

Non-drug treatments for symptoms in dementia: an overview of systematic reviews of non-pharmacological interventions in the management of neuropsychiatric symptoms and challenging behaviours in patients with dementia

Kelly Dickson, Louise Lafortune, Josephine Kavanagh,
James Thomas, Nicholas Mays, Bob Erens



For further details, please contact:

Bob Erens

Policy Research Unit in Policy Innovation Research (PIRU)

Department of Health Services Research & Policy

London School of Hygiene and Tropical Medicine

15–17 Tavistock Place

London WC1H 9SH

Email: Bob.Erens@lshtm.ac.uk

www.piru.ac.uk

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Kelly Dickson, EPPI-Centre, Institute of Education
Louise Lafortune, CLAHRC CP and University of Cambridge
Josephine Kavanagh, EPPI-Centre, Institute of Education
James Thomas, EPPI-Centre, Institute of Education
Nicholas Mays, PIRU, London School of Hygiene and Tropical Medicine
Bob Erens, PIRU, London School of Hygiene and Tropical Medicine



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Summary

Dementia is a progressive degenerative condition that currently affects about 700,000 older adults in the UK. Patients with dementia often suffer from neuropsychiatric symptoms and challenging behaviours, such as agitation, aggression and psychosis. These can cause major problems for both dementia patients and their carers, with the latter often reporting high levels of distress and depressive symptoms.

Antipsychotic drugs, which were developed to treat patients with mental health problems such as schizophrenia, are now one of the main treatments for managing behavioural and psychological symptoms in patients with dementia. However, emerging evidence suggests that, not only do these drugs have few benefits for patients with dementia, they may pose significant risks, especially if used long-term, such as an increased risk of falls, blood clots, stroke and heart problems. For these reasons, the Department of Health is committed to achieving a significant two-thirds reduction in the use of antipsychotic medication among patients with dementia. Despite current clinical guidance which recommends the use of non-pharmacological approaches – that is, treatments or therapies other than medication – to improve behavioural and psychological symptoms in patients with dementia, the widespread use of antipsychotics for these patients continues.

In order to fill this gap in evidence, PIRU was commissioned by the Department of Health to carry out a systematic review of the effectiveness of non-pharmacological treatments or therapies for managing neuropsychiatric and challenging behaviours in patients with dementia. Given the vast literature on this topic, PIRU carried out an ‘overview’ of reviews which involved examining thirty recent systematic reviews in order to summarise their results on the effectiveness of alternative treatments.

In all, 19 non-pharmacological treatments were identified in the systematic reviews. Of these, the most **consistent evidence** for effectively managing behavioural and psychological symptoms was found for **behaviour management techniques** delivered by professional staff, and for **staff and caregiver training and support**.

There was promising evidence for four other alternative treatments – **physical activity/exercise; massage/touch therapies; multi-sensory stimulation (e.g. snoezlen, aromatherapy) and music therapy** – although the evidence for these was not as robust, either because the primary studies were not as rigorous, the results were more mixed or the evidence available was limited.

Only one treatment appeared to be **ineffective** – validation therapy.

For the **vast majority of treatments**, however, the **evidence was inconclusive**, either because it was inconsistent across primary studies, or these studies were of poor quality, or the evidence was almost totally lacking. This general lack of high quality evidence meant that the systematic reviews included in our overview refrained from making policy and practice recommendations. It also leads to the conclusion that more and better research is needed on these alternative interventions in order to inform future policy and practice.



1. Introduction

This project was commissioned by the Department of Health (DH) Policy Research Programme on behalf of the Department's Older People and Dementia Programme to support the implementation plan for the National Dementia Strategy (DH 2009) with regard to the reduction of antipsychotic drugs prescribing. Following an independent report for the government in November 2009, ministers committed to achieving an overall two-thirds reduction in the use of antipsychotic medication within three years. Yet the scientific evidence on the effectiveness, cost-effectiveness and implementation feasibility of non-pharmacological alternatives to antipsychotic drug prescribing has not been collected nor assessed systematically. Without such evidence, current efforts to reduce the prescription of antipsychotic drugs may be inappropriate, inefficient, clinically ineffective, or result in poor patient outcomes or experience.

To partially bridge this gap, this project aimed to conduct an overview of the effectiveness of non-pharmacological interventions – that is, treatments or therapies that do not involve any medication – specifically for the management of neuropsychiatric symptoms and challenging behaviours in all types of patients with dementia. In order to meet this objective, a wide range of non-pharmacological interventions were examined, along with their outcomes. In this report, we only summarise the evidence as it relates to our primary outcome of managing neuropsychiatric symptoms/challenging behaviours. The original plan was also to include reviews on the cost-effectiveness and implementation feasibility of non-pharmacological interventions, but a preliminary search found insufficient evidence to include these.

2. Background

2.1 The condition

Dementia is a progressive, degenerative condition caused by diseases of the brain. Whether it occurs alone, in addition to, or as a complication of, chronic diseases, it is characterised by cognitive and non-cognitive symptoms of variable frequency and severity. The underlying pathological processes and trajectory from mild cognitive impairment to dementia are highly heterogeneous, though typically accompanied by progressive loss of the ability to perform normal activities of daily living (ADL) and marked by the emergence of neuropsychiatric and challenging behaviours (Blesa 2004). The symptoms include agitation (i.e. aggression, restlessness and pacing), usually in the context of distress or anxiety, irritability, hallucinations, persecutory delusions, confabulations, wandering, elation, apathy and sleep problems (Ballard et al. 2008; Tariot et al. 1995; Savva et al. 2009). As many as 60% of community-dwelling people with dementia (Lyketsos et al. 2000), and up to 80% or more of those living in nursing homes develop significant psychopathology (Testad et al. 2005; Zuidema et al. 2007). The lifetime risk of such complications approaches 100% (Testad et al. 2005; Howard et al. 2001). There are about 700,000 (predominantly older) adults in the UK with symptoms of dementia, with a national cost, covering both formal and informal care, of around £17 billion per year (Knapp et al. 2007).



2.2 The social burden

Neuropsychiatric symptoms and challenging behaviours occur throughout the course of the disease, have a profound effect on families, and are associated with more time spent caregiving, higher care costs, greater risk for nursing home placement, and staff caregivers' burnout, turnover and morbidity (Gitlin et al. 2010; Black et al. 2004). Informal caregivers (usually family members and friends) managing behavioural symptoms, often report high levels of distress and depressive symptoms, particularly those who perceive that they have inadequate skills to manage such behaviours (Burke et al. 2009; Gitlin et al. 2010; Ballard et al. 2000). There is also a significant financial strain inflicted on informal caregivers and the health care system as a result of the adverse effects of neuropsychiatric symptoms of dementia (Murman et al. 2005; Beerl et al. 2002).

2.3 The use of antipsychotic medication

As cardinal elements of the illness, neuropsychiatric symptoms and challenging behaviours are among the most devastating aspects of caring for a dementia sufferer and represent a major public health concern.

Efforts to manage problem behaviours typically involve treatments, in particular the wide use of antipsychotic drugs (Sink et al. 2005; Schneider et al. 2006). However, a considerable body of evidence regarding the safety, tolerability and efficacy of these drugs has called into question common prescribing practices with the suggestion that they yield modest to no benefits while posing a considerable risk (Banerjee 2009; Ballard et al. 2008). Moreover, common troublesome behaviours for families (e.g. refusal of care, repetitive vocalizations, argumentation) do not respond to such pharmacological treatment (Gitlin et al. 2010).

For these reasons, current guidance is to recommend the use of non-pharmacological approaches as the initial treatment for behavioural problems in patients with dementia (NICE/SCIE 2006; American Psychiatric Association 2007; Banerjee 2009). However, the widespread prescription of antipsychotics to people with dementia continues, despite the evidence and contrary to the guidance issued by the Food and Drug Administration (FDA) in the US and by the Committee on Safety of Medicines (CSM) in the UK (Ballard et al. 2008).

3. Objectives of this overview

This project examined 30 recent systematic reviews in order to provide a comprehensive overview of the effectiveness of non-pharmacological interventions for managing neuropsychiatric symptoms and challenging behaviours among patients with different types and severity of dementia in a range of settings. The conclusions of all recent high quality systematic reviews are summarised and compared, and knowledge gaps are highlighted, so that the best current evidence can be made available to policy-makers, commissioners and clinicians.



4. Review methods

4.1 Review type

We conducted an overview of the findings from systematic reviews on the effectiveness of non-pharmacological alternatives to the use of antipsychotics in patients with dementia.

Overviews of systematic reviews aim to provide a narrative summary of evidence from two or more systematic reviews at a variety of levels, such as for different populations, outcomes, conditions, adverse effects or severity of disease (Becker et al. 2009). Standardised assessment tools and a rigorous methodology were used to ensure transparency and quality.

4.2 User involvement

Although systematic reviews are increasingly being commissioned to inform policy development and provide recommendations for practice and research, relatively few health or social care systematic reviews have involved the public, patients or service users (Braye et al. 2005; Smith et al. 2009). This report had public involvement in reviewing and commenting on the draft report.

4.3 Consultation with stakeholders

This overview was steered by key DH representatives and reviewed by a Peer Review Group.

4.4 Identification of relevant systematic reviews

The aim was to include all good quality peer-reviewed systematic reviews that focused on the effectiveness of non-pharmacological interventions in the management of neuropsychiatric symptoms and challenging behaviours in patients with dementia. All records of research identified by searches were uploaded to the specialist systematic review software EPPI-Reviewer for duplicate stripping and screening (Thomas et al. 2010).

4.4.1 Definitions

- **Systematic reviews** were included if they presented a defined search strategy and explicit inclusion criteria.
- **Types of dementia** include Alzheimer's disease, vascular dementia, fronto-temporal and Lewy body.
- **Levels of severity** include mild, moderate and severe dementia.
- **Non-pharmacological interventions** include all types of non-drug interventions (e.g. psychological, sensory, behavioural, educational or environmental), which are offered in any of the following settings: community (including home), primary care, secondary care or care homes. Interventions for informal caregivers (e.g. education, support, behaviour management) and health care professionals were also covered.



- **Neuropsychiatric symptoms and challenging behaviours** include agitation (i.e. aggression, restlessness and pacing), depression, anxiety, irritability, hallucinations, persecutory delusions, confabulations, wandering, elation, apathy and sleep problems AND/OR groups of symptoms and behaviours as reported in systematic reviews, i.e. psychotic symptoms, behavioural, neurobehavioral, perceptual and psychomotor disorders.

4.4.2 Outcomes

Data was extracted and reported for the following outcomes:

- Use of antipsychotics and/or other psychotropic agents
- Effect on intensity and/or frequency of neuropsychiatric symptoms and challenging behaviours.

4.4.3 Inclusion and exclusion criteria for systematic reviews

- **Inclusion criteria:**
 - i) **Population** – Systematic reviews that focused on interventions delivered to patients who had a diagnosis of dementia confirmed by the use of a validated cognitive or functional instrument OR by their caregiver AND/OR by health care professionals caring for patients with dementia. AND
 - ii) **Intervention** – Systematic reviews that assessed non-pharmacological interventions in the management of neuropsychiatric symptoms and challenging behaviours. AND
 - iii) **Control or comparator treatment** – Either normal care, no treatment, placebo or attention control, or with some noted standard of care. AND
 - iv) **Outcomes** – Studies where the efficacy of a non-pharmacological intervention was tested on at least one of the outcomes (as described in section 4.4.2). AND
 - v) **Study design** – Any, except single case report. AND
 - vi) **Minimum quality standards** – Systematic reviews that met three criteria of the AMSTAR tool (Shea et al. 2009) (see section 4.6.1).
- **Exclusion criteria:**

Studies were excluded if they:

 - i) Had a primarily pharmacological, alternative and/or herbal medicine treatment focus.
 - ii) Combined a pharmacological and non-pharmacological treatment.
 - iii) Focused on palliative care or end-of-life (unless the focus was specifically on relieving neuropsychiatric or behavioural symptoms of dementia).
 - iv) Solely focused on depression, anxiety, sleep dysfunction or sleep architecture in dementia (unless other neuropsychiatric or behavioural symptoms associated with dementia were also covered).
 - v) Were a single case report.

4.4.4 Search strategy

The main search was conducted (March 2011) in Medline via OVID (1996 to March week 2 2011), the CDR databases (DARE/NHS EED and HTA; no date limits) and the Cochrane Database of Systematic Reviews (no date limits) using



the following key words:

- Dementia, Alzheimer, Alzheimer's disease, AD, Lewy body, VaD
- Non-pharmacological, psychosocial, psychological
- Cognitive or non-directive or sensory or social or behavio* or recreation or environment* or relaxation or talking or nursing or light or psychosocial or psychological) adj3 (therap* or activit* or intervention* or modify or modificat* or program)
- Complementary therapies, combined modality therapy, recreation, relaxation therapy, behaviour therapy, psychotherapy, cognitive therapy, phototherapy.

The search was limited to articles published in English. The search results are presented in Appendix 1.

4.5 Selecting reviews

Two review authors (JK, LL) independently screened the search results by title and abstract to identify relevant systematic reviews. The full texts of the reviews identified as either relevant or possibly relevant from their titles and abstracts were obtained. A number (n=5) of possibly relevant reviews that were not readily available online to the reviewers were not included due to time constraints. Two review authors (JK, LL) selected the relevant reviews by reading the full text according to the criteria mentioned above, resolving disagreements by discussion.

4.6 Quality assessment and data extraction

4.6.1 Quality assessment

Two different quality assessments must be addressed in an overview of systematic reviews: the methodological quality of the reviews included, and the quality of the evidence in these reviews.

- **Quality of systematic reviews**

Two review authors (JK, LL) independently assessed the methodological quality of the included systematic reviews using three priority criteria of the AMSTAR tool (Shea et al. 2009; see Appendix 2):

- Criterion 3: Was a comprehensive literature search performed?
- Criterion 6: Were the characteristics of the included studies provided?
- Criterion 7: Was the scientific quality of the included studies assessed and documented?

The AMSTAR is a validated tool designed to assess the quality of systematic reviews and to be used in reviews of reviews to determine if the potentially eligible reviews meet minimum quality requirements. Any discrepancy between reviewers was resolved by discussion.



- **Quality of the evidence in selected systematic reviews**

The quality of the evidence presented in the included systematic reviews was not reassessed by the authors. Rather, the results were extracted and a narrative summary was provided of the highest rated evidence presented in each of the systematic reviews. This was possible because all the included reviews assessed the quality of their primary studies (meeting AMSTAR criterion 7). For reviews which used the Oxford Centre for Evidence-Based Medicine Levels of Evidence to assess quality, the results are presented according to these levels:

1a	Systematic reviews (with homogeneity) of randomized controlled trials
1b	Individual randomized controlled trials (with narrow confidence interval)
1c	“All or none” randomized controlled trials
2a	Systematic reviews (with homogeneity) of cohort studies
2b	Individual cohort study or low quality randomized controlled trials (e.g. <80% follow-up)
2c	“Outcomes” research; ecological studies
3a	Systematic review (with homogeneity) of case-control studies
3b	Individual case-control study
4	Case-series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”

Ref: www.cebm.net/?o=1025

4.6.2 Data extraction

Data from each study was extracted using standardized data extraction forms by two reviewers (JK, LL). They compared responses to all questions and agreed a version of the data extraction, resolving any differences by discussion and consensus.

4.7 Synthesising the findings across intervention categories

Although the interventions included in this overview are often quite complex and difficult to categorise, for presentational purposes, they have been grouped into the following eight broad types:

- **Sensory enhancement and relaxation:** The aim of these approaches is to increase the overall level of sensory stimulation in the environment to counterbalance any negative impact of sensory deprivation common to the experience of dementia. These interventions include massage/touch, relaxation therapies, music therapy, white noise, multi-sensory stimulation (snoezelen), transcutaneous electrical nerve stimulation (TENS) and light therapy.
- **Social contact (real or simulated):** People living with dementia may often have limited contact with others in their environment. There are a range of interventions which aim to provide people with access to different forms of social



contact. These include real (one to one contact) or simulated (through video or audiotapes) human interaction, and pet or animal-assisted forms of therapy.

- **Cognitive and emotional approaches:** These interventions include:
 - *Validation and reminiscence therapies:* These originate in the humanist psychology tradition and aim to address the feelings and emotional needs of patients with dementia (Finnema et al. 2000). Reminiscence therapy uses tangible prompts (e.g. photographs, household items) and discussion of past activities and events to stimulate memories and enable people to share and value their experiences (Woods et al. 2005). Validation therapy is based on a synthesis of behavioural and psychotherapeutic methods. It is premised on individual uniqueness and intended to give an opportunity to resolve unfinished conflicts by encouraging and validating expression of feelings (Neal et al. 2003; Livingston et al. 2005).
 - *Reality orientation:* Similarly, reality orientation aims to support people to manage the difficult feelings and emotions that occur because of the impact of dementia on cognitive functioning (e.g. mental disorientation, memory loss and confusion) and attempts to improve self-esteem and self-worth. It is based on the idea that impairment in orienting information (day, date, weather, time and use of names) prevents patients with dementia from functioning well and that reminders can improve functioning (Livingston et al. 2005).
 - *Cognitive stimulation:* Derived from reality orientation therapy, cognitive stimulation therapy uses information processing rather than factual knowledge to address functional problems and aims at general enhancement of cognitive and social functioning (Livingston et al. 2005; Clare et al. 2003). Cognitive training typically involves guided practice on a set of standard tasks designed to reflect particular cognitive functions, such as memory, attention, or problem-solving (Clare et al. 2003).
- **Physical activities/exercise:** Managing difficult behaviours associated with dementia can involve structured activities in order to provide people with meaningful and engaging experiences, such as physical activities, outdoor walks or engaging in arts and crafts.
- **Environmental modifications:** This covers a range of interventions which aim to modify the living environment of people with dementia, such as installing exit barriers to restrict wandering, adapting the visual environment to decrease agitation, or increasing the overall safety in the home by removing dangerous kitchen equipment, unplugging electrical equipment or leaving lights on in places such as the bathroom.
- **Behaviour management techniques:** These include a range of interventions which aim to increase pleasant events, or to identify and modify factors which can lead to specific difficult behaviours or their consequences, as well as the use of communication skills or distraction techniques.
- **Caregiver training and support:** These refer to a broad range of interventions which aim to change interactions between caregivers and patients with dementia, including: psycho-education; integrated family support, such as counselling and advocacy; training in awareness and problem solving; and support groups.
- **Special care units:** These units have been designed to support the needs of patients with dementia in nursing homes and residential settings. They typically



include environmental modifications and provide specialist training to assist staff in managing patients with challenging behaviours.

Evidence from high quality reviews (e.g. Cochrane reviews) or studies (RCTs) is described first. Then, results from other studies are presented and discussed in light of their methodological and analytical limitations. As far as possible, we have tried to ascertain the extent to which the same primary studies are included in multiple reviews.

5. Results

5.1 Flow of studies through the review

Systematic searches identified 2438 records of potentially relevant systematic reviews. Following removal of 296 duplicate records, 138 records were considered to meet the inclusion criteria on the basis of a reading of the title and abstract. When full copies of research reports were read and quality assessed against the modified AMSTAR tool, 30 systematic reviews, reported in 31 papers remained to be included in this report. A further three citations related to this area – a review of reviews, a review of practice guidelines, and a review of the literature structured around specific clinical questions – were also identified (and are summarised in section 5.4).

5.2 Characteristics of included studies

Of the 30 reviews included in the overview, 15 were considered to be ‘broad’ reviews (i.e. evaluating multiple interventions across a range of outcomes) and 15 were ‘narrow’ reviews (i.e. reviews of single interventions). Combined, the broad and narrow reviews reported on 651 primary studies, many of which overlapped. A total of 220 mutually exclusive studies provided the data which informed this narrative overview. Despite having applied quality criteria to select the 30 reviews, the quality of included primary studies across systematic reviews varied owing to the different focus and methodological rigour adopted in each review. The analysis deals with the issue by first presenting results of Cochrane Reviews and/or high quality RCTs, followed by a more general discussion of the other sources of evidence.

5.2.1 Description of broad reviews

Overall, 11 of the broad reviews did not either identify or specify the type or stage of dementia and/or included mixed population groups. The remaining four reviews focused on patients with graded levels of dementia (e.g. from mild to severe) or caregivers, both informal and paid staff. One review only included patients with early stage vascular dementia, one did not specify the level of dementia severity and the other focused on informal caregivers.

Ten reviews presented results from primary studies that were conducted in long-term care settings or where the majority of studies were conducted in such settings. Only one review evaluated long-term care interventions delivered in the home. This was a UK review of primary care provision (Robinson et al. 2010).



The remaining reviews evaluated interventions across a range of settings, including three which focused on interventions delivered in community settings, and one in acute settings. The broad reviews are marked by their wide diversity of interventions and outcomes. However, all of the broad reviews included studies that measured the impact of interventions on neuropsychiatric symptoms and/or challenging behaviours.

5.2.2 Description of narrow reviews

The majority (13) of the narrow reviews included studies in which patients presented any level of dementia severity. One review did not specify the severity of dementia, but since it focused on interventions delivered in domestic settings, it is likely that the population had mild to moderate dementia. Another review focused on a population with early stage vascular dementia or Alzheimer's disease. Seven reviews presented results from primary studies conducted in long-term care settings or where the majority of primary studies were conducted in such settings. Two reviews included studies set in the home, and the remainder either did not report the setting or evaluated interventions across multiple settings.

5.3 Summary of evidence across intervention categories

The sections below are structured according to intervention category. First, a table provides a short summary of the evidence for the intervention category, followed by a more detailed description for specific interventions that fall within the category. Priority is given to Cochrane reviews and high quality RCTs in reporting the results.

The main outcomes of interest are whether: a) there is a reduction in the use of antipsychotic (or other psychotropic) medication (section 5.3.1); or b) neuropsychiatric symptoms and challenging behaviours are affected by the intervention (section 5.3.2).

5.3.1 Evidence summary – Reduction in use of antipsychotics

Only two reviews specifically evaluated the impact of interventions on the use of antipsychotic medication (Livingston et al. 2005; Lai et al. 2009). In Livingston et al. (2005), two of the included primary studies were judged to be level 2b evidence on the Oxford Centre for Evidence-Based Medicine Levels of Evidence. Neither study **found any change in antipsychotic medication** use from either **validation therapy interventions**, or **caregiver training in behavioural management techniques**. No significant effect on the use of psychotropic drugs was found in Lai et al's (2009) Cochrane review on the effect of **special care units**.



5.3.2 Evidence summary – Effective management of neuropsychiatric symptoms and challenging behaviours

Sensory enhancement and relaxation:
Massage/Touch

Comparisons: i) usual care (e.g. no touch intervention)

Number of contributing reviews: 6 **and primary studies:** 9

Summary of evidence

Narrow reviews: Based on Hansen’s Cochrane review (2006), one of two studies provides reliable evidence *in favour of massage and touch* interventions for the immediate or *short-term reduction of agitated behaviour*.

Other reviews: In addition, one narrow and four broad reviews reported on massage/touch. A further seven studies were identified which were not included in Hansen’s Cochrane review. Four of these studies *also reported positive outcomes in favour of massage/touch therapies for improving behavioural symptoms* including reducing agitated behaviour. However, the methodological quality of these studies needs to be taken into consideration when interpreting the findings.

Narrow reviews of sensory enhancement included two reviews of *massage and touch* (Harris et al. 2010; Hansen et al. 2006). The Cochrane review by Hansen et al. (2006) found *hand massage* decreased *agitation* (similar findings based on the same study were also reported in Kong et al. 2009), but that there was insufficient evidence to draw conclusions about other behavioural outcomes. Harris et al. (2010) evaluated *slow-stroke back massage and hand massage* and found them to be effective in improving *physiological and psychological indicators of relaxation* (n=2). Studies that specifically assessed patients with dementia also found a *positive effect on behavioural symptoms*.

Therapeutic touch was also found to significantly *reduce pacing*, but not wandering (Robinson et al. 2007, n=1). The review by Kverno et al. (2009) evaluated the effectiveness of ‘*craniosacral still point technique*’, finding a *significant reduction* for *physical and verbal agitation* for patients with moderate dementia (n=1), but reported that there was insufficient evidence to assess the effectiveness of touch therapy on neuropsychiatric symptoms for patients in the advanced stages of the illness. The review by Olazaran et al. (2010) identified three additional studies, but did not judge them to be of sufficient quality to reach conclusions on the use of massage/touch for patients with dementia.

Sensory enhancement and relaxation:
Relaxation therapy

Single study: The findings from one RCT suggest that there is no evidence of a difference of effect between two types of relaxation training techniques on agitation for patients with dementia.



The broad review by O'Connor et al. (2009) reports findings from one RCT rated as 'strong'. The trial compared progressive muscle relaxation training, which relies on procedural (or motor) memory, with an individualized '**imaginal relaxation technique**' that relied on verbal skills, for the treatment of **agitation** in dementia. Although the behaviour rating scores on the Alzheimer's disease scale were lower for both arms, at 2-month follow-up **no significant differences between groups were found**. The authors **refrain** from reaching a conclusion on the effectiveness of relaxation therapy from one study and suggest that further research is conducted in this area.

Sensory
enhancement
and relaxation:
Music therapy

Comparisons: i) usual care, ii) control intervention to reduce behavioural problems or iii) patients acting as their own controls

Number of contributing reviews: 6 **and primary studies:** 24

Summary of evidence

Narrow reviews: A Cochrane review (Vink et al. 2003) reported on the results of **seven RCTs** comparing **music therapy** with a control intervention to reduce behavioural problems. Although identifying a positive effect, the authors concluded that the methodological quality and the reporting of the included studies were **too poor to draw any useful conclusions** regarding the effect of music therapy on behavioural problems.

Other reviews: In addition, one narrow and four broad reviews reported on music therapy. Combined, these reviews reported on 17 primary studies not included in Vink et al. (2003). **Fifteen** of these **studies demonstrated positive outcomes** in reducing the occurrence of some types of **agitated** behaviour, but all were rated as moderate to low in terms of quality.

Music therapy was evaluated in a Cochrane review by Vink et al. (2003). The results of these studies point to **a positive effect of music therapy on behavioural problems**. For example, two studies, which investigated individually based receptive music therapy interventions, both found a significant difference in the frequency of aggressive behaviours. In addition, one of the five studies evaluating active group music therapy found significant differences in agitation (measured by sitting/proximity time) and wandering, while another found a significant decrease in neuropsychiatric symptoms. While one study didn't detect significant change in the BEHAVE-AD scale overall, significant differences were noted on some sub-scales (although no effects were reported at follow-up). Another 15 studies identified in five other reviews (Kverno et al. 2009, O'Connor et al. 2009, Opie et al. 1999, Robinson et al. 2007, Sung et al. 2005) also demonstrated statistically significant effects in reducing agitated behaviours; however, the findings must be treated with caution due to the methodological limitations highlighted. In particular, it was not clear in the other five reviews whether the interventions referred only to therapy delivered by qualified music therapists, or to less structured therapeutic use of music (or both).



Sensory enhancement and relaxation: *White noise*

Single study: Reported in one broad review, there was a small but significant effect in reducing agitation during treatment only. However, the study was judged to be of low methodological quality.

One low quality study on the efficacy of **white noise** found a statistically **significant reduction in agitation during treatment** for patients living with dementia and acting as their own comparison group (Livingston et al. 2005). Review authors rated the study as 4, using the Oxford Centre for Evidence-Based Medicine guidelines which rate studies from 1 to 5 (1 = consistent level of evidence and 5 = troubling inconsistent or inconclusive studies).

Sensory enhancement and relaxation: *Multi-sensory/ Sensory stimulation*

Comparisons: i) usual care, ii) activity sessions, iii) reminiscence therapy, iv) non-aromatherapy oil or v) patients acting as their own controls

Number of contributing reviews: 10 **and primary studies:** 21

Summary of evidence

Narrow reviews: The two RCTs included in the Cochrane Review by Chung et al. (2002) showed no evidence to support the long or short-term effects of snoezelen or multi-sensory stimulation programs on the behaviour of people with dementia.

Other reviews: In addition, nine broad reviews also reported on multi-sensory stimulation. Combined, these reviews reported on 19 primary studies not included in Chung et al. (2002). Although the majority of studies report positive findings for the reduction of agitated behaviour, particularly for aromatherapy, study quality varies and in most cases only short-term outcomes have been measured.

Neither the Cochrane review by Chung et al. (2002) nor the broad review by O'Connor et al. (2009) found any evidence to support the short- or long-term impact of **snoezelen or multi-sensory stimulation** on mood or behavioural outcomes. However, the review by Livingston et al. (2005) contradicts these findings and suggests that there is consistent evidence on the **short-term benefits of snoezelen on agitation**. Their conclusions are based on two RCTs rated as high quality (one of which was also included in two other reviews – Boote et al. 2006, Olazaran et al. 2010). Similarly, two high quality RCTs, in a review of the effects of psychosocial methods on aggressive and apathetic behaviours (e.g. levels of engagement with the environment), suggest that there is evidence that **multi-sensory stimulation (snoezelen)** reduces apathy in people in the later stages of dementia (Verkaik et al. 2005). Findings from seven additional studies (of variable quality) also suggest that multi-sensory interventions have a positive short-term impact on **disruptive and challenging behaviours and mood**; however, the findings were not always statistically significant (Livingston et al. 2005). Robinson et al. (2007) report a **lack of evidence** for the effectiveness of multi-sensory interventions **on wandering**.



Three reviews, which include studies on the efficacy of **aromatherapy**, found **positive short-term benefits** for **reducing agitation** in both moderate and advanced stages of dementia. However, the review authors' caution that, without extended follow-up, the long-term benefits of aromatherapy remain unclear (O'Connor et al. 2009, Kong et al. 2009, Kvervno et al. 2009).

Sensory enhancement and relaxation:
Transcutaneous electrical nerve stimulation (TENS)

Comparisons: i) placebo treatment (disconnected electrodes/no current)

Number of contributing reviews: 2 **and primary studies:** 6

Summary of evidence

Narrow reviews: A synthesis of six RCTs included in the Cochrane review by Cameron et al. (2003) did not find any evidence for the effectiveness of Transcutaneous electrical nerve stimulation (TENS) on neuropsychological or behavioural outcomes.

Other reviews: One broad review identified the same set of studies and did not find sufficient evidence to warrant making any recommendations for practice.

In Cameron et al.'s (2003) Cochrane review, **no overall effect of TENS was found on many of the neuropsychological and behavioural measures** evaluated, either directly after TENS treatment or six weeks after treatment was completed. Although a number of studies suggest that TENS may produce short lived improvements in some neuropsychological measures, the limited presentation and availability of data from these studies does not allow for definite conclusions to be drawn on the potential benefits of this intervention. A recent review by Olazaran et al. (2010) identified the same studies; however, due to lack of study quality they did not report findings or draw any conclusions.

Sensory enhancement and relaxation:
Light therapy

Comparisons: i) dim light

Number of contributing reviews: 5 **and primary studies:** 10

Summary of evidence

Narrow reviews: The Cochrane Review by Forbes et al. (2009) identified four relevant studies but concluded that there is insufficient evidence to determine whether light therapy is effective in managing behaviour or psychiatric disturbances associated with dementia.

Other reviews: Four broad reviews report findings from an additional six studies on the effectiveness of light therapy on agitation and disruptive behaviour. Although three reviews report significant improvements in these outcomes, none of the studies included are of a high enough methodological quality to make sound recommendations.



The Cochrane review by Forbes et al. (2009) detected **no significant effect of light therapy on behavioural or psychiatric disturbances or depression**, irrespective of the time of the day light therapy was administered (and accounting for length of treatment). One broad review came to similar conclusions (Kong et al. 2009), and another did not make recommendations (Olazaran et al. 2010). Three reviews reported a significant reduction in **agitation** (Ayalon et al. 2006, Opie et al. 1999) and **aberrant behaviour** (Kverno et al. 2009), but their findings were based on low quality studies and thus the authors refrained from drawing conclusions on the effectiveness of light therapy.

Social contact –
real or simulated:
*Pets/animal-
assisted therapy*

Single study: One review found a significant effect for the presence of a dog, compared with no dog, on reducing agitation in people with dementia.

Kong et al. (2009) included one study on **the presence of a dog** in a meta-analysis of social contact interventions. The individual effect size showed a small but significant **reduction in agitation** for the treatment group compared with those who had not been exposed to pet therapy.

Social contact –
real or simulated:
*One-on-one
stimulation*

Single study: Reported in one review which failed to find a significant effect for improving neuropsychiatric symptoms after receiving one-on-one stimulation.

One study investigating the impact of **one-on-one stimulation** on neuropsychiatric outcomes was included in a meta-analysis with other studies grouped as ‘set-time interventions’. A significant effect **in favour** of either the **treatment** or control group was **not found**. Another study on one-on-one stimulation was identified but, since it did not include a measurement for neuropsychiatric symptoms, it was not included in the meta-analysis (Vasse et al. 2010).

Social contact –
real or simulated:
*Simulated
interaction/
Family video*

Comparisons: i) usual care, ii) placebo, iii) preferred music or iv) patients acting as their own controls

Number of contributing reviews: 4 **and primary studies:** 8

Summary of evidence

Narrow reviews: None

Other reviews: Four broad reviews included findings from eight primary studies on the impact of simulated interaction. Three randomised trials judged as sound indicate that simulated presence can reduce agitation during treatment. However, no significant differences of effect were found between groups. The remaining five studies report mixed, non-significant findings for a range of behavioural outcomes.



Three randomised trials, judged to be of sound quality, reported across four reviews (Kong et al. 2009, Kverno et al. 2009, Livingston et al. 2005, O'Connor et al. 2009) found that, although simulated presence **reduced physical and verbal agitation during treatment**, no significant differences in agitation or withdrawn behaviours were found between intervention and control groups. Five additional controlled trials were also reported in Livingston et al. (2005). Three of these trials reported non-significant improvement in social interaction and attention, but not aggressive behaviours, while one study also found that patients' well-being deteriorated. The other two single group designs reported mixed results on anxiety, social interaction and agitated behaviour.

Cognitive and emotional approaches: *Cognitive stimulation*

Comparisons: i) structured activities (without any cognitive-based components), ii) wait lists or iii) medication only

Number of contributing reviews: 3 **and primary studies:** 6

Summary of evidence

Narrow reviews: Two RCTs included in the Cochrane review by Clare and Woods (2003) showed no evidence to support the effectiveness of cognitive training intervention on the behaviour of people with dementia.

Other reviews: Two broad reviews also report on the impact of cognitive interventions on behavioural problems. An additional four studies were identified. Two reviews concur with Clare and Woods (2003), while a third review finds a positive impact from two RCTs (Olazaran et al. 2010).

Cognitive stimulation interventions (n=2 RCTs) were evaluated in the Cochrane review by Clare and Woods (2003), who found **no evidence of effectiveness on behavioural problems**. Another review, including two additional studies, also came to the same conclusion (Livingston et al. 2005). However, a more recent review by Olazaran et al. (2010), reporting the findings of two RCTs, suggested that **cognitive stimulation group sessions** can have a **positive effect on the behaviour** of institutionalised patients with dementia.

Cognitive and emotional approaches: *Reality orientation*

Comparisons: i) usual care, ii) reminiscence therapy or iii) patients as their own controls

Number of contributing reviews: 3 **and primary studies:** 14

Summary of evidence

Narrow reviews: None

Other reviews: Ten studies were reported in a single review on the efficacy of reality orientation interventions. The majority of studies reported non-significant impacts on behavioural outcomes. A further four, low quality, studies also failed to find any significant changes in depression for people with dementia.



Ten studies, of variable quality, evaluating the effectiveness of reality orientation therapies on behavioural outcomes were reported in a single review (Livingston et al. 2005). The findings were judged to be inconsistent. The results of two RCT's diverged, one in favour of the intervention for **improving neuropsychiatric symptoms**, while the other **did not report any changes in behaviour** when compared with active ward orientation. The remaining seven controlled trials reported **some improvement in decreasing neuropsychiatric symptoms and delay in being institutionalised**, but many failed to find significant differences between groups (Livingston et al. 2005). Findings from a further four, low quality studies, reported across three reviews (Bates 2004, Livingston et al. 2005, Verkaik et al. 2005) also found **insufficient evidence that reality orientation improves depression**.

Cognitive and emotional approaches:
Validation therapy

Comparisons: i) usual care, ii) reality orientation group or iii) social care

Number of contributing reviews: 6 **and primary studies:** 7

Summary of evidence

Narrow reviews: The Cochrane review by Neal et al. (2009) identified three trials on validation therapy. The lack of any statistically significant differences between validation and social contact, or between validation and usual care, for people with dementia lead the authors to conclude that there is insufficient evidence on the efficacy of validation therapy.

Other reviews: Evidence drawn from four trials, reported in five additional reviews, also found no improvement in challenging or disruptive behaviours for patients with dementia.

Regardless of study quality, **validation therapy was not found to be effective in improving behavioural outcomes**. No significant evidence of effect was found for reducing irritability, aggression or improving other types of neuropsychiatric outcomes, according to the results of seven trials reported across six reviews (Livingston et al. 2005, Neal et al. 2009, O'Connor et al. 2009, Olazaran et al. 2010, Vasse et al. 2010, Verkaik et al. 2005).

Cognitive and emotional approaches:
Reminiscence therapy

Comparisons: i) no treatment or ii) social contact

Number of contributing reviews: 3 **and primary studies:** 12

Summary of evidence

Narrow reviews: None

Other reviews: Three broad reviews included 12 studies on reminiscence therapy but failed to find consistent evidence of effectiveness, with two reviews failing to make any practice recommendations for this type of intervention.



The review by Livingston et al. (2005) identified five studies evaluating the effectiveness of reminiscence therapy, three of which were RCTs. Only one found an improvement in behaviour, but the finding was not significant. Verkaik et al. (2005) reported findings from two studies (one also included in Boote et al. 2006). Only one study reported a significant result for lowered (self-reported) depression scores, but the authors caution that the intervention group had higher scores at baseline. The review by Olazaran et al. (2010) identified six additional studies, but judged them to be of insufficient quality to draw inferences about effectiveness.

**Physical activity/
Exercise**

Comparisons: i) usual care, ii) social contact/visits, iii) night time program or iv) less time-intensive program

Number of contributing reviews: 5 **and primary studies:** 26

Summary of evidence

Narrow reviews: Christofolletti et al. (2007) found discordant results across studies regarding the effects of motor interventions (i.e. physiotherapy, occupational therapy and interdisciplinary intervention) on behavioural outcomes (n=4). The quality of included studies was weak to moderate according to the authors' criteria.

Other reviews: In addition, one narrow and three broad reviews synthesised findings on physical activity/exercise, including outdoor walks. A further 21 studies investigating the impact of physical activity programs on neuropsychiatric symptoms and challenging behaviours were identified. Nineteen of these studies were reported in one review. Many of the studies found a **positive impact on disruptive behaviours**, including wandering and aggression.

Physical activity and exercise interventions were evaluated by five systematic reviews with behavioural outcomes. The majority of studies, judged to be high to moderate quality, were reported in one review, which found that **physical exercise programs** can be effective in improving **agitation, aggression, irritability, wandering and sleep behaviours** (Eggermont et al. 2006). There was also some evidence to suggest that **psychomotor therapy groups** may reduce aggression in nursing home residents diagnosed with probable Alzheimer's disease. However, no significant changes were observed for depression or apathy (Verkaik et al. 2005). One narrow review reported **inconsistent findings** (Christofolletti et al. 2007), while another reported a **lack of evidence** (Forbes et al. 2008) to suggest that **physical motor interventions** are effective in improving behavioural outcomes in people with dementia. A broad review by Opie et al. (1999) identified a single study, rated as moderate, which looked at the effectiveness of a 90 minute walking program. Receipt of the intervention led to a **statistically significant reduction in the mean number of aggressive incidents** reported on non-activity days.



Environmental modifications	<p>Comparisons: Not reported</p> <p>Number of contributing reviews: 4 and primary studies: 14</p> <p>Summary of evidence</p> <p>Narrow reviews: Neither Hermans et al. (2007) nor Price et al. (2001) Cochrane reviews found any RCTs or controlled trials of sufficient quality to assess the effect of subjective environment modifications on the wandering behaviour of cognitively impaired people.</p> <p>Other reviews: However, two broad reviews, which included 14 studies, reported only non-significant improvements in behaviour, mainly from poor quality studies.</p>
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Two Cochrane reviews, Hermans et al. (2007) and Price et al. (2001), sought to evaluate the impact of **environmental modifications** (e.g. subjective barriers, such as exit modification) on the prevention of **wandering** in patients with dementia, but found **no relevant RCTs** to include. The review by Livingston et al. (2005) included two different types of enhanced environmental interventions:

- **Alterations to the visual environment** (e.g. murals, patterns, visual barriers, signposting, mirrors) resulted in a non-significant reduction in exiting behaviours including testing doors to leave, agitation and reduced ambulation (n=7 low quality studies).
- **Designed environments** led to a reduction in anxiety; however, while some studies reported an increase in aggression (n=2 low quality studies), others found a reduction (n=2 low quality studies).

Another review, which also synthesised findings on modifications to the environment, showed a significant improvement in agitation; however, two of the included studies were judged to be of only moderate quality, while the third was classified as weak (Opie et al. 1999).

Behaviour management techniques	<p>Comparisons: i) usual care, ii) placebo or iii) patients acting as their own controls</p> <p>Number of contributing reviews: 3 and primary studies: 12</p> <p>Summary of evidence</p> <p>Narrow reviews: None</p> <p>Other reviews: Three broad reviews report on behaviour management techniques from 12 primary studies. Six RCTs report statistically significant reductions in neuropsychiatric symptoms and an improvement in behavioural outcomes. The remaining studies, mostly low quality, report non-significant reductions in agitation, disruptive vocalisations, aggressive behaviours and wandering.</p>
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Behaviour management techniques (e.g. therapy emphasising pleasant events, analysis and modification of antecedents and consequences of behaviours) appear to have lasting effectiveness for the management of dementia-associated **neuropsychiatric symptoms** (Livingston et al. 2005). Improvements in **wandering** and **behaviour** (lower withdrawal, better emotional control and less disruptive behaviour) were achieved through **targeted behavioural interventions** (e.g. use of distraction techniques to mitigate aggressive episodes; an individualised care routine based on patient preferences) (Robinson et al. 2007, Olazaran et al. 2010; Livingston et al. 2005).

Staff and caregiver training and support	<p>Comparisons: None</p> <p>Number of contributing reviews: 6 and primary studies: 22</p> <p>Summary of evidence</p> <p>Narrow reviews: None</p> <p>Other reviews: Six broad reviews, identifying 22 studies (18 of which were RCTs), investigated the impact of staff and caregiver training. The evidence suggests that some improvements can be found in behavioural outcomes for people with dementia after caregivers had received psycho-education and/or training in managing difficult behaviours. However the findings are not consistent and it is not always possible to identify the precise training components that contributed to effectiveness.</p>
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Several reviews synthesised evaluations of a number of types of caregiver interventions, such as education and support, to help in the management of difficult behaviours. Four reviews (Ayalon et al. 2006, Livingston et al. 2005, Logsdon et al. 2007, Peacock et al. 2003), which identified thirteen studies (including seven RCT's), found that in some cases the **use of psycho-education training programs** for caregivers had **an impact on behavioural outcomes**. However, five reviews (Ayalon et al. 2006, Livingston et al. 2005, Logsdon et al. 2007, Olazaran et al. 2010, O'Connor et al. 2009), which included several RCT's (n=9) on the impact of **training carers in the use of behaviour management techniques** reported some reduction in symptoms (n=2), but a majority of studies (n=7) did not find training in these techniques to be effective.



Special Care Units

Comparisons: Not stated

Number of contributing reviews: 2 **and primary studies:** 25

Summary of evidence

Narrow reviews: A Cochrane review conducted by Lai et al. (2009) included eight non-RCTs evaluating the effectiveness of training, programme activities or care planning provided in special care units for dementia patients with behavioural problems. Significant improvements in outcomes for the intervention group, compared with those who stayed in traditional nursing homes, were reported in some (but not all) studies. The improved outcomes included: agitation (at 6, 12 and 18 months); mood and affect (at 3 months); and neuropsychiatric symptoms (at 3 months).

Other reviews: One broad review (Livingston et al. 2005) also included studies on providing caregiver training in special care units, with (n=6) and without (n=4) designed environments. While the former found significant improvements in behaviour, the latter results were inconclusive.

Both the Cochrane review by Lai et al. (2009) and the broader review by Livingston et al. (2005) included studies (n=4) on **special care units** and found some evidence for a **reduction in neuropsychiatric and behavioural problems**. Another six studies identified by Livingston et al. (2005) on **designed environments combined with staff training** reported only non-significant effects on reducing behavioural disturbances. The lack of high quality research and statistically significant results for this latter group of studies lead the authors to grade findings as inconclusive and to make no further recommendations for practice (Livingston et al. 2005).

5.4 Reviews of reviews and guidelines

Two reviews of reviews (Hulme et al. 2010, Vernooij-Dassen et al. 2010) and a set of **practice guidelines** (Doody et al. 2001) relevant to dementia were identified during the systematic search (see Appendix 5).

The practice guidelines were commissioned by the American Academy of Neurology in response to growing concerns about an ageing US population who are likely to increasingly suffer from Alzheimer’s disease, a situation similar to that in the UK. The guidelines provide a summary of the evidence-base to inform the management of dementia. They consider **the impact of ‘pharmacotherapy’ drugs on cognition** and the benefits of educational programs for family members and staff of long-term care facilities. The **recommendations** for practice include **the use of antipsychotic medication** for agitation and psychosis, as well as **training** and **education to improve caregiver satisfaction**.



The interventions summarised in the two reviews of reviews overlap with this overview, although their focus and scope differ. One review was concerned with the effectiveness of **psychosocial interventions** delivered in long-term care facilities (Vernooij-Dassen et al. 2010). They found behavioural management techniques and cognitive stimulation to be effective in reducing behavioural symptoms and/or depression, and physical exercise to stimulate good behaviour. The other review looks at **non-drug treatments** that could potentially be delivered by informal carers in the home setting (Hulme et al. 2010). In spite of the mixed evidence and limitations in study designs, the authors concluded that several interventions were found to be effective for use with particular symptoms of dementia, including music therapy, hand massage/touch, and physical activity/exercise. The conclusions of both reviews highlight the lack of a robust evidence-base in which to make practice recommendations.

6. Discussion and summary

6.1 Discussion

The Department of Health is committed to a significant reduction in the use of antipsychotic drugs to manage behavioural and neuropsychiatric symptoms in patients with dementia. However, the scientific evidence on the effectiveness of alternative treatments which could support this reduction in antipsychotic drug prescribing is either not available or has not been systematically assessed. PIRU was asked to bridge this gap by carrying out a review of the effectiveness of non-pharmacological interventions in the management of neuropsychiatric symptoms and challenging behaviours in patients with dementia. Given the widespread literature available on this subject, PIRU opted for carrying out an overview of existing systematic reviews; in all, thirty systematic reviews, dating from 1999, were included in this overview.

Overviews of reviews are becoming an established component in the repertoire of evidence informed (or based) policy and practice (Smith et al. 2011; Thomson et al. 2010). Reviewing existing systematic reviews can be a pragmatic solution to the need for evidence in a timescale that does not allow for a new systematic review to be undertaken. Such overviews can also encompass a greater breadth of topic than is practicable within a single systematic review of primary research (e.g. Caird et al. 2010). As systematic reviews aim to inform policy and practice, they can be easier and quicker to locate than primary research – making the task of reviewing them easier than is the case for primary research – and there are many extensive registers of systematic reviews (e.g. the Cochrane Library, DARE and DoPHER). Like primary research, systematic reviews can themselves be conducted to varying degrees of quality; overviews of reviews can take this into account and base their findings only on the most reliable reviews. Where overviews of reviews cover an area that has been well covered by systematic reviews, they are able to make strong claims about the strength of evidence in a given area, as they are based on many systematic searches of the literature, and (often) contain a great many studies.



Though there are many benefits to reviewing systematic reviews, there are also limitations inherent in this approach. A systematic review is only as good as the studies it contains; the same applies to an overview of reviews, with the additional layer of the systematic reviews themselves placed between the reviewer and the evidence. There may be differences in the approaches used by the included systematic reviews (e.g. different quality assessment criteria), which make it difficult for the overview to give a balanced perspective across the research field it is covering. For this report, quality criteria were applied in selecting the included reviews, with priority given to RCTs as a means of addressing this limitation.

A related challenge is that of double-counting, as some primary studies inevitably appear in multiple reviews. Although this was thoroughly checked by the reviewers, it can be difficult to eliminate the problem completely. It is also likely that the overview of reviews will not be as up-to-date as a review of primary studies. The most recent systematic reviews included in this report were published in 2010, with the result that any evidence from primary studies published in the last two years or so is not captured here.

Congruence between the question asked by the overview of reviews and the systematic reviews it includes can be another issue, especially when some, but not all, primary studies within a systematic review are relevant to the overview of reviews. Additionally, systematic reviews may differ in their interpretation/ understanding of the findings of the primary studies. Sometimes this is apparent when reviewers disagree with one another as to the findings of a given study, but often mistakes of this kind will go unnoticed. There is also a risk that any errors in the systematic reviews (e.g. misrepresentations of the results or quality of the primary studies) could be replicated in the overview. Finally, the depth of synthesis that it is possible to conduct is less in an overview of reviews than in a systematic review, because the reviewer is that much further away from the original research studies. Rather than being a true synthesis, the findings of an overview of reviews tend to take the form of thematic summaries of the results of the systematic reviews they contain. In an overview of reviews, the analyst is more reliant on the judgements of his/her predecessors than in reviews of primary studies. A specific challenge for this overview was an inconsistency in the terminology and categorisations used across the broad reviews to describe and group the interventions. This, combined with a narrative reporting of results for the categories of intervention types, made the task of extracting results on effectiveness particularly difficult for some interventions.

Being a rapid systematic overview of reviews, this project has the above strengths and weaknesses together with the additional limitation that it needed to be done quickly. Its searches were not as extensive as would normally be the case and so it cannot claim to be comprehensive, either in terms of the findings it contains, or about any gaps that may be apparent. A less tangible, but still important, limitation of doing the overview rapidly is that there was less thinking time available. This may be manifested in, for example, a less well developed conceptual framework, or a failure always to pick up on the implications of particular findings.



6.2 Summary of the evidence

Altogether, the systematic reviews provided evidence for 19 alternative types of non-pharmacological interventions. The effectiveness of each of these interventions is summarised in a table format in Appendix 6.

Table 6.1 below broadly summarises this evidence by categorising each of the 19 alternative interventions into one of six categories based on: a) the potential effectiveness of each treatment (i.e. likely to be effective, not likely to be effective, unclear); and b) the quality of the evidence on which these assessments are based (good/some evidence vs. poor/little evidence).

Table 6.1 Brief summary of the evidence on the potential effectiveness of non-pharmacological interventions in managing neuropsychiatric symptoms and challenging behaviours in patients with dementia

		Potential effectiveness		
		Not likely to be effective	Unclear	Likely to be effective
Quality of the evidence	Good/some evidence	<ul style="list-style-type: none"> Validation therapy 	<ul style="list-style-type: none"> Simulated interaction Cognitive stimulation Reminiscence therapy Reality orientation Light therapy Special care units 	<ul style="list-style-type: none"> Behaviour management techniques Staff and caregiver training and support Massage/touch Music therapy Multi-sensory/sensory stimulation Physical activity/exercise
	Poor/little evidence		<ul style="list-style-type: none"> Relaxation therapy White noise One-on-one stimulation Environmental modifications TENS Pet/animal-assisted therapy 	

As the table shows, there is good, or at least some, evidence that six of the alternative interventions have potential to be effective. The most consistent evidence is found for behavioural management techniques delivered by professional staff, as well as for paid staff and informal caregiver training and support.



There is also promising evidence on the effectiveness of physical activity/exercise, massage/touch therapies, multi-sensory/sensory stimulation (e.g. snoezelen, aromatherapy) and music therapy, for reducing neuropsychiatric symptoms, particularly agitation. However, there remains a lack of rigorous RCT evidence for these interventions, and research findings did not always show a significant impact (or occasionally gave contradictory results).

Only one intervention, validation therapy, was consistently ineffective for managing challenging behaviours.

For the majority of alternative interventions, however, there is either conflicting evidence on their effectiveness (simulated interaction, cognitive stimulation, reminiscence therapy, reality orientation, light therapy, special care units), or a lack of robust evidence (relaxation therapy, white noise, one-on-one stimulation, environmental modifications, pet/animal-assisted therapy, TENS). For these interventions, it is not possible to give an indication as to whether or not the treatment is likely to be effective in managing neuropsychiatric and behavioural symptoms in patients with dementia or in reducing the use of antipsychotic drugs.

The overall conclusions regarding the effectiveness, or lack thereof, of non-pharmacological interventions concur with those of the two overviews of reviews identified in our systematic search (Hulme et al. 2010, Vernooij-Dassen et al. 2010). A general lack of high quality evidence (as judged by the systematic reviewers) meant that the reviews included in this overview refrained from making policy and practice recommendations. For many of the non-pharmacological interventions, this was because there were only one or two studies available. Even when there were more studies available, the quality of these studies was often judged to be moderate to low, usually because of the study design, small sample size and/or reporting issues. A number of the narrow Cochrane reviews failed to identify any RCTs and, even when they did, they were unable to conduct statistical meta-analysis due to the heterogeneity of the studies (i.e. with regard to the type and measurement of outcomes). Although the overview did assess the quality of included reviews, this assessment for the broader reviews (i.e. AMSTAR criterion 7) was not always clear-cut and often differed across studies, making it difficult to ascertain the extent to which findings are trustworthy. Finally, due to time constraints, a small number of reviews (n=5) that were not available online were not included in this overview. Although some of these reviews would probably not have met the quality criteria, it is difficult to assess the impact of these exclusions on the results.

The widespread conclusion of the systematic reviews examined in this overview is that more and better research is needed on non-pharmacological interventions in order to inform future health policy and practice. Such research would include: 1) conducting trials with robust designs and large enough samples to draw meaningful conclusions; 2) greater consistency in the terminology used to describe interventions and in the measurement of patient outcomes; 3) improved reporting of patient characteristics; and 4) clearer descriptions of the context in which interventions are delivered to enable a better understanding of issues to



do with implementation and transferability across care settings. The methodological and reporting issues are best dealt with by following existing guidelines for carrying out high quality research. Also, more can be learned from the literature and current practice regarding the context in which promising interventions have been tested and implemented. Of course, dementia research is still constrained by factors such as the participant's capacity to give informed consent, pressures on caregivers' time, and identifying patients for studies (Hulme et al. 2010), particularly for interventions delivered in the patient's own home. Despite these challenges, high quality research on alternatives to antipsychotics can be done, and should be prioritised, in order to improve the quality of life of patients with dementia and their caregivers.



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Appendix 1

Search strategy

The following search strategy was used for Medline via OVID.

- 1 dement*.ti. (24826)

- 2 alzheimer*.ti. (34576)

- 3 (dement* or alzheimer* or lewy).ab. (84593)

- 4 exp dementia/ (96436)

- 5 ((endpoint* or "end point*" or outcome*) adj6 (dement* or alzheimer* or AD or VaD or lewy)).ab. (1072)

- 6 ((progress* adj5 (dement* or alzheimer* or AD or VaD or lewy)).ab. (5291)

- 7 or/1-6 (126016)

- 8 nonpharmacological.ti. (243)

- 9 ((Cognitive or non-directive or sensory or social or behavio* or recreation or environment* or relaxation or talking or nursing or light or psychosocial or psychological) adj3 (therap* or activit* or intervention* or modify or modificat* or program*)).ab. (64261)

- 10 (psychosocial or psychological).ti. (40794)

- 11 complementary therapies/ (11646)

- 12 combined modality therapy/ (123554)

- 13 recreation/ (4098)

- 14 relaxation therapy/ (5326)

- 15 behavior therapy/ (21030)

- 16 Psychotherapy/ (37263)

- 17 cognitive therapy/ (11189)

- 18 phototherapy/ (4653)

- 19 nonpharmacological.mp. (1533)

- 20 or/8-19 (295949)

- 21 7 and 20 (3547)

- 22 limit 21 to ("review articles" and "reviews (optimized)") (1013)

- 23 limit 22 to (english language and humans) (804)



Appendix 2 Assessing the quality of systematic reviews

AMSTAR: A measurement instrument tool to assess systematic reviews (Shea 2009)

For this review, systematic reviews were included if they met at least criteria 3, 6 and 7.

Comments

<p>1 Was an “a priori” design provided? The research question and inclusion criteria should be established before the conduct of the review.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable</p>
<p>2 Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable</p>
<p>3 Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated, and where feasible, the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable</p>
<p>4 Was the status of publication (i.e., grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable</p>



Appendix 2 Assessing the quality of systematic reviews

		Comments
5	<p>Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
6	<p>Were the characteristics of the included studies provided? In an aggregated form, such as a table, data from the original studies should be provided on the participants, interventions, and outcomes. The ranges of characteristics in all the studies analysed, e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
7	<p>Was the scientific quality of the included studies assessed and documented? “A priori” methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo-controlled studies, or allocation concealment as inclusion criteria); for other types of studies, alternative items will be relevant.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
8	<p>Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable



Appendix 2 Assessing the quality of systematic reviews

		Comments
9	<p>Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e., Chi-squared test for homogeneity). If heterogeneity exists, a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e., is it sensible to combine?).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
10	<p>Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
11	<p>Was the conflict of interest included? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable

“Can't answer” is chosen when the item is relevant but not described by the authors; “not applicable” is used when the item is not relevant, such as when a meta-analysis has not been possible or was not attempted by the authors.



Appendix 3 Characteristics of systematic reviews with a broad focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Ayalon (2006)	<ul style="list-style-type: none"> • Systematic review – multiple study designs • 3 x RCTs • 6 x Single case design 	<ul style="list-style-type: none"> • Home • Community based • Long-term care setting • Acute care setting 	Patient (severity not specified) and carer	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Neuropsychiatric symptoms 		<ul style="list-style-type: none"> • Behavioural management techniques • Caregiver training
Bates (2004)	<ul style="list-style-type: none"> • Systematic review – multiple study designs • 1 x RCT • 3 x other non-RCTs 	<ul style="list-style-type: none"> • Acute care setting (Day hospital) 	Patient with mild or mild to moderate dementia	Mental health: <ul style="list-style-type: none"> • GDS – Depression (as measure of well-being) 	<ul style="list-style-type: none"> • Communication • Functional outcomes (e.g. ADL) • Cognitive outcomes 	<ul style="list-style-type: none"> • Behavioural therapy (Counselling) • Emotion-oriented approaches
Boote (2006)	<ul style="list-style-type: none"> • Systematic review – any controlled study design • 2 x RCTs • 4 x non-RCTs 	<ul style="list-style-type: none"> • Long-term care setting • Acute care setting (Psychiatric hospital) 	Patient with moderate to severe dementia	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Disruptive behaviour Mental health: <ul style="list-style-type: none"> • Mood 	<ul style="list-style-type: none"> • Functional outcomes: <ul style="list-style-type: none"> – Functional ability – Physical performance – Mobility • Cognition • Well-being in patient • Communication 	<ul style="list-style-type: none"> • Sensory enhancement/Relaxation • Emotion-oriented approaches • Structured activities
Hermans (2007)	<ul style="list-style-type: none"> • Cochrane review • RCTs only – none found 	<ul style="list-style-type: none"> • Home 	Dementia patients (severity not specified)	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Wandering 	<ul style="list-style-type: none"> • Functional outcomes • Quality of life (patient & carer) • Carer strain 	<ul style="list-style-type: none"> • No RCTs were identified
Kong (2009)	<ul style="list-style-type: none"> • Systematic review – RCTs only • 7 x RCTs • 7 x randomised cross-over designs 	<ul style="list-style-type: none"> • Community based • Long-term care setting (All but one intervention evaluated in a long-term care setting.) 	Dementia patients with agitation (not specified further)	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Agitation 		<ul style="list-style-type: none"> • Sensory enhancement/Relaxation • Social contact (real or simulated) • Staff training • Behaviour management techniques



Appendix 3 Characteristics of systematic reviews with a broad focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Kverno (2009)	<ul style="list-style-type: none"> • Systematic review – any controlled study design • 5 x RCTs • 4 x Repeated measures randomised cross-over designs • 6 x Single group designs • 8 x other designs 	<ul style="list-style-type: none"> • Long-term care setting 	Patient with moderately severe to very severe dementia	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Agitation Mental health outcomes: <ul style="list-style-type: none"> • Mood 		<ul style="list-style-type: none"> • Sensory enhancement/Relaxation • Social contact (real or simulated) • Behavioural therapy • Emotion-oriented approaches • Structured activities • Medical & nursing care interventions • Environmental modifications
Livingston (2005)	<ul style="list-style-type: none"> • Multiple study designs • Included 162 studies • 12 x RCTs 	<ul style="list-style-type: none"> • Settings not clearly reported but reviewers assume mostly in long-term care settings 	Dementia patients (severity not specified)	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Use of antipsychotics • Other psychotropic 	<ul style="list-style-type: none"> • Institutionalisation • Use of health and social services (nursing time) • Use of restraints (physical) 	<ul style="list-style-type: none"> • Sensory enhancement/Relaxation • Social contact (real or simulated) • Behavioural therapy • Emotion-oriented approaches • Structured activities • Environmental modifications • Caregiver and staff training • Reminiscence therapy
Logsdon (2007)	<ul style="list-style-type: none"> • Systematic review – RCTs only • 14 x RCTs 	<ul style="list-style-type: none"> • Community based • Long-term care setting 	Dementia patients (severity not specified) Informal and paid caregivers	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Range of behavioural symptoms including aggression and agitation 		<ul style="list-style-type: none"> • Staff training



Appendix 3 Characteristics of systematic reviews with a broad focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
O’Connor (2009)	<ul style="list-style-type: none"> • Systematic review – multiple study designs • 10 x RCTs • 15 x repeated measures/before and after design 	<ul style="list-style-type: none"> • Long-term care setting (Nursing homes or long-stay hospital wards) 	<p>Dementia patients (severity not specified) with significant behavioural problems</p> <p>Informal caregivers x 3 studies</p> <p>Professional carers x 3 studies</p>	Neuropsychiatric & behavioural symptoms		<ul style="list-style-type: none"> • Sensory enhancement/Relaxation • Social contact (real or simulated) • Structured activities (Recreation) • Environmental modifications • Caregiver training (informal & paid caregivers) • Training to nursing home staff (communication and behaviour management techniques)
Olazaran (2010)	<ul style="list-style-type: none"> • Systematic review - RCTs only • 179 x RCTs 	<ul style="list-style-type: none"> • Multiple settings not clearly reported 	<p>Patient and carer (not further specified)</p>	Neuropsychiatric & behavioural symptoms	<ul style="list-style-type: none"> • Cognitive outcomes • Institutionalisation • Physical outcomes e.g. physical health • Functional outcomes • Quality of life (in patient or caregiver) • Use of restraints (physical) 	<ul style="list-style-type: none"> • Sensory enhancement/Relaxation • Behavioural therapy • Caregiver training (e.g. CG education, support, case management, respite care, multicomponent) • Staff training • Reminiscence therapy • Support and psychotherapy • Trans-cranial magnetic • Recreation therapy • Stimulation • Combination therapy • Multicomponent (not further described)



Appendix 3 Characteristics of systematic reviews with a broad focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Opie (1999)	<ul style="list-style-type: none"> • Systematic review – 43 studies, multiple study designs • 5 x RCTs • 16 x other designs rated as high & moderate quality • Results focused on those studies 	<ul style="list-style-type: none"> • Community based • Long-term care setting • Acute care setting 	Dementia patients (severity not specified)	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Agitation • Wandering and pacing • Physical aggression • Sleep • Verbal disruption 	<ul style="list-style-type: none"> • Feasibility (i.e. author assigned a feasibility score to different types of interventions) 	<ul style="list-style-type: none"> • Behavioural therapy • Structured activities • Combination therapy • Environmental modifications • Caregiver training
Peacock (2003)	<ul style="list-style-type: none"> • Systematic review – RCTs only • 11 x RCTs 	<ul style="list-style-type: none"> • Community 	Informal caregivers	Neuropsychiatric & behavioural symptoms	<ul style="list-style-type: none"> • Institutionalisation • Mortality (patient) • Quality of life (caregiver) • Stress and strain (caregiver) 	<ul style="list-style-type: none"> • Caregiver training • Case management • Education/skill development • Psychotherapy
Robinson (2007, 2010)	<p>2007:</p> <ul style="list-style-type: none"> • Systematic review – multiple study designs • 8 x RCTs • 3 x non-RCTs <p>2010:</p> <ul style="list-style-type: none"> • Systematic review – multiple study designs • Update of NICE review 2006, but not clear about the range of study designs included 	<p>2007:</p> <ul style="list-style-type: none"> • Long-term care setting • Community based (All but three of the interventions were evaluated in long-term care setting. The others included day centres) <p>2010:</p> <ul style="list-style-type: none"> • Home • Primary care provision 	<p>2007:</p> <p>Mixed populations with dementia or Alzheimer’s Disease</p> <p>2010:</p> <p>Patient mild to moderate dementia</p>	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Wandering 	<p>2007:</p> <ul style="list-style-type: none"> • Patient satisfaction <p>Costs:</p> <ul style="list-style-type: none"> • No cost-effectiveness studies met inclusion criteria <p>Feasibility:</p> <ul style="list-style-type: none"> • Acceptability of interventions 	<p>2007:</p> <ul style="list-style-type: none"> • Sensory enhancement / Relaxation • Behavioural management therapy • Structured activities <p>2010:</p> <ul style="list-style-type: none"> • Information provision • Carer support, • Case management



Appendix 3 Characteristics of systematic reviews with a broad focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Vasse (2010)	<ul style="list-style-type: none"> • Systematic review – any controlled study design • 19 studies included 	<ul style="list-style-type: none"> • Long-term care setting • Acute care setting 	Patient with any level of dementia severity	Neuropsychiatric & behavioural symptoms	<ul style="list-style-type: none"> • Functional outcomes (e.g. ADL) • Communication skills 	<ul style="list-style-type: none"> • Social contact (real or simulated) • Combination therapy (Walk and talk) • Communication strategies
Verkaik (2005)	<ul style="list-style-type: none"> • Systematic review – multiple study designs • 23 studies included 	<ul style="list-style-type: none"> • Home • Community based • Long-term care setting • Acute care setting 	<p>Patient with any level of dementia severity</p> <p>Carer – non-professional</p>	<p>Neuropsychiatric & behavioural symptoms:</p> <ul style="list-style-type: none"> • Apathy • Aggression <p>Mental health outcomes:</p> <ul style="list-style-type: none"> • Depression 		<ul style="list-style-type: none"> • Sensory stimulation • Social contact (real or simulated) • Behavioural therapy • Structured activities • Reminiscence



Appendix 4 Characteristics of systematic reviews with a narrow focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Cameron (2003)	<ul style="list-style-type: none"> • Cochrane Systematic review • 9 x RCTs 	<ul style="list-style-type: none"> • Any setting • TENS of any kinds and with any pattern of duration 	Any degree of dementia severity	Mental health outcomes: <ul style="list-style-type: none"> • Affect • Depression 	Functional outcomes: <ul style="list-style-type: none"> • Level of independent functioning Cognitive outcomes: <ul style="list-style-type: none"> • Visual and verbal short- and long-term memory and semantic verbal fluency • Physical outcomes: Circadian rest-activity rhythm • Adverse effects • Drop out 	<ul style="list-style-type: none"> • Sensory enhancement/ Relaxation • Transcutaneous electrical nerve stimulation – TENS
Christofolletti (2007)	<ul style="list-style-type: none"> • Systematic review • 10 x RCTs 	<ul style="list-style-type: none"> • Home • Long-term care setting 	Any degree of dementia severity	Neuropsychiatric & behavioural symptoms Mental health outcomes: <ul style="list-style-type: none"> • Affective status 	<ul style="list-style-type: none"> • Physical outcomes e.g. physical health • Functional outcomes: ADL, IADL, mobility, risk of falls • Cognitive outcomes • Caregiver’s distress 	<ul style="list-style-type: none"> • Structured activities: motor intervention (physical activity & exercise)
Chung (2002)	<ul style="list-style-type: none"> • Cochrane Systematic review • 3 x RCTs • Any controlled study design (RCTs and non-RCTs) 	<ul style="list-style-type: none"> • Not specified 	Any degree of dementia severity	Neuropsychiatric & behavioural symptoms Mental health outcomes: <ul style="list-style-type: none"> • Mood 	<ul style="list-style-type: none"> • Cognition • Physical outcomes: (i.e. physiological indices) • Client-carer communication 	<ul style="list-style-type: none"> • Sensory stimulation • Snoezelen (multisensory therapy)



Appendix 4 Characteristics of systematic reviews with a narrow focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Clare and Woods (2003)	<ul style="list-style-type: none"> • Cochrane Systematic review • 9 x RCTs 	<ul style="list-style-type: none"> • Home • Community based • Acute care setting 	Early stage vascular dementia and Alzheimer’s Disease	Neuropsychiatric & behavioural symptoms <ul style="list-style-type: none"> • Quality of life in patient • Caregiver burden, strain, coping 	Institutionalisation: <ul style="list-style-type: none"> • Rate of admission to residential care Functional outcomes: <ul style="list-style-type: none"> • ADL Cognitive outcomes: <ul style="list-style-type: none"> • Rate of progression of dementia Use of health and social services Mental health outcomes: <ul style="list-style-type: none"> • Self-reported depression and anxiety • Caregiver depression & anxiety 	<ul style="list-style-type: none"> • Cognitive training interventions
Eggermont (2006)	<ul style="list-style-type: none"> • Systematic review • Multiple study designs: 27 studies, all either RCT or prospective matched cohort studies or other controlled study design 	<ul style="list-style-type: none"> • Home • Long-term care setting 	Any severity of disease	Neuropsychiatric & behavioural symptoms <ul style="list-style-type: none"> • Affective behaviour 	Functional outcomes: <ul style="list-style-type: none"> • Sleep 	<ul style="list-style-type: none"> • Physical activity/ Structured activities



Appendix 4 Characteristics of systematic reviews with a narrow focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Forbes (2009)	<ul style="list-style-type: none"> • Cochrane Systematic review • 8 x RCTs 	<ul style="list-style-type: none"> • Community • Long-term care setting 	Any level of dementia severity	Neuropsychiatric & behavioural symptoms Mental health outcomes: <ul style="list-style-type: none"> • Depression 	Functional outcomes: <ul style="list-style-type: none"> • ADL Cognitive outcomes Institutionalisation Impact on costs of care	<ul style="list-style-type: none"> • Light therapy
Forbes (2008)	<ul style="list-style-type: none"> • Cochrane Systematic review • 4 x RCTs 	<ul style="list-style-type: none"> • Long-term care • Community 	Mixed types of dementia and levels of severity	Neuropsychiatric & behavioural symptoms Mental health outcomes: <ul style="list-style-type: none"> • Depression • Quality of life (caregiver) 	<ul style="list-style-type: none"> • Cognition • Function (ADL) • Mortality (patient and carer) 	<ul style="list-style-type: none"> • Structured activity (i.e. aerobic exercise training or physical activity programs offered over any length of time)
Hansen (2006)	<ul style="list-style-type: none"> • Cochrane Systematic review • 2 x RCTs 	<ul style="list-style-type: none"> • Any setting • Any type of intervention with at least 3 sessions 	Any level of severity	Neuropsychiatric & behavioural symptoms Mood Depression	<ul style="list-style-type: none"> • Cognitive outcomes 	<ul style="list-style-type: none"> • Massage and touch
Harris (2010)	<ul style="list-style-type: none"> • Systematic review – Multiple study designs • 2 x systematic reviews • 6 x RCTs • 12 x quasi-experimental 	<ul style="list-style-type: none"> • Any setting 	Older patients, irrespective of the dementia status	Neuropsychiatric & behavioural symptoms	<ul style="list-style-type: none"> • Physiological variables • Psychological variables • Sleep 	<ul style="list-style-type: none"> • Sensory enhancement/ Relaxation • Slow-stroke back massage and hand massage
Hermans (2007)	<ul style="list-style-type: none"> • Cochrane review • RCTs only (none found) 	<ul style="list-style-type: none"> • Home 	Dementia patient (severity not specified)	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Wandering 	<ul style="list-style-type: none"> • Quality of life (patient and caregiver) • Functional outcomes • Carer strain 	<ul style="list-style-type: none"> • No RCTs were identified



Appendix 4 Characteristics of systematic reviews with a narrow focus (n=15)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type
Lai (2009)	<ul style="list-style-type: none"> • Cochrane Systematic review – Multiple study designs • 8 x non-RCTs with matched controls 	<ul style="list-style-type: none"> • Special Care Units (designed to accommodate needs of people with dementia – compared with other long-term care settings) 	Patients with dementia, Alzheimer’s Disease and related disorders (level of severity not further specified)	Neuropsychiatric & behavioural symptoms Mental health outcomes: <ul style="list-style-type: none"> • Depression • Use of antipsychotics, other psychotropic drugs • Use of restraints (physical) 	<ul style="list-style-type: none"> • Quality of life (in patient or caregiver) 	<ul style="list-style-type: none"> • Environmental interventions • Caregiver training • Staff training • Special Care Unit <i>Note: The SCU is not a single intervention but a set of related interventions which include the following components: admission of residents with dementia; special selection, training and supervision of staff members; specially designed activity programs; family involvement; specially designed physical environment that is segregated from other areas.</i>
Neal (2003)	<ul style="list-style-type: none"> • Cochrane review • 3 x RCT’s 	<ul style="list-style-type: none"> • Long-term care setting 	Any level of dementia severity	Neuropsychiatric & behavioural symptoms		<ul style="list-style-type: none"> • Validation therapy
Price (2001)	<ul style="list-style-type: none"> • Cochrane Systematic review • Multiple study designs (none found) 	<ul style="list-style-type: none"> • Home • Long-term care setting • Acute care setting 	Any level of dementia severity	Neuropsychiatric & behavioural symptoms: <ul style="list-style-type: none"> • Wandering 		<ul style="list-style-type: none"> • Environmental modifications (i.e. subjective barriers)
Sung (2005)	<ul style="list-style-type: none"> • Systematic review • Multiple study designs (n=8; 2 x RCTs) 	<ul style="list-style-type: none"> • Primary studies all conducted in long-term care setting 	Any level of severity but mostly moderate to severe dementia	Neuropsychiatric & behavioural symptoms		<ul style="list-style-type: none"> • Music therapy
Vink (2011)	<ul style="list-style-type: none"> • Cochrane review – RCTs only • 10 x RCTs (Search conducted until June 2010; update of 2003 review) 	<ul style="list-style-type: none"> • Any settings 	Any level of dementia severity	Neuropsychiatric & behavioural symptoms Mental health: <ul style="list-style-type: none"> • Anxiety and depression 	<ul style="list-style-type: none"> • Cognitive outcomes 	<ul style="list-style-type: none"> • Music therapy (any type of music therapy with at least five sessions)



Appendix 5 Characteristics of other review of reviews and practice guidelines (n=3)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type	Overall recommendations/ conclusion
Doody (2001)	<ul style="list-style-type: none"> Systematic review – multiple study designs <p>This is a practice guideline developed by the American Academy of Neurology. Relevant research questions for this review:</p> <p>3) Do educational interventions improve outcomes in patients and/or caregivers? Controlled observational studies.</p> <p>4) Do other non-pharmacological interventions improve outcomes in patients and/or caregivers? RCTs, observational studies and other designs.</p>	Long-term care setting	Population not described (but intervention delivered to patients only)	<p>Neuropsychiatric & behavioural symptoms:</p> <ul style="list-style-type: none"> Agitation Psychosis <p>Mental Health:</p> <ul style="list-style-type: none"> Depression <ul style="list-style-type: none"> Use of antipsychotics Other psychotropic drugs 	<ul style="list-style-type: none"> Functional outcomes (e.g. ADL) Cognitive outcomes Quality of life (in patient or caregiver) Stress and strain/ burden (caregiver) Institutionalisation Urinary incontinence 	<ul style="list-style-type: none"> Sensory enhancement /Relaxation Social contact (real or simulated) Behavioural therapy Environmental modifications Caregiver training Staff training 	<p>The authors recommend:</p> <p>i) the use of antipsychotics for agitation when manipulations to the environment do not work</p> <p>ii) making educational programs available to family caregivers to improve their quality of life and burden and to support the delay to institutionalisation</p> <p>iii) staff to be more aware of the benefits of alternatives to antipsychotic drugs to minimise their use</p> <p>iv) the use of graded assistance, skills practice, and positive reinforcement to support greater functional independence.</p>



Appendix 5 Characteristics of other review of reviews and practice guidelines (n=3)

Title	Review characteristics	Intervention setting	Intervention recipient	Outcomes – reported in this review	Other outcomes – not reported in this review	Intervention type	Overall recommendations/ conclusion
Hulme (2010)	<ul style="list-style-type: none"> Review of reviews on non-pharmacological approaches for dementia potentially accessed and delivered by informal carers 	Reviewer assumes a range of settings, but may be biased towards home/ community settings since delivered by informal carers	People with mild to severe dementia	Neuropsychiatric & behavioural symptoms	<ul style="list-style-type: none"> Functional outcomes (e.g. ADL) Cognitive outcomes 	<ul style="list-style-type: none"> Emotion-oriented approaches (Reminiscence therapy) Environmental modifications Caregiver and staff training Behaviour management techniques Counselling 	The conclusions focused on the ability of carers to access alternatives ways of supporting people with dementia at no extra cost. However, to be more effective, they suggest that additional training and support might be useful.
Vernooj-Dassen (2010)	<ul style="list-style-type: none"> Review of reviews on a range of psycho-social interventions 	Long-term care	People with mild to severe dementia	Neuropsychiatric & behavioural symptoms	<ul style="list-style-type: none"> Functional outcomes (e.g. ADL) Cognitive outcomes 	<ul style="list-style-type: none"> Sensory enhancement /Relaxation Music therapy Snoezelen Behavioural therapy Cognitive skills Structured activities Physical exercise Caregiver and staff training Behaviour management techniques 	The authors recommend further research to be conducted in the use of psycho-social interventions before those responsible for long-term care of patients with dementia can consider these kinds of interventions when preparing individualised care plans.



Appendix 6 Overall summary table: evidence by type of intervention

This table reports a summary of the findings from the broad and narrow reviews. As far as possible, the overlap in primary studies has been accounted for.

Intervention type	Sources	Summary of evidence
Sensory enhancement and relaxation		
<i>Massage/Touch</i>	<p>Narrow reviews = 2: Hansen et al. (2006); Harris and Richards (2010)</p> <p>Broad reviews = 4: Kong et al. (2009); Kverno et al. (2009); Olazaran et al. (2010); Robinson et al. (2007)</p> <p>Primary studies = 9</p>	<p>Six reviews, reporting a total of nine studies, consider the efficacy of massage/touch therapies on the primary outcomes of interest to this overview. A Cochrane review reports positive findings on agitation but concludes that, with only one high quality study available, there is a lack of evidence in this area. Four reviews (one broad, three narrow) also reported positive outcomes in favour of massage/touch therapies for improving behavioural symptoms.</p>
<i>Relaxation therapy</i>	<p>Broad reviews = 1: O'Connor et al. (2009)</p> <p>Primary studies = 1</p>	<p>Only one study reported in one review found no effect of relaxation therapy on agitation, limiting the conclusions that can be drawn for this intervention type.</p>
<i>Music therapy</i>	<p>Narrow reviews = 2: Vink et al. (2003); Sung et al. (2005)</p> <p>Broad reviews = 4: Kverno et al. (2009); O'Connor et al. (2009); Robinson et al. (2007); Opie et al. (1999)</p> <p>Primary studies = 24</p>	<p>Six reviews reported evidence from twenty-four studies on the impact of music therapy on behavioural problems present in patients with dementia. A Cochrane review (n=7 RCTs) identified a positive effect on behavioural problems, but the quality and reporting of the included studies was too poor to draw useful conclusions. Fifteen of the 17 studies included in the other reviews also demonstrated statistically significant effects in reducing agitated behaviours; again, findings must be treated with caution due to the methodological limitations of these studies.</p>
<i>White noise</i>	<p>Narrow reviews = 1: Livingston et al. (2005)</p> <p>Primary studies = 1</p>	<p>Since only one review provided evidence from one low quality study on the efficacy of white noise on reducing agitation (which showed a small but significant effect during treatment only), the conclusions that can be drawn for this intervention is limited.</p>



Appendix 6 Overall summary table: evidence by type of intervention

Intervention type	Sources	Summary of evidence
Sensory enhancement and relaxation		
<i>Multisensory/Sensory stimulation (aromatherapy; snoezelen)</i>	<p>Narrow reviews = 1: Chung and Lai (2002)</p> <p>Broad reviews = 9: Boote et al. (2006); Kong et al. (2009); Kverno et al. (2009); Livingston et al. (2005); O'Connor et al. (2009); Olazaran et al. (2010); Opie et al. (2009); Robinson et al. (2007); Verkaik et al. (2005)</p> <p>Primary studies = 21</p>	<p>Ten reviews identified twenty-one studies evaluating the impact of multisensory stimulation on neuropsychiatric and behavioural problems. The Cochrane review reported findings from two studies on snoezelen, finding no evidence of impact. A further nine reviews reported evidence from an additional nineteen studies on aromatherapy. In many cases, short-term positive results were found, including reduced agitation and apathy, and improved mood and psychological well-being. However, the quality of the studies varied from good to poor and did not always reach statistical significance, leading the authors to conclude that the long-term impacts are still unknown.</p>
<i>Transcutaneous electrical nerve stimulation (TENS)</i>	<p>Narrow reviews = 1: Cameron et al. (2003)</p> <p>Broad reviews = 1: Olazaran et al. (2010)</p> <p>Primary studies = 6</p>	<p>Six studies evaluating the impact of Transcutaneous electrical nerve stimulation (TENS) have been synthesised across two reviews. Both reviews came to the same conclusion that there is no long-term evidence of an effect on behavioural outcomes.</p>
<i>Light therapy</i>	<p>Narrow reviews = 1: Forbes et al. (2009)</p> <p>Broad reviews = 5: Ayalon et al. (2006); Kong et al. (2009); Kverno et al. (2009); Olazaran et al. (2010); Opie et al. (1999)</p> <p>Primary studies = 10</p>	<p>Six reviews report findings from 10 studies on the impact of bright light therapy. Overall, there is insufficient good quality evidence to determine whether light therapy is effective in managing behavioural or psychiatric disturbances associated with dementia.</p>
Social contact – real or simulated		
<i>Pets/animal-assisted therapy</i>	<p>Broad reviews = 1: Kong et al. (2009)</p> <p>Primary studies = 1</p>	<p>Evidence from one study, showing a positive impact on the presence of a dog on agitation, was reported in a single review.</p>



Appendix 6 Overall summary table: evidence by type of intervention

Intervention type	Sources	Summary of evidence
Social contact – real or simulated		
<i>One-on-one stimulation</i>	Broad reviews = 1: Vasse et al. (2010) Primary studies = 3	Three studies identified in one review examined the impact of one-on-one stimulation on people with dementia. No significant effects were reported for neuropsychiatric and behavioural problems.
<i>Simulated interaction/ Family video</i>	Broad reviews = 4: Kong et al. (2009); Kverno et al. (2009); Livingston et al. (2005); O' Connor et al. (2009) Primary studies = 8	Four reviews identified a total of eight studies on the impact of simulated interaction on neuropsychiatric and behavioural outcomes. Three randomised trials judged as sound indicate that simulated presence can reduce agitation during treatment. However, no significant differences of effect were found between groups. The remaining five studies report mixed, non-significant findings for a range of behavioural outcomes.
Cognitive and emotional approaches		
<i>Cognitive stimulation</i>	Narrow reviews = 1: Clare and Woods (2003) Broad reviews = 2: Livingston et al. (2005); Olazaran et al. (2010) Primary studies = 6	Findings from six studies reported in three reviews provide evidence on the effectiveness of cognitive stimulation programs on behavioural and cognitive outcomes. Two reviews suggest there is no evidence of effect on behavioural problems and positive but limited findings on cognitive outcomes. However, one review, conducted more recently, synthesised results from two RCTs which suggest that there are improvements in both sets of outcomes.
<i>Reality orientation</i>	Broad reviews = 3: Bates et al. (2004); Livingston et al. (2005); Verkaik et al. (2005) Primary studies = 14	Three reviews of 14 studies failed to find any significant improvements in behavioural symptoms as a result of participating in reality orientation interventions.



Appendix 6 Overall summary table: evidence by type of intervention

Intervention type	Sources	Summary of evidence
Cognitive and emotional approaches		
<i>Validation therapy</i>	<p>Narrow reviews = 1: Neal and Wright (2009)</p> <p>Broad reviews = 5: Livingston et al. (2005); O'Connor et al. (2009); Olazaran et al. (2010); Vasse et al. (2010); Verkaik et al. (2005)</p> <p>Primary studies = 7</p>	A total of six reviews and seven studies failed to find a significant impact of validation therapy on behavioural and neuropsychiatric outcomes.
<i>Reminiscence therapy</i>	<p>Broad reviews = 3: Boote et al. (2006); Livingston et al. (2005); Olazaran et al. (2010)</p> <p>Primary studies = 12</p>	Three reviews, of 12 studies, synthesised findings on the effectiveness of reminiscence therapy; they failed to find significant improvements in behavioural outcomes for people with dementia.
Physical activity/Exercise		
<i>Physical activity/Exercise</i>	<p>Narrow reviews = 3: Christofletti et al. (2007); Eggermont et al. (2006); Forbes et al. (2008)</p> <p>Broad reviews = 2: Opie et al. (1999); Verkaik et al. (2005)</p> <p>Primary studies = 26</p>	Five reviews, three of which focus specifically on physical activity, report outcomes from a total of 26 studies. Some of the studies overlapped reviews, but the majority were reported in one review only. The reviews suggest that, even after taking into account methodological weaknesses, high intensity physical activity programs can have a beneficial impact on behavioural outcomes.
Environmental modifications		
<i>Environmental modifications</i>	<p>Narrow reviews = 2: Herman et al. (2009); Price et al. (2001)</p> <p>Broad reviews = 2: Livingston et al. (2005); Opie et al. (1999)</p> <p>Primary studies = 14</p>	A total of four reviews and fourteen studies on natural and enhanced environments were identified. None of the studies reported a significant improvement in neuropsychiatric and behavioural problems.



Appendix 6 Overall summary table: evidence by type of intervention

Intervention type	Sources	Summary of Evidence
Behaviour management techniques		
<i>Behaviour management techniques</i>	<p>Broad reviews = 3: Livingston et al. (2005); Robinson et al. (2010); Olazaran et al. (2010)</p> <p>Primary studies = 12</p>	The six RCTs, reported in the three reviews, showed significant reductions in neuropsychiatric symptoms and improvements in behavioural outcomes. The other studies were mostly low quality, but showed evidence to a similar effect (e.g. reductions in agitation and aggressive behaviours).
Staff and caregiver training and support		
<i>Staff and caregiver training and support</i>	<p>Broad reviews = 6: Ayalon et al. (2006); Livingston et al. (2005); Logsdon et al. (2007); Olazaran et al. (2010); O'Connor et al. (2009); Peacock et al. (2003)</p> <p>Primary studies = 22</p>	Evidence on the impact of caregiver training and support interventions were found in six reviews and reported in 22 studies (including 19 RCTs). There was some indication that disruptive behaviours could improve as a result of psycho-education and support, but not when training carers in the use of behaviour management techniques. Overall, it was not always clear precisely what types of training were being provided.
Special Care Units		
<i>Special Care Units</i>	<p>Narrow reviews = 1: Lai et al. (2009)</p> <p>Broad reviews = 1: Livingston et al. (2005)</p> <p>Primary studies = 25</p>	Twenty-five studies investigating the impact of psycho-social interventions delivered in special care units were included in two reviews. Both reviews reported a reduction in neuropsychiatric symptoms, although findings were not always significant.

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Policy Research Unit in Policy Innovation Research

Department of Health Services Research & Policy
London School of Hygiene & Tropical Medicine
15–17 Tavistock Place, London WC1H 9SH

Tel: +44 (0)20 7927 2784
www.piru.ac.uk