

A systematic review of the clinical effectiveness and cost-effectiveness of sensory, psychological and behavioural interventions for managing agitation in older adults with dementia

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Scientific summary

Interventions for managing agitation in older adults with dementia

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Scientific summary

Introduction

The number of people with dementia is rising dramatically with increased longevity. While the core dementia symptom is cognitive deterioration, agitation (inappropriate verbal, vocal or motor activity) is common, persistent and distressing. Its impact can be devastating for people with dementia, their families, and paid carers, and is associated with distress, deteriorating relationships and nursing home admission. Drug treatments, for example antipsychotics or benzodiazepines, have undesirable effects and modest benefits in agitation, and agitation is often difficult to manage. The 2006 National Institute for Health and Care Excellence (NICE) dementia guidelines recommend non-pharmacological interventions, including aromatherapy, music therapy and dance therapy, but the evidence is unclear. Since then, there have been no large systematic reviews of the evidence for non-pharmacological treatment of agitation.

There is, therefore, a need for an up-to-date systematic evidence synthesis of non-pharmacological management of specific neuropsychiatric symptoms, particularly agitation. Effective management may improve quality of life, reduce inappropriate medication use, delay institutionalisation and be cost-effective.

Review question

Which non-pharmacological interventions are effective for reducing agitation in adults with dementia immediately and in the longer term, considering agitation severity, setting, and whether the intervention is with the person with dementia, their carer, or both?

Methods

Protocol

The protocol registration is at www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42011001370.

Study identification

We searched twice using relevant search terms (9 August 2011 and 12 June 2012) in Web of Knowledge (incorporating MEDLINE); EMBASE; British Nursing Index; Health Technology Assessment programme database; PsycINFO; NHS Evidence; System for Information on Grey Literature; the Stationery Office Official Documents website; the Stationery National Technical Information Service; Cumulative Index to Nursing and Allied Health Literature; and The Cochrane Library. We also searched Cochrane reviews of interventions for behaviour in dementia. We hand-searched reference lists of included papers and relevant reviews, and contacted included papers' authors to ask about relevant studies.

Study selection

Inclusion and exclusion criteria

We defined agitation as having a behavioural component. We included papers in any language. Our inclusion criteria were:

- studies evaluating a psychological, behavioural, sensory or environmental intervention to manage agitation
- studies with a comparator group: separate groups or before/after comparisons
- studies with quantitative agitation results
- studies in which all participants had dementia.

We excluded interventions if every individual was given psychotropic drugs or some participants only had medication but no other intervention.

Data extraction

We extracted methodological characteristics; intervention descriptors; who the intervention was with; statistical methods; relevant outcome measures (including if agitation was reported, quality of life or effect on activities of daily living function); length of follow-up; intervention setting; diagnostic details; and summary outcome data (immediate and longer term).

Quality assessment

Each study was given one quality point for dementia diagnosis reliable; agitation measures valid; agitation measures reliable; participant blinded to intervention group; rater blinded to intervention group; randomised controlled trial (RCT) (analysed as randomised); description and adequacy of randomisation; or, if non-randomised, control group comparability; adequate follow-up rate at primary outcome; all participants accounted for; power calculation; full power calculation details; sufficiently powered ($\geq 80\%$ and achieved within 5% of power calculation); intention-to-treat analysis; appropriate statistical analysis (we reanalysed some of the studies, e.g. studies including intervention and control groups but not directly comparing them, or where one-tailed statistical significance tests were used. For these reasons, in some cases we have obtained a result differing from that reported in the original paper), then gave full points, and correct statistical tests. The researchers then assigned a Centre for Evidence-based Medicine level of evidence:

- level 1b: high-quality RCTs: scoring ≥ 10 , had blinded raters and validated outcome
- level 2b: lower-quality RCTs and higher-quality non-randomised studies (scoring ≤ 11)
- level 2c: moderate-quality non-randomised studies (scoring 6–9)
- level 4: scored < 6 and were not RCTs.

We used quality scores and level of evidence to prioritise higher-quality studies.

The intervention categories were psychological, behavioural, sensory or environmental, and were further subdivided into:

- activities
- music therapy (protocol driven and general)
- sensory interventions (all involved touch; some included other stimulation)
- training paid caregivers in person-centred care or communication skills or dementia care mapping (DCM) with supervision [all focused on training paid caregivers to see people with dementia as individuals, finding out about their wants (as opposed to being task focused) and improving communication]
- light therapy (30–60 minutes of daily bright-light exposure)
- home-like care (the homes resembled a domestic environment and had eight or fewer residents, with meals prepared by a small fixed staff team and residents or family carers)
- aromatherapy
- training family carers in behavioural management
- training family carers in cognitive-behavioural therapy (CBT)
- exercise
- changing the environment
- dementia-specific therapies
- pet therapy.

We integrated the results in each category to consider if the evidence was conclusive, preliminary (pointing in a particular direction but the weight of evidence is inconclusive) or absent.

Level of agitation

We considered interventions treating clinically significant agitation, and those decreasing mean agitation symptoms.

Analysis

Light therapy was the only intervention fulfilling a priori meta-analysis criteria: three or more studies with homogenous interventions and outcome measures, and a quality score ≥ 6 .

Standard effect sizes

As we were generally unable to meta-analyse, we estimated standardised effect sizes (SEs) with 95% confidence intervals (CIs) where possible to compare heterogeneous interventions and outcomes using a common effect measure.

Health economic analysis

The aims of the health economic analysis were:

1. to analyse cost and cost-effectiveness studies of non-pharmacological interventions
2. to analyse the cost of non-pharmacological interventions
3. to undertake a cost-effectiveness analysis of non-pharmacological interventions, measured in terms of the incremental cost per unit improvement in agitation
4. to construct a cost-effectiveness model of a non-pharmacological intervention for reducing agitation in adults with dementia.

To achieve the third aim we:

1. undertook an analysis of health and social care costs associated with agitation
2. undertook an analysis of the change in health-related quality of life associated with agitation.

These analyses used data from our 54-month longitudinal cohort study of patients with Alzheimer's disease from London and the south-east region of the UK [London and the South-East Region – Alzheimer's Disease (LASER-AD)].

Results

Included and excluded studies

One hundred and sixty out of 1916 records fitted our inclusion criteria. We discuss the 97 (61%) higher-quality studies (levels 1b, 2b and 2c) in more detail.

Interventions with evidence to support their efficacy: working with the person with dementia

Activities

Ten studies implemented a group activity, of which three studies individualised the activities.

- Activities in care homes reduce agitation levels and decrease symptomatic agitation in care homes while in place: SES = -0.8 to -0.6 .
- There is no evidence for those who are severely agitated or who are not in care homes.
- Individualising activities does not make significant additional reductions in agitation.

Music therapy using a specific protocol

Ten studies of group music therapy followed a specific protocol; they were led by a trained therapist and included specific content such as a warm-up of a well-known song, and a period of listening to, followed by joining in with, music.

- In care homes, music therapy by protocol is effective for decreasing agitation levels immediately, but has no long-term effect: SES = -0.8 to -0.5 .
- There is no evidence for people with severe agitation. There is minimal evidence outside care homes.

Sensory interventions

Sensory interventions included massage, multisensory stimulation and 'therapeutic touch' (healing-based touch focusing on the whole person).

- Sensory interventions significantly improved all levels of agitation during the intervention: SES = -1.3 to -0.6 .
 - This did not affect activities of daily living in the two higher-quality studies, although one lower-quality study found a positive effect.
- Therapeutic touch has no added advantages.
- There is insufficient evidence about long-term effects or in settings outside care homes.

Interventions with evidence to support their efficacy: working through paid caregivers in care homes

Training paid caregivers in person-centred care or communication skills or dementia care mapping, with supervision

We grouped together person-centred care, communication skills training and DCM with supervision (ongoing advice in implementation).

Communication or person-centred care skills

- There is convincing evidence from high-quality studies that training *and supervising* paid caregivers in communication or person-centred care skills is effective for symptomatic and severe agitation, immediately and up to 6 months after: SES = -1.8 to -0.3 .
- There is preliminary evidence of overall agitation levels reduction in care homes and supported living residences, but no evidence in other settings.

Dementia care mapping

- Dementia care mapping is effective immediately and over 4 months for severe agitation in care homes, but there is no evidence about emergent agitation or in other settings: SES = -1.4 to -0.6 .
- There was no effect on the quality of life of people with dementia.

Interventions with the person with dementia without evidence of efficacy

Light therapy

A meta-analysis of the three light therapy studies using the Cohen-Mansfield Agitation Inventory (CMAI) found no overall effect: SES 0.045 (95% credible interval -1.228 to 1.468), consistent with individual studies.

- Bright-light therapy does not improve symptomatic or severe agitation in care homes.

Home-like care

Four large studies evaluated small-group living for people with dementia.

- Moving people with dementia into home-like care does not reduce, and may increase, agitation. This worsens over time.

Aromatherapy

All six aromatherapy studies were in care homes.

- There is good evidence from high-quality studies that aromatherapy does not improve agitation.
- It did not improve quality of life.

Interventions with too little evidence to make definitive recommendations**Training family caregivers in behavioural management for people with dementia living at home**

- There is evidence that teaching behavioural management techniques to family caregivers does not improve severe agitation, either immediately or in the longer term.
- There is insufficient evidence to evaluate it for reducing overall agitation levels.

Education in cognitive-behavioural therapy for family caregivers

There were three studies of training family caregivers in CBT, two of which were with people with severe agitation. None found significant improvements.

- There is lack of evidence of efficacy for teaching family caregivers CBT to treat agitation.

Music therapy without a specific protocol

The 11 studies on music therapy without a specific protocol were all in care homes and typically of lower quality.

- It is unclear whether or not music therapy without a protocol is therapeutic for agitation.
- There is no evidence for longer-term or for severe agitation.

Exercise

All four exercise intervention studies were in care homes and of low quality.

- There is no convincing evidence that exercise is a therapeutic intervention for agitation, but the studies' low standard precludes confident conclusions.

Training programmes for caregivers without supervision

Training in communication skills and person-centred care was not effective without supervision.

- Training staff without supervision seems to be less effective than with supervision.

Changing the environment

Four small studies tested environmental interventions (8–24 participants).

- Studies of environmental interventions are too small and disparate to draw conclusions.

Dementia-specific therapies

Two studies of cognitive stimulation therapy and one of validation therapy found no significant decrease in agitation.

- There is too little evidence to make recommendations on dementia-specific therapies; they are not designed primarily to improve agitation.

Pet therapy

Three small studies considered pet therapy, using both real and simulated animals, with mixed results.

- There is too little evidence to make recommendations about pet therapy for agitation.

Mixed interventions

- There is not enough evidence to make recommendations on simulated presence therapy, wayfinding or mixed activities.

Secondary outcomes

Four included studies also reported on functioning, and seven on quality of life; the findings were mixed but, overall, few interventions showed either improvement in either.

Health economic analysis

We identified two previous cost and cost-effectiveness studies of non-pharmacological interventions for reducing agitation in adults with dementia, of low to middle quality, providing little information on the cost-effectiveness of interventions in a UK context. The review revealed little pre-existing evidence to inform our cost-effectiveness model.

We calculated the costs of 30 interventions that had a significant impact on agitation. Costs ranged from £80 to £696 (activities), from £13 to £27 (music therapy), from £3 to £527 (sensory interventions) and from £31 to £339 (training and supervising paid caregivers in person-centred care or communication skills, with or without behavioural management training, and DCM). Among the 11 interventions that were evaluated using the CMAI, the incremental cost per unit reduction in CMAI score ranged from £162 to £3480 for activities, £4 for music therapy, from £24 to £143 for sensory interventions and from £6 to £62 for training and supervising paid caregivers in person-centred care or communication skills, behavioural management training or DCM.

Using LASER-AD study data, we found that, after adjusting for sex, age, cognitive impairment, follow-up and individual clustering, NHS and Personal Social Services (PSS) costs increase with Neuropsychiatric Inventory (NPI) agitation scores, from around £7000 over 3 months with non-clinically significant agitation symptoms up to around £15,000 at the most severe levels of agitation. The 95% CIs are wider at higher NPI agitation scores, possibly due to the smaller number of observations. We also found that, after adjusting for sex, age, cognitive impairment and individual clustering, there is some evidence that Dementia Quality of Life-Proxy-U (DEMQL-Proxy-U) scores decline with increasing NPI agitation scores, from around 0.75 with clinically non-significant agitation symptoms to around 0.65 with the most severe agitation. The 95% CIs overlap, however, and there is not a clear trend between the lowest and highest NPI agitation scores, possibly due to the relatively small number of observations.

We constructed a new cost-effectiveness model to evaluate interventions for reducing agitation in dementia. It can evaluate interventions that impact on NPI agitation scores. In an illustrative example, we found that a multicomponent intervention in participants with mild to moderate dementia had a positive

monetary net benefit: an 82.20% probability of being cost-effective at a willingness to pay for a quality-adjusted life-year of £20,000 and a 83.18% probability at a value of £30,000.

Discussion

Training paid caregivers in person-centred care, communication skills and dementia mapping *with supervision* during implementation is efficacious for significant agitation at implementation and for some months after. All three interventions seek to communicate with people with dementia, and to understand and fulfil their wishes and needs. The SEEs were clinically significant, suggesting similar efficacy.

Activities, sensory intervention and music therapy by protocol all prevented worsening agitation during the intervention but longer-term effects are unknown; sensory interventions are also useful for clinically significant agitation. Theory-based activities (neurodevelopmental and Montessori education) were more expensive (£590–696) than general pleasant activities (£173–274).

Aromatherapy, light therapy and home-like care do not appear to be clinically effective. There were few level 1 studies; lack of evidence is not evidence of lack of efficacy.

Some interventions may be helpful in preventing agitation from developing or worsening but impractical in clinically significant agitation. This is the first review to consider this.

We recommend the development and evaluation of a manual-based training for staff in care homes for long-term implementation of interventions with evidence for efficacy. Effective interventions to reduce agitation in people with dementia living in their own homes are needed. Health economic evidence is sparse and further research is required.

Study registration

This study is registered as PROSPERO no. CRD42011001370.

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