CALMING MUSIC AND HAND MASSAGE WITH AGITATED ELDERLY

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ABSTRACT

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Agitated behavior is a widespread problem that adversely affects the health of nursing home residents and increases the cost of their care. Agitated nursing home residents are more likely to be physically or chemically restrained, to fall and to have a lower quality of life. Current strategies to reduce agitated behavior tend to be costly.

This dissertation research examined a relatively inexpensive intervention to reduce the agitated behavior of cognitively impaired nursing home residents. The specific aim was to compare the effect of calming music or hand massage or a combination of calming music and hand massage on the level and type of agitated behavior over time. This four group, repeated measures design used the Progressively Lowered Stress Threshold model (Hall & Buckwalter, 1987) to test the effect of exposure to calming music and hand massage on agitation. This model proposes that in the context of agitation, the stress response can be altered and functionally adaptive behavior achieved by modifying environmental demands and controlling for factors that correlate with the perception of stress.

Power calculations indicated that a sample size of 68 would be adequate to detect significant results. Subjects were randomly assigned to one of four intervention groups: 1) calming music, 2) hand massage, 3) calming music and hand massage simultaneously, or 4) control. Level of agitation was assessed during each of four ten minute observation periods, immediately before the intervention, during the intervention, immediately after the intervention, and at 60 minutes.

Each of the experimental interventions produced a reduction in agitation that was greater than that achieved in the absence of any intervention. The benefit was sustained and increased over time. The level of increased benefit over time was similar in each of the experimental intervention groups. When syndromes of agitated behaviors were examined separately, there were differential levels of reduction of physically aggressive, physically non-aggressive and verbally agitated behaviors. Results of this study provide information on an easily administered intervention that can improve the quality of life for nursing home residents and potentially decrease the cost of their care.

TABLE OF CONTENTS

Page

ACKNOWLEDGMENTS iv

ABSTRACT v

LIST OF TABLES ix

LIST OF FIGURES x

Chapter

1. INTRODUCTION 1

Background and Significance 1
Conceptual Framework 6
Review of Literature 11

Agitation 11

Subject-centered Research 12
Environment-centered Research 14

Music 15
Touch 18

Purpose and Hypotheses 20

2. METHODS 22

Design 22
Sample 23
Instrument 24
Procedure 27

Setting 27
Recruitment and Randomization 27
Instrument 28
Intervention 29

3. RESULTS 33

Subjects 33

Preliminary Analyses 35

Demographics 35
Baseline Levels of Agitation 38

Hypothesis 1, Calming Music 38
Hypothesis 2, Hand Massage 39
Hypothesis 3, Calming Music and Hand Massage 39
Hypothesis 4, Change in Physically Aggressive Behaviors over Time 41
Hypothesis 5, Change in Physically Non-aggressive Behaviors over Time 41
Hypothesis 6, Change in Verbally Agitated Behaviors over Time 42

Additional Analyses 44

Change over Time in All Four Groups 44
Effect of Group on Change Over Time among
Those Receiving Any Experimental Intervention 46

4. DISCUSSION 48

APPENDICES

A. POWER CALCULATIONS 57
B. TRAINING MANUAL FOR RESEARCH ASSISTANTS 61
C. ANOVA SUMMARY TABLES 68
D. HUMAN SUBJECTS COMMITTEE APPROVAL, WORCESTER 70
E. HUMAN SUBJECTS COMMITTEE APPROVAL, AMHERST 71
F. CONSENT FORM 72

REFERENCES 75

LIST OF TABLES

Table		Page
1	Characteristics of the Sample	34
2	Characteristics of the Sample by Site	36
3	Baseline Agitation by Demographic Variables	37
4	Mean Agitation Scores at Baseline	38
5	Mean Agitation Scores after Intervention	40
6	Mean Scores of Physically Aggressive Behaviors over Time	41
7	Mean Scores of Physically Non-aggressive Behaviors over Time	42
8	Mean Scores of Verbally Agitated Behaviors Over Time	43
9	Mean Agitation Scores by Treatment Group over Time	46
10	Mean Agitation Scores of Experimental Treatment Groups Over Time	47

LIST OF FIGURES

Figure		Page
1	Conceptual Framework based on the Progressively Lowered Stress Threshold Model (Hall, & Buckwalter, 1987).	7
2	Calming music and hand massage as interventions to alter the development of agitation in dementia	10
3	Mean agitation scores by treatment group over time	45

CHAPTER I

INTRODUCTION

Background and Significance

Agitation is a widespread problem in the elderly that negatively affects their quality of life (Cohen-Mansfield & Billig, 1986; Teri et al., 1992). The effects of their agitation are also felt by their family members for whom the number of agitated behaviors exhibited in older persons predicts caregiver burden (Hamel et al., 1990) and increases the likelihood that the person will enter a skilled nursing facility (Cohen-Mansfield, 1995; Cohen-Mansfield, Marx, & Rosenthal, 1989; Teri et al., 1992). There, agitation affects the cost of care by increasing the need for staff and for special environmental designs of nursing homes (Cohen-Mansfield, Marx & Rosenthal, 1989).

Agitation is prevalent in the nursing home, affecting between 64% and 93% of residents (Cohen-Mansfield, Marx, & Rosenthal; 1989; Zimmer, Watson, & Treat, 1984). The frequency of agitated behaviors is related positively to the level of cognitive impairment (Cariga, Burgio, Flynn, & Martin, 1991; Cohen-Mansfield, Marx, & Rosenthal, 1990; Cooper, Mungas, & Wheeler, 1990; Swearer, Drachman, O Donnell, & Mitchell, 1988) and may serve as a dysfunctional coping mechanism to protect the cognitively impaired person from real or imaginary threats in the environment (Cohen-Mansfield, Marx, & Rosenthal, 1990). Aggressive agitated behavior occurs more frequently in persons with higher levels of cognitive impairment, whereas verbally agitated behavior is most frequently observed in persons with lower levels of cognitive impairment (Cohen-Mansfield, Marx, & Rosenthal, 1990).

Once in the nursing home, the quality of the agitated older person's life is imperiled still further. The presence of agitated behaviors increases the likelihood that the elderly resident will be physically restrained (Evans & Strumpf, 1990; Werner, Cohen-Mansfield, Braun, & Marx, 1989), and/or chemically restrained (Cariga, Burgio, Flynn, & Martin, 1991). The Omnibus Budget Reconciliation Act (1987) requires that the nursing home resident's regimen be free from unnecessary physical and chemical restraint, but these standards did not address alternative measures to regulate agitated behavior. Thus, there is continued use of restraints in the treatment of agitation (Williams-Burgess, Ugarriza, & Gabbai, 1996).

The prevalence of restraint use in nursing homes ranges from 19% to 85 % (Meyer, Kraenzle, Gettman, & Morely, 1994; Weinrich, Egbert Eleazer, & Haddock, 1995), with a nationwide average of 41% (Evans & Strumpf, 1990). Tinetti, Liu, Marottoli and Gentner (1991) reported that 66% of agitated nursing home residents were restrained at some time, and the mean number of restraint days was 86.5 per year.

In addition to loss of dignity and potential for injury (Lipowski, 1992), residents who were restrained exhibited the same or more agitated behaviors, disorientation, more incontinence and more falls than residents who were not restrained (Tinetti, et al., 1991; Werner, Cohen-Mansfield, Braun, & Marx 1989). These data indicate that agitation in nursing home residents leads to the use of restraints, which in turn leads to a further increase in agitation. Ironically, studies have shown that restraints do not prevent falls associated with serious injury in ambulatory nursing home residents (Evans & Strumpf, 1990) and restraint reduction can actually result in fewer falls and injuries (Meyer et al.,

1994). Additionally, restraint use exposes residents to consequences of immobility such as urinary retention, constipation, osteoporosis, muscle atrophy, limb ischemia, protein-energy malnutrition and dehydration, as well as the potential for strangulation (Meyer et al., 1994; Werner et al., 1989).

Agitated nursing home residents receive more medication to control behavior than the general nursing home population (Cohen-Mansfield, 1986). Cohen-Mansfield (1986) found that 56% of agitated nursing home residents received psychoactive medications. The effectiveness of pharmacological interventions in managing agitated behavior is documented in the literature. Hallucinations and delusions are often treated with neuroleptics such as thioridazine, fluphenazine or haloperidol (Hazzard, Bierman, Blass, Ettinger, & Halter, 1994). Shorter acting benzodiazepines including lorazepam and oxazepam are commonly prescribed to control anxious and agitated behaviors (Gardner & Garrett, 1997). Antidepressants are used to manage co-existing depression (Hazzard, et al., 1994). Beta blockers have been shown to be effective in moderating aggressive behaviors (Gardner & Garrett, 1997). Anticonvulsants are believed to control aggression by affecting neurohormonal mediators (Gardner & Garrett, 1997).

Greater than 90% of the elderly take at least one prescription medication daily, with a higher prevalence among institutionalized elders. Nursing home residents are prescribed between seven and eight medications. Age related changes may result in a longer duration of activity of the drug, a variable drug effect, and an increased incidence of adverse drug reactions. Nursing home residents tend to have a higher disease burden and reduced organ reserve capacity, increasing the potential for drug-drug interactions and

toxicity (Chutka, 1997). Pharmacological interventions as a form of chemical restraint may paradoxically exacerbate the very behaviors they are intended to moderate, causing further cognitive or functional decline (Carlson, Fleming, Smith, & Evans, 1995). Additionally, these interventions introduce the potential for side effects such as gait impairment, falls, difficulty swallowing, anorexia, sedation, hypotension, diminished cognitive function and increased agitation (Carlson et al., 1995; Corrigan, 1989; Gardner & Garrett, 1997; Knopman & Sawyer-Demaris, 1990). Medications used to treat underlying medical conditions can also effect agitated behavior as a side effect of the medication or the resultant change in the resident's health status (Carlson et al., 1995).

Restraints have traditionally been used to control agitated behaviors such as wandering, intrusive behavior, handling things inappropriately, etc., which by nature require intact motor capability. Ironically, fewer physical disabilities were found to be associated with agitated nursing home residents than the general nursing home population (Billig, Cohen-Mansfield, Lipson, & Paulson, 1988). The mean activities of daily living (ADL) score was found to be higher in agitated nursing home residents than the general nursing home population in all areas except bathing (Cohen-Mansfield, 1986). This finding is likely to be due to the greater number of physical disabilities in the non-agitated group necessitating institutionalization. Because nursing homes are usually reimbursed according to the resident's level of ADL functioning, reimbursement is at a lower rate for the agitated, demented resident than the resident with physical disabilities. This presents serious implications for the financial stability of nursing homes that care for a large proportion of demented residents. In order to minimize the use of physical and chemical

restraint, increased staffing is necessary to manage agitated behaviors. This need for increased staff-to-resident ratio coupled with lower reimbursement for the agitated resident underscores the pressing need for the development and utilization of cost effective strategies to manage agitated behavior in elderly nursing home residents.

Nurses, in providing direct care to agitated nursing home residents, are in the position to identify agitated behaviors and intervene promptly, minimizing the escalation of agitation and the use of physical and chemical restraints. Reduction in agitated behaviors of nursing home residents would likely result in decreased costs associated with medications and associated adverse side effects, falls, special environmental designs, and increased staff-to-patient ratios. Because agitation is costly in terms of quality of life for the agitated nursing home resident, as well as in the direct and indirect costs of providing residential care for these persons, the purpose of this study was to evaluate calming music and hand massage as interventions to reduce agitated behavior in agitated nursing home residents with dementia. These interventions are feasible, cost-effective, easily administered, non-pharmacological treatments that can be administered by non-professional, as well as professional caregivers.

Conceptual Framework

The Progressively Lowered Stress Threshold model (PLST) (Hall & Buckwalter, 1987) posits that as the level of dementia increases, the threshold between baseline behavior and agitated behavior decreases. Incremental impairment of the areas of the brain that integrate sensory and cerebral input places the person at greater risk for agitated behaviors. As dementia progresses, fewer stressors are required to move the person toward the threshold beyond which agitation occurs (Figure 1). Together with losses associated with cognition, affect or personality and functioning, there is an increasing frequency of agitated behaviors over the course of the dementing illness. The amount and intensity of perceived stressors contribute to the overall risk for agitated behavior. The greater the total risk, the closer the individual moves toward the threshold beyond which agitation occurs.

The person with dementia becomes less able to receive and process environmental stimuli and tolerate stress because of the progressive loss of brain cells (Hall & Buckwalter, 1987). The PLST model groups symptoms associated with dementing illnesses into four clusters. Intellectual or cognitive losses include deterioration in memory, ability to reason and problem solve, and receptive and expressive language abilities. Affective or personality losses are characterized by emotional lability, social withdrawal, antisocial behavior and psychotic features. Conative or functional losses include the inability to carry out activities necessary for independent living such as managing money, shopping and transportation and progresses to loss of the ability to manage activities of daily living. The fourth cluster relates to the reduction of the stress

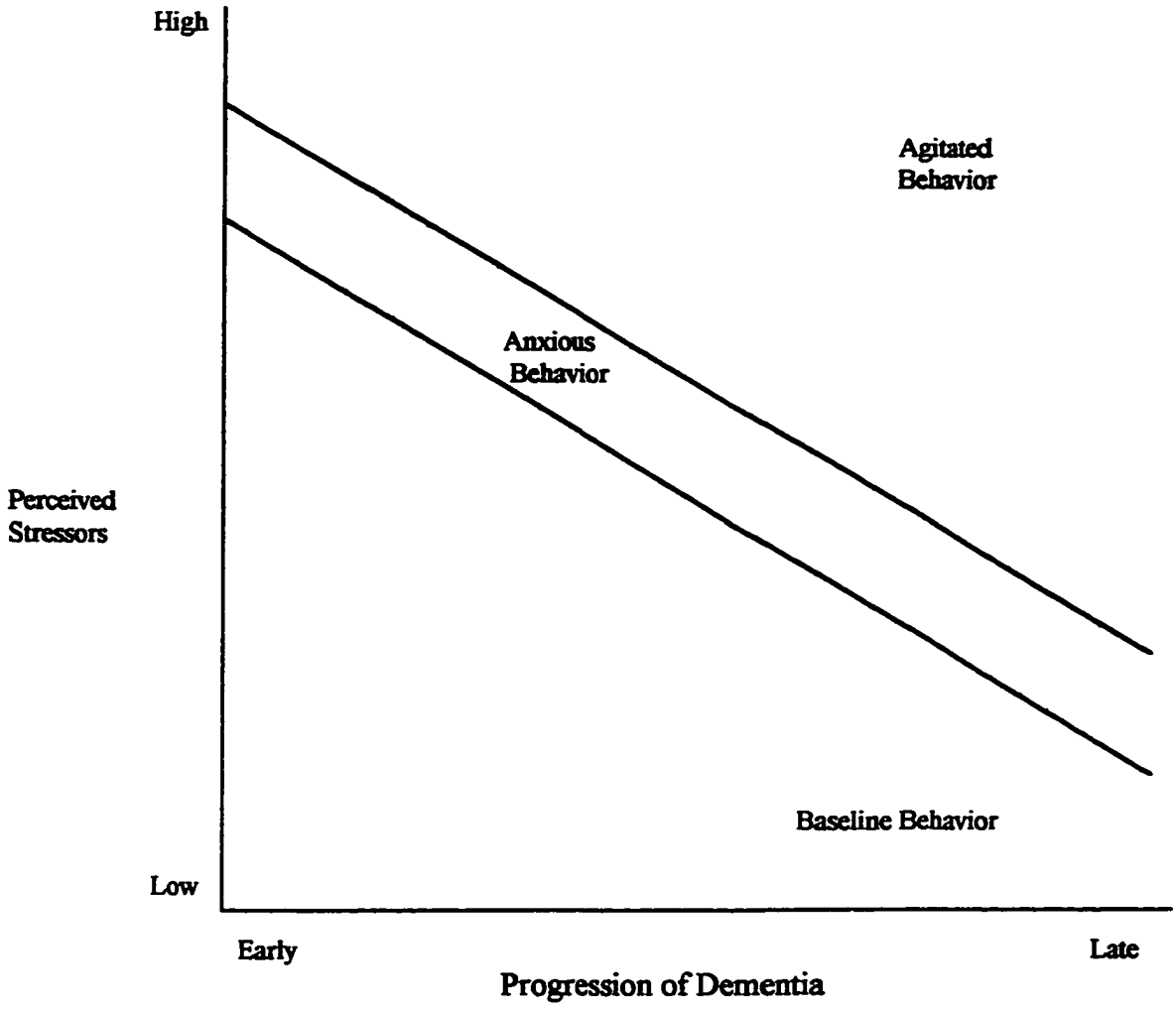

Figure 1. Conceptual framework based on the Progressively Lowered Stress Threshold Model (Hall, & Buckwalter, 1987). Lower line represents baseline between baseline and anxious states; upper line represents threshold between anxious and agitated states.

threshold which results in a greater potential for cognitively and socially inaccessible behaviors (Hall, 1994).

Adults with dementia exhibit three types of behavior; baseline, anxious and dysfunctional, or agitated. As dementia progresses, anxious and dysfunctional behaviors constitute a greater proportion of the behaviors exhibited by the individual (Hall & Buckwalter, 1987). Baseline behavior is a calm state in which individuals are able to communicate and respond to communication from others. They are aware of, and oriented to the environment, and able to function appropriately within the limits of their neurological deficits. Anxious behavior occurs in the presence of perceived stressors. The person avoids eye contact and attempts to evade the offending stimulus. Others in the environment are still able to maintain communication with the person (Hall & Buckwalter, 1987).

If the stressors are sustained, the stress threshold is exceeded and dysfunctional or agitated behavior results (Figure 1). The person becomes unable to communicate or function in the environment appropriately (Hall & Buckwalter, 1987). The prevalence and intensity of agitated behaviors increases as the disease progresses (Hall, 1994). The Progressively Lowered Stress Threshold Model (PLST) (Hall & Buckwalter, 1987) hypothesizes that baseline behavior can be maximized by modifying environmental stimuli and controlling for factors that correlate with the perception of stressors. The stress response can be altered and functionally adaptive behavior achieved by structuring a more supportive environment to compensate for the decreased cognitive abilities of the person with a dementing illness (Hall et al., 1995).

Explicit assumptions of the PLST were derived using theories of coping, adaptation and self-esteem. These are:

1. All humans require some control over their person and their environment and need some degree of unconditional positive regard.
2. All behavior is rooted and has meaning; therefore, all stress-related behaviors have a cause.
3. The agitated patient is not comfortable. All persons have the right to be comfortable (Hall & Buckwalter, 1987).

An assumption implicit in the PLST is that the progression of dementia, hence the progressive lowering of the stress threshold, can not be altered. However, both the environmental stressors and the perception of those stressors are amenable to change. Modulating the amount and intensity of environmental stimuli and/or the perception of these stimuli as stressors can be expected to modify behavior.

Music and touch are two modalities which intervene in different areas within the PLST model (Figure 2). Within the context of agitation, this model suggests that music alters and structures the immediate environment and moderates the intensity of environmental stimuli, or stressors, with a resultant decrease in the level of agitation. Alternately, a gentle tactile intervention alters the perception of stressors, minimizing the effect of environmental stimuli on agitated behavior and potentiating the interchange of calm, baseline behavior for agitation.

Because the interventions are directed at differing aspects in the development of agitation, it is reasonable to examine their joint effects. What is not known is

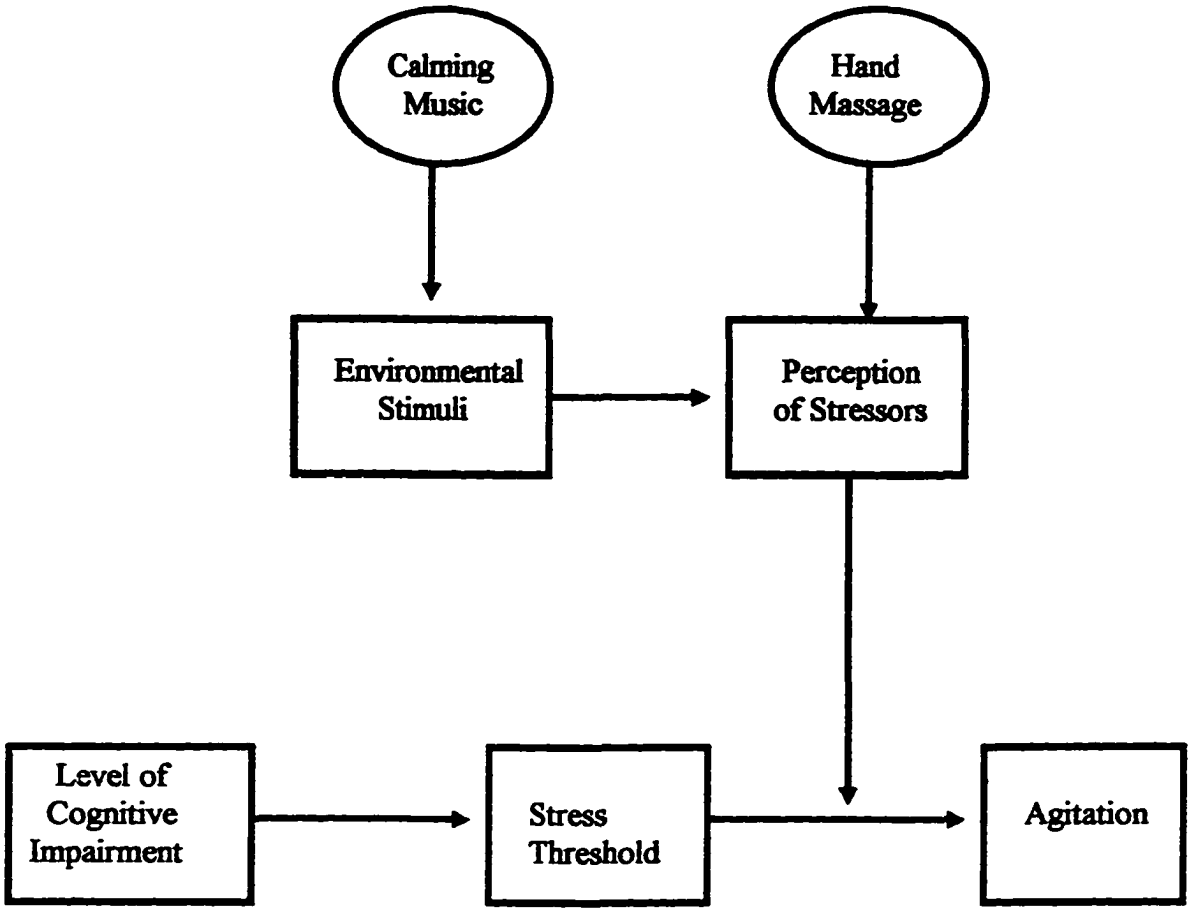

Figure 2. Calming music and hand massage as interventions to alter the development of agitation in dementia

whether music or the tactile intervention modulate behavior equally, or whether one type of intervention is more effective than the other, if there is an additive effect with both interventions, or whether there is a synergistic effect of the two in combination.

Review of Literature

Agitation

The concept of agitation, its etiology and manifestations are not consistently defined in the literature (Cohen-Mansfield & Billig, 1986). Cohen-Mansfield and Billig (1986) proposed that agitation may be a construct of interrelated behavior problems, rather than a unified concept. They defined agitation as inappropriate verbal, vocal or motor activity that is not explained by needs or confusion. Although agitation may result from unmet needs or confusion, these may not be evident to the observer (Cohen-Mansfield & Billig, 1986). Agitation is manifested in three syndromes: physically aggressive behaviors, physically non-aggressive behaviors and verbally agitated behaviors (Cohen-Mansfield, Marx, & Rosenthal, 1989; Miller, Snowdon, & Vaughan, 1995). Behaviors within these syndromes are interrelated and tend to co-occur within individuals (Cohen-Mansfield, Marx, & Rosenthal, 1989; Miller, Snowdon, & Vaughan, 1995; Swearer et al., 1988); therefore, agitation is commonly understood in terms of a construct of related behaviors, rather than a cluster of unrelated behaviors. Cohen-Mansfield (1991) distinguished agitated from non-agitated status within syndromes of agitated behavior as at least one aggressive behavior occurring several times a week, or two or more aggressive behaviors occurring less frequently during one week, or at least one physically non-aggressive or verbally agitated behavior occurring one or more times a day, or two or more of these behaviors occurring less frequently in one week.

Agitated behaviors are a common occurrence in nursing home residents. In a sample of 408 nursing home residents in a single facility, irrespective of the presence of

dementing illness, 93% exhibited agitated behaviors at least once a week and the mean number of agitated behaviors exhibited per resident, per week was 9.3 (SD = 8.6)(Cohen-Mansfield, Marx, & Rosenthal, 1989).

Several investigations of non-pharmacological management strategies for the reduction of agitated behaviors in nursing home residents have yielded favorable results. These intervention studies fall into two categories. Subject-centered research focuses on an intervention directed toward an individual resident in an attempt to decrease agitation. Environment-centered research involves modifying the environment in order to reduce agitation, affecting all persons in the environment concurrently.

Subject-centered Research. Physical restraints are commonly used in the nursing home to treat agitation. To determine whether the use of physical restraints in agitated nursing home residents lead to a change in agitation, Werner, Cohen-Mansfield, Braun, and Marx (1989) conducted hourly observations of 24 nursing home residents over a three month period. Results indicated that restraint use does not reduce agitation. Residents exhibited more agitated behaviors during restrained observations than during nonrestrained observations. Additionally, restraint release resulted in an average decrease in nursing staff time of 150 minutes in an observational study of two nursing home residents (Moorse & McHutchion, 1991).

Sundown syndrome is an often cited cause of increased agitation in nursing homes. Satlin, Volicer, Ross, Herz, and Campbell (1992) hypothesized that exposure to bright light in the evening would decrease agitation and improve sleep in agitated nursing home residents. Ten subjects were exposed to two hours of bright light while seated in a geri-

chair, restrained by a tray. Although sleep patterns were reported to improve, there was no reduction in clinical ratings of agitation.

Premorbid behavior and individual social networks have been linked to the expression of agitation (Kolanowski, 1995). Woods and Ashley (1995) examined the effect of simulated presence therapy on agitated behaviors of nursing home residents (n = 9) with dementia using a pretest-posttest quasi-experimental design. Audiotapes of family members discussing personal topics such as family members and pleasant memories were played for agitated residents. The researchers report that problem behaviors improved significantly after simulated presence therapy.

As cognitive abilities decline, appropriate verbal communication becomes more difficult for the person with dementia. This often makes traditional counseling techniques ineffective. Aroma therapy and massage were used to communicate with nursing home residents with dementia (n = 4) at a more basic level in an attempt to reduce agitated behaviors (Brooker, Snape, Johnson, Ward, & Payne, 1997). Each subject received between eight and 12 trials of each of four treatment conditions (aroma only, massage only, aroma and massage, and no treatment). Results of the case study evaluation of these nursing home residents varied between subjects. Only one subject showed less agitation with aroma therapy. In two subjects, the treatment led to increased agitation. No benefit was shown by the combination of aroma therapy and massage.

Environment-centered Research. An electronic security system as an alternative to restraint use was examined in a group of ambulatory, agitated residents (n = 5) who were considered at risk for wandering off the locked nursing unit. The door to the unit was left unlocked and subjects wore an electronic tag which activated an audio and light alarm at the nurses station if the subject attempted to leave the unit. During the four week study period, exits from the unit decreased 67% (Negley, Molla, & Obenchain, 1990).

Structured group activity sessions held off the unit were shown to reduce agitation in two groups of agitated nursing home residents (Arno & Frank, 1994; Smith-Jones & Francis, 1992). As is with most environment-centered research, additional benefit was realized by nonagitated residents for whom the respite from the disruptive residents increased relaxation, and nursing staff reported increased job satisfaction (Smith-Jones & Francis, 1992)..

The study of visual barriers to prevent exit seeking and intrusion behaviors has shown varied results. Two dimensional grid patterns on the floor in front of exit doors reduced exit attempts in a group of nursing home residents (n = 8) (Hussian & Brown, 1987) however the results were not replicated in a subsequent study (n = 30) (Chafetz, 1990). Camouflaging door knobs with cloth panels resulted in a greater reduction in exit seeking behavior than grid patterns in nursing home residents (n = 7) (Dickinson, McLain, & Marshal-Baker, 1995; Namizi, Rosner, & Calkins, 1989).

Dementia special care units are specially designed units which provide cues for socially desirable behavior and allow for safe, unrestricted wandering. These units have been shown to be effective in decreasing catastrophic reactions in persons with

Alzheimer's disease (Swanson, Maas, & Buckwalter, 1993), reduction in the use of physical restraint, and increased use of chemical restraint (Maas & Buckwalter, 1991; Matthew & Sloane, 1991).

Music

Music has been shown to produce a variety of therapeutic effects in diverse populations. Music was shown to be effective in pain control (Schorr, 1993; Whipple & Glynn, 1992), improving sleep in older persons (Mornhinweg & Voignier, 1995), promoting relaxation in mechanically ventilated patients (Chlan, 1995), reducing anxiety in surgical patients (Winter, Paskin, & Baker, 1995) and in patients who had an acute myocardial infarction (White, 1992), as well as reducing heart rate (Chlan, 1995; White, 1992). Additionally, a music intervention resulted in an increase in positive behaviors and a reduction in restraint use in an acute care setting (Janelli & Kanski, 1997).

An example specific to agitation in nursing home residents is the descriptive study by Cohen-Mansfield and Werner (1995) in which agitated behaviors were decreased when music was present in the environment in a sample of 24 agitated nursing home residents. The author's own research, and that of others, using music to modulate agitated behaviors in nursing home residents has shown favorable results. Although all studies identified were conducted with 30 or fewer subjects, the results indicate that music is an effective intervention to reduce agitated behaviors in nursing home residents. Music has been suggested within the Progressively Lowered Stress Threshold model as a modality which is useful in reducing negative environmental stimuli which lead to the development of agitated behaviors in persons with dementia (Hall, 1994; Hall & Buckwalter, 1987).

Music used as an environment-centered intervention during mealtime reduced agitation in 30 agitated nursing home residents. A 63% reduction in the frequency of agitated behaviors was observed during mealtime with exposure to relaxing music with unrecognizable melodies. There was a differential reduction in the type of agitated behaviors with music. Physically non-aggressive behaviors decreased by 53% and verbally agitated behaviors decreased by 75%. Although no significant decrease in frequency of physically aggressive behavior was observed during the four week study period, fewer types of aggressive behaviors were exhibited among residents indicating a more homogeneous, potentially more easily managed pattern of aggressive behavior (Goddaer & Abraham, 1994).

Ragneskog, Kihlgren, Karlsson and Norberg (1996) investigated the effect of music as an environmental modification to reduce agitation during mealtime in nursing home residents (n = 5) using a quasi-experimental design. When soothing music was played, residents became calmer and exhibited less restlessness. There was a 22 % increase in the time spent on dinner when any type of music was played when compared to the control period, with the largest increase during soothing music, followed by familiar music from the 1920's and 1930's and popular music from the 1980's. While negative behaviors (taking another patient's food, smearing food, pushing away the plate) were observed less frequently when any music was played, these behaviors occurred more often during music from the 1920's and 1930's and popular music than during soothing music. The authors suggest that the change in resident behaviors may have been indirectly

influenced by the relaxing effect of the music on other people in the environment interacting with the agitated resident (Ragneskog, Kihlgren, Karlsson, & Norberg, 1996).

Music was also effective as a subject-centered intervention in the reduction of agitation in nursing home residents. Although music does influence the immediate environment, the focus of the following studies is the effect of music on the individual subject, rather than the effect of an environmental modification on a group of subjects as in the studies cited previously. An individualized music intervention during peak agitation periods was examined in five agitated nursing home residents. Family members were consulted to determine the subject's personal music preference and importance of music to the subject. A reduction in agitated behaviors was shown in four of the subjects during the intervention, and in all subjects one hour postintervention. The findings suggest that there may be a delay in effect due to the amount of time required by the demented individual to process the music and for relaxation to occur. Additionally, the significance of the musical selection to the individual before institutionalization is reported to affect the response (Gerdner & Swanson, 1993).

A pilot study conducted by this author and others (Tabloski, McKinnon-Howe, & Remington, 1995) examined the effect of calming music on the level of agitation in 20 agitated nursing home residents on two occasions. Results indicated that a significant reduction in agitated behaviors occurred both during and 15 minutes after exposure to 15 minutes of calming music. In contrast to the results shown by Gerdner and Swanson (1993), the level of agitation rose slightly after the intervention. This suggests that it was in fact the music that influenced the reduction in agitation. Calming music was shown to

be an effective, non-pharmacologic strategy which caregivers could use to reduce agitated behaviors in nursing home residents. This strategy requires little training and can be used by professional, as well as family caregivers. Recommendations of the study included exploration of tactile interventions that may potentiate the effect of music and increase the calming effect.

While both calming and individualized familiar music have been shown to reduce agitation, the present study will use a standardized piece of calming music to eliminate potential confounding of results by memories or emotions that may be evoked by a familiar tune and their possible influence on agitation.

Touch

As noted with the music literature, touch also appears to elicit therapeutic responses in varied populations. Therapeutic touch was associated with relaxation in healthy subjects, reduction in subjective anxiety in hospitalized subjects and reduction in pain in persons with tension headaches (Gagne & Toye, 1994). Back massage resulted in increased comfort and relaxation in hospice clients (Meek, 1993) and decreased anxiety in nursing home residents (Fraser & Kerr, 1993). Nursing home residents perceived greater affection and immediacy from videotapes portraying a nurse using comforting touch than when the nurse did not use touch (Moore & Gilbert, 1995).

A descriptive study focusing on the relationship between touch and agitation was conducted with agitated nursing home residents (n = 24) (Marx, Werner, & Cohen-Mansfield, 1989). Touch was shown to be differentially related to particular agitated behaviors. Aggressive behaviors were observed more often, and physically non-

aggressive behaviors were observed less often, when residents were touched. The authors hypothesized that, depending on the individual, touch may be viewed as a violation of personal space, resulting in aggression. Alternately, touch may be viewed as a comforting and quieting form of communication, resulting in decreased agitation (Marx, Werner, & Cohen-Mansfield, 1989). The type of touch was not differentiated, and included both comforting touch, as well as the touch involved in providing care and treatments, which may account for the differing responses.

Both hand massage and therapeutic touch produced an increase in relaxation and a decrease in anxious behaviors in a group of nursing home residents (n = 18). A greater response was found with hand massage than with therapeutic touch. There was however, no change in the frequency of agitated behaviors (Snyder, Egan, & Burns, 1995a). In a subsequent study of residents from three Alzheimer's care units (n = 26), the use of hand massage before care activities reduced the frequency and intensity of agitated behaviors during the baseline period and showed inconsistent results during care activities. It was suggested that decreasing the length of the hand massage from ten minutes in the first study to five minutes in the subsequent study may have accounted for the less significant results in the second study (Snyder, Egan, & Burns, 1995b).

Commonalties of the type of touch found in these studies include light pressure, even rhythm and slow strokes. Studies dealing exclusively with therapeutic touch were not considered relevant to this study involving cognitively impaired nursing home residents, as therapeutic touch is described as a reciprocal communication process (Heidt, 1991), and the communication ability of the subjects is likely to be impaired. Additionally,

extensive training and practice is necessary to master therapeutic touch. An anticipated outcome of the present research is an intervention that can be utilized by trained and untrained caregivers to manage agitation. Hand massage was chosen as the form of touch to be used in this study because it is felt to be less threatening in that it is similar to familiar social touch and does not require removal of clothing as is necessary with back massage. Hand massage is proposed as an intervention within the PLST model (Hall & Buckwalter, 1987) which will alter the perception of environmental stressors by redirecting attention from multiple environmental stimuli to a soothing tactile stimulus.

Purpose and Hypotheses

Calming music or hand massage each have been shown to reduce agitated behaviors in nursing home residents with dementia, which is defined as an irreversible decline of cognitive function in the presence of a normal level of consciousness (Rabins & Folstein, 1982). Utilizing a precise definition of agitation, this study investigated the effectiveness of these interventions in reducing agitation, including identifying whether each is equally effective and whether there is an additive or synergistic effect of the combination of interventions on the reduction of agitation in nursing home residents with dementia. The purpose of this study was to compare the effect of calming music, or hand massage, or a combination of calming music and hand massage on the level of agitation in nursing home residents with dementia.

The hypotheses were that:

H1. Agitated nursing home residents with dementia who are exposed to ten minutes of calming music exhibit fewer manifestations of agitation immediately following intervention than those who receive no intervention.

H2. Agitated nursing home residents with dementia who are exposed to ten minutes of hand massage exhibit fewer manifestations of agitation immediately following intervention than those who receive no intervention.

H3. Agitated nursing home residents with dementia who are exposed to ten minutes of a combination of calming music and hand massage exhibit fewer manifestations of agitation immediately following intervention than those who are exposed to calming music alone, hand massage alone or no intervention.

H4. Agitated nursing home residents with dementia experience differential levels of physically aggressive behaviors over time with exposure to calming music, hand massage, a combination of calming music and hand massage, or no intervention.

H5. Agitated nursing home residents with dementia experience differential levels of physically non-aggressive behaviors over time with exposure to calming music, hand massage, a combination of calming music and hand massage, or no intervention.

H6. Agitated nursing home residents with dementia experience differential levels of verbally agitated behaviors over time with exposure to calming music, hand massage, a combination of calming music and hand massage, or no intervention.

CHAPTER 2

METHODS

Design

The Progressively Lowered Stress Threshold model (Hall & Buckwalter, 1987) guided this study of the effect of calming music and hand massage on agitated behavior in nursing home residents with dementia. This chapter reviews the design, sample, instrument, and procedure used to conduct this investigation. The use of a large sample, a precise definition of agitation, and an instrument developed for use in the nursing home to assess agitation address limitations of previous studies.

A four group, repeated measures experimental design was used Agitated nursing home residents were randomly assigned to one of four intervention groups: 1) calming music (CM), 2) hand massage (HM), 3)calming music and hand massage (CM-HM), or 4) control. The CM group received a 10 minute exposure to calming music, the (HM) group received 10 minutes of hand massage, the CM-HM group received 10 minutes of CM and HM administered simultaneously, and the control group received no experimental intervention. The number of occurrences and types of agitated behaviors were recorded on four ten minute occasions using the items on the Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield, Marx, & Rosenthal: 1989): immediately before the intervention, during the intervention, immediately after the intervention, and at one hour.

Sample

With the assistance of Ann Stoddard, Sc.D., Department of Biostatistics and Epedemiology, University of Massachusetts, (personal communication, November 5, 1996), an initial power analysis was performed using PASS software (Hintze, 1996). The level of significance (α), or maximum acceptable risk of rejecting the null hypothesis when it was in fact true, was .05. The probability of rejecting a false null hypothesis, or power ($1-\beta$), was .80. The degree to which the null hypothesis is false, or effect size, was .66 based on prior studies (Goddaer & Abraham, 1994; Snyder, Egan, & Burns, 1995b). With a level of significance of .05, power of .80 and an effect size of .66, a sample size of 40, (ten subjects in each of the four groups) was predicted to be adequate.

To obtain a better estimate of the effect size likely to be realized in this study, a pilot study of 24 agitated nursing home residents was conducted and the data used in a revised power analysis. A power calculation was performed for each pair of groups in the sample for which comparisons were to be performed (APPENDIX A) in order to determine the minimum number of subjects needed to detect significant group difference in reduction in agitation. Effect size in the pilot study was .55. Recalculation of the sample size requirements determined that a total sample of 68 subjects with 17 subjects in each of the four treatment groups is needed to detect significant results with a level of significance of .05 and power of .8.

Subjects in this study were 68 agitated, demented nursing home residents from four nursing homes in Middlesex and Worcester counties in eastern and central Massachusetts. Criteria for inclusion in this study include age of 60 or more years;

diagnosis of dementia (senile dementia of the Alzheimer's type, multi-infarct dementia, senile dementia); exhibition of any agitated behavior occurring an average of one or more times a day during the preceding two weeks as identified by scores on the Cohen-Mansfield Agitation Inventory completed by the charge nurse on the unit; ability to hear; and ability to feel touch on the hands. Subjects who received medication as needed for agitated behavior within the four hours preceding the intervention were excluded. Informed consent was obtained from the family or legal guardian in writing. None refused consent, however two family members requested verbal clarification from the principal investigator prior to giving consent. Verbal assent was obtained from all subjects immediately prior to the intervention. To achieve gender and minority representation in the sample, all residents meeting eligibility criteria in each nursing home were included until the total sample of 68 was obtained.

Instrument

The Cohen-Mansfield Agitation Inventory (CMAI) is a 29 item caregiver rating scale, developed for use in the nursing home, to systematically record the presence and frequency of agitated behaviors in nursing home residents. Each of the 29 items, or agitated behaviors, is rated on a 7-point response format of frequency scaled from 1 (Never) to 7 (Several Times an Hour). Ratings refer to behaviors exhibited during the two weeks preceding the test administration. The CMAI may be administered by a caregiver or by interviewing a staff or family caregiver (Cohen Mansfield, 1991).

Internal consistency of the CMAI has been evaluated using Cronbach's coefficient alpha in a sample of 232 residents of a long-term care facility and reported to be .86, .91

and .87 for the day, evening and night shift, respectively (Finkel, Lyons, & Anderson, 1993). Similar alpha coefficients were reported for a sample of 100 residents of one nursing home, .74, .82 and .87 for the day, evening and night shift (Miller, Snowden, & Vaughan, 1995). Interrater reliability of the CMAI (Pearson's correlation coefficient) has been reported between .82 to .92 (Cohen-Mansfield, Marx, & Rosenthal; 1989; Miller, Snowdon, & Vaughan, 1995).

Content validity of the CMAI was determined by extensive literature search, concept analysis (Cohen-Mansfield & Billig, 1986) and nurses' observations and attributions (Cohen-Mansfield, 1986). Convergent validity of the CMAI was examined by correlating responses on the CMAI and the Behavioral and Emotional Activities Manifested in Dementia (BEAM-D) scale. Correlations of .91, .79 and .92 were reported for the day, evening and night shifts respectively. Similar correlations reported between the CMAI and the Nursing Home Problem Behavior Scale (NHPBS) were .89, .95 and .64 for the day, evening and night shifts (Miller, Snowdon, & Vaughan, 1995). A correlation between the CMAI and the NHBPS was also reported at .91 (Ray, Taylor, Lichtenstein, & Meador, 1992). The CMAI correlated highly with the Brief Agitation Rating Scale (.95, .94 and .95) for the day, evening and night shifts respectively (Finkel, Lyons, & Anderson, 1993). Correlations between the CMAI and the Rapid Disability Rating Scale ranged from .68 to .98 (Chrisman, Tabar, Whall, & Booth, 1991).

Factor analysis in a sample of 408 nursing home residents revealed three factors or syndromes of agitated behavior which were stable across shifts: factor 1, aggressive behavior; factor 2, physically non-aggressive behavior; and factor 3, verbally agitated

behavior (Cohen-Mansfield, Marx, & Rosenthal, 1989). Subsequent factor analysis in a sample of 704 nursing home residents revealed a similar factor structure indicating that the factors represent distinct dimensions of agitation (Miller, Snowdon, & Vaughan, 1995).

The CMAI has been modified from a retrospective data collection instrument to an observer format which is scored for frequency of occurrence of agitated behaviors (Chrisman, Tabar, Whall, & Booth, 1991). A score of "0" indicates that the behavior is not present, "1" indicates that the behavior occurred only once during the observation period, a score of "2" indicates that the behavior occurred two times, etc. The total agitation score is calculated by summing the scores for the individual behaviors. A total score of "0" indicates that the subject is not agitated and a score of one or more indicates the presence of agitation; the higher the score, the greater the agitation.

Interrater reliability of the modified CMAI (CMAI-1) has been reported between .72 and .81 (Pearson correlation) (Chrisman, Tabar, Whall, & Booth, 1991) and 83 to 93 percent agreement (Gerdner, 1998). Interrater reliability for the present study was evaluated by correlating the scores obtained by the principal investigator (PI) and each of the five research assistants (RA) on different occasions. Four observation periods of ten minutes each were compared for each PI and RA pair. Pearson correlations ranged between .93 and 1. A t-test for the five paired samples (PI and RA) verified that there was no significant difference ($t = 1.65$, $df = 28$, $p = .11$) in ratings of agitated behaviors between the principal investigator and the five research assistants.

Convergent validity of the CMAI-1 was examined by correlating the responses on the CMAI-1 with the Ward Behavior Inventory (WBI) and the Confusion Inventory (CI).

Convergent validity was reported to be supported between the modified CMAI and the WBI and the CI, with a stronger correlation between the modified CMAI and the WBI. Correlation coefficients were not reported (Chrisman, Tabar, Whall, & Booth, 1991).

Procedure

This study was approved by the Committee for the Protection of Human Subjects in Research (IRB MULTIPLE ASSURANCE #M-1207) of the University of Massachusetts Medical Center, Worcester, and the University Human Subjects Review Committee of the University of Massachusetts, Amherst (OGCA FILE #97A0641). Letters of agreement to serve as study sites were obtained from the Directors of Nursing and Administrators of the individual nursing homes.

Setting

The Administrator and the Director of Nursing of each facility utilized provided a letter of support of the project. The populations in these nursing homes ranged from 77 to 197 residents, with combined populations of 484 residents. Greater than 90 per cent of the residents of these facilities were 60 years or older and a diagnosis of dementia with agitation was present in approximately 40 per cent of the total population, or approximately 194 people. One of these facilities had a specialized dementia unit, and residents with a diagnosis of dementia were housed throughout each facility.

Recruitment and Randomization

Potential subjects with a medical diagnosis of Alzheimer's disease, multi-infarct dementia or senile dementia were identified by chart review by the principal investigator (PI). The charge nurse was then asked to select from the identified residents, those who

exhibit agitation on a regular basis and document this by completion of the CMAI. If the score on the CMAI indicated that the subject was agitated (at least one agitated behavior occurring one or more times a day or two or more agitated behaviors occurring weekly) the PI then verified this information in the subject's medical record, and if confirmed, the resident was identified as elegible for participation in this study. Informed consent was then obtained in writing from the responsible person listed on the medical record. Demographic data including subject number, gender, age, marital status, diagnosis, length of stay in the nursing home, functional level and level of dementia was collected from the subject's medical record. Prior to data collection, cards were prepared containing a subject number and group assignment and these cards were placed in a sealed envelope. As each subject agreed to participate, an envelope was drawn, providing that subject's number and group assignment. Subjects were thus randomly assigned to one of four groups: 1) CM, 2) HM, 3) CM and HM or, 4) control. Each subject was observed for 10 minutes, the CMAI-1 completed by a trained research assistant to identify the number of agitated behaviors exhibited immediately before the intervention. If a subject's score was less than 1, which indicates the absence of agitation at the time of the study session, he or she was not assigned to an intervention group for that session.

Instrument

The CMAI-1 was utilized to record the number of occurrences of the 29 agitated behaviors during the ten minute observation periods. Training sessions were held prior to data collection, in which research assistants were taught to identify and record occurrences of agitated using the CMAI-1. A predetermined interrater reliability of at

least $r = .80$ was considered adequate to demonstrate proficiency in data collection. Interrater reliability for the five data collectors involved in this study ranged between .93 and 1. Additionally, research assistants practiced the technique for performing the calming music and hand massage protocol until proficiency was demonstrated to the principal investigator.

Intervention

Subjects assigned to the CM group were exposed to 10 minutes of Daniel Kobialka's recording of Pachelbel's Canon in D played on a portable compact disc player at a volume between piano and mezzo-forte, a level slightly higher than the environmental noise level but low enough to allow conversation to be heard. This piece was chosen for its slow tempo (52 beats per minute), soft dynamic levels and repetitive themes. Calming music is neutral and does not contain recognizable melodies that may evoke intense emotional responses. Technically, this music is characterized by slow tempo, soft dynamic levels, and irregular, repetitive themes, and absence of sound impulses (Goddaer & Abraham, 1994).

Subjects assigned to the HM group received ten minutes of hand massage, five minutes on each hand, utilizing the protocol developed by Snyder, Egan and Burns (1995b) as follows:

1. Back of hand massage
   A. Short/medium length straight strokes from wrist to fingertips using moderate pressure.

B. Large half-circular stretching strokes from center to side of hand using moderate pressure.

C. Small circular strokes over entire back of hand using light pressure.

D. Featherlike straight strokes from wrist to fingertips using very light pressure.

2. Palm of hand massage

A. Short/medium length straight strokes from wrist to fingertips using moderate pressure.

B. Gentle milking/lifting of tissue of entire palm of hand using moderate pressure.

C. Small circular strokes over entire palm of hand using moderate pressure.

D. Large half-circular stretching strokes from center of palm to sides using moderate pressure.

3. Finger massage

A. Gentle squeezing of fingers from base to tip on sides and top/bottom using light pressure.

B. Gentle circular range of motion of each finger followed by a gentle squeeze of the nail bed.

4. Completion of hand massage

Lay resident's hand on yours and cover it with your other hand. Gently draw your top hand toward you several times. Turn resident's hand over and gently draw the other hand toward you several times (p.. 61).

Ten minute duration was selected for the HM intervention based on the work of Snyder, Egan and Burns (1995a; 1995b) in which a more significant reduction of agitation was achieved with ten minutes of hand massage than with five minutes. While the preliminary study (Tabloski, McKinnon-Howe, & Remington, 1995) utilized a 15 minute exposure to calming music, this study employed a ten minute intervention to provide consistency in methods. Subjects in the CM-HM group received both of the above interventions simultaneously and subjects in the control group received no experimental intervention during the ten minute intervention period. Preliminary investigation by this author (Tabloski, McKinnon-Howe, & Remington, 1995) has shown maximum effect of music to occur during the intra-treatment measurement. Whereas it was not possible to blind the data collectors to the intervention, a different data collector conducted the intra-treatment measurement.

All subjects were initially assessed for level of agitation and the CMAI-1 scored for time 1 by one research assistant. The CMAI-1 for time 2 was scored during the intervention period by an alternate research assistant in order to blind the data collectors to the assigned intervention. During the ten minutes after the intervention period (time 3) and again at one hour (time 4), subjects were observed for agitated behaviors for ten minutes and the CMAI-1 completed by the original research assistant to determine whether the effect of the intervention was sustained. Research assistants did not initiate conversation with the subject however, they responded to the subject if requested. Subjects were free to discontinue the intervention at any time; none chose to do so.

In order to minimize the potential influence of other environmental stimuli, the intervention was conducted in the patient's room or familiar lounge area. Only one resident was present in the room at the time the resident received an intervention. Times of scheduled activities, meals and routine care administration were avoided to avert stress associated with change in usual routine. As well, interventions were scheduled for the time of day in which peak agitation occurs, as reported by nursing staff for each resident.

CHAPTER 3

RESULTS

Subjects

Subjects were 68 agitated nursing home residents from four long-term care facilities (Table 1). They were mostly women (87%), Caucasian (94%), and ranged in age from 62 to 99 years. The mean age was 82.43. All subjects had a diagnosis of either senile dementia of the Alzheimer's type (SDAT) or multi-infarct dementia on their medical record. Level of dementia for these subjects was indicated as mild (4%), moderate (43%), or severe (53%). Seventeen subjects were married, 31 were widowed, 16 were never married and four were divorced or separated. Length of stay in the nursing home ranged from two months to nine years, four months with 15% residing less than six months, 45% residing between six months and two years, and 40% residing greater than two years. All but one subject were dependent or required assistance with activities of daily living (ADL). ADL scores ranged from "6" indicating independence in six ADL to "18" indicating total dependence, with a median score of 15. Level of education in this sample ranged between no formal education for one subject to a Ph.D. for one subject, with a majority having completed less than a high school education (56%). Thirty-two per cent of the subjects completed high school, six per cent completed Bachelors degrees and three per cent completed Masters degrees.

Table 1. Characteristics of the Sample

	Value	Frequency	Percent
Age	60-69	7	10.3
	70-79	14	20.6
	80-89	30	44.1
	90-99	17	25
Gender	Female	59	86.8
	Male	9	13.2
Race	White	64	94.1
	Non-white	4	5.9
Marital Status	Married	17	25
	Widowed	31	45.6
	Single	16	23.5
	Divorced	2	2.9
	Separated	2	2.9
Education	None	1	1.5
	Less Than High School	38	55.9
	High School	22	32.4
	Bachelors Degree	4	5.9
	Masters Degree	2	2.9
	Ph.D.	1	1.5
Length of Stay	Less Than 6 Months	10	14.7
	6 Months to 2 Years	31	45.6
	More Than 2 Years	27	39.7
Level of Dementia	Mild	3	4.4
	Moderate	29	42.6
	Severe	36	52.9

Preliminary Analyses

Demographics

Site differences in the sample were assessed for the demographic variables of age, gender, marital status, race, education, level of dementia, length of stay, and ADL by site (Table 2) and baseline agitation (Table 3). The only difference found among subjects was with regard to marital status, with site number one having considerably more single subjects (50%) than the other three sites (7%, 8%, and 16% respectively). This site was operated by the Catholic church and housed religious nuns (n = 11) among the general population.

Baseline agitation scores ranged from four to 54 with a mean score of 19.66 (*SD*=10.62). Subjects did not differ with regard to baseline agitation when examined by demographic variables.

Table 2. Characteristics of the Sample by Site

	Site				
	1	2	3	4	*p* value [a]
n	22	14	13	19	
Age					.13
Mean	81.45	86.86	82.00	80.58	
Standard Deviation	5.60	7.85	8.76	9.56	
Gender					.06
% Female	100	71	77	89	
Marital Status					.04
% Married	27	29	46	5	
% Widowed	23	57	46	63	
% Never Married	50	7	8	16	
% Divorced	0	0	0	11	
% Separated	0	7	0	5	
Race					.14
% White	100	93	100	84	
Education-years					.08
Mean	11.64	10.00	9.85	8.63	
Standard Deviation	3.84	2.60	2.64	2.75	
Level of Dementia					.10
% Mild	0	0	8	10	
% Moderate	55	21	61	32	
% Severe	45	79	31	58	
Length of Stay					.64
% < 6 Months	14	14	23	11	
% 6 Mo. - 2 Years	50	57	38	37	
% > 2 Years	36	29	38	52	
ADL					.86
% Independent	0	0	0	5	
% Assisted	23	21	23	16	
% Dependent	77	79	77	79	

[a] = *p*-value from *F* test from one way ANOVA of site differences ($df = 3, 65$) or from x^2 test, as appropriate for continuous or descrete variables respectively.

Table 3. Baseline Agitation by Demographic Variables

		n	Mean	*SD*	*p* value
Site					.94[a]
	1	22	19.86	10.23	
	2	14	19.36	10.26	
	3	13	18.31	5.34	
	4	19	20.58	14.15	
Age					.24[a]
	60 - 69	7	12.57	9.05	
	70 - 79	14	22.50	13.48	
	80 - 89	30	19.57	10.11	
	90 - 99	17	20.41	8.88	
Gender					.42[b]
	Female	59	19.25	10.67	
	Male	9	22.33	10.51	
Marital Status					.39[c]
	Married	17	20.12	9.03	
	Widow	31	18.58	10.37	
	Single	16	20.50	12.67	
	Divorced	2	13.00	1.41	
	Separated	2	32.50	12.02	
Race					.48[b]
	White	64	19.89	10.67	
	Other	4	16.00	10.36	
Education					.51[d]
	None	1	30.00	-	
	<High School	38	20.34	11.61	
	High School	22	20.27	9.46	
	Bachelors Degree	4	11.50	6.35	
	Masters Degree	2	14.00	8.48	
	Ph.D	1	14.00	-	
Level of Dementia					.80[e]
	Mild	3	17.00	11.53	
	Moderate	29	20.52	10.77	
	Severe	36	19.19	10.688	
Length of Stay					.84[e]
	< 6 Months	10	18.00	6.57	
	6 Months-2 Years	31	19.58	11.08	
	> 2 Years	27	20.37	11.51	

p value from One Way ANOVA

[a] $df = 3, 64$: [b] $df = 1, 66$: [c] $df = 4, 63$: [d] $df = 5, 62$: [e] $df = 2, 65$

Baseline Levels of Agitation

A one-way analysis of variance (ANOVA), comparing baseline levels of agitation in the four treatment groups, indicated the adequacy of randomization. The Levene test for homogeneity of variances indicated equal variance among the four groups ($F = .63, p = .60$). Mean agitation scores for the four intervention groups ranged from 16.47 in the HM group to 22 in the CMHM group, and are summarized in Table 4. The overall F test of group differences verified that there were no significant differences among the four group means ($F = 1.09, p = .36$). ANOVA summary tables for this and subsequent ANOVA tests are contained in APPENDIX C.

Table 4. Mean Agitation Scores at Baseline

Group	Calming Music	Hand Massage	Calming Music Hand Massage	Control
Mean	18.41	16.47	22.00	21.76
Standard deviation	11.18	9.94	11.94	9.09
n	17	17	17	17

p-value from one-way ANOVA test of zero group differences = .36 ($F = 1.1$. $df = 3, 64$)

Hypothesis 1, Calming Music

A t-test for independent samples was conducted to test Hypothesis 1, that agitated nursing home residents with dementia who are exposed to ten minutes of calming music exhibit fewer manifestations of agitation immediately following intervention than those who receive no intervention. Scores at Time 3 (after the intervention) from the calming music group and the control group were compared. Results indicated that agitation scores

in the CM group were significantly different than in the control group ($t = 4.18$, $df = 32$. $p = .00$) at Time 3. The mean score at Time 3 for the CM group was 7.65 ($SD = 9.79$), and for the control group was 20.88 ($SD = 8.66$) with a mean difference of 13.24. On average, subjects who were not exposed to calming music exhibited 13 more agitated behaviors during the ten minute observation period (nearly three times the agitation) than those who were exposed to calming music. Hypothesis 1 was not rejected.

Hypothesis 2, Hand Massage

A t-test for independent samples was conducted to test Hypothesis 2 that agitated nursing home residents with dementia who are exposed to ten minutes of hand massage exhibit fewer manifestations of agitation immediately following intervention than those who receive no intervention. Scores Time 3 (after the intervention) were compared for the HM group and the control group. Results indicated that agitation scores in the HM group were significantly different than in the control group ($t = 4.20$, $df = 32$. $p = .00$). The mean score at Time 3 was 7.77 ($SD = 9.55$) for the HM group and 20.88 ($SD = 8.66$) for the control group, with a mean difference of 13.12. The control group exhibited on average, 13 more agitated behaviors than the hand massage group, again, nearly three times the agitation in the control group. Hypothesis 2 was not rejected.

Hypothesis 3, Calming Music and Hand Massage

A one-way ANOVA was conducted to test Hypothesis 3 that agitated nursing home residents with dementia who are exposed to ten minutes of both calming music and hand massage simultaneously exhibit fewer manifestations of agitation immediately following intervention than those who are exposed to calming music alone, hand massage

alone or no intervention. Scores from Time 3 (after the intervention) were compared for the four intervention groups. The Levene test for homogeneity of variances was not significant ($p = .52$) indicating that the assumption of homogeneity of variance was reasonable. The overall F test was significant ($F = 9.79$, $p = .00$) indicating that there was a significant difference in agitation scores among the intervention groups. (Table 5).

Table 5. Mean Agitation Scores after Intervention

Group	Calming Music	Hand Massage	Calming Music Hand Massage	Control
Mean	7.66	7.76	7.06	20.88
Standard deviation	9.78	9.55	7.08	8.66
n	17	17	17	17

p-value from one-way ANOVA test of zero group differences = <.01 ($F = 9.79$. $df = 3, 64$)

Post hoc analysis using Tukey's HSD test with a level of significance of .05 indicated that the control group ($M = 20.88$; $SD = 8.66$)) differed significantly from the CM group ($M = 7.65$; $SD = 9.78$), the HM group ($M = 7.76$; $SD = 9.55$) and the CMHM group ($M = 7.06$; $SD = 7.08$). Subjects in the treatment groups exhibited on average between 13.12 and 13.82 fewer agitated behaviors during the ten minute observation period than the control group. These data provide partial support for Hypothesis 3.

Hypothesis 4, Change in Physically Aggressive Behaviors over Time

Repeated measures analysis of variance was used to test Hypothesis 4 that there is a differential level of reduction of physically aggressive behaviors with calming music, hand massage and a combination of calming music and hand massage over time. The Mauchly sphericiey test was significant, indicating that the sphericity assumption was not met, therefore the Greenhouse-Geisser procedure was used to adjust the degrees of freedom for the F tests. Results showed no significant differences ($F=1.93$, $p=.050$: $F_{cons}=1.93$, $p = .09$) in physically aggressive behaviors among the four groups Mean scores are presented in Table 6. Hypothesis 4 was rejected.

Table 6. Mean Scores of Physically Aggressive Behaviors over Time

		Calming Music	Hand Massage	Calming Music Hand Massage	Control
Time 1	Mean (*SD*)	2.65 (4.12)	3.71 (4.70)	3.35 (4.83)	1.18 (1.70)
Time 2	Mean (*SD*)	.94 (2.30)	2.24 (4.22)	1.47 (2.62)	1.35 (2.09)
Time 3	Mean (*SD*)	.71 (2.02)	1.47 (2.50)	.82 (1.28)	1.24 (1.75)
Time 4	Mean (*SD*)	.29 (.99)	.71 (1.76)	.59 (.94)	1.06(1.75)
n		17	17	17	17

$p = .09$ from F test from repeated measures ANOVA with Greenhouse-Geisser procedure applied ($df = 5.53, 118$)

Hypothesis 5, Change in Physically Non-aggressive Behaviors over Time

Repeated measures ANOVA was performed on the physically non-aggressive subset of behaviors in all four intervention groups. The Mauchly sphericity test was significant, indicating that the sphericity assumption was not met, therefore the

Greenhouse-Geisser procedure was used to adjust the degrees of freedom used to test the F value for significance. This procedure produced a conservative F test and is indicated by F_{cons}. Results indicated that there was a significant difference ($F=3.78$, $p=.00$: $F_{cons}=,3.78$, $p=.00$) among the four groups over time.

Post hoc analysis using Tukey's HSD test with a level of significance of .05 showed no difference in physically non-aggressive behavior between groups at the baseline measure (Time 1). During subsequent measurements (Times 2, 3, and 4) agitation scores in the control group were significantly greater than in the three experimental treatment groups. On average, subjects in the control group exhibited 9 or more physically non-aggressive behaviors than subjects in any of the experimental intervention groups. Mean scores are shown in Table 7. The data provide partial support for Hypothesis 5.

Table 7. Mean Scores of Physically Non-aggressive Behaviors over Time

		Calming Music	Hand Massage	Calming Music Hand Massage	Control
Time 1	Mean (*SD*)	9.76 (6.13)	8.41 (7.13)	10.88 (6.13)	13.29 (7.64)
Time 2	Mean (*SD*)	5.41 (7.21)	5.35 (6.25)	4.06 (4.38)	13.94 (8.68)
Time 3	Mean (*SD*)	4.41 (5.93)	4.65 (5.92)	4.06 (4.34)	13.24 (7.35)
Time 4	Mean (*SD*)	3.59 (6.61)	2.00 (3.81)	1.76 (3.11)	12.94 (9.20)
n		17	17	17	17

$p<.01$ from F test from repeated measures ANOVA with Greenhouse-Geisser procedure applied ($df = 7.36, 157.08$)

Hypothesis 6, Change in Verbally Agitated Behaviors over Time

Repeated measures ANOVA conducted on the subset of verbally agitated behaviors in all four groups. Because the Mauchly sphericity test was significant,

indication that the sphericity assumption was violated, the Greenhouse-Geisser procedure was used to adjust the degrees of freedom used to test the F value for significance. The overall F test indicated that there was no significant difference in agitation scores ($F=1.92$, $p=.05$: $F_{cons}=1.92$, $p=.10$) among the four groups over time.

Post hoc analysis using Tukey's HSD test with a significance level of .05 however, revealed a difference between the control group and the HM group at Time 2 and Time 3, and between the control group and the three experimental treatment groups at Time 4. Mean scores are shown in Table 8. The hand massage group was less vervally agitated at baseline, however that difference was not statistically significant. Hand massage resulted in a consistently greater reduction in verbally agitated behaviors than that found in the other groups. At Time 4, any intervention resulted in a greater reduction in verbally agitated behavior than no intervention. Hypothesis 6 was not rejected.

Table 8. Mean Scores of Verbally Agitated Behaviors Over Time

		Calming Music	Hand Massage	Calming Music Hand Massage	Control
Time 1	Mean (*SD*)	5.29 (6.08)	2.41 (5.20)	5.53 (7.26)	5.65 (5.56)
Time 2	Mean (*SD*)	2.41 (4.24)	.71 (1.49)	2.24 (4.31)	5.00 (5.40)
Time 3	Mean (*SD*)	2.06 (3.80)	.41 (.94)	1.71 (3.79)	4.94 (5.18)
Time 4	Mean (*SD*)	.65 (2.42)	.12 (.33)	1.18 (2.51)	4.88 (5.33)
n		17	17	17	17

$p = .10$ from F test from repeated measures ANOVA with Greenhouse-Geisser procedure applied ($df = 4.53, 96.73$)

Additional Analyses

The repeated measures design used in this study allowed for additional comparisons of the effects of the interventions on subjects over time. Total agitation scores were used to compare the relative effectiveness of calming music, hand massage and calming music, hand massage simultaneously, and no experimental intervention on agitation before intervention, during intervention, immediately after intervention and at one hour.

Change over Time in All Four Groups

One-way analysis of variance for repeated measures was performed to compare the profiles of agitated behaviors over time among the four treatment groups. Scores from each of the treatment groups (CM, HM, CMHM, control) prior to the intervention, during the intervention, immediately after the intervention and at one hour were compared. Geisser and Greenhouse's procedure was used to adjust the degrees of freedom for all F tests because the Mauchley sphericity test was significant, indicating that the sphericity assumption was violated. This procedure produced a conservative F test and is indicated by F_{cons}. The mean levels of agitation over time are shown in Figure 3.

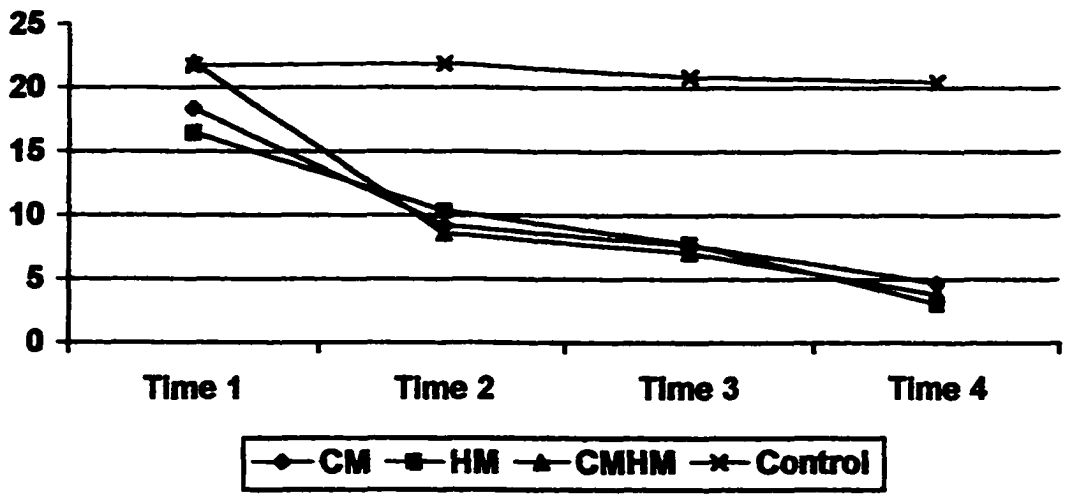

Figure 3 Mean agitation scores by treatment group over time

A significant difference (F=6.47, p=.00; F_{cons}=6.47, p=.00) in level of agitation over time was found among the four groups. Mean agitation scores are summarized in Table 9. Follow-up comparisons using Tukey's HSD procedure with a level of significance of .05, revealed the control group was significantly more agitated than the experimental groups during the intervention, immediately after the intervention and at one hour. No difference was found among the four groups at baseline, or between the three experimental intervention groups during the intervention, immediately after the intervention or at one hour.

Table 9. Mean Agitation Scores by Treatment Group over Time

		Calming Music	Hand Massage	Calming Music Hand Massage	Control
Time 1	Mean (*SD*)	18.41 (11.19)	16.47 (9.94)	22.00 (11.94)	21.76 (9.09)
Time 2	Mean (*SD*)	9.18 (11.11)	10.35 (11.20)	8.59 (7.87)	21.88 (10.38)
Time 3	Mean (*SD*)	7.65 (9.78)	7.76 (9.55)	7.06 (7.08)	20.88 (8.66)
Time 4	Mean (*SD*)	4.65 (7.87)	3.06 (5.44)	3.76 (4.40)	20.47 (10.90)
n		17	17	17	17

$p < .01$ from F test from repeated measures ANOVA ($df = 3, 9$)

Effect of Group on Change Over Time among Those Receiving Any Experimental Intervention

Repeated measures analysis of variance was performed to compare the change in agitated behaviors over time in the three experimental treatment groups; music alone versus hand massage alone versus both music and hand massage. Because the Mauchly's test of sphericity was significant, indicating that the sphericity assumption was violated, the Greenhouse-Geisser procedure was applied to adjust the degrees of freedom used to test the F value for significance. No significant group differences in the change over time in agitation ($F=1.48$, $p=.19$: $F_{cons} = 1.48$, $p = .21$) was found. (Table 10).

Table 10. Mean Agitation Scores of Experimental Treatment Groups Over Time

		Calming Music	Hand Massage	Calming Music Hand Massage
Time 1	Mean (*SD*)	18.41 (11.19)	16.47 (9.94)	22.00 (11.94)
Time 2	Mean (*SD*)	9.18 (11.11)	11.20 (10.35)	8.59 (7.87)
Time 3	Mean (*SD*)	7.64 (9.78)	7.76 (9.55)	7.06 (7.08
Time 4	Mean (*SD*)	4.65 (7.88)	3.06 (5.44)	3.76 (4.40)
n		17	17	17

$p = .21$ from F test from repeated measures ANOVA with Greenhouse-Geisser procedure applied ($df = 4.25, 102$)

CHAPTER 4

DISCUSSION

This study examined the effect of calming music and hand massage as easily administered, cost effective interventions to reduce agitated behavior in nursing home residents with dementia. The following discussion reviews the results of the present study and compares these findings with others cited in the literature. Nursing implications and recommendations for further research are suggested.

Results of this study indicate that calming music and hand massage are effective interventions to reduce the level of agitation in agitated nursing home residents with dementia. The groups who received either of these interventions, alone or in combination, exhibited significantly less agitation than the control group after the intervention. Level of agitation was measured by counting the occurrences of any of the 29 agitated behaviors on the CMAI-1 during each observation period. A score of "1" indicated that one behavior was exhibited during the observation period, and a score of "20" indicated that agitated behaviors occurred with a frequency of 20 times during the observation period. Baseline agitation scores in this sample ranged from four to 54. The large standard deviation, relative to the mean agitation score reflects the wide range of agitation in the sample. The trend in this investigation was for the level of agitation to decrease considerably during the intervention, with further decrease ten minutes after, and again at one hour. In the calming music group, one subject experienced an increase of one agitated behavior during the intervention with decreases at subsequent observations. Upon removal of the treatment, five subjects experienced a small increase in agitation ranging from one to four

occurrences of agitated behavior. All subjects in the hand massage group experienced an initial reduction in agitation during the intervention. Upon removal of the treatment, four subjects exhibited a slight increase in agitation, ranging between one and four behaviors. Similarly, in the calming music-hand massage group, all subjects demonstrated a decrease in frequency of agitated behaviors during the intervention. After the treatment, two subjects showed a small increase (one and two behaviors) and two subjects showed a moderate increase of eight behaviors. Among the subjects who experienced any increase in frequency of agitated behaviors after the removal of the treatment, none returned to baseline levels of agitation during the entire study period. Neither of the interventions alone, or in combination, increased agitation on the whole. This suggests that it was in fact the intervention that influenced the reduction in agitation, and not a temporal variation in behavior.

The receipt of both calming music and hand massage did not appear to result in an additional reduction agitation as originally predicted. Each of the three interventions resulted in significantly greater reduction in agitation than no intervention however, the reduction in agitation was similar in each of the three experimental intervention groups. The Progressively Lowered Stress Threshold model proposed that agitation can be reduced by modifying environmental stimuli and controlling for factors that correlate with the perception of stressors. In this study, touch in the form of hand massage was examined as a means to alter the perception of stressors, and as such it was anticipated that it would result in greater reduction in agitation when combined with calming music. Touch has been described by others as a form of communication (Moore & Gilbert, 1995;

Werner & Cohen-Mansfield, 1989). Viewing hand massage as a form of communication, it would be more of a modification of environmental stimuli, as is calming music, therefore not likely within the PLST framework, to have an additive effect.

When examined over time, the reduction in agitation among subjects receiving any experimental intervention began during the intervention. Further reduction in agitation was observed during the immediate post-intervention period, with even further reduction observed at one hour. This pattern over the intervention periods differs from that found in previous studies which showed positive effects with the use of music or massage with agitated nursing home residents. In the preliminary study (Tabloski, McKinnon-Howe, & Remington, 1995) in which a 15 minute music intervention using the same piece of music played at the same volume, the greatest reduction in agitation occurred during the intervention, followed by a small increase in agitation in the immediate post-intervention period. This suggests that a shorter music intervention may produce a more sustained effect. Alternately, decreasing a hand massage intervention from ten minutes (Snyder, Egan, & Burns, 1995 a) to five minutes (Snyder, Egan, & Burns, 1995 b) resulted in less consistently observed reductions in agitation, suggesting that a five minute intervention may not be sufficient. Data from this study indicate that a ten minute intervention of either calming music or hand massage resulted in both a reduction of agitation, as well as a sustained effect.

The music used for the intervention in this study was chosen for its slow tempo, soft dynamic levels, and repetitive themes. A recognizable melody that may evoke intense emotional responses was purposely avoided. Using a piece of music that had personal

significance to the subject in earlier years, Gerdner (1993) found that there was a lag time in producing an effect of the music intervention. This may be due to the additional cognitive effort required to process memory of a familiar piece of music before a response can occur. Calming music used in this study produced an initial, as well as a progressive response over time.

In summary, either of the interventions investigated in this study produced a reduction in agitated nursing home residents in this group, and each produced similar results. Moreover, the benefit sustained and increased over time at levels that were similar with each of the interventions.

None of the experimental interventions produced a significant reduction in physically aggressive behaviors over the four observation periods. This may be due to the fact that the initial level of these behaviors was low and did not allow for variation over time. These results are similar to those found by Goddaer and Abraham (1994) using music during mealtime. Cohen-Mansfield and Werner (1995) also note a lower prevalence rate of physically aggressive behaviors and propose that these behaviors in a person with dementia may be a response to a perceived noxious stimulus. It may be that calming music or gentle hand massage may have controlled or eliminated the perception of a noxious stimulus, however initial levels of these behaviors was so low that a significant difference was not detected.

Physically non-aggressive behaviors decreased significantly in the presence of each of the three experimental interventions. Similar results were reported with music (Goddaer & Abraham, 1994) and touch (Cohen-Mansfield & Werner, 1995). These

behaviors are the most commonly observed agitated behaviors in the sample nursing home (Cohen-Mansfield & Werner, 1995), as well as in this sample.

Change in verbally agitated behaviors over time was significant in the presence of the experimental interventions. The use of hand massage resulted in less agitation than no intervention at each of the measurement periods, and any intervention resulted in less agitation than no intervention at Time 4 only. Because of the small differences, these results must be interpreted with caution, especially in light of the Cohen-Mansfield and Werner (1989) finding in which verbally agitated behavior increased in the presence of touch.

The findings of this study support the use of either calming music and hand massage for the reduction of agitation in nursing home residents with dementia. Both interventions require little training and are easily administered by both professional and lay caregivers. The cost of providing these interventions is small, especially in comparison with special environmental designs and the administration of medications to control agitation. Time expenditure required by caregivers to provide the interventions is also small however on a busy unit it may be difficult to set aside ten minutes to provide hand massage to an agitated resident at the time when it may be most effective. The use of calming music has an ancillary advantage in that this intervention may be provided while performing other caregiving tasks. Additionally it may be provided to several residents simultaneously.

A limitation of this study pertains to the sample, which was comprised of nursing home residents from middle class communities in central Massachusetts. A majority of the

subjects were female, and there was a relatively large percentage of residents who were never married (50%) in one nursing home . This sample may not be representative of all nursing home residents with dementia.

Persons with cognitive impairment related to conditions other than dementia of the Alzheimer's type and multi-infarct dementia were not included in the sample. This limits generalizability of the results to the management of agitation in persons with agitation resulting from delirium, depression, brain injury, and other dementias, such as AIDS dementia, Pick's disease and Creutzfeldt-Jakob disease.

No single intervention, pharmacological, environmental or behavioral, is universally effective in reducing agitation. This study demonstrates the effectiveness of two easily administered interventions that may be used as a part of a comprehensive plan to address the specific needs of agitated nursing home residents. Calming music and hand massage represent practical treatment options that can be used alone or augment an individualized therapeutic regimen.

As noted earlier, calming music and hand massage are inexpensive measures that are effective in reducing agitation. They are easily administered, require little or no training, and most importantly, have no side effects. This is especially significant in light of escalating health care costs. Currently used treatments are costly in terms of staffing, supplies and physical plant. These are also costly to the resident in the form of injury and side effects. For example, in the use of psychoactive medications there is the monetary cost of the drug and the costs associated with licensed staff time to administer the drug and monitor its effect. Even more consequential are the personal costs to the resident who

receives the medications to control behavior, such as side effects including gait impairment which may lead to falls, sedation which further impairs their functional ability, and difficulty swallowing which may lead to choking. Added to these costs is the concomitant costs of providing care to residents experiencing adverse events associated with the very treatment that was anticipated to relieve their agitation.

If calming music is being played, others in the environment also benefit from the intervention. As suggested by the PLST model, music is an environmental modification that is useful in reducing excessive environmental stimuli which lead to the development of agitated behavior. It has been shown to be effective with individual subjects, and it is reasonable to assume that it will affect others who may be listening.

When using calming music or hand massage to reduce agitation, care should be taken to minimize competing auditory stimuli by turning off intercoms, televisions, and closing doors to service areas. Providing adequate lighting will help to compensate for uncorrected visual impairment and to prevent misinterpretation of environmental stimuli.

Because of the natural variability and inconsistent nature of agitation, timing of the intervention for individual residents is important. Making an effort to provide the interventions before the peak level of agitation is reached provides an individualized strategy that has a maximum benefit to the resident. Further study of the effect of time of day on the development of agitation would aid in the identification and intervention prior to peak agitation. Sundown is frequently cited in the literature as a time in which agitation increases in nursing home residents with dementia. What is not clear is whether this phenomenon is strictly related to time of day or whether it is related to activities that

occur during this time period such as, change of shift of nursing personnel, meal time or care activities.

The results of this study indicate that a brief intervention is effective in reducing agitated behaviors in nursing home residents. Other authors have achieved promising results with interventions of varying length. Further study is indicated to identify the optimum length of time of the intervention is needed to produce maximum reduction in level of agitation as well as duration of its effect. Additionally, it is possible that there is a maximum length of time for which the intervention is effective. Further investigation may identify at what point the benefit is extinguished. It is would also be reasonable to investigate whether or not repeated exposure to the intervention increases the beneficial effect.

While only one subject's level of agitation increased slightly with exposure to calming music, several subjects did experience a small increase in agitation upon removal of the intervention. This further illustrated the need for further study of the factors that influence the achievement of a sustained benefit from these interventions.

The interventions used in this study did not appear to influence physically aggressive behaviors. Additional study is warranted to identify alternate non-pharmacological interventions to reduce these behaviors.

This study illustrates the effectiveness of music in reduction of agitation in nursing home residents. The type of selected for the intervention has been shown to influence the degree of benefit in reduction of agitation in a sample of five nursing home residents in Sweden (Ragneskog, Kihlgren, Karlsson, & Norberg, 1996). Additional study of musical

selections from classical to popular, with a variety of instrumentation, tempos, and dynamic levels may detect the type of music that has the greatest potential to reduce agitation.

Adverse events associated with physical and chemical restraints are well documented in the literature. Their continued use attests to the fact that there is some degree of usefulness of these measures in the care of agitated nursing home residents. Further study comparing the risks and benefits of non-pharmacological interventions, such as calming music and hand massage to medications and physical restraints in the management of agitated behavior.

APPENDIX A

POWER CALCULATIONS

Power calculations were computed using data from the pilot study of 18 subjects receiving experimental intervention. In this sample, agitation scores ranged between four and 35 before intervention and between 0 and 28 after intervention. Mean change scores were 8.0, 8.83. and 16.17. Based on these data, a minimum change of 7 was predetermined as clinically significant.

In order to determine how large a sample size was needed in each treatment group to detect a change of $(\mu_0 - \mu_1) = 7$ or more as significant in subjects receiving the intervention, the following calculation (Daniel, 1995, p. 260) was performed:

$$n = \left[\frac{(z_0 + z_1)\sigma}{\mu_0 - \mu_1}\right]^2$$

where

$Z_0 = 1.645$ = desired alpha, .05
$Z_1 = .8418$ = desired power, .80
μ_0 = the difference in agitation scores at baseline
μ_1 = the difference in agitation scores after treatment
σ = square root of variance of change score

Calming music:

$$n = \left[\frac{(.8148 + 1.645)4.49}{7}\right]^2$$

$$= 2.57$$

Hand Massage:

$$n = \left[\frac{(.8148 + 1.645)4.73}{7}\right]^2$$

$$= 2.9$$

Calming music and hand massage simultaneously

$$n = \left[\frac{(.8148 + 1.645)7.44}{7}\right]^2$$

$$= 7.23$$

For comparisons of two groups on mean changes from baseline, the following power calculations (Meinert & Tomascia, 1986) were made using data from the three treatment groups (n = 18) and a control group (n = 6):

Samples of equal size

$$n_c = \frac{2(Z_\alpha + Z_\beta)^2 \sigma_d^2}{(\mu_{dc} - \mu_{dt})^2}$$

$$n_t = n_c$$

where

$\mu_{dc} = \mu_{1c} - \mu_{0c}$, the difference in agitation at follow-up and baseline for the control group

$\mu_{dt} = \mu_{1t} - \mu_{0t}$, is the corresponding value for the treatment group

μ_{0c} = mean agitation score immediately before the treatment period for the control group

μ_{1c} = mean agitation score after the treatment period

μ_{1t} and μ_{0t} = the corresponding means for subjects assigned to the treatment groups

$\sigma_d^2 = 2(1 - p)\sigma^2$

σ^2 = variance of the agitation score at either baseline or follow-up
p = correlation coefficient between baseline and follow-up agitation scores on a single subject

Any music versus no music

$$n_c = \frac{2(1.6545+.8418)116.82}{7^2}$$

$$= 29.49$$

Any massage versus no massage

$$n_c = \frac{2(1.645+.8418)129.7}{7^2}$$

$$= 32.74$$

Calming music alone versus calming music and hand massage

$$n_c = \frac{2(1.6545+.8418)50.267}{7^2}$$

$$= 12.69$$

Hand massage alone versus calming music and hand massage

$$n_c = \frac{2(1.6545+.8418)30.17}{7^2}$$

$$= 7.62$$

Samples of unequal size ($\lambda \neq 1$)

$$n_c = \frac{(Z_\alpha + Z_\beta)^2 \sigma_d^2 (\lambda + 1)/\lambda}{(\mu_{dc} - \mu_{dt})^2}$$

$$n_t = \lambda n_c$$
$$N = r n_t + n_c$$

Controls versus all experimental interventions, $\lambda = .33$

$$n_c = \frac{(1.6545 + .8418)^2 (92.24)(1.33)/.33}{(7)^2}$$

$$= 46.57$$

$$n_t = 15.52$$

APPENDIX B

TRAINING MANUAL FOR RESEARCH ASSISTANTS

Objectives

The objectives for this training session are that the RA will:

Describe agitation within three syndromes

Use the CMAI-1 to document occurrences of agitated behavior

Demonstrate the calming music intervention

Demonstrate the hand massage protocol

Methods

Teaching methods will include lecture, discussion demonstration and return demonstration.

Content

Agitation

The concept of agitation, its etiology and manifestations are not consistently defined in the literature. Agitation is described as a construct of interrelated behavior problems, rather than a unified concept. In this study, agitation is defined as inappropriate verbal, vocal or motor activity that is not explained by needs that are evident to the observer. Agitation is manifested in three syndromes:

1) physically aggressive behaviors, spitting, hitting, kicking, grabbing onto people, pushing, throwing things, biting, scratching, intentional falling, eating or drinking

inappropriate substances, hurting self or others, making verbal sexual advances, making physical sexual advances.

2)physically non-aggressive behaviors, pacing, aimless wandering, trying to get to a different place, handling things inappropriately, hiding things, hoarding things, tearing things or destroying property, performing repetitious mannerisms, general restlessness.

3)verbally agitated behaviors, cursing r verbal aggression, constant unwarranted requests for attention or help, repetitive sentences or questions, strange noises, screaming, complaining, negativism.

Behaviors within these syndromes are interrelated and tend to co-occur within individuals, therefore, agitation is a construct of related behaviors, rather than a cluster of unrelated behaviors.

Calming Music (CM)

Subjects assigned to the CM group will receive 10 minutes of Daniel Kobialka's recording of Pachelbel's Canon in D played on a portable compact disc player. This piece was chosen for its slow tempo, soft dynamic levels and repetitive themes. Calming music is neutral and does not contain recognizable melodies that may evoke intense emotional responses. Technically, this music is characterized by slow tempo, soft dynamic levels, and irregular, repetitive themes.

Hand Massage (HM)

Subjects assigned to the HM group receive ten minutes of hand massage, five minutes on each hand, utilizing the following protocol:

1. Back of hand massage
   A. Short/medium length straight strokes from wrist to fingertips using moderate pressure.
   B. Large half-circular stretching strokes from center to side of hand using moderate pressure.
   C. Small circular strokes over entire back of hand using light pressure.
   D. Featherlike straight strokes from wrist to fingertips using very light pressure.
2. Palm of hand massage
   A. Short/medium length straight strokes from wrist to fingertips using moderate pressure.
   B. Gentle milking/lifting of tissue of entire palm of hand using moderate pressure.
   C. Small circular strokes over entire palm of hand using moderate pressure.
   D. Large half-circular stretching strokes from center of palm to sides using moderate pressure.
3. Finger massage
   A. Gentle squeezing of fingers from base to tip on sides and top/bottom using light pressure.
   B. Gentle circular range of motion of each finger followed by a gentle squeeze of the nail bed.
4. Completion of hand massage

   Lay resident's hand on yours and cover it with your other hand. Gently draw your top hand toward you several times. Turn resident's hand over and gently draw the other hand toward you several times.

Procedure

Each RA will meet with the PI at the data collection site before data collection. The RA and PI will observe an agitated nursing home resident and record the occurrences of agitated behaviors on the CMAI-1 during four ten minute observation periods. If the Pearson correlation between raters is .8 or greater, the RA will then be approved for data collection independently. If the correlation is less than .8, the RA must attend additional training and repeat the observations with the PI to achieve a correlation of at least .8 before collecting data.

Prior to data collection, cards will be prepared containing a subject number and group assignment and these cards will each be placed in a sealed envelope. As each subject agrees to participate, an envelope will be drawn, providing that subject's number and group assignment. Subjects will thus be randomly assigned to one of four groups: 1) CM, 2) HM, 3) CM and HM or, 4) control. All subjects will be observed for 10 minutes, the CMAI-1 completed to identify the number of agitated behaviors exhibited immediately before the intervention. If a subject's score is less than 1, which indicates the absence of agitation at the time of the study session, he or she will not be assigned to an intervention group for that session and the sealed envelope returned to the pile.. Agitated subjects assigned to the CM group will be exposed to 10 minutes of Daniel Kobialka's recording of Pachelbel's Canon in D played on a portable compact disc player. Subjects assigned to the HM group receive ten minutes of hand massage, five minutes on each hand, utilizing the protocol described above. Subjects in the CM-HM group will receive both of the above

interventions simultaneously and subjects in the control group will receive no intervention during the ten minute intervention period.

In order to blind the data collectors to the intervention, a different data collector will conduct the intra-treatment measurement. All subjects will be assessed for level of agitation and the CMAI-1 completed by the intervention research assistant during the intervention period. During the ten minutes after the intervention period and again at one hour postintervention, subjects will be observed for agitated behaviors for ten minutes and the CMAI-1 completed by the initial research assistant to determine whether the effect of the intervention is sustained. Research assistants will not initiate conversation with the subject however, they will respond to the subject if requested. Subjects will be free to discontinue the intervention at any time.

In order to minimize the potential influence of other environmental stimuli, the intervention will be conducted in the patient's room or familiar lounge area, and only one resident present in the room at that time will receive an intervention. Scheduled activities, meals and routine care administration times will be avoided to avoid stress associated with change in usual routine. Interventions will be planned for the time of day in which peak agitation occurs, as reported by nursing staff for each resident.

CMAI-1

The purpose of the CMAI-1 is to assess the frequency of agitated behaviors in nursing home residents with dementia. The CMAI-1 is a rating scale consisting of 29 agitated behaviors, each rated for the number of occurrences of the behavior during the observation period. Each listed behavior is actually a group of related behaviors. If the

subject manifests an inappropriate behavior which is close to a behavior on the CMAI-1 but not spelled out exactly, add it to that category. For example, if a person squeaks, and this behavior is not listed, use the category of "making strange noises," even though it is not included in the example. Recognize that it is impossible to include all possible examples, but each listed behavior is intended to capture a group of closely related behaviors.

Please read each of the 29 agitated behaviors, and put a mark (I, II, III, IIII, IIII etc.) next to the behavior each time the resident exhibits the behavior during the observation period. If the behavior is constant, enter C.

	Observation 1	2	3	4
1. Pace, aimless wandering				
2. Inappropriate dress or disrobing				
3. Spitting (include at meals)				
4. Cursing or verbal aggression				
5. Constant unwarranted request for attention or help				
6. Repetitive sentences or questions				
7. Hitting (including self)				
8. Kicking				
9. Grabbing onto people				
10. Pushing				
11. Throwing things				
12. Strange noises (weird laughter, crying etc.)				
13. Screaming				
14. Biting				
15. Scratching				

	1	2	3	4
16. Trying to get to a different place (out of room, building etc.)				
17. Intentional falling				
18. Complaining				
19. Negativism				
20. Eating/drinking inappropriate substances				
21. Hurt self or other				
22. Handling things inappropriately				
23. Hiding things				
24. Hoarding things				
25. Tearing things or destroying property				
26. Performing repetitious mannerisms				
27. Making verbal sexual advances				
28. Making physical sexual advances				
29. General restlessness				

APPENDIX C

ANOVA SUMMARY TABLES

One-way ANOVA, Baseline Level of Agitation among the Four Groups

Source	*D.F.*	Sum of Squares	Mean Squares	F Ratio	*p*-value
Between Groups	3	367.8088	122.6029	1.0917	.3591
Within Groups	64	7187.4118	112.3033		
Total	67	7555.2206			

One-way ANOVA, Agitation Scores among Intervention Groups After the Intervention

Source	Degrees of Freedom	Sum of Squares	Mean Squares	F	*p*-value
Between Groups	3	2291.57	763.86	9.79	.00
Within Groups	64	4991.65	77.99		
Total	67	7283.22			

Repeated Measures ANOVA, Physically Aggressive Behaviors Over Time

Source of Variation	Sum of Squares	Degrees of Freedom	Mean Square	F	*p*-value
Intervention	33.59	3	11.2	.54	.66
Time	162.26	3	54.09	16.56	.00
Greenhouse-Geisser		1.84		16.56	.00
Intervention by Time	56.79	9	6.31	1.93	.05
Greenhouse-Geisser		5.53		1.93	.09
Within+Residual	626.94	192	3.27		
Greenhouse-Geisser		118			

Repeated Measures ANOVA, Physically Non-aggressive Behaviors Over Time

Source of Variation	Sum of Squares	Degrees of Freedom	Mean Square	F	*p*-value
Intervention	3375.25	3	1091.75	8.53	.00
Time	1106.60	3	368.87	28.77	.00
Greenhouse-Geisser		2.45		28.77	.00
Intervention by Time	436.37	9	48.49	3.78	.00
Greenhouse-Geisser		7.36		3.78	.00
Within+Residual	2461.53	192	12.82		
Greenhouse-Geisser		157.08			

Repeated Measures ANOVA Summary Table-Intervention by Time

Source of Variation	Sum of Squares	Degrees of Freedom	Mean Squares	F	*p*-value
Intervention	6586.94	3	2195.60	8.22	.00
Time	5045.07	3	1681.69	59.31	.00
Intervention by Time	1650.21	9	183.36	6.47	.00
Within+Residual	5444.47	192	28.36		

Repeated Measures ANOVA- Agitation Over Time by Experimental Treatment

Source of Variation	Sum of Squares	Degrees of Freedom	Mean Squares	F	*p*-value
Intervention	30.47	2	15.24	.06	.94
Time	6380.41	3	2126.80	64.71	.00
Greenhouse-Geisser		2.12		64.71	.00
Intervention by Time	290.94	6	48.49	1.48	.19
Greenhouse-Geisser		4.25		1.48	.21
Within+Residual	4733.15	144	32.87		
Greenhouse-Geisser		102			

APPENDIX D

HUMAN SUBJECTS COMMITTEE APPROVAL, WORCESTER

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Administrative Coordinator

REPORT ON COMMITTEE ACTION

Investigator: Fain, James PH.D. Docket #: 3259
Graduate School of Nursing

Title: Calming Music and Hand Massage with Agitated Elderly

This is to certify that the project identified above has been reviewed by the Committee for the Protection of Human Subjects in Research (IRB MULTIPLE ASSURANCE # M-1207). The Committee has considered:

1. The adequacy of protection of the rights and welfare of the subjects.
2. The risks and potential medical benefits to the subjects in relation to the importance of the knowledge gained.
3. The adequacy and appropriateness of the methods used to secure informed consent.

STUDY IS NEW
THE PROPOSED STUDY HAS BEEN APPROVED BY EXPEDITED REVIEW 2/21/97.
THE PROPOSED STUDY WAS REVIEWED AT MEETING ON _____.
CONDITIONS WERE MET AND STUDY APPROVED ON _____
WITH THE FOLLOWING RESTRICTIONS:

Kathryn L. Edmiston
KATHRYN L. EDMISTON, MD, CHAIR

JOHN R. SALTZMAN, MD, VICE CHAIRPERSON
RICHARD C. BECKER, MD, VICE CHAIRPERSON
MARY A. ELLIS, R Ph, VICE CHAIRPERSON

TO THE PRINCIPAL INVESTIGATOR:

As Principal Investigator for this study, you have the following obligations:

1. To report all serious and unexpected adverse reactions to the Human Subjects Committee within five working days. Any death of a subject, regardless of the cause, must be reported.
2. To use only an HSC-approved version of the consent form. The approval is for no longer than one year and expires on the date stamped on the form.
3. To give every subject a copy of the consent form and, if drugs are involved, to place a signed copy of the consent form in the patient's chart.
4. To obtain approval from the HSC before instituting any change in the protocol or the consent form.

APPENDIX E

HUMAN SUBJECTS COMMITTEE APPROVAL, AMHERST

UNIVERSITY OF MASSACHUSETTS AMHERST
THE GRADUATE SCHOOL
UNIVERSITY HUMAN SUBJECTS REVIEW COMMITTEE

DATE: April 29, 1997

TO: Ruth Remington, Nursing

FROM: Michael Weinberg, UHSRC Chair

SUBJECT: The following action resulted from UHSRC action of your proposal to NIH entitled "Calming Music and Hand Massage with Agitated Elderly"

OGCA FILE # 97A0641
FRG FILE #

1a. ☒ The *UHSRC*, after full review by primary reviewers, has *APPROVED* the above proposal on April 29, 1997.

1b. ☐ Expedited review has been given your proposal, which is now recorded as *ADMINISTRATIVELY APPROVED* by the Chair of the *UHSRC*, under 45CFR46.110(b) on

2a. ☐ The *UHSRC*, after full review by primary reviewers and discussion at it meeting on _____, has *CONDITIONALLY APPROVED* your proposal contingent upon the fulfillment of the conditions noted below. Please alter your proposal accordingly and return to this office ***before*** the next *UHSRC* meeting to be held on _____.

2b. ☐ On _____, as directed by the Committee, the Chair of the *UHSRC* fully *APPROVED* your proposal upon examining the corrections required after the full Committee review(s) of _____.

3. ☐ On _____, the *UHSRC DEFERRED REVIEW* of your proposal until the following items have been clarified, corrected or added: Please see below an excerpt from the minutes of the meeting of which your proposal was reviewed. The next meeting of the *UHSRC* will be held on _____ in Room 508 Goodell Building. The deferred review by the *UHSRC* will take place at that time.

4. ☐ At your request, on _____ the *UHSRC* completed its *"SPECIAL REVIEW"* of the above proposal. Please see below an excerpt from the minutes of the meeting at which the proposal was reviewed.

5. ☐ On , your proposal was determined to be *EXEMPT* under 45CFR46.101. by the Chair of the *UHSRC*.

NOTE: ***Approved proposals and studies are guided by the Standard Operating Procedures of the University of Massachusetts Amherst. If you need a copy, please contact the UHSRC office at 545-0668.***

cc: Department Head/Chair
OGCA

uhscapl.doc

Revised 12/95

UNIVERSITY OF MASSACHUSETTS/AMHERST
UNIVERSITY HUMAN SUBJECTS REVIEW COMMITTEE

Date Approved 4/28/97 Valid Thru 4/28/98
Renewal Approved _____ Thru _____
_____ Thru _____
_____ Thru _____

APPENDIX F

CONSENT FORM

HUMAN SUBJECTS COMMITTEE

APPROVED

UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH
STUDY APPROVAL EXPIRES 2/4/98

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

REVISION # —

Docket # REVISION APPROVAL DATE —

TITLE: CALMING MUSIC AND HAND MASSAGE WITH AGITATED ELDERLY

PRINCIPAL INVESTIGATOR: RUTH REMINGTON, MS, RN, CS

RESEARCH SUBJECT'S NAME:_____Date_____

Purpose

Your family member is invited to participate in a research project to determine whether calming music and hand massage reduces agitation in nursing home residents with Alzheimer's Disease or other forms of cognitive impairment. I am asking your help because your family member has been diagnosed with a cognitive impairment and has periods of agitation on a regular basis. Agitation may include one or more of the following: pacing, repetitive speech or mannerisms, making strange noises, restlessness, hitting. The purpose of this study is to find a non-drug related way to calm the agitated nursing home resident. This research will be carried out in association with the University of Massachusetts, Amherst and Worcester.

Procedures

With your permission, your family member will be observed for ten minutes for agitated behaviors. These observations can be done without any change in your family member's daily routine. He/she may not even be aware that the researcher is making the observations. He/she will then be assigned by chance to receive either ten minutes of calming music, ten minutes of gentle hand massage, ten minutes of both calming music and hand massage simultaneously or no intervention. Following the intervention, the resident will be observed for any change in agitated behavior. Total time spent participating in this project will be approximately 40 minutes.

Risks

There are no known risks associated with participation in this study. It is possible that the intervention may increase agitation in some subjects. To address this potential risk, the investigator will be prepared to discontinue the intervention and alert the nursing staff if it is noted that the level of agitation does increase.

Benefits

There is no promise or guarantee of any medical benefits resulting from participation in this study. The potential benefit of the study is the identification of non-drug related interventions for the management of agitated behavior in nursing home residents.

Alternatives

YOUR FAMILY MEMBER'S PARTICIPATION IS VOLUNTARY. THE QUALITY OF THE CARE HE/SHE RECEIVES AT THIS FACILITY WILL NOT BE AFFECTED IN ANY WAY IF HE/SHE DOES NOT PARTICIPATE OR WITHDRAWS FROM THE STUDY AT ANY TIME.

Costs

There will be no additional cost to you from being in this research study. Patients will not be charged for any materials used in this research study.

Confidentiality

Participant's identity will not be disclosed in connection with the study. Results of the study will be kept in a locked cabinet at the Graduate School of Nursing and will be available only to the researcher involved in this project. The conclusions of this study will be shared only in terms of groups of residents. No individual responses will be shared.

Please feel free to ask any questions you may have about the study or about your family member's rights as a research subject. If other questions occur to you later, you may contact the principal investigator, Ruth Remington, MS, RN,CS at (508)460-9696. If at any time during or after the study, you would like to discuss the study or your family member's research rights with someone who is not associated with the study, you may contact the Administrative Coordinator for the Committee for the Protection of Human Subjects in Research at UMMC, telephone (508)856-4261.

Please sign both copies of the form to indicate your consent and return the green copy in the enclosed envelope and retain the other copy for your records.

Consent to Participate in the Research Project, H-3259 entitled: Calming Music and Hand Massage with Agitated Elderly

Subject's Name:_____P.I. Name: Ruth Remington, MS,RN,CS

The purpose and procedures of this research project have been explained to me and I understand them. I have been told about all of the predictable discomfort, risks, and benefits that might result, and I understand them. I have been told that unforeseen events may occur. I agree to the participation of the above named resident as a volunteer in this research project. I understand that he/she may discontinue participation at any time.

Subject's Name: _____

Signature of Subject's Representative_____

Name: (Print)_____

Relationship to the Subject_____

Date_____

HUMAN SUBJECTS COMMITTEE

APPROVED

STUDY APPROVAL EXPIRES 2/4/98

REVISION # —

REVISION APPROVAL DATE —

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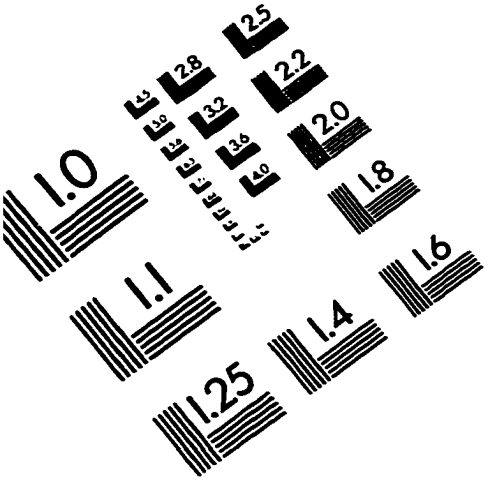
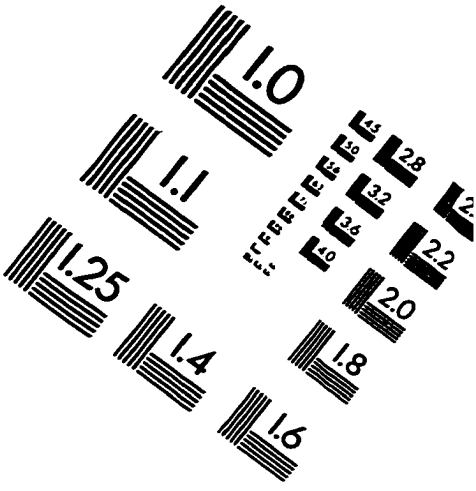
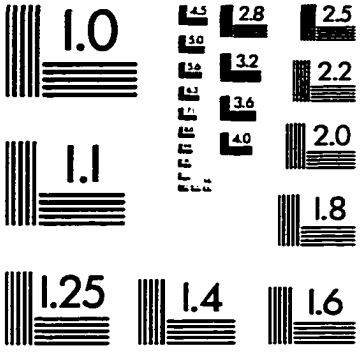
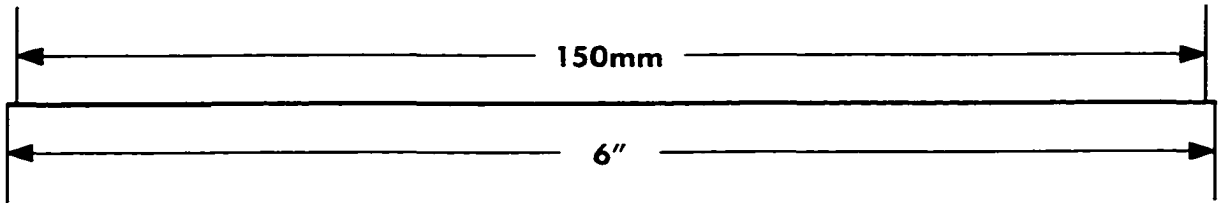
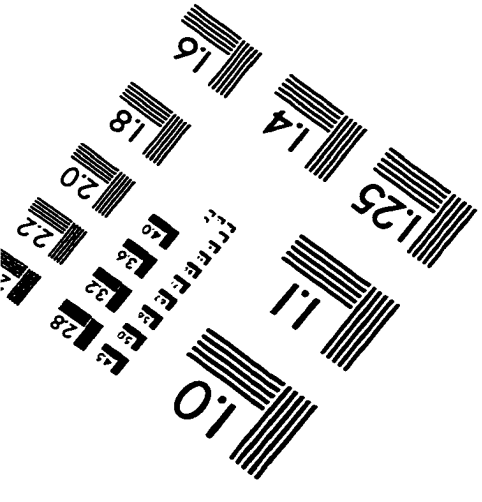
IMAGE EVALUATION TEST TARGET (QA-3)

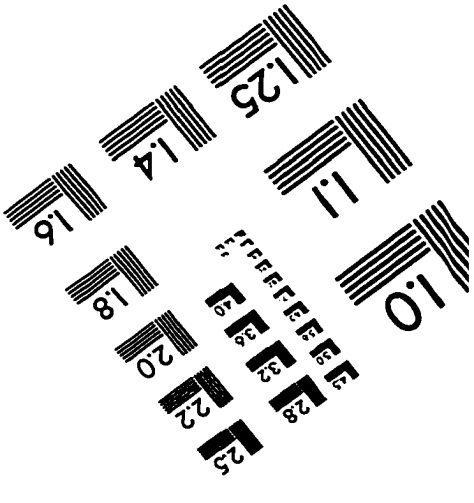












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