University of Alberta

Effectiveness of Doll Therapy in Decreasing Agitation, Aggression, and Use of PRN Medications in Dementia

by

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A thesis submitted to the Faculty of Graduate Studies and Research
in partial fulfillment of the requirements for the degree of

Master of Science
in
Occupational Therapy

Department of Rehabilitation Medicine

Your file Votre référence
ISBN: 978-0-494-33360-0
Our file Notre référence
ISBN: 978-0-494-33360-0

Abstract

This study was designed to investigate the effectiveness of a doll therapy program on individuals with dementia. It was hypothesized that providing a doll therapy program to individuals with moderate to severe dementia would decrease agitated and aggressive behavior, and use of PRN medications. Three variables measured the changes in agitation, aggression, and PRN medication usage among 45 individuals with dementia. The treatment group received doll therapy three days per week for four weeks in addition to regular therapy and standard care. The control group received only regular therapy and standard care during the four-week study period. Following analysis of the data, there were no significant treatment effects noted at the $p < .05$ level. Numerous methodological and design challenges were noted. Additional parameters of behavior, well-being, and quality of life could be addressed in future doll therapy studies.

ACKNOWLEDGEMENTS

This thesis is dedicated to my parents Ken and Anne Thompson. They encourage education and model love, persistence, and hope in spite of significant personal health challenges.

My husband Ross Smillie, daughter Sara, and son, Sean, steadfastly supported me and showed tremendous patience throughout the process. Dr. Rita Bakshi was unwavering in her belief that this degree was achievable for me. Thank you.

Thank you to my thesis committee: Dr. Sharon Warren, Dr. Lili Liu, and Professor Donna Smith for their support and guidance in the preparation of this thesis. I am also grateful to Dr. Hau Chow for her statistical assistance.

I also want to express my appreciation to all the study participants and their guardians and to the Seniors Mental Health Program at the Centennial Centre for Mental Health and Brain Injury (formerly Alberta Hospital Ponoka). Without their support this study would not have been possible.

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CHAPTER 1

PROBLEM STATEMENT

Introduction

Dementia is characterized by the development of multiple cognitive deficits that impact behavior, affect, and functional status (Cohen-Mansfield, 2000). It affects 8% of all individuals over the age of 65 (Canadian Study of Health and Aging Working Group, 1994). Agitation and aggression are two of the most serious behavioral disturbances associated with dementia (Zaraa, 2003). The presence of these behaviors in individuals with dementia is associated with prolonged institutional placement, poor management of other health problems, high health-care costs and poor quality of life (Callahan et al., 2006). Often these patients have to co-exist with other patients exhibiting similar behaviors on a long-term basis in care settings where they are at risk of being harmed or harming others with aggressive behaviors. The high prevalence and significant impact of dementia warrant careful examination of these disabling symptoms and their treatment. Little evidence is available to show practitioners how to effectively treat these behaviors (Cohen-Mansfield, 2001; Fossey et al., 2006).

Treatment of Agitation and Aggression in Dementia

In the last few years, a combination of pharmacological and non-pharmacological approaches has been used to control agitated and aggressive behaviors (Brodaty, Draper & Low, 2003). Some psychotropic medications successfully control agitated and aggressive behaviors but are associated with some disabling side effects e.g. drooling, falls, drowsiness, urinary tract infection, urinary incontinence, and weight gain or loss, which limit their use (Aupperle, 2006; Cohen-Mansfield, 2002; Street et al., 2000). Therefore non-pharmacological treatments have been receiving more serious consideration (Fossey et al., 2006; Spira & Edelstein, 2006). Non-pharmacological care is achieved with an interdisciplinary approach, using the best interventions available, across the disciplines. Interdisciplinary team members identify, monitor, and initiate treatment of aggressive and agitated behaviors in dementia (Callahan et al., 2006).

Non-Pharmacological Treatments

Non-pharmacological treatment interventions for agitated and aggressive behaviors are usually aimed at addressing patient needs and providing a comfortable and stimulating environment. Wide ranges of modalities and approaches have been tested: a) sensory stimulation, b) environment modification, c) psychosocial measures and d) multimodal strategies (Beck et al., 2002).

Occupational therapists have used sensory stimulation, environmental modification, and pleasant familiar activities to manage agitated and aggressive behavior (Bakshi, 2004; Carlson, Fanchiang, Zemke & Clark, 1996). Lack of meaningful pleasant activity during the day may cause several behavioral symptoms, including agitation and aggression. Volicer and Hurley (2003), support the use of meaningful activities

appropriate to the functional abilities of the individual as the first step in managing behavioral difficulties. The provision of daily meaningful activities has been shown to significantly decrease the use of medications for agitated and aggressive behaviors (Simard & Volicer, 2002). The use of dolls in individuals with behavioral difficulties in late stage dementia is a non-pharmacological treatment that has not been widely studied.

Use of Dolls as a Treatment Modality in Dementia

The earliest article that could be located about using dolls with the elderly dates back to 1985 (Milton & MacPhail, 1985). The practice of using dolls in dementia care is evident in many countries including Australia, Canada, England, Israel, Japan and the United States, and all have reported positive effects on their clients (Ehrenfeld & Bergman, 1995; Mackenzie, James, Morse, Mukaetova – Ladinska, & Reichelt, 2006; Milton & MacPhail, 1985; Moore, 2001; Rowland, personal communication, May 14; 2004; Verity, 2006; Webber, 2003; Yonemitsu et al., 2006). Some goals of doll therapy, how it is implemented, and how it affects individuals with dementia have been documented (Verity, 2006).

One pilot study, arguably the first systematic study in the area, examined the use of dolls with elderly people with dementia (Mackenzie et al., 2006). To date, research into the effectiveness of doll therapy in treating agitation and aggression in older people with dementia has been positive, but inconclusive.

Purpose of the Study

The purpose of this applied research study was to assess the effectiveness of using dolls as a treatment modality in decreasing agitated and aggressive behavior associated with dementia. The effectiveness of doll therapy was measured by monitoring: (a) the frequency of agitated behavior observed by nursing staff; (b) the frequency of aggressive behavior observed by nursing staff; and (c) the frequency of *pre re nata* (as circumstances may require [PRN]) medication given by nursing staff for agitated and/or aggressive behavior.

Research Question

The primary research question was: Do persons with moderate to severe dementia residing in a psychiatric hospital who receive doll therapy differ from a group of persons who do not receive doll therapy in the frequency of agitated and aggressive behaviors they exhibit and frequency of PRN medication they receive?

Research Objectives

1. To determine whether doll therapy was effective in decreasing the frequency of agitated behavior as observed by nursing staff.
2. To determine whether doll therapy was effective in decreasing the frequency of aggressive behavior as observed by nursing staff.
3. To determine whether doll therapy was effective in decreasing the utilization of *pre re nata* (as circumstances may require [PRN]) medication by the nursing staff.

Research Hypothesis

1. The individuals with dementia who receive doll therapy will decrease their agitation score as measured by the Cohen- Mansfield Agitation Inventory (CMAI)

(Cohen-Mansfield, Marx & Rosenthal, 1989) (Appendix A) more significantly than the individuals with dementia who did not receive the doll therapy program.

2. The individuals with dementia who receive doll therapy will decrease their aggression score as measured by the Rating Scale for Aggressive Behavior in the Elderly (RAGE) (Patel & Hope, 1992) (Appendix B) more significantly than the individuals with dementia who did not receive the doll therapy program.
3. The individuals with dementia who receive doll therapy will decrease the frequency of use of PRN medication for agitated and aggressive behavior more significantly than the individuals with dementia who did not receive the doll therapy program.

Definitions of Terms

Agitation. Agitation is defined as "inappropriate verbal, vocal, or motor activity that is not explained by needs or confusion *per se*" (Cohen-Mansfield & Billig, 1986, p. 712). Agitated behavior in demented patients can be observed as wandering, repetitive movements, kicking, inability to sit, short attention span, picking at clothing, dressing and undressing, etc. The behavior may be abusive or aggressive toward self or others, or may be an appropriate behavior performed with inappropriate frequency, such as constantly asking questions or chanting a phrase over and over (Cohen-Mansfield, Marx & Rosenthal, 1989). These behaviors are also referred to as disruptive behaviors (Cohen-Mansfield, 1989). In this study, the Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield, Marx & Rosenthal, 1989) (Appendix A) was used to measure the agitated behavior of the participants.

Aggression. Aggression is defined as "an overt act, involving a noxious stimuli to (but not necessarily aimed at) another organism, object or self, which is clearly not accidental" (Patel & Hope, 1992, p. 212). Aggression may be manifested by destructive and attacking behavior (Dorland's Illustrated Medical Dictionary, 1994). In this study, a 21 item rating scale known as the Rating Scale for Aggressive Behavior in the Elderly (RAGE) (Patel & Hope, 1992) (Appendix B) was used to measure aggressive behavior.

Dementia. Dementia is defined as acquired cognitive deficits sufficient to interfere with social or occupational functioning without depression or clouding of consciousness. Dementia is a syndrome characterized by increasing cognitive deficits, behavioral symptoms, personality changes and persistent functional decline (Patterson, et al., 1999). In this study, the severity of dementia was determined by each participant's score on the Folstein Mini-Mental State Examination (MMSE)(Folstein, Folstein & McHugh, 1975) or in cases where the patient was deemed not testable by the psychologist, confirmation by the psychologist that mental functioning was in the moderate to severely impaired ranges.

PRN. PRN (*pre re nata*) medications are those medications used by nurses to minimize agitated and aggressive behaviors when the behaviors are escalating and non-pharmacological strategies are ineffective. PRN medications given for agitated and aggressive behaviors could include anti-psychotics, anti-anxiety, and antidepressant medications and are those medications given over and above regularly scheduled medications (Dorland's Illustrated Medical Dictionary, 1994; personal communication, Dr. Dale Danyluk, February 4, 2005). In this study, PRN medication used by the nursing

staff was collected from the medical record and recorded on the PRN Data Collection Sheet (Appendix C).

Dolls as a Treatment Modality. Doll therapy refers to an individual holding or carrying a doll, tending to needs of a doll as one would a baby, or any type of caring behavior, paying attention to or interacting with a doll they or someone else is holding (Godfrey, 1994; Piccoli, 1998). In this study doll therapy was used to distract individuals who were looking bored, or showing signs if agitation or aggression. As a part of this study, dolls were added into the study environment as an environmental modification. Doll therapy was offered to participants and interaction was on a voluntary basis. Dolls were available in the environment and participants in the study were considered to be receiving doll therapy regardless of the number or type of interactions or whether they had any observable interaction with dolls.

CHAPTER 2

LITERATURE REVIEW

Theoretical Basis for the Use of Dolls in Dementia

In this paper, the author takes the view that the symptoms and behaviors of demented individuals are not solely a manifestation of the underlying disease process, but also reflect the social and environmental context, as well as the demented individual's perceptions and reactions. Psychosocial interventions can address these factors (Kasi-Godley, 2000). Ideally, an intervention should: reflect a theoretical view; build on the knowledge of the impact of dementia, apply strategies that alleviate distress; facilitate coping, support personal resources, and maximize functioning; as well as have empirical evidence for the intervention used with individuals with dementia.

Theoretical models were explored regarding the use of dolls as a treatment modality. Cognitive theory approaches did not fit this intervention and seemed ineffective because specific memory techniques are applicable only to individuals with mild cognitive impairments.

Behavioral theory approaches with non-demented individuals focus on managing disabilities and problems using the principles of learning. Behavioral approaches are altered in the treatment of individuals with dementia. An array of different strategies is recommended for demented persons. The incorporation of external cues or environmental manipulations is part of this model (Gwyther, 1994). In behavioral theory

approaches behavioral problems are believed to be a manifestation of confusion. Measures are taken to simplify the environment by using stimulus control, environmental modification, and distraction, particularly important with individuals with moderate to severe deficits. Doll therapy fits into behavioral approach in the categories of distraction and environmental modification.

Rationale for using a psychodynamic theoretical approach is based on the theory that ego functions and object relationships can be maintained through a safe, accepting therapeutic relationship where the individual with dementia feels understood and supported (Hausman, 1992). For the individual with dementia, it is thought that a sense of self can be maintained through empathic listening, and use of the therapeutic relationship. This therapeutic relationship is used to validate remaining abilities and competencies, and to provide a calming reassuring, and supportive presence (O'Connor, 1993). Sadavoy (1991) proposes that a sense of self is maintained by meeting the demented individual's need to feel competent, worthwhile and supported. It is postulated that the use of dolls as a treatment modality for individuals with agitated and aggressive behaviors may possibly fit into the psychodynamic model by validating remaining abilities and competencies, such as caring behavior toward dolls.

Use of Dolls With the Elderly

For this literature review, Medline, Pub Med, Web of Science, Scopus, Cochrane, and CINAHL databases were searched in English, using the search terms: doll therapy, dementia, agitation, aggression, treatment, non-pharmacological, psychosocial, behavioral, interventions, and elderly, the terms used alone or in combination. Seventeen articles describing the use of dolls with the elderly were found during the search period,

2004-2006. No empirical study or critical review of the use of dolls to treat agitation and aggression in individuals with any level of dementia could be located. The focus of the present study was to investigate the effectiveness of using dolls to decrease agitated and aggressive behavior and use of PRN medication in individuals with moderate to severe dementia.

Descriptive Studies

The use of dolls and stuffed animals in residents in a chronic care geriatric hospital was observed by Milton and MacPhail (1985). They reported that 5% of the total population of the 284-bed facility was using dolls or stuffed animals. Information on user characteristics, types and numbers of dolls/toys used, pattern of usage, nurses', other residents', and families' reactions was gathered through observation and non-standardized interviews. Ten residents using dolls or stuffed toys, one roommate, some of the residents' relatives, and 10 nurses were consulted to discover the role(s) they thought dolls and toys played in the lives of residents who were seen using them. From the interviews they reported a) that commonly the doll or stuffed toy was introduced as a source of comfort or given as an ornament, where upon the elderly person began using it otherwise; b) subsequent dolls /toys were provided when the recipient showed enthusiasm about the first; c) eight of ten residents received their stuffed toys or dolls from significant others, two from nurses; d) doll or toy users were an older segment of the resident population, their mean age was 84.9 years (range 74 to 98), compared to a mean age of 76.7 hospital wide. The dolls and stuffed toys in this study were reportedly used as objects for reminiscence, to express anger, and for sensory stimulation. The

authors concluded that dolls and stuffed animals provided comfort, pleasure, security, companionship and affection to the residents in that setting.

The diagnoses of the subjects in Milton and MacPhails' (1985) study were not explicitly stated. Sample size was not clearly specified (5% of 284 residents is roughly 14, only 10 residents were mentioned). Level of impairment in cognitive functioning was not reported, although some subjects were described as confused and aphasic. It was not clear whether the subjects were from a homogenous sample. Statistical analysis was not evident. No mention was made of any instrument or tool to measure observations. Medication use was not reported.

In a case study Godfrey (1994) reported that providing a doll to an elderly woman with "intermediate level" dementia was very helpful in managing her anxious agitated behavior. The woman, named Julia, resided in a 40-bed facility in Australia. The author described Julia to be constantly trying to provide unwanted assistance to demented co-residents. Many of the co-residents were increasingly agitated by Julia's continuous attention. Staff intervention was necessary so that other residents did not physically hurt Julia. When redirected for her own safety, Julia, unable to provide "assistance" to others, became more agitated and, at times, violent. In response to Julia's need to care for others and imitate staff, Julia was then allowed to feed one willing resident. This was not successful as Julia quickly became confused and offered the meal to everyone, eating little herself. Redirection by the staff again increased Julia's level of distress and the idea of feeding the other resident was discontinued after a two-week trial. Around this time, her family brought in a box with a toy in it. The toy was apparently ignored but the box had a picture of a baby on it, which Julia carried around and was seen kissing, for days.

Noting Julia's attraction to the picture of the baby, the care team then wondered if perhaps a doll might satisfy Julia's need to care for others. The family provided a 20 cm soft plastic doll in a dress and shawl that Julia named Katie. Julia's family and staff reported that with the doll Julia seemed happier and more settled. Godfrey noted that redirecting Julia to Katie successfully dealt with anxious and agitated behavior. The behavior of other residents was also noted: they were reported to inquire after Katie's health and commented on the amount of time babies took to look after.

In this case study, Godfrey (1994) cautions that doll therapy would not be for everyone. The remaining 39 residents in the facility showed only a passing interest in the doll. Godfrey suggests that it would be necessary to determine which residents demonstrate behavior that might lend itself to a caring role, such as mothering, before trialing this management technique. It is not clear whether there were changes in medication that might have modulated the subject's response to the doll, or whether the other residents in the facility were part of the study or not. No statistical analysis or measurement tool was included.

Reactions of patients residing on five psychogeriatric units were studied by Ehrenfeld and Bergman (1995). They placed a variety of dolls in a central spot in activity rooms. More than half appeared interested, happy looking at, and interacting with, the dolls. Other residents in their study appeared disinterested, suspicious or angry. This study mentioned that dolls were introduced to the patients by placing them in a central area on the treatment unit. Other studies did not include this information (Godfrey, 1994; Milton & MacPhail, 1985; Moore, 2001; Wylie, 2001). The sample size in this study was not clearly stated. Data might have been biased by a selective

observation schedule. However, no comparison group to eliminate the probability of other factors contributing to the results was noted. No mention of a measurement instrument could be found and no statistical analysis was done. There was not enough detail about the methods for other investigators to be able to repeat this study.

Residents of a psychogeriatric unit were perceived by staff to be less restless and agitated after dolls were introduced to their program (Piccoli, 1998). The author reported that the dolls that looked and felt like real babies had a more calming effect on individuals. Other authors concur with using realistic looking dolls (Alzheimer's Australia, 2003; Ehrenfeld, 2003; Godfrey, 1994; Verity, 2006). Most refer to using Lee Middleton Original Dolls© (Appendix D). Verity (2006) recommends these dolls for use in doll therapy programs. She described the Lee Middleton dolls as looking and feeling life like, weighted as a six month old baby, with soft cuddly bodies.

The method of introducing the dolls to the intended users in Piccoli's program (Piccoli, 1998) was by trial and error, until the right owner for a particular doll was found. She emphasized the right doll for the right person by telling a story of a lady who became distressed after caring for her baby doll for a considerable time. Upon inquiry Piccoli learned that the lady believed the baby doll was dead because she could not wake it up. The eyes of the doll were closed. That doll was exchanged for one with open eyes and no further problems were noted. The reverse of this has also occurred, where a lady was exhausting herself pushing a stroller. This lady thought that the baby simply would not go to sleep because its eyes were open. This doll was exchanged for another, which had eyes that opened and closed, with good results.

Dolls were thought to be useful for reducing sundowning, especially in men (Piccoli, 1998). Others concur with this idea (Bailey, Gilbert, & Herweyer, 1992; Shalek, personal communication, October 21, 2004). Dolls were said to be helpful at other times, as a source of comfort and companionship. Piccoli cited an example of one man who, newly admitted to a care setting, steadfastly refused to have his picture taken for identification purposes. The gentleman finally agreed to pose for his picture as long as he could be photographed with his baby doll. Sample size, level of cognitive impairment, measurement tools used to assess behaviors, collection of data or statistical data analysis were not mentioned in Piccoli's study.

Positive changes were observed in residents of a dementia care home that introduced dolls to promote a sense of well being for individuals who appeared agitated and unsettled (Moore, 2001). Moore wanted to discover why dolls seemed to be beneficial for some individuals with dementia. He postulated that dolls allowed people with dementia to communicate underlying emotions, meet needs for attachment, purpose and life roles. Among the residents observed, decreased agitation, aggression and wandering behaviors and increased social interaction with family, co-residents and staff were noted. Other staff, patients and families, verbally validated Moore's observations but no behavior rating scale, measure of cognitive impairment, or sample size was specified. No statistical data or analysis was mentioned.

Shalek (personal communication, October 21, 2004) noted the benefit of using dolls with five patients residing on an Alzheimer's care unit. Based on her study, she concluded that overall, there was increased use of language, improved mood, decreased agitation, less inappropriate behavior and less exit- seeking behaviors. In this study, there

appears to be no comparison group, measurement tool, or mention of medication and its effects on the results. There may also be a measurement bias related to the observation schedule, which is not specified. The level of the subjects' cognitive impairment is unclear.

Based on her clinical experience, Verity (2006) advocated doll therapy as a suitable intervention on a case-by-case basis, to individuals with late stage dementia. Two case studies and procedures for the use of doll therapy were outlined. Her approach to doll therapy differed from the majority of other authors. Rather than having dolls available in a central location on dementia care units, as Ehrenfeld and Bergman (1995), Verity recommended a doll only be offered to an individual after complete assessment and careful consideration of whether need warranted the intervention.

In a pilot study, Mackenzie et al. (2006) looked at the use of dolls with residents in two homes for the elderly mentally ill over a three to six-week period. Thirty-seven residents were given the opportunity to choose one of 14 dolls. In both homes involved, residents were invited to pick up dolls from a table in the lounge area. Twelve women and two men each interacted with a doll. Demographics included the residents' diagnoses, and age. When a resident selected a doll, staff monitored his/her interaction with the doll over a 3 to 6 week period. After a minimum of three weeks but not longer than six weeks following the introduction of dolls, 46 care staff completed a 5-item questionnaire. Care staff was referred to as "unqualified" the meaning of which was unclear. The 5-item questionnaire asked the staff about their overall impression of the use of dolls and the perceived general benefits.

A 14-item questionnaire, an expanded version of the five-item questionnaire, was then completed by 14 primary staff working closely with the 14 residents interacting with the dolls in the two care homes. The questions on the 14-item questionnaire asked the primary staff to identify the impact of the use of a doll on a specific resident's activity levels, agitation, and interactions with others. To do this a 1-5 Likert scale (1 being much less, 5 being much more) was utilized. The 14-item questionnaire required primary staff to hypothesize methods of change occurring via the use of dolls (e.g. whether the doll promoted communication between fellow residents and/or staff) and provide details of their overall impression of doll use (Mackenzie et al., 2006). The impact of the use of dolls on the activity and affective states of participants as assessed by the participant's key worker was summarized.

All 46 care staff completing the 5-item questionnaire indicated they thought use of dolls was positive. Forty-five care staff felt there were clear benefits. Sixteen care staff (35%) reported that there had been some problems using the dolls. The problems reported were that arguments had come up between residents about a) ownership of the dolls; b) feeding dolls; c) dolls perceived mislaid (Mackenzie et al., 2006). Thirteen percent of the carers (Mackenzie et al., 2006) reported that they had initially had misgivings related to doll use, for example, "inappropriateness of dolls...dolls were demeaning...patronizing... dolls might cause confusion" (Mackenzie et al., 2006, p. 442). Staff indicated that their initial opinion changed when they observed the positive interaction between the residents and the dolls. A global question to the carers about how residents' lives had been affected following the introduction of the dolls was asked.

Thirty percent of the carers' felt that residents' lives were "a little better", and 70% of the carers' felt that the residents' lives were "much better" (Mackenzie et al., 2006, p. 442).

The 14 primary staff who completed the 14-item survey indicated that the impact of the dolls on the 14 residents was generally positive. They specified that residents tended to be more active, showed greater levels of interaction with staff and fellow residents, appeared happier, less agitated and more amenable to personal care activities. Of note, many of the primary workers indicated that the residents who interacted with a doll had been given a sense of purpose or focus (Mackenzie et al., 2006). Study authors noted that there was evidence that residents could become over-invested in caring for their dolls. The exact behaviors exhibited by the resident(s) that became over-invested were not stated, but there was reference made to some residents becoming over tired.

Weaknesses of the Mackenzie et al. (2006) pilot study include potential biases with respect to the staff's perspectives, as they were not blinded to which resident had received dolls, or to the rationale underpinning the questions on the survey. The measurement tools, five item and 14-item surveys were homemade, not validated or standardized, introducing confounding variables to the findings. For example, the staff's perspectives could have been biased, as they were not blind to which residents had received dolls. The behaviors being rated in the questionnaires were worded in positive terms, possibly influencing the perceptions of the key workers. The severity of dementia in the subjects in the study was not specified, so that comparison to other studies is difficult. Statistical analysis was not evident and medication use was not reported.

There has been intermittent use of dolls at Alberta Hospital Ponoka since 2002. In this setting, Rowland (personal communication, May 13, 2004) noted particular

success with doll therapy in an 81-year-old man whose agitated and aggressive behaviors had previously resulted in the complete destruction of a T.V., computer equipment, drapery, cabinetry, an electric bed, and a stove. The subject was described as moderate to severely cognitively impaired. In a three-month period a doll was used to distract and redirect these behaviors, a marked decrease in the frequency and intensity of agitated and aggressive behaviors and in the frequency of PRN medications used was noted (Rowland, personal communication, May 13, 2004). However, no behavior-rating scale was utilized, and no statistical analysis was done.

Limitations of Previous Studies

Interpretations of the results of the studies are limited, mainly because of the weaknesses in study designs. In all cases, the studies were non-experimental. Some studies did not describe how their participants were selected (Ehrenfeld, 2003; Piccoli, 1998; Shalek, personal communication, October 21, 2004; Verity, 2006). It was not possible to compare participant results in these studies because of small or unspecified sample sizes (Ehrenfeld, 2003; Moore, 2001; Verity, 2006), no consistency regarding the severity of dementia (Godfrey, 1994; Mackenzie et al., 2006; Moore, 2001; Wylie, 2001), and no consistent method of assessing or rating behaviors within and between studies. Sampling, subject, rater and instrument biases also impact the results of these studies. Confounding factors, such as whether doll therapy was only a part of the overall rehabilitation program and the use of medication were not addressed either (Ehrenfeld & Bergman, 1995; Godfrey, 1994; Mackenzie et al., 2006; Milton & MacPhail, 1985; Moore, 2001; Piccoli, 1998 & Yonemitsu et al., 2001).

Authors concluded that use of dolls had a positive effect on the disturbing behaviors associated with dementia (Mackenzie et al., 2006; Moore, 2001; Rowland, personal communication, May 13, 2004). However, the lack of homogeneous samples, small sample sizes, and the lack of control groups, affects the validity of these studies (Ehrenfeld & Bergman, 1995; Godfrey, 1994; Mackenzie et al., 2006; Milton & MacPhail, 1985; Moore, 2001). Furthermore, the differences in the population under study and the different measurement methods make it difficult to interpret and compare the results. It is therefore worthwhile to investigate the effectiveness of a doll therapy program, especially because none of the studies in the present literature specifically addresses the issue of agitation and or aggression.

CHAPTER 3

RESEARCH METHODS

The following section provides a description of the research design, study participants, human subject protections and ethics review, sample size, power analysis, instruments, procedures, doll therapy, regular activity, data collection, and data analysis.

Research Design

A control group design with a repeated measure was used in this study. The repeated measures design allowed effect over time to be identified in addition to differences between the control and experimental groups. It also reduced chance variation and made the experiment more sensitive to differences among the groups. A repeated measures design allowed for the detection of short-and longer term improvement (Portney & Watkins, 1993).

Study Setting and Subjects

The current study involved recruitment of individuals with moderate to severe dementia residing on three special care units in Alberta Hospital Ponoka, a psychiatric hospital in Ponoka, Alberta. The hospital draws clientele from a large geographical region in central Alberta, including rural and urban areas. This setting offers multidisciplinary assessment and treatment of dementia.

The study was open to males and females with a confirmed diagnosis of dementia, according to the Diagnostic and Statistical Manual of Mental Disorders-IV (DSM IV) of the American Psychiatric Association (APA) (1994). All residents on the special care

units with dementia had moderate to severe cognitive impairment with a score of less than 20 on the MMSE (Folstein et al., 1975). A MMSE score of less than 20/30 is rated as moderate to severe cognitive impairment according to Knapp et al. (1994). The last recorded MMSE score in the medical record was used for this study. A chartered psychologist completed the MMSE as part of the assessment and periodic re-evaluation process. Eight potential participants that did not have a recent MMSE score in their medical records. One of the chartered psychologists in the program volunteered to administer the MMSE to these participants.

Approval of Study

The Health Research Ethics Board (HREB) representing the University of Alberta, Capital Health and Caritas Health Group and the Research Committee of the David Thompson Health Region (DTHR) representing the study site were consulted and subsequently approved all procedures (Appendices E and F respectively).

Instruments/Measurement Tools For Agitation and Aggression

Cohen-Mansfield et al. (1989) developed the Cohen – Mansfield Agitation Inventory (CMAI) to assess the frequency of agitated/disruptive behavior of nursing home residents, including residents with dementia. The CMAI consists of 29 items, directly observable behaviors. To get a "correct" CMAI score, the frequency of each behavior in the prior two weeks is rated, on a seven-point scale for a total of 203. A global agitation score is calculated as the sum of the individual item ratings. A low score means less agitation.

Finkel, Lyons, and Anderson (1992) studied the internal consistency, reliability, and validity of the CMAI with a sample size of 90 nursing home residents. The internal

consistency reliability (Cronbach's alpha) was reported as .86, .91, and .87 respectively for the day, evening and night shift raters. Inter-rater agreement coefficients for each behavior on the CMAI were calculated by Cohen-Mansfield, Marx, and Rosenthal (1989) for three sets of raters on three units, at .92 (n=16), .92 (n=23), and .88 (n = 31).

Construct validity of the CMAI was addressed in a study using data from three samples of nursing home patients categorised as having at least mild behavioral and psychological symptoms of dementia (Rabinowitz, Davidson, De Deyn, Katz, Brodaty & Cohen-Mansfield (2005). In this study the CMAI factor structure was analyzed. CMAI data from the baseline assessment of three randomized placebo controlled trials of respiradone for treating elderly nursing home residents was examined. Exploratory factor analyses were conducted on two trials (n = 304; n = 344), and the results of these were then tested with confirmatory factor analysis by use of data from a third trial (n = 617). Four factors emerged on the CMAI: aggressive behavior, physically non-aggressive behavior, verbally agitated behavior, and hiding and hoarding. The results obtained converge reasonably with previous publications concerning the factor structure of the CMAI, suggesting a fairly robust factor structure for the CMAI Rabinowitz, Davidson, De Deyn, Katz, Brodaty & Cohen-Mansfield).

The Rating Scale for Aggressive Behavior in the Elderly (RAGE) is a 21-item rating scale for measuring aggressive behavior in psychogeriatric inpatients and designed to be completed by ward nursing staff (Patel & Hope, 1992). There are 20 items on the scale that rate the frequency of each behavior in the prior three days using a 4-point scale. One item is scored as yes or no. A total score of 61 could be obtained. A low score means less aggression. The inter-rater reliability coefficient of the RAGE is 0.94

(p<0.001), with a sample of 274 nursing home residents with dementia. The test-retest reliability coefficient was r= 0.91, (p < 0.001). The rating scale total score was compared with the total number of recorded occurrences of any type of aggressive behavior for the subjects. The Pearson Correlation Coefficient was 0.86 (p < 0.001) when the total score on the RAGE was compared with the total number of recorded occurrences of any type of aggressive behavior for the sample from the nursing home.

Shah, Chui, and Ames (1997) studied the concurrent validity between the RAGE and the Staff Observation Aggression Scale (SOAS) (Palmsteirna & Wistedt, 1987) with a sample size of 83 subjects. The results showed a significant correlation (r = .83, p < .001) between the RAGE and SOAS for the total score. The subscale scores vary from r = .78 to r = .86, except one subscale score was r = .17 at p = .001. No literature could be located which explored the contruct validity of the RAGE scale.

The RAGE is frequently used in drug studies where manufacturers are looking to treat cognitive or behavioral symptoms of dementia (Sival, Haffmans, Jansen, Duursma & Eikelenboom, 2002).

The CMAI and the RAGE were selected for the study because they had good reliability and validity, had been used with dementia patients and included detailed descriptions of the behaviors being addressed in this study. Other instruments available did not include detailed descriptions of the behaviors or were designed for different populations. While there is some overlap in the two instruments, the researcher used both the CMAI and the RAGE in this study because together they fairly completely included the agitated and aggressive behaviors that this study was trying to measure.

Sample Size and Power Analysis

The number of potential participants in the study restricted the sample size. The power was based on the anticipated number of subjects who could be recruited. For an ANOVA with two groups, 78 participants (2: 1 treatment unit to control unit ratio), alpha = .05 and an effect size set at .50 (medium), power to detect differences between the groups would be at least 80%. Effect size was arbitrarily set at .50 since there are no previous studies that assess the effectiveness of doll therapy in reducing the agitation, aggression, and the frequency of use of PRN medications.

Recruitment Procedures

The social worker from each special care unit made a list of potential participants based on selection criteria. In the order that the potential participants' list was drawn up, patients were assigned a study number by a student occupational therapist. This list of potential participants and all identifying information related to the study were kept in a locked file. Potential participants' guardians were mailed an introductory letter (Appendix G) telling them about the study, including all pertinent and necessary details (Appendix H), and inviting participation in the study. A consent form (Appendix I) and a return stamped addressed envelope were included. Each guardian received a follow-up phone call or was approached by the unit social worker after the initial mailing. A few guardians consented verbally on the phone and then sent in the signed consent form. Questions about the study from guardians were either answered by a staff member or directed to the researcher. Fifty-four (81%) of eligible participants) were recruited for this study. The final sample size was 45.

Once informed consent was received from the guardian, study participants became members of the study, allocated to either the treatment or control group, depending on the unit where they resided. Participants were not randomly assigned. Instead the control unit and the two treatment units were randomly assigned. The control unit and the two treatment units each had 15 study participants.

Doll Therapy

The study was conducted over a four-week period to allow a reasonable time to observe the effects, to coincide with the nursing rotation, and take as little time as possible from the clinical coordinator nurses' day-to-day running of the units. Study dolls were available on the treatment units Tuesday to Thursday, and removed Friday to Monday. The control unit did not receive any additional dolls during the study period.

Doll therapy was defined as any interaction any patients had with dolls Tuesdays, Wednesdays and Thursdays, a 72-hour period, beginning with the day shift on Tuesday and ending at the beginning of the day shift Friday.

At a day/evening shift change meeting in the week before the study started, staff on each of the dementia units was informed that a study looking at the use of dolls in dementia care was being conducted.

Prior to the start of the study doll usage on all units was sporadic, delivered informally, and dolls were not consistently available. At the direction of the University Ethics Committee, the normal availability of one or two dolls continued on the control unit during the study, as there was concern over doll withdrawal.

Protocol for Delivering Doll Therapy

The protocol for delivering doll therapy for the study was altered from the usual delivery at Alberta Hospital Ponoka. During the study, the approach to dolls on the treatment units was more structured than how it was delivered prior to the study. On the treatment units, fourteen dolls were available per unit. Prior to the study, dolls were not kept in any particular location on the unit. For the study, dolls were available in the day room (a central area) so that interested patients helped themselves to the dolls if they chose to do so. Dolls were available in the environment and participants in the study were considered to be receiving doll therapy regardless of the number or type of interactions or whether they had any observable interaction with dolls. The dolls were dressed in distinctively different outfits and their physical characteristics varied, so that no two dolls on any one unit appeared the same, even with their clothes off. This was to help avoid any disputes between participants about ownership and to appeal to a variety of preferences.

Regular Activity

During regular activity, unit staff provided all patients (both treatment and control), the usual standard amount of time and attention, activity, and one-to-one time that they normally received on Tuesdays, Wednesdays and Thursdays, in a 72-hour period. This regular activity was generally comprised of a variety of basic activities of daily living. Activities included things they might engage in on their own or with assistance such as, walking, resting, receiving nourishments and personal care, observing and engaging in interactions with others. More complex activities such as bingo, bowling, card games, crafts, reading, baking, reminiscence groups etc. were not part of

regular activity because these types of activities required much higher cognitive functioning than persons with moderate to severe dementia possess.

Data Collection

Demographic data (gender, age, length of hospital stay, marital status, education level, diagnoses, and names of each PRN medication for agitated and aggressive behaviors, and last recorded MMSE score) were obtained from each participant's medical record.

For the CMAI measure, data was gathered by the clinical coordinator, three times per participant over the study period. Baseline agitation data was captured in the two-week period prior to study implementation, and referred to as Time 1 (T1). Time 2 (T2) captured agitation data from the beginning of week 1 through to the end of week 2, or the first two weeks of the study. Time 3 (T3) captured agitation data from the beginning of week 3 through to the end of week 4 or the last two weeks of the study.

For the RAGE measure, the clinical coordinator gathered data nine times per participant, over the study period. Time 1 (T1), referred to baseline aggression data captured in the three days prior to the study implementation. Aggression data for weeks one and two was collected four times at regular intervals, averaged for each participant, and referred to as Time 2 (T2). Aggression data, collected at regular intervals four times in weeks three and four, was averaged for each participant, and referred to as Time 3 (T3).

For the PRN measure, the clinical coordinator counted the number of PRN medications given in the previous two weeks for agitated or aggressive as follows: Time 1 (T1) captured baseline PRN use for the period two weeks prior to the study. Time 2

(T2) captured data from the beginning of week 1 through to the end of week 2 or the first two weeks of the study. Time 3 (T3) captured data from the beginning of week 3 through to the end of week 4, or the last two weeks of the study. During the study, the clinical coordinator tabulated the type and number of PRN's, taken from the medical record, on each patient's PRN Medication Data Sheet.

Figure 1

Data Collection Schedule

	Administer CMAI & RAGE, Collect # PRN's	Administer RAGE	Administer CMAI & Collect # PRN's
Treatment & Control Groups	Baseline Assessment Monday week 1	Mondays weeks 2, 3,4,5 Fridays weeks 1,2,3,4.	Mondays weeks 3,5

Data Analysis

Descriptive statistics (means and standard deviations) were calculated to describe study participants on the control and treatment units. Chi-square and t –test (Champion, 1981) tests were used to compare the participants on the control and treatment units on demographic characteristics, which might have a bearing on their outcome scores (gender, age, education, MMSE score, and marital status).

Analyses of the study outcome data utilised Analysis of Variance with Repeated Measures (ANOVA) (Moore, 2000). Analysis of Covariance (ANCOVA) (Moore, 2000) with Repeated Measures was used to adjust for baseline outcome measures between

treatment and control groups. Group (treatment versus control) was the between subject variable. Time (T1, T2, and T3) was the within subject variable.

Three main analyses were examined: Group, Time and Group by Time interaction. The three outcome variables were: CMAI, RAGE, and PRN use. The outcome data for all measures for the two treatment groups were examined separately and together. After examination of the outcome data, it was decided that, for all measures, data from both treatment groups would be combined into one treatment group because outcomes were similar. SPSS version 12 (2003) was used to generate the statistical calculations.

CHAPTER 4

RESULTS

This chapter presents the results of the study, beginning with a description of the participants, a comparison of the treatment and control groups on demographic data, and finally an analysis of the impact of doll therapy on agitation, aggression, and PRN medications.

Participants

The participants were recruited from the three-inpatient dementia care units with a total 75 bed at capacity. The dementia care units are part of a seniors mental health program in a large psychiatric hospital in Ponoka, Alberta. Seventy-eight residents' charts were reviewed for the study. Sixty-seven (86%) residents met the inclusion criteria, for severity of dementia and had a formal guardian in place. The other 11 (14%) residents met the dementia criteria but did not have a legal guardian and could not ethically be approached to provide consent for themselves. The guardians of 54 (81%) of the 67 residents agreed to participation in the study and returned the signed consent forms. For various reasons, nine of the 54 participants left the study leaving 45 participants whose data are reported in the final results. Of the nine that left the study, one participant was discharged to another facility before the study began. Three others started the study and then were transferred to other units within the hospital or discharged to other facilities. Five others took part in the study but then were removed when their very long lengths of stay (from 7 to 25 years) were determined to be considerably

atypical. The five outliers were thought to be more "institutionalized" than the other participants whose lengths of stay were one to six years. Including the five outliers data, the initial data analyses of the length of stay data indicated that the control unit mean length of stay was 42.5 months (SD= 82.0). The two treatment groups had mean lengths of stay of 28.6 months (SD = 12.0), and 40.8 months (SD = 54.0) respectively. It was thought that data from the five outliers might skew study results. The individuals with the outlier scores had lengths of stay of 212 and 298 months in the control group, and 100, 130 and 207 months in treatment groups.

Re-analyses of the length of stay data, with N=45, with outliers removed, indicated the mean length of stay for the control unit was 14.1 months (SD = 14.1); and 20.0 months (SD = 17.8) for the two treatment groups combined. There were no significant differences between any of the groups for gender, marital status, age, educational level, MMSE score, or length of stay. Because the target of 78 subjects was not achieved, power for the study was less than 80%.

The demographic information about the participants is summarized in Tables 1, 2 and 3. Table 1 shows the distribution of gender. The study participants consisted of 16 women and 29 men. There were 12 women and 18 men in the treatment group, and 4 women and 11 men in the control group. There were no significant differences in gender distribution between the groups, although both groups contained more men than might be expected in a dementia care setting.

Table 1

Gender of Participants

	Gender	
	Female	Male
Group	n (%)	n (%)
Treatment	12 (40)	18 (60)
Control	4 (27)	11 (73)

Note. Chi square = .76; degrees of freedom = 1, N = 45; p = .51

Table 2 shows the distribution of marital status of the participants. In both groups, the number of men outnumbered the number of women. There was no significant difference between the groups in distribution of marital status, although here was a trend for more of the treatment group to be single which may have been significant with greater study power.

Table 2

Marital Status of the Participants

	Marital Status	
	Married	Single
Group	n / %	n / %
Treatment	12 (40)	18 (60)
Control	11 (73)	4 (27)

Note. Chi square = 4.4; degrees of freedom = 1, p = .06

Table 3 shows the distribution of age, education, MMSE scores and length of stay. The mean age was 84 years (range 74 – 99) for the control group. For the treatment group, the mean age was 78 years (range 55 - 91). The mean educational level was 10 years (range 6 – 16) for the control group. The mean educational level of participants in the treatment group was 10 years (range 4 – 18 years). The mean Mini Mental Score Examination scores were 8.47 (range 0- 17) for the control group, and 6.47 (range 0 –17) for the treatment group. There were no significant differences between any of the groups for age, educational level, MMSE score, or length of stay. Howecver there was a trend for the control group to be younger which may have been significant with greater study power.

Table 3

Demographic Characteristics of Participants

Variable	Treatment Mean (SD)	Control Mean (SD)	t	*df*	*p*
Age (yrs)	78.43 (9.36)	83.73 (6.39)	-1.97	43	.06
Education (yrs)	9.63 (3.12)	10.27 (3.39)	-.62	43	.54
MMSE Scores	6.47 (5.60)	8.47 (6.50)	-1.07	43	.29
Length of Stay (mo)	20.03(17.86)	14.13 (14.14)	1.12	43	.27

Note. MMSE = Mini Mental State Examination
$n = 30$ for the treatment group, $n = 15$ for the control group.

Hypothesis Testing

To examine the effect of doll therapy on the outcome variables (i.e., agitation, aggression and PRN medication usage), multivariate statistics were calculated using the

General Linear Model (ANOVA and ANCOVA) program for repeated measures documented by SPSS 12.0 for Windows (SPSS, 2003).

Hypothesis 1

Hypothesis 1 states that individuals with dementia who receive doll therapy will decrease their CMAI agitation score more significantly than those individuals with dementia who did not receive the doll therapy program.

The data for the CMAI was collected and calculated at baseline (T1), after two weeks (T2) and four weeks (T3) for the treatment and control groups. The means and standard deviations are recorded in Table 4.

Table 4

Descriptive Statistics for CMAI Scores

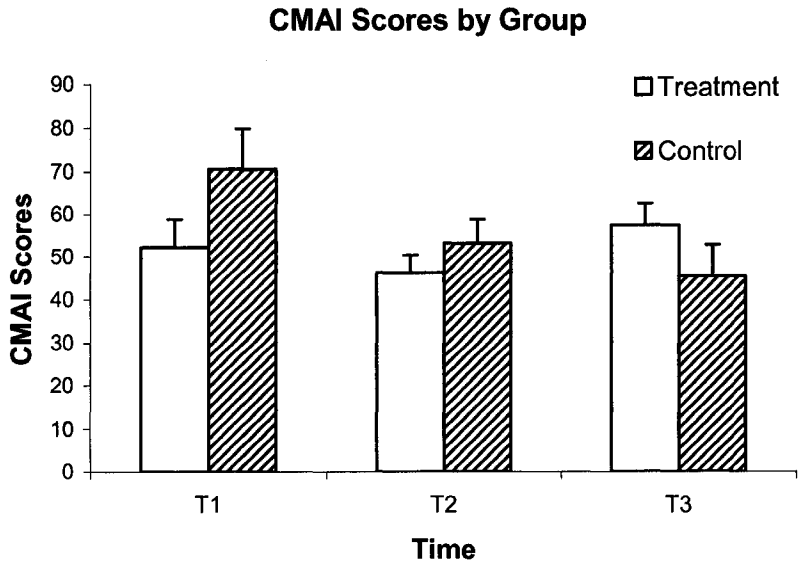
	T1	T2	T3
Group	Mean (SD)	Mean (SD)	Mean (SD)
Treatment	52.23 (15.57)	46.33 (10.69)	57.43 (16.31)
Control	70.60 (21.69)	53.13 (11.48)	45.43 (6.44)

Note. T1 = Baseline, T2 = After 2 weeks; T3 = After 4 weeks.
n = 30 for the treatment group. n = 15 for the control group.

Mean CMAI scores by group are shown in Figure 2. The decrease of the control group's mean CMAI scores and the flat or u-shaped pattern of the treatment group are observed.

Figure 2

CMAI Scores by Group



Note. T1 =Baseline; T2 =After 2 weeks; T3 = After 4 weeks.

ANOVA with repeated measures were calculated (Table 5) and it was concluded that there was an overall significant within-group effect, ($p < .0004$) over time. There was also a significant time by group interaction ($p < .0004$). The treatment group CMAI scores decreased from T1 to T2 and increased when measured at T3 of doll therapy. However, the between-group effect ($p = .2$) was not statistically significant.

Table 5

Summary of Analysis of Variance for CMAI

Source	*df*	SS	MS	F-Value	*p* Value
Time	2	3176.45	1588.23	11.51	<.0004
Group	1	586.68	586.68	1.66	.20
Time X Group	2	4665.16	2332.58	16.9	<.0004

Note. *df* = degrees of freedom, SS = Sum of Squares; MS = Mean Square.

CMAI effects with the baseline CMAI score as the covariate were calculated using ANCOVA with repeated measures (Table 6). ANCOVA was calculated to see if the effects of controlling for the baseline CMAI score would explain the variance in scores. The time by group effect was still significant at ($p < .0004$). The time effect ($p = .62$), and the group effect ($p = .07$), was not statistically significant. The findings of the CMAI data collection did not support hypothesis 1.

Table 6

Summary of Analysis of Covariance Using T1 as Covariant for CMAI

Source	*df*	SS	MS	F value	*p* value
Time	1	20.81	20.81	.26	.62
Group	1	697.31	697.31	3.38	.07
Time X Group	1	1648.58	1648.58	20.26	<.0004
Covariate	1	1320.98	1320.98	6.41	.02
Time X Covariate	1	50.61	50.61	.62	.44

Note. *df* = degrees of freedom; SS = Sum of Squares; MS = Mean Square.

Hypothesis 2

Hypothesis 2 states that individuals with dementia who receive the doll therapy program will decrease their aggression score on RAGE more significantly than the individuals with dementia who did not receive the doll therapy program.

Data for the RAGE was collected and calculated at baseline and referred to as T1. RAGE data collected four times at regular intervals in weeks one and two of the study was averaged for each participant, and referred to as T2. RAGE data for weeks three and four of the study was collected four times at regular intervals, averaged for each participant, and referred to as T3. The mean and standard deviation RAGE scores are recorded in Table 7. The decrease of the control group's mean RAGE scores and the fluctuation of the treatment group scores are observed.

Table 7

Descriptive Statistics of the RAGE Scores

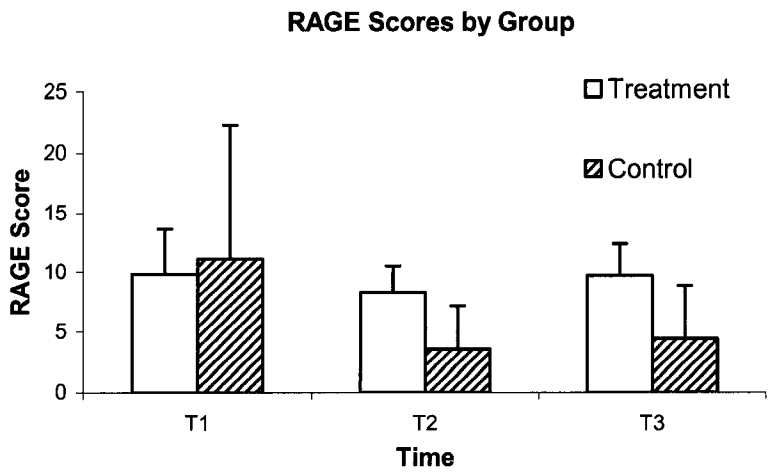
	T1	T2	T3
Group	Mean (SD)	Mean (SD)	Mean (SD)
Treatment	9.83 (10.27)	8.31 (7.27)	9.68 (8.65)
Control	11.13 (10.78)	3.57 (1.98)	4.43 (4.13)

Note. T1 = Baseline; T2 = After 2 weeks; T3 = After 4 weeks.
n = 15 for the control group, n = 30 for the treatment group.

Mean RAGE scores by group are shown in Figure 3. The RAGE scores have a similar pattern to the CMAI scores when graphed: a flat or u - shaped pattern for the treatment group and a general decline in the control group.

Figure 3

RAGE Scores by Group



T1=Baseline, T2 = After 2 weeks; T3 = After 4 weeks.

ANOVA with repeated measures for RAGE scores concluded that there was a significant time effect (p = .002). There was also a significant time by group interaction (p = .02). The treatment group showed relatively little change between T1 versus T2 and T3 (9.83 versus 8.31 and 9.68). However, the control group showed a decrease in RAGE scores between the T1 and T2 and T3 respectively, 11.13 versus 3.57 and 4.43.

Table 8

Summary of Analysis of Variance for RAGE

Source	*df*	SS	MS	F Value	*p* Value
Time	2	448.94	224.47	6.67	.002
Group	1	251.33	251.33	1.89	.18
Time X Group	2	265.15	132.58	3.94	.02

Note. *df* = degrees freedom, SS = Sum of Squares; MS = Mean Square.

RAGE effects with the RAGE T1 baseline score as covariate (ANCOVA) were calculated (Table 9). The time effects, the time by group interaction effects and time by covariate interaction effects were not significant. There was a statistically significant group effect ($p < .005$). The covariate effect was significant ($p = .001$). The findings of the RAGE data collection did not support hypothesis 2.

Table 9

Summary of Analysis of Covariance Using T1 as Covariant for RAGE

Source	*df*	SS	MS	F Value	*p* Value
Time	1	8.88	8.88	0.88	0.35
Group	1	575.85	575.85	8.77	.005
Time X Group	1	1.37	1.37	0.14	0.72
Covariate	1	817.20	817.20	12.45	.001
Time X Covariate	1	0.76	0.76	0.08	0.79

Note. *df* = degrees of freedom, SS = Sum of Squares; MS = Mean Square.

Hypothesis 3

Hypothesis 3 states that individuals with dementia who received doll therapy will decrease the use of PRN medication more significantly than individuals with dementia who did not receive doll therapy. The mean and standard deviation for PRN usage are presented for each group in Table 10.

Table 10

Descriptive Statistics for PRN Usage

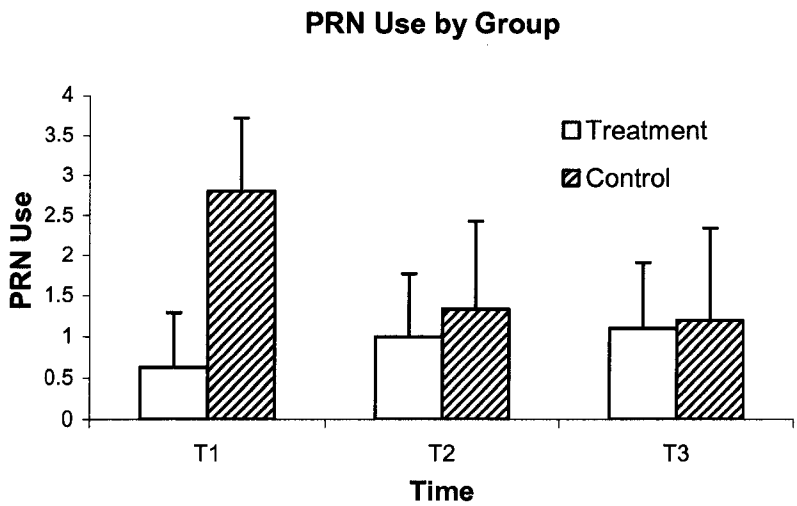
	T1	T2	T3
Group	Mean (SD)	Mean (SD)	Mean (SD)
Treatment	0.63 (1.38)	1.00 (2.08)	1.10 (2.40)
Control	2.80 (2.37)	1.33 (2.13)	1.20 (1.70)

Note. T1 = Baseline; T2 = After 2 weeks; T3 = After 4 weeks.
n = 30 in the treatment group; n = 15 in the control group.

PRN use by group is shown in Figure 4. PRN use decreased in the control group and increased in the treatment group.

Figure 4

PRN Use by Group



Note. T1 = Baseline; T2 = After 2 weeks; T3 = After 4 weeks.

ANOVA with repeated measures for PRN scores concluded that there was not a significant time effect ($p = .13$) (Table 11). There was a significant time by group interaction ($p = .003$). The control group PRN scores showed a sharp decrease from T1 to T2 and a small decrease from T2 to T3. The treatment group showed a smaller variation with scores increasing, from T1 to T2 and T3. Lastly, the group effect was not statistically significant ($p = .11$).

Table 11

Summary of Analysis of Variance With Repeated Measures for PRN

Source	*df*	SS	MS	F - Value	*p* Value
Time	2	8.32	4.16	2.06	0.13
Group	1	22.53	22.53	2.72	0.11
Time X Group	2	25.62	12.81	6.35	0.003

Note. *df* = degrees of freedom, SS = Sum of Squares; MS = Mean Square.

ANCOVA, with the PRN baseline (T1) score as the covariate, were calculated for PRN (Table 12). The time by group interaction effect was no longer significant. The covariate effect at T1 was significant ($p < .0004$). The findings of the PRN data collection did not support hypothesis 3.

Table 12

Summary Analysis of Covariance Using T1 as Covariant for PRN

Source	*df*	SS	*MS*	F Value	*p* Value
Time	1	0.57	0.57	31.00	0.58
Group	1	15.02	15.02	2.72	0.11
Time X Group	1	0.02	0.02	0.01	0.91
Covariate	1	85.14	85.14	15.41	< .0004
Time X Covariate	1	1.40	1.40	0.75	0.39

Note. *df* = degrees of freedom; SS = Sum of Squares; MS = Mean Square.

Ancillary Findings

During the study, staff perception of the doll therapy program was gathered by obtaining feedback from the day shift nursing staff verbally to the researcher or written, passed on at shift change. Nursing staff from both treatment units gave feedback.

During the study period, nurses noted that the dolls received a lot of handling. Some dolls were "fed" and needed minor cleaning up. Other dolls were missing clothing that was located and put back on by staff and/or patients. Dolls were found all over the units, in beds, in washrooms, on the floor. The clinical coordinator or designate periodically gathered up the dolls and returned them to the common area. Study participants and non-study participants used the dolls. Unit staff offered dolls to any residents, when they appeared bored or under stimulated, or began to show signs of agitation or aggression. One resident was noted to line up the dolls on a sofa and spend most of the day arranging and rearranging the dolls. He allowed others to remove and interact with the dolls. One resident had taken off her blouse and undergarment in the common area and was observed to be trying to breastfeed her doll. Staff reported assisting the resident and her doll to her room for her own privacy. Another participant was reported to sleep with her doll. One of the male participants became very attached to a particular doll and he was reported to put his eyeglasses on the doll and coo and hug the doll. This man was observed to be using a doll to shine up a counter. When asked by staff what he was doing he stated "they have to learn how to do hard work early."

The treatment team monitored the behavior of the patients at all times in the study to determine whether there were any particularly negative behaviors right after dolls were withdrawn. There was a plan to return dolls to the units if there was concern over

behaviors related to the absence of dolls. No signs of doll withdrawal were reported to the investigator. Neither were there any reports of staff having to remove dolls for safety reasons during the study period i.e. if a doll was being used as an object to hurt another patient.

Summary

The treatment group scores tended to show no improvement over time. In contrast, the control group scores declined over time for all three variables. The analysis of data using ANOVA with repeated measures revealed that there was no statistically significant effect of the doll therapy on agitation, aggression and PRN usage in individuals with moderate to severe dementia.

CHAPTER 5

DISCUSSION

Overview

This applied research study was designed to investigate the effectiveness of a doll therapy program on individuals with moderate to severe dementia. It was hypothesised that providing doll therapy to individuals with moderate to severe dementia would decrease agitation, aggression and the use of PRN medication. Units were randomly assigned to be control and treatment units. Dolls were provided to the treatment group over the 4-week study period. Three separate variables measured the changes in agitation, aggression, and PRN medication usage among individuals with dementia who resided in one institution.

Demographic information of the study participants was collected to assess differences between the control and the treatment groups with regard to gender, marital status, age, education completed, MMSE score, and length of stay in hospital.

Following the analysis of the data, all three hypotheses were not supported at the $p < .05$ level of significance. While there were no statistically significant treatment effects found in this study, there were trends in the data that warranted further discussion and interpretation.

Interpretation of Results

Demographics

When the treatment and control groups were compared for demographics, no statistically significant differences were evident. There was no statistically significant difference between the groups for marital status. For example, marital status and age might be significant if the sample size were larger. The large variability among subjects is problematic. The variability suggests that the study population was demographically diverse, despite sharing the diagnosis of dementia. This variability complicates finding statistically significant differences within and between groups.

There tended to be more men than women in the study. Men in the study might not have had the same response to doll therapy as women in the study relating to the differences in their past experiences in raising children.

Hypothesis 1

Hypothesis 1 states that individuals with dementia who received doll therapy will decrease their CMAI scores more significantly than individuals with dementia who did not receive doll therapy. CMAI effects with the baseline as covariate were calculated. The overall time effect was no longer significant ($p = .62$). There was still no group effect ($p = .07$). The time by group interaction remained significant ($p < .0004$). This implies that there was some improvement in the groups over time. Post hoc tests are normally conducted in this situation to find out which group has the improvement. In this study post hoc tests were not done because the improvement was in the control group, most dramatically from baseline to T2 (Figure 2). The CMAI score was not significantly lower in the individuals who received the doll therapy program. Some of this decline

might have been regression to the mean. This finding implies that those who received the doll therapy program were not less agitated than those who did not receive the doll therapy program. Conversely, this finding does not necessarily mean that doll therapy was disruptive. There may be other factors that influence agitation in this population. Possible explanations for this outcome are discussed later in this chapter.

Hypothesis 2

Hypothesis 2 states that individuals with dementia who received doll therapy will decrease their RAGE scores more significantly than individuals with dementia who did not receive doll therapy. RAGE effects with the baseline as covariate were calculated. The overall time effect was no longer significant ($p = .35$). Time by group interaction effects were not significant either ($p = .72$). This implied that doll therapy was not effective in reducing aggression. The mean RAGE score of the control group decreased. This implied that participants in the control group became less aggressive over the study period; however doll therapy did not increase aggression in the treatment group. This effect was opposite to what was predicted. Possible explanations for this outcome will be discussed later in this chapter.

Hypothesis 3

Hypothesis 3 stated that individuals with dementia who receive doll therapy would decrease the frequency of use of PRN medication for agitated and aggressive behavior more significantly than the individuals with dementia who did not receive the doll therapy program.

PRN effects with the baseline time as the covariate were calculated. The time by group interaction effect was no longer significant ($p = .91$). There was still no statistically significant group effect ($p = .10$). This finding could be interpreted as consistent with the results of hypotheses one and two. Specifically, as the study progressed, the PRN medication order could have been prescribed as part of regular medication regieme; therefore it was no longer recorded as PRN medication usage. Since the control group was more agitated and aggressive to begin with, this shift may have been more common among them, accounting for an apparent drop in PRN medication.

Other Possible Explanations for Decrease in Control Group Scores

Considering their generally worse baseline scores the control group may have had less problematic behaviors than the treatment group because they were older. Mobility or the lack of mobility was not controlled for in this study but might have allowed some participants to be more or less aggressive. Another possibility is that the control group received deferential treatment from the staff. This was not evident at the time of the study and is only offered in retrospect as one possible explanation.

Strengths and Limitations of the Study

Strengths

The current study improved upon previous studies in a number of ways. Previous studies were non-experimental. Some studies did not describe how their participants were selected (Ehrenfeld, 2003; Piccoli, 1998; Shalek, personal communication, October 21, 2004; Verity, 2006). It was not possible to compare participant results in these

studies because of small or unspecified sample sizes (Ehrenfeld, 2003; Moore, 2001; Verity, 2006), no consistency regarding the severity of dementia (Godfrey, 1994; Moore, 2001; Wylie, 2001), and no consistent method of assessing or rating behaviors within and between studies. Sampling, subject, rater and instrument biases also impact the results of these studies.

Confounding factors, such as whether doll therapy was only a part of the overall rehabilitation program and the use of medication were not addressed either (Ehrenfeld & Bergman, 1995; Godfrey, 1994; Milton & MacPhail, 1985; Moore, 2001; Piccoli, 1998).

The study design was stronger than the others reported in the literature (Ehrenfeld & Bergman, 1995; Godfrey, 1994; Milton & MacPhail; 1985; Moore, 2001; Verity, 2006; Wylie, 2001 & Yonemitsu et al., 2001) as there was a control and a treatment group, participant selection criteria, specified sample size, consistency regarding the severity of dementia, standardised rating of behaviors, and monitoring of the use of medications.

Limitations

There are several limitations of the present study that warrant discussion. The limitations are related to instrument selection, data collection and study design.

The first methodological limitation of the study involves instrument selection. While the instruments used in the study were well-validated and reliable, measures of well -being (Kitwood & Bredin, 1992) and measures of doll - participant interaction (Dean, Proudfoot, & Lindesay, 1993) might have captured positive doll interaction. Lack of data collection (i.e. detailed monitoring) of participants who actually handled dolls in the study period was not captured in the present study. This meant that potentially valuable information regarding the impact on behavior, activity, and affective states of

participants using dolls during actual doll use, was lost. Data collection about characteristics of study participant interactions with dolls, staff, other residents, and whether the participant appeared happier or more content might be better indicators of the effects of doll therapy. In the present study it is not known how many participants actually selected dolls when they were made available to them.

In this study ythe inter-rater reliability of the case coordinators (raters) was not studied. Also, no inter-rater reliability was established between the staff that charted the behaviors of the participants. The charting skills of the nursing staff that recorded participants' behavior in the medical record were not standardised. There was no training given to them prior to the study. This could have resulted in the case coordinators (raters) inaccurately filling out the CMAI and the RAGE score sheets. The fact that the raters were not blinded might also have biased the results. But there seemed no way for raters to accurately complete the CMAI and RAGE measures other than to know the identity of the participant they were rating.

Another design limitation was that there was a lack of structure with the doll therapy approach and whether it could justifiably be called 'doll therapy'. For the study, the nursing staff was not instructed to behave in any certain way except to offer dolls to residents that appeared bored, in need of distraction, or showed signs of becoming agitated or aggressive. Staff interactions might have varied from resident to resident, but this issue was not controlled for. In retrospect, it was possible, but not known, whether some participants in the control group might have received deferential treatment, and this may have accounted for the difference between the control and the treatment group scores.

Prior to the start of the study, having a control and treatment group on each of the dementia units rather than allocating separate control and treatment units had been considered since it might have resulted in more equivalent groups. But in discussions with unit managers, it was decided that this approach would be too difficult to carry out in practice. It was not feasible to give the treatment group participants dolls and withhold dolls from the control participants when they shared the same living space. Taking the treatment group off unit to expose them to dolls did not seem feasible as this might have added to the agitation levels and requires more staff resources.

Unit differences may have been influential in the study. Despite that the units were constructed as to be structurally similar, illness on the units, medication changes, noise, lighting, etc. might be factors causing variability among units that was not accounted for in this study. Results were calculated using the two treatment units together and separately verses the control unit but there was no doll effect either way.

Small sample size is another limitation of the study even though 80% of eligible participants were recruited for the study. Lack of power for the demographic results was discussed in the results section.

Mobility of participants and non-participants was not measured for the study. This variable might have been helpful in detecting differences among the control and treatment groups. Immobile participants may have been the targets of more aggression by others who were mobile. Immobile participants may not have had as many opportunities to be as aggressive toward others. Conversely, mobile aggressive participants might have been more likely to receive PRN's but this was not measured. This is a limitation of the study.

Criticism of the use of dolls in any study with this population is another limitation of the study on the grounds that it is infantilising (Cayton, 2001; Boas, 1998). Infantilization refers to the treatment of old age as a second childhood, with little or no acknowledgment of a lifetime of experiences that separate the elderly from children (Salari, 2002). This issue raises questions about the appropriateness of doll therapy and whether the benefits of doll therapy can justify its use. Cayton (2001) suggests caution because we do not know whether doll therapy is conscious play or deceit. There is continuing debate regarding the acceptability of dolls. In the present study, a couple of nursing aides informed the researcher that they thought dolls were very good for certain people, but in their estimation there were a number of people who appeared to be disinterested in and would therefore obtain no benefit from dolls. The staff was unable to predict which people might benefit until dolls were offered to them and their response noted. There are no guidelines to help identify which patients might benefit from doll therapy.

Implications

Descriptive studies (Ehrenfeld & Bergman, 1995; Milton & MacPhail, 1985) have suggested that dolls and stuffed animals provided comfort, pleasure, security, companionship and affection to the residents in geriatric care settings. No previous studies have focused on agitation, aggression, and the use of PRN medications as extensively as the present study.

The reports from this study of positive participant – doll interaction suggests that doll therapy does no harm. Since doll therapy did not show any adverse physical or

mental side effects it could continue to be used with patients who are attracted to dolls. This researcher plans to encourage other occupational therapists using dolls in dementia settings to improve on the method that was used in this study. Doll therapy is cost effective as it could be offered by any health professional and non-professional working with individuals with dementia once the program is established by an occupational therapist.

The study has implications for occupational therapy education. Students could be made aware that there is use of dolls in many countries with promising descriptive reports but little empirical evidence about its effectiveness. Further study is needed to gather additional information about actual behaviors observed during doll interaction and provide information about characteristics of patients who would likely benefit from using dolls. Effective protocols for delivering doll therapy also need to be developed.

Recommendations for Further Study

The following recommendations for future research are suggested:

1. Conduct a similar study with a larger sample size to increase power.
2. Conduct a similar study for longer than 4 weeks to assess treatment effects over time. Four weeks may not have been adequate.
3. Conduct a study to determine the effectiveness of doll therapy using different variables such as well - being or quality of life.
4. Develop a study design that allows for detailed data collection of doll user behaviors.

5. Develop a study that would test whether one protocol for delivering doll therapy is more effective than another (e.g. environmental put dolls on units vs specific structured interactions with doll users and dolls).
6. Develop a study design that allows for collection of additional demographic information such as history of having children and or history of interaction with children. This might help identify which patients are most likely to benefit from doll therapy.
7. Use a single subject design to study the effect of doll therapy. This design would capture the variability of behaviors over time and allow for each participant to be their own control. Behaviors with and without dolls could be compared to assess for differences.
8. Study the effects of doll therapy using a sample of women. There might be a gender issue. The large number of men in the study may have biased the results in that many men, now elderly, may not be predisposed to doll interaction. Women may interact with dolls based on their history of having experience with childrearing.

Conclusion

Following the analysis of the data, all three hypotheses were not supported at the $p < .05$ level of significance. The result is inconclusive and does not, in and of itself, negate the value of using doll therapy to address agitation and aggression with this population. Since doll therapy did not show any adverse effects it could continue to be used with patients who are attracted to dolls. Further study is needed to gather additional

information about actual behaviours observed during doll interaction and provide information about characteristics of patients who would likely benefit from using dolls. Effective protocols for delivering doll therapy also need to be developed.

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APPENDIX A

Cohen-Mansfield Agitation Inventory

Please read each of the 29 agitated behaviors, and circle how often (from 1-7) each was manifested by the resident during the last 2 weeks.

Please do not mark the name of the patient anywhere on this form.

Study ID #_____

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
	1	2	3	4	5	6	7
1. Pacing, 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							

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
	1	2	3	4	5	6	7
11. Throwing things							
12. Strange noises(weird laughter or crying)							
13. Screaming							
14. Biting							
15. Scratching							
16. Trying to get to different places(e.g. out of room, building)							
17. Intentional falling							
18. Complaining							
19. Negativism							
20. Eating/drinking in inappropriate places							
21. Hurt self or other (cigarette, hot water, etc.)							
22. Handling things inappropriatel y							
23. Hiding things inappropriatel y							
24. Hoarding things							

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
	1	2	3	4	5	6	7
25. Tearing things or destroying property							
26. Performing repetitious mannerisms							
27. Making verbal sexual advances							
28. Making physical advances							
29. General restlessness							

Cohen-Mansfield, J., Marx, M. S., & Rosenthal, A. S. (1989). A description of agitation in the nursing home. *Journal of Gerontology*: Medical Sciences, 44, (3), 77-84.

APPENDIX B

Rating Scale for Aggressive Behaviour in the Elderly (RAGE)

Please do not mark the name of the patient anywhere on this form.
Participant Study ID Number: _____

Rating Scale for Aggressive Behaviour in the Elderly (RAGE)

Has the patient in the past 3 days.

1. Been demanding or argumentative? 0 1 2 3
2. Shouted, yelled, or screamed? 0 1 2 3
3. Sworn or used abusive language? 0 1 2 3
4. Disobeyed ward rules, e.g. deliberately passed urine outside the commode? 0 1 2 3
5. Been uncooperative or resisted help, e.g. whilst being given a bath or medication? 0 1 2 3
6. Been generally in a bad mood, irritable or quick to fly off the handle? 0 1 2 3
7. Been critical, sarcastic or derogatory, e.g. saying someone is stupid or incompetent? 0 1 2 3
8. Been inpatient or got angry if something does not suit him/her? 0 1 2 3
9. Threatened to harm or made statements to scare others? 0 1 2 3
10. Indulged in antisocial acts, e.g. deliberately stealing food or tripping someone? 0 1 2 3
11. Pushed or shoved others? 0 1 2 3
12. Destroyed property or thrown things around angrily, e.g. towels, medicines? 0 1 2 3
13. Been angry with him/herself? 0 1 2 3
14. Attempted to kick anyone? 0 1 2 3
15. Attempted to hit others? 0 1 2 3
16. Attempted to bite, scratch, spit at, or pinch others? 0 1 2 3
17. Used an object (such as a towel or a walking stick) to lash out or hurt someone? 0 1 2 3

    In the past 3 days, has the patient inflicted any injury?

18. On him/herself? 0 1 2 3
19. On others? 0 1 2 3

    0 not at all
    1 mild e.g. a scratch
    2 moderate e.g. a bruise
    3 severe e.g. a fracture

20. Has the patient in the past 3 days been required to be placed under sedation or in isolation or in physical restraints, in order to control his/her aggressiveness?

    0. no; 1. yes

21. Taking all factors into consideration, do you consider the patient's behaviour in the last 3 days to have been aggressive?

    0. not at all
    1. mildly
    2. moderately
    3. severely.

Total score:

Any additional comments:

Rating on frequency basis over last 3 days

0 = Never

1 = At least once in past 3 days

2 = At least once every day in past 3 days

3 = More than once every day in past 3 days

Source: Patel V, Hope R. A (1992). A rating scale for aggressive behaviors in the elderly -the RAGE. *Psychological Medicine* 22: 211-21. Used With Permission.

APPENDIX C

PRN Medication Data Sheet

PRN Medication Used for Agitated and or Aggressive Behaviors

Patient Study ID Number_____

Drug Name and Dose	Total # used, in the 2 weeks prior to the study.	Total # used during the 1st and 2nd weeks of the study.	Total # used during the 1st and 2nd weeks of the study

APPENDIX D

Example of Dolls Used in Study

Source: Lee Middleton Doll Company© Used with Permission.

APPENDIX E

University of Alberta Health Research Ethics Board Approval

Health Research Ethics Board

213 Heritage Medical Research Centre
University of Alberta, Edmonton, Alberta T6G 2S2
p.780.492.9724 (Biomedical Panel)
p.780.492.0382 (Health Panel)
p.780.492.0459
p.780.492.0839
f.780.492.7808

HEALTH RESEARCH ETHICS APPROVAL

Date of HREB Meeting: December 2, 2005

Name of Applicant: Dr. Sharon Warren

Organization: University of Alberta

Department: Rehabilitation Medicine

Project Title: **The Efficacy of Dolls as a Treatment Modality for Individuals with Moderate to Severe Dementia**

The Health Research Ethics Board (HREB) has reviewed the protocol for this project and found it to be acceptable within the limitations of human experimentation.

The approval for the study as presented is valid for one year. It may be extended following completion of the yearly report form. Any proposed changes to the study must be submitted to the Health Research Ethics Board for approval. Written notification must be sent to the HREB when the project is complete or terminated.

The Research Ethics Board assessed all matters required by section 50(1)(a) of the Health Information Act. Subject consent for access to identifiable health information is required for the research described in the ethics application, and appropriate procedures for consent has been reviewed and approved by the Research Ethics Board. The subject information letter and consent form has also reviewed and approved.

Glenn G. Griener

Glenn Griener, PhD.
Chair, Health Research Ethics Board
(B: Health Research)

JAN 17 2006
Date of Approval Release

File number: B-031205

UNIVERSITY OF ALBERTA Capital Health CARITAS HEALTH GROUP

APPENDIX F

David Thompson Health Region Study Approval/Letter of Agreement

David Thompson Health Region

Research Letter of Agreement

Letter of Agreement

Between

David Thompson Health Region (DTHR)
and
The Governors of the University of Alberta

Related to: The Efficacy of Dolls as a Treatment Modality for Individuals with Moderate to Severe Dementia
Name of Study

104
Study Number

A. WHEREAS The Researcher is undertaking a health related research project
B. WHEREAS the University of Alberta Health Research Ethics Board has reviewed the proposed research project and has approved the proposed research project, such approval having been granted on January 17, 2006
C. WHEREAS the David Thompson Health Region's (DTHR) Research Committee has received the required information from the Researcher and reviewed the research proposal following DTHR Policy IT-VII-10 (Health Research) and/or Policy IT-VII-11 (Industry Sponsored Research) and the impact of the research activity on the DTHR patients, staff, facilities and the public have been considered, the decision has been made to approve the conduct of this research activity within DTHR - approval granted on February 21, 2006
D. WHEREAS the David Thompson Health Region is authorized by sections 53 and 54 of the *Health Information Act* to make the disclosures for research purposes under this Agreement; approval has been granted to provide access and disclose health information
E. WHEREAS this Agreement shall be in place for one year from date of signing. At that time a progress note and request for continuation will need to be submitted to the Research and Evaluation Coordinator, David Thompson Health Region, by the Researcher; NOW THEREFORE the parties agree as follows:

1. GENERAL

1.1 The following are attached and incorporated into this Agreement and are deemed to be part hereof:

- Description of the Research Project, including overall timelines of the Research Project
- Description of the involvement of human subjects and copy of the subject information and consent forms
- Description of the information requested, including specific safeguards implemented to safely collect and store information
- Copy of Research Ethics Board Approval from one of the *Health Information Act* designated Alberta Research Ethics Boards
- Confidentiality Agreement for signature by the Researcher
- Departmental Compensation and Impact Agreements
- Financial Agreement (if applicable)

1.2 In this Agreement, "Researcher" means the University of Alberta and the principal investigator(s) Dr. Sharon Warren and Therese Thompson. In this Agreement, "research team member" means: Each co-researcher and each member of the research project staff and when, in the future, one or more new persons becomes a co-researcher or member of the research project staff, shall also include each such new co-researcher or members of the research project staff. In this Agreement, "Health Information" means individually identifying diagnostic treatment and care information or individually identifying registration information or both, that is provided by DTHR

2. RESPONSIBILITIES OF THE RESEARCHER

2.1 USE AND DISCLOSURE OF HEALTH INFORMATION

2.1.1 The Researcher agrees to comply with:

- The Health Information Act and all regulations made under that Act
- Any terms and conditions imposed by the designated Ethics Committee
- Any conditions imposed by the David Thompson Health Region to the use, protection, disclosure, return or disposal of the health information
- Any requirements to provide safeguards against the identification, direct or indirect, of any individual who is the subject of the health information

2.1.2 The Researcher understands that if they knowingly breach the terms and conditions of this Agreement he or she may be liable for a fine up to $50,000 under the *Health Information Act.*

2.2 *RESTRICTION ON USE AND DISCLOSURE OF HEALTH INFORMATION*

2.2.1 The Researcher agrees to use the health information and any other information disclosed by David Thompson Health Region only for the purposes of conducting the proposed research,

2.2.2 The Researcher agrees not to disclose the information for any subsequent or other purpose without the prior approval of the Region,

2.2.3 The Researcher agrees to disclose the information only to individuals working with the Researcher on the research project and agrees that the individuals on the research team who have access to the information comply with the *Health Information Act,*

- Prior to be provided any of the information the Researcher agrees to adequately safeguard the confidentiality and security of the information obtained from the

David Thompson Health Region and completes the DTHR confidentiality agreement form, and

- Shall notify each research team member that the team member is obligated to keep secret and confidential all information received by that person in the course of or as a result of, any research or other activities involving, dealing with or using the information obtained by the Researcher from the David Thompson Health Region for use for the purposes of the Project, and
- Shall keep the written acknowledgement by the research team members that the each understands the legal provisions, duties, and obligations referred to in this Agreement.

2.2.4 The Researcher agrees that no identifying information or information that could be manipulated to identify any individual will be published, or reported outside the research team during the process of the research or upon completion of the research,

2.2.5 The Researcher agrees to report to the David Thompson Health Region any breaches of confidentiality and/or security respecting the information, and to take steps to both remedy the breach and prevent a similar occurrence in the future,

2.2.6 The Researcher agrees to allow the David Thompson Health Region to access and inspect the researcher's premises to confirm that the researcher is complying with the *Health Information Act*,

2.2.7 The Researcher agrees to obtain a new ethics approval and DTHR Research approval if the study databases are to be used for any other purpose not identified in the original study proposal and protocol,

2.2.8 The Researcher agrees to return any databases acquired from the David Thompson Health Region after the research has been completed. Upon completion of the project the Researcher must dispose of the health information provided by David Thompson Health Region both hard copies and the data stored on their hard drive through a data wiping process. The Researcher shall provide David Thompson Health Region with a letter that confirms the date and the means of disposition,

2.2.9 The obligations of the Researcher under the provisions of this Agreement shall survive the termination of this Agreement.

3. PUBLICATION OF RESULTS

3.1 The Researcher agrees that no identifying information or information that could be manipulated to identify any individual will be published,

3.2 The Researcher will provide the Research and Evaluation Coordinator of David Thompson Health Region a proposed copy of the report or publication, which includes the results of the research for review and an opportunity to comment on report prior to submission for publication,

3.3 The report or publication of results must include a statement that David Thompson Health Region provided some of the information used in this study and that David Thompson Health Region expresses no opinion on the interpretation and conclusions in this publication,

3.4 The Researcher agrees to meet with the DTHR Communications Department to develop an appropriate dissemination plan for reporting results of the study to the DTHR Management, DTHR staff, and residents of DTHR.

4. OWNERSHIP OF REPORTS

4.1 Any report, publication and/or materials produced by the Researcher from the Health Information will be the property of the researcher but the David Thompson Health Region is hereby granted, without charge, the right in perpetuity to reproduce and distribute the Reports within the DTHR. Any summaries or excerpts abstracted from Reports used by the David Thompson Health Region must be approved by the Researcher prior to use.

5. COMPENSATION AND IMPACT – NOT APPLICABLE

5.1 The researcher agrees to pay the compensation amounts agreed to on the attached Departmental Compensation and Impact forms within _____ days of the completion of the research activity,

5.2 The Researcher agrees to pay the required overhead fee (15% of the total of the compensation agreements) to the DTHR.

6. CONDUCT OF RESEARCH

6.1 The Researcher agrees to abide by any conditions outlined on the attached Departmental Compensation and Impact forms,

6.2 The Researcher agrees to report any changes in protocol to the Research and Evaluation Coordinator,

6.3 The Researcher agrees to report any safety concerns including adverse reactions and unexpected consequences to the Research and Evaluation Coordinator.

7. INDEMNITY

7.1 The Researcher agrees to hold David Thompson Health Region harmless from any third party claims, demands or actions for which the Researcher is legally responsible, including those arising out of negligence, willful harm or crimes by the Researcher,

7.2 The Researcher agrees to indemnify the custodian for any and all costs or expenses paid or incurred by David Thompson Health Region as a result of any breach of any term or condition of this Agreement or contravention of the *Health Information Act* or a regulation under the Act or arising out of any unauthorized disclosure by the Researcher of the health information that is subject to this Agreement in any manner contrary to the Agreement. Such indemnification will survive the termination of the Agreement. David Thompson Health Region is not responsible for any bodily or personal injury or property damage or business losses that may be suffered or sustained by the researcher in the performance of the Agreement,

7.3 The Researcher agrees that the Researcher has no recourse against David Thompson Health Region for any loss or damage arising from the Researcher's

interpretation or analysis of the information received from the David Thompson Health Region or from the conclusions reached by the Researcher.

7.4 The David Thompson Health Region agrees to not hold the Researcher(s) or the University of Alberta liable for any damages resulting from the use of reports or use of information generated from this project.

8. TERMINATION

8.1 The David Thompson Health Region may terminate this Agreement with 10 business days notice if the David Thompson Health Region has reasonable grounds for believing that:

8.1.1 The Researcher contravenes, breaches, or fails to meet the terms and conditions of this agreement,

8.1.2 The Researcher contravenes, breaches, or fails to meet the terms and conditions of the *Health Information Act* or other legislation affecting collection and use of personal information,

8.1.3 the information has been used or disclosed in contravention of the terms and condition of this agreement. and/or

8.2 In the event of such termination the information obtained by the researcher pursuant to the agreement will be returned forthwith to the David Thompson Health Region.

9. OTHER GENERAL PROVISIONS

9.1 The Researcher agrees that the consent of David Thompson Health Region will be obtained prior to the transfer of the agreement to another person. Consent may be arbitrarily withheld in the discretion of David Thompson Health Region. Successors must be bound by the terms and conditions of this Agreement. If the research agreement is with an individual Researcher rather than a corporate entity, the Agreement should not be transferable.

Signature of Researcher: Sharon Warren Date: April 25/06
Dr. Sharon Warren

Witness: Theresa Thompson

Signature of Researcher: Therese Thompson Date: May 15/06
Therese Thompson

Witness:

Research Committee Chair
David Thompson Health Region: _____ Date: _____
Steve Clelland

Witness: _____

ATTACHMENT TO THE RESEARCH AGREEMENT DATED _____

BETWEEN
THE DAVID THOMPSON HEALTH REGION
AND
Dr. Sharon Warren and Therese Thompson

CONFIDENTIALITY AGREEMENT

We, Dr. Sharon Warren and Therese Thompson UNDERSTAND THAT THE David Thompson Health Region

(a) has provided, or proposes to provide certain confidential health or health-related information from the files of the David Thompson Health Region of Alberta which information has been or will be provided solely for the purposes and for use for bona fide health research conducted by the respecting:
The Efficacy of Dolls as a Treatment Modality for Individuals with Moderate to Severe Dementia (Research ID#104)

(b) has established strict policies with regard to confidentiality of information.

I am aware that the provisions of the *Health Information Act* apply regarding the health or health-related information that I may receive, observe, or have contact with in my role as the researcher or assistant to co-researcher with, or in any other association whatsoever with the researcher.

I will not reveal or make identifiable the name of any individual to whom the information relates without the consent of the individual and the David Thompson Health Region.

A person who discloses any individually identifying information in contravention of the *Health Information Act* may be found to be guilty of an offence under that Act.

In consideration of the researcher(s) and myself given such access, if any, to the information as may be allowed by the David Thompson Health Region, I agree:

a. to treat as private and confidential;
b. not to disclose or reveal; and
c. not to use for any purpose or research other than as described in the above noted Agreement;

Any of the health information received from the David Thompson Health Region of Alberta, including whether such information has been received by me directly and indirectly from the Department of Health and Wellness or otherwise observed or read by me.

Signature: Sharon Warren Date: April 25/06
Dr. Sharon Warren

Witness: Shawna L. Beaudreau Date: April 25/06

Signature: Therese Thompson Date: May 15/06
Therese Thompson

Witness: _____ Date: _____

APPENDIX G

Introductory Letter to Guardians

Mental Health Services Program
Alberta Hospital Ponoka
Phone: 403-783-7749, ext 434 Fax: 403-783-7768
E-mail: tthompson@dthr.ab.ca

<First Name> <Last Name>
<Address Line1>
<Address Line 2>
<Town>, AB <Postal Code>

Dear <Title> <Last Name>:

I would like to tell you about a study that will be taking place soon on the Apollo, Aurora and Horizon units at Alberta Hospital Ponoka. It is a study looking at the use of dolls as a treatment for aggression and agitation for people with late stage dementia. Our records show you are the Guardian for <Patient Name>.

<Patient Name>'s participation in the study would be greatly appreciated. The information gathered may suggest new ways of treating aggression and agitation in late stage dementia. If you are interested in finding out more about this study please read the attached information package for guardians. All information relating to the study will be kept confidential. You will receive a summary of the findings.

We will be calling you to ask whether you are willing to consent to <Patient Name>'s participation in the study. If you have any questions before our call, please contact me or Therese Thompson, Occupational Therapist and investigator, for the study at Alberta Hospital Ponoka. Our phone numbers are listed below.

Thank you for considering our request.

Yours truly,

Marilyn Nakonechny
Program Manager
Seniors Mental Health Program
Alberta Hospital Ponoka
403-783-7777

Therese Thompson
Occupational Therapist/ Study Investigator
Seniors Mental Health Program
Alberta Hospital Ponoka
403-783-7749

APPENDIX H

Study: Information for Guardians

DAVID THOMPSON HEALTH REGION

Mental Health Services Program
Alberta Hospital Ponoka
Phone: 403-783-7749, ext 434 Fax: 403-783-7768
E-mail: tthompson@dthr.ab.ca

Research Study: Information for Guardians

Project Title: The Efficacy of Dolls as a Treatment Modality for Individuals with Moderate to Severe Dementia

Thesis Supervisor: Dr. Sharon Warren, Professor, Faculty of Rehabilitation Medicine, University of Alberta, 348 Corbett Hall, Edmonton, T6G 2G4, Phone: 780-492-7856

Investigator: Therese Thompson, MSc student in Occupational Therapy, University of Alberta, and Occupational Therapist at Alberta Hospital Ponoka, Phone: 403-783-7749

What is the purpose of the study?

This study is being conducted as part of a Master's of Science degree at the University of Alberta. The purpose of this study is to see if doll therapy actually helps patients to be less aggressive, agitated and use less medication. It is known that many people with dementia become agitated and aggressive in the later stages of dementia. Medications can be helpful to treat these behaviours but they are not effective for everyone. Other approaches can be used along with medications or on their own. We have noticed that some patients are more settled if they have access to realistic looking and feeling dolls.

Who is being invited to participate and what do they have to do?

All patients on Apollo, Aurora, and Horizon Units at Alberta Hospital Ponoka are being invited to take part. In the study, one of the units will be randomly assigned as the control unit. The patients on the control unit will continue to receive all standard regular therapies, including any doll usage already taking place. The two other units will be randomly assigned as

experimental units and patients on these units will be offered standard regular therapies and doll therapy. On the experimental units, all patients will periodically be offered a doll to look at, hold, or care for. If any patient refuses dolls or chooses not to interact with dolls at any time this is okay, they will not be forced.

In the study, dolls will be available Tuesdays, Wednesdays, and Thursdays each week of the four-week study. The dolls will not be present on the experimental units Friday through Monday for the four-week study period. This will be monitored and changed if necessary. Participation in the study is voluntary and consent to take part can be withdrawn at any time without any penalty or impact on future care provision.

What information will be collected?

Information about age, diagnosis, number of days in hospital, medications, mental status and behaviors will be collected from the chart. The Cohen-Mansfield Agitation Inventory (CMAI) and the Rating Scale for Aggressive Behaviour in the Elderly (RAGE) tools will be used to measure the behavior. A nurse will fill out the CMAI and the RAGE. After initial assessment using both tools, the CMAI will be administered every 2 weeks. The RAGE will be administered every 3rd day. The study will take place over four weeks.

Who will know the information that is passed on to the researchers?

Only the investigator, social workers and nurses already working with these patients will have access to the information in the patient chart collected for this study. The information collected will be kept for at least five years after the study is done. The information will be kept in a secure area (i.e. a locked filing cabinet). Your name or any other identifying information will not be attached to the information you give. Your name, nor the participant's name, will ever be used in any presentations or publications of the study results. All information will be held private, except when professional ethics or the law requires reporting. The information gathered for this study may be looked at again in the future to help answer other study questions. If so, the ethics board will first review the study to ensure the information will be used ethically.

What are the risks of participating?

There are no known foreseeable risks involved in your family member's/client's participation in this study. The study does not experiment with drugs. No risks to mental or physical well-being should be experienced during this study.

What are some of the benefits of the study?

This study may change the way that people with dementia are treated. Patients in this program may become be less aggressive and agitated. There may not be any direct benefit to people who agree to participate in this study. Some individuals may show improvement, others may not. It is hoped that their overall use of medications may decrease as a result. The information may help in developing better treatments for individuals with dementia in the future. These findings may also be important for other health care workers, including nursing, social workers, occupational therapists, who work with people who have dementia.

As the guardian, you will receive a copy of the findings so that you will know how the study turned out. If doll therapy seems to be helpful, it will continue to be offered at Alberta Hospital Ponoka after the study.

If you have any questions about the study you can contact me or Dr. Sharon Warren, my thesis supervisor, at the number below. You can also contact the social worker on the unit where your family member/client resides. If you have any concerns about how the study is being carried out you can contact Dr. Paul Hagler, Associate Dean for Graduate Studies and Research, Faculty of Rehabilitation Medicine at 780-492-9674.

If your questions and concerns have been answered with information in this letter and you have decided to give consent at this time, you can sign the consent form enclosed

and mail it back in the enclosed self-addressed envelope. Thank you very much for your time and consideration of this study.

Therese Thompson, Occupational Therapist
Investigator for this Study
Seniors Mental Health Program, Alberta Hospital Ponoka
403-783-7749

FOR MORE INFORMATION CONTACT:

Dr. Sharon Warren, Thesis Supervisor of Therese Thompson

Principal Investigator for this study

Professor, Faculty of Rehabilitation Medicine,

University of Alberta, Room 348, Corbett Hall

Edmonton, T6G-2G4 Phone 780-492-7856

Or Contact the Social Worker on the unit where your family member/client resides:

Ina Rodenburg-Hart
Social Worker, Apollo Unit
Alberta Hospital Ponoka
403-783-7710

Paul Fieldhouse
Social Worker, Horizon Unit
Alberta Hospital Ponoka
403-783-7762

George Jason
Social Worker, Aurora Unit
Alberta Hospital Ponoka
403-783-7713

Initials of Investigator: _____ Initials of Participant's Guardian: _____

APPENDIX I

Study Consent Form

DAVID THOMPSON HEALTH REGION

Mental Health Services Program
Alberta Hospital Ponoka
Phone: 403-783-7749, ext 434 Fax: 403-783-7768
E-mail: tthompson@dthr.ab.ca

CONSENT FORM FOR GUARDIANS

Title of Project: **The Efficacy of Dolls as a Treatment Modality for Individuals with Moderate to Severe Dementia**

Part I: Researcher Information

Name of Thesis Supervisor: Dr. Sharon Warren
Affiliation: Professor, Faculty of Rehabilitation Medicine
Contact Information: Room 348-Corbett Hall, Edmonton, T6G-2G4, 780-492-7856

Name of Investigator: Therese Thompson
Affiliation: MSc student in Occupational Therapy, thesis based, University of Alberta, Edmonton
Contact Information: Chinook Unit, Alberta Hospital Ponoka, P.O. Box 1000, Ponoka, Alberta. T6J-1R8. 403-783-7749 (hospital).

Part 2: Consent of Subject/Guardian

Do you understand that your family member/client have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached information sheet?	Yes	No
Do you understand the benefits and risks involved in your family member/client taking part in this research study?	Yes	No
Have you had an opportunity to ask questions and discuss the study?	Yes	No
Do you understand that as the guardian, you are free to decide whether or not your family member/client will participate or withdraw from the study at any time? You do not have to give a reason and it will not affect their care.	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to your family member's/clients' records, including personally identifiable health information?	Yes	No

Part 3: Signatures

I voluntarily agree for my family member/client to take part in this study.

Name of Participant: _____

Signature of Guardian: _____

Printed Name of Guardian: _____

Date: _____

Signature of Witness _____

Printed Name _____

Date: _____

A copy of this consent form must be given to the Guardian.