Evidence-based Synthesis Program

A HSR&D

A Systematic Evidence Review of Non-pharmacological Interventions for Behavioral Symptoms of Dementia

EXECUTIVE SUMMARY

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Prepared by:

Evidence-based Synthesis Program (ESP) Center Portland VA Medical Center Portland, OR Devan Kansagara, MD, MCR, Director

Investigators: Principal Investigator: Maya E. O'Neil, PhD

Co-Investigators: Michele Freeman, MPH Vivian Christensen, PhD Robin Telerant, MD Ashlee Addleman, MPH Devan Kansagara, MD, MCR



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PREFACE

Health Services Research & Development Service's (HSR&D's) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) managers and policymakers, as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout VA.

HSR&D provides funding for four ESP Centers and each Center has an active VA affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence,
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of HSR&D field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at nicole.floyd@va.gov.

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EXECUTIVE SUMMARY

BACKGROUND

In 2004, the Office of the Assistant Deputy Under Secretary for Health for Policy and Planning estimated that the total number of Veterans with dementia would be as high as 563,758 in FY 2010.¹ The VHA Office of Geriatrics and Extended Care (OGEC) in Patient Care Services has primary responsibility for coordination and direction of VHA dementia initiatives. OGEC convened an interdisciplinary Dementia Steering Committee (DSC) in December 2006, with the goal of making recommendations on comprehensive, coordinated care for Veterans with dementia.

The DSC requested VA HSR&D's Evidence-based Synthesis Program (ESP) to review evidence on selected topics, in order to assist with DSC planning efforts. This evidence review addresses the following questions:

Key Question #1. How do non-pharmacological treatments of behavioral symptoms compare in effectiveness with each other, with pharmacological approaches, and with no treatment?

Key Question #2. How do non-pharmacological treatments of behavioral symptoms compare in safety with each other, with pharmacological approaches, and with no treatment?

Key Question #3. How do non-pharmacological treatments of behavioral symptoms compare in cost with each other, with pharmacological approaches, and with no treatment?

METHODS

We conducted searches for systematic reviews of non-pharmacological interventions for dementia in MEDLINE (PubMed), using the following search terms: ("dementia"[MeSH Terms] OR "dementia"[All Fields]) AND systematic[sb]. We also searched in the Cochrane Database of Systematic Reviews and the Cochrane Database of Reviews of Effects (OVID) from database inception through July 2009, using the term dementia.mp. We obtained additional articles from reference lists of pertinent studies. We conducted a separate search for primary studies of animal-assisted therapies because there were no existing systematic reviews on this topic. Additional primary studies were suggested for inclusion by reviewers based on recency and relevance to the field. We summarized the findings of good quality systematic reviews of the primary literature on the various non-pharmacological interventions.

RESULTS

We identified 21 good quality systematic reviews that each examined a single nonpharmacological intervention, and seven good quality systematic reviews that reviewed a variety of interventions. Cognitive/emotion-oriented interventions were reviewed in 10 reports, sensory stimulation interventions in 12 reports, and behavior management techniques in 3 reports. We also added two primary studies related to behavior management techniques identified by our expert panel as neither of these more recent primary articles were included in previous systematic reviews. Three reports reviewed exercise. The search for primary studies of animal-assisted therapies yielded nine prospective studies. Five reports reviewed a variety of interventions for wandering, and one report reviewed various interventions for agitation. Additionally, we added one primary study related to agitation identified by our expert panel as this recent study was not included in the previous systematic reviews. The findings for specific intervention types are summarized below.

Summary of Findings

Key Question #1. How do non-pharmacological treatments of behavioral symptoms compare in effectiveness with each other, with pharmacological approaches, and with no treatment?

Cognitive/Emotion-oriented Interventions

Reminiscence Therapy: Reminiscence therapy involves the discussion of past activities, events, and experiences with another person or a group of people. Two previous systematic reviews identified seven small randomized control trials (RCTs) of reminiscence therapy. This limited body of evidence does not support the use of reminiscence therapy for the treatment of behavioral symptoms of dementia.

Simulated Presence Therapy (SPT): SPT involves the use of audiotapes made by family members containing a scripted conversation about cherished memories about the patient's life. Overall, well-conducted studies are lacking, the evidence that SPT reduces behavioral symptoms of dementia is inconsistent, and SPT may have adverse effects in some patients.

Validation Therapy: Validation therapy is intended to give the individual an opportunity to resolve unfinished conflicts by encouraging and validating expressions of feeling. Four systematic reviews examined the effects of validation therapy in three RCTs as well as other study designs, and found mixed effects. Overall, there is insufficient evidence to draw conclusions about the efficacy of validation therapy for behavioral symptoms, depression, and emotional state associated with dementia.

Sensory Stimulation Interventions

Acupuncture: Acupuncture is an ancient Chinese treatment that has been used for over 3,000 years. One systematic review found no rigorously conducted RCTs. There is no good quality evidence indicating benefit or harm of acupuncture for the treatment of behavioral symptoms for dementia.

Aromatherapy: Aromatherapy consists of the use of fragrant oils from plants, and has been used to promote sleep and reduce behavioral symptoms in individuals with dementia. Overall, there is insufficient evidence that aromatherapy may be an effective treatment for agitation and other behavioral symptoms.

Light Therapy: Light stimulation aims to improve the circadian disturbances in the sleep-wake cycles experienced by individuals with dementia. Two systematic reviews identified six studies, including two RCTs. Although some studies found beneficial effects of bright light therapy on agitation and nocturnal restlessness, studies were generally limited by small sample size and poor quality. The limited body of evidence is insufficient to draw definitive conclusions about the effects of bright light therapy in managing sleep, behavior, or mood disturbances associated with dementia.

Massage and Touch: Massage and touch therapies aim to reduce depression, anxiety, and other behavioral symptoms of dementia. A systematic review identified two small RCTs that reported increased calorie and protein intake in a study that compared touch combined with verbal encouragement during meals to verbal encouragement alone, and reduced agitation in a study that compared hand massage with calming music and with no treatment. This limited body of evidence suggests that, compared with no treatment, hand massage and touch therapy may have beneficial effects.

Music Therapy: Individuals with dementia may retain the ability to sing old songs, and musical abilities appear to be preserved in some individuals despite aphasia and memory loss. Music interventions range from activities administered by a professional music therapist to the presentation of recorded music by caregivers to patients in an individual or group setting. We identified four systematic reviews that examined a variety of study designs. Three RCTs reported reduced aggression, agitation, and wandering while listening to music; and other studies found similar reductions in behavioral symptoms, although there was no evidence of long-term effects. All studies were limited by methodological issues. Overall, well-conducted studies are lacking, but music interventions have potential for reducing agitation in patients with dementia in the short term.

Snoezelen Multisensory Stimulation Therapy: Multisensory stimulation (MSS), otherwise known as Snoezelen therapy, combines the therapeutic use of light, tactile surfaces, music, and aroma. MSS is based on the premise that neuropsychiatric symptoms may result from periods of sensory deprivation. There were six RCTs identified among four systematic reviews. Although the evidence did not consistently demonstrate a durable effect of MSS therapy on behavioral symptoms, preliminary findings of short-term benefits and the reported pleasantness of the treatment suggest that future research is warranted.

Transcutaneous Electrical Nerve Stimulation (TENS): TENS is a non-invasive analgesic technique that is most often used for pain control and occasionally for neurological and psychiatric conditions, such as drug/alcohol dependency, headaches, and depression. A systematic review combined data from three RCTs in individuals with dementia and found no significant effects on sleep disturbances or behavioral symptoms, evaluated immediately after treatment or at six-week follow-up. Although some short-lived improvements in neuropsychological symptoms of dementia have been observed with TENS, definite conclusions on the possible benefits of this intervention cannot be made.

Behavior Management Techniques

Behavior management techniques include a wide variety of behavioral interventions such as functional analysis of specific behaviors, token economies, habit training, progressive muscle relaxation, communication training, behavioral or cognitive-behavioral therapy, and various types of individualized behavioral reinforcement strategies. Findings from three systematic reviews including seven RCTs and two additional more recent trials provide some support for behavior management techniques as effective interventions for behavioral symptoms of dementia. However, mixed study results, the variety of specific interventions across studies, and methodological concerns in many studies suggest that additional research in this area replicating results is warranted.

Other Psychosocial Interventions

Animal-assisted Therapy: There were no RCTs evaluating the effectiveness or harm of pet therapy. Nine non-randomized studies demonstrated decreases in agitated and disrupted behaviors, increases in social and verbal interactions, decreases in passivity, and increases in nutritional intake. The findings suggest that pet therapy has potential for benefit, but more rigorous studies are needed to establish benefit, harms, and feasibility for implementation in VA settings.

Exercise: Three systematic reviews of 59 studies showed inconsistent effects of exercise interventions on behavioral symptoms and functional status. Variations in intensity of exercise intervention, severity of dementia at baseline, and outcome measures make it difficult to draw a firm conclusion. Many of the included studies were small and did not use rigorous methodology. The most consistent evidence showed that exercise did increase sleep duration and decrease nighttime awakenings. While the impact of improved sleep on distal health outcomes remains uncertain, there may be an additional benefit to caregivers who are disproportionally affected by dysfunctional sleep.

Various Interventions Targeting a Specific Behavioral Symptom

Wandering: A variety of interventions for wandering were examined in four systematic reviews. There were no RCTs on the effects of subjective visual barriers, such as mirrors, floor grids, camouflage of doors or doorknobs, and concealment of view through door windows. Two RCTs determined that exercise and walking therapies had no impact on wandering. No evidence is available on the effects of wander gardens. Tracking devices, motion detection devices, and home alarms were generally effective in detecting wandering and locating lost patients in non-randomized studies. Evidence about the effects of sensory stimulation therapies, such as MSS, aromatherapy, and music on wandering, is scant and inconclusive.

Agitation: A systematic review of agitation identified 14 RCTs of a variety of interventions. Three studies of sensory interventions (aromatherapy, thermal bath, calming music, and hand massage) showed a statistically significant decrease in agitation when combined in meta-analysis, but there was substantial variability in the type of intervention, duration of exposure, and outcomes measured. Other interventions including social contact, environmental modification, caregiver training, and behavior therapy showed no effects on agitation. One recently conducted primary study suggested to us by reviewers provided preliminary support for the effectiveness of systematic individualized intervention in decreasing agitation, though a lack of assessor blinding to condition limits the validity of these findings.

Inappropriate Sexual Behavior: There were no systematic reviews that examined the topic of inappropriate sexual behavior among individuals with dementia. Currently, the effectiveness of non-pharmacological treatments for inappropriate sexual behavior is unknown.

Comparative effectiveness among non-pharmacological interventions and between pharmacological and non-pharmacological approaches

None of the systematic reviews captured in our search identified any head-to-head trials that directly compared effectiveness among different non-pharmacological interventions, or between non-pharmacological and pharmacological treatments.

Key Question #2. How do non-pharmacological treatments of behavioral symptoms compare in safety with each other, with pharmacological approaches, and with no treatment?

Cognitive/Emotion-oriented Interventions: One study found that simulated presence therapy increased agitation and disruptive behaviors in some patients. Reality orientation has been observed by caregivers to increase distress, fear, and agitation in individuals with later stages of dementia.

Sensory Stimulation Interventions: For some individuals, the increased stimulation from sensory stimulation therapies such as music therapy and massage/touch therapy may cause increased agitation and aggression. Consideration of the individual preferences in the use of these treatments should be emphasized.

Behavior Management Techniques: None of the systematic reviews nor the primary studies reviewed documented any patient harm or safety concerns resulting from the use of behavior management techniques.

Animal-assisted Therapy: The American Veterinary Medical Association guidelines describe potential physical and emotional harms associated with animal-assisted therapy, but the actual incidence of harms has not been well-studied. Theoretical harms include human injury, zoonotic disease, allergic reactions, and the risk of grief reaction if an animal dies.

Exercise: Potential harms of exercise programs include the increased risk of falls or physical injuries, but risks associated with exercise have not been well studied.

Comparative Safety among Non-pharmacological Interventions and between Pharmacological and Non-pharmacological Approaches

None of the systematic reviews captured in our search identified any head-to-head trials that directly compared safety among different non-pharmacological interventions, or between non-pharmacological and pharmacological treatments.

Key Question #3: How do non-pharmacological treatments of behavioral symptoms compare in cost with each other, with pharmacological approaches, and with no treatment?

None of the systematic reviews or primary articles we retrieved identified direct evidence on the cost-effectiveness of specific interventions. The costs associated with the use of GPS tracking devices and other monitoring systems are high, but the potential increases in patient safety and caregiver peace of mind associated with the use of these devices are notable. The training and veterinary care required for preparing and maintaining a live animal for animal-assisted therapy are costly. Some forms of animal-assisted therapy such as the placement of aquariums in dining areas may be less expensive than more individualized approaches. Behavior management techniques can include a variety of individualized interventions, and therefore expense for these techniques can vary greatly across individuals and settings. Further studies are needed to determine the cost-benefits, harms, and feasibility of these and other non-pharmacological interventions.