic database were excluded.   |
|------------------|---|
| Study design     | Those that provide at least Level IV evidence according to the NHMRC interim levels of evidence for intervention research questions (2008). This includes randomised controlled trials (RCTs) (Level II evidence) of crossover or parallel-group design, and systematic reviews of Level II evidence, pseudo-randomised controlled trials (Level III-1 evidence), non-randomised, experimental trials, cohort studies, case-control studies, interrupted time series (ITS) with a control group (Level III-2 evidence), historical control studies, two or more single arm studies, ITS without a parallel control group (Level III-3 evidence), and case series with either post-test or pre-test/post-test outcomes (Level IV evidence). See Table 5. |
| Study duration   | No study duration specified.  |
| Sample size      | At least 20 evaluable participants per study arm (or exposed to both treatments). This includes:  |
|                  | (1) 20 participants per arm in intervention studies   |
|                  | (2) 10 participants in crossover trials   |
|                  | (3) (n) x (r) = 20 where n = number of participants and r = number of repetitions of measurements in repeated-measure trials (excludes single case study designs).  |

#### Literature search

A systematic method of literature searching and selection was employed in the preparation of this review. Searches were limited to English-language material published from 1999 onwards. The searches were completed on 6th, August, 2009. Therefore, studies published after this date were not eligible for inclusion in the systematic review.

The following databases were searched:

#### Bibliographic databases

- EMBASE
- MEDLINE
- PsycINFO
- CINAHL

#### Review databases

- Cochrane Database of Systematic Reviews
- Cochrane Central Register of Controlled Trials
- Database of Abstracts of Reviews of Effectiveness
- Health Technology Assessment (HTA) database
- NHS Economic Evaluation database

### Health Technology Assessment (HTA) Groups

- INAHTA website database: http://www.inahta.org/Search2/?pub=1
- MSAC: http://www.msac.gov.au/
- ANZHSN: http://www.horizonscanning.gov.au/
- NZHTA: http://nzhta.chmeds.ac.nz/
- NICE: http://www.nice.org.uk/
- AHRQ/USPSTF: http://www.ahrq.gov/
- CADTH: http://www.cadth.ca/
- SBU: http://www.sbu.se
- KCE: http://kce.fgov.be
- CADTH: http://www.cadth.ca/

#### Clinical Practice Guidelines

National Guideline Clearing House database: http://www.guideline.gov/

The reference lists of included papers were scanned to identify any peer reviewed evidence that may have been missed in the literature search. Manual searching of journals, contacting of manufacturers, or contacting of authors for unpublished research was not undertaken in this review. Whilst grey literature and unpublished material such as conference abstracts were not included in the evidence review, they may be referred to in background sections.

Search terms were searched for as keywords, expanded where possible, and as free text within the title and/or abstract, in the EMBASE and MEDLINE databases. Variations on these terms were used for the Cochrane library and other databases, and if required, modified to suit their keywords and descriptors. The search terms, search strategy, and citations identified are presented in **Appendix B**.

## Assessment of study eligibility

Broadly, studies were selected for appraisal using a two-stage process. First, titles and abstracts (where available) identified from the search strategy were scanned and excluded as appropriate. Second, the full-text articles were retrieved for the remaining studies and selected for inclusion and appraisal in the review if they fulfilled the study selection criteria outlined below. Double-checking of the eligibility of full-text articles was undertaken by a second reviewer.

Citations were excluded for the following reasons:

- Not a clinical study: including non-systematic reviews, case reports, animal studies, short notes, letters, editorials, conference abstracts, in-vitro studies, studies not deemed appropriate to the research question or nature of review
- Incorrect population: populations belonging to health care systems that do not closely match New Zealand's or another developed country's health care system in terms of organisational aspects and quality of care. For example, adults living in private (family) home settings (not residential care or rest homes or specialised care facilities) and/or people who do not have dementia (including studies of people with mild cognitive impairment only).
- Incorrect intervention: no intervention or wrong exposure variables. For example, interventions aimed at reducing carer burden only (with no regard to resident-related outcomes) or any pharmacological intervention.
- Incorrect comparator: not including the correct comparator/s 'usual care', 'no intervention', or pharmacological interventions; or: (1) studies that do not compare time periods (pre-intervention and post intervention) within the same population; (2) comparison groups not sampled on the same exposure or interventions/situations (eg, those who have received a specific intervention) versus those who have not; (3) comparison groups not sampled on relevant outcomes; and (4) ecological studies with demographic or other non-modifiable system level variables that cannot be compared or extrapolated to individual levels.
- Incorrect outcomes: not including the results relating to at least one of the identified outcomes of interest (specifically, resident-relevant outcomes); studies that focus on psychometric measures, standardised memory tests or other measures of cognitive performance per se, rather than BPSD.

#### Additional reasons included:

- not in English (due to time constraints, non-English publications were not included)
- fewer than 20 participants per study arm at baseline
- published pre-1999
- full text not available from any source and/or full-text not able to be retrieved within a reasonable timeframe
- other/background information only.

Note: Articles were excluded if they repeated what was already reported, or had been superseded by more recent work. Therefore, general 'non-systematic' review articles or overviews were not included. Publications relating to normal cognitive ageing or cognitive decline in healthy older people or in the general older population were not included. Primary research single case-studies were not included in the review, nor

were treatments that were not evidence-based or the results of expert consultation/consensus. All excluded articles are presented in **Appendix D**, annotated by reason for exclusion based on the exclusion criteria detailed above. Reasons are presented hierarchically, such that the first reason in the list that applied is reported. Other cited publications (eg those providing background material) are presented in the **References**.

## Appraisal of included studies

#### Dimensions of evidence

The aim of this review was to find the highest quality evidence to answer the clinical question. In accordance with NHMRC guidance, the following dimensions of evidence were reviewed for each of the included studies (**Table 5**). It is important to recognise that the value of a piece of evidence is determined by *all* of these dimensions, not just the level of evidence.

**Table 5:** Dimensions of evidence (NHMRC, 2000b)

| Dimension             | Definition   |
|-----------------------|--|
| Strength of evidence  |  |
| Level                 | The study design used, as an indicator of the degree to which bias has been eliminated by design (see Table 6).  |
| Quality               | The methods used by the investigators to minimise bias within a study design.  |
| Statistical precision | The P-value or alternatively, the precision of the estimate of the effect (as indicated by the confidence interval). It reflects the degree of certainty about the existence of a true effect. |
| Size of effect        | The distance of the study estimate from the 'null' value and the inclusion of only clinically important effects in the confidence interval.  |
| Relevance of evidence | The usefulness of the evidence in clinical practice, particularly the appropriateness of the outcome measures used.  |

The evidence was assessed according to the dimensions outlined in **Table 5** above. Each study was also assigned a level of evidence in accordance with the NHMRC (2008) (**Table 6**).

The highest level of evidence available is a systematic review of randomised controlled trials (RCTs), which are considered the study type least subject to bias. Individual RCTs also represent good evidence. However, comparative observational studies such as cohort and case-control studies or non-comparative case series may often be more readily available. Such studies are often conducted early in the development of a technology, or to detect rare outcomes or outcomes which develop long after an exposure (eg, cancer, cardiovascular disease). Nevertheless, these lower levels of evidence remain subject to considerable bias.

#### Table 6: NHMRC additional levels of evidence and grades (NHMRC 2008)

#### **Intervention studies**

| Level | Intervention <sup>1</sup>  |
|-------|--|
|       |  |
| l 2   | A systematic review of level I studies.  |
| II    | A randomised controlled trial.   |
| III-1 | A pseudo-randomised controlled trial (ie alternate allocation or some other method).   |
| III-2 | A comparative study with concurrent controls:  • non-randomised, experimental trial <sup>3</sup> • cohort study  • case-control study  • Interrupted time series with a control group. |
| III-3 | A comparative study without concurrent controls:  • historical control study  • two or more single arm study <sup>4</sup> • Interrupted time series without a parallel control group   |
| IV    | Case series with either post-test or pre-test/post-test outcomes   |

#### **Explanatory notes**

<sup>1</sup> Definitions of these study designs are provided on pages 7-8 *How to use the evidence: assessment and application of scientific evidence* (NHMRC 2000b) and in the accompanying **Glossary**.

**Note A:** Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms (and other outcomes) are rare and cannot feasibly be captured within RCTs, in which case lower levels of evidence may be the only type of evidence that is practically achievable; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

**Note B:** When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question (eg level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence).

**Note C:** Each individual study that is attributed a "level of evidence" should then be rigorously appraised using validated or commonly used checklists or appraisal tools to ensure that factors other than study design have not affected the validity of the results.

Source: Hierarchies adapted and modified from: NHMRC (2008); NHMRC (1999); Bandolier (1999); Lamer et al. (1999); Phillips et al. (2001).

<sup>&</sup>lt;sup>2</sup> A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies, and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower-level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review *quality* should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

<sup>&</sup>lt;sup>3</sup> This also includes controlled 'before and after' (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie utilise A vs. B and B vs. C, to determine A vs. C with statistical adjustment for B).

<sup>&</sup>lt;sup>4</sup> Comparing single arm studies (ie case series from two studies). This would also include unadjusted indirect comparisons (ie utilise A vs. B and B vs. C to determine A vs. C, but where there is no statistical adjustment for B).

#### Quality of evidence

Even within the levels of evidence stated above there is considerable variability in the quality of evidence. In accordance with NHMRC guidelines, it was necessary to consider the quality of each of the included studies. The aim of this literature review was to identify scholarly published research on interventions targeted at the reduction of BPSD among the elderly in residential care facilities. The range of studies included in the review varied from single case study designs on individuals measured over time, through to systematic reviews and meta-analyses. Because of this diversity, a uniform criterion for assigning formal 'quality scores' could not be applied to individual studies. However, the following approaches were used to analyse the quality of individual studies in preparing this review.

For systematic reviews, RCTs, and other non-randomised observational study designs. NHMRC quality checklists (1999) were employed to appraise the included articles. The characteristics and quality of each included study were assessed using a number of standardised quality questions. For other types of study designs (i.e., single case study designs where interventions and either 'usual care' or other alternative procedures were applied in various sequences to participants), a formal quality assessment could not be assigned to individual studies as no suitable quality appraisal checklists are available for these specific study designs. However, for each single case study that was appraised, the American Psychological Association's Task Force guidelines for assessing non-pharmacological interventions (Chambless & Hollon, 1998) were adapted and used to guide quality appraisal. The following minimum criteria were applied: (1) ABAB design (where A denotes no intervention and B, intervention) or multiple baseline designs were allowable because they provide the most compelling evidence of causality; (2) an unambiguous description of the research problem; (3) adequate description of the participants (age, gender, clinical condition); (4) adequate description of the intervention/s and control conditions; (5) assessments of neuropsychiatric symptoms were standardised; (6) appropriate data analyses were conducted.

#### Data extraction

Data was extracted onto specifically-designed data extraction forms, and included information regarding study design, participant characteristics, details of the intervention, relevant outcomes, study quality, and relevant results. Data was extracted by two reviewers and any issues of eligibility or quality were resolved by consensus.

Unless otherwise specified, the data that were most adjusted for confounders and/or multiple comparisons are reported. Furthermore, where subgroup analyses are available, these were reported if they are deemed relevant.

Completed data extraction forms containing detailed information regarding study characteristics and quality, as well as a brief summary of study results, can be found in **Appendix E**.

#### Data synthesis

In addition to the level and quality of evidence of individual studies, the review will consider the body of evidence in total. This will involve consideration of the volume of evidence and its consistency.

For systematic reviews with analyses involving evidence from RCTs, a meta-analysis should be performed when appropriate using the methodology of the Cochrane Collaboration (Mulrow & Oxman, 1997). However, this would only be undertaken if the trial characteristics and participant characteristics are sufficiently homogeneous in order to justify a meta-analysis. Quantitative pooling may not be possible for other research questions or levels of evidence. Data from observational studies is subject to considerable heterogeneity and to biases that vary between studies.

The review presents the statistical precision of the estimated effect size (pooled if possible), together with a discussion of its clinical significance. Finally, the review considers the relevance of the evidence, both with regard to the applicability of the population and the intervention, as well as the relevance to the New Zealand health care setting.

## Limitations of the review methodology

This review used a structured approach to review the literature. However, there were some inherent limitations to this approach. All types of study are subject to bias, with systematic reviews being subject to the same biases seen in the original studies they include, as well as biases specifically related to the systematic review process. Reporting biases are a particular problem related to systematic reviews and include publication bias, time-lag bias, multiple publication bias, language bias, and outcome reporting bias (Egger, Dickersin, & Davey Smith, 2001). A brief summary of the different types of reporting bias is shown in Table 7. Other biases can result if the methodology to be used in a review is not defined a priori (ie, before the review commences). Detailed knowledge of studies performed in the area of interest may influence the eligibility criteria for inclusion of studies in the review and may therefore result in biased results. For example, studies with more positive results may be preferentially included in a review, thus biasing the results and overestimating the treatment effect. A more detailed discussion of the common methodological limitations of the evidence considered can be found in the **Discussion**, under "limitations of current research base".

Table 7: Reporting biases in systematic reviews

| Type of bias         | Definition and effect on results of review  |
|----------------------|---|
| Publication bias     | The publication or non-publication of research findings.  |
|                      | Small, negative trials tend not to be published and this may lead to an overestimate of results of a review if only published studies are included.   |
| Time-lag bias        | The rapid or delayed publication of research findings.  |
|                      | Studies with positive results tend to be published sooner than studies with negative findings and hence results may be overestimated until the negative trials 'catch up'.  |
| Multiple publication | The multiple or singular publication of research findings.  |
| bias                 | Studies with significant results tend to be published multiple times which increases the chance of duplication of the same data and may bias the results of a review.   |
| Citation bias        | The citation or non-citation of research.   |
|                      | Citing of trials in publications is not objective so retrieving studies using this method alone may result in biased results. Unsupported studies tend to be cited often which may also bias results.                   |
| Language bias        | The publication of research findings in a particular language.  |
|                      | Significant results are more likely to be published in English so a search limited to English-language journals may result in an overestimation of effect.  |
| Outcome reporting    | The selective reporting of some outcomes but not others.  |
| bias                 | Outcomes with favourable findings may be reported more. For example, adverse events have been found to be reported more often in unpublished studies. This may result in more favourable results for published studies. |

Adapted from Egger et al. (2001).

Some of these biases are potentially present in this review. Only data published in peer reviewed journals is included. No attempt was made to include unpublished material, as such material typically has insufficient information upon which to base quality assessment, and it has not been subject to the scrutiny of the peer review process. In addition, the search was limited to English-language publications, so language bias is a potential problem as well. Outcome reporting bias and inclusion criteria bias are unlikely, as the reviewers had no detailed knowledge of the topic literature and the methodology used in the review and the scope of the review was defined *a priori*.

The scope of the review was developed with the assistance of MOH staff to support policy and purchasing relevant to New Zealand. All studies included in this review were conducted outside New Zealand, and therefore, their generalisability to the New Zealand population and context may be limited and needs to be considered. This review was confined to an examination of the efficacy and safety of the interventions and did not consider ethical or legal considerations associated with these interventions. Papers published pre-1999 were not considered as these tended to concern outdated methods and practices.

The studies were initially selected by examining the abstracts of the articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full-text article. However, where detail was lacking, ambiguous papers were retrieved as full-text to minimise this possibility. The full citations of included studies are listed in **Appendix C** and reasons for exclusion for every article considered for review are presented in **Appendix D** for transparency. Data extraction, critical appraisal and report preparation was performed by both reviewers.

For a more detailed description of interventions and evaluation methods, and results used in the studies appraised, the reader should refer to the original papers cited.

## **Evaluation of economic implications**

The search of the published literature did not identify any relevant economic evaluations that could inform a qualitative discussion of the incremental costs and outcomes likely to be associated with non-pharmacological interventions for behavioural and psychological symptom management for people with dementia in residential care settings, relative to 'usual care'.

The scope of this review encompasses a range of interventions and intervention components (rather than any one 'standard' intervention) and multiple outcomes. The costs of these interventions are not well documented. Estimating resource utilisation and any possible cost off-sets and/or savings to the health care system remains beyond the scope of this report.

# Results

## Overview

Dementia care generally, and non-pharmacological interventions in particular, are areas that are not well indexed in the bibliographical databases. Therefore, an iterative and comprehensive search process was developed to capture as much of this literature as possible. Given the lack of clear and consistent indexing, there was a high reliance on *phraseology* to capture these interventions and outcomes potentially used in the titles or abstracts, and thus to focus any retrieval. Broadly, the search terms and phraseology included many combinations of known interventions and outcomes. The search did not focus on any specific non-pharmacological intervention or any specific behavioural or psychological symptom of dementia (including neuropsychiatric symptoms) over any other. Thus, the initial search was, by design, broad and overinclusive. Studies that were specifically focussed on carer-related outcomes (only) were excluded from the search (where possible), as these were deemed to be outside the scope of the review question. The search terms, search strategy and number of citations identified are presented in **Appendix B**.

The initial broad search resulted in 4043 titles and/or abstracts being identified as potentially relevant (Figure 2). These 4043 articles were initially processed through a 'first-pass sifting' stage in which articles were rejected if they were identified as: clearly unrelated to the topic, duplicates of any kind (including all variations and repetitions of the same citation, the same article published in different journals, the same study published by different authors, an up-dated version of an earlier article etc), partial records, clearly non-relevant reports including letters, notes, magazine articles and newsletters and any articles relating exclusively to carer-related outcomes. Following the first-pass exclusions (3436 or 84.9% of the titles and/or abstracts), there were 607 non-duplicate articles remaining as potentially eligible for inclusion in the review, and these articles were processed through the 'title and abstract' screening stage (with respect to the detailed inclusion/exclusion criteria as detailed in Table 3 and Table 4. Following the exclusion of 243 (40%) articles based on an assessment of their titles and abstracts, 364 full-text articles were deemed eligible for retrieval in full-text for a more detailed assessment of their eligibility. Of the 364 full papers retrieved, 266 (73.1 %) did not fulfil the inclusion criteria and were therefore excluded. In total, 98 articles remained eligible for inclusion in the review and were further appraised for inclusion in this report. As indicated in Figure 2, there were no studies specifically excluded based only on the comparator, as interventions were compared with all forms of conventional treatment, 'usual care', 'attention control', placebo, no-intervention, no-treatment, or 'head-to-head' with pharmacological interventions.

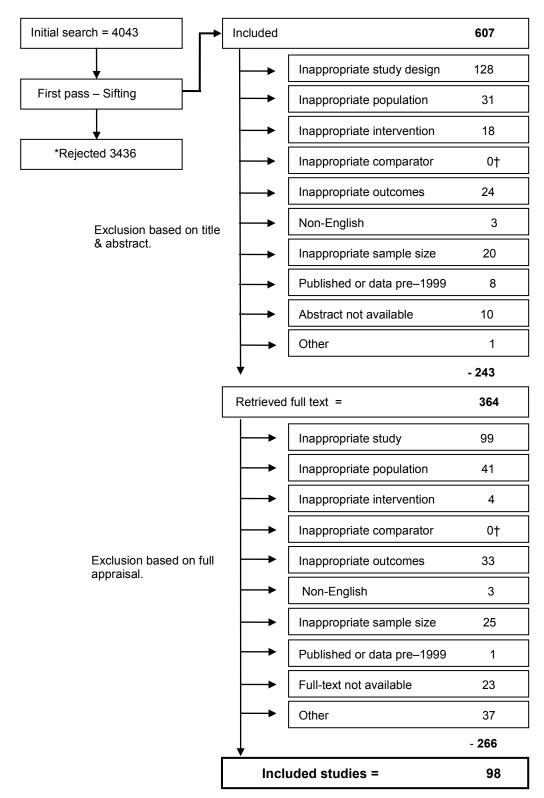


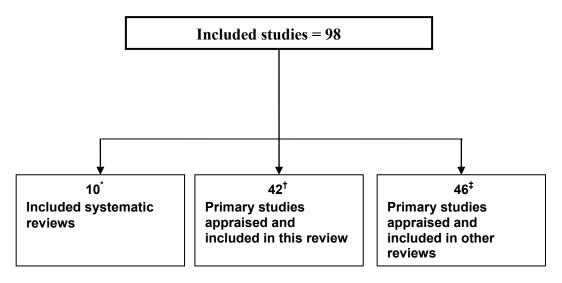
Figure 2: Application of selection criteria to citations

<sup>\*</sup>Papers rejected at the first pass 'sifting' stage comprised duplicates of all kinds, partial records, and clearly non-relevant reports including letters, notes, magazine articles and newsletters.

<sup>†</sup>There were no studies specifically excluded based only on the comparator, as interventions were compared with all forms of 'usual care', 'attention control'/placebo, no-intervention or 'head-to-head' with pharmacological interventions.

Methodological information and findings from the included studies are presented in this section, first for systematic reviews, then for primary studies. Detailed information is available in **Appendix E** or in the original papers. Only data relevant to the current review is presented. Further, it was necessary to assess studies within the context of the whole body of evidence, such that on the one hand, sufficient detail could be presented, while avoiding unnecessary and undesirable duplication and distortion of findings (eg reporting the same findings twice). Therefore, articles were excluded if they repeated what was already reported elsewhere or had been superseded by more recent research on the same population using the same methods (ie up-dated). Of the 98 papers identified as eligible, ten were systematic reviews and 88 were primary research studies. One notable feature of the body of evidence was the considerable overlap between the ten systematic reviews and the 88 primary research studies. Hierarchical cross-checking (by publication date) of all of the eligible primary studies against the ten systematic reviews revealed that 46 studies were common to two or more systematic reviews. Where these studies are adequately appraised and reported within previously published systematic reviews, they are not duplicated further. Thus, 42 primary research studies have been critically appraised and reported in this review. Figure 3 and Table 8, Table 9, and Table 10 provide an overarching guide to the 98 eligible studies and their individual status. That is, whether a study is an included systematic review (n = 10), an included primary research study that has been appraised and reported independently in this review (n = 42), or an eligible primary research study that has been appraised and reported within one of the ten included previously published reviews (n = 46).

Figure 3: Sub-sets of the 98 included studies



<sup>\*</sup> Systematic reviews that have been critically appraised and reported in this review.

<sup>&</sup>lt;sup>†</sup> Primary research studies that have been critically appraised and reported in this review.

<sup>&</sup>lt;sup>‡</sup> Primary research studies that has been appraised and reported within one of the ten included reviews.

Table 8: Alphabetical list of the 10 systematic reviews

| First author and date | Status             |
|-----------------------|--------------------|
| Algase, 2006.         | Systematic review. |
| Bartlett, 2007.       | Review of reviews. |
| Bharani, 2005.        | Systematic review. |
| Forbes, 2009.         | Systematic review. |
| Kverno, 2009.         | Systematic review. |
| Landreville, 2006.    | Systematic review. |
| Livingston, 2005.     | Systematic review. |
| Nguygen, 2008.        | Systematic review. |
| O'Connor, 2009.       | Systematic review. |
| Perkins, 2008.        | Systematic review. |

Table 9: Alphabetical list and status of the 42 primary studies reported in this review

| First author and date  | Status    |
|------------------------|-----------|
| Beshara, 2002.         | Included. |
| Bird, 2007.            | Included. |
| Bowles, 2002.          | Included. |
| Brodaty, 2003.         | Included. |
| Brooker, 2007.         | Included. |
| Buettner, 1999.        | Included. |
| Burns, 2009.           | Included. |
| Chapman, 2007.         | Included. |
| Chenoweth, 2007.       | Included. |
| Chenoweth, 2009.       | Included. |
| Cheston, 2003.         | Included. |
| Cheston, 2007.         | Included. |
| Choi, 2009.            | Included. |
| Chrzescijanski, 2007.  | Included. |
| Churchill, 1999.       | Included. |
| Cohen, 2009.           | Included. |
| Cohen-Mansfield, 2006. | Included. |
| Cohen-Mansfield, 2007. | Included. |
| Cornell, 2004.         | Included. |
| Davison, 2007a.        | Included. |
| Davison, 2007b.        | Included. |
| Deguchi, 2000.         | Included. |
| Dowling, 2007.         | Included. |
| Galik, 2008.           | Included. |
| Hawranik, 2008.        | Included. |
| Hickman, 2007.         | Included. |
| Hicks-Moore, 2005.     | Included. |
| Hicks-Moore, 2008.     | Included. |
| Hodgson, 2008.         | Included. |
| Kolanowski, 2001.      | Included. |
| Kotynia, 2005.         | Included. |
| Kraus, 2008.           | Included. |
| Ledger, 2007.          | Included. |
| Lee, 2008.             | Included. |
| McCabe, 2002.          | Included. |
| Orrell, 2007.          | Included. |
| Politis, 2004.         | Included. |
| Raglio, 2008.          | Included. |
| Tondi, 2007.           | Included. |
| Warren, 2001.          | Included. |
| Yang, 2007.            | Included. |
| Ziv, 2007.             | Included. |

Table 10: Alphabetical list and the status of the 46 primary studies reported in previously published reviews

| First author and date            | Status                      | Published review                    |
|----------------------------------|-----------------------------|-------------------------------------|
| Ancoli-Israel, 2003.             | Reported in →               | Forbes, 2009.                       |
| Ashida, 2000.                    | Reported in →               | Livingston, 2005.                   |
| Baillon, 2004.                   | Reported in →               | O'Connor, 2009.                     |
| Baker, 2003.                     | Reported in →               | O'Connor, 2009.                     |
| Ballard, 2002.                   | Reported in →               | O'Connor, 2009.                     |
| Beck, 2002.                      | Reported in →               | Landreville, 2006.                  |
| Buchanan, 2002.                  | Reported in →               | Livingston, 2005.                   |
| Buettner, 2002.                  | Reported in →               | Livingston, 2005.                   |
| Burgio, 2002.                    | Reported in →               | O'Connor, 2009.                     |
| Camberg, 1999.                   | Reported in →               | O'Connor, 2009.                     |
| DeYoung, 2002.                   | Reported in →               | Landreville, 2006.                  |
| Dunn, 2002.                      | Reported in →               | O'Connor, 2009.                     |
| Finnema, 2005.                   | Reported in →               | Kverno, 2009.                       |
| Garland, 2007.                   | Reported in →               | O'Connor, 2009.                     |
| Gerdner, 2000.                   | Reported in →               | O'Connor, 2009.                     |
| Gerdner, 2008.                   | Reported in $\rightarrow$   | Kverno, 2009.                       |
| Heard, 1999.                     | Reported in →               | Livingston, 2005.                   |
| Holmes, 2002.                    | Reported in $\rightarrow$   | O'Connor, 2009.                     |
| Holmes, 2006.                    | Reported in $\rightarrow$   | Kverno, 2009.                       |
| Hopman-Rock, 1999.               | Reported in $\rightarrow$   | Livingston, 2005.                   |
| Ingersoll-Dayton, 1999.          | Reported in $\rightarrow$   | Landreville, 2006.                  |
| Jennings, 2002.                  | Reported in $\rightarrow$   | Livingston, 2005.                   |
| Kim, 1999.                       | Reported in $\rightarrow$   | Livingston, 2005.                   |
| Kolanowski, 2005.                | Reported in $\rightarrow$   | O'Connor, 2009.                     |
| Kovach, 2004.                    | Reported in $\rightarrow$   | Kverno, 2009.                       |
| Leon, 1999.                      | Reported in $\rightarrow$   | Landreville, 2006.                  |
| Lin, 2007.                       | Reported in $\rightarrow$   | Kverno, 2009.                       |
| Lyketsos, 1999.                  | Reported in →               | Forbes, 2009.                       |
| Magai, 2002.                     | Reported in →               | Kverno, 2009.                       |
| McCallion, 1999.                 | Reported in →               | Landreville, 2006.                  |
| McGilton, 2003.                  | Reported in →               | Algase, 2006.                       |
| Moniz-Cook, 2001.                | Reported in →               | Landreville, 2006.                  |
| Proctor, 1999.                   | Reported in →               | Bharani, 2005.                      |
| Remington, 2002.                 | Reported in →               | O'Connor, 2009.                     |
| Riemersma-van Der Lek, 2008.     | Reported in →               | Forbes, 2009.                       |
| Schrijnemaekers, 2002.           | Reported in →               | Bharani, 2005.                      |
| Shalek, 2004.                    | Reported in →               | Algase, 2006.                       |
| Sherratt, 2004.                  | Reported in →               | O'Connor, 2009.                     |
| Sloane, 2004.                    | Reported in →               | O'Connor, 2009.                     |
| Snow, 2004.                      | Reported in →               | Kverno, 2009.                       |
| Snyder, 2001.                    | Reported in →               | Landreville, 2006.                  |
| Spector, 2003.                   | Reported in →               | Livingston, 2005.                   |
| Testad, 2005.                    | Reported in →               | Livingston, 2005.<br>Bharani, 2005. |
| Van Weert, 2005.<br>Wells, 2000. | Reported in → Reported in → | O'Connor, 2009.                     |
|                                  | •                           |                                     |
| Woods, Craven, & Whitney 2005.   | Reported in →               | Bharani, 2005.                      |

## Interventions

Within the papers reviewed, 22 interventions were identified, listed alphabetically in **Table 11**, as measured by a range of different instruments and rating scales (**Table 13**). Note that dementia care mapping (DCM) is included both as an intervention and as an outcome.

Table 11: Alphabetical list of identified interventions

| Intervention*                | Description   |
|------------------------------|---|
| Advanced Illness Care Teams. | Care teams comprising members from different disciplines including medicine, nursing, social work, psychology, physical and occupational therapy, and nutrition. Included a holistic approach that addressed four domains of care: medical issues; meaningful activities; psychological problems; and behavioural concerns.   |
| Aromatherapy.                | Aromatherapy is one of the most commonly used complementary therapies. There is no standard dose. Aromatherapy oils can be vaporised into the air or soaked into pillows or administered by massage onto the skin. The exact mechanism of action of aromatherapy remains unknown.   |
| Behavioural management.      | Behavioural management interventions are typically based on a combination of individualised, interdisciplinary, and holistic treatments. For example, the ABC model of behaviour management, where the focus is on identifying the A (antecedent or activating event) that led to the B (behaviour) and examining the C (consequence) of the behaviour.   |
| Bright light therapy (BLT).  | The light sources are typically a light box placed approximately one metre away from the participants at a height within their visual fields; a light visor worn on their heads; ceiling mounted light fixtures; or 'naturalistic' light therapy, known as 'dawn-dusk' simulation, that mimics outdoor twilight transitions. Light intensity is typically in the range of 1000 - 10 000 Lx.   |
| Cognitive stimulation.       | Cognitive stimulation therapy uses information processing rather than factual knowledge to address problems in functioning in residents with dementia.  |
| Dementia Care Mapping (DCM). | This is an observational tool that has been used in formal dementia-care settings particularly in the United Kingdom (UK). As an intervention, DCM can be used as an instrument for improving the quality of care via feeding back observational data to care staff, for the purpose of developing improved care practices. DCM can also be used as a 'stand alone' tool in quality-of-life and quality of care research (ie as an outcome measurement instrument). DCM was developed from the pioneering work of the late Professor Tom Kitwood on person-centred care (Kitwood, 1997). In brief, an observer (mapper) tracks participants (persons with dementia) continuously over a representative time period (eg several hours during the waking day). Mapping takes place in communal areas of care facilities. After each 5-minute period, two types of codes are used to record what has happened to each individual. The behavioural category code (BCC) and codes based on behavioural indicators, about the relative state of illbeing or well-being experienced by the person with dementia, called a well-/ill-being value (WIB). Personal detractions (PDs) and positive events (PEs) are also recorded whenever they occur. DCM provides an index of relative well-being for a particular time period for an individual or a group. |
| Environmental modifications. | Changes to the usual environment including: mirrors, visual barriers, signposting, group living, home-like atmosphere, exit modification, changes in physical restraints, door locks and indoor confinement, modification of care and bathing procedures, natural or enhanced environment, reduction of noise level, elimination of environmental triggers, and rearrangement of daily activities and/or re-grouping residents with similar levels of function.   |
| Massage.                     | All hand massage (HM) and other therapeutic touch (TT) therapies and non-specific touch therapies, administered by trained and/or general staff.  |

Table 11: Alphabetical list of identified interventions (continued)

| Intervention*                            | Description   |
|--|---|
| Montessori activity.                     | Montessori-based activities are based on the Montessori principals of 'seriation' (simple to complex task hierarchy), object permanence, symbolic function, and auditory and visual discrimination. Montessori-based activities for long-term care residents with advanced dementia include individual activities and small group activities such as 'memory bingo' and 'group sorting'. Some small, low quality studies report positive effects on engagement, affect and cognition (compared to standard activities programming). The reader is directed to the following original studies for further information (Brenner & Brenner, 2004; Jarrott, Gozali, & Gigliotti, 2008; Judge, Camp, & Orsulic-Jeras, 2000; Lee, Camp, & Malone, 2007; Mahendra et al., 2006; Orsulic-Jeras, Judge, & Camp, 2000; N. M. Schneider & Camp, 2002). |
| Music therapy.                           | Music therapy included all interventions that utilise music (or rhythmic sound) in any form including: music played in common areas, music played in individual's private areas or via headphones, reproduction of natural sounds, preferred music compared to classical music, music during bath times, music during meal times, live music compared to recorded music and commercial music, and participants playing musical instruments and/or singing.  |
| Psychogeriatric case management.         | Treatments supervised by psychiatrists specialising in geriatrics and administered by a multi-disciplinary team. Treatments may include psychosocial interventions, individual supportive therapy, nurse education, family education and participation, behavioural management programmes and the management of medications as appropriate.   |
| Psychomotor therapy.                     | The use of exercise, movement, walking or other physical therapy as an intervention.  |
| Psychosocial interventions.              | A broad group of interventions including physical exercise, psychological approaches including validation, reminiscence and reality orientation, behaviour management, sensory stimulation and the use of music therapy. BLT for example, is generally excluded for the psychological group.  |
| Reality orientation.                     | Reality orientation including reminders. Reality orientation therapy is based on the idea that impairment in orientating information (day, date, weather, time, and use of names) prevents people with dementia from functioning well and that reminders can improve functioning.   |
| Sensory stimulation.                     | A broad group of interventions including music, massage, music and massage, aromatherapy, BLT and Snoezelen/MSS.  |
| 'Simulated presence'.                    | An emotion-oriented approach that usually involves a continuous-play audiotape made by a family member/carer. The audio is often in the form of a 'one sided' telephone call or a 'taped' narration or pleasurable past events.   |
| Snoezelen/multi-sensory therapy.         | Snoezelen therapy (MSS) combines relaxation and exploration of sensory stimuli, such as lights, sounds, and tactile sensations, usually provided within specially equipped multi-sensory rooms.   |
| Special Care Units (SCUs).               | SCUs are long term facilities designed specifically for residents with dementia and staffed by specially trained workers who receive ongoing training. SCUs are reported to offer special care for residents with dementia.   |
| Systematic individualised interventions. | Systematic individualised interventions are generally multi-component interventions that are tailored to individuals' behavioural profiles using a specific method and/or systematic algorithm that considers the type of behavioural 'problem' and possible unmet needs.   |
| Therapeutic activity programmes.         | Any programme of organised, structured and generally supervised activity including: small group discussion, being carried on a bicycle pedalled by volunteers, puzzle play, any structured daily activities in groups, being rocked on a swing, air mat therapy, games, music, exercise and socialising.  |

Table 11: Alphabetical list of identified interventions (continued)

| Intervention*                  | Description  |
|--------------------------------|--|
| Training (carer/staff/family). | All training programmes that aim to achieve positive and valuable changes in family and professional carers' attitudes, knowledge and skills, with the intent being to specifically address BPSD. Staff training programmes typically include in-service meetings at which information on 'problem' behaviours and demonstration of practical skills and strategies for managing such behaviours are provided. |
| Validation therapy (VT).       | VT based on the general principle of validation; the acceptance of the reality and personal truth of another's experiences and includes a variety of techniques. Validation therapy is intended to give an opportunity to resolve unfinished conflicts by encouraging and validating expression of feelings, it is essentially a special method for communicating with elderly people with dementia.           |

\*Not all of the investigators applied the interventions in the same way. For example, some interventions (eg music therapy and MSS) may exert both stimulating and calming effects, and may be used to ameliorate both disengaged and high-arousal needs depending on exactly how the interventions are designed and delivered. Further, the stimulating or calming effect of the same intervention given in the same 'dose' may vary by person, time of day, or by progression of the illness.

#### Outcomes

A number of validated symptom rating scales have been developed for use in clinical research studies involving residents with dementia. Most of these scales rely on a carer-informant interview, as opposed to clinician rating or self-report, but differ in item content, observation period (usually retrospective for one week to one month), and symptom dimensions assessed (ie, frequency or severity of behavioural disturbance or both). A structured or semi-structured interview was identified as the format most commonly used, however some scales may also be used or adapted for recording direct observations. Video recording for subsequent analysis was occasionally used, generally for small sample pilot studies. **Table 13** lists a range of assessment instruments alphabetically. The list is not exhaustive, but it outlines the most commonly used instruments in dementia care research.

The studies included a total of 62 defined outcomes ranging from aggression to wandering (**Table 12**). The most common outcome addressed in these studies included agitation (n = 21, 33.9%) followed by generalised BPSD (n = 11, 17.7%).

Table 12: Alphabetical list of outcomes covered in the reported studies

| Outcome                     | Count | Percentage |
|-----------------------------|-------|------------|
| Aggression.                 | 3     | 4.84       |
| Agitation.                  | 21    | 33.9       |
| Anxiety.                    | 3     | 4.84       |
| Apathy.                     | 2     | 3.23       |
| Depression.                 | 7     | 11.3       |
| General BPSD <sup>†</sup> . | 11    | 17.7       |
| Neuropsychiatric symptoms.  | 3     | 4.84       |
| Sleep, behaviour, mood.     | 6     | 9.68       |
| Social behaviour.           | 3     | 4.84       |
| Stress/affect.              | 1     | 1.61       |
| Wandering.                  | 2     | 3.23       |
| Total*                      | 62    | 100        |

<sup>\*</sup> The total number of reported outcomes exceeds total number of studies because of overlap. †BPSD = behavioural and psychological symptoms of dementia.

Table 13: Alphabetical list of identified outcome measurement instruments

| Instrument   | Description   |
|--|---|
| Agitation behaviour<br>mapping instrument<br>(ABMI) (Cohen-<br>Mansfield, Werner, &<br>Marx, 1989).                            | The ABMI is a direct observation scale that includes 14 items that describe physically agitated behaviours (eg, pacing, repetitive movements) and verbally agitated behaviours (eg, screaming, complaining). Inter-rater reliabilities regarding agitated behaviours for this instrument previously averaged 93%.   |
| Apparent affect rating Scale (AARS) Lawton et al. (1999).  | This scale consists of five items, requires five minutes of observation, and provides reliable and valid readings of depression, anxiety, anger, pleasure, and interest for both the cognitively intact and impaired. Psychometric properties have been well demonstrated in the sample population and documented in earlier studies.   |
| Behavioural pathology in<br>Alzheimer's disease<br>rating scale (BEHAVE-<br>AD) (Reisberg, Ferris, de<br>Leon, & Crook, 1982). | This scale consists of 25 items that include various types of delusions and hallucinations commonly found in dementia. For each item on the BEHAVE-AD the respondent indicates how often the behaviour had been observed over the last 3 weeks. The scale's values are as follows: 1 (not present), 2 (observed once a week), 3 (two or more times a week), 4 (once a day), 5 (two or more times a day), 6 (every hour), and 7 (several times an hour). The validity of the scale has been demonstrated for people with dementia at both early and later stages of the disease; it is particularly useful for rating disturbance in the late stages and in longitudinal studies of behavioural and psychological symptoms.  |
| Behaviour symptom inventory (BSI) (Derogatis & Spencer, 1982).   | This instrument consists of 53 items concerning depression, anxiety, and somatic symptoms. The scale has good internal consistency, test-retest reliability, construct validity, predictive validity and has been found by to correlate well with the Mini Mental State Examination (MMSE).   |
| Cohen-Mansfield<br>agitation inventory<br>(CMAI) (Cohen-<br>Mansfield, Marx, &<br>Rosenthal, 1989).                            | This inventory provides a quantitative method of studying agitated behaviour in elderly people. The CMAI is an interview-based instrument designed to measure the frequency of 29 behaviours as observed by the carer over the previous two weeks. The scale consists of 29 types of agitated behaviour that are rated on a 7-point scale of frequency ranging from resident never manifests the behaviour (1) to resident manifests behaviour several times an hour (7). The CMAI has high inter-rater reliabilities and is suitable for rating agitation in demented people, especially in institutional settings. Through factor analysis of the 29 agitated behaviours, four categories have been identified (in addition to the global score), and it is possible to consider four subscale scores for physically aggressive and non-aggressive behaviour, verbally aggressive and non-aggressive behaviour. |
| Cohen-Mansfield agitation inventory short form (CMAI-SF).  | The CMAI-SF is a short version of the CMAI. It contains 14 items to be rated by carers on a 5-point frequency scale. The items are based on the factor structure of the original inventory.   |
| Cornell Scale for<br>Depression in Dementia<br>(CSDD) (Alexopoulos,<br>Abrams, Young, &<br>Shamoian, 1988).                    | This 19-item instrument is designed to detect depression among persons with dementia, based on interview with the person with dementia and collaterals. Symptom items are rated as follows: 0 = absent; 1 = mild or intermittent; 2 = severe. Scores range from 0 to 38 (most depressed). The scale has good inter-rater reliability (r = 0.67), internal consistency, and validity and it performs well in rating depressive symptomatology in dementia residents regardless of level of severity of cognitive impairment.   |
| Crichton Royal<br>behavioural rating scale<br>(CRBRS) (Evans.,<br>Hughes, & Wilkin, 1981).                                     | The CRBRS is a visual analogue scale that allows relatives and professionals to rate the behaviour of elderly people with dementia. The score for each item ranges from 0–4, except for 0–3 for memory and feeding, with a possible total of 38; the more disabled residents received the higher scores. Scoring the CRBRS is a relatively simple exercise (pencil, paper and exchange of information—no computer) and the scale has proved useful as an indication of the needs of people in long term care. In addition to recording change in function it can be used as an aid to build up an individual's profile. The scale has been shown to have good inter-rater reliability, test-retest reliability and validity. It is suggested that the scale can provide a quick and convenient initial assessment of the person either at home or in hospital, and can also measure change.                       |

Table 13: Alphabetical list of identified outcome measurement instruments *(continued)* 

| Instrument   | Description  |
|--|--|
| Dementia care mapping (Kitwood, 1997).   | DCM is an observational tool used in quality-of-life and quality of care research (DCM can also be used as an intervention). In brief, an observer (mapper) tracks participants (persons with dementia) continuously over a representative time period (ie, several hours during the waking day, in communal areas of care facilities) and behaviours, interactions and positive events are coded. DCM provides an index of relative well-being for a particular time period for an individual or a group.   |
| Faces, legs, activity, cry, consolability behavioural pain scale. (FLACC) (Voepel-Lewis et al. (2010). | The FLACC is an observational pain scale with 5 items rated on a 5-point Likert-type scale. The FLACC was originally validated with children, but it has also been used in nursing home and reliability and hospice settings.  |
| Facial expressions of<br>emotion during a semi-<br>structured interview<br>(MAX) (Izard, 1979).        | Facial expressions are coded by coders trained in the instrument. The person's facial expressive behaviour is observed during a semi-structured interview, the Adult Developmental Interview, which is designed to elicit affective responses from people with dementia. Generally, one researcher (the examiner) conducts the interview and other researchers observe the facial behaviour. Two scores are derived from the facial data, a positive affect score (frequency of joy expressions) and a negative affect score (frequency of contempt, disgust, fear, sadness, anger, and shame).  |
| Geriatric Depression<br>Scale (GDS) (Yesavage,<br>et al., 1982).                                       | The GDS is a 30-item self-report assessment used to identify depression in the elderly. The GDS questions are answered 'yes' or 'no', instead of a five-category response set. This simplicity enables the scale to be used with ill or moderately cognitively impaired individuals. The scale is commonly used as a routine part of a comprehensive geriatric assessment. One point is assigned to each answer and the cumulative score is rated on a scoring grid. The grid sets a range of 0–9 as 'normal', 10–19 as 'mildly depressed', and 20–30 as 'severely depressed'. The test has well-established reliability and validity evaluated against other diagnostic criteria. |
| Minimum Data Set (MDS).  | Introduced in 1997 by the Centers for Medicare and Medicaid Services (CMS), MDS is part of the United States of America (USA) federally mandated process for clinical assessment of all residents in Medicare or Medicaid certified nursing homes. The MDS includes a comprehensive assessment of each resident's functional capabilities and helps nursing home staff identify health problems. Accompanying guidelines follow the format of the assessment instrument questionnaires and give more guidance on how particular questions are to be interpreted.   |
| MOUSEPAD (Allen,<br>Gordon, Hope, & Burns,<br>1996).   | The Manchester and Oxford Universities' scale for the psychopathological assessment of dementia (MOUSEPAD) is administered to carers by an experienced clinician, and takes 15–30 minutes, most items being given a three-point severity score.  |
| Pain in advanced<br>dementia (PAINAD)<br>(Warden, Hurley, &<br>Volicer, 2003).                         | The PAINAD is an observational pain scale with five categories (breathing, negative vocalization, facial expression, body language, and consolability) that are rated on a three-point Likert-type scale. The PAINAD was developed on an inpatient SCU for dementia and has shown adequate interrater reliability.   |
| Pittsburgh agitation scale (PAS) (Rosen, Burgio, Killar, Cain, & Allison, 1994).                       | A 16-point observer-rated scale comprising four domains (aberrant vocalisation, motor agitation, aggression and resistance to care) each rated 0–4 points. A high score denotes high levels of agitation. The PAS demonstrated inter-rater & internal consistency reliability estimates > 0.08.  |
| Quality of life in<br>Alzheimer's disease<br>(QOL-AD)(Logsdon,<br>Gibbons, McCurry, &<br>Teri, 1999).  | The QOL-AD is a 13-item scale for measuring quality of life (QOL) in people with Alzheimer's disease (AD), through ratings from both the care recipients and carers. The care recipient's ratings are given twice the weight of the carer's and a weighted mean score calculated. Higher scores indicate better QOL. Possible totals range from 13 to 52. The QOL-AD includes assessment of physical health, mental health, social and financial domains.  |

Table 13: Alphabetical list of identified outcome measurement instruments *(continued)* 

| Instrument  | Description  |
|---|--|
| The BAGS Aggression<br>Scale (Queen Elizabeth<br>Geriatric Centre, 1992).               | The BAGS is an hourly recorded measure of aggression and the carer's observations are recorded on a scale of 0–4, with 0 being no aggression and 4 being unprovoked physical aggression. The BAGS score takes into account whether aggression occurred when staff approached the resident, when they handled the resident, or for no understandable reason (unprovoked by anything carers could observe in the care-giving environment). Inter-rater reliability has been demonstrated at 92 percent.  |
| The Barthel index (BI) (Mahoney & Barthel, 1965).                                       | The Barthel activity of daily living index is commonly used as a rating scale of physical dependency. The Barthel index produces a score between 0 (dependent) and 20 (independent but not necessarily normal).  |
| The Hamilton rating scale for depression (HRSD) (Hamilton, 1960).                       | The HRSD is a 21-question multiple choice questionnaire that clinicians may use to rate the severity of a patient's major depression. The questionnaire rates the severity of symptoms observed in depression such as low mood, insomnia, agitation, anxiety and weight loss. The clinician must choose the possible responses to each question by interviewing the patient and by observing the patient's symptoms.   |
| The London<br>psychogeriatric rating<br>scale (LPRS) (Hersch,<br>Kral, & Palmer, 1978). | A 36 item scale including four subscales: mental disorientation/confusion, socially inappropriate behaviour, physical disability, and disengagement.   |
| The mini-mental state exam (MMSE) (Folstein, Folstein, & McHugh, 1975).                 | The most commonly used mental status exam for assessing memory, concentration, and other cognitive skills, in the evaluation of AD is the MMSE. This is a research-based set of questions that provides a score about a person's general level of impairment. The MMSE is generally a reliable, valid measure of cognitive impairment and it takes only 5 to 10 minutes to complete. The MMSE assesses the person in the domains of orientation, short term memory (retention), 'attention', short term memory (recall) and language. The maximum score on the MMSE is 30. In general, scores fall into four categories: 24 – 30 'normal' range: 20 – 23 mild cognitive impairment or possible early-stage/mild Alzheimer's disease: 10 – 19 middle-stage or moderate Alzheimer's disease: 0 – 9 late-stage/severe Alzheimer's disease. The MMSE is often used in clinical research studies involving people with dementia as a means of stratifying participants by disease severity. |
| The neuropsychiatric inventory (NPI) (Cummings, et al., 1994).                          | The NPI is a validated informant-based interview that is widely used in clinical research studies to evaluate neuropsychiatric symptoms and their response to treatment in people with dementia. The NPI has been shown to have adequate test-retest and inter-rater reliability, as well as good concurrent validity with relevant items from the BEHAVE-AD and the HRSD. The NPI items can be divided into four subgroups: psychotic, hyperactivity, apathy and affective.   |
| The neuropsychiatric inventory–nursing home version (NPI-NH).                           | The NPI-NH is a commonly used instrument that consists of a structured interview format used to measure the presence, frequency, and severity of both behavioural and psychiatric symptoms commonly exhibited in people with dementia. The NPI-NH was modified from the NPI, to allow professional carers such as nursing home staff to act as informants rather than an informal carer such as a family member.   |

# Systematic reviews: overview

Using the search protocol, a total of 48 systematic reviews of non-pharmacological interventions were initially identified. These reviews varied in scope, outcomes, quality, year range (of the publications selected, on which the reviews were based), and level of detail provided in the description of studies. These 48 reviews included different interventions, different settings (eg family home, long term care, acute care) and different outcomes. General review studies or overviews were not included nor were reviews relating *only* to cognitive ageing or cognitive decline in healthy older people in the general population.

An examination of the search results highlighted considerable overlap between the review articles and the identified primary research articles. A number of primary studies were common to two or more of the identified systematic reviews. In this review, careful cross-examination of the 48 identified review articles resulted in a final selection of ten reviews on the basis of them being non-duplicates and including all key studies that would otherwise be included as primary studies themselves. These ten review articles included a total of 120 unique primary research studies, although not all of these primary research studies fully satisfied the inclusion criteria for the current review (the differences being mainly in publication date range and the exclusion of non-residential settings).

The brief characteristics and main findings of the ten included review articles are listed (alphabetically) in **Table 14** with the full data being presented in separate data extraction tables (**Appendix E, Table 22-31**). Additionally, the excluded review articles are listed at the end of this section in **Table 17** and the full citations can be found in the annotated excluded study list (**Appendix D**).

Table 14: Ten Included systematic reviews: brief characteristics and main findings

| Author/data<br>‡(Level of<br>evidence)        | Studies<br>[total<br>number]   | Methods            | Intervention                                     | Outcome                                | Notes   | Main findings  |
|---|--|--------------------|--|--|---|--|
| Algase<br>(2006).<br>Level III.               | RCTs,<br>pre-<br>test/post-<br>test,<br>repeated-<br>measures<br>[n = 47]. | Generic.           | All applicable.                                  | Wandering.                             | Scope: definition & measurement, epidemiology, associated factors, and intervention & management (16 studies).      | In the main, few intervention studies to manage wandering were sufficiently rigorous, although the evidence for effectiveness of subjective barriers is mounting. Person-focussed therapies included a way-finding intervention, a behavioural communication technique, air mat therapy, exercise and therapeutic touch. Among these, the behavioural communication and the air mat had positive results, therapeutic touch was ineffective and the remaining approaches had limited value.  |
| Bartlett et al.<br>(2007).<br>Level I         | †Review articles and one RCT [n = 12 = 11+1].                              | Generic,<br>NHMRC. | Non-<br>pharmacological.                         | BPSD +.                                | Very comprehensive "review of reviews" of all aspects of dementia.  | Based on the findings from 11 systematic reviews and 1 RCT – the best evidence is for physical exercise, reminiscence therapy and behaviour management while there is no evidence that reality orientation, BLT or Snoezelen are effective treatments for dementia.  |
| Bharani &<br>Snowden<br>(2005).<br>Level III. | RCTs & others [n = 89].  | Generic.           | Non-<br>pharmacological<br>&<br>pharmacological. | Behavioural<br>symptoms:<br>agitation. | Of 89 studies,<br>14 were RCTs<br>for non-<br>pharmacologic<br>al, also<br>included 19<br>pharmacologic<br>al RCTs. | Studies of training interventions used various approaches, and these were often not sufficiently described. Generally, studies with positive outcomes included elements of additional supervision and support for staff and the training interventions that lacked these supervisory/support components were generally ineffective, suggesting that training alone may be insufficient to bring about positive changes in residents' outcomes such as aggression. There is some evidence from 3 randomised trials for the efficacy of activity programmes (but not 'simulated presence'). Activity interventions supported by the evidence include group activities, physical activity, and activity planning based on an evaluation of individual needs/behaviour patterns. Observational trials provided some evidence of efficacy for animal therapy. In the sensory category, music therapy appears to be effective; HM and nonspecific touch therapies have demonstrated benefits. However, aromatherapy and BLT did not appear to be useful. |

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Table 14: Ten Included systematic reviews: brief characteristics and main findings (continued)

| Author/data<br>‡(Level of<br>evidence) | Studies<br>[total<br>number]  | Methods                                    | Intervention             | Outcome                           | Notes   | Main findings   |
|--|---|--|--------------------------|-----------------------------------|---|---|
| Forbes<br>(2009).<br>Level I.          | RCTs [n<br>= 5].  | Cochrane.                                  | BLT.                     | Sleep,<br>behaviour,<br>and mood. | All studies of low methodological quality.  | The review revealed no adequate evidence of the effectiveness of BLT in managing sleep, behaviour, cognitive, or mood disturbances associated with dementia.  |
| Kverno<br>(2008).<br>Level I           | RCTs, pre-test— post-test, repeated- measures (ABCBA) [n = 21].         | JHNEBP.                                    | Non-<br>pharmacological. | Neuropsychi<br>atric<br>symptoms. | Only studies of individuals with advanced, 'moderately-severe' to 'very-severe' dementia. | The 21 studies provide limited moderate to high quality evidence for the use of sensory-focussed strategies, including aroma, preferred or live music, and multi-sensory stimulation (MSS). Emotion-oriented approaches, such as 'simulated presence' may be more effective for individuals with preserved verbal interactive capacity.   |
| Landreville et al. (2006).<br>Level II | RCTs & quasi-<br>experime<br>ntal. [n = 41].                            | Generic.                                   | Non-<br>pharmacological. | Aggression.                       | Comprehensiv<br>e single-<br>outcome<br>review.   | Based on the these 26 dementia studies reporting measures of aggressive behaviour, staff training programmes and environmental modifications appear to be the most effective strategies. Sensory stimulation, which has been examined in several studies, has led to mixed findings. Finally, there is some evidence for the effectiveness of behavioural management, SCUs, structured activities, and psychosocial interventions for aggressive behaviour. However, this observation is based on very few studies and more research on these interventions is needed.  |
| Livingston et al. (2005).<br>Level IV. | RCTs,<br>quasi-<br>experime<br>ntal &<br>single-<br>case. [n =<br>162]. | Oxford centre for evidence based medicine. | Psychological.           | Neuropsychi<br>atric<br>symptoms. | Comprehensiv<br>e review, wide<br>publication<br>range: 1970s -<br>2003.                  | Behavioural management techniques centred on individual residents' behaviour are generally successful for reduction of neuropsychiatric symptoms, and the effects of these interventions can last for months. Further, psycho-education intended to change carers' behaviour is effective, especially if it is provided in individual rather than group settings, and improvements in neuropsychiatric symptoms associated with these interventions are sustained for months. Also, specific types of staff education lead to reductions in behavioural symptoms and use of restraints and to improved affective states. Staff education in communication skills and enhancement of staff members' knowledge about dementia may improve many outcomes related to neuropsychiatric symptoms. Finally, music therapy and Snoezelen, and possibly some types of sensory stimulation, are useful treatments for neuropsychiatric symptoms during the session but have no longer-term effects. The cost or complexity of Snoezelen for such small benefit may be a barrier to its use. |

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Table 14: Ten Included systematic reviews: brief characteristics and main findings (continued)

|  |   | •        |                       |   |  | •  |
|--|---|----------|-----------------------|---|--|--|
| Author/data<br>‡(Level of<br>evidence) | Studies<br>[total<br>number]                            | Methods  | Intervention          | Outcome   | Notes  | Main findings  |
| Nguygen &<br>Paton (2008).<br>Level I. | RCTs [n<br>= 23].                                       | Generic. | Aromatherapy.         | BPSD.   | Included 11<br>randomised<br>studies of<br>aromatherapy. | Available studies reported positive and negative consequences for both people with dementia and their carers. Aromatherapy is a potentially useful treatment for BPSD but data supporting efficacy are scarce. Only 3 individual RCTs were powered to detect even a large treatment effect; 8 of the 11 published studies each had less than 25 participants.  |
| O'Connor et<br>al. (2009).<br>Level I  | RCTs,<br>'before<br>and after'<br>[n = 25].             | NHMRC.   | Psychosocial.         | BPSD.   | Only included studies with 'attention control' group.    | Treatment proved more effective than an 'attention control' condition in reducing behavioural symptoms in only 11 of the 25 studies. Effect sizes were mostly small or moderate. Treatments with moderate or large effect sizes included aromatherapy, ability-focussed carer education, bed baths, preferred music and muscle relaxation training.  |
| Perkins et al. (2008).<br>Level III    | Non-<br>RCTs,<br>pre-<br>test/post-<br>test [n =<br>9]. | Generic. | Dog-assisted therapy. | Social behaviour, agitation, apathy, medication, ward noise, cognition, global function, physiological measures | All studies of low methodological quality.               | Nine studies were identified for inclusion and the results suggest that dog therapy is beneficial for people with dementia. However, no study adopted a RCT design and a number of potentially important factors were not controlled for, including selection biases, and halo effects of animals on carers that may bias carers' responses when acting as proxies for their relatives or residents. |
|  |   |          |                       |   |  |  |

† Treatment articles only, included hundreds of articles across all aspects covered.

‡Each systematic review has been assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. The reviews have been ordered by publication date rather than level of evidence.

Abbreviations: BPSD = Behavioural and psychological symptoms of dementia, JHNEBP = Johns Hopkins Nursing Evidence-Based Practice model; NHMRC = National Health and Medical Research Council; RCT = randomised controlled trial.

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# Systematic reviews: summary and results

# Algase (2006)

Algase (2006) systematically reviewed effectiveness of interventions to reduce wandering in dementia. The scope of the review was broad including: (a) definition and measurement, (b) epidemiology, (c) factors associated with wandering and (d) intervention and management (relevant to this review). All empirical studies containing discrete findings about wandering behaviour, published as journal articles during the three-year period encompassing 2003 through 2005, were evaluated. Some studies contributed information to more than one category but only treatment is considered here. In total, 47 articles were included in the review and 16 of the 47 related to management. Studies reported quantitative outcome measures that were either direct or proxy measures of wandering (eg using part of a larger measure of dementia-related behaviours, records or other documents, or by observation). The Algase Wandering Scale was used in ten studies. In the treatment category, Algase (2006) included two previous review articles and 14 primary research studies of various designs. Of these 14 treatment studies, seven were of non-pharmacological interventions, three trialled pharmacological treatments (not included here) and four evaluated system level interventions (reporting mainly process level outcomes).

Lai et al. (2003) appraised the literature and categorised the interventions as biomedical, psychosocial, and person-environment interaction models. Lai et al. (2003) concluded that the intervention studies were generally weak and that no widely effective intervention was available.

In a later and more detailed publication, Siders et al. (2004) systematically searched and reviewed the literature and identified 31 articles that met specified inclusion criteria and these were grouped into six categories of intervention studies:

- subjective barriers
- alarms
- special environments
- behavioural techniques
- music
- walking/exercise/activity.

Ten studies investigated the effectiveness of subjective barriers including interventions such as tape grids placed on the floor, cloth panels over doors, murals painted over exits, the use of mirrors. Siders et al. (2004) concluded that while the quality of the studies varied greatly, there are data to support the use of objects that obscure exits, and some compelling evidence for the use of tape grids.

Six studies investigated walking, exercise, and structured daily routines for the reduction of wandering in dementia. Four of five experimental studies reported decrease in wandering. However, the effects of structured groups on wandering remain difficult to determine due to the low number of studies.

Three studies reported on the effects of special environments, including studies of facilities with open areas used to redirect wanderers to hazard-free places to provide freedom of movement, a nature scene, and 'enhanced' areas. Siders et al. (2004)

reported that there appeared to be some support for the use of enhanced environments to redirect wandering.

Four studies evaluated the effectiveness of behavioural techniques. Behavioural techniques to reduce wandering including functional analysis, differential reinforcement and stimulus control. Although the results of these studies are encouraging, the use of behavioural techniques to reduce wandering is still underdeveloped.

Music therapy was evaluated in six trials, and alarms and tracking systems were evaluated in a further two trials. Further exploration of the use of music therapy for wandering is warranted as studies consistently report music decreasing wandering at the time it is played but that it generally does not reduce wandering at other times.

Finally, Siders et al. (2004) reported that while the two studies that tested alarms reported reductions in wandering, more research is required.

In conclusion, Siders et al. (2004) suggest that the evidence in support of subjective barriers is compelling. The authors also point out that the questions of whether, for whom, and when wandering is harmful or beneficial have not been resolved, and that efforts to reduce wandering should only be attempted when appropriate for the patient. Siders et al. (2004) suggest that a multifaceted approach to environmental modifications may be more helpful than a singular approach.

Examples of relevant primary research studies include:

Kincaid et al. (2003) used a pre-post design and examined the effect that a wall mural painted over an exit door had on decreasing door-testing behaviours of 12 residents with dementia over a 12-week period. The mural significantly reduced overall door-testing behaviours. Reductions were also significant for two types of door-testing (calm and team efforts), but were not significant for following others through door and/or agitated/hostile door testing.

McGilton et al. (2003) conducted a RCT to examine the effects of a way-finding intervention on 32 residents' ability to find their way in a new environment (the intervention consisted of the use of a location map and a behavioural training technique). The effect of the intervention on the residents' spatial orientation and agitation were also examined. Compared to controls, residents in the treatment group demonstrated an increased ability to find their way to the dining room one week after the intervention. The intervention effect was not sustained three months later.

Miskelly (2004) investigated the feasibility of using electronic equipment derived from prisoner tagging systems, in three different scenarios. Miskelly (2004) tested the equipment for four weeks in two wards at a large teaching hospital, for six months in a medium-sized residential home, and for eight weeks in clients' own homes in the community. The novel system of electronic tagging in patients with dementia was successfully used to identify wandering events into prohibited spaces in all three settings.

Algase (2006) concluded that few intervention studies to manage wandering were sufficiently rigorous, although the evidence for effectiveness of subjective barriers is mounting. Person-focussed therapies included a way-finding intervention, a behavioural communication technique, air mat therapy, exercise and therapeutic touch

(TT). Among these, the behavioural communication and the use of an air mat had positive results, therapeutic touch was ineffective, and the remaining approaches had limited value. Studies of system-level changes to care services were quite diverse. Overall, fewer than half of the studies were framed by an explicit theory or theoretical framework, and although a variety of interventions have been evaluated, studies still lack rigour.

## Bartlett et al. (2007)

Bartlett et al (2007) systematically reviewed the literature on pharmacological and non-pharmacological approaches to treating the non-cognitive/neuropsychiatric symptoms of dementia as well as cognitive and other outcomes. The authors conducted a comprehensive literature search of the treatment of the most frequently occurring dementia subtypes – across eight electronic databases and six additional websites. A stepwise, hierarchical approach to the literature search was adopted with the published and 'grey' literature being searched up to August 2006 (no date limit specified). This was essentially a comprehensive 'review of reviews'. Of 1133 titles identified, 60 systematic reviews/meta-analyses (including 52 Cochrane reviews) were included and in addition, two other review articles, ten primary research articles, two Government commissioned reports, one clinical guideline and five other documents were included.

In Bird et al. (2002), an individually tailored approach to behavioural intervention was trialled. In a RCT (predominantly) psychosocial interventions were evaluated in comparison to a (predominantly) pharmacological approach. Forty-four patients with challenging behaviours secondary to dementia were randomly allocated to either a psychosocial group or a control group that involved usual clinical practice. Results for the psychosocial group showed a 43% decrease in the behaviour for which the patient had been referred and significant improvements in staff or carer distress and attitudes. In addition, the psychosocial intervention was less time-consuming in the longer term.

Cameron et al. (2003) conducted a Cochrane review of the efficacy of transcutaneous electrical nerve stimulation (TENS) for dementia. Eight RCTs were included in the review although data from only three trials could be included in the meta-analysis. The results suggested that TENS may result in some short term benefit in cognition and behaviour but that the data were too limited to draw any firm conclusions and more research is warranted.

Chung et al. (2002) conducted a Cochrane review of the efficacy of Snoezelen or multi-sensory stimulation (MSS)) for patients with dementia. Two trials that had examined the short term effects of Snoezelen therapy (four and eight treatment sessions respectively) on mood, behaviour and cognition in patients with dementia were included in the review and a quantitative synthesis of the data was performed. No significant difference was found between Snoezelen therapy and controls on any measure of behaviour, mood or cognition. It was concluded that there was currently insufficient evidence that Snoezelen therapy is effective for the treatment of dementia, although the evidence base was deemed to be very limited.

In another Cochrane review, Clare et al. (2003) investigated the efficacy of cognitive rehabilitation and cognitive training interventions aimed at improving memory functioning in people in the early stages of Alzheimer's disease or vascular dementia. There were no relevant outcomes included.

Forbes et al. (2004) (citation superseded) conducted a Cochrane review of the efficacy of BLT for improving sleep, behaviour and mood disturbance in patients with dementia. This review was updated and superseded in 2009 (reviewed in full above).

Heyn et al. (2004) conducted a meta-analysis of studies evaluating the effects of physical activity among people with cognitive impairment and dementia. Thirty RCTs that had enrolled a total of 2020 subjects were identified for inclusion in the review and meta-analysis. Most of the studies were small in size and the majority were based on walking as the intervention. Most of the studies were judged to be of medium quality. The authors reported a significant positive effect of medium size for physical exercise: on measures of physical fitness and on measures of functional behaviour (ES = 0.54; 95% CI: 0.36–0.72) and cognition.

The review by Livingston et al. (2005) has been appraised in this section below.

Neal and Barton Wright, (2003) conducted a Cochrane review of the efficacy of VT for people with dementia. Validation therapy is based on the general principle of validation, the acceptance of the reality and personal truth of another's experiences and includes a variety of techniques. Three RCTs were identified that met the inclusion criteria, although it was not possible to pool the data due to methodological differences among the studies. The results indicated no statistically significant effect for measures of cognition or ADL although one study reported a statistically significant improvement on one measure of depression in the VT group following twelve months of treatment. It was suggested that the evidence is insufficient to warrant a conclusion regarding the efficacy of VT for patients with dementia or cognitive impairment.

In an early and arguably superseded systematic review, Opie et al. (1999) assessed psychosocial approaches as interventions for managing challenging behaviours in patients with dementia. Included in the review were five studies that had evaluated the efficacy of music as an intervention. Although the studies had a number of methodological limitations, most reported positive effects of music and a reduction in agitation. Thus, it appears that music may have a useful role in alleviating agitation in patients with dementia, at least in the short-term.

In a Cochrane review, Thorgrimsen et al. (2003) reported on the efficacy of aromatherapy for dementia. Aromatherapy uses pure essential oils from fragrant plants such as peppermint, sweet marjoram and rose, to help relieve health problems and improve quality of life. Although two RCTs were identified, the results were not in a format that was suitable for meta-analysis. One of the trials reported a statistically significant treatment effect for aromatherapy on measures of agitation and neuropsychiatric symptoms. However, the authors cautioned that one small trial is insufficient evidence of efficacy.

In another Cochrane review, Vink et al. (2003) investigated the efficacy of music therapy for people with dementia. Five studies were included in the review, however the methodological quality of studies was deemed to be poor and the study results could not be validated or pooled for further analyses. Vink et al. (2003) concluded that there was no substantial evidence to either support or discourage the use of music therapy in the care of people with dementia.

Woods, Spector, et al. (2005) conducted a Cochrane review of the efficacy of reminiscence therapy for people with dementia. Reminiscence therapy involves the

discussion of past activities, events and experiences with another person or group of people, usually with the aid of tangible prompts such as photographs or other familiar items. Five RCTs were included in the review although only four trials with a total of 144 participants had extractable data. Woods, Spector, et al. (2005) reported that there was some evidence that reminiscence therapy may be effective for patients with dementia, although the studies were small and of relatively low quality.

Bartlett, et al. (2007) concluded that a wide range of psychosocial interventions to improve the cognitive and non-cognitive symptoms of dementia have been evaluated. However, these have been less extensively investigated than the pharmacological approaches, and to date, few RCTs have been conducted. The best evidence is for physical exercise, reminiscence therapy and behaviour management, while there is no evidence that reality orientation, BLT or Snoezelen are effective treatments for dementia.

# Bharani and Snowden (2005)

Bharani and Snowden (2005) conducted a comprehensive review of evidence-based pharmacological and non-pharmacological interventions for nursing home residents with dementia-related behavioural symptoms, in particular, agitation. This review focussed on the effectiveness of non-pharmacological interventions and therefore, the results of pharmacological interventions are not reported. With respect to the studies of non-pharmacological interventions, Bharani and Snowden (2005) included both randomised and observational studies and grouped these as:

- sensory therapy
- training
- activities-based interventions.

The interventions most commonly studied in RCTs include activity and sensory therapies and staff training interventions.

They reviewed a total of 55 non-pharmacological intervention studies, of which 14 were RCTs, and the rest were non-randomised trials. While the reviewers included both randomised and non-randomised trials, only the randomised trials were reported in any detail. All included studies appeared to have been appraised for design strength and quality of evidence, however the method and/or checklist or criteria use were not specified. Limited notes were provided to outline potential biases and quality issues where such issues were identified. A qualitative analysis/synthesis was conducted of the literature, as methodological differences between studies meant that a metaanalysis was not possible. All of the 55 studies of non-pharmacological interventions are listed in Table 24, Appendix E and include six randomised trials of training interventions and six observational studies of training interventions, five randomised trials and fourteen observational studies of activity interventions, three randomised trials of sensory therapy interventions, and twenty-one observational studies of sensory therapy interventions of which almost half involved music therapies. Six reports of RCTs of non-pharmacological interventions (Alessi et al., 1999; Cott et al., 2002; Proctor et al., 1999; Schrijnemaekers et al., 2002; Van Weert et al., 2005; Woods et al., 2005) are described below, as these studies are unique to Bharani and Snowden's (2005) review (ie not included in one of the other nine reviews included in this report).

Alessi et al. (1999) evaluated a daytime physical activity programme plus a night-time programme (aimed to decrease noise and sleep-disruptive nursing care practices) compared with the night-time programme alone (control group). Twenty-nine residents (90% female) from one nursing home participated in the randomised trial of 14 weeks duration. Outcome measurements included daytime physical activity monitoring and structured physical function assessments, night-time wrist activity monitors to estimate night-time sleep, and timed daytime behavioural observations of sleep patterns, and agitation via the Cohen-Mansfield Agitation Inventory (CMAI). The results showed a statistically significant 22% decrease in agitation with exercise versus a 150% increase in agitation in the control group. However, the sample size was small, and the trial used non-blinded outcome assessment.

Cott et al. (2002) conducted a three group randomised trial to evaluate a 'walk and talk' intervention (30 minutes, five times per week for 16 weeks, walking/talking in pairs) versus a talk-only group (30 minutes, five times per week for 16 weeks, talk only in pairs) versus no intervention (control). Eighty-six residents from three rest homes participated and functional and behavioural outcome measures included the functional assessment of communication skills for adults (FACSA), the two minute walk test, and the London psychogeriatric rating scale (LPRS). Some residents with low MMSE scores were included in the trial but were subsequently found to be unable to fully participate in the programme. Residents who received the 'walk and talk' intervention did not demonstrate statistically significant differences in the outcome variables measured post-test (including socially inappropriate behaviour, physical disability, and disengagement, via the LPRS) when compared with residents who received the talk-only intervention or no intervention, even after controlling for individual differences.

Proctor et al. (1999) evaluated a behaviourally-focussed staff training intervention in which care staff in the intervention homes attended seminars from the hospital outreach team and received weekly visits from a psychiatric nurse to assist in developing care planning skills over a six-month programme. Staff in control sites received no such training. The cluster randomised trial included 120 participants from 12 matched nursing and residential homes. The main outcome measures were cognitive impairment and depression, behavioural disturbance, and functional ability: assessed by the Geriatric mental state schedule (GMSS), the Crichton Royal behaviour rating scale (CRBRS), and the Barthel index (BI), respectively. Residents in the intervention group had significantly improved scores for depression. The before and after change difference was -0.5 (95% CI: -0.8 to -0.1) and for cognitive impairment it was -0.7 (95% CI: -1.1 to -0.2) but not for behaviour rating or BI.

Schrijnemaekers et al. (2002) evaluated a staff training programme that focussed on emotion-oriented care (based on the validation approach with insights from other approaches including reminiscence and sensory stimulation). Residents (n = 151) with dementia and behavioural problems were included in the study and randomly assigned by home (eight intervention homes and eight 'usual care' control homes). Outcome measurements were performed by carers and relatives at baseline and after three, six and 12 months of follow-up. The primary outcome measure was the change in behaviour of the residents. The results of multilevel analyses (overall, subgroup and per protocol) showed no statistically significant, nor clinically relevant effects in favour of the intervention group on the behavioural outcome measures.

Van Weert et al. (2005) conducted a non-randomised pre- and post-test design study across six nursing homes with a total of 125 resident participants (61 completed the study) who had moderate to severe dementia and high care dependency. The intervention was an individualised integrated 24-hour Snoezelen programme, based on family history assessment and stimulus preference screening. Carers were trained, and organisational adaptations were made to fulfil the conditions for resident-oriented Snoezelen care. Outcome measurements were made via direct observations using subscales of the Dutch behaviour observation scale for psychogeriatric inpatients, the Dutch version of the CMAI, and the Cornell scale for depression in dementia (CSDD). Residents receiving Snoezelen care demonstrated a significant reduction in agitation on the CMAI aggressive behaviour scale (34% reduction in the experimental group compared to a 32% increase in the control group. There was also a significant treatment effect with respect to their level of apathetic behaviour, loss of decorum, and depression.

Woods, Craven, & Whitney (2005) evaluated therapeutic touch using a three group, double-blind, placebo controlled, randomised trial. Therapeutic touch (given twice daily for five to seven minutes) was compared with a placebo therapeutic touch intervention and 'usual care'. Fifty-seven residents, aged 67 to 93 years, exhibiting behavioural symptoms of dementia, were randomised to one of the three groups within each of three special care units (SCUs) within three long-term care facilities. The main outcome variable was overall behavioural symptoms of dementia, consisting of six categories of behaviours: manual manipulation (restlessness), escape restraints, searching and wandering, tapping and banging, pacing and walking, and vocalization. Behavioural observation was completed every 20 minutes from 8:00am to 6:00pm for three days pre-intervention and for three days post-intervention by trained observers who were blind to group assignment. ANOVA indicated a significant difference in overall behavioural symptoms of dementia, manual manipulation and vocalization when the experimental group was compared to the placebo and control groups.

Overall, the results of the 55 included non-pharmacological intervention trials were as follows—six randomised trials of training interventions were reviewed. Four of six studies reported no between-group differences. In addition, six observational studies of training interventions were reviewed; however, the results were mixed. Five randomised trials of activity interventions were reviewed. Three of five studies reported no between-group differences. Fourteen observational studies were reviewed and reported mixed results. Overall, six of fourteen studies reported significant results favouring the intervention and two reported favourable trends. Four studies reported no benefits. Three randomised trials of sensory therapy interventions were reviewed. Two of three studies reported no between-group differences. Twenty one observational studies were reviewed and almost half of these involved music therapies and of these ten music therapy trials, seven reported statistically significant improvements in levels of agitation. Other results were mixed.

In summary, they concluded that they could not prioritize between various approaches due to lack of comparison studies and suggested that behavioural symptoms are studied as a whole.

## **Forbes et al. (2009)**

Forbes et al. (2009) conducted a systematic review to assess the evidence of effectiveness of BLT in managing sleep, behaviour, mood, and cognitive disturbances associated with dementia. The reviewers included RCTs in which BLT, delivered at variable intensity and duration, was compared with a control condition of non-bright light therapy to study the effect on managing sleep, behavioural, mood, or cognitive disturbances (as well as changes in institutionalisation rates or cost of care) on people with diagnosed dementia of any degree of severity. Any form of intervention involving the use of bright light was considered and the most common light source in the included studies was a 'light box' (placed approximately one metre away from the participants at a height within their visual fields and delivering from 2500 to 10 000 lux (Lx). Other light sources included 'naturalistic' light therapy (known as 'dawndusk' simulation that mimics outdoor twilight transitions; installed in residents' rooms) and the use of ceiling mounted light fixtures installed in the common living area (delivering an all day supplemental exposure of  $\pm 1000$  Lx). Control groups typically received dim red light or dim, low-frequency blinking light, less than 300 Lx. The BLT was typically delivered for one or two hours per day (and 'all day' for the ceiling mounted light fixtures or 'as required' for the 'dawn-dusk' simulation). Several outcomes were reported including cognition, function, sleep, behavioural and psychiatric disturbances. Only the outcomes relevant to this review are reported here, namely, behavioural disturbances, depression, and apathy.

The reviewers identified eight studies of which five studies met eligibility criteria for this review and are described here. Ancoli-Israel et al. (2003) trialled the Apollo "Brite-Lite" box<sup>TM</sup> delivering light >2 500 Lx for two hours daily in the evening or the morning for ten days versus morning dim red light (control). The single blind RCT included 92 nursing home residents (block-stratified randomisation by time of agitation, attrition rate = 23%) and agitation was accessed via the agitated behaviour rating scale (ABRS) and CMAI. The duration of the treatment was ten days with follow-up five days post-treatment. Dowling et al. (2007) also used the Apollo "Brite-Lite" box<sup>TM</sup>, delivering light >2500 Lx for one hour in the morning or afternoon, Monday through Friday for ten weeks, versus usual indoor light (control). The single blind RCT included 70 nursing home residents (attrition rate not reported) and assessment of BPSD was via the neuropsychiatric inventory - nursing home edition (NPI-NH) and occupational disruptiveness scores. Gasio et al. (2003) evaluated ''dawn-dusk' simulation' (maximum 400 Lx morning and evening with treatment time variable to mimic the duration and latitude of dawn and dusk) using an overhead halogen lamp placed behind a diffusing membrane behind the resident's bed simulating a naturalistic form of light therapy versus placebo dim red light (<5 Lx) morning and evening. The single blind RCT included 13 nursing home residents (attrition rate >20%) and assessment of BPSD, cognition and sleep parameters was via, NPI-NH, MMSE, geriatric depression scale (GDS), and sleep logs. Duration of the treatment was three weeks with follow-up three weeks post-treatment. Using a single-blind crossover randomised study design, Lyketsos et al. (1999) evaluated the effectiveness of BLT as administered by using the Apollo "Brite-Lite" box<sup>TM</sup> delivering a full 10 000 Lx at one metre versus a dim digital low-frequency blinking light. Morning bright light was administered to 15 residents (attrition rate >20%) for one hour every morning. Subjects were treated for four weeks, followed by one week of no treatment, prior to being crossed over to the other condition. Outcome assessments included sleep logs and behavioural measures (via the Behaviour

Pathology in Alzheimer's disease rating scale) and depression (via the CSDD). Finally, Riemersma et al. (2008) evaluated 'all day bright light' exposure of ±1000 Lx via ceiling-mounted light fixtures with Plexiglas diffusers containing an equal amount of Philips TLD 840 and 940 florescent tubes in the common living-room versus dim light (300 Lx). This large, double-blind, multi-centre randomised trial, involved 94 nursing home residents (attrition rate up to 42% at two years) during a 3.5 year period. The outcomes assessed included several sleep parameters (eg duration, latency, and efficiency), depression (via CSDD and the Psychogeriatric Dependency Rating Scale (PGCARS)), and cognition (via MMSE). The review suggested no adequate evidence of the effectiveness of BLT in managing sleep, behaviour, cognitive, or mood disturbances associated with dementia (see **Table 25**, Appendix E for a detailed results summary including odds ratios and 95% confidence intervals). Forbes et al. (2009) concluded that... "There is insufficient evidence to assess the value of BLT for people with dementia. The available studies are of poor quality and further research is required"... (p.38). Forbes et al. (2009) added that further research is necessary to identify appropriate illumination intensity, frequency, interval, time of day and length of intervention for individuals with different types and severity of dementia. Also, many issues around practicality, acceptability, low compliance and the cost implications of BLT need to be examined.

# Kverno et al. (2009)

Kverno et al. (2009) evaluated the published literature on non-pharmacological interventions for treating neuropsychiatric symptoms (NPS) in advanced dementia. Included studies were RCTs, single-group pre-test/post-test, non-equivalent group pre-test/post-test, and single-group repeated-measure designs that specifically evaluated non-pharmacological treatments for NPS in individuals with advanced, moderately-severe to very-severe dementia. Dementia severity categories were adopted as previously defined by Tombaugh and McIntyre (1992). Severe dementia was defined as MMSE scores between 0 and 10, or the equivalent, and moderatelysevere to severe dementia was defined as MMSE 10-17. Outcomes of interest included measures of neuropsychiatric symptoms of dementia (agitation or aggressive behaviour, depression, apathy or withdrawal, psychosis, and aberrant motor behaviour). Systematic searches of electronic databases were conducted for studies published between 1974 through May 2008. Out of 215 studies initially identified, only 21 (briefly listed below as per the review authors groupings) specifically focussed on treatments for individuals with 'moderately-severe' to 'very-severe' dementia (see Table 26 for a full summary of the included studies characteristics and results). Out of 21 included studies, 17 met the current review criteria.

Finnema et al. (2005), integrated emotion-oriented care; Magai et al. (2002), carer training; Camberg et al. (1999), family audiotape; Garland et al. (2007), family audiotape versus preferred music versus neutral audiotape; Bellelli et al. (1998), SCUs; Frisoni et al. (1998), SCUs; Morgan and Stewart (1998) SCUs; Ballard et al. (2002), aromatherapy; Holmes et al. (2002), aromatherapy; Lin et al. (2007), aromatherapy; Snow et al. (2004), aromatherapy; Mishima et al. (1998), BLT; Skjerve et al. (2004), BLT; Heyn (2003), multi-sensory exercise programme; Holliman et al. (2001), interactive physical activity; Holmes et al. (2006), music therapy; Svansdottir et al. (2006), music therapy; Baker et al. (2001) and Baker et al. (2003), MSS; Gerdner et al. (2008), touch therapy using the craniosacral still point technique; Kovach et al. (2004), balancing arousal controls and excesses.

Kverno et al. (2009) concluded that the studies provide limited evidence for the use of sensory-focussed strategies, including aromatherapy, preferred or live music, and MSS. Emotion-oriented approaches, such as 'simulated presence' may be more effective for individuals with preserved verbal interactive capacity. Interventions appeared to work best when they were tailored to balance individual arousal patterns. This review highlighted that individuals with severe cognitive impairment do not necessarily respond to neuropsychiatric symptom treatments in the same manner as individuals in the early stages of disease progression. This suggestion may have important implications relating to the feasibility of delivering interventions in common areas, universally, for all residents. Differential responses seem likely, including the possibility of adverse effects.

## Landreville et al. (2006)

Landreville et al. (2006) systematically reviewed the literature relating to the effectiveness of non-pharmacological interventions for aggressive behaviour in older adults living in long-term care facilities. A total of 41 studies were identified and included in the review but not all of the studies necessarily related specifically to dementia. Of the 41 included studies, 26 studies were identified as being conducted with nursing home residents exhibiting behavioural symptoms of dementia, and in a further five studies, the population was probably people with dementia, but this was not specified. Landreville et al. (2006) considered all types of non-pharmacological interventions, and the outcomes of interest were aggressive behaviours (AB), comprising both physical aggression and verbally aggressive behaviours. Treatment effectiveness was examined through two criteria. First, a statistically significant improvement in aggressive behaviour at the p <0.05 level, and secondly, a marked behavioural improvement judged as 'very improved' on a validated clinical improvement rating scale, or reduction of AB by at least 50%. Of these 26 dementia studies (and the five probable dementia studies), 11 met the main criteria for the current review: Ballard et al. (2002); Beck et al. (2002); DeYoung et al. (2002); Dunn et al. (2002); Ingersoll-Dayton et al. (1999); Leon and Ory (1999); Lyketos et al. (1999); McCallion et al. (1999); Moniz-Cook et al. (2001); Remington et al. (2002); Snyder et al. (2001). Of these 11 studies, only three (briefly described below) were unique, that is, not appraised within the more recent Forbes et al. (2009), O'Connor et al. (2009), Kverno et al. (2009), and/or Bharani and Snowden (2005) systematic reviews.

Ingersoll-Dayton et al. (1999) trialled 'training' in a solution-focussed approach with family and certificated nursing aides. The study included 21 nursing home residents with dementia (displaying either physically aggressive behaviours, verbally aggressive behaviours or wandering) in a crossover randomised trial of a staff training programme based on a solution-focussed approach for problem behaviours among nursing home residents. Non-blinded outcome assessment of aggression was made via the caretaker obstreperous behaviour rating assessment (COBRA) and one question assessing mastery. The authors reported a statistically significant decrease in the frequency and severity of AB and a statistically significant increase in mastery.

Leon and Ory (Leon & Ory, 1999) compared the frequency and intensity of residents' AB in specialised dementia care units in nursing homes, versus non-specialised units. The study participants were new admissions to SCUs (n = 432) and new admissions to traditional care units (n = 164). In this non-randomised trial of six months duration, non-blinded assessments of aggression and other outcomes were made using

interviews with family members and facility staff. Data were also obtained via review of medical records, the MDS, and the CMAI physically aggressive behaviour subscale). SCUs appeared to have no effect on the frequency of AB. Increased use of psychotropic medications and reduced use of physical restraints were associated with lower levels of physically aggressive behaviours.

Moniz-Cook et al. (2001) evaluated the effectiveness of individualised environmental modifications (simple changes to environmental triggers) for reducing AB. Four residents of one nursing home, who had dementia and who displayed physically aggressive and verbally aggressive behaviours were studied. Aggressive behaviours were measured via direct observation by non-blinded outcome assessors, using an ABA study design<sup>6</sup>. Moniz-Cook et al. (2001) reported a reduction of AB in all cases, with treatment effects being maintained at eight week follow-up.

Landreville et al. (2006) grouped their findings into seven categories:

- staff training programmes
- environmental modifications
- sensory stimulation
- behavioural management
- structured activities
- SCUs
- psychosocial interventions.

Staff training programmes typically included in-service meetings during which both information on AB and demonstration of practical skills for managing such behaviours were provided. In general, staff training had a positive impact on reducing aggression and the results were statistically significant reductions in all six studies where statistical analyses were performed.

Interventions categorised as environmental modifications included changes in physical restraints, door locks and indoor confinement, modification of care and bathing procedures, natural or enhanced environment, reduction of noise level, elimination of environmental triggers, and rearrangement of daily activities and/or regrouping patients with similar levels of function. Two out of ten studies that evaluated the effect of environmental modifications on AB, reported a statistically significant decrease in target behaviours, four others did not analyse their results with statistical tests but reported a marked reduction in behaviour, and one showed both a statistically and behaviourally significant improvement.

Sensory stimulation interventions included music, massage, music and massage, aromatherapy and BLT. Studies of sensory stimulation demonstrated modest effectiveness in reducing AB. Classical music, massage and touch appeared to be ineffective, however individualised music was shown to be associated with a statistically significant decrease in aggressiveness in all but one study. Aromatherapy appeared to be a promising approach, at least for physical aggression.

Behavioural management interventions included differential reinforcement (alone, and in combination with other behavioural techniques such as 'time out'), antecedents

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 $<sup>^{6}</sup>$  A refers to the non-treatment or control phase of the experiment while B refers to the treatment phase of the experiment.

control, extinction, and cued recall. Behavioural modification was associated with a marked improvement in AB in two out of four studies. The superiority of one behavioural strategy over another could not be established due to the small number of trials.

Structured activity interventions included programmes that used different activities such as musical and social activities, games, creative work and singing, using a glider swing, and group walks. Studies examining the effect of participating in structured activities on aggressiveness demonstrated inconsistent results—some reducing aggressiveness and others increasing aggressiveness. The results highlight the importance of individual differences in the impact of activity interventions.

Of three studies involving SCUs, two reported that SCUs were associated with a significant reduction in physical and verbal aggression. In a third study, after controlling for baseline level of disruptive behaviours, SCUs showed no effect on aggression compared to traditional units.

Psychosocial interventions: Few included studies examined the impact of social contact on AB, and results were inconsistent. Psychosocial interventions included 'simulated presence' therapy, validation group therapy, psychosocial activity and ADL. The results tended to vary according to how the outcomes were measured.

Overall, Landreville et al. (2006) reported staff training programmes and environmental modifications to be the most effective strategies. Sensory stimulation, which was examined in several studies, led to mixed findings. Finally, there is some evidence for the effectiveness of behavioural management, SCUs, structured activities, and psychosocial interventions. However, this suggestion is based on very few studies and more research on these interventions is needed. Landreville et al. (2006) concluded that while non-pharmacological interventions seem effective for managing AB, future studies on the effectiveness of these interventions needs to be more rigorous.

#### Livingston et al. (2005)

Livingston et al. (2005) systematically reviewed the literature on psychological approaches to treating the neuropsychiatric symptoms of dementia. Livingston et al. (2005) included all study types with quantitative outcome measures that were either direct or proxy measures of neuropsychiatric symptoms of dementia, in which the study participants were nursing home residents. The inclusion criteria specified that interventions must be derived from a psychological/psychosocial model, therefore, interventions that either involved medication or were not based on a psychological model (eg, aromatherapy, homeopathy, occupational therapy, light therapy) were *excluded*. Livingston et al (2005) searched selected electronic databases and other sources for relevant articles published between 1975 and July 2003, and a total of 1632 studies were identified. A total of 162 studies satisfied the inclusion/exclusion criteria for the review. Data were extracted, the quality of each study was rated, and an overall rating was given to each study by using the Oxford Centre for Evidence-Based Medicine criteria.

Because of the large number of studies included by Livingston et al. (2005), the amount of detail reported for any individual study was limited, and further, the broad scope of the review resulted in the inclusion of many studies that are not strictly

eligible for inclusion in this review<sup>7</sup>. Due to these factors, it was not always possible to disentangle specific eligible studies and report them separately here; therefore, the relevant results from Livingston and colleagues' (2005) review have been presented in this section in a similar (yet abridged) form as found in the original paper. Livingston et al. (2005) grouped all of the included studies for 'best fit' and categorised them into 26 different intervention types (**Table 15**). Each type of intervention was then given an overall "grade of recommendation" as assessed by the study authors (Livingston et al., 2005) based on the Oxford Centre for Evidence-Based Medicine criteria (see The Oxford Centre for Evidence-Baced Medicine, 2009). The grades ranged from A – D (**Table 16**). Note that the cumulative count of the included studies in **Table 15** exceeds 162 (the number of studies reviewed) as Livingston et al. (2005) grouped some studies twice (eg 'head-to-head' studies that compare two different types of interventions are listed once in each respective intervention group).

Within some of the following sections describing particular intervention types, some studies are briefly described which do not strictly meet all of the criteria for inclusion in this review (eg published pre-1999). Livingston et al. (2005) assigned the 'grades of recommendation' based on the evidence as per their (broader) criteria, and so, to preserve the integrity of those grades (as they were determined at that point in time) some of these 'additional' studies are briefly mentioned. In this way, the Livingston et al. (2005) review has been summarised slightly differently to the other reviews in this report and the reader should be aware of this difference. However, for the purposes of evidence generation (for this review), every effort has been made to give 'weight' to only those studies that meet the current review criteria.

Table 15: Intervention type, number of studies and grade, from Livingston et al. (2005)

| Intervention type listed by grade and number of studies   | Number of studies | Assigned grade |
|---|-------------------|----------------|
| Carer interventions involving psycho-education and teaching carers how to change their interactions with residents. | 9                 | А              |
| Music therapy.  | 24                | B*             |
| Staff education in managing behavioural problems.   | 9                 | В              |
| Implementing standard non-dementia specific behaviour management techniques.  | 6                 | В              |
| Sensory stimulation Snoezelen.  | 6                 | B**            |
| Cognitive stimulation.  | 4                 | В              |
| Changing the environment to obscure the exit.   | 8                 | С              |
| Other sensory stimulation.  | 7                 | C***           |
| Other dementia-specific therapies.  | 2                 | С              |
| Family counselling.   | 2                 | С              |
| Reality orientation therapy.  | 11                | D              |
| Special care units (SCUs).  | 8                 | D              |
| Therapeutic activity programmes.  | 8                 | D              |
| 'Simulated presence'.   | 5                 | D              |
| Group living /homelike environment.   | 5                 | D              |
| Reminiscence therapy.   | 5                 | D              |
| Psychological interventions with carers involving training behavioural management techniques.                       | 4                 | D              |
| Validation therapy.   | 3                 | D              |
| Montessori activities.  | 3                 | D              |
| Exercise.   | 3                 | D              |
| Decreased sensory stimulation.  | 2                 | D              |
| Use of mirrors.   | 2                 | D              |
| Signposting.  | 2                 | D              |
| Unlocking doors.  | 1                 | D              |
| Social interaction.   | 1                 | D              |
| Carer support by specialist nurses.   | 1                 | D              |

<sup>\*</sup>There is no evidence that music therapy is useful for treatment of neuropsychiatric symptoms in the longer term.

Table 16: Grades of recommendation

| Grades of Recommendation | •  |  |
|--------------------------|--|--|
| Α                        | Consistent level of evidence grade of 1.   |  |
| В                        | Consistent level II or III studies or extrapolations from level I studies.         |  |
| С                        | Level IV studies or extrapolations from level II or III studies.                   |  |
| D                        | Level V evidence or troublingly inconsistent or inconclusive studies of any level. |  |

<sup>&</sup>quot;Extrapolations" are where data is used in a situation that has potentially clinically important differences than the original study situation.

Source: Oxford Centre for Evidence-based Medicine - Levels of Evidence (2009)

<sup>\*\*</sup>The effects of Snoezelen appear to be limited to a very short time after the session.

<sup>\*\*\*</sup>Overall the grade of recommendation applies only for the short-term benefits of sensory stimulation as there is no evidence for sustained usefulness.

Results— abridged from Livingston et al. (2005) and ordered by grade and by number of studies.

## Carer interventions involving psycho-education and teaching carers how to change their interactions with residents (Grade = A)

Nine studies (including seven RCTs) involved psycho-education to teach carers how to change their interactions with residents with dementia<sup>8</sup>. In one large trial, improvement in neuropsychiatric symptoms at 16 weeks was found, but the difference only approached significance. In a second trial, improvement in neuropsychiatric symptoms occurred immediately after 12 weeks of training in stress management, dementia education, and coping skills but was not maintained at three-month followup. A third, smaller trial examining the effects of an intervention with individual families found significant improvements at six months in mood and ideational disturbance. In a RCT of an educational programme for family carers that included supportive counselling, psycho-education and training in management strategies, and home visits, the rate of institutionalisation of residents was decreased (for three months but not two years). A fifth RCT involved psycho-education, instruction to carers on how to change their interactions with the residents, or both. Residents' behaviour improved at six months, but the difference only approached significance. Another study examined the effects of carer psycho-education in working with nursing home residents to enhance social activities and self-care; the intervention resulted in a decrease in agitation after six months. Finally, a large high-quality RCT study investigated a comprehensive support and counselling intervention for 406 spouse carers that included problem solving, management of troublesome behaviour, education, and increased practical support, followed by long-term support groups. Residents' neuropsychiatric symptoms were not directly measured, but the intervention was found to delay time-to-institutionalisation by nearly a year. The other studies were non-controlled and showed either improvement that approached significance or significant improvement.

Overall, the grade of recommendation for behavioural management techniques in the form of psycho-education and teaching carers how to change their interactions with residents is A: because evidence from most studies consistently supports these interventions, and the effects have been shown to last months.

#### Music therapy (Grade = B)

Of 24 music/music therapy interventions, six were investigated in RCTs. All were small trials and showed improvements in disruptive behaviour.

In two, behaviour was observed during the music sessions, but there was no evidence that benefit carried over after the sessions. In three studies, behavioural change was observed outside of the music/music therapy session. In the first study, residents were significantly less agitated, both during and immediately after music/music therapy in which the music was chosen to fit the individuals' preference. The results of the second study were similar. In the third study, which assessed music, hand massage (HM), or a combination of both, decreased agitation was observed one hour after the

<sup>&</sup>lt;sup>8</sup> Essentially, instruction given to non-staff carers on how to change their interactions with the residents (mainly visiting family and family carers), and programmes that engage family members in care activities.

intervention. All but one of the other studies was controlled. Most of them found a benefit, although some did not.

Overall, the grade of recommendation for music therapy for immediate amelioration of disruptive behaviour is B. Music therapy decreases agitation during sessions and immediately after. There is, however, no evidence that music therapy is useful for treatment of neuropsychiatric symptoms in the longer term.

## Staff education in managing behavioural problems (Grade = B)

Nine studies (including three RCTs) investigated the effects of staff education in managing behavioural problems<sup>9</sup>. A randomised, controlled trial of communication skills training for nursing and auxiliary staff showed significant reductions in residents' aggression at three months and in residents' depression at six months.

Education of staff to implement an emotion-focussed care programme (validation, reminiscence, sensory stimulation) did not result in any change in neuropsychiatric symptoms. Staff education programmes focussed on knowledge of dementia and potential management strategies to reduce use of physical restraint and, in a non-randomised, controlled trial, decreased aggressive behaviour toward staff. Specialised care programmes for individuals in a residential home plus staff education improved emotional status and quality of life for residents 12 months later. A similar approach in a controlled trial with only 11 people in each arm led to non-significant differences favouring the intervention group. The result of a client-centred approach to agitation and sleep disturbance for 33 residents of a nursing home was equivocal. Verbal aggression decreased significantly, but the (less frequent) episodes of non-verbal agitation increased in one study. Training staff in integrity-promoting care improved residents' anxiety and depressed mood in a small controlled trial. In a large uncontrolled trial, training for nursing staff in using non-standardised observational outcomes led to an increase in restraint use but had no effect on agitated behaviour.

# Implementing standard non-dementia specific behaviour management techniques (Grade = B)

Twenty-five reports described use of non-dementia specific psychological therapies for people with dementia. Nearly all of the studies examined behavioural management techniques. In one RCT, participants received either manual guided treatment for the resident and carer or a problem-solving treatment for the carer only. The two interventions were equally successful in improving depressive symptoms immediately and at six-month follow-up. Two other small RCTs also had positive results. In one of those studies, participants had significantly fewer neuropsychiatric symptoms two months after being taught progressive muscle relaxation. In the other study, the behaviour of residents with the dementia of multiple sclerosis improved with 'neuropsychological counselling' (a cognitive behaviour intervention). There were two other RCTs in which behavioural management techniques were used; these techniques were ineffective in one of the studies. It used a complex, difficult-to-classify intervention that included a variety of techniques (eg, life review, sensory stimulation, single-word commands, and problem-oriented strategies). The second used a token economy, which was more effective in reducing 'bizarre' behaviour in residents with

<sup>9</sup> This differs from "Caregiver interventions involving psycho-education and teaching caregivers how to change their interactions with residents" (above) as it relates to paid staff only.

severe 'dementia, compared to a pre-intervention condition, but less effective than a milieu treatment. Several single-case studies were also identified. Overall, the findings of the larger randomised, controlled trials were consistent and positive, and the effects lasted for months.

#### Sensory stimulation: Snoezelen (Grade = B)

Snoezelen therapy/MSS combines relaxation and exploration of sensory stimuli, such as lights, sounds, and tactile sensations. Of six trials of Snoezelen therapy/MSS, three were RCTs. The first was a very small trial with no clear results. The other two found that disruptive behaviour briefly improved outside the treatment setting but that there was no effect after the treatment had stopped. The other reports described studies of individual cases and an uncontrolled trial in which improvements were found but no statistics were provided. The effects of Snoezelen appear to be limited to a very short time after the session.

#### Cognitive Stimulation (Grade = B)

Cognitive stimulation therapy uses information processing rather than factual knowledge to address problems in functioning in residents with dementia. Three of four RCTs of cognitive stimulation therapy showed some positive results, although the studies used different follow-up endpoints (immediately after therapy to nine months after therapy). There were early behaviour improvements, relative to controls. By nine months, no significant difference between groups was found. One study showed reduced depression, and another showed improvement in quality of life but not in mood. The final study did not report whether the differences in behaviour were significant. Overall, the included evidence is mostly consistent that cognitive stimulation therapy improves aspects of neuropsychiatric symptoms immediately and for some months afterward, although the evidence is not consistent in all respects.

## Changing the environment to obscure the exit (Grade = C)

Eight studies investigated the effects of changing the visual environment. The presence of two-dimensional grids on the floor near doors did not reduce exiting behaviours. However, two studies in which a horizontal grid pattern was used reported significant decreases in residents 'attempts to open doors and in residents' ambulation'. Similar results were found in a study of the effects of murals on the walls above doorways. Blinds and cloth barriers placed over doors/door handles and signs installed to provide a focus of residents' attention were also effective in reducing time spent attempting to exit the ward. Enhancement of the visual environment in a selected area of a residential home was associated with a decrease in agitated behaviours, although the finding was not statistically significant.

### Other sensory stimulation (Grade = C)

Of seven trials of other forms of sensory stimulation, only three were RCTs. The first trial compared massage with a comparison condition, music, or a combination of massage and music and decreased agitation was observed one hour after the intervention. The second trial examined a sensory integration programme that emphasised bodily responses, sensory stimulation, and cognitive stimulation; this intervention had no effect on behaviour. Similarly, a small RCT found that white noise had no effect on sleep disturbance and nocturnal wandering. An 'expressive physical touch' intervention over a ten-day period decreased disturbed behaviour from baseline immediately and for five days after the intervention. White noise tapes led to

immediate decrease in agitation in another trial. A non-randomised controlled trial of stimulation with 'natural elements' while bathing, found that agitation decreased significantly only during bathing. The other study of single cases found no difference in agitation before and after therapeutic touch or massage. In the final two studies, the effects of several forms of sensory stimulation involving touch, smell, and taste were examined. A small RCT reported no change associated with the intervention, and the other study found that the intervention was helpful. Overall the grade of recommendation applies only for the short-term benefits of sensory stimulation as there is no evidence for sustained usefulness.

## Other Dementia-Specific Therapies (Grade = C)

Two other dementia-specific therapies were identified. Firstly, 'individualised special instruction,' consisted of 30 minutes of focussed individual attention and participation in an activity appropriate for each individual. The participants in the pilot RCT were their own wait-list controls. During the intervention period, their behaviour did not deteriorate, compared with deteriorating behaviour before the intervention period. The second dementia-specific therapy was 'self-maintenance therapy', which is intended to help the resident maintain a sense of personal identity, continuity, and coherence. This intervention incorporates techniques from validation, reminiscence, and psychotherapy. A three week admission of residents and carers to a specialist unit in which self-maintenance therapy was provided led to a significant decrease in depression and problematic behaviour, compared to baseline. This outcome may have been partly attributable to the environment.

## Family counselling (Grade = C)

An uncontrolled study suggested that family counselling is helpful in reducing institutionalisation of residents. In a non-randomised trial counselling of a family support group resulted in a decrease in residents' problem behaviour but not in depression.

#### **Reality Orientation Therapy** (Grade = D)

Reality orientation therapy is based on the idea that impairment in orientating information (day, date, weather, time, and use of names) prevents residents with dementia from functioning well and that reminders can improve functioning. Eleven studies assessed reality orientation therapy. The strongest RCT, which had 57 participants, showed no immediate benefit of reality orientation therapy, compared to active ward orientation. In a smaller RCT (n=10), residents who received reality orientation therapy followed by reminiscence therapy had fewer neuropsychiatric symptoms, compared to residents who received the treatments in the reverse order. The other smaller RCTs mostly found benefits in the reality orientation therapy groups in terms of improved mood, decreased neuropsychiatric symptoms, or delayed institutionalisation.

# Special Care Units (Grade = D)

Eight non-randomised, controlled trials investigated the effects of SCUs designed for residents with dementia and staffed by specially trained workers who received ongoing training. In a controlled trial, admission to a 'low-density' SCU was associated with a decrease in disruptive behaviour. Similarly, in a controlled trial, a combination of group living and staff training was found to improve residents' emotional and physical outcomes and was less costly than standard care. In other

studies, SCUs were associated with a reduction in neuropsychiatric symptoms, especially agitation and depression, and with a reduction in use of neuroleptic medication. Aggression and activity disturbances were reduced in another small controlled trial of a SCU, however, three other studies found no effect.

## **Therapeutic activity programmes** (Grade = D)

There were five RCTs of therapeutic activities. In a small-scale RCT, therapeutic activities at home were associated with significant decreases in agitation. Another study found that small group discussion and being carried on a bicycle pedalled by volunteers alleviated residents' depression but not agitation at ten weeks. The third RCT found no effects of 'puzzle play' on social interaction and mood. Similarly, a comparison of games and 'puzzle play' with Snoezelen and another study comparing structured activity with a control condition found no improvements in mood and behaviour.

Among the non-randomised trials, one found no beneficial effects of weekly therapeutic activities on depression, in another study, a combination of group and individualised activity sessions in day care significantly increased agitation over ten weeks. A clinical trial of weekly activity groups led by nursing assistants found no behavioural changes. A specialist day-care programme providing structured daily activities for patients with dementia was associated with decreased institutionalisation and was more cost-effective than nursing home care. Patients who were rocked on a swing did not show a decrease in aggression. Three case studies of diverse group activities (games, music, exercise, socialising) found equivocal effects on behaviour. In two studies that used reading sessions as an intervention, some improvement was seen in wandering and disruptive behaviours were decreased in both patients.

# **'Simulated presence'** (Grade = D)

Six studies investigated the effects of 'simulated presence' therapy (usually involving a continuous-play audiotape made by a family member). One RCT found no change in agitated or withdrawn behaviours. Staff observations suggested reduced agitation in residents who received the intervention, compared to a placebo group but not compared to residents receiving 'usual care' in another trial. A small study found improved social interaction and attention. 'Simulated presence' therapy used to address agitation led to significant decreases in agitation and improved social interaction but no change in AB in another study. When 'simulated presence' therapy was used regularly, problem behaviours were reduced by 91% in another study. Finally, in a series of single case studies, mixed results were reported.

# **Group living /homelike environment** (Grade = D)

Group-living is the name given to specially designed nursing homes that encourage a homelike atmosphere. In a RCT, no change in neuropsychiatric symptoms was found in those in a group-living setting, compared to community-dwelling waiting-list comparisons. Two other randomized controlled trials showed decreased aggression, anxiety, and depression and less use of neuroleptic medication for one year in residents in group-living settings. No differences between group-living and comparison subjects were observed three years later. Both studies were limited, because residents were selected for admission and were ineligible if they had frontal lobe symptoms, severe dementia, or a severe physical morbidity. A smaller, uncontrolled trial on group-living reported beneficial effects on patients'

neuropsychiatric symptoms at six months and reduced use of physical restraints. However, in another study, neuropsychiatric symptoms significantly increased in group-living residents, relative to controls, at six months and one year. In summary, group-living may have beneficial or deleterious effects, or no effect on neuropsychiatric symptoms.

## Reminiscence Therapy (Grade = D)

Reminiscence therapy uses materials such as old newspapers and household items to stimulate memories and enable people to share and value their experiences. Five studies were included (three small RCTs), one reported behavioural improvements and when reminiscence therapy was preceded by reality orientation, but not vice versa, and the other two studies found no benefit. One low-level study reported a significant improvement in mood.

# Psychological interventions with carers involving training behavioural management techniques (Grade = D)

Seven studies involved training the carers to use behavioural management techniques. A RCT found no difference in agitation or global outcome in a comparison of treatment with behavioural management techniques, haloperidol or trazodone alone, or placebo at 16 weeks. Behavioural management techniques taught to carers did not reduce psychotropic drug use or symptom frequency at one-year follow-up. Exercise and behavioural management techniques led to significant improvements in depression at three months but not at two years in another trial. In a smaller RCT, behavioural management techniques based on the progressive lowered stress threshold (PLST) model were taught to carers with the aim of reducing stimulation in response to specific stressors identified by carers. In this study, both groups received the intervention, one in the form of written materials, and the other in a training programme. A positive effect for care recipients was found in the second group. The evidence that behavioural management techniques with carers and exercise training with residents helps depression is strong, but it is unclear which component was the active component. Overall, study findings are inconsistent.

# Validation Therapy (Grade = D)

Validation therapy is intended to give an opportunity to resolve unfinished conflicts by encouraging and validating expression of feelings. Three studies of VT were included. The first, a case series of five individuals, indicated an improvement in irritability after VT. The second (which included five residents who served as their own controls), reported no change in behaviour. A RCT compared VT to 'usual care' or a social contact group in 88 residents with dementia. At the one-year follow-up there was no difference in independent outcome ratings, in nursing time needed, or in use of psychotropic medication and restraint.

#### Montessori activities (Grade = D)

Montessori activities use rehabilitation principles and make extensive use of external cues and progression in activities from simple to complex. Three non-randomised, controlled trials utilised Montessori-based activities and found no change in depression and agitation.

### Exercise (Grade = D)

Three studies examined the use of exercise/movement/walking as an intervention for neuropsychiatric symptoms. A well-conducted randomised, controlled trial found no effects on behaviour in a "walk-talk" programme. A randomised, controlled trial of a psychomotor activation programme found no behavioural effect. In two small non-RCTs, one found a significant reduction in AB on days when a walking group was held and the other study, a small matched controlled trial of exercise groups, found no significant reduction in agitated behaviours.

### **Decreased sensory stimulation** (Grade = D)

Two small studies investigated decreased sensory stimulation. A 'quiet week' intervention (turning off the television, lowering voices and reducing fast movement by staff at a day centre) led to an immediate significant reduction in agitation as measured by a non-standardised scale, compared to the period before the intervention. In another study, residents on a specially designed reduced stimulation unit—without television, radio, telephones; with scheduled rest periods and limited access to visitors—had no reduction in neuropsychiatric symptoms as measured by a standardised scale, compared with the period before the intervention, but use of restraint decreased.

**Use of mirrors** (Grade = D)

Signposting (Grade = D)

**Unlocking doors** (Grade = D)

**Social interaction** (Grade = D)

A small report of single cases studies showed decreased neuropsychiatric symptoms in one third of residents.

## Carer support by specialist nurses (Grade = D)

A single controlled study compared the effects of using specialist nurses who worked in the community with persons caring for residents with dementia—to those of usual treatment and showed no effect on institutionalisation of residents.

### **Conclusions**

Livingston et al. (2005) stated that overall their conclusions were limited because of the paucity of high-quality research. Only nine of 162 included studies were properly designed RCT with narrow confidence intervals. However, notwithstanding the limitations of the evidence base, Livingston et al (2005) concluded that behavioural management techniques centred on individual residents' behaviour are generally successful for reduction of neuropsychiatric symptoms, and the effects of these interventions can last for months.

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 or supervision were found to be beneficial in general, when compared to 'usual care' that did not contain any of these elements. Further, psycho-education intended to change carers' behaviour is effective, especially if it is provided in individual rather than group settings, and improvements in

neuropsychiatric symptoms associated with these interventions may be sustained for months. Also, specific types of staff education lead to reductions in behavioural symptoms (some studies reported reductions in the use of restraints). Staff education was also associated with improved mood states. Staff education in communication skills and enhancement of staff members' knowledge about dementia may improve many outcomes related to neuropsychiatric symptoms. In contrast, staff training programmes aimed at teaching staff emotion-oriented care or programmes aimed at changing staff attitudes or perceptions were not associated with significant changes in outcomes compared to 'usual care'.

Finally, music therapy and Snoezelen, and possibly some types of sensory stimulation, are useful treatments for neuropsychiatric symptoms during the session but have no longer-term effects. The cost or complexity of Snoezelen for such small benefit may be a barrier to its use. The included studies were published from as early as 1975 through to July 2003. Only 60 studies were published from 1999 onwards (76 published pre-1999). Arguably, a more focussed approach (with a narrower publication year range) would have provided more relevant information and allowed for the provision of more detail.

## Nguygen and Paton (2008)

Nguygen and Paton (2008) reviewed the effectiveness of aromatherapy in BPSD. Included studies were RCTs of aromatherapy in people with dementia and clinically significant agitation or other BPSD. The most commonly used oil in the studies was lavender, chosen because of its perceived calming and sedative properties. Also used were lemon balm—claimed to be useful in excitability, restlessness, stress and insomnia—and marjoram which is thought to have sedative properties and be useful for nervous tension. Methods of administering the essential oils included: combining the oils with a base lotion and applying topically, oils added in the bath/footbath, oils soaked in cotton ball or sachet and attached to the lapels of each subject, oils diffused in the air using an electric aroma steam fan, or individually by diffuser. Nguygen and Paton (2008) included all relevant papers (no date limits were specified) up to March 2007. Due to the limited number of papers available, all randomised studies of aromatherapy in patients with BPSD were included. All included studies appeared to have been appraised for design strength and quality of evidence; however, the method and/or checklist or criteria were not specified. Notes were provided to outline potential biases and quality issues where such issues were identified. Eleven prospective randomised studies of aromatherapy in BPSD that included data for 298 patients were identified. Eight of the 11 published studies each had less than 25 participants. The included studies are listed below (see Table 29, Appendix E for a full summary of the studies' characteristics and results).

Included studies: Ballard et al. (2002), melissa oil/lemon balm, combined with a base lotion; Bowles et al. (2002), a blend of oils blended into a cream and applied by massage; Burleigh et al. (1997), individualised oil treatment delivered in the bath/footbath; Gray et al. (2002), lavender, sweet orange, and a tea tree oil-soaked cotton ball attached to lapels; Henry et al. (1994), lavender oil diffused in the air using electric aroma steam fan; Holmes et al. (2002), lavender vapour; Kilstoff et al. (1998), a combination of oils including sweet almond, lavender, geranium and mandarin applied via a hand cream; Lin et al. (2007), lavender delivered by diffuser at night; Mitchell, (1993), lemon balm and lavender oil applied to subject's skin;

Smallwood et al. (2001), lavender oil and massage; Snow et al. (2004), lavender, thyme or grape-seed oil worn on a sachet.

Available studies reported positive and negative consequences for both people with dementia and their carers. "Aromatherapy is a potentially useful treatment for BPSD but data supporting efficacy are scarce. Much remains to be understood about the choice of aromatherapy oil, the optimum method of administration, and the efficacy and side-effect profile" (Nguygen & Paton, 2008, p. 345). Only three individual RCTs were powered to detect even a large treatment effect; eight of the 11 published studies each had less than 25 participants. The aromatherapy oils tested, method of delivery and outcome measures used varied widely across the studies. Most of the studies included very small numbers of patients and were designed in such a way that made interpretation of the findings difficult. Two studies did not use any statistical analysis despite collecting quantitative data and one employed complex statistical techniques to analyse data for just seven patients. There was no clear association between the oil used or method of delivery and study outcome. It is also unclear if individualised treatment offers any benefits over standardised treatment.

### O'Connor et al. (2009)

O'Connor et al. (2009) conducted a systematic review of selected experimental studies of psychosocial treatments of behavioural disturbances in dementia. The focus of the review was to assess the effectiveness of psychosocial treatments based on one of three psychological theories: learning theory, unmet needs theory, and altered stress thresholds theory. The authors reviewed studies published or in press by December 2006. Based on the reviewed literature, O'Connor et al. (2009) described these psychologically-oriented paradigms as follows.

Learning theory states that behaviours are reinforced when carers reward them with attention (Teri, 1998). According to the unmet needs theory, when residents perceive needs or urgencies that they cannot express and the carer fails to either pay attention or fails to appreciate, the residents then express inappropriate behaviours to draw attention to the needs they want alleviated (Cohen-Mansfield, 2001). The theory therefore suggests that strategies to address unmet needs should ensure sufficient meaningful activity for the residents, enable pleasurable social interaction and ensure freedom from pain. According to the theory of stress threshold, dementia reduces the capacity to cope with stress, resulting in inappropriate behaviours (Hall & Buckwalter, 1987). Stress levels can be modulated to tolerable levels by attending to signals of distress and alternating periods of rest and activity. O'Connor et al. (2009) reported that most of the psychosocial treatments they identified in their review blended elements of all three paradigms.

The authors identified a total of 25 studies. In descending order of frequency, the following interventions were identified in this review: music (eight studies), carer education (four studies), sensory enrichment (three studies), simulated family presence (three studies), novel bathing techniques (two studies), aromatherapy (two studies), recreation (one study), relaxation (one study) and VT (one study). Treatment proved more effective than an 'attention control' condition in reducing behavioural symptoms in only 11 of the 25 studies and effect sizes were mostly small or moderate.

Treatments with moderate or large effect sizes 10 included: aromatherapy, abilityfocussed carer education, bed baths, preferred music and muscle relaxation training (see Table 30, Appendix E for a summary of the included studies' characteristics and results). Use of lavender oil reduced the frequency of agitation more than water vapour in one study and massage with lemon balm worked better than sunflower oil in another. Ability-focussed carer education programmes were defined as programmes that enhanced carers' knowledge, empathy and communication skills, and expectedly would lead to significant falls in agitation and aggression. Ability-focussed carer education programmes were effective in one out of three reported studies. Novel bathing techniques were evaluated in two trials. Bath times are commonly associated with peak levels of disturbed behaviours. Both of the bathing studies demonstrated that efforts to make this essential routine more palatable to people with dementia, and safer for carers, are worthwhile. Studies of music therapy included evaluations of natural sounds, preferred music compared to classical music, music during bath times, music during meal times, Baroque music, and live music compared to recorded music and commercial music. Overall, music proved very effective in five out of eight studies. Tailoring music to individuals' preferences is clearly important. O'Connor et al. (2009) point out that other treatments are not necessarily ineffective, but that their benefits could not be attributed confidently to a unique therapeutic modality. Most treatments entailed some measure of human contact, either directly or indirectly. Positive interaction between the person with dementia and a family member or care attendant might form the common basis of many of these interventions. O'Connor et al. (2009) suggest that human contact can be conceptualised as a treatment of agitation that is worthy of study in its own right.

In conclusion, O'Connor et al. (2009, p. 225) state that ... "Some psychosocial interventions appear to have specific therapeutic properties, over and above those due to the benefits of participating in a clinical trial. Their effects were mostly small to moderate with a short duration of action. This limited action means that treatments will work best in specific, time-limited situations. In the few studies that addressed within-group differences, there were marked variations in response. Some participants benefited greatly from a treatment, while others did not. Interventions proved more effective when tailored to individuals' preferences".

### Perkins et al. (2008)

Perkins et al. (2008) reviewed the published literature regarding dog therapy for older people with dementia living in residential aged care facilities. Studies were included if the focus of the research was interactions or outcomes of contact between older people with dementia and dogs. Study designs with assigned levels of evidence above case studies and equivalent were included. No study adopted a RCT design. Participants were individuals with a diagnosis of AD or dementia as documented in the resident's chart. The severity of dementia ranged from mild to severe. All included studies were conducted in a residential aged care setting or adult day care centre.

A literature search for English-language articles published between 1966 and 2007 was conducted using the electronic databases: the Web of Science, PsycINFO, Ovid MEDLINE, CINAHL, ADT, Web of Knowledge, Cochrane and PubMed. Nine

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<sup>&</sup>lt;sup>10</sup> The authors considered an effect size of 0.2 to be small, 0.5 moderate and 0.8 large as per Cohen (1988).

identified studies met the inclusion criteria. Dog contact as therapy for older people with dementia included interventions based on: (a) dog-assisted activity (defined as unstructured, informal, without specific therapeutic goals or recording of outcomes, and conducted by someone without special skills or training and possibly using an uncertified animal) and (b) dog-assisted therapy (defined as structured, one-on-one or in small groups, conducted by suitably trained professionals with specifically certified animals, and requiring active participation with specific therapeutic goals and outcomes recorded).

The review included two studies of dog-assisted therapy while the remaining seven used unstructured dog-assisted activity programmes (only six of the total nine studies are reported here as three were published prior to 1999). Outcome measures included measures of social behaviour, agitation, apathy and other problematic behaviours, also medication use, ward noise levels, measures of cognition, global function, and a range of physiological measures. The results were presented in tables and by way of a narrative synthesis of the main findings.

Kanamori et al. (2001) evaluated animal-assisted activity using visiting dogs and cats in a non-randomised controlled trial of involving 27 participants (with moderate dementia) in a psychiatric hospital day care programme (the treatment group had previous contact with dogs at home). Outcomes included the BEHAVE-AD, the MMSE, the nurse-informant activities of daily living scale (NI-ADL) and salivary CgA (an antibody found in saliva thought to be an indicator of stress). Kanamori et al. (2001) reported that family assessed global care-giving burden reduced in the treatment group (BEHAVE-AD) and a non-significant reduction of CgA was also found (treatment group versus control). In a small test-retest study of animal-assisted activity involving eight residential care participants with mild dementia; Motomura and Ohyama (2004) evaluated the effects of a visiting dog on the outcomes of cognition (MMSE), apathy and irritability (GDS, physical self-maintenance scale (PSMS)). Using staff-assessment measures, the results showed reduced global apathy in the animal-assisted activity group (apathy subscale). Sellers (2005) studied dogassisted therapy (visiting dog) involving four people with moderate to severe dementia in a residential care setting. The outcomes included agitated behaviour, MMSE scores agitated behaviour mapping instrument (ABMI) scores, and scores on the social behaviour observation checklist (SBOC). The incidence of observed agitated behaviour (ABMI) during animal-assisted therapy was reduced and the incidence of observed social behaviour during animal-assisted therapy increased favourably. In addition, three other studies (Churchill, Safaoui, McCabe, & Baun, 1999; B. W. McCabe, Baun, Speich, & Agrawal, 2002; Richeson, 2003) also demonstrated improvements on some outcomes, and these studies are summarised elsewhere in this report (see Bharani and Snowden's 2005 review).

Perkins et al. (2008) reported that of the five studies that examined pro-social behaviour, all reported significant increases in a range of social behaviours such as smiles, looks, verbalisations and touches during the intervention phase, as measured by direct observation. Three of these studies additionally measured agitation reporting significant reductions. A significant reduction in a range of global problem behaviours measured by proxy report on all six subscales of the nursing home behaviour problem scale (NHBPS) was also reported in subjects following the introduction of a resident dog in one residential aged care facility (see McCabe et al., 2002 elsewhere in this report).

Perkins et al. (2008) concluded that while research does suggest that dog therapy is beneficial for people with dementia, the methodological variability of studies makes it difficult to draw firm conclusions. In all studies, the sample size was small (mean sample size was less than 17), no study adopted a RCT design, and a number of potentially important factors were not controlled for, including halo effects of animals on carers that may bias carers' responses when acting as proxies for their relatives or residents. In addition, the pre-morbid relationship with dogs may be an important variable influencing outcome. The evidence for dog therapy in dementia is limited.

Table 17: Excluded systematic reviews and reason for exclusion (n = 48)

| SRs grouped                            | Title  | Reason for exclusion   |
|--|--|--|
| alphabetically                         |  |  |
| Ayalon et al. (2006).                  | Effectiveness of non-pharmacological interventions for the management of neuropsychiatric symptoms in patients with dementia: a systematic review.       | Two relevant studies appraised separately: Moniz-Cook et al. (2001) and McCallion et al. (1999). |
| Bates et al. (2004).                   | Psychosocial interventions for people with a milder dementing illness: a systematic review.  | Inappropriate outcomes.  |
| Buchanan et al. (2007).                | Non-pharmacological interventions for aggression in persons with dementia: a review of the literature.   | Non-systematic literature review/narrative but a good overview based on 18 studies.              |
| Cameron et al. (2003).                 | Transcutaneous electrical nerve stimulation (TENS) for dementia.   | Reviewed in Bartlett et al. (2007).  |
| Christofoletti et al. (2007).          | Effects of motor intervention in elderly patients with dementia: an analysis of randomized controlled trials.  | One relevant study reviewed separately: Hopman-Rock et al. (1999).                               |
| Chung et al. (2002).                   | Snoezelen for dementia.  | Reviewed in Bartlett et al. (2007).  |
| Clare et al. (2003).                   | Cognitive rehabilitation and cognitive training for early-stage AD and vascular dementia.  | Cognitive outcomes.  |
| Cohen-<br>Mansfield<br>(2001).         | Non-pharmacologic interventions for inappropriate behaviours in dementia: a review, summary, and critique.   | Lack of relevant studies.  |
| Cohen-<br>Mansfield<br>(2004).         | Non-pharmacologic interventions for inappropriate behaviours in dementia: a review, summary, and critique.   | Lack of relevant studies.  |
| Diamond et al. (2003).                 | Complementary and alternative medicines in the treatment of dementia: an evidence-based review.  | Outside of the scope of this review.   |
| Doody et al. (2001).                   | Practice parameter: Management of dementia (an evidence-based review): Report of the quality standards subcommittee of the American Academy of Neurology | Lack of relevant studies.  |
| Eggermont & Scherder (2006).           | Physical activity and behaviour in dementia: a review of the literature and implications for psychosocial intervention in primary care.                  | Family home settings.  |
| Filan &<br>Llewellyn-<br>Jones (2006). | Animal-assisted therapy for dementia: a review of the literature.  | Superseded by Perkins et al. (2008).   |
| Finnema et al. (2000).                 | The effects of emotion-oriented approaches in the care for persons suffering from dementia: a review of the literature.                                  | Lack of included studies post 1999.  |
| Forbes et al. (2008).                  | Physical activity programmes for persons with dementia (review).   | Only reported data for cognitive outcomes.   |
| Forbes et al.<br>(2004)                | Light therapy for managing sleep, behaviour, and mood disturbances in dementia.  | Superseded, updated in 2009.   |
| Hansen &<br>Ortenbland<br>(2006).      | Massage and touch for dementia.  | No unique contribution.  |

Table 17: Excluded systematic reviews and reason for exclusion (n = 48) (continued)

|  | (Continuea)  |  |
|--|--|--|
| SRs grouped alphabetically               | Title  | Reason for exclusion   |
| Heyn et al. (2004).                      | The effects of exercise training on elderly persons with cognitive impairment and dementia: a meta-analysis.                         | Reviewed in Bartlett et al. (2007) and mainly cognitive outcomes.  |
| Hill & Brettle (2005).                   | The effectiveness of counselling with older people: results of a systematic review.  | Full-text not available.   |
| Hodgkinson<br>(2007).                    | Managing the wandering behaviour of people living in a residential aged care facility.   | Six relevant studies appraised separately:<br>Baker et al. (2003); Ballard et al. (2003);<br>Ingersoll-Dayton et al. (1999); Woods,<br>Craven & Whitney (2005); Shalek, et al.<br>(2004); Heard & Watson (1999). |
| Holt et al.<br>(2003).                   | Aromatherapy for dementia.   | Two relevant studies appraised separately: Ballard et al. (2002) and Lin et al. (2007).  |
| Hsieh & Wang (2003).                     | Effect of reminiscence therapy on depression in older adults: a systematic review.   | Depression in older adults but not dementia specific.  |
| Kim et al.<br>(2006).                    | Evidence-based practice recommendations for working with individuals with dementia: group reminiscence therapy.                      | Included studies of Incorrect publication year and incorrect population.   |
| Koger et al.<br>(1999).                  | Is music therapy an effective intervention for dementia: a meta-analytic review of literature.                                       | No studies included post-1999.   |
| Lai et al.<br>(2003)                     | Wandering behaviour in people with Dementia.   | Reviewed in Algase et al. (2006).  |
| Logsdon et al. (2007).                   | Evidence-based psychological treatments for disruptive behaviours in individuals with dementia.                                      | Only 2 of 14 studies conducted in residential care, one appraised separately (Proctor et al. 1999) and the other is excluded.  |
| Mahendra et al. (2006).                  | Evidence-based practice recommendations for working with individuals with dementia: Montessoribased interventions.                   | Although published in 2006, the search was completed in 2002: no unique contribution.  |
| McCabe et al. (2007).                    | Effectiveness of staff training programmes for behavioural problems among older people with dementia.                                | Non-systematic literature review/narrative but a good overview based on 22 studies.  |
| Neal & Barton<br>Wright (2003).          | Validation therapy for dementia.   | Reviewed in Bartlett et al. (2007).  |
| Opie et al.<br>(1999).                   | The efficacy of psychosocial approaches to behaviour disorders in dementia: a systematic literature review.                          | No included studies post 1999.   |
| Robinson et al. (Robinson, et al., 2007) | Effectiveness and acceptability of non-<br>pharmacological interventions to reduce<br>wandering in dementia: a systematic<br>review. | Four relevant studies appraised separately: Ballard et al. (2003); Ingersoll-Dayton et al. (1999); Woods, Craven & Whitney (2005); Baker et al. (2003).  |
| Siders et al. (2004).                    | Evidence for implementing non-<br>pharmacological interventions for<br>wandering.  | Reviewed in Algase et al. (2006).  |
| Sitzer et al. (2006).                    | Cognitive training in AD: a meta-analysis of the literature.   | A review of 19 studies with a fundamentally cognitive focus.   |
| Skjerve et al.<br>(2004).                | Light therapy for BPSD.  | Three relevant studies appraised separately: Lyketsos et al. (1999); Ancoli-Israel et al. (2003); Haffmans et al. (2001).  |

Table 17: Excluded systematic reviews and reason for exclusion (n = 48) (continued)

| SRs grouped alphabetically           | Title  | Reason for exclusion   |
|--------------------------------------|--|--|
| Snowden et al. (2003).               | Assessment and treatment of nursing home residents with depression or behavioural symptoms associated with dementia: a review of the literature. | Non-systematic literature review/narrative.  |
| Spira &<br>Edelstein<br>(2006).      | Behavioural interventions for agitation in older adults with dementia: an evaluative review.   | Non-systematic literature review/narrative.  |
| Sung & Chang (2005).                 | Use of preferred music to decrease agitated behaviours in older people with dementia: a review of the literature.                                | Non-systematic literature review/narrative.  |
| Thorgrimsen et al. (2003)            | Aromatherapy for dementia.   | Reviewed in Bartlett et al. (2007).  |
| Tilly & Reed (2007).                 | Literature review: intervention research on caring for people with dementia in assisted living and nursing homes.                                | Non-systematic literature review/narrative, but a good overview based on 72 studies.   |
| Turner (2005).                       | Behavioural symptoms of dementia in residential settings: a selective review of non-pharmacological interventions.                               | Non-systematic literature review/narrative.  |
| Verbeek, et al. (2009).              | Small, homelike care environments for older people with dementia: a literature review.   | International comparison of care concepts only.  |
| Verkaik et al. (2005).               | The effects of psychosocial methods on depressed, aggressive and apathetic behaviours of people with dementia: a systematic review.              | Most of the 19 studies were published pre-1999—four relevant studies appraised separately: Finnema et al. (2000); Schrijnemaekers et al. (2002); Spector et al. (2001); Hopman-Rock et al. (1999). |
| Vink et al. (2003).                  | Music therapy for people with dementia.  | Reviewed in Bartlett et al. (2007).  |
| Von Gunten et al. (2008).            | Vocally disruptive behaviour in the elderly: a systematic review.  | Aetiology.   |
| Williams &<br>Jenkins<br>(2008).     | Dog visitation therapy in dementia care: a literature review.  | Non-systematic literature review/narrative.  |
| Witzke et al. (2008).                | How sweet the sound: research evidence for the use of music in Alzheimer's dementia.   | Two relevant studies appraised separately: Hicks-Moore (2005); Gerdner (2000).   |
| Woods,<br>Spector, et al.<br>(2005). | Reminiscence therapy for dementia.   | Reviewed in Bartlett et al. (2007).  |
| Zetteler<br>(2008).                  | Effectiveness of 'simulated presence' therapy for individuals with dementia: a systematic review and meta-analysis.                              | Three relevant studies appraised separately: Camberg et al. (1999); Garland et al. (2007); Cheston et al. (2007).  |

# Original primary studies: characteristics and results

A total of 88 primary studies were identified as eligible for this review. Of these, 46 studies have been adequately appraised and reported within previously published systematic reviews and the remaining 42 original primary research studies have been critically appraised and reported in this review. These 42 studies involved a total of 2449 individuals. The summary characteristics of all of the 42 included studies and the 46 previously appraised studies (as reported within published systematic reviews) are presented together in Table 18, Table 19 and Table 20 (the 46 previously reviewed studies are denoted by grey shading). Heterogeneity of the studies in terms of the interventions assessed, control groups, as well as the outcome measures and follow-up periods, precluded the conduction of a meta-analysis. Therefore, throughout the following section, the study results are grouped 11 according to the 'main outcome' or 'focus' of the study (listing the more frequently reported outcomes first), and within these groupings: accordingly from higher to lower level of evidence; according to publication date order; and according to the following broad categories of effectiveness-effective, uncertain, or ineffective. For each of the 'outcome' groupings, a narrative description of each included study follows, and then a narrative synthesis/summary of the evidence and a discussion of the limitations of the evidence base conclude this section.

11 Outcome groupings (a) agitation and aggression (b) generalised BPSD outcomes (c) anxiety, depression or apathy.

Table 18: Study characteristics and main findings: agitation and aggression

| Study*                                   | Design                        | = u      | Intervention   | Outcome                           | Main findings  | Effective? |
|--|-------------------------------|----------|--|-----------------------------------|--|------------|
| Level II evident                         | ce: interventi                | ions for | Level II evidence: interventions for the management of agitation and aggression.                 | of agitation and                  | d aggression.  |            |
| Chenoweth<br>et al. (2009).              | Cluster<br>RCT.               | 324      | Person-centred care (PCC) vs. DCM vs. 'usual care'.  | Agitation.                        | Agitation significantly lower in sties providing DCM (mean difference 10.9 points, 95% CI: 0.7-21.1) and PCC (mean difference 13.6, 95% CI: 3.3-23.9, p = 0.01) at follow up, relative to 'usual care' sites. However, there was no statistically significant difference between PCC and DCM.  | Effective. |
| Hicks-<br>Moore &<br>Robinson<br>(2008). | RCT<br>(three<br>groups).     | 14       | Relaxation techniques such as music and massage.   | Agitation.                        | Compared to no treatment, all three treatments (HM, favourite music (FM) and the massage/music combination) showed a significant decrease in agitation scores over time (p <0.05).   | Effective. |
| Cohen-<br>Mansfield<br>et al. (2007).    | Cluster<br>RCT<br>(12 sites). | 167      | Multi- component interventions using a systematic algorithm tailored to the individual profiles. | Agitation.                        | ABMI scores decreased from 5.05 (Standard deviation (SD) = $3.36$ ) to $4.10$ (SD = $3.47$ ) in the control group and $5.17$ (SD = $3.75$ ) to $3.23$ (SD = $3.16$ ) in the intervention group (a significant between-group difference, p = $0.002$ ). In addition, implementation of individualised interventions for agitation resulted in statistically significant increases in pleasure and interest (p < $0.001$ ).  | Effective. |
| Chapman & Toseland (2007).               | Crossover<br>RCT.             | 118      | Advanced illness care team (AICT) intervention.  | Agitation.                        | Intervention group residents experienced a significantly greater decrease in physically non-aggressive behaviours (only), compared to 'usual care' residents (p $\leq$ 0.01). All CMAI subscales showed a significant time effect over the two-month intervention period (p $\leq$ 0.01) and intervention group residents had greater reductions in their agitation scores than 'usual care' residents, but these the differences were not statistically significant.          | Effective  |
| Yang et al.<br>(2007).                   | Crossover<br>RCT.             | 20       | Acupressure.   | Agitation<br>(also<br>wandering). | Significant differences between the 2 groups: for agitation, scores on the CMAI decreased in the acupressure group from 79.3 (SD = 16.74) at baseline to 59.85 (SD = 9.63) post-test and increased in the control from 72.4 (SD = 12.76) to 74.55 (SD = 9.96) and this difference was significant (p <0.001). The severity of wandering decreased post-test revealing a modest effect on wandering participants (5368 steps per day pre-test to 3374 steps per day post-test). | Effective. |

Table 18: Study characteristics and main findings: agitation and aggression (continued)

| Study*                    | Design            | <b>u</b> = | Intervention  | Outcome                         | Main findings   | Effective? |
|---------------------------|-------------------|------------|---|---------------------------------|---|------------|
| Lin et al.<br>(2007).     | Crossover<br>RCT. | 02         | Aromatherapy (lavender vs. sunflower control, delivered by diffuser).                             | Agitation.                      | Decrease in agitation with lavender treatment (p <0.001). No change following sunflower treatment.  | Effective. |
| Garland et<br>al. (2007). | Crossover<br>RCT. | 30         | Family audiotape vs. preferred music vs. neutral audiotape.                                       | Agitation/ag<br>gression.       | For physically agitated behaviours, rates fell by 30% from baseline during 'simulated presence' (p = 0.003), 25% during personalised music (p = 0.04) and 15% during placebo. For verbally agitated behaviours, rates fell by 33% from baseline during 'simulated presence' (p = 0.04), 18% during music and 29% during placebo (p = 0.03). Both physical and verbal behaviour counts were still lower than baseline 15 minutes later. Roughly half the participants showed a fall in behaviour counts of 50% or more during one or other condition. A few became more disturbed. | Effective. |
| Kovach et<br>al. (2004).  | RCT.              | 82         | Individualised activity schedule to balance high-arousal and low-arousal states vs. 'usual care'. | Agitation.                      | The balancing arousal controls excesses (BACE) intervention resulted in reduced agitation between pre-test and post-test (p <0.001), with no change in the control group. Effects mostly gone by 10 weeks.  | Effective. |
| Sloane et<br>al. (2004).  | Crossover<br>RCT. | 69         | Person-centred bed bath vs. person-centred shower vs. 'usual care'.                               | Agitation<br>and<br>aggression. | Rates of agitation and aggression fell significantly in both person-centred conditions (showering 32%, bed bath 37%), versus 8% in 'usual care' (p <0.02), but neither condition was better than the other.   | Effective. |
| Ballard et<br>al. (2002). | Cluster<br>RCT.   | 11         | Aromatherapy.   | Agitation.                      | Scores on the CMAI fell by 35% on average in the melissa group versus 11% for sunflower oil (p <0.0001). There were also positive changes in social engagement and constructive activity.   | Effective. |
| Dunn et al.<br>(2002).    | Crossover<br>RCT. | 15         | Bed bath vs. tub<br>bath.   | Agitation.                      | Mean total behaviour counts of 14 specified agitated behaviours (assessed from the moment of undressing to bath completion) were 50% lower during bed baths than conventional ones (p <0.001).  | Effective. |

Table 18: Study characteristics and main findings: agitation and aggression (continued)

| Study*                                 | Design                    | n = | Intervention   | Outcome                           | Main findings  | Effective? |
|--|---------------------------|-----|--|-----------------------------------|--|------------|
| Holmes et<br>al. (2002).               | Crossover<br>RCT.         | 15  | Aromatherapy with lavender vapour vs. water vapour.                                      | Agitation.                        | Using the PAS in the final hour of 10 sessions, median behaviour scores were $20\%$ lower while exposed to lavender compared to water (p = 0.016).   | Effective. |
| Gerdner<br>(2000).                     | Crossover<br>RCT.         | 39  | Preferred music vs. classical music.   | Agitation.                        | Rates of agitated behaviours fell from baseline by 49% during classical music and 61% during individualised music. Specially chosen music proved superior to 'off the shelf music during the intervention and even 30 minutes later (p <0.0001).   | Effective. |
| Wells et al.<br>(2000).                | Cluster<br>RCT.           | 40  | Ability-focussed morning care vs. usual morning care:                                    | Agitation.                        | Scores on the PAS fell by 51% in the experimental group compared with an increase of 14% for controls (p = 0.02). Residents in the experimental group also showed better function (and their carers were more resident-focussed).  | Effective. |
| Ingersoll-<br>Dayton et<br>al. (1999). | Crossover<br>RCT.         | 21  | A solution-<br>focussed<br>approach with<br>family and<br>certificated<br>nursing aides. | Aggression<br>(and<br>'mastery'). | Significant decrease of frequency and severity of AB. Significant increase of 'mastery'.   | Effective. |
| Burns et al.<br>(2009).                | RCT.                      | 48  | Bright light therapy (BLT).  | Agitation.                        | Agitation improved in the immediate post-treatment phase in both the BLT and placebo group, but the between-group comparison was not significant at week four (p = 0.51) nor at week eight (p = 0.56). The change in agitation from baseline to four weeks was significantly negatively associated with day length in the BLT group (r = $-0.52$ , p = $0.013$ ), but not in the placebo group (r = $0.03$ , p = $0.90$ ). BLT may off-set the effects of reduced daylight hours and low light levels in rest home settings during winter, rather than being a treatment for agitation in people with dementia per se. | Uncertain. |
| Dowling et<br>al. (2007).              | RCT<br>(three<br>groups). | 70  | Bright light therapy (BLT): morning exposure vs. afternoon exposure vs. control.         | Agitation.                        | Significant differences between groups on agitation/aggression, however, actual changes in scores were less than 1 point on a 12-point scale. Doubtful that the differences found represent clinically meaningful changes.   | Uncertain. |
| Davison et<br>al. (2007).              | Crossover<br>RCT.         | 113 | Staff training<br>and peer<br>support.   | Agitation.                        | Changes in overall ratings of residents' behaviours following training (relative to the control group) approached but did not reach significance (p >0.05). No additional effect of peer support (relative to the training only group) on overall ratings of residents' behaviours (p >0.05).  | Uncertain. |

Table 18: Study characteristics and main findings: agitation and aggression (continued)

| Study*                       | Design   | n = | Intervention   | Outcome    | Main findings   | Effective?   |
|------------------------------|--|-----|--|------------|---|--------------|
| Kolanowski<br>et al. (2005). | Crossover<br>RCT.                                  | 30  | Recreation activities suited to interests and skills vs. recreation suited to interest only vs. skills only.                         | Agitation. | All treatment conditions worked better than baseline in reducing agitation (p <0.01) but none proved superior to another.   | Uncertain.   |
| Burgio et<br>al. (2002).     | Cluster<br>RCT.                                    | 79  | Behaviour<br>management<br>training with<br>continued<br>supervision vs.<br>behaviour<br>management<br>training without<br>continued | Agitation. | Agitated behaviours declined in both groups, but with no significant difference between-group differences. At six-month follow-up, the intensive supervision group showed superior skill retention.   | Uncertain.   |
| Remington<br>(2002).         | RCT.   | 68  | Baroque music<br>vs. HM vs.<br>music &<br>massage.   | Agitation. | When agitated behaviours were counted during treatments by trained observers, mean agitation counts fell from baseline by 50% with music tapes, 37% with massage and 61% with both. These differences were all statistically significant compared to baseline (p <0.01) but no treatment worked better than another.  | Uncertain.   |
| Hawranik et<br>al. (2008)    | RCT.<br>(Three<br>group,<br>repeated-<br>measures) | 51  | Therapeutic touch (TT) vs. sham therapeutic touch ('attention control') vs. 'usual care'   | Agitation. | The TT intervention did not have a greater influence on physically aggressive or verbally agitated behaviours than did the sham TT intervention or the 'usual care' group approach. The TT intervention did appear to be effective in reducing physically non-aggressive behaviours (only) compared to the 'usual care' condition (p <0.05, TT vs. 'usual care') but not the 'attention control' (sham TT). | Ineffective. |

Table 18: Study characteristics and main findings: agitation and aggression (continued)

| Study*                                | Design            | = u | Intervention  | Outcome   | Main findings  | Effective?   |
|---------------------------------------|-------------------|-----|---|---|--|--------------|
| Testad et<br>al. (2005).              | Cluster<br>RCT.   | 140 | Staff training.   | Agitation & aggression (also use of restraint). | No change in agitation score post-intervention (statistically significant reduction in the use of restraint in the treatment group vs. control, p = 0.013).  | Ineffective. |
| Ancoli-<br>Israel et al.<br>(2003).   | RCT.              | 92  | BLT morning<br>2500 Lx.   | Agitation.                                      | The mean agitation scores (as measured with CMAI & ARBS) for the experimental BLT group were not significantly different to the morning dim red light (control) group. Agitation was not ameliorated. However, the results indicated that BLT shifted the peak of the agitated behaviour (in time) and this might be generalisable to residents with milder forms of AD (but it is debatable whether or not this apparent shift is clinically useful). | Ineffective. |
| Baillon et<br>al. (2004).             | Crossover<br>RCT. | 20  | MSS vs.<br>reminiscence<br>therapy.   | Agitation.                                      | No differences in levels of agitation emerged, though some participants clearly responded positively to both treatments.   | Ineffective. |
| Schrijnema<br>ekers et al.<br>(2002). | Cluster<br>RCT.   | 151 | Staff training programme in emotion-oriented care (validation approach) vs. 'usual care'. | Agitation & aggression.                         | The results of multilevel analyses (overall, subgroup and per protocol) showed no statistically significant, nor clinically relevant effects in favour of the intervention group on the behavioural outcome measures.  | Ineffective. |
| Hopman-<br>Rock et al.<br>(1999).     | RCT.              | 134 | Psychomotor<br>activation<br>programme.   | Agitation<br>(and<br>cognition).                | No overall effect on behaviour (however a beneficial effect on cognition).   | Ineffective. |
| Camberg et<br>al. (1999).             | Crossover<br>RCT. | 54  | Family audiotape vs. neutral audiotape vs. placebo.                                       | Agitation.                                      | Overall, there were no differences in observed behaviours between the treatment, placebo and 'usual care' conditions.  | Ineffective. |

Study characteristics and main findings: agitation and aggression (continued) Table 18:

| Study*                     | Design   | = u       | Intervention  | Outcome  | Main findings   | Effective? |
|----------------------------|--|-----------|---|--|---|------------|
| Level III eviden           | ice: intervent                                     | tions for | Level III evidence: interventions for the management of agitati | of agitation a   | on and aggression.  |            |
| Gerdner et<br>al. (2008).  | Single<br>group<br>repeated-<br>measures.          | 11        | Touch therapy (using the craniosacral still point technique).   | Agitation.   | Reduction in mean modified CMAI total (p <0.001) and subscale scores (physically aggressive (p <0.01), non-aggressive (p <0.001), and verbal agitation (p <0.001) at post-test. Reduction continued through post-treatment period for physically nonaggressive agitation (p <0.001) and verbal agitation (p <0.001).  | Effective. |
| Davison et<br>al. (2007).  | Single<br>group<br>'before<br>and after'<br>study. | 31        | Individualised<br>psychosocial<br>interventions.                | Agitation.   | Overall, the frequency of behavioural symptoms among participants decreased significantly during the course of the study the mean CMAI score reduced from 80.68 (SD = 25.19) to 68.64 (SD = 19.94); p = 0.003). The CMAI indicated that the frequency of verbally agitated and aggressive behaviours declined significantly during the course of the intervention but no significant change in physically non-aggressive behaviours, or hiding and hoarding.                      | Effective. |
| Ziv et al.<br>(2007)       | Single<br>group<br>repeated-<br>measures.          | 28        | Music<br>(background).  | Agitation.   | Mean positive behaviours in the music group was $5.18$ (SD = $3.62$ ) compared to $1.36$ (SD = $2.08$ ) in the non-music group (p = $0.001$ ); mean negative behaviours in the music group was $2.43$ (SD = $3.2$ ) compared to $5.96$ (SD = $4.13$ ) in the non-music group (p = $0.001$ ). No difference in neutral behaviours.   | Effective. |
| Hicks-<br>Moore<br>(2005). | Single<br>group<br>repeated-<br>measures.          | 30        | Music (evening<br>meal times).                                  | Agitation.   | Relaxing music played at meal times was found to be effective in minimising the frequency of verbally agitated and physically non-aggressive behaviours.  | Effective. |
| DeYoung et<br>al. (2002).  | Single<br>group<br>repeated-<br>measures.          | 32        | Staff training (behaviour management programme (BMP)).          | Aggressive,<br>agitated, or<br>disruptive<br>behaviours. | Participation in the BMP decreased the total number and frequency of aggressive, agitated, or disruptive behaviours, with a significant decrease from the baseline to 6-month measurements. Seven behaviours were significantly reduced at 6 months. The interventions that were effective in reducing aggressive, agitated, or disruptive behaviours included: verbal distraction, time-out, activity diversion, getting to know the patient well, and managing the environment. | Effective. |
| Jennings & Vance (2002).   | Single<br>group<br>repeated-<br>measures.          | 16        | Music therapy.  | Agitation.   | Agitation was significantly reduced compared to the baseline measure. Specifically, music therapy reduced most types of agitation except for the majority of physical agitation such as hitting or spitting.  | Effective  |

Table 18: Study characteristics and main findings: agitation and aggression (continued)

| Study*                               | Design   | = u | Intervention   | Outcome                               | Main findings  | Effective?   |
|--------------------------------------|--|-----|--|---------------------------------------|--|--------------|
| Lee & Kim<br>(2008).                 | Single<br>group<br>repeated-<br>measures.                      | 23  | Indoor<br>gardening.   | Agitation (also sleep and cognition). | Significant improvements in agitation—the mean pre-intervention agitation score was 5.09 (SD = 2.76) and the post-intervention agitation score was 3.13 (SD = 2.30). The study did not use an 'attention control' condition; therefore it is possible that the reduction in agitation scores was confounded simply by the engagement of the residents in "meaningful activities".  | Uncertain.   |
| Churchill et<br>al. (1999).          | Single<br>group<br>'before<br>and after'<br>study.             | 28  | Dog therapy.   | Agitation (and socialisation).        | Significant decreases in agitation scores. However, there was no interaction between duration of interaction with the dog and agitation score changes and there was also no association between the severity of dementia and the presence of therapy dog.  | Uncertain.   |
| Buettner<br>(1999).                  | Crossover<br>RCT (at<br>the site<br>level: two<br>sites only). | 51  | Sensori-motor recreational activities programme (simple pleasures).                                | Agitation.                            | The authors found significant treatment and time effects in the study. At the intervention site, the mean agitation score was 2.30 at baseline and 1.30 following intervention and at the control site, the mean agitation score was 1.20 and remained at 1.25. There was insufficient information to judge the quality of this study: specifically, the randomisation process and scope for observation bias.                             | Uncertain.   |
| Ledger &<br>Baker<br>(2007).         | Two group<br>repeated-<br>measures.                            | 45  | Music therapy<br>(group).  | Agitation                             | Music therapy participants showed short-term reductions in agitation, but no significant differences between the groups in the range, frequency, and severity of agitated behaviours manifested over time.   | Ineffective. |
| Chrzescijan<br>ski et al.<br>(2007). | Single<br>group<br>'before<br>and after'<br>study.             | 43  | Staff education: 'understanding of the emotions and subsequent needs of the person with dementia'. | Aggression.                           | Aggression scores following the introduction of the intervention resulted in a lower mean frequency of episodes (32.23 vs. 28.09), but similar intensity (18.63 vs. 18.33) in aggression scores prior to the staff education. There was a sharp drop in aggression scores in the first two weeks following the education intervention, but the difference in the mean total aggression scores over time was not statistically significant. | Ineffective. |

Table 18: Study characteristics and main findings: agitation and aggression (continued)

| Study*                                     | Design   | n =    | Intervention  | Outcome         | Main findings  | Effective?   |
|--|--|--------|---|-----------------|--|--------------|
| Cohen-<br>Mansfield &<br>Jensen<br>(2006). | Single<br>group<br>'before and<br>after', non-<br>randomised<br>crossover. | 20     | Tailored self-<br>care<br>intervention.   | Agitation.      | Significantly more positive than negative responses but no effect on agitation. Mean agitation scores pre-intervention were 24.4 (SD = 6.07) and the post-intervention 24.7 (SD = 7.84), non-significant. Self-care practices can increase positive symptoms in residents with dementia. | Ineffective. |
| Leon and<br>Ory (1999).                    | Two group<br>"before and<br>after"<br>study.                               | 596    | SCUs in nursing homes vs. non-specialised units ('usual care').   | Aggression.     | SCUs appeared to have no effect on the frequency of AB. Increased use of psychotropic medications and reduced use of physical restraints show a relationship with lower CMAI physically aggressive behaviours subscale scores.   | Ineffective. |
| Level IV evider                            | nce: interventi  | ons fo | Level IV evidence: interventions for the management of agitation and aggression.                                | of agitation an | d aggression.  |              |
| Moniz-Cook<br>et al. (2001).               | ABA study<br>design.   | 4      | Individualised environmental modifications (simple changes to environmental triggers for aggressive behaviour). | Aggression.     | Reduction of AB in all cases. Treatment effects maintained at follow-up.   | Effective.   |
| Beshara &<br>Giddings<br>(2002).           | Case series<br>with<br>repeated-<br>measures.                              | 10     | Aromatherapy.   | Agitation       | Between baseline, 1 month, 3 months, and 6 months follow-up, there was a reduction in agitation scores for all residents.  | Effective.   |
|  |  |        |   |                 |  |              |

Study characteristics and main findings: agitation and aggression (continued) Table 18:

| Study*                          | Design  | ı. | Intervention  | Outcome                                    | Main findings                                      | Effective?   |
|---------------------------------|---|----|---|--|--|--------------|
| Buchanan<br>& Fisher<br>(2002). | Case<br>series with<br>repeated-<br>measures. | 2  | Behavioural management techniques/funct ional assessment/ non-contingent reinforcement. | Agitation/<br>disruptive<br>vocalisations. | Significant reduction in disruptive vocalizations. | Effective.   |
| Snow et al. (2004).             | Repeated-<br>measures<br>(ABCBA).             | 7  | Aromatherapy with lavender vs. thyme vs. grape seed oil (sachet worn by participant).   | Agitation.                                 | Total absence of treatment effect.                 | Ineffective. |

<sup>\* &#</sup>x27;No shading' in rows denotes studies appraised and reported within this review (n = 42).

'Grey shading' in rows denoted studies appraised and reported within previously published systematic reviews (n = 46).

Abbreviations: AD = Alzheimer's Disease, ARBS = Agitated behaviour rating scale, BLT = Bright light therapy, CANE = The Camberwell Assessment Questionnaire for the Needs in Elderly, CI = Confidence interval, CMAI = Cohen-Mansfield Agitation Inventory, DCM = Dementia Care Mapping, FVEP = Family Visit Education Program, PCC = Person-centred care, RAID = Rating for anxiety in dementia, RCC = Residential Care Centres, RCT = Randomised controlled trial, SCU = Special care unit, SD = Standard deviation, SPT = 'Simulated presence' tapes, TT = Therapeutic touch, UC = 'usual care', VT = Validation therapy.

Study characteristics and main findings: generalised BPSD outcomes Table 19:

| Study                                     | Design            | = u     | Intervention  | Outcome                                   | Main findings   | Effective? |
|---|-------------------|---------|---|---|---|------------|
| Level II evidenc                          | e: interventi     | ons for | Level II evidence: interventions for the management of generalised BPSD outcomes      | of generalised E                          | 3PSD outcomes   |            |
| Raglio et al.<br>(2008).                  | RCT               | 59      | Music therapy.  | BPSD.                                     | The NPI total score significantly decreased in the experimental group at 8th, 16th, and 20th weeks (p = 0.002). The effects persisted 4 weeks after treatment. Specific BPSD (ie, delusions, agitation, anxiety, apathy, irritability, aberrant motor activity, and night-time disturbances) significantly improved. In this study, Music therapy appeared to be effective in reducing BPSD in residents with moderate-severe dementia. | Effective. |
| Holmes et<br>al. (2006).                  | Crossover<br>RCT. | 64      | Music therapy –<br>live music vs.<br>pre-recorded<br>music vs.<br>silence.            | Apathy.                                   | Results for apathy (category E) on the DCM —greater positive engagement during live music than silence (p <0.01). Greater engagement during live music than pre-recorded music (p <0.01). Engagement during pre-recorded music was not significantly different than silence.  | Effective. |
| Finnema et<br>al. (2005).                 | Cluster<br>RCT.   | 194     | Integrated<br>emotion-<br>oriented care<br>vs. 'usual care'.                          | Behavioural<br>and mood<br>disturbances.  | Participants with mild and moderate severity of dementia benefited from emotion-focussed care, showing greater emotional adaptation than those in 'usual care'. No benefit over 'usual care' for participants with severe dementia.   | Effective  |
| Woods,<br>Craven, &<br>Whitney<br>(2005). | RCT three groups. | 57      | Therapeutic touch vs. placebo (placebo therapeutic touch) vs. control ('usual care'). | Behavioural<br>symptoms of<br>dementia    | Results indicated a significant difference in overall behavioural symptoms of dementia, manual manipulation and vocalization when the experimental group was compared to the placebo and control groups.  | Effective. |
| Spector et<br>al. (2003).                 | Cluster<br>RCT.   | 201     | Cognitive<br>stimulation.   | Quality of life (and cognitive function). | Significant improvements in quality of life—Alzheimer's disease scale scores (p = $0.028$ ) (also improved cognition via the MMSE [p = $0.044$ ] and the Alzheimer's disease assessment scale – cognition [p = $0.014$ ]).  | Effective. |

Table 19: Study characteristics and main findings: generalised BPSD outcomes (continued)

| Study                       | Design                         | II  | Intervention   | Outcome   | Main findings  | Effective?   |
|-----------------------------|--------------------------------|-----|--|---|--|--------------|
| Beck et al.<br>(2002).      | RCT.                           | 127 | Activities of daily living intervention vs. a psychosocial activity intervention vs. a combination of the two. | Disruptive behaviours and affect.   | Findings indicated significantly more positive affect but not reduced disruptive behaviours in treatment groups compared to control groups.  | Effective.   |
| Proctor et<br>al. (1999).   | Cluster<br>RCT.                | 120 | Staff training in behavioural intervention vs. no staff training (control sites).                              | Depression, behavioural disturbance, functional ability and (cognition).  | Residents in the intervention group had significantly improved scores for depression the before and after change difference was -0.5 (95% CI: -0.8 to -0.1) and for cognitive impairment was -0.7 (95% CI -1.1 to -0.2) but not for behaviour ratings.   | Uncertain +. |
| McCallion<br>et al. (1999). | RCT,<br>repeated-<br>measures. | 99  | Family visit education programme (FVEP) or 'usual care' (UC).  | Psychosocia<br>I functioning,<br>depression,<br>agitated<br>behaviour,<br>degree of<br>positive<br>social<br>interaction. | FVEP was effective for reducing residents' problem behaviours and for decreasing their symptoms of depression and irritability. It was also effective for improving the way family members and other visitors communicated with residents, but, with the exception of reducing the use of mechanical restraints, it was not effective in changing nurses' management of residents' behaviour problems. | Uncertain.   |

Table 19: Study characteristics and main findings: generalised BPSD outcomes (continued)

| Study                           | Design                        | n = | Intervention  | Outcome   | Main findings   | <b>Effective?</b>        |
|---------------------------------|-------------------------------|-----|---|---|---|--------------------------|
| Kolanowski<br>et al. (2001).    | Crossover<br>RCT.             | 10  | Tailored therapeutic recreational activities.   | BPSD:<br>engagement,<br>affect, mood,<br>agitation.   | During treatment, the activities resulted in greater subject engagement (p = 0.04) and more displays of positive affect during the activity sessions (p = 0.05), compared with control activities; however, the effects were not apparent following the sessions. For agitation, the mean score for the intervention group was $3.4$ (SD = $5.2$ ) and for the control group, $4.6$ (SD = $5.0$ ), $p = 0.32$ . Most of the outcomes measured had trended in the favourable direction but the small sample size probably limited the demonstration of statistically significant findings. | Uncertain                |
| Buettner & Fitzsimmon s (2002). | RCT                           | 70  | Therapeutic biking (15 minutes, 5 days a week).   | Agitation & depression.                               | Significant reduction in depression at 10-week follow-up, but no significant effects on agitation.  | Uncertain.               |
| Magai<br>(2002).                | Cluster<br>RCT.               | 91  | Carer training (manualised) vs. behavioural placebo vs. control (waitlist)  | BPSD:<br>behaviour,<br>affect.                        | No differences in behaviours between groups. Positive affect increased sharply during the first six weeks following non-verbal sensitivity training (p < .05), but no differences between groups remained by 12 weeks.  | Uncertain                |
| Baker et al.<br>(2003).         | RCT.                          | 127 | MSS<br>(Snoezelen)<br>vs. activity<br>session.  | BPSD:<br>behaviour<br>and mood<br>(and<br>cognition). | Neither treatment changed staff ratings of behaviour during or after treatment.   | Ineffective.             |
| Orrell et al. (2007).           | Cluster<br>RCT (24<br>sites). | 237 | Liaison intervention: including a comprehensive assessment (CANE) covering 24 areas of social, medical, psychological, and environmental needs. | BPSD and quality of life.                             | The liaison intervention did not significantly reduce total unmet needs relative to the control group. However, unmet needs such as sensory problems, mobility, drugs, and psychological distress were reduced in the intervention group at follow-up. The CANE assessment may have led to unmet needs being reduced at follow- up in both groups.  | lneffective/un<br>clear. |

Table 19: Study characteristics and main findings: generalised BPSD outcomes (continued)

| Study                      | Design   | 11      | Intervention   | Outcome   | Main findings   | Effective?   |
|----------------------------|--|---------|--|---|---|--------------|
| Kotynia et<br>al. (2005).  | RCT.   | 106     | Early<br>psychiatric<br>case<br>management.  | BPSD.   | 12-month programme, no statistically significant difference was found ameters used to determine the BPSD outcomes.  | Ineffective. |
| Lyketsos et<br>al. (1999). | Crossover<br>RCT.  | 15      | Bright light therapy (Morning BLT at 10 000 Lx).   | BPSD: Sleep<br>architecture,<br>behaviour<br>and<br>depression. | BLT did not lead to improvements in agitated behaviours and depression in institutionalised patients with dementia with non-disturbed sleep-wake cycles. However, residents in the BLT condition exhibited statistically significant improvements in noctumal sleep from a mean of 6.4 hrs/night to 8.1 hrs night four weeks later.   | Ineffective. |
| Level III eviden           | ice: interventic   | ons for | Level III evidence: interventions for the management of generalised BPSD outcomes  | t of generalised  | BPSD outcomes   |              |
| Bird et al. (2007).        | Two group non- randomised controlled clinical trial with repeated- measures. | 33      | A tailored package of psychosocial interventions using a causality-focussed approach vs. 'usual care', based mainly on psychotropic medications. | BPSD.   | This trial did not involve a comparison of a specific treatment but rather, a clinical approach. Measures of behaviour and staff response showed significant improvement in both groups at 2- and 5-months' follow-up. However, there was no difference between the groups. Antipsychotic use in the intervention group decreased over time while in the control group it increased. Both approaches produced equivalent improvements in resident-level outcomes: the differences were mainly in human and financial costs. | Effective    |

Study characteristics and main findings: generalised BPSD outcomes (continued) Table 19:

| Study                          | Design  | = u | Intervention   | Outcome  | Main findings  | Effective? |
|--------------------------------|---|-----|--|--|--|------------|
| Tondi et al.<br>(2007).        | Two group<br>before and<br>after' study.        | 50  | Validation therapy (VT).   | Neuropsychia<br>tric<br>symptoms.                  | Overall, the results show a marked decrease of the average NPI symptom score in the intervention group (from 22.0 to 9.5) compared to a rise in the control group (from 21.7 to 24.1). Agitation, apathy, irritability and night-time behaviours were the most improved NPI items among the residents who underwent the VT. However, no estimate of statistical precision was given. | Effective  |
| Galik<br>(2008).               | Single<br>group<br>repeated-<br>measures.       | 94  | Restorative care (a staff training programme based on social cognitive theory and additional supervision). | Functional performance, activity, mood, agitation. | There was significant improvement in resident mood (p = 0.02) and behavioural symptoms (p = 0.04), but no significant change in physical function or overall reported physical activity.   | Effective. |
| Chenoweth<br>& Jeon<br>(2007). | Single<br>group<br>'before and<br>after' study. | 35  | DCM.   | Agitation, disruption and depression.              | For all residents taken together, there was a significant reduction in agitation (change in agitation score -11.94; SD = $23.1$ ; p = $0.04$ ), a trend towards reduced depression (change -2.65; SD = $7.11$ ; p = $0.06$ ) but little change in disruption scores. DCM may be effective in improving agitation profiles of residents.  | Effective  |
| Van Weert<br>et al. (2005).    | Single<br>group with<br>repeated-<br>measures.  | 125 | Snoezelen.   | Agitation,<br>depression,<br>apathy.               | Residents receiving Snoezelen demonstrated a significant reduction in agitation on the CMAI aggressive behaviour scale (34% reduction in the experimental group vs. 32% increase in the control group). There was also, a significant treatment effect with respect to their level of apathetic behaviour, loss of decorum, and depression.  | Effective. |
| Shalek et<br>al. (2004).       | Single<br>group with<br>repeated-<br>measures.  | 20  | Air mat<br>therapy.  | Wandering.   | Air mat therapy reduced agitated wandering and agitation pre- and post- intervention.<br>An overall effect on agitation was demonstrated after 10 days air mat therapy.  | Effective. |

Study characteristics and main findings: generalised BPSD outcomes (continued) Table 19:

| Study                           | Design   | = u | Intervention  | Outcome  | Main findings  | Effective? |
|---------------------------------|--|-----|---|--|--|------------|
| McCabe et<br>al. (2002).        | Single<br>group<br>repeated-<br>measures.          | 22  | Dog therapy.  | BPSD.  | A sustained decrease over 4 weeks in behavioural problems during the day shift (intervention condition). However, this study was open to observation bias, and few individuals were studied.   | Effective  |
| Kim and<br>Buschmann,<br>(1999) | Single<br>group<br>repeated-<br>measures.          | 29  | Expressive physical touch with verbalisation.                   | Behaviour<br>and anxiety.  | Improvement in behaviour during intervention and for 5 days afterward but only short-term reductions in anxiety.   | Effective  |
| Choi et al.<br>(2009).          | Single<br>group<br>'before<br>and after'<br>study. | 20  | Music therapy<br>(group).                                       | Agitation,<br>aggression,<br>depression,<br>and apathy.          | Statistically significant differences in the change scores between the intervention and the control groups for agitation. However, there were no other statistically significant differences in any of the other scores (although there were, in general, improvements in other behavioural outcomes). | Uncertain. |
| Sherratt et<br>al. (2004).      | Single<br>group<br>repeated-<br>measures.          | 24  | Live music vs.<br>recorded<br>music vs.<br>commercial<br>music. | BPSD: well-being, engagement, challenging behaviours, wandering. | Engagement and well-being were highest when music was played live (p <0.01), and rates of meaningless behaviour and sleep were lowest (p <0.01), however counts of wandering and other challenging behaviours were similar across all conditions.  | Uncertain. |
| McGilton et<br>al. (2003).      | RCT.   | 32  | Location map<br>and a<br>behavioural<br>training<br>technique.  | Wandering.   | Compared to controls, residents in the treatment group demonstrated an increased ability to find their way to the dining room 1 week after the intervention. The intervention effect was not sustained three months later.   | Uncertain. |

Study characteristics and main findings: generalised BPSD outcomes (continued) Table 19:

| Study                    | Design   | = u | Intervention   | Outcome   | Main findings  | Effective?   |
|--------------------------|--|-----|--|---|--|--------------|
| Snyder et<br>al. (2001). | Single<br>group<br>repeated-<br>measures.                                  | 30  | A glider swing.  | Emotions,<br>relaxation,<br>and AB.                         | The results of the study indicate that the glider intervention significantly improved emotions and relaxation. The most noted changes were found after 10 minutes of swinging. However, no differences were found in AB.   | Uncertain.   |
| Warren et<br>al. (2001). | Two group non-randomised controlled clinical trial with repeated-measures. | 80  | Residential care centres (RCCs) vs. special care units (SCUs). | Physical, cognitive, behavioural and emotional functioning. | The results did not demonstrate significant between-group differences in the decline of functional levels of the residents in the two models of care. There was a minor benefit in mood profile of the residents in the RCC. In general, while the RCC residents showed slightly better outcomes compared to SCUs, their overall rates of decline were similar with the residents at SCUs. Power to detect differences in the outcomes of possible clinical significance was limited by the small sample size. | Uncertain.   |
| Bowles et<br>al. (2002). | Two group<br>'before and<br>after' study.                                  | 56  | Aromatherapy<br>& touch.                                       | BPSD.   | The results did not demonstrate significant between-group differences. During the period of oil application, both groups showed a significant decrease in the average frequency and severity of dementia-related behaviours occurring at times other than during nursing care, compared to the control condition.  | Ineffective. |

Study characteristics and main findings: generalised BPSD outcomes (continued) Table 19:

|                   | )                      |         |  | )                   |   |            |
|-------------------|------------------------|---------|--|---------------------|---|------------|
| Study             | Design                 | = u     | n = Intervention   | Outcome             | Main findings   | Effective? |
| Level IV evider   | nce: intervent         | ions fo | Level IV evidence: interventions for the management of generalised BPSD outcomes | nt of generalisec   | BPSD outcomes   |            |
| Heard &<br>Watson | Case<br>series,        | 4       | Individual<br>behavioural  | Wandering.          | Individualised interventions reduced wandering.   | Effective. |
| (1999).           | repeated-<br>measures. |         | intervention<br>programmes.  |                     |   |            |
| Cornell (2004)    | Case<br>series,        | 4       | Snoezelen.   | Mood,<br>behaviour, | The results indicated an overall positive mood/behaviour change lasting 30 minutes after the end of the Snoezelen session for all residents. However, the benefits of   | Uncertain. |
|                   | before and after.      |         |  | anxiety,<br>general | 'before', 'during' and 'after' Snoezelen sessions showed no increase over the eight sessions indicating that the benefits of the Snoezelen sessions were not long-term. |            |
|                   |                        |         |  | happiness           | The quality of evidence is low.   |            |
|                   |                        |         |  | and<br>confusion.   |   |            |
| Deguchi et        | Case                   | 10      | Bathing  | BPSD.               | Four out of 10 participants had reduced aggression, 5 out of 10 participants had  | Uncertain. |
| al. (2000)        | series,                |         | routines: night-   |                     | reduced restlessness, and sleeplessness had reduced the most. This limited evidence   |            |
|                   | 'before and            |         | time vs.   |                     | suggests night time bathing may be effective but the quality of evidence is low.  |            |
|                   | after'.                |         | afternoon.   |                     |   |            |

\* 'No shading' in rows denotes studies appraised and reported within this review (n = 42).

'Grey shading' in rows denoted studies appraised and reported within previously published systematic reviews (n = 46).

Abbreviations: AD = Alzheimer's disease, ARBS = Agitated behaviour rating scale, BLT = Bright light therapy, CANE = The Camberwell Assessment Questionnaire for the Needs in Elderly, CI = Confidence interval, CMAI = Cohen-Mansfield Agitation Inventory, DCM = Dementia Care Mapping, EVEP = Family Visit Education Program, PCC = Person-centred care, RAID = Rating for anxiety in dementia, RCC = Residential Care Centres, RCT = Randomised controlled trial, SCU = Special care unit, SD = Standard deviation, SPT = 'Simulated presence' tapes, TT = Therapeutic touch, UC = 'usual care', VT = Validation therapy.

Table 20: Study characteristics and main findings: anxiety, depression or apathy

| Study                     | Design  | n =    | Intervention  | Outcome   | Main findings  | Effective?   |
|---------------------------|---|--------|---|---|--|--------------|
| Level II evident          | ce: interventio                                 | ons fo | Level II evidence: interventions for the management of anxiety, depression or apathy  | t of anxiety, dep   | ession or apathy   |              |
| Hodgson et<br>al. (2008). | Crossover<br>RCT with<br>repeated-<br>measures. | 21     | Reflexology.  | Affect, stress<br>(salivary<br>alpha-<br>amylase),<br>pain. | When receiving the reflexology treatment condition, as compared to the control condition, the residents demonstrated a significant reduction in observed pain (p = 0.031) and in the bio-marker salivary alpha-amylase (p = 0.049); however there were no significant changes in affect in either group. No adverse events were recorded during the study period.  | Effective.   |
| Riemersma et al. (2008).  | Cluster<br>RCT<br>2 x 2<br>factorial<br>design. | 46     | BLT. All day bright light of ±1000 Lx via ceiling-mounted lights in common area vs. dim light (300 Lx) both with evening melatonin 2.5 mg or placebo. | BPSD: agitation, depression, sleep (and cognition).         | The results indicated that all-day BLT may have a modest benefit in improving some cognitive and non-cognitive symptoms of dementia. Melatonin adversely affected scores for positive affect and negative affect and melatonin also increased withdrawn behaviour, although these effects were not seen if given in combination with light.  | Uncertain.   |
| Politis et al.<br>(2004). | RCT.  | 37     | Reminiscence based activity 'kit' vs. 'one-one' attention control'.   | Apathy.   | Results showed a significant reduction in apathy scores in both treatment groups. Despite the substantial improvement in apathy scores during the course of the study, there was no clear advantage to the reminiscence-based intervention and that the 'kit' activity as the 'one-on-one' control activity had comparable efficacy. The 'one-on-one' control may have provided more actual social contact than the scripted, and hence somewhat impersonal, 'kit' intervention. | Uncertain +. |
| Brodaty et<br>al. (2003). | RCT.  | 98     | Psychogeriatric case management vs. specialist psychogeriatric consultation vs. standard care.  | Depression<br>and<br>psychosis.                             | There were no significant between-group differences for any outcome measure. All three groups improved from pre-treatment to post-treatment on depression scales for depression groups and psychosis scales for psychosis groups. There may have been 'leakage' of the intervention elements between the groups (ie unintentional generalisation of active intervention techniques to control participants).   | Uncertain.   |

Table 20: Study characteristics and main findings: anxiety, depression or apathy (continued)

| Study                     | Design                                    | = u    | Intervention  | Outcome                  | Main findings  | Effective?   |
|---------------------------|---|--------|---|--------------------------|--|--------------|
| Hickman et<br>al. (2007). | Cluster,<br>crossover<br>RCT.             | 99     | Bright light therapy (BLT): morning bright ight vs. evening bright light vs. standard light, implemented in the common areas. | Depression.              | Significant gender differences were found in depression scores in response to evening light (p = 0.003), all-day light (p = 0.001), and standard light (p = 0.001). Morning light appeared to have the greatest effect on both genders: in response to morning light, women's depressive symptoms decreased approximately 25%, whereas men's depressive symptoms increased approximately 50%. The unexpected findings do not support the use of ambient BLT as a treatment for depressive symptoms in persons with dementia. | Ineffective. |
| Level III evide           | ence: interve                             | utions | Level III evidence: interventions for the management of   |                          | anxiety, depression or apathy  |              |
| Cheston et<br>al. (2003). | Single<br>group<br>repeated-<br>measures. | 42     | Group<br>psychotherapy.   | Anxiety &<br>depression. | Results showed a statistically significant treatment effect for Cornell depression scores which was maintained at follow-up and a similar reduction in anxiety as measured by the rating for anxiety in dementia (RAID) which was borderline for significance. Group psychotherapy is not indicated for all individuals with dementia.   | Effective    |
| Brooker et<br>al. (2007). | Single<br>group<br>repeated-<br>measures. | 127    | Individualised<br>case<br>plan/activities.  | Anxiety &<br>depression. | There was a significant reduction in levels of depression. No significant changes in anxiety, health status, hospitalisations, or psychotropic medication usage were observed.   | Effective    |
| Cohen et al. (2009).      | Three<br>group<br>repeated-<br>measures.  | 33     | A novel therapeutic game vs. usual visits by family members vs. playing another game or reading.                              | Mood and depression.     | Reductions in signs of depression/sadness using the game were statistically significant. An increase in residents' pleasure was highly significant (p <0.0001). Each condition lasted for a period of only five minutes and was videotaped for later assessment. The effects of the intervention (if any) beyond the period of observation/engagement with the game are not known.   | Uncertain.   |
| Ashida<br>(2000).         | Single<br>group<br>repeated-<br>measures. | 20     | Reminiscence-<br>based group<br>music therapy<br>sessions.  | Depression.              | Group music therapy sessions reduced depressive symptoms during and after therapy, but no lasting effect.  | Uncertain.   |

Study characteristics and main findings: anxiety, depression or apathy (continued) Table 20:

| Study           | Design          | = u     | Design n = Intervention Outcome Main findings | Outcome         | Main findings  | Effective? |
|-----------------|-----------------|---------|---|-----------------|--|------------|
| Level IV evider | nce: interventi | ons for | the management                                | of anxiety, dep | Level IV evidence: interventions for the management of anxiety, depression or apathy   |            |
| Cheston et      | Case series     | 9       | Simulated                                     | Distressed      | The findings suggest that 'simulated presence' tapes (SPT) may reduce levels of        | Effective  |
| al. (2007).     | with            |         | presence.                                     | and pro-        | distress in people with moderate levels of dementia, and in particular those residents |            |
|                 | repeated-       |         |   | social          | who ask to leave for home. The reductions in distressed behaviour did not generalise   |            |
|                 | measures.       |         |   | behaviour.      | beyond the end of the tape.  |            |
| Kraus et al.    | Case series     | 2       | Cognitive                                     | Anxiety.        | The results showed 'clinically meaningful' changes in levels of anxiety.               | Uncertain. |
| (2008).         | with            |         | behavioural                                   |                 |  |            |
| `               | repeated-       |         | therapy.                                      |                 |  |            |
|                 | measures.       |         |   |                 |  |            |

<sup>\* &#</sup>x27;No shading' in rows denotes studies appraised and reported within this review (n = 42).

'Grey shading' in rows denoted studies appraised and reported within previously published systematic reviews (n = 46).

Abbreviations: AD = Alzheimer's Disease, ARBS = Agitated behaviour rating scale, BLT = Bright light therapy, CANE = The Camberwell Assessment Questionnaire for the Needs in Elderly, CI = Confidence interval, CMAI = Cohen-Mansfield Agitation Inventory, DCM = Dementia Care Mapping, FVEP = Family Visit Education Program, PCC = Person-centred care, RAID = Rating for anxiety in dementia, RCC = Residential Care Centres, RCT = Randomised controlled trial, SCU = Special care unit, SD = Standard deviation, SPT = 'Simulated presence' tapes, TT = Therapeutic touch, UC = 'usual care', VT = Validation therapy

# **Summary of interventions for the management of AGITATION** or **AGGRESSION**

This group includes all of the eligible studies that were identified involving the management of agitation and aggression as symptoms of dementia. Nine of nineteen studies (47%) were RCTs and the remainder were either 'before and after' trials (including repeated-measures designs) or case series with repeated-measures.

Effective interventions – compared to 'usual care' or placebo or no specified treatment

PERSON-CENTRED CARE

AGITATION/AGGRESSION - EFFECTIVE - LEVEL II EVIDENCE

Chenoweth et al. (2009) asserted that evidence for improved outcomes for people with dementia through provision of person-centred care and dementia-care mapping was largely observational. Based on earlier work (Chenoweth & Jeon, 2007), Chenoweth et al. (2009) conducted a large cluster randomised controlled trial (C-RCT) involving 324 residents in 15 centres in Australia, with the overall aim of comparing Person-Centred Care (PCC), DCM, and 'usual care'. Chenoweth et al. (2009) aimed broadly to establish whether DCM improved residents' quality of life, tended to reduce drug usage, and was cost effective. Sites were randomly assigned by the study statistician (blinded allocation) to either DCM versus PCC, DCM versus 'USUAL CARE', or PCC versus 'usual care'. Broadly, carers received training and support in either DCM or PCC interventions or continued 'usual care'. DCM elements included staff training in identifying factors related to resident well-being and positive and negative care delivery, observation data were reported back to nurses within 24 hours of mapping, and based on these observations, care plans were developed then implemented with support from researchers. The person-centred care intervention involved training staff in a range of elements including 'behaviour as communication', acknowledgment of feelings, feelings as expressions of needs for care, contributions of staff actions to resident behaviour and included a review of residents' life histories and information on how to develop effective care practices. The outcomes included measures of quality of care as well as agitation via the CMAI. Measurements were taken at baseline (pre-intervention), after four months of intervention, and after four months of follow-up. Three assistants collected agitation, depression and quality of life data by direct observations (using the CMAI, GDS, and quality of life in late-stage dementia (QALID) scales respectively) and possible confounding or bias was adjusted for by multivariate analysis. Group differences were analysed across the three time points: baseline, four and eight weeks.

Compared to 'usual care', and based on a model adjusted for baseline CMAI, agitation of residents was significantly lower in sites providing DCM (mean difference 10.9 points, 95% CI: 0.7-21.1) and PCC (mean difference 13.6, 95% CI: 3.3-23.9, p = 0.01) at follow up, relative to 'usual care' sites. However, there was no statistically significant difference between PCC and DCM. Thus it appears that PCC was more effective in reducing aggression/agitation compared to DCM. Chenoweth et al. (2009) suggested that individually tailored behavioural interventions are the most "promising" treatments. The authors concluded that the DCM approach was less

personal compared to the direct personal involvement in PCC, and Chenoweth et al. (2009) recommended PCC over DCM.

### **MUSIC AND MASSAGE**

AGITATION/AGGRESSION - EFFECTIVE - LEVEL II EVIDENCE

Hicks-Moore and Robinson (2008) conducted a small three group repeatedmeasures RCT to evaluate the effectiveness of relaxation techniques such as music and massage, to decrease agitation and improve quality of life in individuals with dementia. Forty-one people with mild to moderate dementia residing in three SCUs participated in a study to test the effectiveness of favourite music (FM) and hand massage (HM) in reducing agitated behaviours. Agitated residents were randomly assigned to either the treatment or control groups. Residents in the treatment group received each of three treatments, HM, FM, or HM and FM together, with each treatment assigned in random order, and each lasting ten minutes. For the FM intervention, compact discs were produced with each participant's FM and the music was played at a low enough volume to allow for other conversations. The HM intervention involved five minutes of massage given to each hand—slow strokes, light pressure, even rhythm to back, palm, fingers, thumb. For the HM and FM intervention, both HM and FM were administered simultaneously. Residents in the control group received no treatment. Agitation was measured by a non-blinded research assistant using the CMAI at three different intervals: at baseline before any hand message or FM was played, immediately following treatment, and one hour post treatment. Hicks-Moore and Robinson (2008) reported no significant differences in aggression scores over time or across the three treatment types, and no significant interaction between treatment type and time. Although the outcome assessment was non-blinded, and therefore open to observation bias, the results did show a significant reduction in verbally agitated behaviour over time and a significant reduction in nonverbal aggression over time, but not across the three different treatment modalities. Compared to no treatment, all three treatments (HM, FM and the massage/music combination) showed a significant decrease in agitation scores over time (p <0.05). Hicks-Moore and Robinson (2008) concluded that FM and HM individually and combined are effective in significantly decreasing agitation immediately following the intervention and also one hour post-intervention.

### INDIVIDUALISED MULTI COMPONENT

AGITATION/AGGRESSION - EFFECTIVE - LEVEL II EVIDENCE

Cohen-Mansfield et al. (2007) conducted a large, cluster randomised, placebo-controlled evaluation of systematic individualised non-pharmacological interventions for reducing agitated behaviours in nursing home residents with dementia. The participants were 167 (n = 89 intervention versus n = 78 control) elderly nursing home residents (mean age 86 years, range 59–103 years) with dementia (diagnosis by DSM-IV or ICD-10 criteria) residing in one of 12 nursing home buildings. Observations of agitation were recorded by trained research assistants via Cohen-Mansfield's ABMI (1989) and in addition, positive and negative affect was evaluated based on direct observation. Participants in the experimental group received multicomponent interventions that were tailored to the individual profiles of agitated participants using a systematic algorithm that considered type of agitation and unmet needs. This approach, 'treatment routes for exploring agitation' (TREA) was provided for ten days during the four hours of greatest agitation and the component activities included: music, family videotapes and pictures, illustrated magazines and large print books, board games and puzzles, plush toys, sorting cards with pictures and words,

stress balls, baby dolls, electronic massagers, pain treatment, outdoor trips to the nursing home garden, perfume, a 'busy apron', building blocks, and Play-Doh. A placebo intervention was provided for the control buildings in the form of an educational presentation that described the different syndromes of agitation, their aetiologies, and possible non-pharmacological treatments. Results were analysed via repeated-measures analyses of covariance (ANCOVAs).

The implementation of personalised, non-pharmacological interventions resulted in statistically significant decreases in overall agitation in the intervention group relative to the control group from baseline to follow-up. Specifically, ABMI scores decreased from 5.05 (SD = 3.36) to 4.10 (SD = 3.47) in the control group and 5.17 (SD = 3.75) to 3.23 (SD = 3.16) in the intervention group (a significant between-group difference, p = 0.002). In addition, implementation of individualised interventions for agitation resulted in statistically significant increases in pleasure and interest (p <0.001). The authors concluded that the findings support the use of individualised non-pharmacological interventions to treat agitation in persons with dementia. However, they acknowledge the limitation that the interventions were delivered by research staff, not trained rest-home staff, and this may represent optimal rather than typical implementation.

### **ADVANCED ILLNESS CARE TEAM**

AGITATION/AGGRESSION - EFFECTIVE - LEVEL II EVIDENCE

Chapman and Toseland (2007) conducted a crossover RCT to evaluate an Advanced Illness Care Team (AICT) intervention. The hypothesis for this study was that nursing home residents assigned to the AICT intervention would experience statistically significant decreases in pain, depression, and agitation as compared with residents assigned to the 'usual care' condition. The participants were residents (n = 118; 60 intervention, 58 control) with moderate to severe dementia, from five units in two large nursing homes in a major metropolitan area in the north-eastern United States. The homes were private, not-for-profit, skilled nursing facilities. The intervention group received care from advanced illness care teams comprising members from the disciplines of medicine, nursing, social work, psychology, physical and occupational therapy, and nutrition. AICTs used a holistic approach that addressed four domains of care: medical issues; meaningful activities; psychological problems; and behavioural concerns. Each of the teams met five times (weeks one, two, three, five, and eight) during the eight-week intervention period. Residents in the control group received all the services typically provided by the facility, including medication management and monitoring, ongoing nursing care, social-recreational activities, pastoral care as appropriate, occupational and physical therapies when medically indicated, and social work services (such as educational and emotionally supportive contact with residents and their families). Outcome data were collected during a two-week baseline period and within two weeks after the end of the eight-week intervention by social work staff (it was unclear how these staff were, or were not involved in the study). Intervention group residents experienced a significantly greater decrease in physically nonaggressive behaviours (only), compared to 'usual care' residents ( $p \le 0.01$ ). All CMAI subscales showed a significant time effect over the two-month intervention period (p < 0.01) and intervention group residents had greater reductions in their agitation scores than 'usual care' residents, but these differences were not statistically significant. There was also a significant decrease in mean pain and depression scores for residents in both conditions, however, between-group differences were not statistically significant. The authors claimed that the results of the study provided

some support for the hypothesis that residents receiving the AICT intervention would experience significant decreases in pain, depression, and agitation. However, the effect sizes were small. The analysis showed significant changes in all three CMAI subscales over time for residents in the intervention group and the control group and this may indicate a spill-over of treatment effects to the control group. Cluster randomisation may have prevented the suspected contamination of the control group, and blinded outcome assessment should have been implemented to reduce bias. These findings illustrate the difficulty in conducting well-controlled research in the nursing home setting.

### **ACUPRESSURE**

AGITATION/AGGRESSION - EFFECTIVE - LEVEL | | EVIDENCE

Yang et al. (2007) conducted a small crossover randomised pilot study to assess the efficacy of acupressure for decreasing agitated behaviours in dementia. The participants were twenty residents in a nursing home caring specifically for people with dementia, and all had clinical diagnoses of dementia and exhibited severe agitation as measured by the CMAI at baseline. Individual treatments of acupressure lasted 15 minutes, and occurred twice a day, five days a week, for four weeks. The treatments were conducted by a researcher with two years of clinical experience and Chinese medicine nursing and acupressure training credits. Validity was assessed by five traditional Chinese medicine specialists via assessment of the precision of acupoint direction, consistency of the applied pressure and expert evaluations about the suitability of the protocol. The 'attention control' protocol entailed the principal investigator going into the room, greeting residents and then sitting and talking with them for 15 minutes. After a treatment-free period of one week, all the subjects 'crossed-over' and served as controls. Outcomes measured included agitation, wandering and ease of care. The CMAI was used to measure agitation, divided into non-physical and physical attacks, non-verbal attacks and verbal attacks. Wandering was measured by pedometer and a subjective assessment of ease of care was conducted using an ease-of-care inventory scale ranging from (1) very difficult, to (5) very easy. A paired t-test was used to compare the difference of behaviour changes between the acupressure period and the control period. Repeated-measures were used to compare the difference of daily agitation behaviours during the acupressure and control protocols. Comparison between the control and experimental phases indicated significant differences between the two groups on all outcome measures. For agitation, scores on the CMAI decreased in the acupressure group from 79.3 (SD = 16.74) at baseline to 59.85 (SD = 9.63) post-test and increased in the control from 72.4 (SD = 12.76) to 74.55 (SD = 9.96) and this between-group difference was significant (p <0.001). The severity of wandering decreased post-test revealing a modest effect on wandering participants (5368 steps per day pre-test to 3374 steps per day post-test). Yang et al. (2007) concluded that acupressure is an efficacious and non-intrusive method for decreasing the agitation behaviours in people with dementia. The acupressure protocol used in this study required a highly trained therapist to deliver 15 minutes per treatment, twice daily to participating residents. It could be argued that this may not be feasible for nursing staff in typical residential care settings. Further, although the study utilised an 'attention control' condition, the study does not illuminate the unique benefits (if any) of acupressure, specifically, as compared with simple touch or relaxing massage. Notwithstanding these possible limitations, acupressure could provide carers with a viable alternative to use with residents with dementia.

#### INDIVIDUALISED PSYCHOSOCIAL

AGITATION/AGGRESSION - EFFECTIVE - LEVEL III-3 EVIDENCE

Davison et al. (2007) conducted a small preliminary study to evaluate the impact of individualised psychosocial interventions for the alleviation of behavioural symptoms in dementia. Interventions were delivered to a resident group of 31 psychogeriatric aged care residents (MMSE score 10.2, SD = 9.42) who presented with a mean of 2.6 (SD = 1.3) behavioural symptoms of dementia and had failed to respond to pharmacological treatment approaches. Outcome data on severity of behaviours, health service utilisation and staff burden of care were collected. Agitation was assessed at baseline and post-intervention using the CMAI as completed by facility staff. The intervention involved a specialist psychosocial team consisting of two psychiatric nurses and two clinical psychologists. The duration of the involvement of this team ranged from 47 to 231 days, with a median time of 90 days. Intervention components were based on the behaviour therapy model, specifically; approaches to psychological problems based primarily on Pavlovian (classical) and Skinnerian operant conditioning and the 'needs deficit' model (ie all behaviour serves a function, typically being an attempt to fulfil an unmet need). Staff ratings of the overall frequency of behavioural symptoms among participants decreased significantly during the course of the study (mean CMAI score reduced from 80.68(SD = 25.19) to 68.64(SD = 19.94); p = 0.003). Examination of the individual subscales of the CMAI indicated that the frequency of verbally agitated and aggressive behaviours declined significantly during the course of the intervention. However, there was no significant change in the frequency of physically non-aggressive behaviours, or hiding and hoarding behaviours. Davison et al. (2007) concluded that the modest but significant reduction in staff ratings of the severity of aggressive and verbally agitated behavioural symptoms supported the use of individualised psychological strategies for behavioural symptoms at all stages of dementia.

### MUSIC (BACKGROUND)

AGITATION/AGGRESSION - EFFECTIVE - LEVEL III-3 EVIDENCE

Ziv et al. (2007) investigated the effect of background music on behaviour in people with Alzheimer's disease. Previous studies have focussed either on improvement of cognitive and social skills, or reduction of agitation symptoms. This study focussed on the effect of background music on both positive and negative behaviours, during a time in which residents were not occupied with any structured activity. The study involved 28 participants with medium-advanced cognitive decline (MMSE < 11) from one nursing home, in a one-sample repeated-measure intervention trial. The intervention, music therapy, consisted of background music played from a specially prepared 17 minute compilation disc with six popular 'upbeat' and well known songs from 1964, assumed to be familiar to all participants. Subjects acted as their own controls and the music condition was compared with a 'no music' control condition. Multiple baseline observations (repeated in four consecutive weeks) and treatment and control observations (over three consecutive weeks) were conducted using a momentary time sampling technique. This technique, commonly used in social science studies, involves trained observers being prompted by an audio tape to observe and record behaviours at pre-determined intervals (in this case one minute intervals followed by 30 seconds to categorise and record the behaviour). The measurement instrument was a customised score sheet based on the three following outcomes: positive behaviours (including contact, laughing, smiling, calming other, singing, humming, drumming, rocking, shaking hands, touching); negative behaviours

(including agitation, vocal repetition, rising, manipulation of objects); and neutral behaviours (neither positive or negative). A practice measurement session demonstrated high (91-100%) inter-rater agreement for the use of the measurement instrument. In the final analysis, music-related behaviours such as moving to the rhythm and singing were excluded as these only occurred in the music exposure condition. Ziv et al. (2007) reported that the mean for positive behaviours in the music group was 5.18 (SD = 3.62) compared to 1.36 (SD = 2.08) in the non-music group, and this difference was significant (p = 0.001), and that the mean for negative behaviours in the music group was 2.43 (SD = 3.2) compared to 5.96 (SD = 4.13) in the non-music group and this difference was also significant (p = 0.001). No difference in neutral behaviours was evident. Ziv et al. (2007) added that aggressive and socially inappropriate behaviour appeared without music and disappeared with music in four participants and that music exerted the most pronounced effect on the enhancement of positive social behaviour and a strong effect on reduction of repetitive agitated behaviours. Ziv et al. (2007) acknowledged the sample size was not large and the trial did not involve randomisation. However, the music did appear to have a clear and immediate effect (albeit short lived). To introduce background music in common areas is technically easy.

MUSIC (EVENING MEAL TIMES)

AGITATION/AGGRESSION — EFFECTIVE — LEVEL III-3 EVIDENCE

Hicks-Moore (2005) investigated the effects of relaxing music played at meal times in nursing homes, using a within-sample repeated-measures study design. The study aimed to find an association between relaxing music and dementia-related agitation in a nursing home setting. The trial involved a convenience sample of 30 nursing home residents with dementia, living in a 120 bed nursing home special care unit. The facilities included a large, bright, airy dining room area with four to six-seater dining tables with meals being prepared in centralised kitchen and individually served to each resident by staff. The intervention was 'relaxing music at meal time' and comprised playing music selected as being composed to promote relaxation by being quiet, melodic and peaceful, without sudden changes in tempo (55-70 beats/minute) or volume (65-69 dB), yet with sufficient variation to avoid boredom. Music used in this study included "Relax with classics, volume 1: Largo" and "Relax with classics, volume 2: Adagio" (Lind Institute, 1987). Agitation was measured using a modified Cohen Mansfield Agitation Inventory (CMAI). The study protocol was as follows: week one involved the recording of agitated behaviours under 'no music' conditions; week two involved relaxing music played during the evening meal time (agitated behaviours were recorded); week three 'no music' (agitated behaviours recorded); week four, music re-introduced during the evening meal time and again agitated behaviours were recorded. In addition, notes were maintained to record researchers' general observation of the residents. During meal times, the presence or absence of any behaviour displayed by any of the participants was recorded by the study observers. Hicks-Moore (2005) reported that the incidence of AB decreased in the weeks music was played. Further, during the week during which music was played, the environment in the dining room changed to more positive, and participants were seen to be seated quietly in their seated area, compared to the weeks in which music was not played. The author concluded that relaxing music played at meal times was found to be effective in minimising the frequency of verbally agitated and physically non-aggressive behaviours. Further, Hicks-Moore (2005) noted that music is an easy, inexpensive, and non-invasive intervention that may be a valuable strategy in

reducing the overall incidence of agitated behaviours, and that music should be incorporated into the daily care regimens of nursing home residents.

#### **AROMATHERAPY**

AGITATION/AGGRESSION - EFFECTIVE - LEVEL IV EVIDENCE

Beshara and Giddings (2002) conducted a small case series study in which ten residents from one long term care facility (diagnosed with dementia, five women and five men) were selected on the basis of their extreme behaviour. The authors aimed to investigate the effectiveness of aromatherapy with essential oils in reducing agitation and associated behaviour. The intervention, aromatherapy, comprised one drop of an essential oil blend placed in a fan diffuser 9am–5pm daily Monday through Saturday. The outcome, agitation, was measured as the number of times specific behaviours were observed by the healthcare team at the facility (based on the MDS tool. Essentially, the study was a one-sample, repeated-measures design with measurements conducted at baseline, aromatherapy intervention, one month, three months and six months follow-up. The authors reported that between baseline, one month, three months, and six months follow-up, there was a reduction in agitation scores for all residents. Overall, there was a reduction in agitated behaviour with aromatherapy; however, the level of evidence was somewhat low.

Interventions of uncertain effectiveness – compared to 'usual care' or placebo or no specified treatment

#### **BRIGHT LIGHT THERAPY**

AGITATION/AGGRESSION - UNCERTAIN - LEVEL II EVIDENCE

Burns et al. (2009) conducted a single centre RCT to assess the effects of BLT on agitation and sleep in people with dementia. The trial involved people with dementia (n = 22 intervention versus n = 26 placebo) in a single rest home setting, comprising a diagnostically heterogeneous participant population. Participants had a clinical diagnosis of dementia, sleep disruption at least two nights per week or the presence of one or more agitated behaviours via the CMAI. Participants were stratified according to high or low MMSE scores (cut off MMSE of 10). In the intervention arm, full spectrum BLT 10 000 Lx for two hours was administered daily during the second and third weeks between 10am and 12 noon. In the control arm, standard light via standard fluorescent tubes at 100 Lx was administered on the same dosage protocol. The primary outcome was agitation as measured by the CMAI and assessments were carried out during the baseline week and in weeks four and eight by independent assessors. Secondary outcome measures included the MMSE, CSDD, Manchester and Oxford Universities' scale for the psychological assessment of dementia (MOUSEPAD), CRBRS, sleep charts, and wristwatch-size Actigraph (a validated measure of agitation in people with dementia). Burns et al. (2009) reported that agitation (measured by the CMAI) improved in the immediate post-treatment phase in both the BLT and placebo group, but the between-group comparison was not significant (p = 0.51) at week four, nor at week eight (p = 0.56). Comparison of placebo and active treatment by day length showed that the change in agitation (as measured by the CMAI) from baseline to four weeks was significantly negatively associated with day length in the BLT group (r = -0.52, p = 0.013), but not in the placebo group (r = 0.03, p = 0.90). Burns et al. (2009) proposed that BLT may off-set the effects of reduced daylight hours and low light levels in rest home settings during winter, rather than being a treatment for agitation in people with dementia per se. The

authors concluded that there was limited evidence of a reduction in agitation in people on active treatment, sleep was improved, but efficacy may be greater in the winter months. The practical application of BLT appears to be relatively 'staff intensive' and potentially limited by the availability of staff to supervise residents during treatment.

#### **BRIGHT LIGHT THERAPY**

AGITATION/AGGRESSION - UNCERTAIN - LEVEL II EVIDENCE

Dowling et al. (2007) evaluated the effects of BLT in a randomised clinical trial designed to compare two experimental groups that received morning or afternoon bright light exposure and to a control group that was exposed only to usual indoor light levels. The trial tested the effects of bright light exposure on the presence, frequency, severity, and occupational disruptiveness of neuropsychiatric behaviours in nursing home residents with Alzheimer's disease. Participants were randomly assigned to one of three groups: one that received morning light (n = 29) or one that received afternoon light (n = 24), or to the control group (n = 17). The study protocol was 11 weeks in duration. Outcome measures were assessed at the end of the baseline week and after the last week of intervention. Unlike other studies that have required participants to sit continuously in front of light boxes during the exposure, participants in the experimental conditions received their 'dose' of light in a variety of ways. Experimental group participants received either morning (9:30–10:30am) or afternoon (3:30–4:30 pm) light in groups (three to eight residents together) as they participated in activities in a brightly lit area, either outdoors or in an indoor space with windows to let in ample natural light or light boxes were used when necessary to supplement the ambient light (light boxes providing 10 000 Lx exposure at 0.6metres and 2500 Lx 1.2metres) A calibrated precision light meter was used to monitor light levels in the gaze direction for each participant. The control group participants participated in activities similar to those provided to the experimental group participants. Outcomes were assessed at the end of the baseline week and after the last week of intervention using the neuropsychiatric inventory-nursing home version (NPI-NH) to assess behaviour at baseline and end of the intervention. The NPI-NH was modified from the neuropsychiatric inventory and is designed to allow professional carers such as nursing home staff to act as informants rather than an informal carer such as a family member. In addition, carers rate the amount of distress or work time and effort they incur when caring for a resident exhibiting a particular behaviour. These ratings are used to generate an occupational disruptiveness score that ranges from (0) no distress to (5) 'very-severe' distress for each item. Repeated measures of ANOVA revealed statistically significant differences between groups on agitation/aggression. depression/dysphoria, aberrant motor behaviour. appetite/eating disorders. However, the authors cautioned that while the changes were statistically significant, the actual changes in scores were less than one point on a 12point scale. Dowling et al. (2007) concluded that it seems doubtful that the statistically significant differences found represent clinically meaningful changes that would affect the care of these residents. In this study, BLT did not clinically affect neuropsychiatric behaviours.

#### STAFF TRAINING AND PEER SUPPORT

AGITATION/AGGRESSION - UNCERTAIN - LEVEL II EVIDENCE

**Davison et al. (2007)** conducted a C-RCT to evaluate the impact of an eight-session training programme for aged-care staff in managing dementia-related challenging behaviours. The trial involved 113 residents with challenging behaviours from six aged-care facilities and 90 participating staff members. Resident-centred outcomes

(agitation) and staff attitudes, knowledge and skills were measured (the staff outcomes are not reported here). The intervention was a staff training programme with an additional five-session peer-support group and this was compared with both participation in training only, and a wait-list control condition. Measures were collected pre- and post-intervention, and at six month follow-up. Agitation was assessed at both time points by a minimum of two staff raters using the CMAI. analyses of covariance were conducted on the change scores (eg post-intervention minus baseline), with baseline scores serving as the covariate. Results showed that changes in overall ratings of residents' behaviours following training (relative to the control group) approached but did not reach significance (p >0.05). Post-hoc analysis found no additional effect of peer support (relative to the training-only group) on overall ratings of residents' behaviours (p >0.05). Davison et al. (2007) concluded that while the intervention did improve staff-related outcomes (ratings of self-efficacy, skills and knowledge), unfortunately, the training appeared to have little effect on the frequency of challenging behaviours among residents.

#### **INDOOR GARDENING**

AGITATION/AGGRESSION - UNCERTAIN - LEVEL III-3 EVIDENCE

Lee and Kim (2008) evaluated the effects of indoor gardening on sleep, agitation, and cognition in a small pilot study involving 23 people with dementia in a residential care facility. The purpose of the study was to examine whether indoor gardening resulted in reduced agitation, and improved sleep and cognition. The trial used a within-subjects repeated-measures design with one week of baseline measures (no indoor gardening exposure) and four weeks of treatment. Indoor containerised watergardening of edible dropwort and bean sprout was chosen as the activity, and each participant was allowed to select the preferred plant and residents were helped to tend to the plants every morning and afternoon for the 28 days of intervention. The following activities were performed: selecting plants, setting out roots/planting, watering and touching, cleaning, arranging, harvesting, wiping, and washing. Agitation was measured using a modified version of the CMAI and additional measures included the Hasegawa Dementia scale and sleep diaries. Lee and Kim (2008) reported that indoor gardening produced significant improvements in agitation and cognition, but there was no statistically significant improvement in sleep onset, wake up time, or total sleep time. The mean pre-intervention agitation score was 5.09 (SD = 2.76) and the post-intervention agitation score was 3.13 (SD = 2.30). The study did not use an 'attention control' condition; therefore it is possible that the reduction in agitation scores was confounded by corresponding improvements in sleep patterns, or simply by the engagement of the residents in 'meaningful activities'. In summary, this study provides low-level evidence that indoor gardening may reduce levels of agitation.

#### THERAPY DOG

AGITATION/AGGRESSION - UNCERTAIN - LEVEL III-3 EVIDENCE

Churchill et al. (1999) investigated the effectiveness of introducing a therapy dog into a common area of residential care facilities for a short period of time during the sundown hours for the reduction of agitation and improvements in socialisation behaviours. The authors included 28 participants in the study, living in three residential care facilities in midwestern United States of America (USA), and measured the extent of change in ABMI scores. The therapy dog was introduced in the common area of the residential care facilities for 30 minutes between 5:00pm and 5:30pm, and the residents' behaviours were videotaped and later analysed using a

protocol. Churchill et al. (1999) found significant decreases in agitation scores. However, there was no interaction between duration of interaction with the dog and agitation score changes and there was also no association between the severity of dementia and the presence of the therapy dog. Thus, this study provides limited evidence that use of a therapy dog may be beneficial in the improvement of socialisation and agitation in elderly residents with dementia.

# SENSORI-MOTOR RECREATIONAL ACTIVITIES AGITATION/AGGRESSION — UNCERTAIN — LEVEL III-3 EVIDENCE

Buettner (1999) studied the efficacy of using sensori-motor recreational items simple pleasure items (SP) for nursing home residents. All participants received the SP sensori-motor recreational items but in different sequences—either SP first followed by 'usual care' or 'usual care' first and the SP sensori-motor tailored recreational items later. The study was conducted with 51 residents in two nursing homes (randomisation was at the level of the nursing homes). Agitation was the outcome measured by CMAI, and MMSE was used to measure the level of cognitive functioning of each individual. The authors found significant treatment and time effects in the study. At the intervention site, the mean CMAI agitation score was 2.30 at baseline and this came down to 1.30 following intervention. At the same time, at the control site, the CMAI score was 1.20 and remained at 1.25. During the crossover phase (following a two month gap), the agitation scores in the intervention group went up from 1.8–1.9 and for the control site, it stayed at 1.28 to 1.26. The authors reported that several of the simple pleasures items that had a calming effect on the residents were also items that warmed the residents (eg fleecy muff, polar fleece hot-water bottle, sensory vest made from polar fleece fabric). The researchers theorised that idle times for residents are associated with agitated or disruptive behaviours, hence the effectiveness of simple pleasurable items that the residents can play with or use. However, this research suggested limited effectiveness of simple pleasurable items on reducing either agitation or wandering. There was insufficient information presented in the publication to judge the quality of this study, including the lack of a detailed description of the randomisation process, and the scope for observation bias. However, there is some evidence that SP sensori-motor recreational items may be beneficial in reducing agitation in dementia residents.

Interventions that are not likely to be beneficial (ineffective) – compared to 'usual care' or placebo or no specified treatment

THERAPEUTIC TOUCH

AGITATION/AGGRESSION - INEFFECTIVE - LEVEL | EVIDENCE

Hawranik et al. (2008) evaluated the effect of therapeutic touch (TT) on the agitation behaviours of older residents with Alzheimer's disease compared with those who received a simulated TT (sham intervention) and another group of residents who received 'usual care'. Hawranik et al. (2008) employed a randomised, multiple time series, three-group experimental study design, and the outcome of interest was agitation as measured using the CMAI. Participants (n = 51) had a diagnosis of senile dementia of the Alzheimer's type, a score of 23 or less on the MMSE, were aged 65 years or older (mean age 82.8 years), reported consistent agitated behaviour, and were residents of one long-term care facility unit for at least two months prior to study commencement. Intervention participants (n = 17) received therapeutic touch (TT)

once per day for five consecutive weekdays. The practitioners spent approximately 30-40 minutes implementing their treatment. The five phases of 'non-touch' TT were administered by practitioners who had completed an advanced level of TT training. The sham intervention was conducted over five consecutive weekdays. The volunteers spent approximately 30-40 minutes implementing their simulated treatment. The volunteers followed standardised instructions for silently repeating simple mathematical calculations while moving their hands over the participant (n = 16), the intent of this measure was to prevent the volunteer 'practitioners' from directing any energy. The 'usual care' group (n = 18) received no treatment and no one was present with the residents in this group. Using the CMAI, residents' physical aggression, physical non-aggression and verbal agitation were recorded (a) two hours after each treatment, (b) 24 hours after the final treatment, (c) one week after the final treatment, and (d) two weeks after the final treatment. The frequency of the behaviours within each category was summed and the data analysed using multivariate analysis. The results demonstrated that the TT intervention did not have a greater influence on physically aggressive or verbally agitated behaviours than did the simulated TT intervention or the 'usual care' group approach. The TT intervention did appear to be effective in reducing physically non-aggressive behaviours (only) compared to the 'usual care' condition (p <0.05, TT versus 'usual care') but not the 'attention control' (simulated TT). Based on the evidence, the authors' claim that TT 'may prevent or delay the use of pharmacotherapy and other strategies' appears optimistic.

#### **MUSIC THERAPY**

AGITATION/AGGRESSION - INEFFECTIVE - LEVEL III-2 EVIDENCE

Ledger and Baker (2007) conducted an investigation into the long-term effects of group music therapy on agitation levels of people with AD. The study employed a two-group longitudinal repeated-measures design conducted over a one-year period to detect changes in agitation. Residents were recruited from 13 nursing homes in Queensland and Victoria and 60 residents participated with 45 completing the study (26 in the intervention versus 19 controls, with allocation based on convenience not randomisation). The intervention group received weekly music therapy and the control group received standard nursing home care not involving music. The music therapy intervention consisted of regular musicians' visits of 30-45 minutes per week for 42 weeks. The music therapy sessions were held in groups (two to 10 participants/ group) and the music choice depended on participants' assessed needs, abilities, backgrounds, preferences. Outcome assessment was via the CMAI (completed by nursing staff) and the music therapist also kept a log of each resident's behaviour. Agitation levels were measured five times over one year; at baseline, three months, six months, nine months and one year following study initiation. Data were analysed by repeated-measures ANOVA over the five time points for the experimental and control groups. Ledger and Baker (2007) reported that music therapy participants showed short-term reductions in agitation, but there were no significant differences between the groups in the range, frequency, and severity of agitated behaviours manifested over time. While there were some (p < 0.05) within-participant effects over time across the four domains of the CMAI (verbally non-aggressive, verbally aggressive, physically non-aggressive, and physically aggressive behaviours), there were no significant between-group differences over time. The therapist's observations suggested that prior to sessions most participants wandered, fidgeted, and/or yelled, but these behaviours were reputedly progressively less with music therapy. The lack

of significant differences in measured agitation over time indicates that music therapy has only immediate effects on agitated behaviours. Based on reporting by the nurse attendants, it was possible that there were some immediate short-term effects in controlling agitation. However, as the primary outcome of this study was the long-term effects of group music therapy on agitation levels of people with AD, this study provided medium level evidence that music therapy for agitation is of limited effectiveness in this context. Multiple measures of treatment efficacy are necessary to better understand the long-term effects music therapy programmes have on this population.

#### STAFF EDUCATION

AGITATION/AGGRESSION - INEFFECTIVE - LEVEL III-3 EVIDENCE

Chrzescijanski et al. (2007) evaluated the impact of a staff education intervention in reducing dementia-related aggression as displayed by people with dementia living in residential aged care. The staff education programme was designed to change staff attitudes and perceptions regarding the care of persons with dementia. Forty-three residents and 85 staff were involved in the study, comprising a convenience sample of four 'for-profit' residential care settings in Brisbane, Australia. The educational intervention was developed with the aim of improving staff understanding of the emotions and subsequent needs of the person with dementia. The training intervention emotional responses as quality indicators (ERIC) intervention involved staff watching a 40-minute video, which showed six emotions commonly displayed by people with dementia. These emotions were affection, anger, pleasure, anxiety/fear, helplessness and pain/discomfort. Following the training, it was anticipated that staff would be able to identify these emotions when displayed by residents and that staff would develop a sense of empathy and understanding of resident's feelings, and thus be able to respond appropriately to any unmet needs.

Residents' aggression was measured for 14 consecutive days at baseline and again post-intervention, using the BAGS Aggression Scale (Queen Elizabeth Geriatric Centre, 1992), an hourly observational measure of aggression. Carer's observations are recorded on a scale of 0-4, with 0 being no aggression and 4 being unprovoked physical aggression. The BAGS score takes into account whether or not aggression occurred, and if so, the nature of the carer-resident interaction. Staff attitudes to their work were also assessed before and six weeks after the education intervention using a rating scale (this staff-level outcome is not reported here). Chrzescijanski (2007) reported that mean aggression scores following the introduction of the ERIC intervention resulted in a lower frequency of episodes (32.23 versus 28.09), but similar intensity (18.63 versus 18.33) in aggression scores prior to the ERIC staff education. There was a sharp drop in aggression scores in the first two weeks following the education intervention, but the difference in the mean total aggression scores over time was not statistically significant. Chrzescijanski et al. (2007) concluded that the fact that the beneficial effect was not sustained over time highlights the need for regular, formal, long-term staff education sessions if the benefits of changed staff perceptions are to have an impact on the levels of aggression displayed by persons with dementia over time. Overall, the evidence is poor that this form of staff training was effective in reducing resident aggression, in spite of the strong theoretical justification and some short term benefits.

#### **SELF CARE PRACTICES FOR AGITATION**

AGITATION/AGGRESSION - INEFFECTIVE - LEVEL III-3 EVIDENCE

Cohen-Mansfield and Jensen (2006) investigated whether interventions bringing current self-care practices into greater correspondence with those performed before the onset of dementia benefits residents with dementia. The authors proposed that the effectiveness of interventions such as music or other personalised therapies may be because of the importance that the resident attaches to them. The study evaluated the effectiveness of a tailored self-care intervention for reduction in agitation in 20 nursing home residents with dementia. Past and current self-care routines were determined by responses obtained from spouses and nursing assistants, respectively, using the self-maintenance habits and preferences in elderly questionnaire (SHPE). Interventions were proposed based on current practices that were consistent with those practiced in the past and that had been important to residents. The pilot study utilised a one sample 'before and after' design with non-randomised crossover. Half of the participants engaged in the interventions presented daily for one week, and half engaged in 'usual care' before swapping over. The interventions were developed for each individual resident based on current practices that were consistent with those practiced in the past and were important to residents. The interventions were grouped into five main categories—personal items, environmental modifications, personal products, activities and personal care—and residents received between five and 11 different personalised interventions. Outcomes measured included cognitive ability, physical function and agitation (only agitation is reported here). Agitation was measured using the short form of the CMAI (CMAI-SF) which measures 14 agitated behaviours on a 5-point scale. Residents showed engagement with the interventions, and these resulted in significantly more positive than negative or neutral responses, but there was no effect on agitation. Mean agitation scores pre-intervention were 24.4 (SD = 6.07) and the post-intervention 24.7 (SD = 7.84). Cohen-Mansfield and Jensen (2006) concluded that tailored self-care practices can increase positive symptoms in dementia residents. However, the study did not find statistically significant differences between changes in agitation scores pre- and post-intervention.

# Summary of interventions for the management of Generalised BPSD outcomes

This group includes all of the eligible studies that were identified involving the management of generalised BPSD. Four of fourteen (28%) studies were RCTs and the remainder were either 'before and after' trials (including repeated-measures designs) or case series with repeated-measures.

Effective interventions – compared to 'usual care' or placebo or no specified treatment

**MUSIC THERAPY** 

GENERALISED BPSD - EFFECTIVE - LEVEL | EVIDENCE

**Raglio et al. (2008)** conducted a RCT to study the efficacy of non-verbal instrumental music on a number of BPSD captured by the neuropsychiatric inventory scale (NPI). The authors compared 59 residents of a nursing home with significant dementia problems and randomly allocated them to either the intervention (ie 30 music therapy sessions over 16 weeks), or no music but reading or other type of entertainment for the control group. Raglio et al (2008) also measured the behaviour of the residents

during and after the music therapy and independently evaluated their mental and behavioural status. After adjusting for dementia severity, the mean NPI total scores significantly decreased in the experimental group at 8th, 16th, and 20th weeks (interaction time x group:  $F_{3,165} = 5.06$ , p = 0.002). The effects persisted four weeks after treatment. Specific BPSD (ie, delusions, agitation, anxiety, apathy, irritability, aberrant motor activity, and night-time disturbances) significantly improved. The empathetic relationship and the residents' active participation in the music therapy approach also improved in the experimental group. The authors concluded that the study showed that music therapy is effective to reduce behavioural and psychological symptoms in residents with moderate-severe dementia.

#### **PSYCHOSOCIAL INTERVENTIONS**

GENERALISED BPSD - EFFECTIVE - LEVEL III-1 EVIDENCE

Bird et al. (2007) compared psychosocial interventions with psychotropic medications in a non-randomised, naturalistic controlled trial with 33 residential care clients. The intervention was a tailored package of psychosocial interventions for each individual under intervention; the control group (n = 22) received 'usual care', based mainly on psychotropic medications. For between-group comparisons of behaviour at three time points, two measures were used: the dementia behaviour disturbance scale (DBDS) (Baumgarten, Becker, & Gauthier, 1990) and additionally, direct care staff used the retrospective perception of behaviour scale (RPBS) (Bird, et al., 2002) to record whether they felt specific behaviours had deteriorated or improved. For both groups, chart reviews provided: (a) frequency of general practitioner (GP) and psychogeriatric service or geriatrician visits to the facility to deal with disturbed behaviour; (b) frequency of changes to medication prescribed because of the behaviour; (c) drug side effects; and (d) hospitalisations because of the behaviour. High attrition (predominantly death) was experienced, with attrition from baseline reaching 24% for the intervention group and 45% for the control group. This trial did not involve a comparison of treatments but rather, an evaluation of a specific clinical approach addressing causality that enabled a series of cases of BPSD to be treated using a predominantly psychosocial approach, with psychotropic medication as an adjunct where required. This causality-focussed approach was compared with what was characterised as 'usual care' (predominantly a pharmacological approach). Measures of behaviour and staff response showed significant improvement in both groups at two- and five-months follow-up. However, there was no difference between the groups. Antipsychotic use in the intervention group decreased over time while in the control group it increased. Both approaches produced equivalent improvements in measures of behaviour frequency, disruptiveness, staff-perceived behaviour change, staff stress, and attitude to the referred residents. The differences were mainly in human and financial costs. The causality-focussed approach resulted in less wastage of medications, fewer drug side-effects, and fewer hospitalisations. There is also evidence that the causality-focussed approach resolved more cases after the fivemonth follow-up.

#### **VALIDATION THERAPY**

GENERALISED BPSD - EFFECTIVE - LEVEL III-2 EVIDENCE

**Tondi et al. (2007)** conducted a two group pre-post intervention study to evaluate the effectiveness of VT in reducing multiple BPSD. Validation therapy aims to affirm the person's feelings with empathy and non-judgmental communication. The intervention group underwent both individual and group VT. Tondi et al. (2007) studied 50 individuals in residential care facilities who were comparable at the start of the trial

and non-randomly allocated (the allocation of the participants to either VT or the 'usual care' groups was not described) 27 residents to VT and 23 residents to standard treatment, for four months. The participants were assessed using the NPI at the beginning of the study and at the end of the study, and the differences in the scores were noted to represent the changes in their levels of symptoms. NPI scores for those who received the VT intervention reduced from 22 at baseline to 9.5 at follow-up. The same scores for the control participants increased from 21.7 at baseline to 24.1. The distress score for NPI decreased for the intervention group from 8.6 to 3.5, while for the controls it increased from 10.7 to 11.0. Overall, the results show a marked decrease of the average NPI symptom score in the intervention group (from 22.0 to 9.5) compared to a rise in the control group (from 21.7 to 24.1). Agitation, apathy, irritability and night-time behaviours were the most improved NPI items among the residents who underwent the VT. However, in addition to the lack of information relating to the allocation of the participants, Tondi et al. (2007) also failed to describe the participants' baseline characteristics or provide an estimate of statistical precision for any of the outcomes reported.

#### RESTORATIVE CARE

GENERALISED BPSD - EFFECTIVE - LEVEL III-3 EVIDENCE

Using a single group multiple baseline repeated-measures study design, Galik et al. (2008) conducted pilot feasibility and impact testing of a restorative care intervention (RCI) for the cognitively impaired. The participants were 46 nursing home residents with moderate to severe cognitive impairment at a single nursing home designed for individuals with dementia. The intervention was based on social cognitive theory and aimed to enhance residents' self-efficacy, and individual judgment and confidence. The intervention, essentially staff training and supervision, was a two-tiered motivational intervention delivered primarily to/with nursing assistants. The first level of training involved a four week educational series provided by two advanced practice nurses. The education series involved four 20-30 minute classes covering: the philosophy of restorative care, motivating cognitively impaired residents to participate in functional activities and exercise, incorporating restorative care interventions into the resident's daily life and documentation and coordination of restorative care. The second level of intervention involved the advanced practice nurses for a total of 20 hours a week over a period of four consecutive months. During this period, the advanced practice nurses worked with the nursing assistants to: develop individualised care goals for each resident, coach and mentor nursing assistants, and provide weekly encouragement and support for the implementation of the individualised care plans. Two rounds of baseline measures were taken during the first two months of the study between recruitment and the start of the intervention phase. Outcomes were again measured at four and six months post intervention. The outcomes included measures of functional performance, activity, mood (via the CSDD), and agitation (via the CMAI). Galik et al. (2008) reported that the restorative care interventions were feasible and that there was significant improvement in resident mood (p = 0.02) and behavioural symptoms (p = 0.04), but no significant change in physical function or overall reported physical activity. Further, despite the usual trend of functional decline in this population, the results of this study demonstrated stability. Galik et al. (2008) also noted the tendency for other researchers to promote interventions such as relaxation, distraction and emotionoriented approaches, however, they concluded that this study provided some evidence that engaging residents in physical and functional activity is effective in improving or maintaining outcomes, and that this can be done without aggravating the depressive and behavioural symptoms of dementia. This study provided a low level of evidence that restorative care (individualised interventions) might be beneficial for residents in long term care facilities for agitation and mood.

#### **DEMENTIA CARE MAPPING (DCM)**

GENERALISED BPSD - EFFECTIVE - LEVEL III-3 EVIDENCE

Chenoweth and Jeon (2007) investigated the efficacy of DCM as an outcome measure and a process for change in a pilot study of 35 dementia care residents in three secure residential care units in Australia. DCM is commonly employed as an outcome measure of well-being and as a process to assist staff to improve quality of care (an intervention). Chenoweth and Jeon (2007) aimed to subject DCM to the rigorous scrutiny of a RCT to establish its efficacy as an outcome measure, and/or as an intervention. As a guide to the planned RCT, this pilot study was conducted to determine the sensitivity of DCM against the validated baseline and outcome. The pre-test/post-test study was conducted in five stages over nine months, specifically: recruitment and training two staff in DCM and establishing inter-rater reliability; preintervention baseline measurement: one month intervention: post-test assessments: and data analysis, study findings, and de-brief. During the intervention phase, each participant was observed over a 12-hour time period and continuous DCM observations were recorded during the daytime at each site. In addition, the number of interactions between residents and staff during four separate one-hour observations was also recorded. The DCM process, as an intervention, includes feeding back the DCM data to staff and assisting them to re-focus care towards a person-centred approach. Carers were also assisted to re-write residents' care plans and behaviour management strategies. Thus, DCM may improve staff's attention to monitoring and attending to residents' well-/ill-being (WIB) status. While a number of parameters and outcomes were studied in this research, only agitation, disruption, and depression (as three measures of BPSD) are reported here, as measured by the CMAI. For all residents taken together, there was a significant reduction in agitation (change in mean agitation score -11.94; SD = 23.1; p = 0.04), a trend towards reduced depression (change -2.65; SD = 7.11; p = 0.06), but little change in disruption scores. The authors concluded that the DCM process appeared to assist staff to refocus care towards a person-centred approach and agitation was reduced. However there was no evidence that DCM improved the residents' quality of life. This study provided very low-level evidence that DCM may be effective in improving agitation profiles of residents as measured by the CMAI.

#### PET THERAPY

GENERALISED BPSD - EFFECTIVE - LEVEL III-3 EVIDENCE

McCabe et al. (2002) studied the effectiveness of introducing a pet residential dog into a residential facility to reduce problem behaviours among the residents. A total of 22 persons with dementia in one residential care unit were studied. Prior to introduction of the dog, the participants' behaviours were mapped using the NHBPS. Then a neutered male blue heeler was introduced into the unit of the residential facilities and the participants were allowed to interact with the dog. Repeated measurements of the NHBPS scores were conducted over 12 weeks and the scores were analysed. It was found that there was a sustained decrease over four weeks in behavioural problems during the day shift compared to the night shifts. The findings support the long-term therapeutic effects of dogs for persons residing in Alzheimer's

SCUs. However, because this study was open to observation bias, and few individuals were studied, the level of evidence is low.

Interventions of uncertain effectiveness – compared to 'usual care' or placebo or no specified treatment

TAILORED THERAPEUTIC RECREATIONAL ACTIVITIES

GENERALISED BPSD — UNCERTAIN — LEVEL II EVIDENCE

Kolanowski et al. (2001) conducted a small crossover randomised pilot study of therapeutic recreation activities for persons with dementia. The thesis proposed was that activities tailored to match the pre-morbid personality style and current skill level of residents would result in enhanced positive behavioural responses compared to activities matched to skill levels alone. Ten nursing home residents served as their own controls and were assigned to treatment and control activities for 12 consecutive days, each in a random order. Pre-morbid personality was assessed using the NEO Five Factor Inventory (NEOFFI)(Costa & McCrae, 1992) via interviews with a nominated responsible party (eg a family member) and additional information was collected via chart audit and cognitive testing. The NEOFFI allows a comprehensive assessment of adult personality in five domains: neuroticism, extraversion, openness, agreeableness and conscientiousness. Three treatment activities (such as games, dancing, music, craft, woodwork and cooking etc) were selected for each participant based on functional/cognitive ability and personality type. Three control activities were selected for each participant based only on abilities. Study outcomes were measured by blinded assessors and included: engagement (time on task), affect (via the affect rating scale), mood (via the dementia mood picture test, agitation (via the CMAI), and other cognitive measures.

During treatment, the activities resulted in greater subject engagement (p = 0.04) and more displays of positive affect during the activity sessions (p = 0.05), compared with control activities. However, the effects were not apparent following the sessions. For dementia related behaviour measured by CMAI scores, the mean score for the intervention group was 3.4 (SD = 5.2) and for the control group, 4.6 (SD = 5.0), p = 0.32. Kolanowski et al. (2001) reported that most of the outcomes measured had trended in the favourable direction and suggested that the small sample size probably limited the demonstration of statistically significant findings. Kolanowski et al. (2001) concluded that a larger scale study may show that tailored therapeutic recreational activities can be beneficial for nursing home residents with dementia.

MUSIC THERAPY (GROUP)

GENERALISED BPSD — UNCERTAIN — LEVEL III-2 EVIDENCE

Choi et al. (2009) reported the results of a 'before and after' intervention study on 20 people with dementia (and 22 carers, the carer-related outcomes are not provided here) to test the effectiveness of group music therapy on a number of outcomes mapped by the NPI (including agitation, aggression, depression, and apathy). The participants were non-randomly allocated to either 15 sessions of music therapy (the process of allocation was not described) or 'usual care'. The group music sessions consisted of singing songs, analysis of librettos, instrument making, playing and writing songs. There were four phases in the music therapy starting with a rapport establishment phase among the participants and their carers and progressing to what the authors described as 'providing happiness and enjoyment to the residents'. Pre-test

NPI scores prior to the initiation of the programme and post-test NPI scores after 15 weeks of 50 minute sessions (three times a week for five weeks) were compared for both intervention and control group participants. The authors reported that there were statistically significant differences in the change scores between the intervention and the control groups for agitation. However, there were no other statistically significant differences in any of the other scores although there were, in general, improvements in other behavioural features attributed to dementia in elderly residents in long-term care facilities. This study provided limited evidence that grouped music therapy may be beneficial in the improvement of agitation in dementia residents in long-term care facilities.

#### RESIDENTIAL CARE CENTRES

GENERALISED BPSD - UNCERTAIN - LEVEL III-2 EVIDENCE

Warren et al. (2001) assessed functional outcome related variables including physical, cognitive, behavioural and emotional functioning in either residential care centres (RCCs) as opposed to SCUs. The study was a between-samples repeatedmeasures design with 36 RCC residents and 44 SCU residents. The RCC units were residential units that allowed more freedom of movement and enabled active lifestyles for the residents. The RCCs placed an emphasis on independence and freedom of choice, minimum use of restraints, and maximum engagement in activities and family involvement in care. Compared to the RCCs, the SCUs offered care more aligned with the 'medical model' of care. The outcomes (including socio-demographic data) were assessed using a range of methods including chart review, and the use of a series of validated measurement instruments such as the CSDD, the MMSE, and measures of ADL. The investigators did not find significant changes in the relative decline of functional levels of the residents in the two models of care; however, there was a minor benefit in the mood profiles of the residents in the RCC. In general, while the RCC residents showed slightly better outcomes compared to SCUs, their overall rates of decline were similar to the residents at SCUs. Given the low level of evidence, the effects of RCCs are uncertain in terms of any additional benefits over either SCUs or usual nursing home based treatments for the management of specific behavioural and psychological symptoms in individuals with dementia.

#### SNOEZELEN THERAPY

GENERALISED BPSD - UNCERTAIN - LEVEL IV EVIDENCE

Cornell (2004) reported a case series of four women in moderate to advanced stages of AD or vascular dementia, who received Snoezelen therapy. Cornell (2004) did not describe the Snoezelen practice in detail, but measured 'before and after' changes in several outcomes (mood, behaviour, anxiety, general happiness, confusion) across eight Snoezelen therapy sessions, twice a week for four weeks. The results indicated an overall positive mood/behaviour change lasting 30 minutes after the end of the Snoezelen session for all residents. However, the benefits measured before, during and after Snoezelen sessions showed no increase over the eight sessions, indicating that the benefits of the Snoezelen sessions were not long-term. In terms of 'response to equipment' this was generally a positive experience. It was concluded that the results of this study support the notion that Snoezelen environments offer a valuable adjunct to the care of older people with a dementing illness.

# NIGHT TIME BATHING RITUALS GENERALISED BPSD — UNCERTAIN — LEVEL IV EVIDENCE

**Deguchi et al. (2000)** examined the effectiveness of changing bathing routines, from a day-bath to a night-time bath in a hot spa, for multiple symptoms of dementia using a within-subjects study design. Ten individuals were selected with senile dementia, and their bathing times were changed from afternoons (2-3 pm) to evenings (6-7 pm). Observations during the intervention months were compared with observations done two weeks prior to the start of night-time bathing routines. The authors reported that four out of ten residents were less aggressive, five out of ten residents had reduced restlessness, and in general, sleeplessness improved the most. This limited evidence suggests night-time bathing may be effective, but the quality of evidence is low.

Interventions that are not likely to be beneficial (ineffective) – compared to 'usual care' or placebo or no specified treatment

**LIAISON INTERVENTION TO REDUCE UNMET NEEDS**GENERALISED BPSD — INEFFECTIVE — LEVEL II EVIDENCE

Orrell et al. (2007) conducted a single blind, cluster randomised trial to evaluate the efficacy of a liaison intervention to reduce behavioural symptoms identified in accordance with 'unmet needs theory'. Randomisation was at the level of the institution and 24 institutions were selected for the study, 12 residential homes were included in the intervention arm (n = 118 residents) and 12 residential homes were included in the control arm (n = 120 residents). At baseline all residential facilities and the residents had equal profiles of their unmet needs and quality of life. For both sets of homes, unmet needs were analysed prior to randomisation. For the intervention group, for one hour every week for 20 weeks a liaison input was conducted in each home to deliver a personalised intervention package aimed at reducing unmet needs of the residents. The Camberwell assessment questionnaire for the needs in elderly (CANE) (Orrell & Hancock, 2004) was used to obtain data about the needs and the quality of life for Alzheimer's disease (QOL-AD) (Logsdon, et al., 1999) was used to assess the quality of life scores. At the end of 20 weeks of intervention, there were no statistically significant between-group differences in any of the measures to suggest that the specific liaison programme aimed at reducing unmet needs was better than the 'usual care' group. At follow-up the total number of unmet needs was reduced in both the intervention and control groups, but analysing the groups by clusters there were no significant differences in either unmet needs or quality of life. The unmet needs of people with dementia can be identified using the CANE. The CANE assessment may have led to unmet needs being reduced at follow-up, but the liaison intervention did not significantly reduce total unmet needs relative to the control group. Unmet needs such as sensory problems, mobility, drugs, and psychological distress were especially reduced in the intervention group at follow-up. This was a well conducted RCT with appropriate blinding and use of robust instruments to measure the constructs associated with unmet needs theory. Although specific symptoms were not measured, this study provides some evidence that liaison intervention may not be effective for management of behavioural symptoms attributable to unmet needs theory.

#### EARLY PSYCHIATRIC CASE MANAGEMENT

GENERALISED BPSD - INEFFECTIVE - LEVEL | EVIDENCE

Kotynia et al. (2005) conducted a single blind, RCT with 106 residents with psychiatric co-morbidity (53 participants in each arm), to study the efficacy of early referral to a psychiatric case management team. All 26 residential care facilities in Perth, Western Australia were approached for participation in the study; 22 of the 26 facilities agreed to participate. The intervention was to screen all residents for psychiatric morbidity based on a geriatric depression scale (short form with 15 questions) (GD-15) score of 5+, or NPI > 0 in any of the 12 domains. Then, if psychiatric morbidity was detected, the resident was referred to a psychiatric case management team for further evaluation and management. The participants in the control condition received 'usual care' (even if psychiatric morbidity was detected, it did not automatically trigger referral to the case management team). At the end of the 12-month programme, no statistically significant difference was found in any of the parameters used to determine significant BPSD outcomes, since multiple outcomes were studied in this trial. Although not clinically significant, use of psychotropic medications and restraints increased in the intervention group as opposed to control group. The investigators concluded that systematic mental health screening of older adults admitted to residential care facilities and early clinical intervention does not change 12-month health outcomes.

#### **AROMATHERAPY AND TOUCH**

GENERALISED BPSD - INEFFECTIVE - LEVEL III-2 EVIDENCE

Bowles et al. (2002) studied the effectiveness of a blend of essential oils in the form of a cream and gentle touch, as compared to essential oils used in other formats, on the behaviours of residents with dementia living in a nursing home (n = 56). In the intervention, essential oils of lavender, sweet marjoram, patchouli and vetiver were blended into an aqueous cream (content of essential oil blend = 3.5 millilitres/100 grams aqueous cream) and five grams was gently massaged five times/day onto the bodies and limbs of 56 aged care facility residents (age range 70–92 years) with moderate to severe dementia. The control group participants did not receive the gentle touch but received cream-based massage. During the period of oil application, both groups showed a significant decrease in the average frequency and severity of dementia-related behaviours occurring at times other than during nursing care, compared to during the baseline and the 'no oil' periods.

Resistance to nursing care procedures increased, however, for participants in one of the groups during the essential oil application period, which may reflect increased mental alertness and awareness caused by the oils. The outcomes were measured by using the CMAI and the MMSE. Before and after comparison of MMSE scores showed 13.25 (before), and 16.38 (after), p = 0.02 (however, based on only eight responses). Essentially, based on the CMAI and intensity x frequency counts of severity, there were no statistically significant between-group differences (whether they received, oils or no oils). However, there were significant differences between receiving no treatment at all versus touch or oil therapy. Unexpectedly, resistive behaviours were found to *increase* in a subgroup of individuals in this study after aromatherapy and massage.

# Summary of interventions for the management of ANXIETY or DEPRESSION or APATHY

This group lists all of the eligible studies that were identified involving the management of anxiety, depression or apathy as symptoms of dementia. Four of nine (44%) studies were randomised trials and the remainder were either 'before and after' trials (including repeated-measures designs) or case series with repeated-measures.

Effective interventions – compared to 'usual care' or placebo or no specified treatment

REFLEXOLOGY

ANXIETY/DEPRESSION/APATHY -EFFECTIVE - LEVEL II EVIDENCE

Using a randomised repeated-measures crossover study design, **Hodgson et al. (2008)** evaluated the effects of a weekly reflexology intervention on nursing home residents' distress, pain, and affect. The study participants (n = 21) were residents (for at least 6 months) of one large nursing home with mild-to-moderate stage dementia, aged over 75 years, and with times since diagnoses ranging between three and seven years. The participants took part in a 30-minute reflexology session once per week for four weeks. A typical treatment included a progressive relaxation exercise, followed by light stretching of the foot or hand. Specific finger pressure techniques were then applied to the foot or hand following a protocol designed and supervised by a certified reflexologist. The control condition comprised a 30-minute 'friendly visit' by the same certified reflexology practitioner. These visits began with similar five minute progressive relaxation exercise followed by 25 minutes of companionship and conversation only. Data was collected for four weeks, at four intervals across the day, by nurses trained in observational and physiologic data collection techniques. The data collectors were blind to group conditions. The study differed from other common observational approaches to behavioural and psychological outcome measurement in that it used a bio-marker (salivary alpha-amylase) as an indicator of participant distress (the primary outcome). Affect was measured via five-minute observations of affect (eg anger, depression, anxiety) using the apparent affect rating scale (AARS) (Lawton, et al., 1999) (and pain was measured using a validated checklist of nonverbal pain indicators). Additional measures included blood pressure, pulse, and cognitive assessment. Data analysis was via repeated-measures ANOVA. The findings established that when receiving the reflexology treatment condition, as compared to the control condition, the residents demonstrated a significant reduction in observed pain (p = 0.031) and salivary alpha-amylase (p = 0.049). However, there were no significant changes in affect in either group. No adverse events were recorded during the study period. The authors concluded that the study provided preliminary support for the efficacy of reflexology as a treatment of stress in nursing home residents with mild-to-moderate dementia. How such a reduction in salivary alphaamylase and observed pain translates into a clinical/nursing home context was not fully established, and the low participation rate in the study (23 residents consented of 48 eligible residents approached in a 324-bed nursing home) means that the generalisability of the findings is uncertain.

#### **GROUP PSYCHOTHERAPY**

ANXIETY/DEPRESSION/APATHY -EFFECTIVE - LEVEL III-2 EVIDENCE

Cheston et al. (2003) studied the effects of group psychotherapy with 42 individuals with dementia (19 completed the evaluations for this research). The interventions were six one-hour long group psychotherapy sessions given over a ten week time period. The participants were their own controls, and the outcomes studied were depression and anxiety using a repeated-measures analysis (four measurements were made using baseline assessments, assessment prior to group formation and administration of psychotherapy, a post group psychotherapy interview, and follow up at ten weeks. Analysis of the data for depression and anxiety levels using a repeated measure ANOVA showed a statistically significant treatment effect for Cornell depression scores which was maintained at follow-up and a similar reduction in anxiety as measured by the rating for anxiety in dementia (RAID) which was borderline for significance. The sample size of this study was low, and the study design was open to observer bias. Additionally, group psychotherapy is not indicated for all individuals with dementia. These factors limited the external validity of the study. However, given these limitations, the results of this study suggest that group based psychotherapy may be beneficial for reduction in the levels of depression but results do not indicate significant effect in individuals with anxiety.

#### **INDIVIDUALISED ACTIVITIES**

ANXIETY/DEPRESSION/APATHY - EFFECTIVE - LEVEL III-3 EVIDENCE

Brooker et al. (2007) conducted a one sample 'before and after' study with 127 residents in three specialist nursing homes in the UK. The enriched opportunities programme had three essential components: (1) availability of specialist expertise to a senior staff member of the care team working with vulnerable individuals, (2) the staff team assessed the residents individually and drafted an individualised care plan, and (3) training for staff in management and leadership. A total of 127 residents were initially selected and data were available for 76 individuals in the final follow-up and 99 individuals at baseline. A repeated-measures within-subjects design was employed. collecting quantitative and qualitative data at three time-points over a twelve-month period in each facility with follow-up seven to 14 months later. There was a statistically significant increase in levels of observed well-being and in diversity of activity following the intervention. The investigators found no change in the number of negative staff interventions overall. There was a significant reduction in levels of depression. No significant changes in anxiety, health status, hospitalisations, or psychotropic medication usage were observed. In summary the 'enriched opportunities' programme demonstrated a positive impact on the lives of people with dementia in nursing homes in a short period of time, even though the homes were already offering a relatively good standard of care. Based on these findings, the authors commented that the refined programme requires further evaluation to establish its portability. Being a single-sample repeated-measures design, this study has limited evidence that a comprehensive programme incorporating both individualised tailored interventions coupled with carer level interventions had any effect in reducing anxiety or depression among the elderly in residential care facilities.

#### 'SIMULATED PRESENCE'

ANXIETY/DEPRESSION/APATHY -EFFECTIVE - LEVEL IV EVIDENCE

Cheston et al. (2007) examined the effectiveness of 'simulated presence' therapy using tapes of the carer's voice as compared with music tapes, or 'usual care' with six individuals with dementia. Individualised tapes of carers' voices, music tapes, and 'no intervention' (control condition) were repeated in different sequences over 21 periods. The findings suggest that 'simulated presence' tapes (SPT) may reduce levels of distress in people with moderate levels of dementia, and in particular those residents who repeatedly ask to leave for home. However, the reductions in distressed behaviour did not generalise beyond the end of the tape.

Interventions of uncertain effectiveness – compared to 'usual care' or placebo or no specified treatment

REMINISCENCE BASED ACTIVITY THERAPY 'KIT'

ANXIETY/DEPRESSION/APATHY — UNCERTAIN — LEVEL II EVIDENCE

Politis et al. (2004) conducted a four-week, single blind, randomised controlled clinical trial of activity therapy for apathy in people with dementia residing in longterm care. The trial compared a reminiscence based 'kit' intervention to a time and attention 'one-on-one' control, for the treatment of apathy in 37 residents with dementia. The participants all had a clinical diagnosis of dementia, and the presence of apathy based on the judgment of staff (that the resident had relatively low interest and involvement in day-to-day activities). Outcome measures were administered at baseline and follow-up and included: the apathy score of the neuropsychiatric inventory (NPI), the NPI total score, the Alzheimer's disease related quality of life scale (ADRQL), and the Copper Ridge activity index (CRAI). The reminiscence based activity intervention (the experimental intervention) was a standardised, structured activity method that attempted to provide mental stimulation intended to be helpful to apathetic residents. The choice of activity was based on the participant's interests and was often rotated from visit to visit. The kit included five types of activities: geography, fun foods, farm animals, vegetables, and musical instruments. The musical instrument kit, for example, contained a tape that played music from an instrument and the resident had to identify the type of instrument being played and say whether they liked the music. The control intervention comprised a one-on-one 'attention control' intervention in which the same activity therapist conducted visits that were unstructured, relaxed interactions. The assigned intervention was administered three times a week for 30 minutes, over four weeks, by a trained activity therapist. Politis et al. (2004) reported that there was a significant reduction in NPI apathy scores in both treatment groups. The only significant difference between the two treatment groups was a modest advantage for the control intervention on the CRAI cueing subscale (p = 0.027), but not on the other CRAI subscales. There was also a greater within-group improvement in quality of life ratings in the control intervention (p = 0.03). Politis et al. (2004) concluded that despite the substantial improvement in apathy scores during the course of the study, there was no clear advantage to the reminiscence-based intervention and that the 'kit' activity and the one-on-one control activity had comparable efficacy. Politis et al. (2004) went further to suggest that the one-on-one control may have provided more actual social contact than the scripted, and hence somewhat impersonal, 'kit' intervention. Generally, regular one-on-one personal contact provided by any staff member (including a

trained aide), may lead to improvements in neuropsychiatric disturbance and apathy in residents with dementia.

#### PSYCHOGERIATRIC TEAM CASE MANAGEMENT

ANXIETY/DEPRESSION/APATHY - UNCERTAIN - LEVEL II EVIDENCE

**Brodaty et al. (2003)** conducted a RCT of different models of care for nursing home residents with dementia complicated by depression or psychosis. The 12-week trial compared psychogeriatric case management, general practitioners with specialist psychogeriatric consultation, and standard care for nursing home residents. Eighty-six residents with significant cognitive impairment from 11 nursing homes in Sydney participated: some with dementia and depression (n = 34) others with dementia and psychosis (n = 33) and (n = 19) with dementia, depression and psychosis. All participants received full psychiatric assessments and physical examinations at baseline, and detailed management plans were formulated by a multidisciplinary team before random assignment to one of three interventions.

Intervention (1): Psychogeriatric case management—treatments supervised by two geriatric psychiatrists and administered by a multi-disciplinary team. Treatments included psychosocial interventions, individual supportive therapy (four to eight hours over 12 weeks), nurse education, families prompted to participate in the programme, and behavioural management programmes. Medications were adjusted as appropriate.

Intervention (2): Psychogeriatric consultation (n = 27), the detailed management plans that were formulated by the multidisciplinary team were provided to the nursing home staff and to the residents' general practitioner. The project team were available for further consultation as requested during the 12-week intervention phase—in a model similar to usual practice for nursing homes with access to psychogeriatric services.

Intervention (3) (control): Management plans formulated by a multidisciplinary team, then standard care only for nursing home residents.

A battery of instruments was used to assess the outcomes of depression and psychosis. Depression measures included the Hamilton rating scale for depression (HRSD), CSDD, and the GDS and psychosis measures included the behavioural pathology in Alzheimer's disease rating scale, NPI, and scale for the assessment of positive symptoms. Additional data were obtained from nursing home records on prescription of psychotropic medication and demographic information. Analyses of variance and Chi square analysis were used to examine between-group differences and post-hoc analysis was used to assess medication adequacy. Brodaty et al. (2003) reported that all three groups improved from pre-treatment to post-treatment on depression scales for depression groups and psychosis scales for psychosis groups. There were no significant between-group differences for any outcome measure. Neither use of antidepressants nor use of antipsychotics predicted depression or psychosis outcomes. The formula-driven psychogeriatric team case management approach was not found to be significantly more effective than a consultative approach or standard care. This study (like many others) demonstrates the difficulties, and limits to the feasibility, of conducting service-oriented research in nursing homes. While the participants were randomised to one of three groups, they remained within their original nursing homes. Brodaty et al. (2003) acknowledged that 'leakage' of the intervention elements may have occurred between the groups (ie unintentional generalisation of active intervention techniques to control participants). All three groups improved from pretreatment to post-treatment, possibly because of the presence of the multidisciplinary team, and the resulting increased (and probably therapeutic) attention that the residents received.

#### **THERAPEUTIC GAME**

ANXIETY/DEPRESSION/APATHY - UNCERTAIN - LEVEL III-3 EVIDENCE

Cohen et al. (2009) reported on the effectiveness of a novel therapeutic game titled, "Memory Game" in a group of 33 elderly residents with dementia in a long-term care facility. Cohen et al. (2009) compared the impact of this game on mood and depression with two control conditions: either usual visits by family members or playing another game or other similar situations (for example reading a magazine). The study was conducted using a within-subjects multiple comparison study design with two control conditions for the intervention. The game was non-competitive, where the participant was given a dice or a card (whichever was easier to manipulate and use). Following a throw of the dice or drawing of a card, the resident was directed to pick up a card and move to a specific square on a board and allowed to spend time reminiscing about the specific event/place/person/object. The control conditions were either usual visits from family members or use of a magazine cover to elicit memories of specific events. Cohen et al. (2009) found that compared to conditions such as spending time with family members or using other cognitive cues such as magazines for reminiscence, the use of this game was associated with a significant improvement in mood and a reduction in depressive symptoms or facial expressions. However, given the study design, the level of evidence is low. There is some evidence based on this study to suggest that therapeutic games may be beneficial in the management of mood in elderly dementia residents in long-term care facilities.

COGNITIVE BEHAVIOURAL THERAPY: ANXIETY/DEPRESSION/APATHY — UNCERTAIN — LEVEL IV EVIDENCE

**Kraus et al. (2008)** reported a case series with two participants and evaluated the impact of eight different types of cognitive behavioural approaches conducted in nine sessions over ten weeks in two participants. The investigators reported 'clinically meaningful' changes in the levels of anxiety.

Interventions that are not likely to be beneficial (ineffective) – compared to 'usual care' or placebo or no specified treatment

**BRIGHT LIGHT THERAPY** 

ANXIETY/DEPRESSION/APATHY -INEFFECTIVE - LEVEL II EVIDENCE

Hickman et al. (2007) conducted a cluster randomised trial (C-RCT) to evaluate the effect of ambient BLT on depressive symptoms in persons with dementia. The crossover-trial involved four lighting conditions: morning bright light, evening bright light, all-day bright light, and standard light. The interventions were implemented in the common areas of two geriatric units in a state-operated psychiatric hospital in North Carolina and in a dementia-specific residential care facility in Oregon. Sixty-six older adults with severe or 'very-severe' dementia participated in the trial. Ambient BLT was delivered through a high-intensity, low-glare lighting system installed in the public areas of the units at both sites. Each lighting condition was provided for multiple three-week periods in a predetermined sequence. Staff carers completed the CSDD in the last week of each three-week period to provide information about participants' moods. Analysis indicated a gender-by-treatment interaction (p = 0.008).

Significant gender differences were found in CSDD scores in response to evening light (p = 0.003), all-day light (p = 0.001), and standard light (p  $\leq$  .001). Hickman et al. (2007) reported that morning light appeared to have the greatest effect on both genders, but the effect was favourable in women and unfavourable in men. In response to morning light, women's depressive symptoms decreased approximately 25%, whereas men's depressive symptoms increased approximately 50%. Hickman et al. (2007) conceded that the unexpected findings do not support the use of ambient BLT as a treatment for depressive symptoms in persons with dementia, although a subpopulation of persons with dementia may benefit from this intervention. It is likely that individual rather than unit-level interventions are a more effective strategy for delivering BLT for this population.

### **Discussion**

This report systematically reviewed the evidence on the effectiveness of non-pharmacological interventions for behavioural and psychological symptom management for individuals with dementia, in residential care settings. In interpreting the relative effectiveness of different interventions in this context, it is also important to consider an intervention's utility value.

The initial search process identified more than 4000 publications. Only about 100 publications were finally appraised for the generation of evidence. Thus, more than 95% of the studies were excluded because they did not meet the specified criteria. Other reviews on this topic have also reported high rejection rates (Livingston, et al., 2005; O'Connor, et al., 2009). The generally high rates of exclusion indicate that while on the one hand non-pharmacological interventions for dementia have been well investigated and/or reviewed, on the other hand, the studies have not been particularly rigorous or well focussed. In turn, only a relatively small proportion of the published literature was found to be suitable for generating sufficient evidence to guide policy and public health decisions regarding treatment strategies.

A wide range of interventions have been studied in the context of reducing behavioural and psychological symptoms, reflecting the apparent lack of consensus as to which category or categories of interventions might be generally effective. Similarly, while BPSD are commonly viewed as an entity, several different 'component-outcomes' have been studied either singularly or in combination. Of all these outcomes, agitation, aggression, depression, wandering, and multiple outcomes have been extensively reported in the literature. Further, many studies also assess cognitive outcomes, focussing on psychometric measures, standardised memory tests or other measures of cognitive performance. However, cognitive outcomes are outside the scope of this review. Still more complex, other studies include BPSD, cognitive, and carer-related outcomes simultaneously (common carer-related outcomes include knowledge, distress, attitudes and behaviours). Within this review, the studies have been grouped together for 'best fit' based on the intervention and/or outcomes deemed to be the main focus of the research, and generally, secondary outcomes and/or those that are outside the scope of this review are not reported in any detail.

Undoubtedly, for professional carers in residential facilities, the effective management of specific behavioural and psychological symptoms attributed to dementia is important, or more specifically, the efficiency with which appropriate management goals can be achieved. It would appear that to date, most research has been driven by these professional carer-related factors, with studies being oriented towards the evaluated carer-related outcomes: as opposed to what might be perceived to be more meaningful to immediate family members and/or the patients themselves. As Cohen-Mansfield and Billig (1986) point out, agitation and other 'problem' or 'difficult' behaviours are usually judged by an outside observer and the point of view of the person with dementia is frequently unknown. This review was restricted to resident-related BPSD outcomes. However, interventions aimed at modifying carer behaviour were also studied in depth with respect to the (possible) resultant residentlevel effects. This indicates that the worth of any intervention might lie, at least in part, beyond the scope of influencing only resident-level outcomes directly. Thus a pragmatic evaluation of the usefulness of any intervention might include the consideration of a broad range of factors. In general, for the various interventionoutcome combinations, comments on the effectiveness were made taking into account both statistical and clinical significance, usually based on effect size and as indicated by other measures as detailed in the original studies. Throughout this review, a broad-based theme emerged: that individualised behavioural management focussed towards the residents, training or education of immediate carers (such as family members) and professional-carers, were all beneficial in the management of BPSD.

#### Limitations

In interpreting these results, several limitations imposed by the nature of the evidence warrant discussion: including, 'attention effects' 12, the 'Hawthorne effect' 13, halo effects<sup>14</sup>, 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). O'Connor et al. (2009) stated that life in nursing homes is typically so lacking in stimulation that personal attention of any kind relieves anxiety and agitation. Arguably, 'usual care' may be so deficient in attention and stimulation that it acts as a 'negative intervention': thus doing 'anything at all' is better than nothing. There is an argument that only true randomised 'attention control' studies go anywhere near addressing these research limitations. Studies that investigated personalised behavioural modification programmes did not specifically control for the amount of attention, and few studies effectively used a placebo or a proxy measure of attention as the control condition. Nevertheless, all studies that involved behavioural modification, and were based on repeated-measures study designs, effectively had an implicit 'attention control' or 'attention factor'. However, the role of 'attention' as an intervention element may have had a beneficial influence and may, at least in part, explain the success of personalised behavioural modification-related interventions. The use of pet therapy is a relevant example because of the additional attention and alertness required on behalf of the carers to administer this intervention. This review also found that carer-level interventions were generally successful in the management of agitation and anxiety, and in part this could be explained by the alternation of carers' behaviour when they are under observation, so that 'desirable' behaviour is increased (Hawthorne effect). No study specifically attempted to control for the Hawthorne effect, and therefore, even though carer-level interventions were found to be beneficial, it is unclear how much of that benefit was derived from the effects of observation/performance biases.

Double-blinded RCTs are often considered the 'gold-standard'. However, RCTs are often unaffordable, blinding is impracticable, and participant retention is usually compromised by participants' advanced age (high drop-out rates due to death). Therefore, to accommodate some of the realities of aged care research, the reviewers included non-randomised 'before and after' or repeated-measures studies (in which all participants receive treatment and act as their own controls). The inclusion of such study designs is considered reasonable given that the potential for learning effects, treatment carry-over and disease progression are unlikely to be a problem in short-term, non-pharmacological trials in people with marked dementia. However, while

<sup>13</sup> The phenomenon in which subjects in behavioral studies change their performance in response to being observed.

<sup>&</sup>lt;sup>12</sup> Stimulating or personal attention of any kind exerting (generally unintentionally) an intervention effect.

<sup>&</sup>lt;sup>14</sup> A cognitive bias in which traits are interpreted, perceived and generalized because of pre-existing expectations.

these factors mean that short-term repeated-measures studies are practicable, they are not without limitations. Many studies are of short duration and this limits the ability to demonstrate effectiveness over time: behaviours often tend to regress towards baseline in the absence of an active intervention and/or reinforcement and this cannot be captured by short-term studies. Another serious threat to internal validity is observation bias; as few objective measures of BPSD exist and non-blinded assessment of outcomes is common yet (arguably) avoidable. In addition to the nonrandomised 'before and after' and repeated-measures studies, this review included several studies that utilised single case designs (common in behavioural research) where repeated measurements are made by observers over time with a small number of individuals. While these studies can provide important insights into the role of different interventions for specific outcomes, these studies are also open to observation bias, low power, and correlated errors. While the results from these studies have been taken into account, the level of evidence is noted to be low. In general, the lack of blinding, failure to measure and report on the fidelity of the interventions<sup>15</sup>, and the failure to account for cluster effects<sup>16</sup> makes many of the findings problematic.

Although several outcomes and intervention-outcome pairs were considered, no effect size summary estimate could be provided. This is because the heterogeneity in the nature of the primary studies precluded pooling together the results of the individual trials. Other reviews on non-pharmacological interventions have reported similar concerns. For instance, in a large review of non-pharmacological interventions, Livingston et al. (2005) stated that overall their conclusions were limited because of the paucity of high-quality research. Only nine of 162 included studies were properly designed RCTs with narrow confidence intervals. The included studies were published from as early as 1975 through to July 2003 (76 published pre-1999). Arguably, a more focussed approach (with a narrower publication year range) would have provided more relevant information and allowed for the provision of more detail.

Finally, numerous scales and instruments have been used to measure a range of outcomes in different studies, and in addition, non-randomised comparison trials have not addressed other potential confounding variables. These factors have limited the strength of the evidence, and have precluded direct comparisons between studies. As an example, several studies of non-pharmacological interventions for dementia-related neuropsychiatric symptoms have focussed on individuals with mild to moderate cognitive impairment. However, Kverno et al. (2009) hypothesised that individuals with severe cognitive impairment may not necessarily respond to treatments in the same manner as the less impaired. Kverno et al. (2009) suggest that future studies should be specifically designed to further explore the stage-specific efficacy of non-pharmacological therapies for patients with advanced dementia.

## **Key findings**

The results of this review need to be interpreted in the light of the limitations described above: imposed by the study designs employed in the primary research, and by the methodologies employed in the corresponding reviews on which this systematic review is based. Notwithstanding these limitations, and based on a

<sup>&</sup>lt;sup>15</sup> The degree to which an intervention is implemented versus what was intended.

<sup>&</sup>lt;sup>16</sup> The tendency for items or individuals within a cluster to respond alike due to cluster-level (or site-level) variables.

synthesis of the body of evidence pertaining to the effectiveness of different interventions related to the management of BPSD in aged care residents— the following seven themes emerged. Note that the seven themes are ordered only subjectively by effectiveness — not as the result of any statistical comparison of effect size, ranking of numerical quality rating scores, or cost-effectiveness—as there was insufficient data to formalise these comparisons. The key findings, which relate specifically to 'wandering behaviours', are summarised briefly as an additional theme.

#### TRAINING PROGRAMMES: CARES, STAFF, FAMILY

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; Galik, et al., 2008; Landreville, et al., 2006; Livingston, et al., 2005). Further, psycho-education intended to change carers' behaviour is effective, especially if it is provided in individual rather than group settings, and improvements in neuropsychiatric symptoms associated with these interventions may be sustained for months. Also, specific types of staff education lead to reductions in behavioural symptoms (and the use of restraints) and to improved affective states. Staff education in communication skills and enhancement of staff members' knowledge about dementia may improve many outcomes related to neuropsychiatric symptoms. In contrast, staff training programmes aimed at teaching staff emotion-oriented care or programmes aimed at changing staff attitudes or perceptions were not associated with significant changes in outcomes compared to 'usual care' that did not incorporate these elements (Chrzescijanski, et al., 2007; Schrijnemaekers, et al., 2002).

#### INDIVIDUALLY TAILORED BEHAVIOURAL MANAGEMENT PROGRAMMES

Individually tailored behavioural management programmes were generally effective for a range of conditions(M. Bird, et al., 2007; Brooker, et al., 2007; Cohen-Mansfield, et al., 2007; Davison, et al., 2007; Landreville, et al., 2006; M. P. McCabe, et al., 2007). Livingston et al. (2005) concluded that behavioural management techniques centred on individual patients' behaviour are generally successful for the reduction of neuropsychiatric symptoms, and the effects of these interventions can last for months. The exceptions to this general observation were the studies by Kolanowski, et al. (2001) and Buettner (1999) which raised questions about whether individually tailored recreational activities were beneficial. Both the Buettner (1999) and Kolanowski et al. (2001) studies were small (five and ten individuals respectively) and while they did not find statistically significant changes in behaviour, both the authors commented that the changes they observed overall were favourable and clinically meaningful. Thus, on the whole, individual tailored behavioural management programmes for residents appear to be beneficial.

#### 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). In addition to vocal music, there was some evidence that non-vocal instrumental music was effective in improving several BPSD (Raglio, et al., 2008). Further, Ledger and Baker (2007) found music to be beneficial in reducing

agitation immediately after the sessions, although they did not find long term beneficial effects. Livingston et al. (2005) reported that music therapy is a useful treatment for neuropsychiatric symptoms during the session, but the longer-term effects may be limited. Finally, a Cochrane meta-analysis of five studies by Vink and colleagues (Vink, et al., 2003, reviewed in Bartlett, 2007) did not find enough evidence of the effectiveness of music for the reduction of agitation. Overall, there is some evidence that music, either personal-preferred music or music therapy in groups or music played in common areas, may be beneficial.

#### PHYSICAL ACTIVITY BASED TREATMENT PROGRAMMES

Physical activity based treatment programmes might be beneficial for agitation and/or aggression. In a relatively large meta-analysis of 30 studies (n = 2020 participants) (Heyn, 2002, reviewed in Bartlett et al 2007), physical activity among individuals with cognitive impairment and dementia was associated with a reduction in aggression (and other cognitive and physical functioning outcomes). Other studies indicate that walking, exercise, or structured daily routines are associated with reduced wandering, or improvement in agitation (Algase, 2006). In contrast, another large review did not find appreciable benefits of physical activity therapy (Livingston, et al., 2005).

#### AROMATHERAPY

Some evidence suggests that lavender, lemon balm, or marjoram extracts used in aromatherapy might be beneficial in reducing agitation. A systematic review by Landreville et al. (2006) and a pre-post intervention study (n = 10) individuals by Beshara and Giddings (2002) found the use of aromatherapy to be beneficial in agitation. Further, a larger study by Bowles, et al. (2002) did not find sufficient evidence in favour of aromatherapy for reducing agitation but did find aromatherapy to be effective for reducing 'withdrawn social behaviour' and for increasing the time residents spent engaged in constructive activities. In addition, Lin et al. (2007) found aromatherapy administered via a diffuser during the night to effectively reduce agitation in 70 residents participating in a crossover RCT. A review of 11 randomised trials by Nguygen and Paton (2008), on balance, did not find sufficient evidence in favour of aromatherapy for reducing agitation. Thus, while aromatherapy has been investigated in reference to agitation reduction in dementia residents, 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. The aromatherapy oils tested and the methods of delivery, dose, and outcomes measured have varied widely across studies. Aromatherapy is a commonly used 'alternative therapy' but the efficacy and side-effect profiles remain largely unknown.

#### 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. Three studies were identified that investigated the use of therapy dogs in residential care units (Churchill, et al., 1999; B. W. McCabe, et al., 2002; Perkins, et al., 2008). While each study found that the introduction of pet dogs was associated with significant reductions in the agitation profile scores of the residents, each study was conducted on a small number of individuals and used a 'pre-post' intervention study design that was considerably less rigorous than a RCT. Therefore, while there is some evidence in favour of the use of therapy (pet) dogs, the level of evidence is low.

#### BRIGHT LIGHT THERAPY AND SNOEZELEN

There is insufficient evidence in favour of modification of the immediate environment either in the form of administration of Snoezelen or periodic treatment with bright light. None of the three systematic reviews (including one Cochrane meta-analysis) found sufficient evidence of Snoezelen being beneficial for any BPSD. However, one study found Snoezelen therapy, compared to usual treatment, to be beneficial in reducing agitation. Livingston et al. (2005) assigned Snoezelen therapy a grade of recommendation B, indicating that Snoezelen was effective. However, despite some physiological/neurological justification for the use of Snoezelen in some circumstances, overall, and in the light of more recent equivocal studies, Snoezelen therapy was not found to be effective in the management of agitation and aggression in dementia (at least for the specific population studied).

A systematic review by Forbes et al. (2009) and two RCTs (Burns, et al., 2009; Hickman, et al., 2007) found no evidence that treatment with 10 000 Lx artificial illumination, when compared with 'usual care', was beneficial in the management of depression. One randomised trial by Dowling et al. (2007) found that compared to 'usual care', individuals in residential care units treated with 10 000 Lx bright lights had lower rates of aggression and the difference was statistically significant. However, the authors cautioned against attaching any clinical significance to the results since the observed changes did not represent clinically meaningful changes in aggression scores. The statistically non-significant results of some studies may have been related to the small sample sizes, which contribute to insufficient power to detect a difference, if one is present. Notable exceptions were the Ancoli-Israel (2003) trials that included 92 participants and the Riemersma (2008) study that included 94 participants. These trials were adequately powered, yet still failed to demonstrate any significant between-group differences. Another plausible reason for the lack of significant effect of light therapy was the heterogeneity within several of the trials in terms of participants' diagnosis and severity of dementia. The response to light therapy of individuals with different diagnoses and severity of dementia may differ (eg Alzheimer's disease versus vascular dementia, 'mild-moderate' versus 'severe'). Small sample sizes and the small number of included trials precluded any analyses. Further, light-boxes were used in the majority of studies which require participants to sit in front of the box for approximately two hours, usually under supervision. Practically, this may be difficult to achieve, so compliance may be problematic. Ceiling-mounted light fixtures in common areas and/or 'dawn-dusk simulation' may be a more practical solution to delivering BLT, if the delivery of BLT can be shown to be effective. Based on these findings, there is insufficient evidence in support of the effectiveness of either BLT or Snoezelen for the management of BPSD.

#### INTERVENTIONS SPECIFICALLY FOR WANDERING BEHAVIOURS

In a review by Algase et al. (2006), 14 empirical studies containing discrete findings about wandering behaviour (published 2003 through 2005) were evaluated. In the main, few intervention studies to manage wandering were sufficiently rigorous, although the evidence for effectiveness of subjective barriers is mounting. Ten studies of interventions such as tape grids placed on the floor, cloth panels over doors, murals painted over exits, and the use of mirrors were evaluated. The quality of the studies varied greatly; however, there are data to support the use of objects that obscure exits and some compelling evidence for the use of tape grids. Other interventions with

potential include walking/exercise/activity, behavioural techniques, music (short–term effect), alarms, and electronic tracking.

#### **Economic considerations**

There is insufficient information to inform an economic analysis, given the multiple intervention types and/or components identified and the range of outcomes reported. This is complicated further by inconsistent and/or partial reporting of the outcomes and the use of a wide range of measurement instruments. This review summarises the evidence pertaining to a range of interventions and intervention components, rather than one 'standard' intervention, and the costs of these interventions are not known.

The cost-effectiveness of programmes aimed at behavioural and psychological symptom management for people with dementia are not well documented. Estimating resource utilisation and any possible cost off-sets and/or savings to the health care system remains beyond the scope of this report.

## **Conclusions**

This report systematically reviewed the evidence for the effectiveness of non-pharmacological interventions for BPSD management, for people with dementia in residential care settings. The methods that have been trialled in residential care setting to reduce agitation and aggression and other BPSDs are diverse.

The main findings from this review suggest that training of staff members associated with the care of the dementia patients in residential facilities, individually tailored behavioural modification programmes, training of staff members associated with the care of the dementia patients in residential facilities, and incorporating physical activities, music therapy, and aromatherapy, might be beneficial for the management of key elements of BPSD, most notably agitation, aggression, and/or several symptoms in combination. On the other hand, while bright light and Snoezelen therapy have been studied in various different contexts, this review did not identify sufficient evidence to suggest that these were indeed beneficial for people with dementia.

One notable observation is the large number of studies reporting statistically significant benefits in both the intervention group/s and the control group/s (for example, Brodaty, Draper, & Low, 2003; Buettner, 1999; Burgio, et al., 2002; Burns, et al., 2009; Kolanowski, Litaker, & Buettner, 2005; Lee & Kim, 2008; Magai, Cohen, & Gomberg, 2002; Politis, et al., 2004; Remington, 2002). These studies would generally be described as 'negative studies' because of the failure to demonstrate statistically significant between-group differences. However, with respect to dementia care, it can be argued that this phenomenon is a potentially important finding in its own right, and at least in part, demonstrates the potential positive effect of simple 'attention'. Based on the body of evidence, it seems reasonable to attest that the potential effects of simple attention should not be overlooked, and any lack of evidence does not necessarily equate to a lack of efficacy, nor should it necessarily be a barrier to implementation. One feature of the dementia research in general is the propensity of individuals with dementia to respond to interventions (or not) in individualised ways. There is no panacea, and arguably, from a practical perspective, simple case-by-case solutions may be as valid as more complex intervention programmes.

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# **Glossary**

**Bias:** Any tendency to influence the results of a trial (or their interpretation) other than the experimental intervention.

**Blinding:** This is a technique used in research to eliminate bias by hiding the intervention from the patient, clinician, and/or other researchers who are interpreting results (see Double blinded RCT).

Case-control study: Involves identifying patients who have the outcome of interest (cases) and control patients without the same outcome, and looking to see if they had the exposure of interest.

Case-series: A report on a series of patients with an outcome of interest. No control group is involved.

**Chi square test:** A statistical test to determine if the relationship between two crosstabulated variables is significant.

Clinical practice guideline: A systematically developed statement designed to assist HCPs and patients make decisions about appropriate health care for specific clinical circumstances.

**Cochrane collaboration:** A worldwide association of groups who create and maintain systematic reviews of the literature for specific topic areas.

**Cohort study:** Involves the identification of two groups (cohorts) of patients, one which did receive the exposure of interest, and one which did not, and following these cohorts forward for the outcome of interest.

**Confidence interval (CI):** The range around a study's result within which we would expect the true value to lie. CIs account for the sampling error between the study population and the wider population the study is supposed to represent.

**Confounding variable:** This is a variable which is not the one you are interested in but which may affect the results of trial.

**Double blinded RCT:** A RCT where some of the persons involved (e.g. the patients and the doctors) are prevented from knowing certain information that might lead to conscious or unconscious bias which can possibly invalidate the results.

**Effectiveness:** A measure of the benefit resulting from an intervention for a given health problem under usual conditions of clinical care for a particular group.

**Efficacy:** A measure of the benefit resulting from an intervention for a given health problem under the ideal conditions of an investigation.

**Heterogeneity:** In systematic reviews, the amount of incompatibility between trials included in the review, whether clinical (ie the studies are clinically different) or statistical (ie the results are different from one another).

**Incidence:** The number of new cases of illness commencing, or of persons falling ill, during a specified time period in a given population.

**Intention-to-treat:** Characteristic of a study where patients are analysed in the groups to which they were originally assigned, even though they may have switched treatment arms during the study for clinical reasons.

**MeSH:** Medical Subject Headings: a thesaurus of medical terms used by many databases and libraries to index and classify medical information.

**Meta-analysis:** A systematic review which uses quantitative methods to summarise the results.

**Odds ratio:** A ratio of events to non-events. If the event rate for a disease is 0.2 (10%), its non-event rate is 0.8 and therefore its odds are 2/8.

**Paired t-test:** A test of the null hypothesis that the difference between two responses measured on the same statistical unit has a mean value of zero.

**P-value:** The probability that a particular result would have happened by chance.

**Publication bias:** A bias in a systematic review caused by incompleteness of the search, such as omitting non-English-language sources, or unpublished trials (inconclusive trials are less likely to be published than conclusive ones, but are not necessarily less valid).

Randomised controlled clinical trial: A group of patients is randomised into an experimental group and a control group. These groups are followed up for the variables/outcomes of interest.

**Systematic review:** An article in which the authors have systematically searched for, appraised, and summarised all of the medical literature for a specific topic.

**Validity:** The extent to which a variable or intervention measures what it is supposed to measure or accomplishes what it is supposed to accomplish. The internal validity of a study refers to the integrity of the experimental design. The external validity of a study refers to the appropriateness by which its results can be applied to non-study patients or populations.

# **Appendix A: Mental Health and Addiction of Older People and Dementia Working Party Membership**

Table 21: Mental Health and Addiction of Older People and Dementia Working Party membership

| Name           | Area of expertise and affiliation  |
|----------------|--|
| Roz Sorensen   | Senior Project Manager, Policy and Service<br>Development Mental Health Group, Population<br>Directorate, MOH. |
| Anne Foley     | Senior Advisor, Health of Older People Policy, MOH.  |
| Anne Bell      | Development Manager, Disability Support Services, Community Living, MOH.                                       |
| Scott Connew   | Policy Analyst, Mental Health Policy and Service Development, MOH.   |
| Claire Tennent | Policy Analyst, Office of the Director of Mental Health, MOH.  |

# **Appendix B: Search Strategy**

# Description of Search Strategy for Relevant Data

The EMBASE and MEDLINE databases plus The Cochrane Library, CINAHL, PsycINFO and The Campbell Library were searched to find:

# Non-pharmacological interventions for the management of behavioural and psychological symptoms of dementia.

Details of the literature searches appear in this appendix— the searches were limited to articles published in English from 1999.

The following terms were used for the EMBASE.com search:

#### P: Patient, Population, Problem terms

#### Population

- 1 dementia/exp
- 2 (dementia\* OR amentia):ti,ab
- 3 (dementing OR demented OR demention):ti,ab
- 4 (Alzheimer OR "diffuse cortical sclerosis"):ti,ab
- 5 ("Lewy body disease" OR "Lewy body diseases"):ti,ab

#### Patient Type/Problem

- 1 "behavioral and psychological symptoms of dementia":de
- 2 ("Behavioral \*1 psychological symptom" OR "Behavioral \*1 psychological symptoms"):ti,ab
- 3 ("Behavioural \*1 psychological symptom" OR "Behavioural \*1 psychological symptoms"):ti,ab
- 4 ("behavioral signs \*2 symptoms" OR "behavioural signs \*2 symptoms"):ti,ab
- 5 ("behavioral \*1 psychological signs" OR "behavioural \*1 psychological signs"):ti,ab
- 6 ("behavioral \*1 psychological problem" OR "behavioral \*1 psychological problems"):ti,ab
- 7 ("behavioural \*1 psychological problem" OR "behavioural \*1 psychological problems"):ti,ab
- 8 (bpsd OR cbbd):ti,ab
- 9 neuropsychiatry/de AND (symptomatology/de OR symptom/de OR (symptom OR symptoms):ti,ab)
- 10 (neuropsychiatric OR "neuro psychiatric"):ti,ab AND (symptomatology/de OR symptom/de OR (symptom OR symptoms):ti,ab)
- 11 "behavior symptom":de
- 12 "psychological symptom":de
- 13 "neuropsychiatric symptom":de
- 14 ("Neuropsychiatric disturbance" OR "Neuropsychiatric disturbances"):ti,ab
- 15 ("Neuro psychiatric disturbance" OR "Neuro psychiatric disturbances"):ti,ab
- 16 "behavior disorder"/de
- 17 "psychological aspect"/de
- 18 agitation/de
- 19 aggression/de
- 20 aggressiveness/de
- 21 anxiety/de
- 22 "anxiety disorder"/de
- 23 apathy/de
- 24 delusion/de
- 25 depression/de

- 26 "disruptive behavior"/de
- 27 "eating disorder"/de
- 28 euphoria/de
- 29 hallucination/de
- 30 "visual hallucination"/de
- 31 irritability/de
- 32 "mood disorder"/de
- 33 "oppositional defiant disorder"/de
- 34 psychosis/de
- 35 restlessness/de
- 36 "screaming syndrome"/de
- 37 sociopathy/de
- 38 "verbal hostility"/de
- 39 violence/de
- 40 "wandering behavior"/de
- 41 hoarding:de
- 42 "compulsive hoarding":de
- 43 screaming:de
- 44 "sexual disinhibition":de
- 45 sundowning:de
- 46 "sundown syndrome":de
- 47 "sundowning syndrome":de
- 48 "challenging behavior":de
- 49 ("challenging behavior" OR "challenging behaviors"):ti,ab
- 50 ("challenging behaviour" OR "challenging behaviours"):ti,ab
- 51 ("behavioral disturbance" OR "behavioral disturbances"):ti,ab
- 52 ("behavioural disturbance" OR "behavioural disturbances"):ti,ab
- 53 ("dangerous behavior" OR "dangerous behaviors"):ti,ab
- 54 ("dangerous behaviour" OR "dangerous behaviours"):ti,ab
- 55 ("difficult behavior" OR "difficult behaviors"):ti,ab
- 56 ("difficult behaviour" OR "difficult behaviours"):ti,ab
- 57 ("disruptive behavior" OR "disruptive behaviors"):ti,ab
- 58 ("disruptive behaviour" OR "disruptive behaviours"):ti,ab
- 59 ("exiting behavior" OR "exiting behaviors"):ti,ab
- 60 ("exiting behaviour" OR "exiting behaviours"):ti,ab
- 61 ("inappropriate \*1 behavior" OR "inappropriate \*1 behaviors"):ti,ab
- 62 ("inappropriate \*1 behaviour" OR "inappropriate \*1 behaviours"):ti,ab
- 63 ("oppositional behavior" OR "oppositional behaviors"):ti,ab
- 64 ("oppositional behaviour" OR "oppositional behaviours"):ti,ab
- 65 (agitation OR aggression OR aggressiveness OR aggressivity):ti,ab
- 66 (anxiety OR depression OR euphoria):ti,ab
- 67 (apathy OR hoarding OR violence OR pacing):ti,ab
- 68 (delusion OR delusions OR hallucination OR hallucinations):ti,ab
- 69 (psychosis OR psychotic):ti,ab
- 70 (restlessnes OR shadowing OR trespassing OR wandering):ti,ab
- 71 (irritability OR noisiness OR screaming OR cursing):ti,ab
- 72 (sundowning OR "sundown syndrome"):ti,ab
- 73 ("mood disorder" OR "mood disorders"):ti,ab
- 74 ("mood disturbance" OR "mood disturbances"):ti,ab
- 75 ("abnormal vocalization" OR "abnormal vocalisation"):ti,ab
- 76 ("abnormal vocalizations" OR "abnormal vocalisations"):ti,ab
- 77 ("disruptive vocalization" OR "disruptive vocalisation"):ti,ab

- 78 ("repetitive verbalization" OR "repetitive verbalisation"):ti,ab
- 79 ("repetitive verbalizations" OR "repetitive verbalisations"):ti,ab
- 80 ("sexual disinhibition" OR "sexual disinhibitions"):ti,ab

#### I: Intervention terms

- 1 dementia/exp/dm th
- 2 therapy/de
- 3 (nonpharmacologic\* OR "non pharmacologic" OR "non pharmacological"):ti,ab
- 4 ("alternative to pharmacotherapy" OR "alternatives to pharmacotherapy"):ti,ab
- 5 ("alternative \*2 pharmacologic" OR "alternatives \*2 pharmacologic"):ti,ab
- 6 ("alternative \*2 pharmacological" OR "alternatives \*2 pharmacological"):ti,ab
- 7 ("non drug therapy" OR "non drug therapies"):ti,ab
- 8 ("nondrug therapy" OR "nondrug therapies"):ti,ab
- 9 psychotherapy/exp
- 10 "alternative medicine"/de
- 11 aromatherapy/de
- 12 phototherapy/de
- 13 "physical activity"/de
- 14 "bright light therapy":de
- 15 "ambient bright light therapy":de
- 16 "brief psychodynamic interpersonal therapy":de
- 17 "dementia care mapping":de
- 18 "interactionist interpersonal therapy":de
- 19 "interpersonal psychotherapy":de
- 20 "interpersonal therapy":de
- 21 "metacognitive interpersonal therapy":de
- 22 "multisensory environment therapy":de
- 23 "psychodynamic interpersonal therapy":de
- 24 "residential interpersonal therapy":de
- 25 "reality orientation therapy":de
- 26 "Reminiscence therapy":de
- 27 (aromatherapy OR "activity therapy" OR "bright light therapy"):ti,ab
- 28 ("behavior therapy" OR "behaviour therapy"):ti,ab
- 29 ("behavioral therapy" OR "behavioural therapy"):ti,ab
- 30 ("complementary therapy" OR "complementary therapies" OR "complementary medicine"):ti,ab
- 31 ("alternative therapy" OR "alternative therapies" OR "alternative medicine"):ti,ab
- 32 ("dementia care mapping" OR dcm OR "reality orientation"):ti,ab
- 33 ("environment therapy" OR "Reminiscence therapy"):ti,ab
- 34 ("environmental intervention" OR "environmental interventions"):ti,ab
- 35 ("interpersonal therapy" OR "Interpersonal psychotherapy"):ti,ab
- 36 ("multi sensory approach" OR "multi sensory approaches"):ti,ab
- 37 ("multisensory approach" OR "multisensory approaches"):ti,ab
- 38 ("physical activity" OR "carer education"):ti,ab
- 39 "psychosocial care"/de
- 40 ("psychosocial approach" OR "psycho social approach"):ti,ab
- 41 ("psychosocial approaches" OR "psycho social approaches"):ti,ab
- 42 ("psychosocial intervention" OR "psycho social intervention"):ti,ab
- 43 ("psychosocial interventions" OR "psycho social interventions"):ti,ab
- 44 ("psychosocial method" OR "psycho social method"):ti,ab

- 45 ("psychosocial methods" OR "psycho social methods"):ti,ab
- 46 ("psychosocial support" OR "psycho social support"):ti,ab
- 47 ("psychosocial therapy" OR "psycho social therapy"):ti,ab
- 48 ("psychosocial therapies" OR "psycho social therapies"):ti,ab
- 49 "social therapy":ti,ab
- 50 ("caregiving intervention" OR "care giving intervention"):ti,ab
- 51 ("caregiving interventions" OR "care giving interventions"):ti,ab

This strategy was modified and repeated in the Cochrane Library, CINAHL, PsycINFO and the Campbell Library databases. Slight changes were required to the syntax of the search, which is dependent upon the search platform used and to accommodate indexing differences in the databases. These searches were limited to articles published in English from 1999, when possible. The citations and abstracts provided were obtained and prepared independently as they appeared in EMBASE.com, the Cochrane Library, CINAHL, PsycINFO and the Campbell Library. The citations and abstracts were printed verbatim and may have original errors and misspellings. A single electronic file of the literature search results comprising all records retrieved via the database searches (as documented herein) was created by exporting records from the respective platforms and importing them into an EndNote Library database. The indexed subject headings/keywords were retained for all records and in addition, each record was tagged with its source database:

- EMBASE.com
- Cochrane Library Systematic Review
- Cochrane Library DARE
- Cochrane Library CENTRAL
- Cochrane Library CMR
- Cochrane Library HTA
- Cochrane Library NHSEED
- Campbell Library
- CINAHL record
- PsycINFO record
- Scopus
- Web of Science

Other resources searched included the U.S. National Institutes of Health ClinicalTrials.gov, ADEAR (Alzheimer's disease clinical trials database) and the UK Current Controlled Trials. Citation searches on a number of pivotal references for articles known to provide some evidence to support the effectiveness of some non-pharmacological treatments were performed in Scopus and Web of Science to track the citing of these articles and assess their relevance. The citing records were processed in the same way and along with the records retrieved via the EMBASE and MEDLINE databases plus The Cochrane Library, CINAHL, PsycINFO and the Campbell Library. To locate other key documents, a search of web-based resources was conducted to identify relevant sources.

A total of 5389 published papers were identified via the database searches including duplicate records.

# Search Strategy: main search results.

EMBASE.com (EMBASE+MEDLINE) was searched for articles using the search terms for the disease treatment under evaluation. A summary of the search of EMBASE.com is presented below – the search was limited to articles published in English from 1999.

# EMBASE.com search, 1999 to 27 July 2009 (\*)

| No. | Query   | Results |
|-----|---|---------|
| #1  | 'dementia'/exp  | 143 087 |
| #2  | dementia*:ti,ab OR amentia:ti,ab  | 55 762  |
| #3  | dementing:ti,ab OR demented:ti,ab OR demention:ti,ab  | 7 993   |
| #4  | alzheimer:ti,ab OR 'diffuse cortical sclerosis':ti,ab   | 67 308  |
| #5  | 'lewy body disease':ti,ab OR 'lewy body diseases':ti,ab                                       | 766     |
| #6  | #1 OR #2 OR #3 OR #4 OR #5  | 159 751 |
| #7  | 'behavioral and psychological symptoms of dementia':de  | 11      |
| #8  | 'behavioral *1 psychological symptom':ti,ab OR 'behavioral *1 psychological symptoms':ti,ab   | 357     |
| #9  | 'behavioural *1 psychological symptom':ti,ab OR 'behavioural *1 psychological symptoms':ti,ab | 171     |
| #10 | 'behavioral signs *2 symptoms':ti,ab OR 'behavioural signs *2 symptoms':ti,ab                 | 18      |
| #11 | 'behavioral *1 psychological signs':ti,ab OR 'behavioural *1 psychological signs':ti,ab       | 39      |
| #12 | 'behavioral *1 psychological problem':ti,ab OR 'behavioral *1 psychological problems':ti,ab   | 20      |
| #13 | 'behavioural *1 psychological problem':ti,ab OR 'behavioural *1 psychological problems':ti,ab | 14      |
| #14 | bpsd:ti,ab OR cbbd:ti,ab  | 310     |
| #15 | #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14   | 642     |
| #16 | #6 AND #15  | 587     |
| #17 | 'neuropsychiatry'/de  | 4 873   |
| #18 | neuropsychiatric:ti,ab OR 'neuro psychiatric':ti,ab   | 12 076  |
| #19 | #17 OR #18  | 14 523  |
| #20 | 'symptomatology'/de   | 73 191  |
| #21 | 'symptom'/de  | 65 485  |
| #22 | symptom:ti,ab OR symptoms:ti,ab   | 546 408 |
| #23 | #20 OR #21 OR #22   | 605 374 |
| #24 | #19 AND #23   | 4 175   |
| #25 | 'behavior symptom':de   | 286     |
| #26 | 'psychological symptom':de  | 4       |
| #27 | 'neuropsychiatric symptom':de   | 5       |
| #28 | 'neuropsychiatric disturbance':ti,ab OR 'neuropsychiatric disturbances':ti,ab                 | 231     |
| #29 | 'neuro psychiatric disturbance':ti,ab OR 'neuro psychiatric disturbances':ti,ab               | 11      |
| #30 | #24 OR #25 OR #26 OR #27 OR #28 OR #29  | 4 612   |
| #31 | #6 AND #30  | 1 294   |
| #32 | 'behavior disorder'/de  | 32 161  |
| #33 | 'psychological aspect'/de   | 388 216 |
| #34 | 'agitation'/de  | 10 178  |
| #35 | 'aggression'/de   | 30 433  |
| #36 | 'aggressiveness'/de   | 1 588   |
| #37 | 'anxiety'/de  | 71 374  |

| #38                     | 'anviety disorder'/de   | 21 205  |
|-------------------------|---|---------|
| #39                     | 'anxiety disorder'/de   | 21 203  |
| #40                     | 'apathy'/de 'delusion'/de   | 8 190   |
| # <del>4</del> 0<br>#41 |   | 173,999 |
| # <del>4</del> 1<br>#42 | 'depression'/de   | 512     |
|                         | 'disruptive behavior'/de  |         |
| #43                     | 'eating disorder'/de  | 9 705   |
| #44                     | 'euphoria'/de   | 2 703   |
| #45                     | 'hallucination'/de  | 13 579  |
| #46                     | 'visual hallucination'/de   | 2 311   |
| #47                     | 'irritability'/de   | 8 110   |
| #48                     | 'mood disorder'/de  | 13 464  |
| #49                     | 'oppositional defiant disorder'/de  | 670     |
| #50                     | 'psychosis'/de  | 42 003  |
| #51                     | 'restlessness'/de   | 5033    |
| #52                     | 'screaming syndrome'/de   | 17      |
| #53                     | 'sociopathy'/de   | 2 473   |
| #54                     | 'verbal hostility'/de   | 290     |
| #55                     | 'violence'/de   | 25 854  |
| #56                     | 'wandering behavior'/de   | 86      |
| #57                     | hoarding:de   | 58      |
| #58                     | 'compulsive hoarding':de  | 23      |
| #59                     | screaming:de  | 27      |
| #60                     | 'sexual disinhibition':de   | 4       |
| #61                     | sundowning:de   | 7       |
| #62                     | 'sundown syndrome':de   | 2       |
| #63                     | 'sundowning syndrome':de  | 3       |
| #64                     | 'challenging behavior':de   | 3       |
| #65                     | 'challenging behavior':ti,ab OR 'challenging behaviors':ti,ab                     | 216     |
| #66                     | 'challenging behaviour':ti,ab OR 'challenging behaviours':ti,ab                   | 447     |
| #67                     | 'behavioral disturbance':ti,ab OR 'behavioral disturbances':ti,ab                 | 1 801   |
| #68                     | 'behavioural disturbance':ti,ab OR 'behavioural disturbances':ti,ab               | 973     |
| #69                     | 'dangerous behavior':ti,ab OR 'dangerous behaviors':ti,ab                         | 174     |
| #70                     | 'dangerous behaviour':ti,ab OR 'dangerous behaviours':ti,ab                       | 89      |
| #71                     | 'difficult behavior':ti,ab OR 'difficult behaviors':ti,ab                         | 74      |
| #72                     | 'difficult behaviour':ti,ab OR 'difficult behaviours':ti,ab                       | 87      |
| #73                     | 'disruptive behavior':ti,ab OR 'disruptive behaviors':ti,ab                       | 1 452   |
| #74                     | 'disruptive behaviour':ti,ab OR 'disruptive behaviours':ti,ab                     | 309     |
| #75                     | 'exiting behavior':ti,ab OR 'exiting behaviors':ti,ab                             | 7       |
| #76                     | 'exiting behaviour':ti,ab OR 'exiting behaviours':ti,ab                           | 1       |
| #77                     | 'inappropriate *1 behavior':ti,ab OR 'inappropriate *1 behaviors':ti,ab           | 554     |
| #78                     | 'inappropriate *1 behaviour':ti,ab OR 'inappropriate *1 behaviours':ti,ab         | 182     |
| #79                     | 'oppositional behavior':ti,ab OR 'oppositional behaviors':ti,ab                   | 153     |
| #80                     | 'oppositional behaviour':ti,ab OR 'oppositional behaviours':ti,ab                 | 29      |
| #81                     | agitation:ti,ab OR aggression:ti,ab OR aggressiveness:ti,ab OR aggressivity:ti,ab | 32 906  |
| #82                     | anxiety:ti,ab OR depression:ti,ab OR euphoria:ti,ab                               | 234 196 |
| #83                     | apathy:ti,ab OR hoarding:ti,ab OR violence:ti,ab OR pacing:ti,ab                  | 48 392  |
| #84                     | delusion:ti,ab OR delusions:ti,ab OR hallucination:ti,ab OR hallucinations:ti,ab  | 11 789  |
| #85                     | psychosis:ti,ab OR psychotic:ti,ab  | 37 481  |
| #86                     | restlessnes:ti,ab OR shadowing:ti,ab OR trespassing:ti,ab OR wandering:ti,ab      | 3 927   |
| #87                     | irritability:ti,ab OR noisiness:ti,ab OR screaming:ti,ab OR cursing:ti,ab         | 5 974   |
| #88                     | sundowning:ti,ab OR 'sundown syndrome':ti,ab                                      | 76      |
|                         | • · · · · · · · · · · · · · · · · · · ·   |         |

| #89    | 'mood disorder':ti,ab OR 'mood disorders':ti,ab   | 7 820   |
|--------|---|---------|
| #90    | 'mood disturbance':ti,ab OR 'mood disturbances':ti,ab   | 1 338   |
| #91    | 'abnormal vocalization':ti,ab OR 'abnormal vocalisation':ti,ab  | 5       |
| #92    | 'abnormal vocalizations':ti,ab OR 'abnormal vocalisations':ti,ab  | 2       |
| #93    | 'disruptive vocalization':ti,ab OR 'disruptive vocalisation':ti,ab  | 11      |
| #94    | 'repetitive verbalization':ti,ab OR 'repetitive verbalisation':ti,ab  | 0       |
| #95    | 'repetitive verbalizations':ti,ab OR 'repetitive verbalisations':ti,ab  | 4       |
| #96    | 'sexual disinhibition':ti,ab OR 'sexual disinhibitions':ti,ab   | 58      |
| #97    | #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75 OR #76 OR #77 OR #78 OR #79 OR #80 OR #81 OR #82 OR #83 OR #84 OR #85 OR #86 OR #87 OR #88 OR #89 OR #90 OR #91 OR #92 OR #93 OR #94 OR #95 OR #96 | 847 464 |
| #98    | #6 AND #97  | 28 507  |
| #99    | #16 OR #31 OR #98   | 28 892  |
| #100   | 'dementia'/exp/dm th  | 4 732   |
| #101   | 'therapy'/de  | 900 843 |
| #102   | nonpharmacologic*:ti,ab OR 'non pharmacologic':ti,ab OR 'non pharmacological':ti,ab   | 7 629   |
| #103   | 'alternative to pharmacotherapy':ti,ab OR 'alternatives to pharmacotherapy':ti,ab   | 27      |
| #104   | 'alternative *2 pharmacologic':ti,ab OR 'alternatives *2 pharmacologic':ti,ab   | 105     |
| #105   | 'alternative *2 pharmacological':ti,ab OR 'alternatives *2 pharmacological':ti,ab   | 225     |
| #106   | 'non drug therapy':ti,ab OR 'non drug therapies':ti,ab  | 156     |
| #107   | 'nondrug therapy':ti,ab OR 'nondrug therapies':ti,ab  | 109     |
| #108   | #100 OR #101 OR #102 OR #103 OR #104 OR #105 OR #106 OR #107  | 913 347 |
| #109   | #99 AND #108  | 2 508   |
| #110   | 'psychotherapy'/exp   | 143 800 |
| #111   | 'alternative medicine'/de   | 25 445  |
| #112   | 'aromatherapy'/de   | 421     |
| #113   | 'phototherapy'/de   | 10 846  |
| #114   | 'physical activity'/de  | 39 512  |
| #115   | 'bright light therapy':de   | 17      |
| #116   | 'ambient bright light therapy':de   | 1       |
| #117   | 'brief psychodynamic interpersonal therapy':de  | 1       |
| #118   | 'dementia care mapping':de  | 4       |
| #119   | 'interactionist interpersonal therapy':de   | 1       |
| #120   | 'interpersonal psychotherapy':de  | 46      |
| #121   | 'interpersonal therapy':de  | 35      |
| #122   | 'metacognitive interpersonal therapy':de  | 2       |
| #123   | 'multisensory environment therapy':de   | 1       |
| #124   | 'psychodynamic interpersonal therapy':de  | 2       |
| #125   | 'residential interpersonal therapy':de  | 2       |
| #126   | 'reality orientation therapy':de  | 9       |
| #127   | 'reminiscence therapy':de   | 4       |
| #128   | aromatherapy:ti,ab OR 'activity therapy':ti,ab OR 'bright light therapy':ti,ab  | 880     |
| #129   | 'behavior therapy':ti,ab OR 'behaviour therapy':ti,ab   | 5 079   |
| #130   | 'behavioral therapy':ti,ab OR 'behavioural therapy':ti,ab   | 5 331   |
| #131   | 'complementary therapy':ti,ab OR 'complementary therapies':ti,ab OR   | 3 272   |
| #132   | 'complementary medicine':ti,ab  'alternative therapy':ti,ab OR 'alternative therapies':ti,ab OR 'alternative  | 9 257   |
| #133   | medicine':ti,ab 'dementia care mapping':ti,ab OR dcm:ti,ab OR 'reality orientation':ti,ab   | 3 205   |
| ., .00 | as  |         |

| #134 | 'environment therapy':ti,ab OR 'reminiscence therapy':ti,ab  | 112     |
|------|--|---------|
| #135 | 'environmental intervention':ti,ab OR 'environmental interventions':ti,ab  | 465     |
| #136 | 'interpersonal therapy':ti,ab OR 'interpersonal psychotherapy':ti,ab   | 697     |
| #137 | 'multi sensory approach':ti,ab OR 'multi sensory approaches':ti,ab   | 2       |
| #138 | 'multisensory approach':ti,ab OR 'multisensory approaches':ti,ab   | 11      |
| #139 | 'physical activity':ti,ab OR 'carer education':ti,ab   | 35 548  |
| #140 | #110 OR #111 OR #112 OR #113 OR #114 OR #115 OR #116 OR #117 OR #118 OR #119 OR #120 OR #121 OR #122 OR #123 OR #124 OR #125 OR #126 OR #127 OR #128 OR #129 OR #130 OR #131 OR #132 OR #133 OR #134 OR #135 OR #136 OR #137 OR #138 OR #139 | 242 496 |
| #141 | #99 AND #140   | 1 960   |
| #142 | 'psychosocial care'/de   | 6 224   |
| #143 | 'psychosocial approach':ti,ab OR 'psycho social approach':ti,ab  | 201     |
| #144 | 'psychosocial approaches':ti,ab OR 'psycho social approaches':ti,ab  | 132     |
| #145 | 'psychosocial intervention':ti,ab OR 'psycho social intervention':ti,ab  | 849     |
| #146 | 'psychosocial interventions':ti,ab OR 'psycho social interventions':ti,ab  | 1 645   |
| #147 | 'psychosocial method':ti,ab OR 'psycho social method':ti,ab  | 3       |
| #148 | 'psychosocial methods':ti,ab OR 'psycho social methods':ti,ab  | 27      |
| #149 | 'psychosocial support':ti,ab OR 'psycho social support':ti,ab  | 1 377   |
| #150 | 'psychosocial therapy':ti,ab OR 'psycho social therapy':ti,ab  | 137     |
| #151 | 'psychosocial therapies':ti,ab OR 'psycho social therapies':ti,ab  | 106     |
| #152 | 'social therapy':ti,ab   | 148     |
| #153 | 'caregiving intervention':ti,ab OR 'care giving intervention':ti,ab  | 4       |
| #154 | 'caregiving interventions':ti,ab OR 'care giving interventions':ti,ab  | 16      |
| #155 | #142 OR #143 OR #144 OR #145 OR #146 OR #147 OR #148 OR #149 OR #150 OR #151 OR #152 OR #153 OR #154   | 9 351   |
| #156 | #99 AND #155   | 235     |
| #157 | #109 OR #141 OR #156   | 3 894   |
| #158 | #157 AND [english]/lim   | 3 070   |
| #159 | #158 AND [1999-2010]/py  | 1 874   |

<sup>\*</sup> The search was conducted using EMBASE.com on 28 July 2009.

The Cochrane Library was searched for controlled trials and publications using the search terms for the disease treatment under evaluation. A summary of the search of the Cochrane Library is presented below—the search was limited to articles published from 1999.

The Cochrane Library search, 2009 Issue 3 (\*)

| ID  | Search  | Hits  |
|-----|---|-------|
| #1  | MeSH descriptor Dementia explode all trees  | 2 867 |
| #2  | dementia* OR amentia  | 6 788 |
| #3  | dementing OR demented OR demention  | 443   |
| #4  | Alzheimer OR "diffuse cortical sclerosis"   | 3 867 |
| #5  | "Lewy body disease" OR "Lewy body diseases"   | 42    |
| #6  | (#1 OR #2 OR #3 OR #4 OR #5)  | 7 966 |
| #7  | (Behavioral OR behavioural) NEAR/1 ("psychological symptom" OR "psychological symptoms")    | 0     |
| #8  | ("behavioral signs" OR "behavioural signs") NEAR/2 symptoms                                 | 1     |
| #9  | (behavioral OR behavioural) NEAR/1 "psychological signs"                                    | 0     |
| #10 | (behavioral OR behavioural) NEAR/1 ("psychological problem" OR "psychological problems") $$ | 0     |
| #11 | bpsd OR cbbd  | 34    |
| #12 | (#7 OR #8 OR #9 OR #10 OR #11)  | 35    |
| #13 | (#6 AND #12)  | 33    |
| #14 | MeSH descriptor Dementia explode all trees with qualifier: PX                               | 827   |
| #15 | MeSH descriptor Neuropsychology explode all trees   | 13    |
| #16 | MeSH descriptor Behavioral Symptoms, this term only   | 63    |
| #17 | MeSH descriptor Affective Symptoms explode all trees  | 260   |
| #18 | (neuropsychiatric OR "neuro psychiatric") NEAR/1 (symptom* OR disturbance*)                 | 94    |
| #19 | (#14 OR #15 OR #16 OR #17 OR #18)   | 1 216 |
| #20 | (#6 AND #19)  | 890   |
| #21 | MeSH descriptor Mental Disorders, this term only  | 1 835 |
| #22 | MeSH descriptor Psychomotor Agitation, this term only                                       | 301   |
| #23 | MeSH descriptor Aggression explode all trees  | 638   |
| #24 | MeSH descriptor Anxiety explode all trees   | 3 603 |
| #25 | MeSH descriptor Anxiety Disorders explode all trees   | 3 530 |
| #26 | MeSH descriptor Delusions explode all trees   | 95    |
| #27 | MeSH descriptor Depression explode all trees  | 3 471 |
| #28 | MeSH descriptor Eating Disorders explode all trees  | 539   |

| #29 | MeSH descriptor Euphoria explode all trees                | 158    |
|-----|---|--------|
| #30 | MeSH descriptor Hallucinations explode all trees          | 178    |
| #31 | MeSH descriptor Irritable Mood explode all trees          | 70     |
| #32 | MeSH descriptor Mood Disorders explode all trees          | 6 776  |
| #33 | MeSH descriptor Psychotic Disorders explode all trees     | 1 138  |
| #34 | MeSH descriptor Hostility explode all trees               | 203    |
| #35 | MeSH descriptor Social Behavior Disorders, this term only | 125    |
| #36 | MeSH descriptor Violence, this term only                  | 279    |
| #37 | MeSH descriptor Wandering Behavior explode all trees      | 0      |
| #38 | "challenging behavior" OR "challenging behaviors"         | 6      |
| #39 | "challenging behaviour" OR "challenging behaviours"       | 56     |
| #40 | "behavioral disturbance" OR "behavioral disturbances"     | 129    |
| #41 | "behavioural disturbance" OR "behavioural disturbances"   | 132    |
| #42 | "dangerous behavior" OR "dangerous behaviors"             | 30     |
| #43 | "dangerous behaviour" OR "dangerous behaviours"           | 13     |
| #44 | "difficult behavior" OR "difficult behaviors"             | 3      |
| #45 | "difficult behaviour" OR "difficult behaviours"           | 12     |
| #46 | "disruptive behavior" OR "disruptive behaviors"           | 210    |
| #47 | "disruptive behaviour" OR "disruptive behaviours"         | 78     |
| #48 | "exiting behavior" OR "exiting behaviors"                 | 0      |
| #49 | "exiting behaviour" OR "exiting behaviours"               | 0      |
| #50 | inappropriate NEAR/1 (behavior* OR behaviour*)            | 47     |
| #51 | "oppositional behavior" OR "oppositional behaviors"       | 18     |
| #52 | "oppositional behaviour" OR "oppositional behaviours"     | 10     |
| #53 | agitation OR aggression OR aggressiveness OR aggressivity | 2 582  |
| #54 | anxiety OR depression OR euphoria                         | 33 222 |
| #55 | apathy OR hoarding OR violence OR pacing                  | 3 668  |
| #56 | delusion OR delusions OR hallucination OR hallucinations  | 927    |
| #57 | psychosis OR psychotic                                    | 4 053  |
| #58 | restlessnes OR shadowing OR trespassing OR wandering      | 236    |
| #59 | irritability OR noisiness OR screaming OR cursing         | 917    |
| #60 | sundowning OR "sundown syndrome"                          | 4      |
| #61 | "mood disorder" OR "mood disorders"                       | 820    |
| #62 | "mood disturbance" OR "mood disturbances"                 | 239    |
| #63 | "abnormal vocalization" OR "abnormal vocalisation"        | 0      |
| #64 | "abnormal vocalizations" OR "abnormal vocalisations"      | 0      |

| #65 | "disruptive vocalization" OR "disruptive vocalisation"   | 2      |
|-----|--|--------|
| #66 | "repetitive verbalization" OR "repetitive verbalisation"   | 0      |
| #67 | "repetitive verbalizations" OR "repetitive verbalisations"   | 1      |
| #68 | "sexual disinhibition" OR "sexual disinhibitions"  | 4      |
| #69 | (#21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68) | 46 708 |
| #70 | (#6 AND #69)   | 1 580  |
| #71 | (#13 OR #20 OR #70)  | 2 120  |
| #72 | MeSH descriptor Dementia explode all trees with qualifier: TH  | 275    |
| #73 | (nonpharmacologic* OR "non pharmacologic" OR "non pharmacological")  | 1 052  |
| #74 | "alternative to pharmacotherapy" OR "alternatives to pharmacotherapy"  | 8      |
| #75 | (alternative OR alternatives) NEAR/2 (pharmacologic OR pharmacological)  | 64     |
| #76 | "non drug therapy" OR "non drug therapies"   | 27     |
| #77 | "nondrug therapy" OR "nondrug therapies"   | 12     |
| #78 | (#72 OR #73 OR #74 OR #75 OR #76 OR #77)   | 1 399  |
| #79 | (#71 AND #78)  | 192    |
| #80 | MeSH descriptor Psychotherapy explode all trees  | 9 870  |
| #81 | MeSH descriptor Complementary Therapies, this term only  | 295    |
| #82 | MeSH descriptor Phototherapy explode all trees   | 1 420  |
| #83 | MeSH descriptor Motor Activity, this term only   | 1 237  |
| #84 | aromatherapy OR "activity therapy" OR "bright light therapy"   | 255    |
| #85 | "behavior therapy" OR "behaviour therapy"  | 4 730  |
| #86 | "behavioral therapy" OR "behavioural therapy"  | 1 777  |
| #87 | "complementary therapy" OR "complementary therapies" OR "complementary medicine"   | 1 402  |
| #88 | "alternative therapy" OR "alternative therapies" OR "alternative medicine"   | 1 191  |
| #89 | "dementia care mapping" OR dcm OR "reality orientation"  | 140    |
| #90 | "environment therapy" OR "Reminiscence therapy"  | 35     |
| #91 | "environmental intervention" OR "environmental interventions"  | 103    |
| #92 | "interpersonal therapy" OR "Interpersonal psychotherapy"   | 331    |
| #93 | "multi sensory approach" OR "multi sensory approaches"   | 0      |
| #94 | "multisensory approach" OR "multisensory approaches"   | 0      |
| #95 | "physical activity" OR "carer education"   | 3 526  |
| #96 | (#80 OR #81 OR #82 OR #83 OR #84 OR #85 OR #86 OR #87 OR #88 OR #89 OR #90 OR #91 OR #92 OR #93 OR #94 OR #95)   | 19 995 |

| #97  | (#71 AND #96)  | 291 |
|------|--|-----|
| #98  | "psychosocial approach" OR "psycho social approach"  | 16  |
| #99  | "psychosocial approaches" OR "psycho social approaches"                                      | 14  |
| #100 | "psychosocial intervention" OR "psycho social intervention"                                  | 345 |
| #101 | "psychosocial interventions" OR "psycho social interventions"                                | 386 |
| #102 | "psychosocial method" OR "psycho social method"  | 1   |
| #103 | "psychosocial methods" OR "psycho social methods"  | 7   |
| #104 | "psychosocial support" OR "psycho social support"  | 163 |
| #105 | "psychosocial therapy" OR "psycho social therapy"  | 41  |
| #106 | "psychosocial therapies" OR "psycho social therapies"  | 31  |
| #107 | "social therapy"   | 10  |
| #108 | "caregiving intervention" OR "care giving intervention"                                      | 1   |
| #109 | "caregiving interventions" OR "care giving interventions"                                    | 3   |
| #110 | (#98 OR #99 OR #100 OR #101 OR #102 OR #103 OR #104 OR #105 OR #106 OR #107 OR #108 OR #109) | 851 |
| #111 | (#71 AND #110)   | 50  |
| #112 | (#79 OR #97 OR #111)   | 408 |
| #113 | (#112), from 1999 to 2009  | 306 |
|      |  |     |

### Breakdown of database retrieval from the Cochrane Library, 2009 Issue 2

\* The search was conducted using Wiley Interscience on 29 July 2009.

| Database   | Results |
|--|---------|
| Cochrane Database of Systematic Reviews                  | 82      |
| Database of Abstracts of Reviews of Effects (DARE)       | 44      |
| Cochrane Central Register of Controlled Trials (CENTRAL) | 200     |
| Cochrane Methodology Register (CMR)                      | 1       |
| Health Technology Assessment Database (HTA)              | 4       |
| NHS Economic Evaluation Database (NHSEED)                | 14      |
| Cochrane Groups  | (*)5    |
| Total  | 350     |

<sup>\*</sup> These records representing information on Review Groups of The Cochrane Collaboration were not exported – their names, with links to the information about them, appear below:

### Cochrane Dementia and Cognitive Improvement Group

http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/DEMENTIA/frame.html

#### Cochrane Depression, Anxiety and Neurosis Group

http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/DEPRESSN/frame.html

#### Cochrane Stroke Group

http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/STROKE/frame.html

# Brazilian Cochrane Centre

http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/CE000080/frame.html

Cochrane Pain, Palliative and Supportive Care Group

# http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/SYMPT/frame.html

CINAHL was searched for articles using the search terms for the disease treatment under evaluation. A summary of the search of CINAHL is presented below—the search was limited to articles published in English from 1999 and to exclude MEDLINE records.

# CINAHL search, 1999 to 30 July 2009 (\*)

| #    | Query  | Results     |
|------|--|-------------|
| S127 | S91 or S109 or S123<br>Limiters - Publication Year from: 1999-2009; English-language; Exclude MEDLINE records                                      | 1 998       |
| S126 | S91 or S109 or S123<br>Limiters - Publication Year from: 1999-2009; English-language   | 3 400       |
| S125 | S91 or S109 or S123<br>Limiters - English-language   | 4 139       |
|      | S91 or S109 or S123<br>S80 and S122  | 4 195<br>88 |
|      | S110 or S111 or S112 or S113 or S114 or S115 or S116 or S117 or S118 or S119 or S120 or S121   |             |
| S121 | TI ( "caregiving interventions" OR "care giving interventions" ) or AB ( "caregiving interventions" )  | 12          |
| S120 | TI ( "caregiving intervention" OR "care giving intervention" ) or AB ( "caregiving intervention" OR "care giving intervention" )                   | 6           |
| S119 | TI "social therapy" or AB "social therapy"   | 4           |
| S118 | ${\sf TI}$ ( "psychosocial therapies" ${\sf OR}$ "psychosocial therapies" ) or AB ( "psychosocial therapies" ${\sf OR}$ "psychosocial therapies" ) | 19          |
| S117 | TI ( "psychosocial therapy" OR "psycho social therapy" ) or AB ( "psychosocial therapy" OR "psycho social therapy" )                               | 21          |
| S116 | TI ( "psychosocial support" OR "psycho social support" ) or AB ( "psychosocial support" OR "psycho social support" )                               | 503         |
| S115 | TI ( "psychosocial methods" OR "psycho social methods" ) or AB ( "psychosocial methods" OR "psycho social methods" )                               | 6           |
| S114 | TI ( "psychosocial method" OR "psycho social method" ) or AB ( "psychosocial method" OR "psycho social method" )                                   | 1           |
| S113 | TI ( "psychosocial interventions" OR "psycho social interventions" ) or AB ( "psychosocial interventions" OR "psycho social interventions" )       | 597         |
| S112 | TI ( "psychosocial intervention" OR "psycho social intervention" ) or AB ( "psychosocial intervention" OR "psycho social intervention" )           | 263         |
| S111 | TI ( "psychosocial approaches" OR "psycho social approaches" ) or AB ( "psychosocial approaches" OR "psycho social approaches" )                   | 33          |
| S110 | ${\sf TI}$ ( "psychosocial approach" ${\sf OR}$ "psycho social approach" ) or AB ( "psychosocial approach" )                                       | 59          |
| S109 | S80 and S108   | 2 372       |
| S108 | S92 or S93 or S94 or S95 or S96 or S97 or S98 or S99 or S100 or S101 or S102 or S103 or S104 or S105 or S106 or S107                               | 83 816      |
| S107 | TI ( "physical activity" OR "carer education" ) or AB ( "physical activity" OR "carer education" )   | 10 343      |
| S106 | munisensory approach OR munisensory approaches )   | 12          |
| S105 | TI ( "multi sensory approach" OR "multi sensory approaches" ) or AB ( "multi sensory approaches" )   | 3           |
| S104 | TI ( "interpersonal therapy" OR "Interpersonal psychotherapy" ) or AB ( "interpersonal therapy" OR "Interpersonal psychotherapy" )                 | 139         |
| S103 | TI ( "environmental intervention" OR "environmental interventions" ) or AB ( "environmental intervention" OR "environmental interventions" )       | 141         |
| S102 | TI ( "environment therapy" OR "Reminiscence therapy" ) or AB ( "environment therapy" OR "Reminiscence therapy" ) $$                                | 84          |

| S101 | TI ( "dementia care mapping" OR dcm OR "reality orientation" ) or AB ( "dementia care mapping" OR dcm OR "reality orientation" )   | 268     |
|------|--|---------|
| S100 | TI ( "alternative therapy" OR "alternative therapies" OR "alternative medicine" ) or AB ( "alternative therapy" OR "alternative therapies" OR "alternative medicine" )   | 3 644   |
| S99  | TI ( "complementary therapy" OR "complementary therapies" OR "complementary medicine" ) or AB ( "complementary therapy" OR "complementary therapies" OR "complementary medicine" )   | 2 231   |
| S98  | TI ( "behavioral therapy" OR "behavioural therapy" ) or AB ( "behavioral therapy" OR "behavioural therapy" )   | 1 260   |
| S97  | TI ( "behavior therapy" OR "behaviour therapy" ) or AB ( "behavior therapy" OR "behaviour therapy" )   | 697     |
| S96  | TI ( aromatherapy OR "activity therapy" OR "bright light therapy" ) or AB ( aromatherapy OR "activity therapy" OR "bright light therapy" )   | 552     |
| S95  | (MH "Motor Activity")  | 1 740   |
| S94  | (MH "Phototherapy")  | 768     |
| S93  | (MH "Alternative Therapies")   | 13 958  |
| S92  | (MH "Psychotherapy+")  | 56 179  |
| S91  | S80 and S90  | 2 446   |
| S90  | S81 or S82 or S83 or S84 or S85 or S86 or S87 or S88 or S89  | 4 338   |
| S89  | TI ( "nondrug therapy" OR "nondrug therapies" ) or AB ( "nondrug therapy" OR "nondrug therapies" )   | 35      |
| S88  | TI ( "non drug therapy" OR "non drug therapies" ) or AB ( "non drug therapy" OR "non drug therapies" )   | 14      |
| S87  | TI alternatives N2 pharmacological or AB alternatives N2 pharmacological   | 12      |
| S86  | TI alternative N2 pharmacological or AB alternative N2 pharmacological   | 35      |
| S85  | TI alternatives N2 pharmacologic or AB alternatives N2 pharmacologic   | 10      |
|      |  |         |
| S84  | TI alternative N2 pharmacologic or AB alternative N2 pharmacologic   | 22      |
| S83  | TI ( "alternative to pharmacotherapy" OR "alternatives to pharmacotherapy" ) or AB ( "alternative to pharmacotherapy" OR "alternatives to pharmacotherapy" )   | 6       |
| S82  | TI ( (nonpharmacologic* OR "non pharmacologic" OR "non pharmacological") ) or AB ( (nonpharmacologic* OR "non pharmacologic" OR "non pharmacological") )   | 1 930   |
| S81  | (MH "Dementia+/TH")  | 2 349   |
| S80  | S21 or S31 or S79  | 21 249  |
| S79  | S6 and S78   | 21 228  |
| S78  | S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43 or S44 or S45 or S46 or S47 or S48 or S49 or S50 or S51 or S52 or S53 or S54 or S55 or S56 or S57 or S58 or S59 or S60 or S61 or S62 or S63 or S64 or S65 or S66 or S67 or S68 or S69 or S70 or S71 or S72 or S73 or S74 or S75 or S76 or S77 | 133 186 |
| S77  | TI ( "sexual disinhibition" OR "sexual disinhibitions" ) or AB ( "sexual disinhibition" OR "sexual disinhibitions" )   | 9       |
| S76  | TI ( "repetitive verbalizations" OR "repetitive verbalisations" ) or AB ( "repetitive verbalizations" )  | 4       |
| S75  | TI ( "repetitive verbalization" OR "repetitive verbalisation" ) or AB ( "repetitive verbalization" )   | 0       |
| S74  | TI ( "disruptive vocalization" OR "disruptive vocalisation" ) or AB ( "disruptive vocalization" OR "disruptive vocalisation" )   | 6       |
| S73  | TI ( "abnormal vocalizations" OR "abnormal vocalisations" ) or AB ( "abnormal vocalizations" OR "abnormal vocalisations" )   | 0       |
| S72  | TI ( "abnormal vocalization" OR "abnormal vocalisation" ) or AB ( "abnormal vocalization" OR "abnormal vocalisation" )   | 0       |
| S71  | ${\sf TI}$ ( "mood disturbance" ${\sf OR}$ "mood disturbances" ) or AB ( "mood disturbance" ${\sf OR}$ "mood disturbances" )   | 319     |
| S70  | TI ( "mood disorder" OR "mood disorders" ) or AB ( "mood disorder" OR "mood disorders" )   | 825     |
| S69  | TI ( sundowning OR "sundown syndrome" ) or AB ( sundowning OR "sundown syndrome" )   | 34      |

| S68 | TI ( irritability OR noisiness OR screaming OR cursing ) or AB ( irritability OR noisiness OR screaming OR cursing )                 | 650                 |
|-----|--|---------------------|
| S67 | TI ( restlessnes OR shadowing OR trespassing OR wandering ) or AB ( restlessnes OR shadowing OR trespassing OR wandering )           | 405                 |
| S66 | TI ( psychosis OR psychotic ) or AB ( psychosis OR psychotic )   | 2 938               |
| S65 | TI ( delusion OR delusions OR hallucination OR hallucinations ) or AB ( delusion OR delusions OR hallucination OR hallucinations )   | 951                 |
| S64 | TI ( apathy OR hoarding OR violence OR pacing ) or AB ( apathy OR hoarding OF violence OR pacing )                                   | <sup>R</sup> 15 026 |
| S63 | TI ( anxiety OR depression OR euphoria ) or AB ( anxiety OR depression OR euphoria )   | 34 552              |
| S62 | TI ( agitation OR aggression OR aggressiveness OR aggressivity ) or AB ( agitation OR aggression OR aggressiveness OR aggressivity ) | 3 212               |
| S61 | TI ( "oppositional behaviour" OR "oppositional behaviours" ) or AB ( "oppositional behaviour" OR "oppositional behaviours" )         | 1                   |
| S60 | TI ( "oppositional behavior" OR "oppositional behaviors" ) or AB ( "oppositional behavior" OR "oppositional behaviors" )             | 27                  |
| S59 | TI inappropriate N1 behaviour* or AB inappropriate N1 behaviour*   | 59                  |
| S58 | TI inappropriate N1 behavior* or AB inappropriate N1 behavior*   | 149                 |
| S57 | TI ( "exiting behaviour" OR "exiting behaviours" ) or AB ( "exiting behaviour" OR "exiting behaviours" )                             | 0                   |
| S56 | TI ( "exiting behavior" OR "exiting behaviors" ) or AB ( "exiting behavior" OR "exiting behaviors" )                                 | 0                   |
| S55 | TI ( "disruptive behaviour" OR "disruptive behaviours" ) or AB ( "disruptive behaviour" OR "disruptive behaviours" )                 | 84                  |
| S54 | TI ( "disruptive behavior" OR "disruptive behaviors" ) or AB ( "disruptive behavior" OR "disruptive behaviors" )                     | 384                 |
| S53 | TI ( "difficult behaviour" OR "difficult behaviours" ) or AB ( "difficult behaviour" OR "difficult behaviours" )                     | 47                  |
| S52 | TI ( "difficult behavior" OR "difficult behaviors" ) or AB ( "difficult behavior" OR "difficult behaviors" )                         | 37                  |
| S51 | TI ( "dangerous behaviour" OR "dangerous behaviours" ) or AB ( "dangerous behaviour" OR "dangerous behaviours" )                     | 15                  |
| S50 | TI ( "dangerous behavior" OR "dangerous behaviors" ) or AB ( "dangerous behavior" OR "dangerous behaviors" )                         | 30                  |
| S49 | TI ( "behavioural disturbance" OR "behavioural disturbances" ) or AB ( "behavioural disturbance" OR "behavioural disturbances" )     | 105                 |
| S48 | TI ( "behavioral disturbance" OR "behavioral disturbances" ) or AB ( "behavioral disturbance" OR "behavioral disturbances" )         | 198                 |
| S47 | TI ( "challenging behaviour" OR "challenging behaviours" ) or AB ( "challenging behaviour" OR "challenging behaviours" )             | 419                 |
| S46 | TI ( "challenging behavior" OR "challenging behaviors" ) or AB ( "challenging behavior" OR "challenging behaviors" )                 | 88                  |
| S45 | (MH "Wandering Behavior")  | 370                 |
| S44 | (MH "Violence")  | 6 140               |
| S43 | (MH "Social Behavior Disorders")   | 1 082               |
| S42 | (MH "Psychotic Disorders+")  | 32 196              |
| S41 | (MH "Affective Disorders")   | 1 438               |
| S40 | (MH "Hallucinations")  | 613                 |
| S39 | (MH "Eating Disorders+")   | 5 598               |
| S38 | (MH "Depression")  | 25 395              |
| S37 | (MH "Delusions")   | 402                 |
| S36 | (MH "Anxiety Disorders+")  | 9 528               |
| S35 | (MH "Anxiety+")  | 9 385               |
| S34 | (MH "Aggression+")   | 25 688              |
| S33 | (MH "Psychomotor Agitation")   | 229                 |

| S32   | (MH "Mental Disorders")  | 16 022 |
|-------|--|--------|
| S31   | S6 and S30   | 2 371  |
| S30   | S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29   | 3 837  |
| S29   | TI "neuro psychiatric" N1 disturbance* or AB "neuro psychiatric" N1 disturbance*                                 | 0      |
| S28   | TI "neuro psychiatric" N1 symptom* or AB "neuro psychiatric" N1 symptom*   | 0      |
| S27   | TI neuropsychiatric N1 disturbance* or AB neuropsychiatric N1 disturbance*                                       | 21     |
| S26   | TI neuropsychiatric N1 symptom* or AB neuropsychiatric N1 symptom*   | 208    |
| S25   | (MH "Affective Symptoms")  | 672    |
| S24   | (MH "Behavioral Symptoms")   | 398    |
| S23   | (MH "Neuropsychology")   | 571    |
| S22   | (MH "Dementia+/PF")  | 2 075  |
| S21   | S6 and S20   | 152    |
| S20   | S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19                             | 169    |
| S19   | TI ( bpsd OR cbbd ) or AB ( bpsd OR cbbd )   | 75     |
| S18   | TI behavioural N1 "psychological problems" or AB behavioural N1 "psychological problems"                         | 5      |
| S17   | TI behavioural N1 "psychological problem" or AB behavioural N1 "psychological problem"                           | 0      |
| S16   | TI behavioral N1 "psychological problems" or AB behavioral N1 "psychological problems"                           | 10     |
| S15   | TI behavioral N1 "psychological problem" or AB behavioral N1 "psychological problem"                             | 0      |
| S14   | TI behavioural N1 "psychological signs" or AB behavioural N1 "psychological signs"                               | 4      |
| S13   | TI behavioral N1 "psychological signs" or AB behavioral N1 "psychological signs"                                 | 3      |
| S12   | TI "behavioural signs" N2 symptoms or AB "behavioural signs" N2 symptoms   | 0      |
| S11   | TI "behavioral signs" N2 symptoms or AB "behavioral signs" N2 symptoms   | 3      |
| S10   | TI Behavioural N1 "psychological symptoms" or AB Behavioural N1 "psychological symptoms"                         | 54     |
| S9    | TI Behavioural N1 "psychological symptom" or AB Behavioural N1 "psychological symptom"                           | 0      |
| S8    | TI Behavioral N1 "psychological symptoms" or AB Behavioral N1 "psychological symptoms"                           | 85     |
| S7    | TI Behavioral N1 "psychological symptom" or AB Behavioral N1 "psychological symptom"                             | 0      |
| S6    | S1 or S2 or S3 or S4 or S5   | 22 787 |
| S5    | ${\rm TI}$ ( "Lewy body disease" OR "Lewy body diseases" ) or AB ( "Lewy body disease" OR "Lewy body diseases" ) | 41     |
| S4    | TI ( Alzheimer OR "diffuse cortical sclerosis" ) or AB ( Alzheimer OR "diffuse cortical sclerosis" )             | 1 261  |
| S3    | TI ( dementing OR demented OR demention ) or AB ( dementing OR demented OR demention )                           | 909    |
| S2    | TI ( dementia* OR amentia ) or AB ( dementia* OR amentia )   | 11 593 |
| S1    | (MH "Dementia+")   | 20 574 |
| * The | search was conducted using EBSCOhost on 31 July 2009.  |        |

PsycINFO was searched for articles using the search terms for the disease treatment under evaluation. A summary of the search of PsycINFO is presented below—the search was limited to articles published in English from 1999.

# PsycINFO search, 1999 to July Week 4 2009 (\*)

| #   | Searches   | Results   |
|---|--|---|
| 1   | exp dementia/  | 34 526  |
| 2   | (dementia* or amentia).ti,ab,id.   | 30 480  |
| 3   | (dementing or demented or demention).ti,ab,id.   | 4 340   |
| 4   | (Alzheimer or diffuse cortical sclerosis).ti,ab,id.  | 5 755   |
| 5   | (Lewy body disease or Lewy body diseases).ti,ab,id.  | 221   |
| 6   | or/1-5   | 42 749  |
| 7   | "behavioral & psychological symptoms of dementia".id.  | 29  |
| 8   | "behavioral and psychological symptoms of dementia".id.  | 9   |
| 9   | "behavioral and psychotic symptoms of dementia".id.  | 1   |
| 10  | "Behavioral and Psychological Signs and Symptoms of Dementia".id.  | 1   |
| 11  | "behavioral & psychological symptoms".id.  | 84  |
| 12  | ((Behavioral or behavioural) adj1 (psychological symptom or psychological symptoms)).ti,ab,id.           | 90  |
| 13  | ((behavioral signs or behavioural signs) adj2 symptoms).ti,ab,id.  | 18  |
| 14  | ((behavioral or behavioural) adj1 "psychological signs").ti,ab,id.                                       | 7   |
| 15  | ((behavioral or behavioural) adj1 (psychological problem or psychological problems)).ti,ab,id.           | 10  |
| 16  | (bpsd or cbbd).ti,ab,id.   | 244   |
| 17  | or/7-16  | 320   |
| 18  | 6 and 17   | 292   |
| 19  | Symptoms/  | 30 498  |
| 20  | Psychiatric Symptoms/  | 7 799   |
| 21  | $\hbox{((neuropsychiatric or neuro psychiatric) adj1 (symptom* or disturbance*)).} ti,ab,id.$            | 827   |
| 22  | Behavioral Symptoms.id.  | 523   |
| 23  |  | 020   |
|   | Behavioural Symptoms.id.   | 11  |
| 24  | Behavioural Symptoms.id. psychological symptoms.id.  |   |
|   |  | 11  |
| 24  | psychological symptoms.id.   | 11<br>1 152   |
| 24<br>25  | psychological symptoms.id.  Psychiatric Symptoms.id.   | 11<br>1 152<br>2 113                                    |
| 24<br>25<br>26  | psychological symptoms.id. Psychiatric Symptoms.id. Symptoms.id.   | 11<br>1 152<br>2 113<br>36 438                          |
| <ul><li>24</li><li>25</li><li>26</li><li>27</li></ul>                       | psychological symptoms.id. Psychiatric Symptoms.id. Symptoms.id. dementia Symptoms.id.                   | 11<br>1 152<br>2 113<br>36 438<br>53                    |
| <ul><li>24</li><li>25</li><li>26</li><li>27</li><li>28</li></ul>            | psychological symptoms.id. Psychiatric Symptoms.id. Symptoms.id. dementia Symptoms.id. or/19-27          | 11<br>1 152<br>2 113<br>36 438<br>53<br>51 815          |
| <ul><li>24</li><li>25</li><li>26</li><li>27</li><li>28</li><li>29</li></ul> | psychological symptoms.id. Psychiatric Symptoms.id. Symptoms.id. dementia Symptoms.id. or/19-27 6 and 28 | 11<br>1 152<br>2 113<br>36 438<br>53<br>51 815<br>2 907 |

| 33 | aggressive behavior/  | 16 578  |
|----|---|---------|
| 34 | Anxiety Disorders/  | 10 028  |
| 35 | Anxiety/  | 33 525  |
| 36 | exp delusions/  | 3 451   |
| 37 | Eating Disorders/   | 8 066   |
| 38 | Euphoria/   | 195     |
| 39 | hallucinations/   | 2 067   |
| 40 | visual hallucinations/  | 608     |
| 41 | irritability/   | 412     |
| 42 | psychosis/  | 14 613  |
| 43 | hostility/  | 3 804   |
| 44 | restlessness/   | 272     |
| 45 | violence/   | 16 595  |
| 46 | patient violence/   | 873     |
| 47 | Senile Psychosis/   | 32      |
| 48 | wandering behavior/   | 126     |
| 49 | hoarding behavior/  | 142     |
| 50 | (challenging behavior or challenging behaviors).ti,ab,id.             | 1 007   |
| 51 | (challenging behaviour or challenging behaviours).ti,ab,id.           | 498     |
| 52 | (behavioral disturbance or behavioral disturbances).ti,ab,id.         | 1 846   |
| 53 | (behavioural disturbance or behavioural disturbances).ti,ab,id.       | 253     |
| 54 | (dangerous behavior or dangerous behaviors).ti,ab,id.                 | 302     |
| 55 | (dangerous behaviour or dangerous behaviours).ti,ab,id.               | 40      |
| 56 | (difficult behavior or difficult behaviors).ti,ab,id.                 | 183     |
| 57 | (difficult behaviour or difficult behaviours).ti,ab,id.               | 49      |
| 58 | (disruptive behavior or disruptive behaviors).ti,ab,id.               | 3 032   |
| 59 | (disruptive behaviour or disruptive behaviours).ti,ab,id.             | 249     |
| 60 | (exiting behavior or exiting behaviors).ti,ab,id.                     | 4       |
| 61 | (exiting behaviour or exiting behaviours).ti,ab,id.                   | 0       |
| 62 | (inappropriate adj1 (behavior* or behaviour*)).ti,ab,id.              | 1 123   |
| 63 | (oppositional behavior or oppositional behaviors).ti,ab,id.           | 350     |
| 64 | (oppositional behaviour or oppositional behaviours).ti,ab,id.         | 25      |
| 65 | (agitation or aggression or aggressiveness or aggressivity).ti,ab,id. | 36 843  |
| 66 | (anxiety or depression or euphoria).ti,ab,id.                         | 195 683 |
| 67 | (apathy or hoarding or violence or pacing).ti,ab,id.                  | 37 370  |
| 68 | (delusion or delusions or hallucination or hallucinations).ti,ab,id.  | 12 829  |
| 69 | (psychosis or psychotic).ti,ab,id.                                    | 42 679  |
| 70 | (restlessnes or shadowing or trespassing or wandering).ti,ab,id.      | 1 219   |
| 71 | (irritability or noisiness or screaming or cursing).ti,ab,id.         | 3 999   |
|    |   |         |

| 72  | (sundowning or sundown syndrome).ti,ab,id.   | 55      |
|-----|--|---------|
| 73  | (mood disorder or mood disorders).ti,ab,id.  | 7 185   |
| 74  | (mood disturbance or mood disturbances).ti,ab,id.                                      | 1 118   |
| 75  | (abnormal vocalization or abnormal vocalisation).ti,ab,id.                             | 1       |
| 76  | (abnormal vocalizations or abnormal vocalisations).ti,ab,id.                           | 2       |
| 77  | (disruptive vocalization or disruptive vocalisation).ti,ab,id.                         | 9       |
| 78  | (repetitive verbalization or repetitive verbalisation).ti,ab,id.                       | 0       |
| 79  | (repetitive verbalizations or repetitive verbalisations).ti,ab,id.                     | 5       |
| 80  | (sexual disinhibition or sexual disinhibitions).ti,ab,id.                              | 55      |
| 81  | or/30-80   | 344 912 |
| 82  | 6 and 81   | 9 824   |
| 83  | 18 or 29 or 82   | 11 111  |
| 84  | (nonpharmacologic* or non pharmacologic or non pharmacological).ti,ab,id.              | 1 621   |
| 85  | (alternative to pharmacotherapy or alternatives to pharmacotherapy).ti,ab,id.          | 17      |
| 86  | ((alternative or alternatives) adj2 (pharmacologic or pharmacological)).ti,ab,id.      | 92      |
| 87  | (non drug therapy or non drug therapies).ti,ab,id.                                     | 15      |
| 88  | (nondrug therapy or nondrug therapies).ti,ab,id.                                       | 22      |
| 89  | or/84-88   | 1 743   |
| 90  | 83 and 89  | 153     |
| 91  | exp psychotherapy/   | 139 895 |
| 92  | exp alternative medicine/  | 4 217   |
| 93  | phototherapy/  | 560     |
| 94  | physical activity/   | 3 448   |
| 95  | interpersonal psychotherapy/   | 663     |
| 96  | (aromatherapy or activity therapy or bright light therapy).ti,ab,id.                   | 387     |
| 97  | (behavior therapy or behaviour therapy).ti,ab,id.                                      | 9 328   |
| 98  | (behavioral therapy or behavioural therapy).ti,ab,id.                                  | 6 862   |
| 99  | (complementary therapy or complementary therapies or complementary medicine).ti,ab,id. | 475     |
| 100 | (alternative therapy or alternative therapies or alternative medicine).ti,ab,id.       | 1 326   |
| 101 | (dementia care mapping or dcm or reality orientation).ti,ab,id.                        | 359     |
| 102 | (environment therapy or Reminiscence therapy).ti,ab,id.                                | 103     |
| 103 | (environmental intervention or environmental interventions).ti,ab,id.                  | 288     |
| 104 | (interpersonal therapy or Interpersonal psychotherapy).ti,ab,id.                       | 1 021   |
| 105 | (multi sensory approach or multi sensory approaches).ti,ab,id.                         | 8       |
| 106 | (multisensory approach or multisensory approaches).ti,ab,id.                           | 67      |
| 107 | (physical activity or carer education).ti,ab,id.                                       | 8 449   |
| 108 | or/91-107  | 158 613 |
| 109 | 83 and 108   | 391     |
|     |  |         |

| 110 | psychosocial renabilitation/  | 28/6  |
|-----|---|-------|
| 111 | (psychosocial approach or psycho social approach).ti,ab,id.           | 246   |
| 112 | (psychosocial approaches or psycho social approaches).ti,ab,id.       | 215   |
| 113 | (psychosocial intervention or psycho social intervention).ti,ab,id.   | 878   |
| 114 | (psychosocial interventions or psycho social interventions).ti,ab,id. | 1 624 |
| 115 | (psychosocial method or psycho social method).ti,ab,id.               | 4     |
| 116 | (psychosocial methods or psycho social methods).ti,ab,id.             | 29    |
| 117 | (psychosocial support or psycho social support).ti,ab,id.             | 677   |
| 118 | (psychosocial therapy or psycho social therapy).ti,ab,id.             | 139   |
| 119 | (psychosocial therapies or psycho social therapies).ti,ab,id.         | 124   |
| 120 | social therapy.ti,ab,id.  | 188   |
| 121 | (caregiving intervention or care giving intervention).ti,ab,id.       | 12    |
| 122 | (caregiving interventions or care giving interventions).ti,ab,id.     | 16    |
| 123 | or/110-122  | 6 269 |
| 124 | 83 and 123  | 83    |
| 125 | 90 or 109 or 124  | 583   |
| 126 | limit 125 to English-language   | 536   |
| 127 | limit 126 to vr="1999 -Current"                                       | 345   |

<sup>\*</sup> The search was conducted using OvidSP on 4 August 2009.

# **Appendix C: Included Studies**

- Algase, D. L. (2006). What's new about wandering behaviour? An assessment of recent studies. International Journal of Older People Nursing, 1, 226-234.
- Ancoli-Israel, S., Martin, J. L., Gehrman, P., Shochat, T., Corey-Bloom, J., Marler, M., et al. (2003). Effect of light on agitation in institutionalized patients with severe Alzheimer disease. The American Journal of Geriatric Psychiatry(2), 194-203.
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- Brooker, D. J., Woolley, R. J., & Lee, D. (2007). Enriching opportunities for people living with dementia in nursing homes: an evaluation of a multi-level activity-based model of care. Aging and Mental Health, 11(4), 361-370.
- Buchanan, J. A., & Fisher, J. E. (2002). Functional assessment and noncontingent reinforcement in the treatment of disruptive vocalization in elderly dementia patients. Journal of Applied Behavior Analysis, 35(1), 99-103.
- Buettner, L. L. (1999). Simple Pleasures: a multilevel sensorimotor intervention for nursing home residents with dementia. American Journal of Alzheimer's Disease, 14(1), 41-52.
- Buettner, L. L., & Fitzsimmons, S. (2002). AD-venture program: therapeutic biking for the treatment of depression in long-term care residents with dementia. American Journal of Alzheimer's Disease and Other Dementias, 17(2), 121-127.
- Burgio, L. D., Stevens, A., Burgio, K. L., Roth, D. L., Paul, P., & Gerstle, J. (2002). Teaching and maintaining behavior management skills in the nursing home. Gerontologist, 42(4), 487-496.
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### Appendix D: Excluded Studies Annotated by Reason for Exclusion

- Abramowitz, L. (2008). Working with advanced dementia patients in a day care setting. Journal of Gerontological Social Work, 50(3-4), 25-35. Title/abstract: Included, Full paper: Excluded. Inappropriate study design.
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- Andrew, A. (2006). The ethics of using dolls and soft toys in dementia care. Nursing and Residential Care, 8(9), 419-421. Title/abstract: Included, Full paper: Excluded. Inappropriate study design.
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  Full paper: Excluded. Inappropriate study
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- Vink, A. C., Birks, J., Bruinsma, M. S., & Scholten, R. J. P. M. (2003). Music therapy for people with dementia. Cochrane Database of Systematic Reviews, (4). Retrieved from http://www.mrw.interscience.wiley.com/cochra ne/clsysrev/articles/CD003477/frame.html. doi:10.1002/14651858.CD003477.pub2 Title/abstract: Included, Full paper: Excluded. Other.
- Von Gunten, A., Alnawaqil, A. M., Abderhalden, C., Needham, I., & Schupbach, B. (2008). Vocally disruptive behavior in the elderly: a systematic review. International Psychogeriatrics, 20(4), 653-672. Title/abstract: Included, Full paper: Excluded. Inappropriate study design.
- Williams, C. L., & Tappen, R. M. (2008). Exercise training for depressed older adults with Alzheimer's disease. Aging & Mental Health, 12(1), 72-80. Title/abstract: Included, Full paper. Excluded. Inadequate sample size.
- Williams, E., & Jenkins, R. (2008). Dog visitation therapy in dementia care: a literature review. Nursing Older People, 20(8), 31-35. Title/abstract: Included, Full paper: Excluded. Inappropriate study design.
- Witzke, J., Rhone, R. A., Backhaus, D., & Shaver, N. A. (2008). How sweet the sound: research evidence for the use of music in Alzheimer's dementia. Journal of Gerontological Nursing, 34(10), 45-52. Title/abstract: Included, Full paper: Excluded. Other.
- Wood, S., & Cummings, J. L. (1999). Measuring outcomes in Alzheimer's disease research: assessment of the effectiveness of interventions. Disease Management and Health Outcomes, 5(1), 1-12. Title/abstract: Included, Full paper: Excluded. Full-text not available from any source.
- Woods, B., Spector, A. E., Jones, C. A., Orrell, M., & Davies, S. P. (2005). Reminiscence therapy for dementia. Cochrane Database of Systematic Reviews, (2). Retrieved from http://www.mrw.interscience.wiley.com/cochra ne/clsysrev/articles/CD001120/frame.html
  Title/abstract: Included, Full paper: Excluded.
  Other
- Woods, D. L. (1999). The effect of therapeutic touch on glucocorticoids and agitated behaviour in individuals with dementia of the Alzheimer type. Dissertation Abstracts International:

- Section B: The Sciences and Engineering, 60(4B), 1538. Title/abstract: Included, Full paper: Excluded. Inappropriate outcomes.
- Yu, F., Rose, K. M., Burgenr, S. C., Cunningham, C., Buettner, L. L., Beattie, E., et al. (2009). Cognitive training for early-stage Alzheimer's disease and dementia. Journal of Gerontological Nursing, 35(3), 23-29. Title/abstract: Included, Full paper: Excluded. Inappropriate outcomes.
- Zec, R. F., & Burkett, N. R. (2008). Non-pharmacological and pharmacological treatment of the cognitive and behavioral symptoms of Alzheimer

- disease. Neurorehabilitation, 23(5), 425-438. Title/abstract: Included, Full paper: Excluded. Inappropriate study design.
- Zetteler, J. (2008). Effectiveness of simulated presence therapy for individuals with dementia: a systematic review and meta-analysis. Aging and Mental Health, 12(6), 779-785. Title/abstract: Included, Full paper: Excluded. Other.

### **Appendix E: Data Extraction Tables**

### Systematic Reviews (Alphabetical)

**Table 22: Algase (2006)** 

| Algase, D. L. (2006). What's new abou recent studies. International Journal of   | t wandering behaviour? An assessment of Older People Nursing, 1, 226-234.  |
|--|--|
| Level IV.  |  |
| To systematically review the literature on recent findings relating to wandering in dementia. The scope was broad, and was subdivided into four categories (47 studies met inclusion criteria): (a) definition and measurement (not relevant to this review), (b) epidemiology (not relevant to this review), (c) factors associated with wandering (not relevant to this review) and (d) intervention and management (relevant to this review: 16 studies). Some studies contributed information to more than one category but only treatment is considered here.   |  |
|  | ndings about wandering behaviour published as eriod encompassing 2003 through 2005.  |
| Nursing home residents exhibiting wan  | dering behaviours.   |
| All interventions aimed at reducing war  | ndering behaviours.  |
| (eg using part of a larger measure of d  | ere either direct or proxy measures of wandering ementia-related behaviours, records or other gase wandering scale was used in 10 studies.   |
| Narrative synthesis  |  |
| Review articles (2). Lai et al. (2003). Siders et al. (2004). Primary research articles (14). Beattie et al. (2004). ‡Cherry et al. (2004). Feliciano et al. (2004). ‡Fenton et al. (2004). †Katz et al. (2004).   | Kincaid et al. (2003). Ø Landi et al. (2004). McGilton et al. (2003). †Meguro et al. (2004). ‡Miskelly (2004). †Rabinowitz et al. (2004). Ø Shalek et al. (2004). ‡Ward et al. (2003). Ø Woods, Craven, & Whitney (2005.)  |
| Lai et al. (2003) categorised the interver environment interaction models. Lai et studies were generally weak and that in Siders et al. (2004) (Review article). Systematic searches and review identifierported the following:  Subjective barriers: Included 10 stud the floor, cloth panels over doors, murally walking/exercise/activity: Included 6.  Special environments: Included 3 studies used to redirect wanderers to ha movement, a nature scene, and enhanded be an analysis.  Music: The effects of music were studies. The effects of music were studies. The effects of music were studies and the effects of music were studies. In an experimental multiple case study trialled with 3 rest home residents to reconstruction. In an experimental pre-post design studies implementing the Alzheimer's diseas respect to wandering behaviours. | dies including studies of facilities with open zard-free places to provide freedom of ced areas.  Ir studies of behavioural techniques to reduce s, differential reinforcement and stimulus control. dies in 6 trials.  Ind reported reductions in wandering.  |
|  | recent studies. International Journal of Level IV.  To systematically review the literature of dementia. The scope was broad, and wet inclusion criteria): (a) definition and epidemiology (not relevant to this review) and (d) interver 16 studies). Some studies contributed treatment is considered here.  Empirical studies containing discrete filipurnal articles during the three-year per Nursing home residents exhibiting wan Quantitative outcome measures that we (eg using part of a larger measure of documents, or by observation). The Ale Narrative synthesis  Review articles (2). Lai et al. (2003). Siders et al. (2004). Primary research articles (14). Beattie et al. (2004). ‡Cherry et al. (2004). ‡Fenton et al. (2004). ‡Fenton et al. (2004).  Lai et al. (2003) (Review article). Lai et al. (2003) (Review article). Lai et al. (2003) (Review article). Systematic searches and review identir reported the following:  — Subjective barriers: Included 10 stud the floor, cloth panels over doors, murally subjective barriers: Included 3 studies were generally weak and that reported the following:  — Subjective barriers: Included 10 stud the floor, cloth panels over doors, murally subjective barriers: Included 3 studies were generally weak and that reported the following:  — Subjective barriers: Included 10 stud the floor, cloth panels over doors, murally subjective barriers: Included 3 studies were generally weak and that reported the following:  — Subjective barriers: Included 10 studithe floor, cloth panels over doors, murally subjective barriers: Included 3 studies were generally weak and that reported the following:  — Walking/exercise/activity: Included 6  — Special environments: Included 3 studies are subjective barriers: Included for wandering including functional analysis.  — Music: The effects of music were study trialled with 3 rest home residents to reconstruction of the subject was study trialled with 3 rest home residents to reconstruction. |

prohibited area.

#### Fenton et al. (2004).

In a quantitative, cross-sectional, descriptive study, 2015 nursing home residents who were referred for psychiatric consultation were assessed for wandering behaviours. **Kincaid et al. (2003).** 

This study used a pre-post design and examined the effect that a wall mural painted over an exit door had on decreasing door-testing behaviours of 12 residents with dementia over a 12-week period.

### McGilton et al. (2003).

Conducted a RCT to examine the effects of a way-finding intervention on 32 residents' ability to find their way in a new environment (the intervention consisted of the use of a location map and a behavioural training technique). The effect of the intervention on the residents' spatial orientation and agitation were also examined.

#### Miskelly (2004).

This feasibility study tested equipment, derived from prisoner tagging systems, in three different scenarios: for 4 weeks in two wards at a large teaching hospital, 6 months in a medium sized residential home and 8 weeks in clients' own homes in the community. The novel system of electronic tagging in residents with dementia was used to identify wandering events into prohibited spaces in all three settings.

### Shalek et al. (2004).

Single sample of 20 residents.

### Ward et al. (2003).

Fifty family carers of people with dementia were identified in a survey of mental disorder [system level intervention, no individual-level outcomes].

# Study quality \* See below for "AG" quality criteria questions

- **A. Adequate.** The objective of the study was very clearly defined and specific and included any non-pharmacological intervention aimed at reducing wandering (also included definition and measurement, epidemiology, and factors associated with.
- **B. Adequate.** Searched electronic databases covering the three year period encompassing 2003 through 2005. Studies were identified through electronic searches of MEDLINE, CINAHL and PsycINFO.
- **C.** Adequate. The inclusion criteria were appropriate but broad including all studies with the inclusion of results specific to wandering, way-finding, getting lost or eloping.
- **D. Unknown.** Research reports were reviewed and data was abstracted to characterise quantity and rigour. However, no specific quality checklist of framework was specified.
- **E. Adequate.** Studies were summarised in the text and study characteristics and outcome data were available in tables, however the level of detail presented for most of the studies was rather limited (almost certainly limited by the broad scope, resulting in a large number of studies being included).
- **F. Adequate.** Due to methodological differences between studies, meta-analysis was not possible.
- **G.** Adequate. The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

## Results (within scope of this systematic review)

Results of trials of non-pharmacological interventions for wandering not reviewed in subsequently published systematic reviews.

| Study                    | Main findings  |
|--------------------------|--|
| Lai et al.<br>(2003).    | The intervention studies were generally weak and no widely effective intervention was available.   |
| Shalek et al.<br>(2004). | Air mat therapy reduced agitated wandering and agitation pre-<br>and post- intervention. An overall effect on agitation was<br>demonstrated after 10 days air mat therapy.   |
| Siders et al. (2004).    | Subjective barriers: Included 10 studies of interventions such as tape grids placed on the floor, cloth panels over doors, murals painted over exits, the use of mirrors. The quality of the studies varied greatly; however, there are data to support the use of objects that obscure exits and some compelling evidence for the use of tape grids.      Walking/exercise/activity: Included 6 studies of structured daily routines. Decreases in wandering were reported in four of five experimental studies. The effects of structured groups on wandering remain difficult to determine due to the low number of studies.      Special environments: Included 3 studies including studies of facilities with open areas used to redirect wanderers to be a randered. |
|                          | facilities with open areas used to redirect wanderers to hazard-<br>free places to provide freedom of movement, a nature scene,  |

| 1 / /                   |  |   |
|-------------------------|--|---|
|                         |  | and enhanced areas. There appears to be some support for the use of enhanced environments to redirect wandering.  — Behavioural techniques: Included 4 studies of behavioural techniques to reduce wandering including functional analysis, differential reinforcement and stimulus control. Although the results of these studies are encouraging, the use of behavioural techniques to reduce wandering is still underdeveloped.  — Music: The effects of music were studied in 6 trials. Further exploration of this topic is warranted as studies consistently report music decreasing wandering at the time it is played but that it does not reduce wandering at other times (generally).  — Alarms: Two studies tested alarms and reported reductions in wandering. More research is required.  Siders et al. (2004) concluded that the evidence in support of subjective barriers was compelling. The authors also point out that the questions of whether, for whom, and when wandering is harmful or beneficial have not been resolved, and that efforts to reduce wandering should only be attempted when appropriate for the resident. Siders et al. (2004) suggest that a multifaceted approach to environmental modifications may be more helpful than a singular approach. |
|                         | Beattie et al. (2004).  Cherry et al. (2004).  | Decreased table-leaving and increased food intake and time at table during meals.  Resulted in increased risk assessment for wandering behaviour from 8% prior to 74% post intervention. Social workers conducted 68% (versus 32% by MDs) of these  |
|                         | Feliciano et al. (2004).   | assessments (no individual-level outcomes).  Reduced entries into a prohibited area from a rate of 7.6 per hour to an average rate of 0.4 per hour across all intervention variations. Redirection alone was not successful without the barrier.  |
|                         | Fenton et al. (2004).  | Nursing home residents who were referred for psychiatric consultation had a higher mean for wandering than those not referred. Wandering was not a significant (p = 0.07) predictor of psychiatric consultation, whereas aggression and agitation were.   |
|                         | Kincaid et al. (2003).   | Mural significantly reduced overall door-testing behaviours. Reductions were also significant for 2 types of door-testing (calm and team efforts), but were not significant for following others through door and/or agitated/hostile door testing.   |
|                         | McGilton et al. (2003).  | Compared to controls, residents in the treatment group demonstrated an increased ability to find their way to the dining room one week after the intervention. The intervention effect was not sustained three months later.  |
|                         | Miskelly<br>(2004).  | The system proved very reliable and 2 incidences of external wandering were successfully detected. Compliance was excellent.  |
|                         | Ward et al. (2003).  | System level intervention, no individual-level outcomes.  |
| Authors'<br>conclusions | In the main, few intervention studies to manage wandering were sufficiently rigorous, although the evidence for effectiveness of subjective barriers is mounting. Person-focussed therapies included a way-finding intervention, a behavioural communication technique, air mat therapy, exercise and therapeutic touch. Among these, the behavioural communication and the air mat had positive results, therapeutic touch was ineffective and the remaining approaches had limited value. Studies of system-level changes to care services were quite diverse. Fewer than half of the studies were framed by an explicit theory or theoretical framework. A variety of interventions have been evaluated, but studies lack rigour. |   |
| Reviewers' notes        | several shortcom<br>Samples were of<br>type, thereby we<br>validity included   | er of the studies reviewed were theoretically sound and well-designed, ings were recurrent. Many studies had threats to external validity. ten small, non-random and heterogeneous with regard to dementia akening ability to generalise or apply findings. Other threats to external an unclear or unspecified referent population and low response rates. Threats to internal validity included: (a) potential for bias in ratings,   |

|                             | (b) some instruments without established psychometrics, (c) insufficiently described methods and (d) interventions with insufficient theoretical and/or empirical support, unknown fidelity, and absent rationale for frequency, duration, or other 'dosing' specifications. |
|-----------------------------|--|
| Relevance to study question | Systematically reviewed the literature on recent findings relating to wandering in dementia. The body of evidence is relatively small.   |

- \*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):
- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?
- Ø Also reviewed in Bharani & Snowden (2005).
- † Pharmacological interventions (not reported here).
- ‡ System level interventions.

### Table 23: Bartlett et al. (2007)

|   | ` ,  |
|---|--|
| Citation  | Bartlett, H., Gray, L., Byrne, G., Travers, C., & Lui, C. (2007). Dementia research mapping project: final report. Canberra: Department of Health and Ageing.  |
| NHMRC Level of evidence   | Level IV.  |
| Objective   | The aim of the dementia research mapping project was to map published national and international dementia research with a view to developing a resource for stakeholders and identifying gaps in dementia research. The report includes a chapter on "Treatments of Dementia" (chapter 7: 7.2 Pharmacological Treatments; 7.7.5 other non-pharmacological treatments). In addition, a separate literature search was conducted for each of the following topics included in the report: epidemiology, aetiology and pathophysiology, risk and protective factors, diagnosis and assessment, care and support for people with dementia and their carers.  |
| Type of included studies  | There was no restriction on the methodology employed and both observational (epidemiological) and experimental studies were included. The review/study was required to relate specifically to one of the most frequently occurring subtypes of dementia in humans (ie Alzheimer's disease, vascular dementia, mixed dementia, Lewy Body dementia, Parkinson's disease, frontotemporal dementia, mild cognitive impairment, early onset dementia). An adequate description of the methodology was required, including an adequate description of the design, study population, sampling procedures and diagnostic criteria. In the case of meta-analyses, an adequate description of the included studies, the pooling method and analytic technique were required.  Included: 60 Systematic reviews/meta-analyses including 52 Cochrane reviews (In addition, 2 Review articles, 10 primary research articles, 2 Government/Commissioned reports, 1 Clinical guideline & 5 other documents—statements/letters/press releases were included.)       |
| Types of participants   | Studies were required to relate specifically to one of the most frequently occurring subtypes of dementia in humans (ie AD, VD, mixed dementia, DLB, Parkinson's disease, frontotemporal dementia, mild cognitive impairment, early onset dementia). All settings, not just residential care settings, were included.  |
| Type of intervention  | All pharmacological and non-pharmacological treatments and therapies for dementia (reviewed separately), that have demonstrated evidence of their effectiveness.   |
| Outcomes  | All outcomes   |
| Data analyses & statistics  | Narrative synthesis and data pooling if appropriate.   |
| Alphabetical list of all included studies (broadly within the scope of this systematic review).  Description of relevant trials (broadly within the scope of this systematic review). | Bird (2002).  Cameron et al. (2003).  Chung et al. (2002).  Clare et al. (2003).  Forbes et al. (2004) [Updated – now Forbes et al., 2009].  Heyn et al. (2004).  §Livingston et al. (2005).  Neal & Briggs, (2003)  Opie et al. (1999)  Thorgrimsen et al. (2003)  Vink et al. (2003)  Woods, Spector et al. (2005)  Bird, Llewellyn-Jones, Smithers, & Korten, (2002). An individually tailored approach to behavioural intervention. A trial of (predominantly) psychosocial interventions in comparison to a (predominantly) pharmacological approach, non-randomised controlled trial involving 44 participants. Forty-four residents with challenging behaviours secondary to dementia were randomly allocated to either a psychosocial group or a control group that involved usual clinical practice. The psychosocial intervention involved a range of strategies, including changes in staff and carer behaviour as well as environmental modifications, and was developed following a detailed analysis of the behaviour at the outset. |
|   | Cameron, Lonergan, & Lee, (2003). A Cochrane review of the efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) for dementia was conducted in December 2002. Eight RCTs were included in the review although data from only 3 trials could be included in the meta-analysis.  Chung, Lai, Chung, & French, (2002). A Cochrane review of the efficacy of  |
|   |  |

Snoezelen (or MSS) for people with dementia. Two trials that had examined the short term effects of Snoezelen therapy (4 and 8 treatment sessions respectively) on mood, behaviour and cognition in people with dementia were included in the review and a quantitative synthesis of the data was performed.

**Clare, Woods, Moniz Cook, Orrell, & Spector, (2003)**. A Cochrane review of the efficacy of cognitive rehabilitation and cognitive training interventions aimed at improving memory functioning in people in the early stages of AD or VD.

**Forbes et al., (2004).** A Cochrane review of the efficacy of BLT for improving sleep, behaviour and mood disturbance in residents with dementia (Now up-dated and replaced by Forbes et al. 2009 and reviewed separately).

**Heyn, Abreu, & Ottenbacher, (2004).** Studies of the effects of physical activity among people with cognitive impairment and dementia were systematically reviewed. Thirty RCTs that had enrolled a total of 2020 subjects were identified for inclusion in the review and meta-analysis. Most of the studies were small in size and the majority were based on walking as the intervention. Most of the studies were judged to be of medium quality.

§ Livingston, Johnston, Katona, Paton, & Lyketsos, (2005). A systematic review of studies that had assessed the efficacy of pharmacological and non-pharmacological interventions across a range of outcomes.

**Neal & Briggs, (2003)**. A Cochrane review of the efficacy of Validation therapy for people with dementia. Validation therapy is based on the general principle of validation, the acceptance of the reality and personal truth of another's experiences and includes a variety of techniques. Three RCTs were identified that met the inclusion criteria, although it was not possible to pool the data due to methodological differences among the studies.

**Opie, Rosewarne, & O'Connor, (1999).** An early systematic review that assessed psychosocial approaches as interventions for managing challenging behaviours in residents with dementia. Included in the review were five studies that had evaluated the efficacy of music as an intervention.

**Thorgrimsen, Spector, Wiles, & Orrell, (2003)**. A Cochrane review of the efficacy of aromatherapy for dementia. Aromatherapy uses pure essential oils from fragrant plants such as peppermint, sweet marjoram and rose, to help relieve health problems and improve quality of life. Although two RCTs were identified, the results were not in a format that was suitable for meta-analysis.

Vink, Birks, Bruinsma, & Scholten, (2003). A Cochrane review of the efficacy of music therapy for people with dementia. Five studies were included in the review although the methodological quality of studies was deemed to be poor and the study results could not be validated or pooled for further analyses.

Woods, Spector, Jones, Orrell, & Davies, (2005). A Cochrane review of the efficacy of reminiscence therapy for people with dementia. Reminiscence therapy involves the discussion of past activities, events and experiences with another person or group of people, usually with the aid of tangible prompts such as photographs or other familiar items. Five RCTs were included in the review although only 4 trials with a total of 144 participants had extractable data.

## Study quality \* See below for "A-G" quality criteria questions

- **A.** Adequate. The objective of the study was very clearly defined as a mapping project to map published national and international dementia research. A sub-section of the report (7.7.5 other non-pharmacological treatments) is relevant to this review.
- **B.** Adequate. The authors conducted a comprehensive literature search of the treatment of the most frequently occurring dementia subtypes across eight electronic databases and six additional websites. A stepwise, hierarchical approach to the literature search was adopted with the published and 'grey' literature being searched backwards from August 2006. The search included both national and international literature, but was limited to English-language publications. Titles Identified: n = 1133.
- C. Adequate. The inclusion criteria were detailed and appropriate.
- **D. Adequate.** The literature review was guided by a panel of experts comprised of leading researchers with national and international reputations in the field of dementia research. The principal project consultants, in consultation with the panel of experts developed specific inclusion criteria and the literature was searched for additional

consensus criteria.

- **E. Adequate.** The level of detail presented for most of the studies was adequate given the broad scope of the report.
- **F. Adequate.** Due to methodological differences between studies, meta-analysis was not possible.
- **G. Adequate.** The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

### Results (within scope of this systematic review)

Results- from 11 included systematic reviews and one RCT.

| Study                      | Main findings   |  |
|----------------------------|---|--|
| Bird et al.<br>(2002).     | Results for the psychosocial group showed a 43% decrease in the behaviour for which the resident had been referred and significant improvements in staff or carer distress and attitudes  |  |
| Cameron et al. (2003).     | The results suggested that TENS may result in some short term benefit in cognition and behaviour but that the data were too limited to draw any firm conclusions and more research is warranted.  |  |
| Chung et al.<br>(2002).    | No significant difference between Snoezelen therapy and control on any measure of behaviour, mood or cognition. It was concluded that there is currently no evidence that Snoezelen therapy is effective for the treatment of dementia, although the evidence base is very limited. |  |
| Clare et al. (2003).       | No relevant outcomes included.  |  |
| Forbes et al. (2004).      | There was no evidence that BLT is effective in managing sleep, behavioural or mood disturbances associated with dementia. The three studies included in the analysis were of poor quality.  |  |
| Heyn et al.<br>(2004).     | A significant positive effect of medium size for physical exercise on measures of physical fitness and on measures of functional behaviour (ES =.54; 95% CI: .36–.72) and cognition.  |  |
| §Livingston et al. (2005). | The results of this review are reported in detail elsewhere in this report.   |  |
| Neal & Briggs,<br>(2003).  | No statistically significant effect for measures of cognition or ADLs although one study reported a statistically significant improvement on one measure of depression in the VT group following twelve months of treatment. Insufficient evidence to warrant a conclusion.         |  |
| Opie et al.<br>(1999.)     | Although the studies had methodological limitations, most reported positive effects of music and a reduction in agitation.  |  |
| Thorgrimsen et al. (2003). | A statistically significant treatment effect of aromatherapy on measures of agitation and neuropsychiatric symptoms, however 1 small trial is insufficient evidence of efficacy.  |  |
| Vink et al.<br>(2003).     | No substantial evidence to either support or discourage the use of music therapy in the care of people with dementia.   |  |
| Woods et al.<br>(2005).    | A statistically significant improvement in cognition and general behaviour for the treatment group. Small relatively low quality studies. Some evidence that reminiscence therapy may be effective for residents with dementia.   |  |

| Authors' conclusions        | Only limited research into non-pharmacological approaches to treat the cognitive and behavioural symptoms of dementia has been undertaken to date and few RCTs have been conducted. The best evidence, however, is for physical exercise, reminiscence therapy and behaviour management while there is no evidence that reality orientation, BLT or Snoezelen are effective treatments for dementia. Well-designed RCTs are required to further assess the safety and efficacy of the intervention and to determine estimates of the effect size and whether the treatments are equally effective for the various subtypes of dementia. |
|-----------------------------|---|
| Reviewers' notes            | Section 7.7.5 'other non-pharmacological treatments' is the only relevant section to this review.   |
| Relevance to study question | A wide range of psychosocial interventions to improve the cognitive and non-cognitive symptoms of dementia have been evaluated, although these have been less extensively investigated than the pharmacological approaches. These include physical exercise, psychological approaches including validation, reminiscence and reality orientation, behaviour management, sensory stimulation and the use of music therapy.   |

<sup>\*</sup>The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations**: AD = Alzheimer's disease, ADL = Activities of daily living, BLT = Bright light therapy, ES = Effect size, MSS = Multi-sensory stimulation, RCT = Randomised controlled trial, Transcutaneous electrical nerve stimulation (TENS), VD = Vascular dementia, VT = Validation therapy.

§ Included separately within this report.

### Table 24: Bharani and Snowden (2005)

| Citation  | Bharani, N., & Snowden, M. (2005). Evidence-based interventions for nursing home residents with dementia-related behavioural symptoms. Psychiatric Clinics of North America, 28(4), 985-1005.  |   |
|---|--|---|
| NHMRC Level of evidence   | Level III.   |   |
| Objective   | To systematically review the literature on particular treatments for dementia-related agitation i  |   |
| Type of included studies  | Randomised and observational studies of as sensory, training, and activities interver  | non-pharmacological interventions: classified ntions.   |
| Types of participants   | Nursing home residents with behavioural s  | symptoms of dementia.   |
| Type of intervention  | interventions most commonly studied in R and staff training interventions. Note: the r   | ing agitation in nursing home residents. The<br>CTs include activity and sensory therapies<br>review also includes pharmacologic<br>in nursing home residents; but these are not  |
| Outcomes  | Agitation and behavioural outcomes.  |   |
| Data analyses & statistics  | A qualitative analysis/synthesis was conduprimary outcomes of behavioural symptom  |   |
| Alphabetical list of all included studies of non-pharmacological interventions (only).                      | Alessi et al. (1999). †Ancoli-Israel et al. (2003). ΔAronstein et al. (1996). Beck et al. (2002). ΔBrotons et al. (1996). ΔBuettner et al. (1996). ‡ΔBurgio et al. (1996). ‡Camberg et al. (1999). ΔCasby & Holm (1994). Churchill et al. (1999). ‡ΔCohen-Mansfield et al. (1997). ‡ΔCohen-Mansfield et al. (1998). Cott et al. (2002). De Young et al. (2002). ΔDenny (1997). §Finnema et al. (2005). ‡Gerdner, (2000). ΔGoddaer & Abrahm (1994). ¤Gray & Clair, (2002). ‡ΔGroene (1993). ΔHall et al. (1997). Kim & Buschmann, (1999). Kolanowski et al. (2001). §Kovach et al. (2004). Landi et al. (2004).   | Libin & Cohen-Mansfield, (2004).  ALovell, et al. (1995).  McCabe et al. (2002).  McCallion et al. (1999).  AMentes et al. (1989).  Miller et al., (2001).  Proctor et al. (1999).  ‡Remington, (2002).  Richeson, (2003).  Roth et al. (2002).  ARovner et al. (1996).  Schrijnemaekers et al. (2002).  Shalck et al. (2004).  §¤Snow et al. (2004).  Snyder and Olson (1996).  ASnyder et al. (1995).  ASnyder et al. (1996).  Snyder et al. (1995).  Thorpe et al. (1997).  Thorpe et al. (2000).  Van Weert et al. (2005).  AWerner et al. (1994).  AWilliams et al. (1995).  Woods, Craven, & Whitney, (2005). |
| Alphabetical list of relevant RCTs of non-pharmacological interventions not included in earlier reviews.    | Landi et al. (2004).  Alessi et al. (1999).  Cott et al. (2002).  Proctor et al. (1999).  Schrijnemaekers et al. (2002).  Van Weert et al. (2005).  Woods Craven, & Whitney (2005).  |   |
| Description of relevant included RCTs of non-pharmacological interventions not included in earlier reviews. | Alessi et al. (1999). Daytime physical activity (14 weeks in duration) plus a night-time programme (to decrease noise and sleep-disruptive nursing care practices, 5 nights in duration) vs. the night-time programme alone (control group). Twenty-nine residents (mean age 88.3 years, 90% female) from one nursing home participated in the randomised trial. Outcome measurements included daytime physical activity monitoring and structured physical function assessments; night-time wrist activity monitors to estimate night-time sleep; and timed daytime behavioural observations of sleep versus wakefulness, either in or out of bed, and agitation via the CMAI.  Cott et al. (2002). Walking programme: 'walk and talk' group (30 minutes, 5 times per week for 16 weeks, walking/talking in pairs) vs. talk-only group (30 minutes, 5 times per |   |

from three rest homes were randomly assigned to one of 3 groups. Functional and behavioural outcome measures included the FACSA, the 2-minute walk test, and LPRS. Some residents with low MMSE scores were included in the trial but were subsequently found to be unable to fully participate in the programme.

**Proctor et al. (1999)**. Behavioural intervention (care staff in the intervention homes attended seminars from the hospital outreach team and received weekly visits from a psychiatric nurse to assist in developing care planning skills over 6 months) vs. no staff training (control sites). The cluster randomised trial included 120 participants from 12 matched nursing and residential homes. The main outcome measures were cognitive impairment and depression, behavioural disturbance, and functional ability, assessed by the geriatric mental state schedule, CRBRS and BI, respectively.

**Schrijnemaekers et al. (2002)**. Emotion-oriented care (staff training programme with regard to emotion-oriented care: based on the validation approach with insights from other approaches including reminiscence and sensory stimulation) vs. 'usual care'. Residents (n = 151) with dementia and behavioural problems were included in the study and randomised by home (8 intervention homes and 8 control homes). Outcome measurements were performed by carers and relatives at baseline and after 3, 6 and 12 months of follow-up. The primary outcome measure was the change in behaviour of the residents.

Van Weert et al. (2005). Snoezelen (individual integrated 24-hour Snoezelen programme, based on family history-taking and stimulus preference screening) vs. 'usual care'. Quasi-experimental pre- and post-test design with 125 residents (of 6 nursing homes) with moderate to severe dementia and care dependency included in the pre-test and 128 in the post-test; 61 completed (included in both pre- and post-test). Carers were trained, and organisational adaptations were made to fulfil the conditions for resident-oriented Snoezelen care. Outcome measurements were made via direct observations using subscales of the Dutch Behaviour Observation Scale for Psychogeriatric Inpatients (DBOSPI)—the Dutch version of the CMAI— and the CSDD.

Woods Craven, & Whitney (2005). Therapeutic touch (given twice daily for 5-7) vs. placebo (placebo therapeutic touch) vs. control ('usual care'). Fifty-seven residents, aged 67 to 93 years, exhibiting behavioural symptoms of dementia, were randomised (double-blind) to one of the 3 groups within each of 3 SCUs within 3 long-term care facilities. The main outcome variable was overall behavioural symptoms of dementia, consisting of 6 categories of behaviours: manual manipulation (restlessness), escape restraints, searching and wandering, tapping and banging, pacing and walking, and vocalization. Behavioural observation was completed every 20 minutes from 8:00am to 6:00pm for three days pre-intervention and for three days post-intervention by trained observers who were blind to group assignment.

# Study quality \* See below for "AG" quality criteria questions

- **A.** Adequate. The objective of the study was very clearly defined and specific and included non-pharmacological and pharmacological interventions (the pharmacological interventions being beyond the scope of this review).
- **B.** Adequate. Systematic search of electronic databases for articles published from January 2000 to March 2005, including MEDLINE, CINAHL, PsycINFO, and EMBASE.
- **C. Inadequate.** The inclusion criteria were appropriate, however, while the reviewers included randomised trials and non-randomised trials, only the randomised trials were reported in any detail (eg the study characteristics and results summaries were only tabulated for randomised trials).
- **D. Unknown/Not reported.** All included studies appeared to have been appraised for design strength and quality of evidence; however the method and/or checklist or criteria were not specified. Notes were provided to outline potential biases and quality issues where such issues were identified.
- **E. Inadequate.** Included studies were summarised in the text but study characteristics and outcome data were only available in tables for some comparisons (within randomised trials).
- **F. Adequate.** Due to methodological differences between studies, meta-analysis was not possible.
- **G. Adequate.** The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

## Results (within scope of this systematic review)

Results—narrative summary

A total of 89 articles were reviewed (34 drug and 55 non-drug trials) of which 14 were randomised trials of non-pharmacological interventions and 41 were non-randomised trials of non-pharmacological interventions).

Six randomised trials of training interventions were reviewed. Four of six studies reported no between-group differences. In addition, six observational studies of training interventions were reviewed; however, the results were mixed.

Five randomised trials of activity interventions were reviewed. Three of five studies reported no between-group differences. Fourteen observational studies were reviewed and reported mixed results. Overall, 6 of 14 studies reported significant results favouring the intervention and two reported favourable trends. Four studies reported no benefits.

Three randomised trials of sensory therapy interventions were reviewed. Two of three studies reported no between-group differences. Twenty-one observational studies were reviewed and almost half of these involved music therapies and of these 10 music therapy trials, 7 reported statistically significant improvements in levels of agitation. Other results were mixed.

Results of randomised trials of non-pharmacological interventions not reviewed in subsequently published systematic reviews.

| Study                                    | Main findings   |  |
|--|---|--|
| Alessi et al. (1999).                    | Statistically significant 22% decrease in agitation with exercise vs. 150% increase in agitation in the control group. However, small sample size and non-blind assessments.  |  |
| Cott et al. (2002).                      | Residents who received the 'walk and talk' intervention did not demonstrate statistically significant differences in the outcome variables measured post-test when compared with residents who received the talk-only intervention or no intervention, even after controlling for individual differences.                                       |  |
| Proctor et al. (1999).                   | Residents in the intervention group had significantly improved scores for depression (before and after change difference -0.5 [95% CI -0.8 to -0.1]) and for cognitive impairment (-0.7: 95% CI: -1.1 to -0.2) but not for behaviour rating or BI.  |  |
| Schrijnemaek<br>ers et al.<br>(2002).    | The results of multilevel analyses (overall, subgroup and per protocol) showed no statistically significant, nor clinically relevant effects in favour of the intervention group on the behavioural outcome measures.   |  |
| Van Weert et al. (2005).                 | Residents receiving Snoezelen care demonstrated a significant reduction in agitation on the CMAI aggressive behaviour scale (34% reduction in the experimental group vs. 32% increase in the control group. There was also, a significant treatment effect with respect to their level of apathetic behaviour, loss of decorum, and depression. |  |
| Woods<br>Craven, &<br>Whitney<br>(2005). | Analysis of variance (ANOVA) (F = 3.331, p = 0.033) and the Kruskal-Wallis test (Chi <sup>2</sup> = 6.661, p = 0.036) indicated a significant difference in overall behavioural symptoms of dementia, manual manipulation and vocalization when the experimental group was compared to the placebo and control groups.                          |  |

### Authors' conclusions

Discussion: A number of studies failed to use validated outcome measures or scales, and few studies quantified changes in medications during the trial period (most studies continued medications). Studies of training interventions used various approaches, and these were often not sufficiently described. Generally, studies with positive outcomes included elements of additional supervision and support for staff and the training interventions that lacked these supervisory/support components were generally ineffective, suggesting that training alone may be insufficient to bring about positive changes in resident's outcomes such as aggression. There is some evidence from three randomised trials for the efficacy of activity programmes (but not 'simulated presence'). Activity interventions supported by the evidence include group activities, physical activity, and activity planning based on an evaluation of individual needs/behaviour patterns. Observational trials provided some evidence of efficacy for animal therapy. In the sensory category, music therapy appears to be effective; HM and non-specific touch therapies have demonstrated benefits. However, aromatherapy and BLT did not appear to be useful.

The authors conclude that generally, the cost benefit ratio of these interventions is low, and a more aggressive use of these treatments is warranted.

### Reviewers' notes

The authors attempted to systematically review the literature on both pharmacological and non-pharmacological treatments for dementia-related agitation in nursing home residents. In doing so, a total of 89 articles were reviewed. However, the degree of detail reported for any one trial is compromised and this is particularly in the case for the non-randomised trials of non-pharmacological interventions.

### Relevance to study question

This article systematically reviews the literature on pharmacologic and non-pharmacologic treatments for dementia-related agitation in nursing home residents.

- \*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):
- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations:** ANOVA = Analyses of variance, BI = Barthel index, BLT = Bright light therapy, CI = Confidence interval, CMAI = Cohen-Mansfield agitation inventory, CRBRS = Crichton Royal behaviour rating scale, CSDD = Cornell scale for depression in dementia, ES = Effect size, FACSA = Functional assessment of communication skills for adults, HM = Hand massage, LPRS = The London psychogeriatric rating scale, MMSE = Mini-mental state examination, RCT = Randomised controlled trial, SCU = Special care unit.

- † Also reviewed in Forbes et al. (2009).
- ‡ Also reviewed in O'Connor (2009).
- § Also reviewed in Kverno et al. (2009).
- □ Also reviewed in Nguygen et al. (2008).
- ° Also reviewed in Landreville et al. (2006).
- $\Delta$  Published outside this review's date range (ie pre 1999).

### Table 25: Forbes et al. (2009)

| therapy for managing sleep, behaviour, and mood disturbances in dementia (Review Cochrane Database of Systematic Reviews, (4).  NHMRC Level of evidence  Level I.  Level I.  Type of included  Studies  Type of included studies  Type of included studies  Type of included studies  Type of included studies  Types of participants  Types of participants  Types of participants  People with a diagnosis of dementia of any degree of severity as defined by accepte or the National Institute of Neurological and Communicative Disorders and Stroke and 12-keimer's Disease and Related Disorders (SSM-IV), the National Institute of Neurological and Communicative Disorders and Stroke and 12-keimer's Disease and Related Disorders (Association, or WHO criteria.  Type of intervention  Type of intervention  Any form of intervention involving the use of bright light. The light sources in the participants at a height within their visual fields, or haturalistic light therapy, known diawn-dusk' simulation that mimics outdoor twilingth transitions. The treatment groups received light therapy ranging from light boxes that ranged from 2500 to 10 000 Lx either in the morning or evening, for one to two hours, for ten days to ten weeks usual psychiatric disturbances. The outcomes relevant to this review are outlined below.  Behavioural Disturbances  Behavioural disturbances (e.g. agilation) were measured in five studies using several instruments: the ABRS, BEHAVE-AD scale, NPI scale, and the CMAI.  Depression  Depression was measured in four studies using the depression/dysphoria domain of the NPI-NH, the GDS, and the CSDD.  Apathy  Apathy and indifference were measured using a domain of the NPI-NH in one study.  Other outcomes – not summarised here  Steep: Several parameters of sleep were measured via wrist activity monitors worn b participants, including changes in the incidence or frequency of sleep-wake disturbances.  Data analyses & statistically significant differences in changes in outcomes from baseline to end of treatment and from basel | F_2                         |  |
|--|-----------------------------|--|
| Objective  The review assesses the evidence of efficacy of bright light therapy (BLT) in managin sleep, behaviour, mood, and cognitive disturbances associated with dementia.  RCTs in which BLT, at any intensity and duration, was compared with a control group of the effect on managing sleep, behavioural mood, or cognitive disturbances (as we as changes in institutionalization rates or cost of care) on people with dementia of any degree of severity as defined by accepted criteria such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), the National Institute of Neurological and Communicative Disorders and Stories (DSM-IV), the National Institute of Neurological and Communicative Disorders and Stories of Alzheimer's Disease and Related Disorders Association, or WHO criteria.  Type of intervention  Type of int | Citation                    | Forbes, D., Morgan, D. G., Bangma, J., Peacock, S., & Adamson, J. (2009). Light therapy for managing sleep, behaviour, and mood disturbances in dementia (Review). Cochrane Database of Systematic Reviews, (4).   |
| Seep, behaviour, mood, and cognitive disturbances associated with dementia.  |                             | Level I.   |
| for the effect on managing sleep, behavioural, mood, or cognitive disturbances (as we schanges in institutionalization rates or cost of care) on people with dementia of an degree of severity.  People with a diagnosis of dementia of any degree of severity as defined by accepter criteria such as the Diagnositic and Statistical Manual of Mental Disorders (DSM-IV), the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association, or WHO criteria.  Type of intervention  Any form of intervention involving the use of bright light. The light sources in the included studies were: a light box' placed approximately one metre away from the participants at a height within their visual fields; or 'naturalistic' light therapy, known a 'dawn-dusk' simulation that mimics outdoor twilight transitions. The treatment groups received light therapy ranging from light boxes that ranged from 2500 to 10 000 Lx either in the morning or evening, for one to two hours, for ten days to ten weeks. The were two exceptions: the use of dealing mounted light fixtures installed in the common living area (delivering an all day supplemental exposure of 14000 Lx). Control groups received dim red light or dim, low-frequency blinking light, less than 300 Lx.  Several outcomes were measured including cognition, function, sleep, behavioural a sturbances. Behavioural disturbances (e.g., agitation) were measured in five studies using several instruments: the ABRS, BEHAVE-AD scale, NPI scale, and the CMAI.  Depression  Depression was measured in four studies using the depression/dysphoria domain of the NPI-NH, the GDS, and the CSDD.  Apathy  Apathy and indifference were measured using a domain of the NPI-NH in one study. Other outcomes—reter exert and the cSDD.  Apathy  Apathy and indifference were measured using a domain of the NPI-NH in one study. Other outcomes—reter of the participants, including changes in the incidence or frequency of sleep-wake disturbances.  Cognition.  Alph | Objective                   | The review assesses the evidence of efficacy of bright light therapy (BLT) in managing sleep, behaviour, mood, and cognitive disturbances associated with dementia.  |
| criteria such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Type of intervention  Type of intervention  Type of intervention  Any form of intervention involving the use of bright light. The light sources in the participants at a height within their visual fields; or 'naturalistic light therapy, known a 'dawn-dusk' simulation that mimics outdoor whight transitions. The treatment groups received light therapy ranging from light boxs bata ranged from 2500 to 10 000 Lx either in the morning or evening, for one to two hours, for ten days to ten weeks. The were two exceptions: the use of 'dawn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the venture of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' simulation (maximum 400 Lx supplementation) and the use of 'elamyn-dusk' supplementation (maximum 400  |                             |  |
| included studies were: a "light box" placed approximately one metre away from the participants at a height within their visual fields; or "naturalistic" light therapy, known a 'dawn-dusk' simulation that mimics outdoor twilight transitions. The treatment groups received light therapy ranging from light boxes that ranged from 2500 to 10 000 Lx either in the morning or evening, for one to two hours, for ten days to ten weeks. The were two exceptions: the use of 'dawn-dusk' simulation (maximum 400 Lx supplementation) and the use of ceiling mounted light fixtures installed in the commo living area (delivering an all day supplemental exposure of ±1000 Lx). Control groups received dim red light or dim, low-frequency blinking light, less than 300 Lx.  Several outcomes were measured including cognition, function, sleep, behavioural an psychiatric disturbances. The outcomes relevant to this review are outlined below:  Behavioural Disturbances  Behavioural Disturbances  Behavioural Disturbances  Behavioural Disturbances (eg. agitation) were measured in five studies using several instruments: the ABRS, BEHAVE-AD scale, NPI scale, and the CMAI.  Depression  Depression was measured in four studies using the depression/dysphoria domain of the NPI-NH, the GDS, and the CSDD.  Apathy  Apathy and indifference were measured using a domain of the NPI-NH in one study.  Other outcomes—not summarised here  Sleep: Several parameters of sleep were measured via wrist activity monitors worn b participants, including changes in the incidence or frequency of sleep-wake disturbances.  Cognition.  Activities of daily living.  Changes in rate of institutionalisation.  Impact on cost of care.  Statistically significant differences in changes in outcomes from baseline to end of included studies  Ancoli-Israel et al. (2003a).  Graf et al. (2003).  Ancoli-Israel et al. (2003b).  Graf et al. (2003).  Ancoli-Israel et al. (2003b).  Dowing et al. (2005).  Dow |                             | the National Institute of Neurological and Communicative Disorders and Stroke and the  |
| psychiatric disturbances. The outcomes relevant to this review are outlined below:  Behavioural Disturbances Behavioural disturbances Behavioural disturbances (eg, agitation) were measured in five studies using several instruments: the ABRS, BEHAVE-AD scale, NPI scale, and the CMAI.  Depression Depression Depression and the CSDD. Apathy Apathy Apathy and indifference were measured using a domain of the NPI-NH in one study. Other outcomes— not summarised here Sleep: Several parameters of sleep were measured via wrist activity monitors worn b participants, including changes in the incidence or frequency of sleep-wake disturbances. Cognition. Activities of daily living. Changes in rate of institutionalisation. Impact on cost of care.  Data analyses & statistics  Statistically significant differences in changes in outcomes from baseline to end of treatment and from baseline to follow-up, between the light therapy and control group were examined. Each study was summarised using a measure of effect (eg mean difference).  Alphabetical list of included studies  Ancoli-Israel et al. (2003a). Ancoli-Israel et al. (2003b). Dowling et al. (2005). Dowling et al. (2005). Dowling et al. (2007). Mishima et al. (1998). Dowling et al. (2005). Remersma et al. (2008).  Description of included studies (listed alphabetically)  Ancoli-Israel et al. (2003a). Apollo "Brite-Lite" box placed one metre from resident delivering light > 2500 Lx for 2 hours daily in the evening or the morning vs. morning dim red light (control), 92 nursing home residents (attrition rate = 8.7%), RCT design, single blind, outcome measurement of nine sleep parameters (eg bellind, outcome measurement of nine sleep param | Type of intervention        | included studies were: a 'light box' placed approximately one metre away from the participants at a height within their visual fields; or 'naturalistic' light therapy, known as 'dawn-dusk' simulation that mimics outdoor twilight transitions. The treatment groups received light therapy ranging from light boxes that ranged from 2500 to 10 000 Lx either in the morning or evening, for one to two hours, for ten days to ten weeks. There were two exceptions: the use of 'dawn-dusk' simulation (maximum 400 Lx supplementation) and the use of ceiling mounted light fixtures installed in the common living area (delivering an all day supplemental exposure of ±1000 Lx). Control groups   |
| were examined. Each study was summarised using a measure of effect (eg mean difference).  Alphabetical list of included studies  Ancoli-Israel et al. (2003a). Graf et al. (2003). Graf et al. (2001). Dowling et al. (2005). Lyketsos et al. (1999). Dowling et al. (2007). Mishima et al. (1998). Dowling et al. (2008).  Description of included studies (listed alphabetically)  Ancoli-Israel et al. (2003a). Apollo "Brite-Lite" box placed one metre from resident delivering light > 2500 Lx for 2 hours daily in the evening or the morning vs. morning dim red light (control), 92 nursing home residents (attrition rate = 8.7%), RCT design, single blind, outcome measurement of nine sleep parameters (eg wake after sleep onset, total sleep time, percent sleep etc.) via wrist activity monitors worn by participants, duration of treatment was ten days with follow-up five days post-treatme (Dose = > 2500 Lx for 2 hours daily (5000 Lx hours) x 10days = 50 000 Lx hours.)  | Data analyses &             | Behavioural Disturbances Behavioural disturbances (eg, agitation) were measured in five studies using several instruments: the ABRS, BEHAVE-AD scale, NPI scale, and the CMAI.  Depression Depression was measured in four studies using the depression/dysphoria domain of the NPI-NH, the GDS, and the CSDD.  Apathy Apathy and indifference were measured using a domain of the NPI-NH in one study. Other outcomes— not summarised here Sleep: Several parameters of sleep were measured via wrist activity monitors worn by participants, including changes in the incidence or frequency of sleep-wake disturbances. Cognition. Activities of daily living. Changes in rate of institutionalisation. Impact on cost of care.  Statistically significant differences in changes in outcomes from baseline to end of |
| Dowling et al. (2005). Dowling et al. (2007). Dowling et al. (2008).  Description of included studies (listed alphabetically)  Ancoli-Israel et al. (2003a). Apollo "Brite-Lite" box placed one metre from resident delivering light > 2500 Lx for 2 hours daily in the evening or the morning vs. morning dim red light (control), 92 nursing home residents (attrition rate = 8.7%), RCT design, single blind, outcome measurement of nine sleep parameters (eg wake after sleep onset, total sleep time, percent sleep etc.) via wrist activity monitors worn by participants, duration of treatment was ten days with follow-up five days post-treatme (Dose = > 2500 Lx for 2 hours daily (5000 Lx hours) x 10days = 50 000 Lx hours.)  | Alphabetical list of        | were examined. Each study was summarised using a measure of effect (eg mean difference).  Ancoli-Israel et al. (2003a).  Gasio et al. (2003).  |
| delivering light > 2500 Lx for 2 hours daily in the evening or the morning vs. morning dim red light (control), 92 nursing home residents (attrition rate = 8.7%), RCT design, single blind, outcome measurement of nine sleep parameters (eg wake after sleep onset, total sleep time, percent sleep etc.) via wrist activity monitors worn by participants, duration of treatment was ten days with follow-up five days post-treatme (Dose = > 2500 Lx for 2 hours daily (5000 Lx hours) x 10days = 50 000 Lx hours.)  | included studies            | Dowling et al. (2005). Lyketsos et al. (1999). Dowling et al. (2007). Mishima et al. (1998).   |
|  | included studies<br>(listed | delivering light > 2500 Lx for 2 hours daily in the evening or the morning vs. morning dim red light (control), 92 nursing home residents (attrition rate = 8.7%), RCT design, single blind, outcome measurement of nine sleep parameters (eg wake after sleep onset, total sleep time, percent sleep etc.) via wrist activity monitors worn by participants, duration of treatment was ten days with follow-up five days post-treatment. (Dose = > 2500 Lx for 2 hours daily (5000 Lx hours) x 10days = 50 000 Lx hours.)  Ancoli-Israel et al. (2003b). Apollo "Brite-Lite" box placed one metre from resident delivering light > 2500 Lx for two hours daily in the evening or the morning vs. morning dim red light (control), 92 nursing home residents (attrition rate = 23%), RCT design                          |

measurement of agitation accessed via the ABRS and CMAI, duration of treatment was ten days with follow-up five days post-treatment.

(Dose = > 2500 Lx for 2 hours daily (5000 Lx hours) x 10days = 50 000 Lx hours.)

**Dowling et al. (2005).** Apollo "Brite-Lite" box > 2500 Lx for 1 hour, phase 1 assigned to morning bright light or usual indoor light (control)and phase 2 assigned to morning bright light or afternoon bright light, 70 nursing home residents (attrition rate not reported), RCT design, non-blinded outcome assessment at end-point, outcome measurement of several sleep parameters (eg sleep efficiency, night sleep time, night wake time) via wrist activity monitors worn by participants, daily exposure Monday through Friday for ten weeks.

(Dose = > 2500 Lx for 1 hour daily (Monday-Friday only) (2500 Lx hours) x 10 weeks/50hrs = 125 000 Lx hours).

**Dowling et al. (2007).** Apollo "Brite-Lite" box > 2500 Lx for 1 hour morning bright light or afternoon bright light vs. usual indoor light (control), 70 nursing home residents (attrition rate not reported), RCT design, single blind, outcome assessment of BPSD via NPI-NH and occupational disruptiveness scores, daily exposure Monday through Friday for ten weeks.

(Dose = > 2500 Lx for 1 hour daily (Monday-Friday only) (2500 Lx hours) x 10 weeks/50hrs = 125 000 Lx hours).

**Dowling et al. (2008).** Apollo "Brite-Lite" box > 2500 Lx for 1 hour, participants assigned to 1 of 3 groups: morning light and melatonin or morning light and placebo or usual indoor light (control), RCT design, single blind (only reported on blinding to melatonin group), 50 nursing home residents (attrition Rate = 0%), outcome assessment of night sleep time, night wake bouts, number of night-time awakenings, day sleep time, day/night sleep ratio, 24-hour rest-activity rhythm via wrist activity monitors worn by participants, daily exposure Monday through Friday for ten weeks. (Dose (with or without melatonin) = > 2500 Lx for 1 hour daily (Monday-Friday only) (2500 Lx hours) x 10 weeks/50hrs = 125 000 Lx hours).

**Gasio et al. (2003).** 'Dawn-dusk' simulation (max. 400 Lx morning and evening with treatment time variable to mimic the duration and latitude of dawn and dusk) using an overhead halogen lamp placed behind a diffusing membrane behind the resident's bed simulating a naturalistic form of light therapy vs. placebo dim red light (< 5 Lx) morning and evening, RCT design, single-blind, 13 nursing home residents (attrition rate > 20%), outcome assessment of BPSD, cognition and sleep parameters via, MMSE, NPI-NH, GDS, CERAD and sleep logs. Duration of the treatment was three weeks with follow-up three weeks post-treatment.

(Dose = 400 Lx max daily of variable duration x 3 weeks).

**Graf et al. (2001).** Afternoon bright light placed 90 cm from resident =  $3000 \, \text{Lx}$  for 2 hours daily vs. afternoon dim red dim light <  $100 \, \text{Lx}$ , RCT design, single-blind, 23 nursing home residents (attrition rate > 20%), outcome assessment of cognition via MMSE. treatment received daily for ten days.

(Dose = > 3000 Lx for 2 hours daily (6k Lx hours) x 10days = 60k Lx hours).

**Lyketsos (1999).** Morning bright light administered for 1 hour every morning using a 10 000 Lx at one metre vs. a dim digital low-frequency blinking light, crossover RCT design, single-blind, 15 nursing home residents (attrition rate > 20%). Subjects were treated for 4 weeks, followed by 1 week of no treatment, prior to being crossed over to the other condition. Outcome assessments included sleep logs and behavioural measures (via the BEHAVE-AD) and depression (via the CSDD).

(Dose =  $10\ 000\ Lx$  for 1 hour daily ( $10\ 000\ Lx$  hours) x 4 weeks/28 days =  $280\ 000\ Lx$  hours).

 $\Delta$  **Mishima et al. (1998).** Morning bright light of between 5000 - 8000 Lx at one metre administered for 2 hours every morning vs. dim morning light of 300 Lx administered for 2 hours every morning, crossover RCT design, single-blind, 22 nursing home residents (attrition rate < 10%) received treatment daily for 2 weeks before 4 weeks washout followed by the alternate condition. Outcome assessment included several sleep parameters (eg average daily total activity, average daytime activity, and average night-time activity).

(Dose = 8000 Lx max for 2 hours daily (16 000 Lx hours) x 2 weeks/14 days = 224 000 Lx hours).

Riemersma et al. (2008). All day bright light exposure of ±1000 Lx via ceiling-mounted light fixtures with Plexiglas diffusers containing an equal amount of Philips TLD 840 and 940 florescent tubes in the common living room vs. dim light (300 Lx), multi-centre RCT design, double-blinded, 94 nursing home residents (attrition rate up to 42% at two years), study duration 3.5 years. Outcome assessment included several sleep parameters (eg duration, latency, and efficiency) and assessment of depression (via CSDD and PGCARS) and cognition (via MMSE).

(Dose = 1 000 Lx for nine hours daily (9k Lx hours) continually = 63k Lx hours/week every week).

# Study quality \* See below for "AG" quality criteria questions

- A. Adequate. The objective of the study was very clearly defined.
- **B.** Adequate. The trials were identified from a search of the Specialised Register of the Cochrane Dementia and Cognitive Improvement Group (covers The Cochrane Library, MEDLINE, EMBASE, PsycINFO, CINAHL and LILACS and many ongoing trial databases and other grey literature sources) on the 4th of March 2008 for all years.
- **C.** Adequate. Yes. The review excluded all non-randomised trials and the exclusion criteria of the included studies ensured that many of the potential confounders were eliminated. For example, residents who were blind or severely visually impaired or had severe motor symptoms or primary psychiatric disorders, were not included in the studies
- **D. Adequate.** Study quality was assessed using criteria adapted from the Cochrane Handbook for Systematic Reviews of Interventions and the following factors were assessed: sequence generation, allocation concealment, attrition rate, compliance, control of potential confounders, blinding for data collection and outcome measures, presence of point estimates, and measures of variability for the outcomes.
- **E. Adequate.** Included studies were summarised in the text and outcome data were available in forest plots for all comparisons.
- **F. Adequate.** There was heterogeneity between the studies which limited the pooling of data.
- **G. Adequate.** Statistical heterogeneity was assessed using the  $l^2$  test to measure the degree of inconsistency across studies. Sensitivity analyses would have been conducted to determine how sensitive the results of the analyses were to changes in the way they were conducted, if the number of included studies had been larger.

## Results (within scope of this systematic review)

Results summary: In total, 8 trials (10 articles) met the relevance and risk of bias criteria and were included in the review. The review revealed no adequate evidence of the effectiveness of BLT in managing sleep, behaviour, cognitive, or mood disturbances associated with dementia.

#### Behavioural Disturbances- agitation

Morning or daytime BLT With light therapy administered during the morning or day time, behavioural disturbances measured by ABRS scores (Ancoli-Israel 2003b), NPI scores (Dowling 2007) and CMAI scores (Riemersma 2008) were pooled. The results revealed that light therapy administered during the morning or daytime had no effect on behavioural disturbances (SMD = -0.02, 95%CI: -0.45 to 0.40, p = 0.91) following 10 to 50 days of light therapy. Similarly, no effect on behavioural disturbances was observed in the evening assessment following 10 days of treatment (MD = 0.11, 95%CI: -0.23 to 0.45, p = 0.52; Ancoli-Israel 2003b) after 5 days of follow-up measured in the morning (MD = 0.02, 95%CI: -0.23 to 0.27, p = 0.87; Ancoli-Israel 2003b), in the evening (MD = 0.07, 95% CI: -0.26 to 0.40, p = 0.67; Ancoli-Israel 2003b), following 1 year of treatment (MD = -2.00, 95% CI: -11.71to 7.71, p = 0.69; Riemersma 2008), and after 2 years of light therapy (MD = -9.00, 95%CI: -21.34 to 3.34, p = 0.15; Riemersma 2008).

### Afternoon or evening BLT

To assess behavioural disturbances following the administration of afternoon or evening light therapy, ABRS scores (Ancoli-Israel 2003b) and NPI scores (Dowling 2007) were pooled. The results revealed that light therapy administered in the afternoon or evening had no effect on reducing behavioural disturbances when assessed during the morning (SMD= 0.16, 95%CI: -0.31 to 0.64, p = 0.50;) following 10 to 50 days of light therapy (Ancoli-Israel 2003b; Dowling 2007) or when assessed during the evening (MD = 0.07, 95% CI: -0.26 to 0.40, p = 0.67) following 10 days of treatment (Ancoli-Israel 2003). Similar results were found after 5 days of follow-up during morning assessments (MD = 0.10, 95% CI: -0.16 to 0.36, p = 0.46; Ancoli-Israel 2003) and during evening assessments (MD = 0.11, 95%CI: -0.23 to 0.45, p = 0.53; Ancoli-Israel 2003b).

**Depression:** Four studies measured depression: Dowling (2007), Gasio (2003), Lyketsos (1999), and Riemersma (2008). No significant differences in scores of depression were found between groups at each time point. Pooled data (Dowling 2007; Riemersma 2008) revealed no effect on depression following 42 to 50 days of light therapy (SMD = 0.12, 95%CI: 0.06 to 1.30, p = 0.84). In addition, Riemersma (2008)

190 data revealed no effect on depression at 1 year (MD = -0.30, 95%CI: -4.36 to 3.76, p = 0.88) and after 2 years of treatment (MD = -4.40, 95%CI: -10.82 to 2.02, p = 0.18). However, administering the light therapy in the afternoon resulted in an effect after 50 days of treatment (MD = 3.20, 95% CI: 0.86 to 5.51, p = 0.007), favouring the control group. Analysis of the data provided by Gasio 2003 revealed no effect on depression scores after 3 weeks of treatment (MD = -0.82, 95%CI: -4.33 to 2.69, p = 0.65) or at follow-up (MD = -1.29, 95%CI: -3.99 to 1.41, p = 0.35).Apathy: Apathy and indifference were measured using a domain of the NPI-NH following 50 days of treatment (Dowling 2007). There was no effect on apathy or indifference in either the morning administration of bright light (MD =1.00, 95%CI: -2.21 to 4.21, p = 0.54) or afternoon administration (MD = 0.40, 95% CI: -3.00 to 3.80, p = "There is insufficient evidence to assess the value of BLT for people with dementia. **Authors'** The available studies are of poor quality and further research is required.' conclusions Specifically, Forbes et al. (2009) conclude that further research is necessary to identify appropriate illumination intensity, frequency, interval, time of day and length of intervention for individuals with different types and severity of dementia. Also, many issues around practicality, acceptability, low compliance and the cost implications of bright light therapy need to be examined. The non-significant results may have been related to small sample sizes that contribute Reviewers' notes to insufficient power to detect a difference, if one is present. Notable exceptions were the Ancoli-Israel (2003a) and Ancoli-Israel (2003b) trials that included 92 participants and the Riemersma (2008) study that included 94 participants. These trials were adequately powered yet failed to demonstrate any significant between-group differences. Another plausible reason for the lack of significant effect of light therapy was the heterogeneity within several of the trials in terms of participants' diagnosis and severity of dementia. The response to light therapy of individuals with different diagnoses and severity of dementia may differ (eg AD vs. vascular, mild-moderate vs. severe). Unfortunately, because of the small sample sizes and small number of included trials, analyses could not be conducted. Light-boxes were used in the majority of studies; however, these light-boxes require participants to sit in front of the box for approximately two hours, usually under supervision. Practically, this may be difficult to achieve, so noncompliance may be a problem. Ceiling-mounted light fixtures in common areas and/or 'dawn-dusk' simulation' may be a more practical solution to delivering BLT, if the delivery of BLT can be shown to be effective. Given the methodological shortcomings in the published studies, they do not constitute good evidence that light therapy is ineffective. There is preliminary evidence from some studies that light therapy improves nocturnal Relevance to study sleep, while other studies demonstrate no improvement in people with dementia. Thus, question it is important to test the hypothesis that circadian disturbances in people with dementia may be reversed by BLT. Considerably more research is still required.

\*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

Abbreviations: AD = Alzheimer's disease, ABRS = Agitated behaviour rating scale, BEHAVE-AD = The Behavioural pathology in Alzheimer's disease scale, BLT = bright light therapy, BPSD = Behavioural and psychological symptoms of dementia; CERAD = Consortium to Establish a Registry for Alzheimer's Disease; CMAI = Cohen-Mansfield Agitation Inventory, CSDD = Cornell scale for depression in dementia, DSM-IV = Diagnostic and Statistical Manual of Mental Disorders (4th Ed.), GDS = Geriatric depression scale, MD = Mean difference, MMSE = Mini-mental state examination, NPI = Neuropsychiatric inventory, NPI-NH = Neuropsychiatric inventory - nursing home edition, RCT = Randomised controlled trial, SMD = Standardised mean difference, WHO = World Health Organisation.

Note: This review includes a comprehensive table describing the rating scales used in the included studies

 $\Delta$  Published outside this review's date range (ie pre 1999).

### Table 26: Kverno et al. (2009)

| Citation   | Kyerno K Black B Nolan M & Dabina   | P (2000) Research on treating   |
|--|---|---|
| Citation   | Kverno, K., Black, B., Nolan, M., & Rabins, P. (2009). Research on treating neuropsychiatric symptoms of advanced dementia with non-pharmacological strategies, 1998–2008: a systematic literature review. International Psychogeriatrics, 21(05), 825-843.   |   |
| NHMRC Level of evidence  | Level I -   |   |
| Objective  | To evaluate the published literature on no neuropsychiatric symptoms (NPS) in adva  | n-pharmacological interventions for treating  |
| Type of included studies   | RCTs, C-RCTs, crossover RCTs, single-group pre-test/post-test, non-equivalent groups pre-test/post-test, single-group repeated-measures (ABABAB) and single-group repeated-measures (ABCBA) designs that specifically evaluated non-pharmacological treatments for neuropsychiatric symptoms (NPS) in individuals with advanced, 'moderately-severe' to 'very-severe' dementia.   |   |
| Types of participants  | Individuals with advanced, 'moderately-severe' to 'very-severe' dementia. Severe dementia defined by MMSE scores between 0 and 10, or the equivalent and 'moderately-severe' to severe dementia is defined as MMSE 10–17 (Tombaugh and McIntyre, 1992).   |   |
| Type of intervention   | Any non-pharmacological intervention.   |   |
| Outcomes   | Measures of neuropsychiatric symptoms of behaviour, depression, apathy or withdraw behaviour).  | of dementia (including agitation or aggressive val, psychosis, and aberrant motor   |
| Data analyses & statistics                                       | Between-group differences in changes in and from baseline to follow-up were exam  | outcomes from baseline to end of treatment ined.  |
| Alphabetical list of included studies                            | Baker et al. (2001). Baker et al. (2003). Ballard et al. (2002). Bellelli et al. (1998). Camberg et al. (1999). Finnema et al. (2005). Frisoni et al. (1998). Garland et al. (2007). Gerdner et al. (2008). Heyn (2003). Holliman et al. (2001).  | Holmes et al. (2002). Holmes et al. (2006). Kovach et al. (2004). Lin et al. (2007). Magai et al. (2002). Mishima et al. (1998). Morgan and Stewart (1998). Skjerve et al. (2004). Snow et al. (2004). Svansdottir et al. (2006).   |
| Description of relevant included studies (listed alphabetically) | individualised according to preferences ar control (requiring intellectual or physical sl attrition), RCT with repeated-measures, or via INTERACT, REHAB, BMD and BRS, it post-treatment.  ‡ Baker et al. (2003), UK. MSS (2x 30 mindividualised according to preferences are control (requiring intellectual or physical sl attrition), RCT design, measurement via In quality study with follow-up at one month provided the provided statement of the provided statement | kills), 50-day hospital participants (4% utcome measurement of behaviour and mood high quality study with follow-up at one month mute sessions/week over a 4 week period, and functional abilities) vs. activity group kills), 127 day-hospital participants (7% NTERACT, REHAB, BMD and BRS, high post-treatment.  If with melissa oil/lemon balm (combined with a both arms twice daily) vs. neutral oil control, clinically significant agitation, nested RCT ent via CMAI (assessed every 5 minutes over ng quality study, of 4 weeks duration.  If pecial training of nursing staff to reducing Eight SCUs and 55 consecutive residents est/post-test design, outcome measurement of PI at baseline, three months, and six months diotape vs. neutral audiotape, 54 participants, outcome measurement via direct ding Short CMAI and MOSES, moderate |
|  | Finnema et al. (2005), Netherlands. Integ   | grated emotion-oriented care (integrated into   |

24 hour care) vs. usual care, 194 residents (25% attrition) of 16 psychogeriatric wards in 14 nursing homes, stratified by severity, pre-test/post-test, cluster (by ward) RCT with blind outcome assessment of behavioural and mood disturbances via CSDD and CMAI at baseline, three and seven months. Moderate quality study.

 $\Delta$  **Frisoni et al. (1998)**, Italy. SCUs (treatment not described), 43 nursing homes, 25 SCUs and 66 residents (attrition not reported), non-equivalent groups, pre-test/post-test design with outcome measurement of behavioural disturbances via NPI, CMAI and CSDD at baseline and three months after admission. Low quality study.

**‡ Garland et al. (2007)**, Australia. Family audiotape vs. preferred music vs. neutral audiotape, 30 participants, crossover RCT with blinded observers, outcome measurement via direct observation, strong quality study of four weeks duration.

**Gerdner et al. (2008)**, USA. Touch therapy using the craniosacral still point technique (delivered by a certified craniosacral therapist in conjunction with Progressively Lower Stress Threshold (PLST) model of care, mean treatment length 5 minutes), 2 nursing homes, 11 residents (18% attrition), single-group design with repeated-measures of agitation via modified CMAI, weekly assessments during 3 weeks of baseline, 6 weeks of treatment, and three weeks post-treatment. Low quality study.

**Heyn (2003)**, USA. Multi-sensory exercise programme (3 times per week for 8 weeks, duration of exercise increased over time from 15min. to 70min.), 13 nursing home residents (no attrition), single-group pre-test/post-test study with direct assessment of engagement and mood during exercise programme via the Menorah Park engagement scale (MPES) and caregiver mood report (CMR). Low quality study.

**Holliman et al. (2001)**, USA. Interactive physical activity (30 min 3 times/week for 3 weeks, socialization with snack followed activity) vs. unspecified control, 28 geriatric psychiatry facility residents (14% attrition), pre-test/post-test with random assignment to either the interactive physical activity or control group, repeated-measures of behavioural disturbances via PBRS (for exercise group only) and PGDRS (behaviour subscale), at baseline, twice during intervention sessions, and once at post-test (a total of 4 times) for each session. Low quality study.

**‡Holmes et al. (2002)**, UK. Aromatherapy with lavender vapour vs. water vapour, 15 participants, crossover RCT with blinded observers, outcome measurement via PAS, moderate quality study of 2 weeks duration.

**Holmes et al. (2006)**, UK. Music therapy – live music vs. pre-recorded music vs. silence (each of the 3 musical conditions was presented in 1 session lasting 90 minutes —30 minutes per condition), 64 residents of 4 residential and nursing homes stratified by severity (no attrition), crossover randomised trial with repeated-measures of apathy via participant videos rated for engagement (category E) on the DCM. DCM category E scores were obtained 10 times during each condition for each participant. Moderate quality study.

Kovach et al. (2004), USA. Balancing arousal controls excesses (BACE) (Individualised activity schedule to balance high-arousal and low-arousal states) vs. 'usual care', 78 residents (24% attrition) of 13 long-term care facilities, double-blind RCT with pre-test/post-test measures of agitation. Agitation measured via the arousal states in dementia (ASD) visual analogue of the CMAI. Direct observations: Phase 1 a 12-hour observation, Phase 2 individualisation of activity schedule, and Phase 3 another 12 hours of observation (observations made for 3 minutes every 15 minutes from 8 am–8 pm). Moderate quality study.

Lin et al. (2007), Hong Kong. Aromatherapy with lavender vs. sunflower control (aromas were delivered by diffuser at night for at least 1 hour for 3 weeks), 70 residents (no attrition) of 'care and attention' homes (equivalent to long-term rest homes), crossover RCT with repeated-measures (with 2 weeks washout). Outcome assessment of agitation via the Chinese versions of CMAI (CCMAI) and NPI before and after each treatment period. Moderate quality study.

**Magai et al. (2002)**, USA. Carer training (manualised carer training administered over two weeks by a psychologist who was blind to condition and hypotheses vs. behavioural placebo vs. control (waitlist), 91 residents of three nursing homes (8% attrition), double-blind, cluster (by nursing home) randomised trial with repeated-measures of affect and behaviour via BEHAVE-AD, CMAI, CSDD, and facial

expression. Assessment conducted at baseline and every three weeks until 12 weeks post-training (of carers). High quality study.

†Δ **Mishima et al. (1998)**, Japan. Morning bright light of between 5000–8000 Lx at one metre administered for two hours every morning vs. dim morning light of 300 Lx administered for 2 hours every morning, crossover RCT design, single-blind, 22 nursing home residents (attrition rate < 10%) received treatment daily for 2 weeks before 4 weeks washout followed by the alternate condition. Outcome assessment included several sleep parameters (eg average daily total activity, average daytime activity, and average night-time activity).

 $\Delta$  **Morgan and Stewart (1998)**, Canada. SCUs with lower social and spatial densities vs. traditional SCU (control), 50 residents of two long-term care facilities (10% attrition), non-equivalent groups 2×3 factorial design with outcome assessment of disruptive and non-disruptive behaviour via EBIC at baseline, 6 months and 1 year following relocation (comparison group sample remained in the traditional SCU).Moderate quality study.

**Skjerve et al. (2004)**, Norway. BLT for 45 minutes each morning for 4 weeks), 11 residents of 2 psychogeriatric institutions (9% attrition), single-group repeated-measures study design. Repeated-measures of agitation and behavioural symptoms via CMAI and BEHAVE-AD, and additionally, continuous activity monitoring for 6 weeks (one week of baseline and post-treatment) using Actigraph monitors. Low quality study.

**Snow et al. (2004)**, USA. Aromatherapy with lavender vs. thyme vs. grape seed oil (oils were worn for three hours on a sachet near the collarbone on treatment days following four weeks of baseline, each treatment was given for 2 weeks in the same order), 7 residents (no attrition) of 1 nursing home, single-group repeated-measures (ABCBA) study design, with measures of agitation via the CMAI (every other day during the 4 week baseline, 10 week intervention and 2 weeks post-treatment. Low quality study.

**Svansdottir et al. (2006)**, Iceland. Music therapy (interactive music group received 18 sessions singing familiar music with guitar, 30 min each,3 times/week for 6 weeks vs. 'usual care' (not described). Forty-six residents of 2 nursing homes and 2 psychogeriatric wards participated (17% attrition) in this RCT with blinded pre-test/post-test assessment of behavioural disturbances via the BEHAVE-AD, administered at baseline, 6 weeks, and 4 weeks post-treatment. Moderate quality study.

# Study quality \* See below for "AG" quality criteria questions

- A. Adequate. The objective of the study was very clearly defined and specific.
- **B. Adequate.** Systematic search of electronic databases for articles published from as early as 1974 through May 2008, including MEDLINE, CINAHL, PsycINFO, EMBASE, Dissertations International, and the Cochrane Database of Systematic Reviews. In addition, the reference lists of systematic reviews were manually searched and databases continued to be manually searched up through September 2008.
- **C.** Adequate. Yes. The review excluded all non-experimental trials, and additionally, all participants were required to have met the criteria for severe or 'very-severe' dementia documented by the use of a validated cognitive or functional measurement instrument, and included studies were required to report NPS as the primary outcome variable(s).
- **D. Adequate.** All studies meeting inclusion criteria were appraised for design strength and quality of evidence using an adapted version of the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) model (Newhouse et al., 2007).
- **E. Adequate.** Included studies were summarised in the text and study characteristics and outcome data were available in tables for all comparisons.
- **F. Adequate.** There was heterogeneity between the studies which prevented the pooling of data.
- **G. Adequate.** The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

## Results (within scope of this systematic review)

Out of 215 studies, 21 specifically focussed on treatments for individuals with 'moderately-severe' to 'very-severe' dementia. The studies provide limited moderate to high quality evidence for the use of sensory-focussed strategies, including aroma, preferred or live music, and MSS. Emotion-oriented approaches, such as "simulated presence' may be more effective for individuals with preserved verbal interactive capacity.

| apacity.  Study            | Main findings  |
|----------------------------|--|
|                            |  |
| Emotion-orient             |  |
| Finnema et al. (2005).     | No benefit over 'usual care' for participants with severe demential Participants with mild and moderate severity of demential benefite from emotion-focussed care, showing greater emotional adaptation than those in 'usual care'.  |
| Magai et al. (2002).       | No differences in behaviours between groups. Positive affect increase sharply during the first 6 weeks following non-verbal sensitivity trainin (p <0.05), but no differences between groups remained by 12 weeks.   |
| 'Simulated pres            | sence'   |
| Camberg et al. (1999).     | Staff observations: 'Simulated presence' was better in reducin agitation and withdrawal than 'usual care' (p <0.001) or placebo (p .001). Weekly staff surveys on CMAI and MOSES did not show an benefit from "simulated presence' over 'usual care' and both resulted i more positive affect than placebo (p <0.001). |
| Garland et al. (2007).     | Decreased physical agitation during treatment with "simulated presence' compared to placebo (p <0.01) and 'usual care' (p <0.01 Decreased verbal agitation during treatment with "simulated presence compared to 'usual care' (p <0.05). No difference between "simulated presence' and music.                         |
| Behavioural an             | d environmental treatments   |
| Bellelli et al.<br>(1998). | Decreases in agitation (p <0.05), apathy (p <0.01), and aberrant moto (p <0.001) at 3 months. Decreases in agitation (p <0.001), apathy (<0.05), and aberrant motor (p <0.001) at 6 months.  |
| Frisoni et al.<br>(1998).  | Reduction in NPI motor subscale (p <0.01) and CSDD (p <0.05) i both groups after 3 months, although the patterns of specific NP reductions differed.   |
| Morgan and Stewart (1998). | Greater decrease over time in disruptive behaviours in the experimental (low-density) group than in the comparison (constant hig density) group ( $p < 0.01$ ).  |
| Aromatherapy               |  |
| Ballard et al. (2002).     | Reductions in agitation (p <0.01) in both groups. Irritability an aberrant motor activity improved to a greater extent with aromatherap compared to placebo (p <0.001). Greater reduction in social withdrawa and increase in time spent in constructive activities with aromatherap compared to placebo (p <0.01).    |
| Holmes et al.<br>(2002)    | The median PAS score was lower (reduced agitation) durin aromatherapy compared with placebo (p <0.05).   |
| Lin et al. (2007).         | Decrease in agitation with lavender treatment with reduced scores of both CCMAI and C-NPI (p <0.001). No change following sunflowed treatment.   |
| Snow et al. (2004).        | Total absence of treatment effect.   |
| Bright light the           |  |
| Mishima et al.<br>(1998).  | Reduction in night-time activity and percentage of night-time activity total activity with bright light for subjects with vascular dementia (<0.01) but not for those with Alzheimer's dementia.   |
| Skjerve et al.<br>(2004).  | Decrease in agitation and behavioural symptoms from pre to pos treatment (p <0.01). No improvement in sleep-wake measure (Actigraph), one participant was dropped due to increased agitation.  |
| Movement The               |  |
| Heyn (2003).               | Sixty-nine percent of the participants engaged in more than half of th activity (MPES). Sixty-one percent of the participants showe improvement ratings of facial expression/mood (CMR).   |
| Holliman et al. (2001).    | Exercise group participants had less disruptive behaviour and mor positive behaviour during group sessions than before (PBRS). N lasting benefits: Exercise group had more disruptive behaviour that control group (PGDRS) following sessions (p <0.05).   |
| Music Therapy              |  |
| Holmes et al. (2006).      | Greater positive engagement during live music than silence (p <0.01 Greater engagement during live music than pre-recorded music (<0.01). Engagement during pre-recorded music was not significant different than silence.   |
| Svansdottir et al. (2006). | Reduction in combined symptom scores for activity disturbance aggressiveness, and anxiety (p <0.01). No change in control group Benefits of music therapy disappeared by four weeks follow-up.   |

| 193                         |  |  |  |
|-----------------------------|--|--|--|
|                             | Multi-sensory stimulation (MSS)  |  |  |
|                             | Baker et al. Improved mood and interest after both treatments (p <0.01). Greater increase in attentiveness to environment after MSS than activity sessions (p <0.05). Greater improvement in mood and behaviour at home compared to the activity group whose behaviour deteriorated (p <0.05). Benefits disappeared by one month follow-up.  Baker et al. (2003).  Apathy decreased in both groups (p <0.01). Severity by time interaction (p <0.01). MMSE 0–9 were less apathetic at post-trial following MSS and more apathetic following activity group. MMSE 10–17 had the opposite pattern. Benefits disappeared by one month follow-up.  |  |  |
|                             | Touch Therapy  |  |  |
|                             | Gerdner et al. Reduction in mean M-CMAI total (p <0.001) and subscale scores (physically aggressive (p <0.01), non-aggressive (p <0.001), and verbal agitation (p <0.001) at post-test. Reduction continued through post-treatment period for physically non-aggressive agitation (p <0.001) and verbal agitation (p <0.001).  |  |  |
|                             | Balancing Arousal  |  |  |
|                             | Kovach et al. BACE resulted in reduced agitation between pre-test and post-test (p <0.001), with no change in the control group. Effects mostly gone by 10 weeks.  |  |  |
| Authors'<br>conclusions     | Most studies of interventions for dementia-related NPS have focussed on individuals with mild to moderate cognitive impairment. Individuals with severe cognitive impairment do not necessarily respond to NPS treatments in the same manner. Future studies should be specifically designed to further explore the stage-specific efficacy of non-pharmacological therapies for people with advanced dementia. Areas of particular need for further research include movement-based therapies, hands-on (touch) therapies, and interventions that can be provided during personal care routines. Interventions appear to work best when they are tailored to balance individual arousal patterns. |  |  |
| Reviewers' notes            | This review highlights that that individuals with severe cognitive impairment do not necessarily respond to NPS treatments in the same manner as individuals in the early stages of disease progression. This suggestion may have important implications relating to the feasibility of delivering interventions in common areas, universally, for all residents. Differential responses seem likely, including the possibility of adverse effects.  |  |  |
| Relevance to study question | Advanced dementia is characterised by severe cognitive and functional impairments that lead to almost total dependency in self-care. Non- pharmacological interventions offer the potential for safer alternatives to pharmacotherapy, but little is known about their efficacy. This review evaluates the published literature on non-pharmacological interventions for treating NPS in advanced dementia.  |  |  |

\*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations:** ASD = Arousal states in dementia scale, BACE = Balancing arousal controls excesses, BEHAVE-AD = Behaviour pathology in Alzheimer's disease rating scale, BLT = Bright light therapy, BMD = Behaviour and mood disturbance scale, BPSD = Behavioural and psychological symptoms of dementia, BRS = Behaviour rating scale, CMAI = Cohen-Mansfield agitation inventory, CMR = Caregiver mood report, CNA = Certified nursing assistant, CNPI = Chinese neuropsychiatric inventory, CSDD = Cornell scale for depression in dementia, DCM = Dementia care mapping, EBIC = Environment-behaviour interaction code, INTERACT = The effects of Snoezelen on demented elderly scale, JHNEBP = Johns Hopkins Nursing Evidence-Based Practice model, MMSE = Mini-mental state examination, MOSES = Multi-dimensional observation scale for elderly subjects, MPES = Menorah Park engagement scale, MSS = Multi-sensory stimulation, NPI = Neuropsychiatric inventory, NPI-NH = Neuropsychiatric inventory — nursing home edition, NPS = Neuropsychiatric symptoms, PAS = Pittsburgh agitation scale, PBRS = Patient behaviour rating scale, PGDRS = Psychogeriatric dependency rating scale, RCT = Randomised controlled trial, REHAB = Rehabilitation evaluation, SCU = Special care unit.

#### Additional references:

Newhouse, R., Dearholt, S., Poe, S., Pugh, L. and White, K. (2007). *Johns Hopkins Nursing Evidence- based Practice Model and Guidelines*. Indianapolis, IN: Sigma Theta Tau International.

Tombaugh, T. and McIntyre, N. (1992). The Mini-mental State Examination: a comprehensive review. *Journal of the American Geriatrics Society*, 40, 922–935.

- † Also reviewed in Forbes et al. (2009).
- ‡ Also reviewed in O'Connor (2009).
- $\Delta$  Published outside this review's date range (ie pre-1999).

### Table 27: Landreville et al. (2006)

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|---|--|---|--|
| Citation  | Landreville, P., Bedard, A., Verreault, R., Desrosiers, J., Champoux, N., Monette, J., et al. (2006). Non-pharmacological interventions for aggressive behavior in older adults living in long-term care facilities. International Psychogeriatrics, 18(1), 47-73.   |   |  |
| NHMRC Level of evidence   | Level IV.  |   |  |
| Objective   | To systematically review the literature on the effectiveness of non-pharmacological interventions in institutional settings.   |   |  |
| Type of included studies  | A total of 41 studies were identified and included in the review with twenty-six out of the 41 studies being conducted with residents with dementia.   |   |  |
| Types of participants   | Nursing home residents with behavioural symptoms of dementia.  |   |  |
| Type of intervention  | All types of non-pharmacological interventions.  |   |  |
| Outcomes  | Aggressive behaviour (AB)  |   |  |
| Data analyses & statistics  | Treatment effectiveness was examined through two criteria: (1) statistically significant improvement (p <0.05) and (2) marked behavioural improvement, defined as behaviour judged as "very improved" on a clinical improvement rating scale or reduction of AB by at least 50%.   |   |  |
| Alphabetical list of all identified studies.  | Balderston et al. (1990). Ballard et al. (2002). Beck et al. (2002). Bird et al. (1995). Block et al. (1987). Bourgeois and Vezina (1998). Clark (1998). Cohen-Mansfield and Werner (1998). Denney (1997). DeYoung et al. (2002). Dunn (2002). Fitzwater and Gates (2002). Goddaer and Abraham (1994). Hagen and Sayers (1995). Holmberg (1997). Ingersoll-Dayton et al. (1999). Leon and Ory (1999). Lewin and Lundervold (1987). Lykestos et al. (1996). Maxfield et al. (1996).   | McCallion et al. (1999).  McMinn and Hinton (2000).  Mentes and Ferrario (1989).  Meyer et al. (1992).  Mintzer et al. (1997).  Monahan (1993).  Moniz-Cook et al. (2001).  Namazi and Johnson (1992).  Remington (2002).  Rosberger and MacLean (1983).  Shah and De (1998).  Sival (1997).  Snyder et al. (1996).  Snyder et al. (2001).  Thomas et al. (1997).  Toseland et al. (1997).  Werner et al. (1994).  Whall (1997).  Williams et al. (1994).  Woods and Ashley (1995).   |  |
| Relevant 1999 onwards studies conducted with residents with dementia  Description of                              |  | †Lykestos et al. (1999).  »McCallion et al. (1999).  Moniz-Cook et al. (2001) [see below].  ‡Remington et al. (2002).  »Snyder et al. (2001).  ere conducted specifically with residents with   |  |
| relevant primary<br>studies of non-<br>pharmacological<br>interventions not<br>included in<br>subsequent reviews. | dementia. In a further five studies, the population was probably people with dementia, but not specified. Of these 26 dementia studies, 11 met the main criteria for this current review (listed above). Of these 11 studies, 7 (briefly described below) were unique, that is, not already appraised within the more recent Forbes et al. (2009), O'Connor et al. (2009), Kverno et al. (2009), Landreville et al. (2006), and/or Bharani and Snowden (2005) systematic reviews.  Beck et al. (2002). RCT. Activities of daily living intervention vs. a psychosocial activity intervention vs. a combination of the two, to determine their efficacy in reducing disruptive behaviours and improving affect in nursing home residents with dementia. The study had 3 treatment groups (activities of daily living, psychosocial activity, and a combination) and 2 control groups (placebo and no intervention). Nursing assistants employed at the nursing homes recorded the occurrence of disruptive behaviours in 127 residents. Raters analysed videotapes filmed during the study to determine the interventions' influence on affect.  DeYoung et al. (2002) conducted a single-group repeated-measures study to evaluate the effectiveness a staff training behaviour management programme (BMP) in decreasing aggressive, agitated, or disruptive (AAD) behaviours. The sample consisted of all patients (n = 32) who resided in the unit for at least 3 months. The nursing home behaviour problem scale (NHBPS) was used to collect data. |   |  |

**Ingersoll-Dayton et al. (1999).** A Solution-focussed approach with family and certificated nursing aides. Twenty-one nursing homes residents with dementia displaying either physically aggressive behaviours, verbally aggressive behaviours or wandering. Crossover randomised trial, non-blind outcome assessment of aggression via the caretaker obstreperous behaviour rating assessment (COBRA) and one question assessing mastery.

**Leon and Ory (1999)**. Specialised dementia care units in nursing homes vs. non-specialized units within a 6- month placement. The study participants (non-randomised) were new admissions to SCUs (n = 432) and new admissions to traditional care units (n = 164). Non-blinded assessment of outcomes via interviews with family members and facility staff, review of medical records, MDS, and the CMAI (Physically aggressive behaviours subscale).

**McCallion et al. (1999).** This study was designed to examine the impact of the family visit education programme (FVEP) on family members, nursing staff, and nursing home residents with dementia. The study employed a 2 x 3 single- blind, RCT design with two study conditions, FVEP or 'usual care' (UC), and three times of measurement—baseline, 3-months, and 6- months. Sixty-six residents with dementia and their primary visitor were randomly assigned to FVEP (n = 32) or UC (n = 34). Residents were assessed for (1) psychosocial functioning, (2) depression, (3) agitated behaviour, and (4) degree of positive social interaction (also carer outcomes).

**Moniz-Cook et al. (2001)**. Individualised environmental modifications (simple changes to environmental triggers for AB). Four residents with dementia and physically aggressive and verbally aggressive behaviours, residing in 1 nursing home. Outcome measurement by direct observation via non-blinded outcome assessment and using an ABA study design.

**Snyder et al. (2001)** employed a quasi-experimental, repeated-measures design study to measure the effects of a glider swing on emotions, relaxation, and AB in a group of nursing home residents with dementia (n = 30). Data were obtained during a 5-day baseline phase, a 10-day intervention phase, and a 5-day post-treatment phase. Subjects were placed on the glider for 20 mins. each day during the intervention phase.

# Study quality \* See below for "AG" quality criteria questions

- **A. Adequate.** The objective of the study was very clearly defined and specific and included non-pharmacological interventions focusing on aggressive behaviour.
- **B. Adequate.** Article selection was made through PsycINFO (1967–2003), CINAHL (1982–2003), Ageline (1978–2003), MEDLINE (1960–2003) and Current Contents (2003). Review papers obtained through these databases and the reference list of selected papers were also screened to identify additional articles relating to the management of AB in institutional settings.
- **C. Adequate.** The inclusion/exclusion criteria were appropriate as follows: inclusion (a) assessment of a non-pharmacological intervention, (b) the age of individual participants or the mean age of samples was at least 60 years, (c) some results are specific to AB, and (d) a measure of change in behaviour was obtained (eg baseline, pre-test assessment or control group). Papers were excluded if the study was conducted with persons living in the community or family home, if participants only had a diagnosis of psychiatric illness, such as schizophrenia (because such "pure" cases are rare in residential care), or if results on AB were mixed with other problematic behaviours (eg the agitation/aggression subscale of the NPI).
- **D. Adequate.** All included studies were appraised for design characteristics and quality of evidence. However, the method and/or checklist or criteria were not specified. Notes were provided to outline potential biases and quality issues where such issues were identified.
- **E. Adequate.** Included studies were summarised in the text and study characteristics, quality, limitations and outcome data were available in tables for all studies.
- **F. Adequate.** Due to methodological differences between studies, meta-analysis was not possible.
- **G.** Adequate. The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

## Results (within scope of this systematic review)

#### Results-narrative summary

Staff training programmes: These programmes typically include in-service meetings during which both information on AB and demonstration of practical skills for managing such behaviours are provided. In general, positive findings were reported using staff training. Statistically significant reductions in AB were reported in all studies where statistical analyses were performed (6/6).

Environmental modifications: These interventions included changes in restraints – physical restraints, door locks and indoor confinement, modification of care and bathing procedures, natural or enhanced environment, reduction of noise level, elimination of environmental triggers, and rearrangement of daily activities/re-grouping residents with similar functional level. Of the 10 studies that evaluated the effect of environmental modifications on AB: 2 report a statistically significant decrease of target behaviours; 4r others did not analyse their results with statistical tests but reported a marked reduction in behaviour; and 1 showed both a statistically and behaviourally significant improvement.

Sensory stimulation: These interventions included music, massage, music and massage, aromatherapy and bright light therapy. Sensory stimulation shows modest effectiveness in reducing AB. While classical music, massage and touch appear to be ineffective, individualized music is associated with a statistically significant decrease in aggressiveness in all but one study. Aromatherapy is a promising approach, at least for physical aggression.

Behavioural management: Behavioural management interventions, include differential reinforcement alone and combined with other behavioural techniques (such as time out) and antecedents control, extinction, and cued recall. Behavioural modification was associated with a marked improvement in AB in 2 out of 4 studies. The superiority of 1e behavioural strategy over another could not be established due to the small number of trials

Structured activities: Structured activity interventions include activity programmes using different activities such as musical and social activities, games, creative work and singing, using a glider swing, and group walks. Studies examining the effect of participating in structured activities on aggressiveness demonstrated inconsistent results – some reducing aggressiveness and others increasing aggressiveness. The results highlight the importance of individual differences in the impact of activity interventions.

Special care units: SCUs are reported to offer special care for residents with dementia. Of three studies, two programmes were associated with a significant reduction of physically and verbal aggression. In a third study, after controlling for baseline level of disruptive behaviours, SCUs showed no effect on aggression compared to traditional units.

Psychosocial interventions: Few included studies examined the impact of social contact on AB and results were inconsistent. Psychosocial interventions included 'simulated presence' therapy, validation group therapy, psychosocial activity and activities of daily living. Results varied according to how the outcomes were measured.

Results from relevant primary studies of non-pharmacological interventions not included in subsequent reviews.

| Study                    | Main findings   |
|--------------------------|---|
| Beck et al.<br>(2002)    | Findings indicated significantly more positive affect but not reduced disruptive behaviours in treatment groups compared to control groups.   |
| DeYoung et<br>al. (2002) | Participation in the BMP decreased the total number and frequency of AAD behaviours, with a significant decrease from the baseline to 6-month measurements. Seven behaviours were significantly reduced at 6 months. The interventions that were effective in reducing AAD behaviours included verbal distraction, time-outs, activity diversion, getting to know the patient well, and managing the environment. |
| Ingersoll et al. (1999). | Significant decrease of frequency and severity of AB. Significant increase of 'mastery'.  |

| 199                               |  |  |  |
|-----------------------------------|--|--|--|
|                                   | Leon and Ory<br>(1999)   | SCU show no effect on frequency of AB. Increased use of psychotropic medicines and reduced use of physical restraints show a relationship with lower levels of PAB.  |  |
|                                   | McCallion et al. (1999).   | FVEP was effective for reducing residents' problem behaviours and for decreasing their symptoms of depression and irritability. It was also effective for improving the way family members and other visitors communicated with residents, but, with the exception of reducing the use of mechanical restraints, it was not effective in changing nurses' management of residents' behaviour problems. |  |
|                                   | Moniz-Cook<br>et al. (2001).   | Reduction of AB in all cases. Treatment effects maintained at follow-up.   |  |
|                                   | Snyder et al.<br>(2001).   | The glider intervention significantly improved emotions and relaxation. The most noted changes were found after 10 minutes of swinging. However, no differences were found in AB.  |  |
|                                   |  |  |  |
| Authors' overview and conclusions | Staff training programmes and environmental modifications appear to be the most effective strategies. Sensory stimulation, which has been examined in several studies, has led to mixed findings. Finally, there is some evidence for the effectiveness of behavioural management, special care units, structured activities, and psychosocial interventions. However, this observation is based on very few studies and more research on these interventions is needed. While non-pharmacological interventions seem effective for managing AB, future studies on the effectiveness of these interventions needs to be more rigorous.   |  |  |
| Reviewers' notes                  | This article provides a review of the literature on the effectiveness of non-pharmacological interventions in institutional settings, which are aimed at specifically reducing aggression (in particular physical aggression). However, the review included studies in institutional settings in which the study populations may or may not have dementia. Of the 41 included studies, only 26 were reportedly conducted with residents with dementia and of these 26 dementia studies, all but 11 were conducted in the late 1980s and 1990s. While inferences may be drawn for the entire body of evidence, caution is required in interpreting the results and conclusions, as generalisability may be limited. |  |  |
| Relevance to study question       |  | esises the current knowledge on the effectiveness of non-<br>interventions in institutional settings.  |  |
|                                   |  |  |  |

\*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations:** AB = Aggressive behaviour; COBRA = Caretaker obstreperous behaviour rating assessment, CMAI = Cohen-Mansfield agitation inventory, FVEP = Family visit education programme, MDS = Minimum data set, NHPBS = Nursing home problem behaviour scale, NPI = Neuropsychiatric inventory, PAB = Physically aggressive behaviour, RCT = Randomised controlled trial, SCU = Special care unit.

- † Also reviewed in Forbes et al. (2009).
- ‡ Also reviewed in O'Connor et al. (2009).
- § Also reviewed in Kverno et al. (2009).
- □ Also reviewed in Nguygen et al. (2008).
- ° Also reviewed in Landreville et al. (2006).
- »Bharani and Snowden (2005).
- $\Delta$  Published outside this review's date range (ie pre–1999).

Table 28: Livingston et al. (2005)

| Citation   | Livingston, G., Johnston, K., Katona, C., Paton, J., Lyketsos, C. G., & Old Age Task Force of the World Federation of Biological Psychiatry (2005). Systematic review of psychological approaches to the management of neuropsychiatric symptoms of dementia. American Journal of Psychiatry, 162(11), 1996-2021.  |
|--|--|
| NHMRC Level of evidence  | Level IV.  |
| Objective  | To systematically review the literature on psychological approaches to treating the neuropsychiatric symptoms of dementia.   |
| Type of included studies   | All study types with quantitative outcome measures that were either direct or proxy measures of neuropsychiatric symptoms.   |
| Types of participants  | Nursing home residents with behavioural symptoms of dementia.  |
| Type of intervention   | Any therapy derived from a psychological/psychosocial model (therefore excluding aromatherapy, homeopathy, occupational therapy and light therapy).  |
| Outcomes   | Quantitative outcome measures that were either direct or proxy measures of neuropsychiatric symptoms of dementia.  |
| Data analyses & statistics   | Narrative synthesis.   |
| Alphabetical list of all included studies  | The search identified 1632 potentially relevant articles and 162 satisfied the inclusion criteria for the review. Included studies were published from as early as 1975 through to July 2003. Only 60 studies were published from 1999 onwards (76 published pre-1999). The 162 included studies are not listed here due to space limitations.   |
| Alphabetical list of relevant trials (broadly within the scope of this systematic review). | Ashida, S. (2000). Buchanan & Fisher (2002). Buettner (1999). Buettner & Fitzsimmons (2002). Heard & Watson (1999). Hopman-Rock et al. (1999). Jennings & Vance (2002). Ø Kim & Buschmann (1999). Spector et al. (2003). Testad et al. (2005).   |
| Description of relevant included studies not included in earlier reviews.                  | Ashida (2000). Group music therapy, reminiscence music therapy sessions, non-randomised 'before and after' study involving 20 residents who were their own controls. Buchanan & Fisher (2002). Behavioural management techniques, including functional assessment of disruptive vocalisations followed by non-contingent reinforcement. Two residents were their own controls (2 single cases). Low level of evidence. Assessment of frequency of disruptive vocalisations.  Buettner & Fitzsimmons (2002). Therapeutic biking for the treatment of depression in long-term care residents with dementia. Small-group discussion, then 15 minutes of biking (total of 1 hour a day, 5 days a week), followed by 10-week maintenance period that included biking twice a week. RCT involving 70 residents.  Heard & Watson (1999). Behaviour management using differential reinforcements. Individual behavioural intervention programmes aimed at reducing wandering by persons with dementia were trialled with 4 residents (low-level evidence).  Hopman-Rock et al. (1999). Psychomotor activation programme. Individual behaviour and group behaviour were scored using 2 scales developed and validated for use in psychogeriatric populations. Cognition was measured with the short and the long versions of the cognitive screening test (CST-14 and CST-20). Disability was measured with the Barthel index. Medicine use, falls, other accidents and life events were registered. One hundred and thirty-four subjects entered the study, 42 of whom dropped out. Post-test after 6 months.  Kim and Buschmann, (1999). Expressive physical touch with verbalisation, single group repeated-measures design involving 29 residents and measurement of behaviour and anxiety.  Jennings & Vance (2002). Music therapy (30-min. music class once a week for 4 consecutive weeks). Sixteen elderly day-care centre participants diagnosed as having AD were included in the study. Agitation, as measured by the modified CMAI, was assessed by each participant's primary day-care staff person 1 week prior to the tr |

**Spector et al. (2003)**. Cognitive stimulation (14 cognitive stimulation sessions), single blind, multi-centre, RCT involving 201 older people with dementia. The main outcome measures were change in cognitive function and quality of life.

**Testad et al. (2005)**. Staff training aimed at reducing problem behaviour and the use of restraint in demented residents (a full day seminar, followed by a 1-hour session of guidance per month over 6 months). The content of the educational programme focussed on the decision making process in the use of restraint and alternatives to restraint consistent with professional practice and quality care. The study was a multicentre randomised single-blind controlled trial. The primary outcome measures were number of restraints per resident in the nursing homes in 1 week and agitation as measured with the brief agitation rating scale (BARS), rated before and immediately after the intervention.

# Study quality \* See below for "AG" quality criteria questions

- **A.** Adequate. The objective of the study was very clearly defined and specific and included any non-pharmacological therapy derived from a psychological approach.
- **B.** Adequate. Searched electronic databases through July 2003, reference lists from individual and review articles, and the Cochrane Library and sought expert knowledge of additional studies, including those published after July 2003. A total of 1632 studies were identified, and 162 satisfied the inclusion criteria for the review.
- **C.** Adequate. The inclusion criteria were appropriate. Studies of people without dementia, dementia secondary to head injury, or interventions that either involved medication or were not based on a psychological model (eg, aromatherapy, homeopathy, occupational therapy, light therapy) were excluded.
- **D. Adequate**. Data were extracted, the quality of each study was rated, and an overall rating was given to each study by using the Oxford Centre for Evidence-Based Medicine criteria.
- **E. Inadequate**. Not all included studies were summarised in the text but study characteristics and outcome data were available in tables. The level of detail presented for most of the studies was minimal (almost certainly limited by the broad scope, resulting in a large number of studies being included).
- **F. Adequate**. Due to methodological differences between studies, meta-analysis was not possible.
- **G.** Adequate. The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

## Results (within scope of this systematic review)

\*\*Results- abridged narrative summary from Livingston et al. (2005).

#### Reminiscence Therapy

Reminiscence therapy uses materials such as old newspapers and household items to stimulate memories and enable people to share and value their experiences. Of 5 studies (3 small RCTs), one reported behavioural improvements when reminiscence therapy was preceded by reality orientation, but not vice versa, and the other two studies found no benefit. One level-4 study reported a significant improvement in mood.

• The grade of recommendation for reminiscence therapy is D.

#### Validation Therapy

Validation therapy is intended to give an opportunity to resolve unfinished conflicts by encouraging and validating expression of feelings. Three studies of VT were included. The first, a case series of 5 individuals, indicated an improvement in irritability after VT. The second, which included 5 residents who served as their own comparison subjects, reported no change in behaviour. A RCT compared VT to 'usual care' or a social contact group in 88 residents with dementia and at one-year follow-up, there was no difference in independent outcome ratings, in nursing time needed, or in use of psychotropic medication and restraint.

• The grade of recommendation for validation therapy is D.

#### Reality Orientation Therapy

Reality orientation therapy is based on the idea that impairment in orientating information (day, date, weather, time, and use of names) prevents residents with dementia from functioning well and that reminders can improve functioning. Eleven studies assessed reality orientation therapy. The strongest RCT, which had 57 participants, showed no immediate benefit of reality orientation therapy, compared to active ward orientation. In a smaller RCT (n = 10), residents who received reality orientation therapy followed by reminiscence therapy had fewer neuropsychiatric symptoms, compared to residents who received the treatments in the reverse order. The other smaller RCTs mostly found benefits in the reality orientation therapy groups in terms of improved mood, decreased neuropsychiatric symptoms, or delayed institutionalisation.

• The grade of recommendation for reality orientation therapy is D.

#### Cognitive Stimulation

Cognitive stimulation therapy uses information processing rather than factual knowledge to address problems in functioning in residents with dementia. Three of four RCTs of cognitive stimulation therapy showed some positive results, although the studies used different follow-up endpoints (immediately after therapy to nine months after therapy). There were early behaviour improvements, relative to controls. By nine months, no significant difference between groups was found. One study showed reduced depression, and another showed improvement in quality of life but not in mood. The final study did not report whether the differences in behaviour were significant.

• The grade of recommendation is B (given the mostly consistent evidence that cognitive stimulation therapy improves aspects of neuropsychiatric symptoms immediately and for some months afterward, although the evidence is not consistent in all respects).

#### Other Dementia-Specific Therapies

Two other dementia-specific therapies were identified. Firstly, 'individualised special instruction', consisted of 30 mins. of focussed individual attention and participation in an activity appropriate for each individual. The participants in the pilot RCT were their own waiting-list comparison subjects. During the intervention period, their behaviour did not deteriorate, compared with deteriorating behaviour before the intervention period. The second dementia-specific therapy was 'self-maintenance therapy', which is intended to help the resident maintain a sense of personal identity, continuity, and coherence. This intervention incorporates techniques from validation, reminiscence

intended to help the resident maintain a sense of personal identity, continuity, and coherence. This intervention incorporates techniques from validation, reminiscence, and psychotherapy. A 3-week admission of residents and carers to a specialist unit in which self-maintenance therapy was provided led to a significant decrease in depression and problematic behaviour, compared to baseline. This outcome may have been partly attributable to the environment.

• The grade of recommendation for these other therapies is C.

#### Non-Dementia-Specific Psychological Therapies

Twenty-five reports described use of non-dementia specific psychological therapies for residents with dementia. Nearly all of the studies examined behavioural management techniques. In 1 RCT, participants received either manual guided treatment for the resident and carer or a problem-solving treatment for the carer only. The two interventions were equally successful in improving depressive symptoms immediately and at 6-month follow-up. Two other small RCTs also had positive results. In 1 of those studies, participants had significantly fewer neuropsychiatric symptoms 2 months after being taught progressive muscle relaxation. In the other study, the behaviour of residents with the dementia of multiple sclerosis improved with 'neuropsychological counselling' (a cognitive behaviour intervention).

There were 2 other RCTs in which behavioural management techniques were used; these techniques were ineffective in one of the studies. It used a complex, difficult-to-classify intervention that included a variety of techniques (eg, life review, sensory stimulation, single-word commands, and problem-oriented strategies). The second used a token economy, which was more effective in reducing 'bizarre' behaviour in residents with severe dementia, compared to a pre-intervention condition, but less effective than a milieu treatment. Several single-case studies were also identified.

• The grade of recommendation for standard behavioural management techniques in dementia is B (the findings of the larger randomised, controlled trials were consistent and positive, and the effects lasted for months).

#### Carer interventions involving training

Nineteen reports describe interventions with family carers designed to ameliorate neuropsychiatric symptoms or frequency of institutionalisation in dementia. Seven studies involved training the carer to use behavioural management techniques. A RCT found no difference in agitation or global outcome in a comparison of treatment with behavioural management techniques, haloperidol or trazodone alone, or placebo at 16 weeks. Behavioural management techniques taught to carers did not reduce psychotropic drug use or symptom frequency at 1-year follow-up. Exercise and behavioural management techniques led to significant improvements in depression at 3 months but not at 2 years in another trial. In a smaller RCT, behavioural management techniques based on the progressive lowered stress threshold model were taught to carers with the aim of reducing stimulation in response to specific stressors identified by carers. In this study, both groups received the intervention, one in the form of written materials, and the other in a training programme. A positive effect for care recipients

was found in the second group. The evidence that behavioural management techniques with carers and exercise training with residents helps depression is strong, but it is unclear which component was the active component.

• The grade of recommendation for teaching carers behavioural management techniques to manage psychological symptoms is D (because the findings of other studies are inconsistent).

#### Other carer interventions

Nine studies (including 7 RCTs) involved psycho-education to teach carers how to change their interactions with residents with dementia. In one large trial, improvement in neuropsychiatric symptoms at 16 weeks was found, but the difference only approached significance. In a second trial, improvement in neuropsychiatric symptoms occurred immediately after 12 weeks of training in stress management, dementia education, and coping skills but was not maintained at 3-month follow-up. A third, smaller trial examining the effects of an intervention with individual families found significant improvements at 6 months in mood and ideational disturbance. In a RCT of an educational programme for family carers that included supportive counselling, psycho-education and training in management strategies, and home visits, the rate of institutionalisation of residents was decreased (for 3 months but not 2 years). A fifth RCT involved psycho-education, instruction to carers in how to change their interactions with the resident, or both. Residents' behaviour improved at 6 months, but the difference only approached significance. Another study examined the effects of carer psycho-education in working with nursing home residents to enhance social activities and self-care; the intervention resulted in a decrease in agitation after 6 months. Finally, a large high quality RCT study investigated a comprehensive support and counselling intervention for 406 spouse carers that included problem solving, management of troublesome behaviour, education, and increased practical support, followed by long-term support groups. Residents' neuropsychiatric symptoms were not directly measured, but the intervention was found to delay time-to-institutionalisation by nearly a year. The other studies were non-controlled and showed either improvement that approached significance or significant improvement.

• The grade of recommendation for behavioural management techniques in the form of psycho-education and teaching carers how to change their interactions with residents is A, (because evidence from level-1, level-2, and level-4 studies consistently supports these interventions, and the effects have been shown to last months.

#### Family counselling

An uncontrolled study suggested that family counselling is helpful in reducing institutionalisation of patients. In a non-randomised trial, a family support group resulted in a decrease in problem behaviour but not in depression.

• The grade of recommendation for family counselling is C.

#### Carer support by specialist nurses

A single controlled study compared the effects of using specialist nurses who worked in the community with persons caring for people with dementia—to those of usual treatment and showed no effect on institutionalisation of patients.

• The grade of recommendation for carer support by specialist nurses in the community is D.

#### Music therapy

Of 24 music/music therapy interventions, 6 were investigated in RCTs. All were small trials and showed improvements in disruptive behaviour. In 2, behaviour was observed during the music sessions, but there was no evidence that benefit carried over after the sessions. In 3 studies, behavioural change was observed outside of the music/music therapy session. In the first study, residents were significantly less agitated, both during and immediately after music/music therapy in which the music was chosen to fit the individuals' preference. The results of the second study were similar. In the third study, which assessed music, HM, or a combination of both, decreased agitation was observed 1 hour after the intervention. All but one of the other studies were controlled. Most of them found a benefit, although some did not.

• The grade of recommendation for music therapy for immediate amelioration of disruptive behaviour is B. Music therapy decreases agitation during sessions and immediately after. There is, however, no evidence that music therapy is useful for treatment of neuropsychiatric symptoms in the longer term.

#### **Sensory stimulation**

Snoezelen therapy/MSS combines relaxation and exploration of sensory stimuli, such

as lights, sounds, and tactile sensations. Of 6 trials of Snoezelen therapy/MSS, three were RCTS. The first was a very small trial with no clear results. The other 2 found that disruptive behaviour briefly improved outside the treatment setting but that there was no effect after the treatment had stopped. The other reports described studies of individual cases and an uncontrolled trial in which improvements were found but no statistics were provided.

• The grade of recommendation for Snoezelen for amelioration of disruptive behaviour immediately after the intervention is B, but the effects are apparent only for a very short time after the session.

#### Other sensory stimulation.

Of seven trials of other forms of sensory stimulation, only 3 were RCTs. The first trial compared massage with a comparison condition, music, or a combination of massage and music and decreased agitation was observed 1 hour after the intervention. The second trial examined a sensory integration programme that emphasised bodily responses, sensory stimulation, and cognitive stimulation; this intervention had no effect on behaviour. Similarly, a small RCT found that white noise had no effect on sleep disturbance and nocturnal wandering. An 'expressive physical touch' intervention over a ten-day period decreased disturbed behaviour from baseline immediately and for five days after the intervention. White noise tapes led to immediate decrease in agitation in another trial. A controlled trial of stimulation with 'natural elements' while bathing found that agitation decreased significantly only during bathing. The other study of single cases found no difference in agitation before and after therapeutic touch or massage. In the final 2 studies, the effects of several forms of sensory stimulation involving touch, smell, and taste were examined. A small RCT reported no change associated with the intervention, and the other study found that the intervention was helpful.

• The grade of recommendation for short-term benefits of sensory stimulation is **C**, (but there is no evidence for sustained usefulness).

#### 'Simulated presence' therapy and therapeutic activities

Six studies investigated the effects of 'simulated presence' therapy (usually involving a continuous-play audiotape made by a family member). One RCT found no change in agitated or withdrawn behaviours. Staff observations suggested reduced agitation in residents who received the intervention, compared to a placebo group but not compared to residents receiving 'usual care' in another trial. A small study found improved social interaction and attention. 'Simulated presence' therapy used to address agitation led to significant decreases in agitation and improved social interaction but no change in AB in another study. When 'simulated presence' therapy was used regularly, problem behaviours were reduced by 91% in another study. Finally, in a series of single case studies, mixed results were reported.

• The grade of recommendation for 'simulated presence' therapy is D.

#### Other structured activity and alteration of the visual environment

There were five RCTs of therapeutic activities. In a small-scale RCT, therapeutic activities at home were associated with significant decreases in agitation. Another study found that small group discussion and being carried on a bicycle pedalled by volunteers alleviated residents' depression but not agitation at 10 weeks. The third RCT found no effects of 'puzzle play' on social interaction and mood. Similarly, a comparison of games and 'puzzle play' with Snoezelen and another study comparing structured activity with a control condition found no improvements in mood and behaviour. Non-randomised trials: 1 found no beneficial effects of weekly therapeutic activities on depression, in another study, a combination of group and individualised activity sessions in day care significantly increased agitation over 10 weeks. A clinical trial of weekly activity groups led by nursing assistants found no behavioural changes. A specialist day-care programme providing structured daily activities for residents with dementia was associated with decreased institutionalisation and was more costeffective than nursing home care. Residents who were rocked on a swing did not show a decrease in aggression. Three case studies of diverse group activities (games, music, exercise, socialising) found equivocal effects on behaviour. In 2 studies that used reading sessions as an intervention, some improvement was seen in wandering and disruptive behaviours were decreased in both residents.

• The grade of recommendation for therapeutic activity programmes is D.

#### Montessori activities.

Montessori activities use rehabilitation principles and make extensive use of external cues and progression in activities from simple to complex. Three non-randomised, controlled trials utilised Montessori-based activities and found no change in depression

and agitation.

• The grade of recommendation for Montessori activities is D.

#### Other environmental manipulation

Exercise. Three studies examined the use of exercise/movement/walking as an intervention for neuropsychiatric symptoms. A well-conducted randomised, controlled trial found no effects on behaviour in a 'walk and talk' programme. A randomised, controlled trial of a psychomotor activation programme found no behavioural effect. In two small non-randomised controlled trials, 1 found a significant reduction in AB on days when a walking group was held and the other study, a small matched controlled trial of exercise groups, found no significant reduction in agitated behaviours.

• The grade of recommendation for exercise is D.

#### Staff education in managing behavioural problems

Nine studies (including 3 RCTs) investigated the effects of staff education in managing behavioural problems. A randomised, controlled trial of communication skills training for nursing and auxiliary staff showed significant reductions in residents' aggression at three months and in residents' depression at 6 months. Education of staff to implement an emotion-focussed care programme (validation, reminiscence, sensory stimulation) did not result in any change in neuropsychiatric symptoms. Staff education programmes focussed on knowledge of dementia and potential management strategies reduced use of physical restraint use and, in a non-randomised, controlled trial. decreased aggressive behaviour toward staff. Specialised care programmes for individuals in a residential home plus staff education improved emotional status and quality of life for residents 12 months later. A similar approach in a controlled trial with only 11 people in each arm led to non-significant differences favouring the intervention group. The result of a client-centred approach to agitation and sleep disturbance for 33 residents of a nursing home was equivocal. Verbal aggression decreased significantly, but the (less frequent) episodes of non-verbal agitation increased in 1 study. Training staff in integrity-promoting care improved residents' anxiety and depressed mood in a small controlled trial. In a large uncontrolled trial, training for nursing staff in using unstandardised observational outcomes led to an increase in restraint use but had no effect on agitated behaviour.

• The grade of recommendation for specific staff education programmes in managing neuropsychiatric symptoms is B.

#### **Special Care Units**

Eight non-randomised, controlled trials investigated the effects of special care units (SCUs) designed for residents with dementia and staffed by specially trained workers who received ongoing training. In a controlled trial, admission to a 'low-density' SCU was associated with a decrease in disruptive behaviour. Similarly, in a controlled trial, a combination of group living and staff training was found to improve residents' emotional and physical outcomes and was less costly than standard care. In other studies, SCUs were associated with a reduction in neuropsychiatric symptoms, especially agitation and depression, and with a reduction in use of neuroleptic medication. Aggression and activity disturbances were reduced in another small controlled trial of a SCU, however, 3 other studies found no effect.

• The grade of recommendation for special care units is D.

#### Social interaction.

A small report of single cases studies showed decreased neuropsychiatric symptoms in one third of participants.

• The grade of recommendation for enforced social interaction is D.

#### Decreased sensory stimulation.

Two small studies investigated decreased sensory stimulation.

 $\bullet$  The grade of recommendation for decreased sensory stimulation is D.

#### Other

- •The grade of recommendation for changing the environment to obscure the exit is C.
- The grade of recommendation for use of mirrors is D.
- The grade of recommendation for signposting is D.
- The grade of recommendation for group living is D.
- The grade of recommendation for unlocking doors is D.

| 206                  |   |   |
|----------------------|---|---|
|                      | Results of trials of systematic review  | of relevant interventions not reviewed in subsequently published  |
|                      | Study   | Main findings   |
|                      | Ashida (2000).  | Group music therapy sessions reduced depressive symptoms during and after therapy, but no lasting effect.   |
|                      | Buchanan &<br>Fisher (2002).  | Significant reduction in disruptive vocalisations (low level of evidence).  |
|                      | Buettner &<br>Fitzsimmons<br>(2002).  | Significant reduction in depression at ten-week follow-up, no significant effects on agitation.   |
|                      | Heard &<br>Watson (1999).   | Individualised interventions reduced wandering (low-level evidence).  |
|                      | Hopman-Rock et al. (1999).  | A beneficial effect on cognition but no overall effect on behaviour.  |
|                      | Jennings &<br>Vance (2002).   | Agitation was significantly reduced compared to the baseline measure. Specifically, music therapy reduced most types of agitation except for most types of physical agitation such as hitting or spitting.                |
|                      | Kim &<br>Buschmann,<br>(1999)   | Improvement in behaviour during intervention and for 5 days afterward but only short-term reductions in anxiety.  |
|                      | Spector et al. (2003).  | Significantly improvements in cognition via the Mini-Mental State Examination (p = 0.044), the Alzheimer's disease Assessment Scale – Cognition (p = 0.014) and Quality of Life – Alzheimer's disease scales (p = 0.028). |
|                      | Testad et al. (2005).   | Statistically significant reduction in the use of restraint in the treatment group vs. control (p = 0.013) but no change in agitation score post-intervention.  |
| Authors' conclusions | Livingston et al. (2005) stated that overall; their conclusions were limited because of the paucity of high-quality research. Only 9 of 162 included studies were level-II evidence (ie a properly designed RCT with narrow confidence intervals). However, notwithstanding the limitations of the evidence base, Livingston et al. (2005) concluded that behavioural management techniques centred on individual residents' behaviour are generally successful for reduction of neuropsychiatric symptoms, and the effects of these interventions can last for months. Further, psycho-education intended to change carers' behaviour is effective, especially if it is provided in individual rather than group settings, and improvements in neuropsychiatric symptoms associated with these interventions are sustained for months. Also, specific types of staff education lead to reductions in behavioural symptoms and use of restraints and to improved affective states. Staff education in communication skills and enhancement of staff members' knowledge about dementia may improve many outcomes related to neuropsychiatric symptoms. Finally, music therapy and Snoezelen, and possibly some types of sensory stimulation, are useful treatments for neuropsychiatric symptoms during the session behave no longer-term effects. The cost or complexity of Snoezelen for such small benefit may be a barrier to its use. |   |
| Reviewers' notes     | The included stud   | dies were published from as early as 1975 through to July 2003. Only published from 1999 onwards (76 published pre-1999). Arguably, a pproach (with a narrower publication year range) would have provided                |

\*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

more relevant information and allowed for the provision of more detail.

to the management of neuropsychiatric symptoms of dementia.

This review synthesises the evidence on the effectiveness of psychological approaches

(A) Was a clinical question clearly defined?

Relevance to study

question

- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

\*\*Each type of intervention was then given an overall "grade of recommendation" as assessed by the study authors (Livingston et al., 2005) as per the Oxford Centre for Evidence-Based Medicine criteria. The grades ranged from A (consistent level of evidence grade of 1) to D (level of evidence grade of 5 or troublingly inconsistent or inconclusive studies at any level).

**Abbreviations:** AB = Agitated behaviour, BARS = Brief agitation rating scale, HM = Hand massage, MSS = Multi-sensory stimulation, RCT = Randomised controlled trial, SCU = Special care unit, VT = Validation therapy.

Ø Also reviewed in Bharani & Snowden (2005).

#### Table 29: Nguygen and Paton (2008)

| Citation   | Nguygen, Q., & Paton, C. (2008). The use of aromatherapy to treat behavioural problems in dementia. International Journal of Geriatric Psychiatry, 23(4), 337-346.  |
|--|---|
| NHMRC Level of evidence  | Level I.  |
| Objective  | To review the evidence supporting the use of aromatherapy in BPSD.  |
| Type of included studies   | RCTs of aromatherapy in residents with dementia.  |
| Types of participants  | People with dementia with clinically significant agitation or other BPSD.   |
| Type of intervention   | The most commonly used oil in the studies was lavender, chosen because of its perceived calming and sedative properties. Also used were lemon balm, claimed to be useful in excitability, restlessness, stress and insomnia, and marjoram, thought to have sedative properties and be useful for nervous tension. Methods of administering the essential oils included: combing the oils with a base lotion and applying topically, oils added in the bath/footbath, oils soaked in cotton ball or sachet and attached to the lapels of each subject, oils diffused in the air using electric aroma steam fan or individually by diffuser.  |
| Outcomes   | BPSD.   |
| Data analyses & statistics                                       | Narrative synthesis.  |
| Alphabetical list of included studies                            | Ballard et al. (2002).  Bowles et al. (2002).  Burleigh et al. (1997).  Gray et al. (2002).  Henry et al. (1994).  Holmes et al. (2002).  Kilstoff et al. (1998).  Lin et al. (2007).  Mitchell, (1993).  Smallwood et al. (2001).  Snow et al. (2004).   |
| Description of relevant included studies (listed alphabetically) | ‡ § Ballard et al. (2002), UK. Aromatherapy with melissa oil/lemon balm (combined with a base lotion, applied topically to face and both arms twice daily) vs. neutral oil control, 71 participants with severe dementia with clinically significant agitation, nested RCT design, double-blind, outcome measurement via CMAI (assessed every 5mins over a 6 hour period, weekly for 4 weeks), strong quality study, of 4 weeks duration.  Bowles et al. (2002), Australia. Aromatherapy with a blend of oils (blended into a cream, and massaged onto the back, shoulders, neck and arms of each subject five times daily) vs. no oils, 56 residents with severe dementia, crossover RCT with non-blinded assessment of the frequency and severity of occurrence of resistance to nursing care procedures and other dementia-related behaviours at the end of each shift.  Δ Burleigh et al. (1997). Aromatherapy with a combination of oils, within-subjects design, seven residents with severe dementia each received their own individualised oil treatment. The study was conducted over a 12-week period: Weeks 1–3: Essential oils in the bath/footbath five times per week and oils applied to the pillows at night. Weeks 4–6: Three weeks oil free. Weeks 7–9: Oils in the bath/footbath/basin and applied to pillows. Subjects were massaged with oils on their hands, neck, face and shoulders five times per week. Weeks 10–12: Oils discontinued. Behaviour was assessed using the BASOLL scale at the end of weeks 3 and 12.  Gray et al. (2002), USA. Aromatherapy with lavender, sweet orange, tea tree (oil soaked in cotton ball and attached to the lapels of each subject) vs. no-aroma (control), 13 participants with dementia and 'difficult to manage behaviours' as identified by nursing staff, placebo controlled trial with participants videotaped and rated according to how long it took to administer medication and the frequency of resistive behaviours during each administration.  Δ Henry et al. (1994). Aromatherapy with lavender oil (essential oil diffused in the air using elec |
|  | ‡ § Holmes et al. (2002), UK. Aromatherapy with lavender vapour vs. water vapour, 15 participants, crossover RCT with blinded observers, outcome measurement via PAS,   |

moderate quality study of 2 weeks duration.

- Δ **Kilstoff et al. (1998)**. Aromatherapy with a combination of oils including sweet almond, lavender, geranium and mandarin essential oils (oils were applied via a hand cream to the fingers, back of hands and wrists of each subject using gentle massage), 16 participants with moderately severe symptoms of dementia, within subject pre-post design with non-blinded outcome assessment via interviews, focus group discussions, client observation logbooks (quantified using a 4point Likert scale) and the REPDS.
- § Lin et al. (2007), Hong Kong, Aromatherapy with lavender vs. sunflower control (aromas were delivered by diffuser at night for at least 1 hour for 3 weeks), 70 residents (no attrition) of 'care and attention' homes (equivalent to long term rest homes), crossover RCT with repeated-measures (with 2 weeks washout). Outcome assessment of agitation via the Chinese versions of CMAI and NPI before and after each treatment period. Moderate quality study.
- Δ **Mitchell**, **(1993)** Aromatherapy with lemon balm and lavender oil (lemon balm applied to subjects skin [on the chin] and lavender applied in subjects immediate environment [in bath, wash basin or on the pillow]) vs. placebo, 12 participants, crossover randomised trial. Two groups: group A received treatment oils for two weeks, then 1 week washout, then 2 weeks control and group B the reverse order. Blinded assessment, weekly, on 6 criteria chosen to reflect functional disabilities and behavioural difficulties experienced by residents and carers.

**Smallwood et al. (2001)**, Aromatherapy (twice weekly) with lavender oil and massage vs. plain oil and massage vs. conversation and aromatherapy, 21 participants with severe dementia, 3 group controlled trial with single blind assessment of behaviours. Behaviours were assessed via two 15 min. video recordings during 4 periods of the day at baseline and following treatment.

§ Snow et al. (2004), Aromatherapy with lavender vs. thyme vs. grape seed oil (oils were worn for 3 hours on a sachet near the collarbone on treatment days following four weeks of baseline, each treatment was given for 2 weeks in the same order), 7 residents (no attrition) of 1 nursing home, single-group repeated-measures (ABCBA) study design, with measures of agitation via the CMAI (every other day during the four week baseline, 10 week intervention and 2 weeks post-treatment. Low quality study.

# Study quality \* See below for "AG" quality criteria questions

- **A. Adequate.** The objective of the study was very clearly defined and specific.
- **B.** Adequate. Systematic search of EMBASE, MEDLINE, Cochrane, and the reference lists of all relevant papers up to March 2007.
- **C.** Adequate. Yes. Due to the limited number of papers available, all randomised studies of aromatherapy in residents with BPSD were included.
- **D. Unknown/Not reported.** All included studies appeared to have been appraised for design strength and quality of evidence; however the method and/or checklist or criteria were not specified. Notes were provided to outline potential biases and quality issues where such issues were identified.
- **E. Adequate.** Included studies were summarised in the text and study characteristics and outcome data were available in tables for all comparisons.
- **F. Adequate.** Due to methodological differences between studies, meta-analysis was not possible.
- **G.** Adequate. The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.

## Results (within scope of this systematic review)

Eleven prospective randomised studies of aromatherapy in BPSD were identified that included data for 298 residents,. Eight of the 11 published studies each had less than 25 participants. Two studies did not use any statistical analysis despite collecting quantitative data and one employed complex statistical techniques to analyse data for just 7 residents. There was no clear association between the oil used or method of delivery and study outcome. It is also unclear if individualised treatment offers any benefits over standardised treatment.

#### **Results summary**

| Study                      | Main findings   |
|----------------------------|---|
| Ballard et al. (2002).     | Reductions in agitation in both groups (p <0.01). Irritability and aberrant motor activities improved to a greater extent with aromatherapy compared to placebo (p <0.001). Greater reduction in social withdrawal and increase in time spent in constructive activities with aromatherapy compared to placebo (p <0.01).   |
| Bowles et al. (2002).      | Most subjects receiving aromatherapy had increased frequency x severity scores for resistive behaviours compared to baseline to aromatherapy. There was no significant difference in scores between oil treatments and 'no oils'. There were no significant differences in frequency x severity scores for resistive behaviours between any of the treatment periods. |
| Burleigh et al.<br>(1997). | Challenging behaviours were significantly reduced in five female subjects. The 2 male subjects had an increase in challenging behaviour.  |
| Gray et al. (2002).        | No statistically significant differences across all four aromatherapy interventions.  |
| Henry et al.<br>(1994).    | Without lavender resident's slept an average 7.69 hrs (range 0.5–9 h) SD = 1.26 hrs, with lavender, average length of sleep was 8.14 h (range 1–9 h) SD = 1.1 hrs.  |
| Holmes et al. (2002).      | The median PAS score was lower (reduced agitation) during aromatherapy compared with placebo (p <0.05).   |
| Kilstoff et al.<br>(1998). | The findings indicate a positive strengthening of the relationship between the person with dementia and their family carer, however, no quantified results were reported and there is no evidence of statistical tests being applied.   |
| Lin et al.<br>(2007).      | Decrease in agitation with lavender treatment with reduced scores on both CCMAI and C-NPI (p <0.001). No change following sunflower treatment.  |
| Mitchell,<br>(1993).       | No difference between treatments.   |
| Smallwood et al. (2001).   | Aromatherapy and massage superior to aromatherapy and conversation at one time point only (3pm-4pm).  |
| Snow et al. (2004).        | Total absence of treatment effect.  |

### Authors' conclusions

Available studies reported positive and negative consequences for both people with dementia and their carers. "Aromatherapy is a potentially useful treatment for BPSD but data supporting efficacy are scarce. Much remains to be understood about the choice of aromatherapy oil, the optimum method of administration, and the efficacy and side-effect profile." (p. 345).

#### Reviewers' notes

Only 3 individual RCTs were powered to detect even a large treatment effect; 8 of the 11 published studies each had less than 25 participants. The aromatherapy oils tested, method of delivery and outcome measures used varied widely across the studies. Most of the studies included very small numbers of participants and were designed in such a way that interpretation of the findings was difficult.

### Relevance to study question

Aromatherapy is one of the most commonly used complementary therapies. This review evaluates the evidence from RCTs as to the efficacy of aromatherapy in the treatment of BPSD.

- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?

<sup>\*</sup>The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations:** BASOLL = Behaviour assessment scale of later life, BPSD = Behavioural and psychological symptoms of dementia, CMAI = Cohen-Mansfield agitation inventory, CMMSE = Chinese Mini-mental state examination, CNPI = Chinese neuropsychiatric inventory, NPI = Neuropsychiatric inventory, PAS = Pittsburgh agitation scale, RCT = Randomised controlled trial, REPDS = Revised elderly persons' disability scale.

- † Also reviewed in Forbes et al. (2009)
- ‡ Also reviewed in O'Connor (2009)
- § Also reviewed in Kverno et al. (2009)
- $\Delta$  Published outside this review's date range (ie pre 1999)

#### Table 30: O'Connor et al. (2009)

| Citation  | O'Connor, D. W., Ames, D., Gardner, B., & King, M. (2009). Psychosocial treatments of behavior symptoms in dementia: a systematic review of reports meeting quality standards. International Psychogeriatrics, 21(2), 225-240.  |  |  |
|---|---|--|--|
| NHMRC Level of evidence   | Level I   |  |  |
| Objective   | To provide a systematic review of selected experimental studies of psychosocial treatments of behavioural disturbances in dementia.   |  |  |
| Type of included studies  | English-language reports published or in press by December 2006; studies were included only if a treatment was compared with another treatment and/or an 'attention control' condition; random allocation in the case of studies with distinct treatment and control arms; sufficient information about a study's methods to permit replication; a total of 10 or more participants; the use of cognitive and behaviour measures; some statistical analysis; assessors blinded either to treatment allocation or to the study's aims. When the nature of the intervention rendered blinding impracticable, that behaviour measures were generated (i) by a single individual, or (ii) by multiple individuals with high inter-rater reliability, or (iii) through the use of mechanical or electronic counters.  Note: Treatments with a pharmacological, physiological or environmental focus (eg psychotropic medications, light therapy and modifications to premises to prevent exiting). |  |  |
| Types of participants   | All study participants had both dementia and significant behavioural symptoms.  |  |  |
| Type of intervention  | Psychosocial treatments: strategies derived from 1 of 3 psychologically oriented paradigms (learning theory, unmet needs and altered stress thresholds). Identified interventions in descending order of frequency were music (n = 8), carer education (n = 4), sensory enrichment (n = 3), simulated family presence (n = 3), novel bathing techniques (n = 2), aromatherapy (n = 2), recreation (n = 1), relaxation (n = 1) and VT (n = 1).   |  |  |
| Outcomes  | Main outcomes: agitation, aggression, disinhibition and other challenging behaviours.   |  |  |
| Data analyses & statistics  | Effect sizes based on mean differences and standard deviations were calculated for studies that reported sufficient information. For randomised studies, the effect size was the difference between the treatment mean and the 'attention control' mean divided by an estimate of standard deviation pooled from both groups. Baseline means were incorporated if available.  |  |  |
| Alphabetical list of included studies                                 | Baillon et al. (2004).  Baker et al. (2003).  Ballard et al. (2002).  Burgio et al. (1996).  Burgio et al. (2002).  Camberg et al. (1999).  Clark et al. (1998).  Cohen-Mansfield and Werner (1997).  Cohen-Mansfield and Werner (1998).  Dunn et al. (2002).  Garland et al. (2007).  Gerdner (2000).  Gormley et al. (2001).  Groene (1993).  Holmes et al. (2002).  Ragneskog et al. (1996).  Remington (2002).  Sherratt et al. (2004).  Sloane et al. (2004).  Suhr et al. (1999).  Teri et al. (2000).  Thomas et al. (1997).  Toseland et al. (1997).  Wells et al. (2000).  Gormley et al. (2001).  |  |  |
| Description of included studies (listed in review Authors' groupings) | Aromatherapy Ballard et al. (2002). Aroma therapy with melissa oil vs. neutral oil, 71 participants, nested RCT design, blinded observers, outcome measurement via CMAI, strong quality study, of 4 weeks duration.  Holmes et al. (2002). Aromatherapy with lavender vapour vs. water vapour, 15 participants, crossover RCT design, blinded observers, outcome measurement via PAS, moderate quality study of 2 weeks duration.  Bathing Dunn et al. (2002). Bed bath vs. tub bath, 15 participants, crossover RCT design, measurement via direct observation (CMAI), moderate quality study of 8 weeks duration.  Sloane et al. (2004). Person-centred bed bath vs. person-centred shower, 69 participants, crossover RCT design, blinded observers, outcome measurement via   |  |  |
|   | direct observation (CMAI), strong quality study of 12 weeks duration.   |  |  |

#### Carer Education

**Burgio et al. (2002).** Behaviour management training with continued supervision vs. behaviour management training without continued supervision, 79 participants, nested RCT design, blinded observers, outcome measurement via direct observation, strong quality study of 26 weeks duration.

**Gormley et al.** (2001). Behaviour management training vs. discussion groups, 62 participants, RCT design, blinded observers, outcome measurement via RAGE, strong quality study of 8 weeks duration.

**Teri et al. (2000).** Behaviour management training vs. haloperidol vs. trazodone, 148 participants, RCT design, measurement via CGIC, weak quality study of 16 weeks duration.

**Wells et al. (2000).** Ability-focussed morning care vs. usual morning care, 40 participants, nested RCT design, outcome measurement via PAS, moderate quality study of 26 weeks duration.

#### Music/sound

**Burgio et al. (1996).** Natural sounds vs. headphone only, 13 participants, crossover RCT design, outcome measurement via direct observation, moderate quality study of 3 weeks duration.

**Clark et al. (1998).** Preferred music during bath vs. usual bath, 18 participants, crossover RCT design, outcome measurement via direct observation, strong quality study of 3 weeks duration.

**Gerdner (2000).** Preferred music vs. classical music, 39 participants, crossover RCT design, outcome measurement via direct observation, moderate quality study of 3 weeks duration.

**Groene (1993).** Music therapy vs. reading, 30 participants, RCT design, outcome measurement via direct observation using counting devices, moderate quality study of 1 week duration.

**Ragneskog et al. (1996).** Music during meal time vs. usual meal time, 20 participants, crossover RCT design, blinded observer, outcome measurement via GBS, moderate quality study of 7 weeks duration.

**Remington (2002).** Baroque music vs. HM, 68 participants, RCT design, outcome measurement via direct observation, moderate quality study of < 1 weeks duration.

**Sherratt et al. (2004).** Live music vs. recorded music vs. commercial music, 24 participants, repeated-measures study design, outcome measurement via direct observation, moderate quality study of 1 week duration.

**Thomas et al. (1997).** Preferred music during bathing vs. usual bath, 14 participants, repeated-measures study design, outcome measurement via direct observation, moderate quality study of 2 weeks duration.

#### **Sensory enrichment**

**Baillon et al. (2004).** MSS vs. reminiscence therapy, 20 participants, crossover RCT design, measurement via direct observation (CMAI), moderate quality study of 5 weeks duration.

**Baker et al. (2003).** MSS vs. activity session, 127 participants, RCT design, measurement via INTERACT, strong quality study of 4 weeks duration.

**Cohen-Mansfield and Werner (1998).** Enriched corridor vs. usual corridor, 27 participants, crossover RCT design, outcome measurement via direct observation using counting devices, moderate quality study of 4 weeks duration.

#### 'Simulated presence'

**Camberg et al. (1999).** Family audiotape vs. neutral audiotape, 54 participants, crossover RCT design, blinded observers, outcome measurement via direct

observation, moderate quality study of 10 weeks duration.

**Cohen-Mansfield and Werner (1997).** Family videotape vs. preferred music vs. social interaction, 32 participants, crossover RCT design, outcome measurement via direct observation, weak quality study of 6 weeks duration.

**Garland et al. (2007).** Family audiotape vs. preferred music vs. neutral audiotape, 30 participants, crossover RCT design, blinded observers, outcome measurement via direct observation, strong quality study of 4 weeks duration.

#### Other

**Kolanowski et al. (2005).** Recreation suited to interests and skills vs. recreation suited to interest only vs. skills only, 30 participants, crossover RCT design, blinded observers, outcome measurement via direct observation, moderate quality study of 6 weeks duration.

**Suhr et al. (1999).** Muscle relaxation training vs. imagery relaxation training, 34 participants, RCT design, single observer, outcome measurement via BRAD, moderate quality study of eight weeks duration.

**Toseland et al. (1997).** VT vs. social group, 88 participants, RCT design, outcome measurement via direct observation, weak quality study of 53 weeks duration.

### Study quality \* See below for "A-G" quality criteria

questions

- A. Adequate. The objective of the study was very clearly defined.
- **B.** Adequate. From December 2006 (i) searches of MEDLINE, CINAHL, PsycINFO and Cochrane databases, (ii) checks of references in earlier reviews and monographs, and (iii) approaches to researchers.
- C. Adequate. Yes, the inclusion criteria were very specific.
- **D. Adequate.** This review was compiled in line with Australian National Health and Medical Research Council recommendations (NH&MRC). Using the Forbes quality rating scale (Forbes, 1998)†, 6 of the 25 studies were rated as 'strong',16 as 'moderate', three as 'weak' and none as "poor."
- **E. Adequate.** Included studies were summarised in the text and outcome data were available in a table. The interventions were grouped by type.
- **F. Adequate.** There was heterogeneity between the studies and therefore data were not pooled.
- **G.** Adequate. The studies included a range of interventions and outcome measures.

## Results (within scope of this systematic review)

Only 25 of 118 relevant studies met every specification. Treatment proved more effective than an 'attention control' condition in reducing behavioural symptoms in only 11 of the 25 studies. Effect sizes were mostly small or moderate. Treatments with moderate or large effect sizes included aromatherapy, ability-focussed carer education, bed baths, preferred music and muscle relaxation training.

Results summary (note that ">" means the treatment "was more effective than" at the p <0.05 level).

| Baillon et al. (2004).             | Treatment = Control.           | Groene (1993).            | Treatment = Control.                       |
|------------------------------------|--------------------------------|---------------------------|--|
| Baker et al. (2003).               | Treatment = Control.           | Holmes et al. (2002).     | Treatment > control.                       |
| Ballard et al. (2002).             | Treatment > Control.           | Kolanowski et al. (2005). | Treatment = Control.                       |
| Burgio et al. (1996).              | Treatment > Control.           | Ragneskog et al. (1996).  | Treatment = Control.                       |
| Burgio et al. (2002).              | Treatment = Control.           | Remington (2002)          | Treatment = Control > baseline (p <0.001). |
| Camberg et al. (1999).             | Treatment = Control.           | Sherratt et al. (2004).   | Treatment a & b = Control.                 |
| Clark et al. (1998).               | Treatment > Control.           | Sloane et al. (2004).     | Treatment = Control.                       |
| Cohen-Mansfield and Werner (1997). | Treatment > Control.           | Suhr et al. (1999).       | Treatment = Control.                       |
| Cohen-Mansfield and Werner (1998). | Treatment a & b & c > Control. | Teri et al. (2000).       | Treatment a = b = c.                       |
| Dunn et al. (2002).                | Treatment > Control.           | Thomas et al. (1997).     | Treatment = Control.                       |
| Garland et al. (2007).             | Treatment > Control.           | Toseland et al. (1997).   | Treatment less than Control.               |
| Gerdner (2000).                    | Treatment > Control.           | Wells et al. (2000).      | Treatment > Control.                       |
| Gormley et al. (2001).             | Treatment = Control.           |                           |  |

### Authors' conclusions

"Some psychosocial interventions appear to have specific therapeutic properties, over and above those due to the benefits of participating in a clinical trial. Their effects were mostly small to moderate with a short duration of action. This limited action means that treatments will work best in specific, time-limited situations. In the few studies that addressed within-group differences, there were marked variations in response. Some participants benefited greatly from a treatment, while others did not. Interventions proved more effective when tailored to individuals' preferences".

#### Reviewers' notes

This review highlights several areas of relevance when considering the evidence for the effectiveness of non-pharmacological interventions for the treatment of behavioural disturbances in people with dementia. Firstly, the review included studies that were generally of higher than average quality. Secondly, while double-blind RCTs are often considered the 'gold-standard', RCTs are often unaffordable, blinding is impracticable, and participant retention is usually compromised by participants' advanced age (high drop-out rates due to death). Therefore, to accommodate some of the realities of agedcare research, the reviewers included 'before and after' or repeated-measures studies. in which all participants receive treatment and act as their own controls. The inclusion of such study designs is considered reasonable given that the potential contamination of repeated-measures designs by learning effects, treatment 'carry over' and disease progression are unlikely to be a problem in short-term, non-pharmacological trials in people with marked dementia. Thirdly, and arguably most importantly, O'Connor et al. (2009) point out that life in many nursing homes is so un-stimulating that personal attention of any kind (including the presence and activities of researchers) relieves anxiety and agitation and these placebo effects are powerful. O'Connor et al. (2009) included only studies that compared the intervention to a control condition (or alternative treatment) that provided equivalent attention and diversion.

### Relevance to study question

This review is relevant as it considers the evidence for the effectiveness of non-pharmacological interventions for the treatment of behavioural disturbances in people with dementia. Because people with dementia often respond positively to personal contact, studies were included only if control conditions entailed similar levels of social attention or if one treatment was compared with another. Thus, the reviewers included studies of 'better than average' quality and gave consideration to a number of practical and methodological issues that reflect the realities of aged care research.

Quality = High

\*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (A) Was a clinical question clearly defined?
- (B) Was an adequate search strategy used?
- (C) Were the inclusion criteria appropriate and applied in an unbiased way?
- (D) Was a quality assessment of included studies undertaken?
- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations:** BRAD = Behaviour rating in Alzheimer's disease scale, CGIC = Clinical Global Impression of Change, CMAI = Cohen-Mansfield agitation inventory, GBS = Scandinavian psychiatric scale, HM = Hand Massage, INTERACT = The effects of Snoezelen on demented elderly scale, MSS = multi-sensory stimulation, PAS = Pittsburgh agitation scale; RAGE = Rating scale for aggressive behaviour in the elderly, RCT = Randomised controlled trial; VD = Validation therapy.

**Additional references:** Forbes, D. A. (1998). Strategies for managing behavioural symptomatology associated with dementia of the Alzheimer's type: a systematic overview. *Canadian Journal of Nursing Research*, 30, 67–86.

**Notes:** †The scale addresses study design, participation and retention rates, measurement issues and statistical analysis, and has an algorithm to generate ratings of 'strong', 'moderate', 'weak' and 'poor'. It follows standard pathways but, in contrast to other scales, it makes allowance for repeated measure designs and the use of non-blinded observers. Only RCTs can qualify as "strong."

#### Table 31: Perkins 2008

| Perkins, J., Bartlett, H., Travers, C., & Rand, J. (2008). Dog-assisted therapy for older people with dementia: a review. Australasian Journal on Ageing, 27(4), 177-182.  NHMRC Level of evidence  Dipictive  This review summarises and critiques the published literature regarding dog therapy for older people with demential inking in residential aged care facilities.  Type of included studies were included if the focus of the research was interactions or outcomes of contact between older people with demential and dogs. All study designs were included (only levels of evidence above case studies and equivalent).  Types of participants with a diagnosis of AD or dementia as doose. All study designs were included (only levels of evidence above case studies and equivalent).  Type of intervention  Type of outcomes, and conducted by someone without specific therapeutic goals or recording of outcomes, and conducted by someone without special skills or training and possibly using an uncertified animal, and (b) dog-assisted therapy (defined as structured, one-on-one or in small groups, conducted by suitably trained professionals with specifically certified animals, and requiring active participation with specific therapeutic goals or recorded)  Outcomes  Data analyses & statistics  Alphabetical list of all included studies  Alphabetical list of all included studies (studies not). Repair of the properties  |  |  |   |  |
|--|--|--|---|--|
| Objective Object | Citation   |  |   |  |
| older people with dementia living in residential aged care facilities.  Type of included studies were included if the focus of the research was interactions or outcomes of contact between older people with dementia and dogs. All study designs were included (only levels of evidence above case studies and equivalent).  Participants with a diagnosis of AD or dementia as documented in the resident's chart. The severity of dementia ranged from mild to severe. All included studies were conducted in a residential aged care setting or adult day care centre.  Dog contact as therapy for older people with dementia, including: (a) dog-assisted therapy (defined as unstructured, informal, without specific slaving or recording of outcomes, and conducted by someone without special skills or training and possibly using an uncertified animals) and (b) dog-assisted therapy (defined as structured, one-on-one or in small groups, conducted by suitably trained professionals with specifical prediction and possibly using an uncertified animals, and requiring active participation with specific therapeutic goals and outcomes recorded).  Outcomes  Data analyses & statistics  Alphabetical list of all included studies  Alphabetical list of all included studies of the studies  |  | Level IV.  |   |  |
| contact between older people with dementia and dogs. All study designs were included (only levels of veidence above case studies and equivalent).  Types of participants  Participants with a diagnosis of AD or dementia as documented in the resident's chart. The severity of dementia ranged from mild to severe. All included studies were conducted in a residential aged care setting or adult day care centre.  Dog contact as therapy for older people with dementia, including: (a) dog-assisted activity (defined as unstructured, informal, without specific therapeutic goals or recording of outcomes, and conducted by someone without special skills or training and possibly using an uncertified animal) and (b) dog-assisted therapy (defined as structured, one-on-one or in small groups, conducted by suitably trained professionals with specifical yearfield animals, and requiring active participation with specifies therapeutic goals and outcomes recorded).  Passures of social behaviour, agitation, apathy and other problematic behaviours, also medication use, ward noise levels, measures of cognition, global function, and a range of physiological measures.  Pata analyses & statistics  Alphabetical list of all included studies  Studied studies and the studies of the | Objective  | This review summarises and critiques the published literature regarding dog therapy for older people with dementia living in residential aged care facilities.   |   |  |
| Type of Intervention  Type of Intervention  Type of Intervention  Type of Intervention  Dog contact as therapy for older people with dementia, including: (a) dog-assisted activity (defined as unstructured, informal, without specific therapeutic goals or recording of outcomes, and conducted by someone without specific therapeutic goals or recording of outcomes, and conducted by someone without specific therapeutic goals or recording of outcomes, and conducted by someone without specific therapeutic goals or recording of outcomes and conducted by suitably trained professionals with specifically certified animals, and requiring active participation with specific therapeutic goals and outcomes recorded).  Measures of social behaviour, agitation, apathy and other problematic behaviours, also medication use, ward noise levels, measures of cognition, global function, and a range of physiological measures.  Narrative synthesis  Alphabetical list of all included studies  Alphabetical list of all included studies  Alphabetical list of all included studies (at (1998).  Thurchill et al. (1998).  Thurchill et al. (1998).  Thurchill et al. (1998).  Thurchill et al. (1999).  Thurchill et al. (1998).  Thurchill |  | contact between older people with dementia   | a and dogs. All study designs were included   |  |
| activity (defined as unstructured, informal, without special skills or training and possibly using an uncertified animal) and (b) dog-assisted therapy (defined as structured, one-on-one or in small groups, conducted by suitably trained professionals with specifically certified animals, and requiring active participation with specific therapeutic goals and outcomes recorded).  Outcomes  Measures of social behaviour, agitation, apathy and other problematic behaviours, also medication use, ward noise levels, measures of cognition, global function, and a range of physiological measures.  Narrative synthesis  Alphabetical list of all included studies  Alphabetical list of sall included studies  Alphabetical list of companies and the companies of the |  | The severity of dementia ranged from mild t  | to severe. All included studies were  |  |
| medication use, ward noise levels, measures of cognition, global function, and a range of physiological measures.  Narrative synthesis  Batson et al. (1998),  | Type of intervention   | activity (defined as unstructured, informal, without specific therapeutic goals or recording of outcomes, and conducted by someone without special skills or training and possibly using an uncertified animal) and (b) dog-assisted therapy (defined as structured, one-on-one or in small groups, conducted by suitably trained professionals with specifically certified animals, and requiring active participation with specific  |   |  |
| Alphabetical list of all included studies  Batson et al. (1998).   | Outcomes   | medication use, ward noise levels, measure of physiological measures.  |   |  |
| all included studies    Churchill et al. (1999).   TRicheson (2003).   Sellers (2005).   | -  | Narrative synthesis  |   |  |
| Batson et al. (1998), test-retest study of animal-assisted activity programme with a visiting dog, 22 residents of a special residential care unit for dementia (probable AD). Outcomes included in earlier reviews).  Kanamori et al. (2001), non-randomised controlled trial of animal-assisted activity using visiting dogs and cats, 27 participants with moderate dementia in a psychiatric hospital day care programme (treatment group had previous contact with dogs at home). Outcomes included MMSE, N-ADL, BEHAVE-AD and salivary CgA.  Kongable et al. (1989), test-retest study of animal-assisted activity, 12 residents of a dementia special care unit (prior pet owners). Outcomes included 8 pro-social behaviours (smiles, leans, looks, laughs, touches, verbalisations, name-calling, others).  Motomura and Ohyama (2004), test-retest study of animal-assisted activity involving 8 residential care participants with mild dementia and a visiting dog. Outcomes included MMSE, apathy and irritability scale, GDS, PSMS.  Sellers (2005), test-retest study of dog-assisted therapy (visiting dog) involving 14 people with moderate to severe dementia in residential care. Outcomes included agitated behaviour, MMSE, ABMI, social behaviour observation checklist (SBOC).  Walsh et al. (1995), non-randomised controlled trial of dog-assisted activity (visiting dog) involving 13 residents (with severe dementia and behavioural difficulties) residing in a SCU. Outcomes included Brighton Clinic adaptive behaviour scale (BCABS), blood pressure, heart rate, and ward noise levels.  Study quality  * See below for "A-G" quality criteria questions  A. Adequate. A literature search was conducted using the electronic databases: the Web of Science, PsycINFO, Ovid MEDLINE, CINAHL, ADT, Web of Knowledge, Cochrane and PubMed for English-language articles published between 1966 and 2007.  C. Adequate. The inclusion criteria were appropriate but broad.  D. Unknown. Research reports were reviewed and data was abstracted. While no specific quality checklist or framewor | •  | †Churchill et al. (1999).<br>Kanamori et al. (2001).<br>Kongable et al. (1989).  | †Richeson (2003).<br>Sellers (2005).  |  |
| * See below for "A-G" quality criteria questions  B. Adequate. A literature search was conducted using the electronic databases: the Web of Science, PsycINFO, Ovid MEDLINE, CINAHL, ADT, Web of Knowledge, Cochrane and PubMed for English-language articles published between 1966 and 2007.  C. Adequate. The inclusion criteria were appropriate but broad.  D. Unknown. Research reports were reviewed and data was abstracted. While no specific quality checklist or framework was specified, several issues relating to threats to internal and external validity were discussed.  E. Adequate. Studies were summarised in the text and study characteristics and outcome data were available in tables.   | relevant included<br>studies (studies not<br>included in earlier | Batson et al. (1998), test–retest study of ar visiting dog, 22 residents of a special resided Outcomes included social behaviours (BDR skin temperature.  Kanamori et al. (2001), non-randomised cousing visiting dogs and cats, 27 participants hospital day care programme (treatment gronome). Outcomes included MMSE, N-ADL, Kongable et al. (1989), test–retest study of dementia special care unit (prior pet owners behaviours (smiles, leans, looks, laughs, tom Motomura and Ohyama (2004), test–retest study of dognamical care participants with mild demincluded MMSE, apathy and irritability scales Sellers (2005), test-retest study of dognamical services and irritability scales sellers (2005), test-retest study of dognamical services and irritability scales sellers (2005), test-retest study of dognamical services and irritability scales sellers (2005), test-retest study of dognamical services severe dementia ir agitated behaviour, MMSE, ABMI, social be walsh et al. (1995), non-randomised control dog) involving 13 residents (with severe derin a SCU. Outcomes included Brighton Clin | ential care unit for dementia (probable AD). (S) and also blood pressure, heart rate and controlled trial of animal-assisted activity with moderate dementia in a psychiatric pup had previous contact with dogs at BEHAVE-AD and salivary CgA. (F) animal-assisted activity, 12 residents of a sol. Outcomes included 8 pro-social uches, verbalisations, name-calling, others). (It study of animal-assisted activity involving mentia and a visiting dog. Outcomes e., GDS, PSMS. (Isted therapy (visiting dog) involving 4 in residential care. Outcomes included enaviour observation checklist (SBOC). (Isled trial of dog-assisted activity (visiting mentia and behavioural difficulties) residing ic adaptive behaviour scale (BCABS), blood |  |
|  | * See below for "A-<br>G" quality criteria                       | intervention, dog-assisted therapy for deme B. Adequate. A literature search was condicted Web of Science, PsycINFO, Ovid MEDLINE Cochrane and PubMed for English-languag 2007.  C. Adequate. The inclusion criteria were ap D. Unknown. Research reports were review specific quality checklist or framework was a to internal and external validity were discussed. Adequate. Studies were summarised in outcome data were available in tables.  | entia.  Sucted using the electronic databases: the E, CINAHL, ADT, Web of Knowledge, e articles published between 1966 and expropriate but broad.  Wed and data was abstracted. While no specified, several issues relating to threats sed.  The text and study characteristics and   |  |

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|  | not possible.  |  |     |  |
|  | <b>G. Adequate</b> . The studies included a range of designs, interventions and outcome measures therefore heterogeneity was expected.   |  |     |  |
| Deculte (within                                  | 1  |  |     |  |
| Results (within scope of this systematic review) | Nine studies met the inclusion criteria and the results of the 6 studies not already included in previous reviews are reported below. No RCTs of dog-assisted therapy were identified. Two studies used dog-assisted therapy and 7 dog-assisted activity. Of the five studies that examined pro-social behaviour, all reported significant increases in a range of social behaviours such as smiles, looks, verbalisations and touches during the intervention phase, as measured by direct observation. Three of these studies additionally measured agitation reporting significant reductions. A signific 6 subscales of the NHBPS) was also reported in subjects following the introduction of a resident dog in one residential aged care facility. |  |     |  |
|  | Results of   | six of nine trials of non-pharmacological interventions  |     |  |
|  | Study  | Main findings  | 1   |  |
|  | Batson et al. (1998).  | Increase in duration and frequency of social behaviour during animal-assisted activity programme (AAA); improvements unrelated to severity of dementia (BDRS). |     |  |
|  | Kanamori et al. (2001).  | Family assessed global care giving burden reduced in AAA group (BEHAVE-AD); non-significant reduction of CgA in AAA group.                                     |     |  |
|  | Kongable et al. (1989).  | Increase in incidence of pro-social behaviour; equal improvements for both resident and visiting dog mode.   |     |  |
|  | Motomura<br>and Ohyama<br>(2004).  | Staff-assessed reduced global apathy in AAA group (apathy subscale).   |     |  |
|  | Sellers<br>(2005).   | Incidence of observed agitated behaviour during AAT was reduced (ABMI); incidence of observed social behaviour during AAT increased (SBOC).                    |     |  |
|  | Walsh et al.<br>(1995).  | Reduced heart rate and ambient ward noise levels in AAA group.   |     |  |
| Authors'<br>conclusions                          | Nine studies were identified for inclusion and although the methodological variability of studies makes it difficult to draw firm conclusions, research suggests that dog therapy is beneficial for people with dementia. The most frequently reported findings were an increase in social behaviour and a decrease in agitated behaviour during dog contact. Improvement in social behaviour was found to be unrelated to the severity of dementia. Various improvements on measures of global function were also reported. The premorbid relationship with dogs may be an important variable influencing outcome.  |  |     |  |
| Reviewers' notes                                 | No study adopted a RCT design and a number of potentially important factors were not controlled for, including halo effects of animals on carers that may bias carers' responses when acting as proxies for their relatives or residents.  |  |     |  |
| Relevance to study question                      |  | shed literature regarding dog therapy for older people with dement<br>Il aged care facilities, but the evidence is limited.                                    | tia |  |
| *The quality of systematic                       | c reviews was asses  | sed using the following questions (rated Adequate; Inadequate;   |     |  |

\*The quality of systematic reviews was assessed using the following questions (rated Adequate; Inadequate; Unknown/Not reported):

- (A) Was a clinical question clearly defined?
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- (E) Were the characteristics and results of the individual studies appropriately summarised?
- (F) Were the methods for pooling the data appropriate?
- (G) Were sources of heterogeneity explored?

**Abbreviations**: AAA = animal-assisted activity, AAT = animal-assisted therapy, ABMI = Agitated behaviour mapping instrument, BDRS = Bourke dementia rating scale, BEHAVE-AD = Behaviour Pathology in Alzheimer's disease rating scale, BPSD = Behavioural and psychological symptoms of dementia, CMAI = Cohen-Mansfield agitation inventory, GDS = Geriatric depression scale, MMSE = Mini-mental State Examination, MI-ADL = Nurse-informant activities of daily living, NHBPS = Nursing home behaviour problem scale, PSMS = Physical self-maintenance scale, RCT = Randomised controlled trial, SBOC = Social behaviour observation checklist.

† Already included in Bharani and Snowden (2005).