Critical review: Three systematic reviews of three treatments for people with dementia of the Alzheimer type (DAT): Montessori-based interventions (MBI); simulated presence therapy (SimPres); and group reminiscence therapy (RT).

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This paper will examine three systematic reviews of studies on three separate treatments for patients with DAT, listed above. As these treatment types are all currently being used in clinical settings, it was felt that a critical examination of each for evidence of efficacy, and any documented levels of evidence, was in order. Recommendations for future research and clinical practice are provided.

Introduction

In 2001, the Academy of Neurologic Communication Disorders and Sciences (ANCDS), the American Speech-Language Hearing Association (ASHA) and the Veteran's Administration of the United States collaborated to establish a committee to provide evidence-based practice guidelines for speech-language pathologists (SLPs) who serve people with DAT. These dementia practice guidelines (DPG) are discussed in depth in Fratali et al., (2003).

Grabowski and Damasio (2004) define dementia as an "acquired and persistent impairment of intellectual faculties" which significantly interfere with activities of daily living, as well as social and occupational operation (Kim, Cleary, Hopper et al., 2006). According to Katzman and Bick (2000), DAT accounts for 66% of people with dementia. Since risk of acquiring dementia is correlated to aging, it is expected that the number of people with dementia will increase dramatically in the years to come as the "baby boomer" generation enters its senior years. Ripich and Horner (2004) therefore expect this cohort to comprise the fastest-growing population treated by SLPs.

Pharmaceutical intervention has made many advances and continues to be a vital form of treatment; however, as Kim, Cleary, Hopper et al. (2006) point out, "SLPs, with their expertise in cognition and communication, are increasingly called on to design and implement interventions that either focus directly on the individual with dementia, or indirectly through managing aspects of their environment, including interactions with caregivers."

Montessori-based interventions in DAT are direct and indirect behavioral interventions, based on the Montessori method (Montessori, 1964). Some features of these techniques include a well-structured environment for the patient, progressing from simple, concrete activities to increasingly more abstract tasks, and using real-life, tangible materials (Mahendra, Hopper, Bayles et al., 2006).

SimPres, short for Simulated Presence Therapy is a patented intervention owned by the SimPres Corporation of Boston, Massachusetts. It involves the use of pre-recorded tapes made by a family member or established caregiver. These tapes are played to the person with DAT in the hope that they may provide comfort and reduce problem behaviors in the patient (Bayles, Kim, Chapman et al. 2006).

RT, short for Group Reminiscence Therapy, is based on the work of Butler (1963) who "...posited that reminiscing about the past would serve an adaptive function for older adults, whereby they could achieve a sense of psychological well-being..." The technique utilizes music, pictures, objects, photographs, or any item germane to the individual's past (Kim, Cleary, Hopper et al. 2006).

Objectives

The primary objective of this paper is to critically evaluate these three systematic reviews and the treatments they examine, respectively. The recommendations section of this paper will provide conclusions based on these evaluations regarding which treatment(s) has the strongest evidence of efficacy.

Methods

Search Strategy

The three treatment types, MBI, SimPRes and RT were chosen as all three have undergone systematic review in the past two years, with the results published in the *Journal of Medical Speech-Language Pathology*.

Mahendra, Hopper, Bayles et al., (2006) (MBI) Bayles, Kim, Chapman et al., (2006) (SimPres) both conducted literature searches in the following databases: Medline, CINHAL, PsychINFO, Cochrane Database of Systematic Reviews, Health

Reference Center, ERIC, the Social Sciences Citation Index and PubMed.

The search terms for MBI were: Montessoribased activities, Montessori methods, education and principles, Montessori programming and materials, as well as several terms related to dementia and Alzheimer's.

The search terms for SimPres were: Simulated Presence Therapy, SimPres, and several other terms related to dementia, senile dementia and Alzheimer's.

The RT review (Kim, Cleary, Hopper et al. 2006) conducted a search as follows: Medline, CINHAL, HealthSTAR, PsychINFO, EBM Reviews, Cochrane Database of Systematic Reviews, ACP Journal Club, Database of Abstracts of Reviews of Effectiveness, Cochrane Controlled Trials Register, AMED and Academic Search Elite. Search terms included: reminiscence, reminiscence therapy, life review dementia of the Alzheimer's type and Alzheimer's disease. Additional hand-searches were also conducted.

In all cases, searches were limited to articles written in English.

Selection Criteria and Data Collection

Mahendra, Hopper, Bayles et al. (2006), (MBI), restricted their inclusion of papers to those which presented original research on Montessoribased interventions for people with DAT, of which the reviewers selected five articles. Descriptive or derivative sources of information were excluded.

Bayles, Kim, Chapman et al. (2006), (SimPres), selected five papers: a description of a feasibility and pilot study, a thesis report of a case study, an article describing an efficacy study, an article on taped memories and related sense of emotional security, and an article describing the perceived effect of SimPres on four individuals with DAT.

Kim, Cleary, Hopper et al.(2006), (RT), excluded all articles which a) did not present a clear diagnosis of DAT in the subjects and b) articles in which "outcome measures did not include assessment of cognitive-linguistic functioning." The reviewers selected six articles which they felt met this criteria.

Classification of Evidence

Mahendra, Hopper, Bayles et al. (2006) and Kim, Cleary, Hopper et al. (2006) utilized the evidence table template developed by the DPG writing committee for classification of evidence contained in articles for review purposes. This table presents five key questions that are intended to assist the reviewer in determining the quality of evidence. The format for the table is taken from Sohlberg et al.

(2003) and Hopper et al. (2005). Bayles, Kim, Chapman et al., (2006) did not employ this format.

Results

Montessori-Based Interventions

Mahendra, Hopper, Bayles et al. (2006) examined participant selection, type activity/intervention used, out-come measures, methodological concerns, and internal, external and construct validities. Further, Montessori-based interventions were assessed for type intervention/activity, and whether these methods were consistent with established Montessori methods.

In their conclusions, the authors rate the five studies reviewed as providing Class II and Class III evidence from Phase I and Phase II studies. These classifications represent weak to moderate levels of evidence.

Clinically applicable trends were recognized across the five studies, suggesting that Montessori activities were "...more beneficial than regular or routine activities in improving performance on cognitive measures...engagement levels...affective states...and social interaction." However, only one of the studies applied standardized tests to the data and the authors stated that they could not provide strong conclusions regarding the correlation between MBI and desired outcomes. (The authors also found significant variation in outcome measures used across the studies, as there were differing target behaviors of interest.)

The authors describe the pooled participants (N=74) as having diagnoses of possible or probable DAT. Of the five articles included, three established a reliable diagnosis of DAT in patients.

In the remaining two studies, no diagnostic criteria is provided.

The authors examined the studies for a range of criteria, including severity of DAT among the patients, living conditions, multiple or comorbidities, ESL and a host of other conditions and found that overall "...there was disparity across the reviewed studies in the type and amount of information about study participants."

In their recommendations, the authors suggested that MBI would likely prove most effective with mild-moderate dementia and reliable auditory and visual abilities, and provided both screening criteria for selection of subjects in future studies, as well as a list of suggested outcome measures.

SimPres

Bayles, Kim, Chapman et al. (2006) focus their review mainly on the feasibility study and its subsequent pilot study, and the efficacy study. The authors conclude that these three studies, taken together, "...support the positive effects of SimPres on agitated and withdrawn behaviors produced by individuals with moderate to severe DAT." However, they also observe that both the feasibility and pilot studies had no control group, and that the data were largely anecdotal. Furthermore, in the efficacy study, the difference in reduction of anxiety between a placebo tape and the SimPres tape was not found to be statistically significant.

Pooled, the participants across the three studies totaled 90, with 54 of these individuals coming from the efficacy study.

Observed trends in the data were limited to nurses and family members reporting favorable impressions of SimPres.

The authors report that the key outcome measures across these three studies, reduction of agitation and withdrawn behaviors, appear to have been met the majority of the time, as reported in the respective study data; again, however, this data is strictly qualitative in nature and anecdotal. Therefore, one can only conclude that this systematic review provides a very weak level of evidence of the efficacy of SimPres.

In their recommendations, with regard to future research, the authors call for a study "...of how SimPres affects language production and whether it is a good stimulus for the production of meaningful language."

Reminiscence Therapy

Kim, Cleary, Hopper et al. (2006) examined six intervention studies containing 122 individuals, and found Class II evidence from Phase I or Phase II research.

The authors examined the studies according to 11 categories: number of subjects, number receiving RT, mean age, gender, diagnosis, severity, vision (screened or not), hearing (screened or not), residence, depression (screened or not) and ethnicity (if mentioned).

Outcome measures varied across the six studies; therefore the authors chose to look at those measures that might truly indicate a change in function due to an intervention.

Four of the six studies provided a group treatment design versus a control group. Of these, only two utilized proper random assignment of participants. The authors further noted that each group had a small number of subjects receiving RT (5-10) and this was seen as limiting generalizability (due to low power).

Taken individually, the two fully randomized, group treatment designs might provide compelling evidence, but the number of participants in each is far

too low. Since the designs and screening methods of the studies are so discrepant from one another, the results cannot be pooled in any meaningful way. Therefore, these six studies provide only moderate levels of evidence, at best.

As far as clinically applicable trends, the authors made the four following conclusions, based on their analyses:

- 1) RT "...may contribute to improved cognitive functioning as measured by the MMSE." (Mini-Mental State Examination)
- 2) RT "...may contribute to improved discourse."
- 3) RT "...may contribute to increased well-being in individuals with dementia and their caregivers."
- 4) "The social nature of the activities ay be an important factor in promoting positive outcomes related to cognition, communication and well-being."

The authors make several recommendations for future research, in particular better screening criteria for potential participants for type and/or subtype of dementia.

Discussion

Appraisal of the Results

It is felt that both the MBI and RT systematic reviews present moderate levels of evidence for the efficacy of their respective treatments. However, the authors uncovered significant methodological weaknesses in the studies they reviewed, and as a result, no strong nor compelling conclusions can be made.

Kim, Cleary, Hopper et al. (2006) conclude that there exists at least preliminary evidence for the positive effects of RT. Mahendra, Hopper, Bayles et al. (2006) make a similar case for MBI. Claims of evidence demonstrating the efficacy of SimPres made by Bayles, Kim, Chapman et al. (2006) are unsubstantiated by the data they present, and therefore cannot be taken as any indication of evidence of the clinical benefit of SimPres.

Subject Selection

By far the most common weakness in subject selection across these studies and these three systematic reviews is in the poor data regarding diagnosis of type, subtype and severity of dementia.

This directly affects the generalizability of the results as it casts the very nature of the population being tested into doubt.

Furthermore, the lack of proper randomization in the majority of studies leaves them vulnerable to confounding variables and hidden treatment effects.

Methodology

Both the MBI and RT reviews raised concerns regarding internal, external and construct validities. Mahendra, Hopper, Bayles et al. (2006) assessed their studies according to four criteria: 1) whether they contained sufficient information to allow replication (external validity); 2) whether the treatment was clearly described and consistently administered; 3) whether measured outcomes were causally related to treatments implemented; and 4) whether participant samples were "well characterized" by the study criteria—that is, were the participants well chosen for the particular study.

The authors concluded that there were "several threats to internal validity" across the five studies...that necessitate caution in interpreting a strict cause-effect relationship between Montessori treatment and observed outcomes."

Kim, Cleary, Hopper et al. (2006) expressed concerns in the data of the two randomized, group treatment design studies regarding patient attrition due to failing health, inconsistencies in staff members participating in the study and disparities between the different settings used across the studies. It was, therefore, not felt that the internal validity of these two studies was particularly strong.

The authors expressed similar reservations regarding the external validity of the studies in question. The main area of concern was in the poor level of detail regarding the patients' diagnoses. There was not consistent nor reliable enough data on dementia type and/or subtype to allow the reviewers to make strong conclusions as to replicability.

Bayles, Kim, Chapman et al. (2006) maintained that the data they examined indicated efficacy of the SimPres method, questions have been raised here as to this conclusion. It does not seem supported by the data, and the authors note many confounding variables (unclear diagnosis, patient illness, caregiver non-compliance) which clearly compromise the internal validity of the work they examined.

The authors concluded that the description of the efficacy study was in sufficient detail to be replicated, and this may be the case; but the opinion expressed here is that a host of new and carefully defined outcome measures is needed.

Recommendations for Future Research

It is felt that both MBI and RT have the most reliable basis from which to conduct further studies. SimPres results suggest that there may be merit to the technique, but there is simply no statistical evidence to support this conclusion at this time. Therefore, further preliminary study is warranted before more elaborate work is attempted.

Screening procedures are vital to the validity of any future studies and should be handled with caution. Criteria should include screening participants for depression, medications affecting wakefulness of cognition, hearing and vision acuity, and, above all, as clear as possible a diagnosis of dementia type and/or subtype. Expense permitting, both MBI and RT would at this time merit a large, randomized control trial with carefully defined outcome measures.

Recommendations for Clinical Practice

Caregivers and clinicians should recognize that the 'problem behaviors' observed in patients with DAT and other dementias are often due to the patients' suffering from significant fear and anxiety cause by their confused state. Montessori-based intervention, group reminiscence therapy and SimPres all work from the basis of attempting to calm and soothe the patient, to assuage such fears and anxieties, with the hope of then proceeding forward and unlocking communication skills.

References

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