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Evidence-Based Practice Recommendations for Working with Individuals with Dementia: Simulated Presence Therapy

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The Academy of Neurologic Communication Disorders and Sciences (ANCDS), the American Speech-Language-Hearing Association (ASHA), its Special Interest Division 2 (SID-2: Neurophysiology and Neurogenic Speech and Language Disorders) and the Veterans Administration (VA) collaborated to establish evidence-based practice guidelines for diagnosing and treating individuals with dementia of the Alzheimer type (DAT). A committee was formed to review the literature and evaluate the evidence for effects of direct and indirect interventions on the communicative functioning of individuals with DAT. In this clinical report are a description and evaluation of the evidence for using simulated presence therapy (SimPres), using personal memories for enhancing well-being, for persons with DAT.

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The Dementia Practice Guidelines (DPG) Committee was formed to develop clinical practice guidelines for diagnosing and treating the cognitive-communicative problems of individuals with DAT. The DPG was charged with searching the literature, evaluating all research related to tests and therapeutic interventions reported to be used with individuals with DAT, and disseminating results of the committee's work through a series of clinical articles. Interventions judged to be within the scope of practice of speech-language pathologists (SLPs), such as those designed to facilitate cognitive-communicative functioning, were reviewed. In this clinical article, the research related to SimPres is evaluated.

CLASSIFICATION OF EVIDENCE

For evaluating research related to interventions for individuals with dementia, the DPG writing committee developed a protocol that included review of the purpose of the study; characteristics of enrolled participants; factors affecting internal, external, and content validity; dose-response characteristics (frequency, intensity, and duration) of the treatment; outcome measures; study results; and methodological issues related to the conduct of the study. To ensure reliability of judgments about the research evidence, each article was rated independently by two members of the DPG writing committee. In this article, one in a series of reports, evidence is presented related to the use of SimPres for persons with DAT.

Alzheimer disease is a neurodegenerative disorder that prominently affects memory and other cognitive domains and interferes with the ability to carry out daily life activities (American Psychiatric Association, 1994). Currently, approximately 4 million Americans have a diagnosis of DAT, and the prevalence doubles every 5 years after age 65 (National Institutes on Aging, 2000). Thus, the need for evidence-based behavioral intervention techniques for people with DAT has never been greater.

Behavioral interventions for persons with dementia are of two types—direct and indirect—depending on whether the interventions are implemented directly by SLPs with persons with Alzheimer disease or indirectly, through caregiver training, modification to the physical environment, and development of routines and activities carried out by others (see Clark, 1995; Hopper, 2001; Mahendra, 2001). SimPres is considered an indirect intervention for persons with DAT.

SIMULATED PRESENCE THERAPY

SimPres is a technique in which a family member, or established caregiver, makes an audiotape about positive events in the life of the individual with dementia that is played to simulate their presence. It is a patented intervention of SimPres Incorporated, Boston, Massachusetts, comprising a "telephonic audiotape recording module" that allows individuals to tape only the caller's portion of a conversation. The authors claim that by exposing an individual with DAT to an audiotape made by a familiar person, an environment is created that may provide comfort and reduce problem behaviors through stimulation of preserved remote memories and positive emotions associated with those memories. SimPres tapes are played through headphones, and the patient wears a hip pack containing an autoreverse cassette player. The use of headphones minimizes ambient noise, and the hip pack provides patient mobility and safety. The audiotapes contain the pauses normal in a two-person conversation that allow the patient-listener to respond if inclined.

LITERATURE REVIEW

An extensive literature search was conducted in several electronic databases: Medline (1966–August 2002), CINAHL (1982–August 2002), HealthSTAR (1980–August 2002), PsychINFO via EBSCO Host (1967–August 2002), Cochrane Database of Systematic Reviews, Health Reference Center (1980–August 2002), ERIC via EBSCO Host (1966–August 2002), the Social Sciences Citation Index (1966–August 2002), and PubMed. Also, manual searches were conducted of relevant textbooks, journals not available electronically, review articles, and book chapters. The following search terms were used: dementia, dementia of the Alzheimer's type, senile dementia, Alzheimer's dementia, Simulated Presence Therapy, SimPres.

Five papers (six studies; Woods & Ashley, 1995, contained two studies) on SimPres were identified through literature search: one by Woods and Ashley (1995) who described a feasibility and subsequent pilot study of SimPres; a thesis report of a case study of the use of SimPres with an individual with dementia with behavioral problems (Protheroe, 1999); an article by Byatt and Cheston (1999) about taped memories as a source of emotional security; an article by Camberg, Woods, Ooi et al. (1999) describing an efficacy study; and a chapter by Cam-

berg, Woods, and McIntyre (1999) that contains an account of the history of SimPres with a report of its effect on the emotional state of four individuals with dementia (three of whom had DAT).

Committee members excluded two papers from review: the case study by Protheroe (1999), which is an unpublished Bachelor's thesis, and the article by Byatt and Cheston (1999), which is not a research study. Three studies were evaluated and included the two reports by Woods and Ashley (1995) and one report by Camberg and colleagues (1999). Woods and Ashley (1995) report results of a feasibility study of SimPres and their follow-up pilot study of the effect of planned use of SimPres on target behaviors in DAT patients. Later, Camberg, Woods, Ooi et al. (1999) describe a collaborative effort to validate the extent to which SimPres improved the psychoemotional status of individuals with DAT.

METHOD OF STUDIES AND RESULTS

Participants

Collectively, the number of participants in the feasibility, pilot, and efficacy studies totaled 90, with the largest sample (N = 54) in the efficacy study. All were reported as having DAT, although limited information was provided about how the diagnosis was made. The 27 individuals in the feasibility study had "moderate to moderately severe cognitive impairment" according to the Global Deterioration Scale (GDS) (Reisberg, Ferris, DeLeon, & Crook, 1982). The 9 DAT patients in the pilot study had "moderate cognitive impairment" on the GDS and the 54 individuals in the efficacy study had "severe cognitive impairment" according to scores on the Mini-Mental State Examination (Folstein, Folstein & McHugh, 1975) (Mean = 5.1, SD = 4.4).

Information about subject age, gender, and residence was provided in the three investigations. Although Camberg, Woods, Ooi et al. (1999) reported that 95% of the participants in their sample were "white," no information was available about the ethnicity or race of participants in the feasibility and pilot studies by Woods and Ashley (1995). Only the efficacy study by Camberg, Woods, Ooi et al. (1999) contained information about hearing, depression, or history of psychiatric illness; namely that individuals were excluded if they had a "severe hearing impairment or premorbid history of psychiatric illness." However, information was not provided about how hearing or affect were assessed. No mention was made of the status of vision.

Method: Feasibility Study

The purposes of the Woods and Ashley (1995) feasibility study were (a) to determine the effect, if any, of SimPres on individuals with DAT and a history of problem behaviors; (b) to identify criteria for the selection of individuals who might benefit from SimPres; and (c) to develop a protocol for using SimPres. Twenty-seven cognitively impaired nursing home residents participated in the study. According to nursing staff report, each had a previously observed problem behavior, such as agitation, and a family member willing to make a SimPres tape. To personalize the content of the audiotapes for the individuals with DAT, family members completed an "asset inventory" designed to elicit information about the patient's favorite memories such as best loved people, family anecdotes, favorite prayers, poems, hobbies, and interests. The researchers reviewed the inventory with each family member to select potential content for the SimPres audiotape. The potential topics were then presented to participants in a conversation that was taped using the telephonic recording module that records both sides of a conversation. Those topics that had a positive impact on the subject's behavior were identified, and a script was subsequently developed for a telephone conversation that became the SimPres tape. Family members were instructed to convey positive emotion through voice as well as content. Each tape approximated 15 minutes in length.

The SimPres tapes were played for residents over a 1-month trial period whenever they displayed the problem behavior previously noted by nursing staff. The nursing staff made a record of the patient's response to the tape (problem behavior lessened or stopped, remained unchanged, or worsened).

Results: Feasibility Study

SimPres was used to treat three types of problem behaviors: social isolation, agitation, and verbal or physical aggression. It appeared most effective in treating social isolation that was displayed by 93% of study participants. Agitation was the second most common problem occurring in 67% of participants; only 7% of participants exhibited aggressive behavior.

The majority of participants (81.5%) responded positively to SimPres. Only five participants failed to show a positive response. Of the types of problem behaviors, SimPres was most effective in treating social isolation as evident from appropriate verbal responses to the content of the tape, smiling, singing, and a reduction or elimination of purpose-

less body movements. Of participants who displayed agitation, 78% displayed improved behavior with SimPres. For the two participants who displayed aggression, the effects of SimPres were equivocal. When participants did not respond favorably to SimPres, their behavior did not worsen but remained unchanged.

Method: Pilot Study

After the feasibility study, Woods and Ashley (1995) recruited nine nursing home residents from two units in a large nursing home for a pilot study. The criteria for inclusion in the study included:

1. a diagnosis of DAT, although how the diagnosis was made was unspecified,
2. history of one or more behavioral problems,
3. a retained capacity for verbal interaction, and
4. a family member willing to participate in the study.

For each subject, one of the recurring problem behaviors was designated as the "target" behavior.

SimPres tapes were made using the method developed in the feasibility study. A target behavioral problem and the time of its likely occurrence were identified for the nine participants from chart review and staff report. Study participants were scheduled to receive SimPres twice daily, in the morning and afternoon or early evening when the problem behavior was anticipated but not necessarily exhibited. Nursing home staff were instructed to record the subject's behavior before SimPres and after on a standard form. Training sessions were conducted with all nursing home staff to familiarize them with study procedures.

The application of SimPres was carried out for a 2-month period during which time the behavior of study participants and their responses to SimPres were documented. There were 425 instances of problem behavior noted, the most common being social isolation that accounted for 39% of the observations. Verbal aggressiveness accounted for 33% although only four residents exhibited the behavior. Agitation was observed in six participants and accounted for 27% of the episodes. All residents exhibited at least one type of problem behavior and most exhibited several; the average for a resident was 47 episodes over the 2-month period.

Results: Pilot Study

The target problem behaviors were observed to improve 91% of the time (388 of the 425 observations) when SimPres was used. In only 7% of the observations did the target problem behavior remain unchanged or worsen. SimPres was refused 2% of the time. The frequency of positive response to SimPres varied across participants ranging from improvement 100% of the time to 68% of the time. SimPres was reported to be as effective for improving disruptive behavior as it was for reducing social isolation.

The nursing staff reported that participants seemed to enjoy the SimPres tapes, and staff perceived SimPres to be more effective than the other forms of intervention they typically used when patients displayed a problem behavior such as distraction. For two participants, the use of SimPres reduced the necessity for pharmacologic intervention to reduce problem behaviors. Also, the nursing staff reported anecdotally that the use of SimPres reduced their own stress in caring for the dementia patients.

The acceptance of the SimPres tapes was high among those patients with "verbal interactive capacity" who were defined as being capable of making appropriate verbal responses and listening when it was appropriate. Six participants continued with the SimPres therapy for 9 months with positive results. In four cases, the tapes were used daily for more than 2 years.

The perceptions of family members about patients' responses to the SimPres tapes mirrored those of the nursing staff. Without exception, all families wanted the nursing staff to continue to use the tapes after the conclusion of the study.

Limitations of the Feasibility and Pilot Studies

Both the feasibility and pilot studies had small sample sizes and no control group. Further, the data indicating a positive response to SimPres were anecdotal, and the people reporting the effect of SimPres were not blind to the treatment given or study purpose. In the feasibility study, the length of the observation period before and after administration of SimPres was unspecified. Also, SimPres was reportedly used when a problem behavior was "anticipated," as well as when one occurred. Lacking is information about how staff decided when a problem behavior seemed imminent. Reviewers were unable to distinguish between the effect of SimPres when it was administered after a problem behavior and when a problem was "anticipated" but not displayed.

Manipulation checks, to ensure adherence to the research protocol, were not mentioned in the descriptions of the feasibility and pilot studies nor was

there information about the reliability of judgments regarding occurrence of problem behaviors or response to SimPres. Treatment fidelity was rated as good for the pilot study because nursing staff recorded observations on a target behavior form that was routinely used, prior to the study, for documenting the existence of problem behaviors, precipitating factors, and outcomes of interventions. Also, researchers had three meetings with staff to educate them about the use of SimPres and documentation procedures.

Method: Efficacy Study

The purposes of the efficacy study were (a) to validate pilot observations made by nursing home staff, and (b) to carry out a more rigorous assessment of the extent to which SimPres improved psychoemotional well-being as evident from the resolution of agitated or withdrawn behaviors. A Latin Squares crossover design (Andersen & Mclean, 1974) with three factors was used: (1) treatment, (2) time, and (3) facility type. The treatments comprised SimPres, a placebo tape, and "usual care."

Description of Treatments

The SimPres tapes were made in the same way in the efficacy study as in the feasibility and pilot studies; however, for 14 of the 54 study participants, a family member was unavailable to make the SimPres tape. Instead, an experienced staff member, familiar with the residents, made the recording.

The nonpersonalized placebo tapes were produced by having an individual, unrelated to the participants, read emotionally neutral articles from the newspaper. "Usual care" was described as including the routine interventions used by nursing staff for behavior management including redirection, physical restraints, and staff interaction.

Each treatment was applied for 17 days over a 4-week course followed by a 10-day washout period.

Study Participants

The 54 individuals who participated in the efficacy study came from nine nursing homes. Five homes were for-profit facilities, three were nonprofit, and one was a Veterans Affairs (VA) facility. Study participants had a "documented diagnosis" of Alzheimer disease or related dementia, but information about the distribution of individuals with DAT or related dementias was not provided. All were 50 years of age or older, were medically stable, and had resided in the nursing home for at least 3 months. Each had a daily history of exhibiting at least one agitated behavior from those listed on the short form of the Cohen-Mansfield Agitation Inventory (Cohen-Mansfield, 1991) or "one indication of withdrawn behavior defined either by 'sounding sad' or 'crying' that occurred at least 'often,'" or were, according to the Multidimensional Observation Scale for Elderly Subjects (Helmes, Csapo, & Short, 1987), seldom interested in activities, social interaction, or in their immediate environment. Resident participants all had a "verbal interactive capacity" that was apparent from their responding and pausing appropriately at "least some of the time" during a conversation in which five questions and comments were introduced by the researchers. Only individuals who tolerated listening through headphones for 5 minutes were included in the study.

Cognitive and Functional Assessments

Numerous cognitive and functional assessments were administered to study participants to characterize their mental status (Mini-Mental State Exam, Folstein et al., 1975; Test for Severe Impairment, Albert & Cohen, 1992), severity of dementia (Bedford Alzheimer's Nursing Scale, Volicer, Hurley, Lathi, & Kowall, 1994), and ability to perform activities of daily living (The ADL Self-Performance Scale, Morris, Fries, & Mehr, 1993).

Outcome Measures

Resolution of agitation and withdrawn behaviors were designated as outcome measures. Agitation was operationally defined as:

> behaviors that communicate to others that the subject is experiencing an unpleasant state of excitement, are observable without subjective interpretation, are not invoked strictly by caregiving activities (to distinguish from resistiveness), are unrelated to known physical needs of the patient that can be remedied (should be addressed by means other than the intervention), and are without motivational intent. p. 448

Withdrawal was defined as "lack of interest in people, activities, or things in the subject's environment, combined with sad mood" (p. 448).

Validity Checks for Identification of Well-Being

Several methods were employed to identify well-being: direct observations by trained nonparticipant observers, daily staff observation logs of partici-

pants' responses to interventions, and weekly behavioral rating surveys by nursing staff.

Trained nonparticipant observers completed a 7-item Observed Agitation Scale developed by the researchers, an agitation visual analog scale, two positive affect items (interest and pleasure) from the Philadelphia Geriatric Center Affect Rating Scale (a withdrawal visual analog scale), and facial diagrams of mood. The staff observation log was similar to the one used in the pilot study and required staff to document the target behavior, the specific intervention, the duration of intervention, and the participant's response. Nursing staff documented daily except for weekends. For the weekly staff survey, the short form of the Cohen-Mansfield Agitation Inventory (Cohen-Mansfield, 1991) was used to document staff observations about frequency of agitated behaviors. Selected items from the Multidimensional Observation Scale for Elderly Subjects (Helmes et al., 1987) were used to record the interest and mood of participants.

Reliability of Observations

A structured time-sampling technique was used by trained nonparticipant observers to complete the measures of well-being. Each subject was observed for at least 3 hours and 20 minutes per week. Interobserver reliability was measured for each observer during training and each phase of data collection. The average overall interobserver reliability was 0.84 across all items. Staff also made and recorded observations on several scales, and their observations correlated with those made by nonparticipant observers (correlations ranged between 0.94 and 0.51).

Results: Efficacy Study

Camberg, Woods, Ooi et al. (1999) reported that SimPres reduced agitation 67% of the time and was significantly better for reducing agitation than usual care or the placebo tape. Similarly, SimPres improved withdrawn behavior 69% of the time and was significantly better than usual care. Although SimPres was not statistically significantly better than the placebo tape for improving withdrawn behavior, improvement occurred nearly twice as often with SimPres as it did with the placebo tape.

Limitations and Evaluation of the Efficacy Study

Internal Validity

A positive feature of the study was that staff members were blind to whether they were administering SimPres or a placebo tape. Also, using staff to evaluate the effect of interventions adds to the validity of the study because of their familiarity with patients and knowledge of their typical behaviors.

Although staff administered a tape intervention (placebo or SimPres), on average, twice daily, they did not necessarily administer them when a target behavior occurred. Instead, the intervention tapes were often used when staff had time to provide them. Although the inclusion of direct observations by trained nonparticipant observers was a desirable feature of the study, they rarely observed the administration of an intervention. In fact, the administration of SimPres was observed only 11.7% of the time in the 8,000 direct observations that were made. Then too, when the observation coincided with the administration of a tape intervention, it did not cover the whole event from start to finish. Using the facial diagrams of mood completed by the observers, study participants were observed with happy expressions during the SimPres intervention "about as often" as during usual care and more often than during the placebo tape.

The most convincing data of the benefit of SimPres came from the report of nursing staff who documented a total of 2,547 responses to interventions for agitation and 1,981 responses to interventions for withdrawn behavior. According to their reports, SimPres reduced agitation significantly more often than the placebo tape and usual care and reduced withdrawn behavior significantly better than usual care but not the placebo tape.

Using responses by staff who completed the short form Cohen-Mansfield Agitation Inventory (Cohen-Mansfield, 1991) and the Multidimensional Observation Scale for Elderly Subjects (Helms et al., 1987) weekly, no significant difference was found between the effect of SimPres and either the placebo tape or usual care. Results indicated a statistically significant difference only between usual care and the placebo tape.

Although the data indicate that SimPres can produce a reduction in agitated and withdrawn behaviors, they did not provide reviewers with a sense of how long the positive effect lasted or the degree to which SimPres was better than usual care or the placebo tape. However, there was some evidence that the SimPres tape elicited more interest from study participants than the other interventions, but participants displayed about the same frequency of agitation during the SimPres phase of the study as during the usual care phase. None of the interventions surpassed each other in influencing mood. Five participants were too ill to participate in all the treatment phases; however, their available information was retained for the statistical analyses.

Lack of compliance by staff in following the directions of the researchers (to administer the interventions when a target behavior occurred) and the limited data about subject response to interventions from the nonparticipant observers limit the conclusions that can be drawn about the efficacy of SimPres compared to other interventions. Nonetheless, reviewers concurred that the study contained evidence that SimPres generally was effective for reducing agitated and withdrawn behaviors.

External Validity: Replicability

Reviewers judged the description of the efficacy study to contain sufficient detail for replication. The SimPres and placebo interventions were well described. Although usual care was less well explained and the reviewers were uncertain as to its form during the study phases, it was not judged to limit the replicability of the study.

Treatment Fidelity and Generalizability of Results

The investigators conducted training sessions with nursing staff prior to beginning the study and included a study monitor to ensure that the research protocol was followed. Unfortunately, however, nursing home staff did not use the audiotapes consistently to "treat" the occurrence of target behaviors, and the study monitors failed to identify this compliance problem. A strength of the study was the use of a standard form for recording problem behaviors, the intervention used by staff to manage the behavior, and the effect of the intervention on the problem behavior. Reviewers judged the results of the investigations to be generalizable to other Caucasian individuals with moderate-severe DAT who receive SimPres.

Outcome Measures

The primary outcome in the efficacy study was well-being, and it was defined as "resolution of agitation and withdrawn behaviors." The investigators used numerous measures of well-being, adding rigor and validity to the study. The results of the reliability checks indicate high interobserver agreement in making judgments about the behavior of participants and the effect of interventions on agitated and withdrawn behaviors.

Dose-Response

Nursing staff were instructed to use the audiotape (SimPres or placebo) at least twice daily Monday through Friday when a target problem behavior occurred. Each treatment continued for 17 days with a 10-day washout period afterwards. Study data confirmed that the interventions were used twice daily although not necessarily to "treat" a target problem behavior.

TRENDS IN DATA

Taken together, the feasibility, pilot, and efficacy studies support the positive effects of SimPres on agitated and withdrawn behaviors produced by individuals with moderate to severe DAT. SimPres appears most effective for individuals who have retained communication skills. Nursing staff were favorably impressed with the effect of SimPres on patient behavior and in some cases continued to use it after the conclusion of the study. Family members also reported positive feelings about SimPres and their participation in making the tapes. The technique capitalizes on the frequent preservation of remote memories in individuals with DAT and the desire of family members to contribute meaningfully to patient care.

CANDIDACY FOR SIMPRES

Results of the SimPres studies suggest that the best candidate for SimPres is an individual with moderate to severe DAT, who does not have a serious bilateral hearing loss, who retains conversational skills, and who is unable to remember recent events. Although the researchers assumed that SimPres would be most useful for individuals with DAT who were unable to remember recent events, it may be that future research will show that it is beneficial for and well-received by individuals in the early, mild stages of dementia.

A criterion for including individuals with DAT in the efficacy study was the ability to tolerate headphones for at least 5 minutes. However, individuals with DAT who cannot tolerate headphones may, nonetheless, benefit emotionally from listening to a SimPres tape without earphones.

Another criterion for inclusion in the Camberg, Woods, Ooi et al. (1999) study was retention of conversational skills. However, it could be the case that future research will yield data that support a behavioral and/or emotional benefit to individuals with DAT who are unable to produce any meaningful conversation.

USE OF SIMPRES BY SLPs

The SLP has a role in determining who is a good candidate for SimPres. SLPs are experienced in

screening hearing, communication skills, and the cognitive processes that support communication. As previously mentioned, candidates for SimPres need to retain some remote memories but not the previous administration of the SimPres tape. Tests of verbal episodic memory requiring individuals to remember a short story for retelling after hearing it and again later after a short delay are frequently given by SLPs. These types of tests are useful for determining whether an individual will remember the event of having heard a SimPres tape in the recent past.

SLPs participate in creating functional maintenance plans for nursing home residents, and SimPres should be considered for reducing agitated behaviors and social isolation. SLPs can oversee the development of the SimPres tape and consult with the caregivers about how to convey positive content and vocal tone. Then too, SLPs can train caregivers in the use of SimPres. Future research may reveal that SimPres is an effective technique for stimulating conversation with individuals with DAT, much like memory wallets and notebooks that are widely used.

FUTURE RESEARCH

Whereas the literature contains many studies of the effect of the physical environment on the behavior of individuals with DAT, relatively little has been published about the effect on behavior and affect of various types of linguistic prompts. The premise underlying SimPres is that the activity of remembering pleasant past events is pleasurable and will produce positive behavior and/or affect. The authors of the SimPres investigations focused on the effect of SimPres on agitated and withdrawn behaviors and not on their language. Needed is a study of how SimPres affects language production and whether it is a good stimulus for the production of meaningful language.

Other research needs related to SimPres include

1. Understanding the length of the effect (positive or negative) on behavior after hearing the tape
2. Comparison of the benefit of developing and using SimPres tapes to the cost of their production
3. Investigating the usefulness of SimPres for individuals with dementia from other causes
4. Documenting the effect of the following variables on the effectiveness of SimPres
   - Tape length
   - The frequency with which it is used
   - Severity of dementia
   - Hearing ability
   - Relation of the person on the tape to the patient
   - Degree of memory impairment

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