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Improving Caloric Intake and Nutrition for Elderly Dementia Patients by Modifying the Environment

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Abstract

Visual perception, difficulty distinguishing objects, judging distance and determining color or contrast are common problems contributing to weight loss and nutritional decline in dementia clients. Mealtime burdens and challenges for individuals with dementia can be minimized or eliminated by some simple, inexpensive alterations in the physical environment that can profoundly influence how patients feel, behave, and function; as well as ease frustration and promote more independent functioning. The purpose of this pilot study was to examine the effect of table setting contrast on residents' weight, oral intake, arm circumference, and feeding behaviors during meals in an assisted living facility serving individuals with dementia. A three-day calorie count, weight and arm circumference measurements were administered at baseline, two and four months post intervention, along with the Edinburgh Feeding Evaluation in Dementia Questionnaire at baseline and post intervention four months later. This study demonstrates why the application of table setting contrast should be implemented as a noninvasive means of accommodating residential quality of life and minimizing weight loss, confusion, and frustration associated with eating among individuals with dementia. This article discusses implications for nursing practice innovations and further research.

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Improving Caloric Intake and Nutrition for Elderly Dementia Patients by Modifying the Environment

Chapter 1: Background and Significance

Adequate nutrition is important for all age groups, but is of particular importance in the elderly population with dementia. It must be addressed to ensure a strong, healthy body and mind. Dementia patients are at high risk for eating and feeding difficulties and inadequate food and fluid intake. Dementia is a condition characterized by a progressive, irreversible decline in mental ability, accompanied by changes in behavior and personality. There is commonly a loss of memory and skills that are required to carry out activities of daily living (The Encyclopedia of Nursing and Allied Health). Depending on the severity of cognitive impairment, someone with dementia may forget to eat, forget they have already eaten, fail to recognize food, or eat things that are not food (Amella & Lawerence, 2007). Malnutrition and unintentional weight loss contribute to progressive decline in health, reduced physical and cognitive functional status, increased utilization of health care services, and increased mortality (Evans, 2005).

The majority of the elderly population with Alzheimer's disease or Related Disorders (ADRD) is in fair to poor physical health and experience limitations in their daily activities and exhibit behavior disturbances. Over three quarters (80%) of people age 70 and older with Alzheimer's disease (AD) are limited in one or more activities of daily living (ADLs). About 94% of this same population are limited in one or more instrumental activities of daily living (IADLs), such as meal preparation, grocery shopping, making telephone calls, taking medications, and money management (National Academy On An Aging Society, 2000).

More than 60% of the people with ADRD have a decline in one or more visual capacities including motion, depth, color, and contrast. These limitations may cause patients to confuse food with non-food items, thus attempting to eat non-food items. This may require altering the

patient's environment. Color perception, or the ability to see colors, is a problem for most elderly people, but even more so for individuals with dementia. Colors in the blue-violet range tend to cause the majority of deficits because they all look very similar. Research indicates that increasing color contrasts may help the person with dementia to locate items more easily and may also provide a better form of reference (Rosa-Brady & Dunne, 2007).

Problem Statement

Malnutrition and poor nutritional status are common problems among dementia patients, and interventions to date have only been moderately successful in reducing these effects. New interventions that can reduce or prevent these problems need to be recognized. Since the incidence and prevalence of ADRD increases with age, the number of people with these conditions will also grow rapidly. The World Health Organization (WHO) predicts that by the year 2025, the number of older persons (defined as aged 60 and over) worldwide is expected to reach more than 1.2 billon (World Health Organization, 2009). An estimated 5.3 million Americans of all ages have AD and 500,000 Americans under the age of 65 have AD. The 85-years-and-older population currently includes about 2.4 million people with AD. Every 70 seconds, someone in America develops AD. It is projected that the state of Tennessee currently has 120,000 individuals aged 65 and older with ADRD. AD was the seventh-leading cause of death across all ages in the United States in 2006 and was the fifth-leading cause of death for those aged 65 and older (Alzheimer's Association, 2010).

Older Americans represent approximately 12% of the population. However, they comprise 26% of physician office visits, approximately a third of all hospital stays, a third of all prescriptions, nearly 40% of all emergency medical responses and 90% of nursing home residents (National Academy of Sciences,). There are nearly 10 million Americans providing 8.4

billion hours of unpaid care to people with some form of dementia-valued at 89 billion dollars (Alzheimer's Association, 2008).

The National Health and Nutrition Examination Survey (NHANES) data indicates that 16% of community-dwelling Americans older than 65 years consumed fewer than 1000 calories per day, a statistic that places individuals at high risk for under nutrition. The incidence of malnutrition ranges from 12% to 50% among the hospitalized elderly population and from 23% to 60% among institutionalized older adults (National Health and Nutrition Examination Survey, 2003-2006). Up to 40% of those with AD lose so much weight as the disease advances that it threatens their overall health (Dunne, Neargarder, Cipolloni, & Cronin-Golomb, 2004). Members of this population are also at increased risk of drug-induced nutritional deficiencies due to the alarming number of medications they consume daily. Additionally, The Department of Health and Human Services has identified nutrition as a priority area in the health goals for the nation in *Healthy People 2010* (United Stated Department of Health and Human Services, 2000, p. 82).

Statement of Purpose

Current evidence does not reveal that AD alters a patient's nutritional requirements. However, research does indicate that it affects the ability to eat. A recent study reports that setting the table with boldly colorful cups and plates may be an easy, practical way to help loved ones with AD stay properly nourished. Researchers found that using colorful tableware appeared to make it easier for those with advanced AD to see the food and beverages in front of them, leading them to eat and drink at least 25% more at mealtimes (Dunne, Neargarder, Cipolloni, & Cronin-Golomb, 2004).

The purpose of this study was to test an intervention to reduce or prevent malnutrition and inadequate caloric intake, specifically in patients with dementia. The purpose was to determine the effectiveness of environmental modifications using table setting contrasts by applying green tablecloths and white plates to tables during meal times. This study has the following objectives: (1) to develop and implement an alternative method for reducing malnutrition and weight loss while improving feeding behaviors for patients with dementia; (2) to test four hypotheses concerning the relative effectiveness of the alternative method on weight, intake, arm circumference, and feeding behaviors; and (3) to use the findings to guide future clinical practice and research.

Judging distance and determining color or contrast is often a problem contributing to weight loss and nutritional decline in dementia clients. The intervention was relatively easy to modify in an attempt to facilitate increased caloric intake at mealtimes by allowing dementia residents to actually visualize what they were eating and where the food was located. To address these problems, caloric intake was measured using a three-day tray completion percentage, along with arm circumference, and weight. Nutrition status was assessed utilizing the combined caloric intake measurements, along with a medical history and physical at baseline, two months, and four months. Feeding behaviors were measured using the Edinburgh Feeding Evaluation in Dementia Questionnaire (EdFED-Q) administered at baseline and four months (See Appendix B).

Hypotheses

It was hypothesized that exposing subjects with dementia to table settings using contrast during meal times would result in (1) weight increase or stability (2) increased nutritional intake (3) increased arm circumference measurement and (4) improved feeding behaviors. Based on

this hypothesis, the following research question was asked: For subjects with dementia what are the affects of table setting contrast on: 1) weight 2) nutritional intake 3) arm circumference, and 4) feeding behaviors?

Framework

A theoretical framework applied to the study of malnutrition and weight loss in elderly dementia patients is Neuman's Systems Model (Neuman, 2008). This framework suggests that in partnership, caregivers and clients must understand the client's relationship with the environment. This will allow them to intervene appropriately through preventative, corrective, and rehabilitative measures to ensure that desired outcome goals will be met. With progression of the disease, a person will experience increased difficulty navigating his or her living space and interpreting environmental information. The correlation between the declining competence and environmental burdens may result in negative behavior and functional outcomes (Gitlin, Liebman, & Winter, 2003). By modifying a dementia client's environment to suit individual needs, malnutrition and weight loss can be prevented, improved, and sustained.

This systems theory encompasses all elements (physiological, psychological, sociocultural, developmental, and spiritual) of the client. Neuman's model incorporates and illustrates the collaborative decision-making process concerning three levels of prevention, which are intrapersonal, interpersonal, and extrapersonal stressors. Dementia residents face a multitude of stressors at all levels of prevention and rely on their caregiver's support and assistance to create a flexible line of defense that will result in reduced stress and improved outcomes. This framework suggests that as competency declines and the physical and social environment remain unchanged, significant burdens are imposed to persons with dementia. Betty Neuman's Systems Model provides justification for manipulating the environment and

determining the effectiveness of particular environmental modifications in order to improve nutritional status, intake, and feeding behaviors in dementia clients.

Conceptual and Operational Definitions

Dementia is characterized by the loss of or decline in memory and other cognitive abilities severe enough to interfere with daily life. To be classified as dementia, symptoms must include decline in memory and in at least one of the following cognitive abilities: (1) ability to generate coherent speech or understand spoken or written language; (2) ability to recognize or identify objects, assuming intact sensory function; (3) ability to execute motor activities, assuming intact motor abilities, sensory function and comprehension of the required task; and (4) ability to think abstractly, make sound judgments and plan and carry out complex tasks. Different types of dementia have been associated with distinct symptom patterns and distinguishing microscopic brain abnormalities. The symptoms of different types of dementia overlap and can be further complicated by coexisting medical conditions (Alzheimer's Association, 2010).

Feeding behaviors are defined as behavioral responses or sequences associated with eating including modes of feeding, rhythmic patterns of eating, and time intervals (Find Health Articles, 2009). In this study, eating and feeding difficulties (requiring supervision and physical help, spillage, leaving food on plate, refusing to eat, refusing to swallow, spitting out food, and allowing food to drop out of mouth) were assessed using the EdFED-Q. Improved feeding behaviors were determined by an improved rank score from baseline measurement on the EdFED-Q.

Table setting is defined as the decorative elements used to set a table, and contrast is defined as the perceived difference in a color when it is surrounded by a different color, will be

applied in attempt to improve feeding behaviors, intake, and nutritional status (World English Dictionary, 2009). Green tablecloths were applied under white, porcelain plates for the table setting and contrast in this study.

The term Geriatric nutrition applies nutrition principles to delay effects of aging and disease in order to aid in the management of the physical, psychological, and psychosocial changes commonly associated with growing old (Krapp & Cengage, 2002). Several risk factors such as, physical difficulties, disease, agitation/distraction, eating style or preference, environment, and/or food quality may contribute to a dementia patients decline in nutritional status and caloric intake. Two goals of this study were to improve intake and nutritional status. Good nutrition is defined as the intake of a balanced diet containing all the essential nutrients to meet the body's requirements for energy maintenance, and growth. Adequate intake is defined as an estimate of average requirements when evidence is not available to establish a Recommended Daily Allowance (Stanfield & Hui, 2003). For the purpose of this study, improved nutritional status and adequate intake were determined by an increase from pre-intervention weight, arm circumference, and tray completion.

Physical and social environmental characteristics contribute to making mealtime one of the most challenging activities for institutionalized older adults (Griffin, 2005). Previous research illustrates that dining environments that are overcrowded, noisy, poorly lit, and contain objectionable odors do not support good eating habits. Characteristics of an adequate dining environment for dementia patients defined by the Alzheimer's Association (2007) contains quiet surroundings, simple table settings with contrast, minimal utensils, patient staff members, adequate time for consumption, memory aids, and easy to eat foods with few selections.

Assumptions

Assumptions of this research are that 1) caregiver documentation was correct and complete, and 2) scales provided accurate weights.

Major Limitations

As with many population-based studies, there were numerous variables outside the researchers' control. One weakness of the study was the small sample size limiting generalizability of the results. A threat to internal validity was the loss of study participants due to a variety of factors including hospitalizations, transfer to other facilities, new diagnosis, and/or death. Other limitations that may have occurred during this research include: 1) incomplete charting 2) hospitalizations, 3) residents eating outside of facility, and 4) snacks eaten away from dining area without documentation and potentially affecting weight.

Before diagnosing an eating problem as a stage of ADRD, the caregiver must determine that the change in nutritional status is not related to other problems. It is difficult for Alzheimer's patients to express pain; therefore, often times the only indication that they are in pain or have another medical condition may be when they refuse to eat. On the other hand, the patient may have increased caloric needs due to constant activity such as walking or involuntary body movements. The primary problems leading to decline in nutritional status include: physical conditions (diabetes, heart disease or stomach problems), physical difficulties (poor dentition, mouth sores, limited use of extremities), depression, constipation, and agitation (Litchford, 2002). Therefore, all participating residents with congestive heart failure (CHF) diagnosis were not eliminated from the study but were treated with diuretic therapy due to the potential to cause weight increase resulting from fluid retention. This information was documented to prevent misrepresentation of results. Residents consuming routine psychotropic

medication with a potential for appetite stimulation were documented but not eliminated from the study.

Research reveals the difficulties that patients with dementia face regarding eating and drinking, but there are limited studies addressing specific interventions to promote eating and drinking specific for this population. According to one review, when Certified Nursing Assistants (CNAs) used verbal prompts to remind people how to eat and positive reinforcement, residents were more likely to complete eating and drinking tasks (Coyne & Hoskins, 1997). Another study found that when residents listen to music while eating, they consumed more food and were less irritable and anxious (Ragneskog, Brane, Karlsson, & Kihlgren, 1996). Research has demonstrated that individuals with Alzheimer's disease often experience increased difficulty with depth perception, spatial orientation, and judging colors and contrast. When contrast is increased, people with AD are able to read more quickly and easily (Anderson & Nawrot, 2000). Although numerous studies and research indicate that the dining environment contributes to caloric intake, there is little research that suggests specific environmental modifications that will directly and positively influence intake and nutrition for dementia patients.

Due to the startling increase and perilous effects of malnutrition in the elderly population, a research study was proposed to explore the impact and effectiveness of table setting contrast on oral intake, nutritional status, and feeding behaviors during meals in an assisted living facility specific for dementia residents. The information will be utilized to provide recommendations for changing and/or improving existing interventions, and will in turn, guide future clinical practice and research.

Chapter 2: Review of Literature

Introduction

A literature review utilizing CINAHL, Pub Med, Ovid, Medline, and PsycINFO databases was conducted to examine the current body of knowledge regarding nutrition, feeding behaviors, and caloric intake among elderly patients with dementia. The areas of concern that were reviewed and discussed in this study are nutrition, caloric intake, nutritional supplementation, appetite stimulants, and environmental modifications regarding elderly and dementia patients. Numerous quantitative and qualitative research designs were utilized to summarize the findings within this review.

Dementia is an acquired deterioration in cognitive abilities that impairs independence in performing activities of daily living. Memory is the most common cognitive ability lost with dementia. Dementia results from disorders of cerebral neuronal circuits and is a result of neuronal loss combined with the specific location of this loss (Kasper et al., 2005 p. 2393-2394).

Nutritionally speaking, multiple problems occur with dementia such as forgetfulness and disorientation, pacing, inability to eat independently, weight gain or loss, dysphasia, food behavioral problems, and dehydration. Persons with dementia often have to be reminded to chew, swallow, and drink fluids. These problems can have a profound effect on the nutritional status; therefore, increasing caloric intake in a dementia patient is necessary to prevent weight loss (Peckenpaugh, 2007, p 427). Because the risk of poor nutrition is so common among dementia patients, multiple means have been incorporated to help alleviate this problem. Appetite stimulants, nutritional supplements, and environmental modifications with varying levels of effectiveness are some interventions. This research was designed to supplement

knowledge about manipulation of the environmental setting in order to promote increased caloric intake and nutritional status in the dementia patient.

Research Literature

Lighting and contrast. Brush, Meehan, and Calkins (2002), conducted a pilot study, "Using the Environment to Improve Intake for People with Dementia." In the study, lighting and table setting contrast were enhanced at mealtimes by measuring for adequate lighting and applying dark green tablecloths and navy blue tray liners under white plates for contrast. Both oral intake and functional abilities were improved for residents with dementia living in long term care facilities.

At Facility One, there was more than 1,000-calorie increase in the average calorie count but did not achieve statistical significance (p<0. 16). At Facility Two, the average total calories consumed increased significantly (p<0. 01) (Brush, Meehan, & Calkins, 2002).

In addition to measuring caloric consumption, two meal-related screenings were conducted. Communication Outcome Measure of Functional Independence (COMFI) measures how an individual functions and communicates within the long-term care facility. In Facility One, total COMFI scores increased significantly (p< 0. 05) from 54 at baseline to 74 at posttest. There were statistically significant increases from baseline to posttest in the frequency in which the residents engaged in conversations with staff (p< *0. 05).* In Facility Two, scores increased from 48 to 60 (p< 0. 115). The Meal Assistance Screening Tool (MAST) focuses on the components of the entire mealtime experience. The MAST scores at Facility One remained consistent from baseline (10.7) to posttest (10.8), and MAST scores at Facility Two decreased from 6.2 to 4.8 (p< 0. 331) (Brush, Meehan, & Calkins, 2002). These scores indicate overall

improvement in measures of intake and functional independence relating to mealtime experiences (Brush, Meehan, & Calkins, 2002).

The interpretation of the data establishes an overall improvement in the following areas: caloric intake, conversation engagement, level of anxiety, assistance required, ability to follow simple directions, frequency in which residents initiate conversations, frequency with which questions were answered with on topic responses, residents' ability to find and use their napkin, and improved staff morale. This study provides evidence that by modifying lighting and table setting contrast both oral intake and functional abilities in persons with ADRD can be significantly improved. By combining the lighting and contrast interventions simultaneously, this study may have failed to recognize if the interventions were effective independently. It may not be feasible and practical to change inadequate lighting due to intensive remodeling and fiscal implications, but the table setting contrast is easy to implement and cost effective. Another weakness of this study is that evidence is documented stating that people with dementia have greater deficits in the ability to see colors in the blue-violet range, and the tablecloths used in this study were navy blue (Rosa-Bray & Dunne, 2007). Therefore, the purposed study will test the table setting contrast separately from the lightning intervention using green tablecloths to determine if this intervention independently will provide significance.

Predictive factors for eating behavior disorders. Riviere, Gillette-Guyonnet, Andreu, Nourhashemi, Lauque, Cantet, et al. *(2002)* investigated predictors of aversion feeding behaviors (AFBs) among AD patients living at home with a caregiver during a one-year interval. The researchers sought to provide an intervention for caregivers that would provide an objective appraisal of the patient's current functional status and feeding difficulties so that interventions could be implemented appropriately. All studies were enrolled in a European Health Promotion

Program, but only 150 patients and their caregivers attended nine, one-hour nutritional meetings over a one year time span. The remaining 74 caregivers did not attend the meetings. Numerous assessment tools were used to determine nutritional, psychological, and functional outcome measures on the 224 AD patients at baseline as well as one year later.

Results indicate that initial feeding difficulties, Aversive Feeding Behavior Intervention (AFBI) scores, were significantly associated with the age of the caregiver, the initial severity of the disease, and the initial patient's autonomy and psychological functioning. The initial AFBI score was significantly decreased (*P=0.0054)* in AD patients living with children. Patients' who had an increase in feeding difficulties during the study period proved to be more severely affected in psychological (mood and behavior disorders) and functional outcome measures (IADLs). Increased feeding difficulties and AFBs were also noted in AD patients who had a more affected caregiver at baseline. Logistic regression analysis indicates a positive association between AFBs worsening and the initial caregiver's burden after controlling for nutritional status, and validates memory impairment was inversely associated with AFBs (Riviere, et al, 2002).

Current literature verifies the existing problems associated with AD and nutritional deficiencies. Numerous studies have focused on weight loss and eating behavior disorders, but little has been explored about which factors are related to eating behavior disorders, such as which patients should be fed, interpretations of various feeding problems, and clinical management of these problems. This study presented parameters through multidisciplinary assessments that predict AFBs in AD patients. Limitations of the study include the time gap between the baseline and one-year assessment and questionable accuracy of reporting by caregivers.

Music at mealtimes. A study documented by Hicks-Moore (2005) examined the relationship between relaxing music and agitation in a group of 30 elderly nursing home residents in Canada with significant dementia.**.** The subjects were exposed to relaxing music during the evening meal on week two and week four of the project. During the first and third weeks, no music was played, but observation took place at all evening meals over the four-week study period. The focus of the study was to determine presence or absence of behaviors, rather than the number of times behaviors occurred or who demonstrated the behavior.

Four dimensions of agitation (agitated behaviors, physically non-aggressive, verbally agitated, and hiding and hording) were measured using the modified Cohen-Mansfield Agitation Inventory (CMAI). All of these suggest unpredictability in incidence, excluding hoarding (due to absence of observed behavior). However, the incidence of these observed agitated behaviors decreased in the weeks that music was played in comparison to the weeks that music was not played. Other changes documented that occurred during the weeks that music was played and were not captured on the CMAI include, a more relaxed, harmonious environment, more smiling, and less restlessness (Hicks-Moore, 2005).

In this study, agitated behaviors decreased when music was introduced during the evening meal, rebounded when it was withdrawn, and declined again with reintroduction of music. The results of this study justify music as an easy, inexpensive, and non-invasive intervention that may reduce the overall level of agitation among nursing home residents with severe cognitive. Limitations of this study include a small sample size and short study period.

Alterations in meal routine and environment. A study by Mamhidir, Karlsson, Norberg, and Kihlgren (2007) addresses the benefits of altering meal routines and meal environment after implementing an integrity promoting care staff training programmed over a

three-month period in a long-term ward. The training program stemmed from prior research, Integrity Promoting Care, based on Erikson's theory of eight stages of man and its application to dementia care, which included three main messages; 1) promoting integrity, 2) quality interaction, and 3) calm, homelike environment.

Researchers sought to follow weight changes in patients with moderate to severe dementia and analyze how the weight changes related to biological and psychological parameters after the staff was trained and supportive intervention information from the course was applied and implemented on the intervention ward containing 18 patients. Weight was obtained from each subject at the start and completion of the intervention. Weight changes were analyzed through documentation in diaries created by staff members, including meal environments and changes in work and routines.

The results indicate that 13 intervention ward patients gained weight after the intervention and five lost weight. Two control ward patients demonstrated an increase in weight and twelve patients demonstrated a decrease in weight, while one maintained their weight. According to the Gottfries-Brane-Steen (GBS) Scale measurements ($P<0.01$), individual weight changes correlated to changes in the intellectual functions, which demonstrates a relation between improved weight and improved intellectual function during the study period (Mamhidir, Karlsson, Norberg, & Kihlgren, 2007). There were no significant relationship between weight change, increased motor function and increased appetite, nor were there any significant relationship between weight changes and biochemical parameter changes. According to the documentation from staff diaries, when the course information was applied to practice by changing the meal environment and routines, patient contact increased and a more pleasant environment resulted.

Although, there were limitations to this study, such as food intake was not weighed or recorded, small sample size, and absence of power calculation; the positive results were suggested to be reliable due to the alignment of results from the main project. The findings indicate that by educating staff and adjusting the meal environment to suit individual needs for patients with moderate to severe dementia; weight gain was achieved (Mamhidir, Karlsson, Norberg, & Kihlgren, 2007).

Environmental manipulations. In a single-subject experimental design study conducted by Cleary, Van Soest, Milke, and Misiaszek (2008), the investigators infused the aroma of baking bread into the dining room during meal times, at a long term care facility. After the infusion of the aroma, the amount of food consumed, the level of staff assistance required, and the frequency of independent feeding were measured. Three subjects participated in the study where measurements of food intake and level of assistance required to complete meals were taken at baseline and after intervention using an ABAB design. The findings showed a 6.7% increase in food consumption with the presence of the baking bread aroma, and the participants were independent with self-feeding 98% of the time. These findings of this study emphasize the significance of the physical environment on the functional level of older adults living in a long-term care setting. The characteristics of the physical environment can be facilitators or barriers to older adults (Cleary, 2008).

In a second study using environmental manipulations, Cleary, Hopper, Forseth, Van Soest (2008) used a single-subject experimental design to research the effect of a routine meal time seating plan on the behaviors of older adults with dementia at mealtime. Measurements included the amount of food and liquid intake, the amount of time the patient was required to wait for the meal, and the time it took them to eat the meal. Three residents of a long-term care

facility participated in the study. The subjects were videotaped from the time they were seated until they finished eating for a total of 12 meals. (Cleary, 2008).

Outcomes of the study showed that Participant One had more food and fluid intake using a routine seating plan than a non-routine seating plan. Participant Three had more food and fluid intake using a routine seating plan and continued to eat and drink more when the routine seating plan was withdrawn and then increased to an even higher level of both food and fluid intake when the routine seating was re-introduced in the final treatment phase. Participant Two had a higher level of food and fluid intake in the first treatment phase and second baseline phase but had a decrease of food and fluid intake during the final treatment phase. Secondly, with the routine seating plan the wait time for meals to be served went from 26.55 minutes at baseline, to 9.11 minutes during the treatment phase, showing a average reduction in wait time of 65%. Finally, there was no significant difference in the baseline or treatment phase regarding the time required for the participants to complete their meals (Cleary, 2008).

Appetite stimulant use. Rueben, Hirsch, Zhou, Greendale (2005) conducted a placebo-controlled randomized clinical trial of 47 elderly persons (average age 83) who had recently been discharged from an acute care hospital and had a fair or poor appetite. The trial compared three doses of Megestrol acetate 200mg (n=12), 400mg (n=11), and 800mg (n=12) with a placebo (n=12). The participant's appetite, quality of life, and adverse effects were measured at baseline, 20, 42, and 63 days. Serum nutritional markers were also measured at baseline, 20, and 63 days. The results of the study showed an increase in prealbumin at 20 days across the four groups by 0.4, 5.1, 7.5, 9.0mg/dL, respectively. The participants in the 400-mg and 800-mg groups had significant increases in prealbumin at 20 days over the placebo group (P=0.009 *and* P=0.004, respectively) but the 400-mg group was the only statistically significant group at 63 days

(*P*=0.02). Serum albumin levels did not change in any of the groups in the follow up period (Rueben, 2005).

Cortisol levels were measured at 20 days in the 400mg *P*=0.003) and 800mg *P*=0.02) of Megestrol acetate and were significantly lower than the placebo group. Participants in the 400-mg (*P*= 0. 005) and 800-mg (*P*=0.02) groups were more likely to have cortisol levels less than 8ng/mL than those in the placebo group. There were no reports of clinical symptoms of adrenal insufficiency. Diarrhea developed in three participants (2 in the 400-mg group and 1 in the 800-mg group), two developed thromboembolism, one had deep vein thrombosis (DVT), and one had DVT and multiple pulmonary emboli (1 in the 200-mg group and 1 in the 400-mg group). The findings showed some evidence of appetite improvement with all three treatment doses and improvement in the appetite with the placebo in the 800-mg dose at 20 days. Overall, there was no statistically significant treatment effect with any dose of Megestrol acetate on serum albumin, weight, functional status, or health-related quality of life; therefore the drug did not give any benefit on nutritional or clinical outcomes. (Rueben, 2005).

Nutrition supplements. Young, Greenwood, Reekum, and Binns (2004) examined the efficacy of providing nutritional supplements to institutionalized seniors with probable Alzheimer's disease (AD) at a geriatric teaching facility affiliated with a home for the aged. For a sample of 34 institutionalized seniors with probable AD who ate independently, nutrition supplements were provided between breakfast and lunch for 21 consecutive days and compared with 21 consecutive days of habitual intake. During the supplementation phase, group mean analyses indicate 24-hour energy, protein, and carbohydrate intake increased (*P<0 .001)*, whereas, fat intake (*P= 0. 071)* remained unchanged. However, five out of 31 subjects who completed all study phases, reduced lunch intake to compensate for the energy consumed from

the supplement. Therefore, 21 of 31 subjects who completed the trial experienced enhanced 24-hour energy intake. Subjects that received supplement in Phase 2 and Phase 4 did not have differing mean compensation values (*P= 0. 911).* Subjects with lower body mass indices were less likely to enhance overall intake with the intervention (*P=0.004)* due to compensating for the supplement by reducing lunch intake. Intervention response varied greatly at the individual level and was highly associated with body weight status (Young, Greenwood, Reekum, & Binns, 2004).

The data indicated that institutionalized seniors with probable AD and low body weight status have a tendency to compensate for additional energy consumed from the nutritional supplements by decreasing mealtime intake. This study was limited due to the small, homogeneous population, and suggested that providing a midmorning nutritional supplement to seniors with probable AD, especially those with lower body mass indices, increased aberrant motor behavior, poorer attention, and increased mental confusion is not a globally efficacious intervention (Young, Greenwood, Reekum, & Binns, 2004). In an attempt in taking a first step at identifying patients with low body weight that are likely to benefit from nutrition supplements, exploratory analyses were conducted to identify subject characteristics predictive of positive intervention response. Larger-scale, longitudinal research was recommended to examine long-term results to the intervention.

Summary

This literature review supplemented the researchers' knowledge on the area concerning nutritional and functional deficiencies in dementia residents and revealed that dementia residents are vulnerable to nutritional deficiencies resulting from inadequate caloric intake. The current body of knowledge summarizes a variety of methods to approach dementia residents at risk for

inadequate nutrition and feeding behaviors. This research addressed a cost effective, non-invasive approach to aid in improving the nutritional status, intake, and feeding behaviors associated with dementia.

Chapter 3: Methods and Procedures

Research Design

A quasi-experimental, single-subject, time series design was utilized. The quasi-experimental design allowed the application of interventions with the ability to exclude randomization and a control group. This allowed all the subjects to be exposed to the intervention. The single-subject design was used to gather information about the intervention based on the responses of the small number of research participants under the controlled environment. The time series design allowed for information to be collected over an extended period of time, and the intervention introduced at any time during that period (Polit & Beck, 2008).

Specifically, the AB design was utilized which involved gathering data at baseline (A) and during the intervention (B). The main evaluation criteria, which allowed the effectiveness of this intervention to be evaluated was the increase in intake measured by a three-day tray completion count, arm circumference, and weight [Time Frame: Baseline, two months, four months]. The Edinburgh Feeding Evaluation in Dementia Questionnaire (EdFED-Q) was administered [Time Frame-baseline and four months] while the Mini Mental Status (MMSE) was administered [Time Frame-baseline, two months, and four months] to determine the level of impairment as well as evaluate the need for possible psychosocial and clinical interventions, such as referral for speech therapy, environmental modifications, dietary alterations, and communication techniques (Amella & Lawerence, 2007).

Sample and Setting

A representative sample of dementia residents living in a long-term, 32-unit memory care facility was selected to participate in the study. Residents were considered eligible if they had a

physician diagnosis of dementia, ate their meals at a table in a dining room, and were physically able to feed themselves 25% of a meal at least two days per week. Subjects were excluded from the study if they had a diagnosis of cancer, were taking the medications Marinol and/or Megace, had physician orders for routine nutritional supplements, and/or received Hospice Care. The population included both male and females who were greater than 65 years of age. The investigators reviewed the participant's charts and medical administration records (MARs), assessed the residents, and obtained pertinent information from direct care providers to determine eligible participants.

Ethical Considerations

Approval to conduct the research was requested from Southern Adventist University's Institutional Review Board (IRB) and the long-term care facilities owners and Vice President of Operations (See Appendix A). All subjects participating in this study were considered vulnerable due to cognitive impairment; therefore, an informative, educational meeting discussing the purpose, anticipated results, and risks vs. benefits was offered to all participant's Guardians, Power of Attorney's, or Conservator's prior to the study. Informed consent was obtained and signed by all subject's Guardians, Powers Of Attorney, or Conservator's prior to the study. All ethical principles, such as, beneficence, respect for human dignity, and justice were practiced at all times throughout the study.

The research intervention was not invasive and comprised only minor changes to the subjects' routine environment. All records and information were kept confidential and participants anonymous utilizing HIPPA compliance. To ensure maximum protection of privacy, all subjects' anonymity was ensured through the use of first and last initials and room numbers only. Explicit information about the locale and name of the facility was avoided. All

documents remained securely locked in the principle investigators office and all identifying information was shredded as quickly as practical after the completion of the research.

Instrumentation

The EdFED-Q is a 10-item questionnaire that was utilized to identify eating and feeding difficulties and to determine the level of assistance needed. Total scores range from 0 to 20, with 20 being the most serious. Amella and Lawerence (2007) conducted a study, Eating and Feeding Issues in Older Adults with Dementia: Part I: Assessment, to determine the efficacy of the EdFED-Q in hospitalized older adults with diagnosed or suspected dementia. This study concluded that the EdFED-Q was not clinically diagnostic, but it allowed the assessor to determine the level of impairments as well as evaluate the need for possible psychosocial and clinical interventions, such as referrals for speech therapy, environmental, dietary modification alterations, and communication techniques (Amella & Lawerence, 2007). Through secondary data analysis, researchers established that the EdFED-Q was deemed a valid and reliable observational instrument, developed through Mokken scaling of items and factor analysis from previous studies conducted by Watson and Deary (1997) and Watson, McDonald, and McReady (2001). The population sample from Amella and Lawerence's study was the same for this project, making the reliability estimate from Amella and Lawerence's study a reasonably good index of the instrument's accuracy for this study (Polit & Beck, 2008). Permission to utilize the EdFED-Q was granted by The Hartford Institute for Geriatric Nursing, College of Nursing, New York University (Amella & Lawerence, 2007). Also permission for use of this tool in this study was given by the developer of the EdFED-Q, Dr. Roger Watson (personal communication via email).

A Nutritional Worksheet was developed by the researchers and was implemented to collect data and record nutritional status findings (See Appendix B). The 14-item tool contained demographic, dichotomous, and fill in the blank queries. The individual queries for data collection included: age, gender, date of admission, level of cognitive impairment, weights, arm circumference, percentage of tray completion, usage of psychotropic and diuretic medication, presence and degree of edema, hospitalization during study, Ed Fed- Q scores, and diagnosis of Congestive Heart Failure (CHF). The data were collected through assessment by researchers, chart, Medication Administration Record (MAR) review, and caregiver documentation. The worksheet contained multiple subscales, each of which tapped distinct and related concepts.

A subpart on the Nutrition Worksheet was the level of cognitive impairment that was evaluated utilizing the Mini Mental State Examination (MMSE) at baseline, 2 months, and 4 months. The MMSE test included simple questions and problems concerning memory, arithmetic, language use and comprehension, and basic motor skills. The maximum MMSE score was 30 points. A score of 20-24 suggested mild dementia, 13-20 suggested moderate dementia, and less than 12 indicated severe dementia (Alzheimer's Association, 2009). Researchers performed secondary data analysis demonstrating the high level of reliability and validity of the MMSE among numerous groups of neurologically impaired individuals including dementia patients from a previous study by Folstein, Folstein, and McHigh (2000).

Psychometric assessment. The EdFed-Q instrument has been used clinically in areas such as nursing home settings and a community-based setting. Twenty four pairs of raters found it to have acceptable inter-rater ($r=0.59$, $p=0.013$) and intra-rater ($r=0.95$, $p<0.0001$) reliability (Watson, McDonald, & McReady, 2001). Therefore, for the purpose of this study, each researcher collected data on the same participants throughout the course of the study.

The MMSE, created by Marshal Folstein, was designed to give a practical clinical assessment of change in cognitive status in geriatric inpatients. This tool has been used clinically in numerous hospital settings and long-term care settings since 1975. The test-retest reliability has been examined in various studies by multiple researchers. Regarding a review of his own studies, Folstein reports that for samples of psychiatric and neurological patients, the test-retest reliability, "has not fallen below 0.89; inter-rater reliability has not fallen below 0.82" (Crooks, Ferris, & Bartus, 1983, p.47). Research indicates that the MMSE forms the leading screening instrument in North America (McDowell, 2006, p. 436).

The nutritional worksheet was used for data collection and was reviewed for content validity by three faculty members at Southern Adventist University School of nursing. Reliability and validity is addressed with repeated use of an instrument (F. Johnson, personal communication, April 17, 2009).

Data Collection

The primary forms of data collection for this study consisted of existing data from medical records, biophysiologic measures, a feeding evaluation, and a cognitive screening tool. Demographic and medical data were obtained through medical records rather than by asking caregivers. Information obtained from medical records included: date of admission, age, gender, medications, physician orders, weight, percentage of tray completion, and diagnosis. The biophysiologic outcomes included weight and arm circumference measurements. Weight measurements were obtained from a manual scale that was wheelchair accessible and arm circumference was measured by wrapping a standard tape measure around the resident's bicep. One dependent variable was the measure of the resident's feeding behavior which was measured

utilizing the EdFED-Q administered by the researchers. The researchers also administered the MMSE to measure cognitive impairment of the participants.

The researchers randomly divided the study participants into two groups by printing off a census sheet (provided by the facility) and drawing a line straight down the middle. The individuals in each group were assessed by the same researcher throughout the study for intra-rater reliability. The different ratings were compared by means of correlation to prevent contamination of knowledge from previous findings.

Data Analysis

Collected data consisted of nominal, ordinal, interval, and ratio levels of measurement. Measurements were entered into SPSS, version 15 for analysis of data. Descriptive Statistics were used to analyze and summarize the demographic characteristics including age, gender, date of admission, arm circumference, weight, and tray percentage completion at baseline, two months and four months. Researchers compared mean differences on each individual resident using the paired sample *t* test. Mean differences compared between different participants were analyzed using the independent samples *t* test. A One-Way ANOVA was applied to test the hypothesis and the sum of squares within groups was used to analyze the sum of the squared deviations of each individual score from its own group means (Polit & Beck, 2008).

Limitations

This pilot study had numerous factors that affected or had the potential to affect the outcomes. The primary limitation in this study was the small sample size which limited significance and ruled out the possibility for a regression analyses. A regression analyses would have had particular importance in this study to determine the correlation between cognitive functioning and the four hypotheses. A sample size analyses or effect size should have been

performed prior to the study and is recommended for future research. Another limitation is that there was no between factors in grouping. Each patient was their own control comparing baseline data to the next subsequent measurement. The study would have produced more significant results if there were two groups and were randomized.

Other factors affecting the outcomes include: a diagnosis of CHF, edema, diuretic therapy, and use of psychotropic medications; all of which had the potential to affect weight. Lastly, researchers believe that the retina has more receptors to see the color red, making it an easier color for most to see and should have been the selected tablecloth color for the project (Rosa-Brady, & Dunne, 2007).

Plan for Dissemination of Findings

The findings of the study were presented before Southern Adventist University School of Nursing Research presentation symposium. Query letters will be sent to journals for potential publication in a peer review nursing journal. A request will be made to present the finding at the annual mid-south Alzheimer's Association Conference. Researchers will submit the research findings to the National Alzheimer's Association and the Tennessee Assisted Living Federation of American for assimilation in other facilities of this evidence based practice alternative for the improvement of the nutritional status of patients with dementia.

Chapter 4: Data Analysis

Introduction

Statistical procedures were used to organize, interpret, and communicate numeric information collected during this review. Descriptive Statistics were used to describe and synthesize the demographic characteristics. Nominal measurements were used to code dependent variables (CHF diagnosis, gender, psychotropic and diuretics medications, and edema at baseline versus not at 4-month and 6-month post intervention). Ordinal measurement was utilized to code the client's cognitive impairment: (1) normal or intact cognitive functioning (> or equal to 25 score), (2) mild cognitive impairment (21-25 score), (3) moderate cognitive impairment (10-20 score), or (4) severe cognitive impairment (<9 score). An interval-level Likert-type scale was used to measure eating and feeding difficulties and track change with the EdFED-Q, a 10-item scale with scores that can range from 0-20. Several dependent variables included nutritional outcomes measured on a ratio scale, including arm circumference, weight, and oral intake. The four levels of measurement were used to categorize measures to assist with analyses.

Participation

Fourteen participants had their nutritional and clinical assessments at baseline, four months post intervention, and six months post intervention. The original plan anticipated data collection at baseline, two months post interventions and four months post intervention, but was altered due to needs of the facility. General acceptance of participation in the table setting and contrast study was excellent. Of 31 eligible residents for whom the consent process was completed, no one declined to be exposed to the table setting and contrast at meal times. Fourteen of 31 individuals assessed met the researcher's inclusion criteria. The sample size of

N= 14 did not allow the detection of a true mean difference in intake, weight, arm circumference, and feeding behaviors. This indicated a 90% chance of having a type II error (or not rejecting hypothesis) which was not the results the researches were looking for, but was encouraging to note as the probability for significance in further testing with a larger sample size and randomization is anticipated.

Demographic Data

The nutrition worksheet contained demographic and clinical characteristics of the study population, including dietary intake, admission diagnosis, chronic illnesses and medication usage that were capable of affecting weight. Baseline characteristics varied among the study participants. Of the 14 research participants, ten were female and four were male. The average age of the participants was 82.6 years old. Seven participants were taking psychotropic medication. Two participants were on diuretic therapy at baseline and this increased to four at the four month measurement. None of the participants had a diagnosis of congestive heart failure. Two participants at base line were measured with 1+ pitting edema and one with 2+ pitting edema. At four months, two had 1+ pitting edema, three had 2+ pitting edema, and one had 3+ pitting edema. Amount of gain or loss in intake, weight, and arm circumference was calculated based on the difference between each participant's (N=14) total intake, weight, and arm circumference percentage at baseline versus the 6-month trial with table setting and contrast.

At baseline, four residents had mild cognitive impairment, six had moderate cognitive impairment, and four had severe cognitive impairment. Post intervention, four had mild cognitive impairment, five had moderate cognitive impairment, and five had severe cognitive impairment. These results indicate a decline in overall cognitive impairment.

Instrument Reliability

For the purpose of this research two existing instruments were used as a part of the data collection. The EdFED-Q and the Mini Mental State Examination instruments had been proven reliable and accurate through previous research. In addition, a nutritional worksheet was created by the researchers for the purpose of documenting the data which were collected and measured in the research. There were no tests of validity or reliability of this worksheet as its purpose was only for documenting the data collected at baseline, four month, and six months.

Analysis of Hypothesis

Results were analyzed using repeated measures to determine the mean and standard deviation at baseline, 2 months, and 4 months, along with the significance for weight, arm circumference, and oral intake. Overall weight from baseline increased from M1=149.67 (34.17), M2= 148.43 (33.40), M3= 151.43 (34.78); F = .524, p=.482, which is not significant. Overall arm circumference from baseline increased from M1=10.8 (1.6), M2= 10.8 (1.9), M3=10.9 (1.9); F= .488, p=.515, which is not significant. Although this did not achieve statistical significance the fact that there was slight improvement is encouraging. Even if the figures were just maintained would be encouraging due to the fact that as AD progresses, weight loss is anticipated. Overall intake percentage from baseline decreased from M1= 91.9 (12.3), M2= 90.1 (13.8), M3= 89.9 (17.9); F=.218, p=.648, which is not significant. Due to the small sample size we would have only shown significance at 80% and the power of this research was only 8%.

In addition to measuring weight, arm circumference, and intake, feeding behaviors were measured utilizing the Ed-FED-Q. This tool was used to track changes and determine the level of assistance required by each participant. The overall Ed-FED-Q scores from baseline indicated

increased ability and increased need for assistance. The Wilcoxon Signed Ranks test was used to determine the size of the differences from lowest to highest Z=-2.724, N=9, p 0.05 which is significant, but the hypothesis states an improvement in feeding behaviors and this indicates a decline in feeding behaviors. This may be attributed to the decline in cognitive impairment that was observed and documented in the research.

Summary

Although statistical significance was not achieved, clinical significance was detected, as evidenced by the increase and maintenance in weight and arm circumference. Facility staff members were informally asked their opinion of the table clothes and table setting contrast. The vast majority of caregivers verbalized that they felt like the dining room looked better and helped the residents see what they are eating and doing while at the tables. It was also observed that several residents participated in arranging the tablecloths and place settings. Several residents were also heard stating that they liked the formal table settings because they were raised with an understanding that tables should always be set with tablecloths and place settings. The overall increase in MMSE and Ed-FED-Q scores reveal progression of the disease process which may have skewed the outcomes of the project. Researches may have seen greater improvements in weight, arm circumference, and intake post intervention if cognitive impairments were maintained.

Chapter 5: Discussion, Conclusions, and Recommendations

Discussion

Patients with ADRD are always at risk of poor nutrition and despite all efforts, weight loss may be inevitable. Many ADRD patients do not recognize the feelings of hunger and thirst, and often live in unfavorable conditions with inadequate environmental modifications unequipped to meet their needs; therefore, it becomes the responsibility of the healthcare team to anticipate and meet these needs.

Previous research indicates that judging distance and determining color or contrast is often a problem contributing to weight loss and nutritional decline in dementia clients. It is recommend through best research evidence along with patient preferences, clinical circumstance, and available health care resources to apply table setting contrast at meal times for individuals with ADRD. The table setting contrast intervention is a simple, low cost alternative to traditional management that may facilitate increased caloric intake at mealtimes by allowing dementia residents to actually visualize what they are eating and where it is located. Through observation of meal times, family discussion, and staff reports, researchers revealed unmeasured positive outcomes such as: resident and family verbalization of contentment with table setting, less spillage, and better accuracy with retrieving food, drink, and condiments. Although the residents were unable to clearly articulate their opinions of the changes, the implementation of the dining room modifications enticed several residents to participate in applying the table settings before meals. Attention to the progress highlights the fact that staff and residents enjoyed enhancing their milieu, and that the advantages from making even small environmental changes to the dining room may extend beyond the dining experience.

Despite control limitations, there were clear and marked improvements in the overall average weight gain and arm circumference indicating clinical significance but did not achieve statistical significance due to the sample size. The sample size significantly affected this study. For example, a dramatic change in intake, weight, or arm circumference experienced by a single individual would skew the entire results of the study. This suggests that researchers should further investigate the impact of modifying barriers in the dining environment with a larger sample size.

Recommendations

Subsequent studies should collect more detailed information about resident's vision and cognition. The level of cognition should be obtained prior to the study and should be used to either determine inclusion/exclusion criteria or the significance between groups. Cognition and the signs and symptoms associated with a decline in the disease process overrides whatever small amount of significant results were retrieved from the intervention; as evidenced by the marked increased in overall MMSE and EdFed-Q scores. Although, this information may be useful to guide future research to focus on individuals with advanced cognitive decline attributable to the results representing more of a need for environmental modifications as people advance in the disease process. A regression analysis is recommended for future studies to determine the correlation between cognition and intake, weight, and arm circumference. A randomized prospective cohort analysis would be beneficial for future studies including a group with table cloths and one without table cloths. The results of this study were beneficial in determining factors that are ideal to guide future research and clinical practice.

Summary

In summary, the designed physical environment for people living with ADRD can profoundly influence how patients feel, behave, and function. Mealtime generates numerous burdens and challenges for individuals with ADRD and it is our responsibility as health care professionals to advocate for simple, non-pharmaceutical, inexpensive alterations that will ease frustration and promote more independent functioning. Table setting contrast is one non-invasive intervention that should be implemented as a means of accommodating residential quality of life and minimizing weight loss, confusion, and frustration associated with eating among individuals with ADRD.

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APPENDIX A: Approval Communication

1. Approval from Facility to Conduct Research
2. IRB Form

The researchers have secured the letters requesting and granting permission to do research at the health care facility to protect the privacy of the facility.

Southern Adventist University

RESEARCH APPROVAL FORM

Form A

Directions**: Please complete this form and submit with the following documents if used: (1) Informed Consent Form, (2) Data Collection Instrument (e.g., questionnaire) or Protocol.**

Level I review**: Obtain approval and signature from the course professor/student club or association sponsor. Submit** Form A **with signature to course professor and keep copy for self.**

Level II review**: Obtain approval and signature(s) from Chair/Dean. Submit copies of** Form A **with signatures to course professor, Chair/Dean(s), and self.**

I. Identification of Project

Principal Investigator-Tiffany Hobbs, RN, BSN
Address-7006 Northside Drive Chattanooga, TN 37421
Tel. & E-mail -423-309-9673 thobbs@southern.edu
Co-Investigator(s)-Sheila Hutchens, RN, BSN
Address – 6800 Pine Drive Chattanooga, TN 37421
Tel. & E-mail-423-322-3078 srhutchens@epbfi.com

Title of Project- Improving Caloric Intake, Nutrition, and Feeding Behaviors for Elderly Dementia Patients by Modifying the Environment
Department-MSN
Faculty Supervisor (for student investigator)- Holly Gadd PhD FNP-BC
Starting Date –June 23, 2009 Estimated Completion Date-August 2010
External Funding Agency and Identification Number-N/A
Grant Submission Deadline-N/A

II. Purpose of Study The purpose of this study is to determine if caloric intake, nutritional status, and feeding behaviors can be improved through environmental modifications for elderly patients with dementia. Specifically, contrast will be added to table settings using a burgundy/red tablecloth and white plates to all three meals per day for four months.

III. Description and Source of Research Subjects ***(e.g., humans, animals, plants, documents)***

Humans Diagnosed with Dementia

If human subjects are involved, please check any of the following that apply:

_____ Minors

_____ *Prison inmates*

__x__ *Mentally impaired*

_____ *Physically disabled*

___x__ *Institutionalized residents*

__x__ *Vulnerable or at-risk groups, e.g., minority, poverty, pregnant women (or fetal tissue), substance abuse populations*

___x_ *Anyone unable to make informed decisions about participation*

If any of the above is checked, proposal requires Level III review. Form B must be completed in addition to Form A.

IV. Materials, Equipment, or Instruments

- Nutritional Worksheet
- Edinburgh Feeding Evaluation in Dementia Questionnaire
- Mini Mental Status Examination
- Red/Burgundy tablecloths with white plates
- Weight Scale
- Tape Measure

V. Methods and Procedure

- Consent from families
- Baseline assessment measures
- Apply tablecloths to tables
- Mini Mental Status Exam (MMSE) [time frame: baseline]
- 3-day tray completion percentage [time frame: baseline, 2 months, and 4 months].
- Arm circumference measurement [time frame: baseline, 2 months, and 4 months].
- Weight [time frame: baseline, 2 months, and 4 months].
- Nutrition Worksheet [time frame: baseline, 4 months]
- Edinburgh Feeding Evaluation in Dementia Questionnaire [time frame: baseline and 4 months]

The inclusion criteria:

- Diagnosis of Dementia
- Ate meals at a table in a dining room
- Physically able to feed themselves 25% of a meal at least two days per week

The Exclusion Criteria:

- Diagnosis of Cancer
- Residents taking Marinol and/or Megace
- Physician orders for routine nutritional supplements
- Residents receiving Hospice care

VI. Sensitivity: *Psychological discomfort or harm experienced by human participants because of topic under investigation, data collection, or data dissemination.*

On a scale of 0 (not sensitive) to 5 (extremely sensitive), rate the degree of sensitivity of the behavior being observed or information sought:

___0___ Sensitivity of behavior to be observed or information sought.
If greater than "1" proposal requires Level III review. Form B must be completed in addition to Form A.

VII. Invasiveness: *Extent to which data collected is in public domain or intrusive of privacy of human participants within context of the study and the culture.*

On a scale of 0 (not sensitive) to 5 (extremely sensitive), rate the degree of invasiveness of the behavior being observed or information sought.

____1__ Sensitivity of behavior to be observed or information sought.
If greater than "1" proposal requires Level III review. Form B must be completed in addition to Form A.

VIII. Risk: *Any potential damage or adverse consequences to researcher, participants, or environment. Includes physical, psychological, mental, social, or spiritual. May be part of protocol or may be a remote possibility.*

On scale of 0 (no risk) to 5 (extreme risk), rate the following by filling each blank.

Extent of Risk	**To Self**	**To Subjects**	**To Environment**
Physical harm	0	0	0
Psychological harm	0	0	
Mental harm	0	0	
Social harm	0	0	
Spiritual harm	0	0	

If any blank is greater than "1," proposal requires Level III review. Form B must be completed in addition to Form A.

IX. Benefit-Risk Ratio (Benefits vs. Risks of this Study)

Overall benefits:

- Cost effective
- Improves overall nutritional status which in turn decreases potential for co-morbidities, polypharmacy, and mortality.
- Improves overall physical and mental well being
- Improves overall feeding behaviors

No risks identified.

X. Confidentiality/Security Measures

- Collection-by chart review, physical assessment, and observation
- Coding-initials and room numbers will be used for the participant
- All documents and research materials will be stored in researchers office
- Analyzing with SPSS- No identification of individuals in analysis
- All documents will be shredded
- Reporting –to committee members, query letters with potential for journal publication, and power point presentation.

XI. Informed Consent Process

- An informative, educational meeting discussing the purpose and anticipated results of the study will be offered to all participant's Guardians, Power of Attorneys, and/or Conservators prior to the study.
- Informed consent will be signed by family members prior to the study.

_____ Potential for coercion, which is considered any pressure placed upon another to comply with demand, especially when the individual is in a superior position. Pressure may take the form of either positive or negative sanctions as perceived by the participants within the context and culture of the study.

_____ Coercion or Deception involved. If so, explain.
If either checked, proposal requires Level IV Full Review.

XII. Debriefing Process- with committee members

- Routine meetings with committee to discuss research progress and any problems or concerns.

XIII. Dissemination of Findings

- SAU-MSN
- Facility- families invited

____**x**_ Potential for presentation or publication outside of University.
If so, proposal requires Level II Review.

XIV. Compensation to Participants-NA

Southern Adventist University

Signature Page

Form A

By compliance with the policies established by the Institutional Review Board of Southern Adventist University, the principal investigator(s) subscribe to the principles and standards of professional ethics in all research and related activities. The principal investigator(s) agree to the following provisions:

- *Prior to instituting any changes in this research project, a written description of the changes will be submitted to the appropriate **Level of Review** for approval.*
- *Development of any unexpected risks will be immediately reported to the **Institutional Review Board**.*
- *Copies of approval for off-campus sites of data collection will be obtained from the site and submitted in triplicate to the appropriate **Level of Review** prior to data collection.*
- *Close collaboration with and supervision by faculty will be maintained by SAU student investigator.*

Principal Investigator Signature_____Date_____

Co-Principal Investigator(s) Signature_____Date_____

_____

* * * * *

As the supervising faculty, I have personally discussed the proposed study with the investigator(s), and I approve the study and will provide close supervision of the project.

Supervising Faculty/Sponsor Signature_____Date_____
(Required by all SAU student investigators)

* * * * *

As Dean/Chair, I have read the proposed study and hereby give my approval.

Chair(s)/Dean(s) Signature_____ Date_____

_____ Date_____
(If **Level II** approval required)

Southern Adventist University

RESEARCH APPROVAL FORM

Form B

This form is required in addition to Form A because of involvement of one or more of the following factors:

1. *At-risk participant populations*
2. *Sensitivity*
3. *Invasiveness*
4. *Risk*
5. *Deception*

*Please answer the following question(s) as appropriate to the proposed research and submit **6 copies of Form A and Form B** to Subcommittee Chair. If coercion or deception is involved, submission must be made to IRB for full review.*

1. ***Describe the at-risk participant population.***
   a. Elderly Dementia residents with cognitive impairment residing in a memory care assisted living facility.

   Measures to be used to protect the participants from harm.

   - Informed consent will be signed by all subject's Guardians, Power of Attorneys, and/or Conservators prior to the study.
   - All ethical principles, such as, beneficence, respect for human dignity, and justice will be practiced at all times throughout the study.
   - All records and information will be kept confidential and participants anonymous.

2. Describe the sensitive nature of the topic under investigation, data collection, or data dissemination.
   Not Applicable

3. Describe the degree of invasiveness.
   Not Applicable

4. Describe the degree of risk.
   Not Applicable

5. Describe the use of coercion and/or deception.
   None

   Justify its use in this project. *Not Applicable*

   Safeguards that will minimize harm. *Not Applicable*

Signature Page

Form B

By compliance with the policies established by the Institutional Review Board of Southern Adventist University, the principal investigator(s) subscribe to the principles and standards of professional ethics in all research and related activities. The principal investigator(s) agree to the following provisions:

- *Prior to instituting any changes in this research project, a written description of the changes will be submitted with 6 copies to the appropriate **Level of Review** for approval.*
- *Development of any unexpected risks will be immediately reported to the **Institutional Review Board**.*
- *Copies of approval for off-campus sites of data collection will be obtained from the site and submitted in triplicate to the appropriate **Level of Review** prior to data collection.*
- *Close collaboration and supervision by faculty will be maintained.*

Principal Investigator Signature_____Date_____

Co-Principal Investigator(s) Signature_____Date_____

_____

* * * * *

The IRB Subcommittee has reviewed the proposal and hereby grants approval to the project.

Name of IRB Subcommittee_____

Subcommittee Chair Signature_____Date_____
(If **Level III** approval required)

* * * * *

The IRB has reviewed the proposal and hereby grants approval to the project.

IRB Chair Signature_____Date_____
(If **Level IV** approval required)

APPENDIX B: Miscellaneuos Data and Forms

1. Nutritional Worksheet
2. Mini Mental Status Exam
3. EdFed-Q

Nutrition Worksheet

1. Participant Initials_____ Room Number_____

2. Gender M____ F____

3. Age _____

4. Date of Admission_____

5. Level of cognitive impairment_____

6. Weight

   Admission weight_____
   Weight 1 month prior to study_____
   Weight 2 months prior to study_____
   Weight 3 months Prior to study_____
   Baseline weight_____
   Two Month weight_____
   Four Month weight_____

7. Arm Circumference
   Baseline_____
   Two Months_____
   Four Months_____

8. Percent of tray completion
   Baseline_____
   Two Months_____
   Four Months_____

9. Patient taking Psychotropic Medication with appetite stimulant effects? Y____ N_____

   List Medications:

   _____

10. Patient taking Diuretic? Y____N_____

    List Medications:

    _____

11. Diagnosis of CHF? Y____N_____

12. Edema? Y____N_____

    Degree? _____

    Location? _____

13. EdFED-Q Score
    Baseline_____
    Four Months_____

Mini Mental Status Exam and EdFED-Q

Researchers were given permission to use the Mini Mental Status Exam and EdFED-Q but were not granted permission to copy the tools due to copyright laws.