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Non-Pharmacological Interventions Project: Treatment for Dementia

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Non-Pharmacological Interventions Project: Treatment for Dementia

by

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A capstone project submitted to the faculty of
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Approval Page

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Abstract

In response to the Office of Inspector General's research report on atypical antipsychotic off label treatment of elderly dementia residents in long-term care, the Centers for Medicare and Medicaid Services developed a non-pharmacological intervention known as the Hand In Hand training tool. This projects focus was on training the direct care nursing staff with the Hand In Hand tool and evaluating for decrease in behavior and psychological symptoms in their patients. A retrospective chart review was utilized for the Minimum Data Sets tool Brief Interview of Mental Status (BIMS) and Mood interview. Pre training and post training scores were analyzed using descriptive statistical paired sample *t* test. No statistical significance was shown on the pre and post BIMS or Mood scores. Six months of Pharmacy Review Summaries were collected and averaged for pre and post medication prescriptions for residents during six months of this project. No increase was found on the administration of atypical antipsychotics during this period.

Keywords: Dementia, Off-label atypical antipsychotics

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CHAPTER I

Introduction

Non-Pharmacological Interventions Project: Treatment for Dementia

A major concern to healthcare of the elderly is the use of off-label atypical antipsychotic medication to treat dementia. Risks associated with atypical antipsychotic medications include confusion, sedation, postural hypotension, and increase in death (Casey, 2011; Shekelle et al., 2007). Traditional medications for dementia are used and in some long-term facilities there are non-pharmacological treatments such as music and art therapy being used. More rigorous research in non-pharmacological management of behaviors is needed to confirm their use in treatment of behavior and psychological symptoms in dementia (BPSD) (O'Neil et al., 2011).

This capstone project focus was on a non-pharmacological intervention called Hand In Hand training for care givers of residents with dementia, and producing outcomes to show the need to reduce the use of atypical antipsychotic medications. The Centers for Medicare and Medicaid (CMS) developed the Hand In Hand modules in 2013 to aid care givers in nursing centers with assessment and management of dementia behaviors (Centers for Medicare and Medicaid Services, 2013). These modules emphasize person centered care, communication, meeting the resident's needs, refocusing, and redirecting the resident during times of behavior and psychological symptoms of dementia.

Dementia: what is it and what are the effects on people? According to the National Institute of Health it is a disease that has many symptoms (National Institute of Health, 2013). Dementia affects cognitive, emotional, behavioral functions, and even the

personality of those with the disorder. Memory, language, and problem solving skills can all be affected. Diseases of Alzheimer's or Huntington's can cause dementia and also disorders of deficiencies in nutrition, tumors of the brain, and even medication reactions.

Residents can demonstrate symptoms of wandering, agitation, aggression, pacing, irritability, and sleep disturbances. These can be present in the neuropsychiatric symptoms of dementia (Ballard & Corbett, 2010).

The Hand In Hand training modules, developed by Centers for Medicare and Medicaid Services (CMS), is for improving the management of behaviors in dementia patients. The goal is to decrease the potential risk of decline and negative side effects from antipsychotic medications in the elderly with dementia through training of staff emphasizing person-centered care. This project implemented the Hand In Hand training and gathered data to analyze outcomes of behavior and medication regimes post training.

Problem Statement

Powerful antipsychotic medications have been shown to cause serious side effects in the elderly and increase the risk of death (Shekelle et al., 2007). Despite these warnings many nursing care centers, where elderly residents with dementia reside, continue to treat dementia residents with atypical antipsychotic medications. There are few high grade level research studies to support the use of non-pharmacological clinical treatments for dementia, which has led to increased management of behavior and psychological symptoms in dementia through off-label atypical antipsychotics.

Justification of Project

From January 1 through June 30 of 2007, 14% or 2.1million elderly residents in nursing homes had at least one claim for Medicare reimbursement of an atypical

antipsychotic at a cost of 309,028,317 dollars (Appendix A). Of those claims, 83% were for off-label use and 88% were being used in conditions against the Food and Drug Administration (FDA) boxed warning (Appendix B). These erroneous claims totaled to \$116 million (Appendix C) (Office of Inspector General (OIG), 2011). A total of 22% were administered against CMS standards for treatment of unnecessary drugs (Appendix D) (OIG, 2011). The costs in both lives and dollars to the health care systems (Medicare, Medicaid, and Insurance) are staggering (OIG, 2011).

As the baby boomer generation, those born from 1946 through 1964, continues to age and join the healthcare system, this burden will increase by 76 million boomers (Blumenthal, 2011). The trend in nursing homes is to favor the use of these drugs for dementia treatment. Researchers have found that prescribing rates were directly linked to residents' characteristics (36%), characteristics of the facility (23%), and 81% to the nursing home culture of prescribing (Huybrechts, Rothman, & Brookhart, 2012). Staffing issues, problems with medication reconciliation, and family wishes also are significant barriers to changes in treatment of dementia in the elderly. Resident quality of life and independence helps to lessen the caregivers burden (Kurt, 2011). Stricter monitoring of these drugs, assessments of side effects, and use of non-pharmacological interventions can reduce risk to the patients (Lindsey, 2009).

Medicare Claims

Despite the evidence of the dangers of off-label atypical antipsychotic medication use with the elderly, these drugs continue to be prescribed for elderly dementia residents within nursing facilities. The claims for Medicare reimbursement produce evidence of

the use of these drugs for behavioral and psychological treatments for diagnoses against recommended use.

The Department of Health and Human Services (DHHS) Office of Inspector General's (OIG) report of May 2011 evaluated claims to Medicare concerning off-label atypical antipsychotic drugs for nursing home residents 65 years or older during January 1-June 30, 2007 (OIG, 2011). The OIG's concerns for increase in off label atypical antipsychotic drug claims and their costs prompted them to ask the question whether these medications were being used appropriately. Findings revealed off label use of these drugs were being prescribed for treatment of dementia and not necessarily for recommended use according to FDA.

Atypical Antipsychotics

Currently only eight antipsychotic medications are approved for treatment of behaviors associated with schizophrenia and bipolar disorder (OIG, 2011). Part of the regulation of the Centers for Medicare and Medicaid (CMS) provides protection of residents from the use of drugs not warranted and the length and dosage amounts given. Medicare uses the Minimum Data Sets (MDS) part B & D to identify the medication claims. This instrument is done at least every three months on each resident (OIG, 2011).

This extensive review of Medicare claims included International Classification of Diseases (ICD-9) codes for claims. Nursing home inpatient and skilled nursing home data was compared over a six month period for transfers to other facilities. The Prescription Drug Event (PDE) program data was examined, due to their summary not individual dosages. Individual nursing home documentation included pharmacy review

records, admission records, resident care plans, nurse's notes, consultations notes from behavioral monitoring, and MDS assessments.

The statistical reports are from the Office of Inspector General's (2011) report on off-label atypical antipsychotics for the Department of Health and Human Services. (Appendix A-D) Findings indicated that 14% of the nursing home elderly had Medicare claims for at least one atypical antipsychotic. Of those claims surveyed, 83% were for off-label use and 88% were prescribed for conditions listed in the FDA warning box. Erroneous claims were 51%, at a cost of \$116 million. The atypical antipsychotics, 22%, were given despite the standards that the CMS considers as unnecessary drugs.

Although only eight drugs are approved, physicians often prescribe off label and the practice is permitted. The Department of Veterans Affairs found in 2009 that 60.2% of these atypical anti psychological drugs being prescribed had no record of the diagnosis for which it was being used.

Despite the CMS guidelines for using these drugs, the medical criteria for accepted use were not applied. The CMS guidelines also required quality and safety standards for nursing facilities. One such requirement is freedom from drugs that are not necessary. According to the standards set by CMS and drug criteria, these off-label drugs do not qualify for compensation for treatment. Findings revealed that off- label atypical antipsychotic drugs were without adequate monitoring and were shown to be lacking any indication of their use (OIG, 2011).

This report reviewed over eight million medication claims: of the claims reviewed, 1,678,874 met criteria. A sample size of 700 was included in the report. Office of Inspector General admitted limitations to the report including length of the

study, pharmacy did not provide the drug information, and clinical staff was not a part of the evaluation.

Risks

In 2007, The Agency for Healthcare Research and Quality (AHRQ) studied and concluded that these off-label drugs increase risk of death for dementia residents. Why are these drugs so dangerous in the elderly? The answer lies within the changes to their bodies' systems. In people 65 or older, the systems such as cardiovascular, liver, and kidney functions show the most profound effect from the impact of these drugs. The multi-organ inability to function at full capacity makes them more vulnerable and the drugs upset the balance of their health. Due to sensitivity in the brain's receptor sites and decreases in function of the brain, there are serious outcomes from use of the benzodiazepines, antidepressants, and antipsychotics.

These drugs can actually increase confusion, sedation, and postural hypotension in the elderly. Older resident often have poly-pharmacy medication regimens which also increases risk and adverse responses to these types of medications. The imbalance of their homeostasis and cognitive impairment further complicates therapeutic effects of these types of medications. Drugs often lose therapeutic effect from increasing dosages leading to toxic effects (Casey, 2011). In the OIG (2011) report, the failure of monitoring the drugs for reduction was significant to the safety issues for prescribing. Non-pharmacological interventions are the alternative means when dealing with the behaviors, as recommended by the OIG (2011) report.

Purpose

The purpose of this capstone project's focus was on training direct care staff to utilize non-pharmacological interventions in management of the elderly with dementia in long term care. The goal was reduction in behavioral and psychological symptoms and potentially to illustrate the need to decrease usage of atypical antipsychotic drugs.

Project Question

Can non-pharmacological intervention training of direct care staff decrease behavior and psychological symptoms in elderly dementia residents and potentially demonstrate a need for reduction in atypical antipsychotic medication use?

Definition of Terms

The following are definitions of terms referred to in this capstone project paper. The terms are used to define the symptomatic disorder of dementia and the descriptive term of the classification of medications that the elderly with dementia are being prescribed.

- Dementia: not specifically a disease but symptoms from many disorders like Alzheimer's or brain tumors that affect the mind, behavior, personality, or emotional stability. It can affect memory, cause emotional outbursts and agitation, and change personality (Dictionary.com).
- Off-label atypical antipsychotic: second generation drugs that are given for other disorders not specific for the diagnosis for schizophrenia or bipolar disorder (Kohen, Lester & Lam 2010; Shekelle, et al., 2007).

Summary

The capstone project addressed the use of atypical antipsychotics for dementia and attempted to add support for the use of non-pharmacology intervention. The training implemented the Hand In Hand training to affect behavior and endeavored to demonstrate the need for non-pharmacological interventions in the treatment of dementia in the elderly.

CHAPTER II

Research Based Evidence

Effects of atypical antipsychotics on the elderly can be a serious risk. The Agency for Healthcare Research and Quality (AHRQ) compared efficacy of the off label atypical antipsychotics in their 2007 report (Shekelle et al., 2007). In this executive summary of findings, the risks were cardiovascular, increase risk of death, and extra pyramidal symptoms. Studies included 15 placebo-controlled trials, and a large head to head placebo controlled trial. The AHRQ concluded that the risk of death was small but so was the benefit of the off label atypical antipsychotic drugs and felt more information was needed about the death risks and found that conventional or typical antipsychotic drugs were potentially more risky. The findings indicated not enough high level research had been done to prove efficacy of atypical antipsychotics, and until evidence was available no one could conclude safety and efficacy of their use. These second generation antipsychotic drugs continued to be prescribed despite the questions of efficacy and safety.

Review of Literature

A review of the literature by Kohen et al. (2010) of the efficacy and safety of one of the treatments of a second generation antipsychotic drug aripiprazole (Abilify), had little evidence to support use of the drug but did not discount Abilify. The suggestion from the review was that Abilify may be better than other drugs due to its metabolic benefits. The delusions, psychosis, and hallucinations accompanying the drug were considered as related to dementia. In three 10 week studies of 487 nursing home residents, there were no significant outcomes between the treatment with Abilify and

placebo with 256 residents. Kohen et al. (2010) conclusions felt that second generation antipsychotics are greater risks to the elderly and not treating in mild dementia might be a practical choice. Additional comparative studies involving non-pharmacological interventions and atypical antipsychotics would provide possible options for treating the mild dementia patient. There is not enough research evidence to decrease the use of these drugs in dementia or treat mild dementia effectively. Warning labels from the FDA have not prompted a reduction in the use of the off-label atypical antipsychotics.

Safety and Efficacy

Kim, Brown, Ding, Kiel and Berry (2011) questioned safety in other medications commonly given to residents with dementia and Alzheimer's dementia such as cholinesterase inhibitors and Memantine. A RCT meta-analysis was conducted to examine the safety and fall rates associated with the treatments using both drugs. This study considered the impact of falls, fractures related to falls, syncopial incidents, and injuries that were accidental (Kim et al., 2011). Of the 156, RCT considered only 54 were eligible due to lack of data on adverse events related to falls. Findings indicated that cholinesterase did increase risk of syncope, but no effect related to falls, fracture, or accidents. Memantine actually had beneficial effects on fractures, a surprising finding. The findings were not conclusive due to under reporting and decreased outcome events available. The study only looked at two common drugs administered to dementia residents and their side effects. More research was needed to include the eight most prescribed atypical antipsychotics and their effects on the elderly.

Maher et al. (2011) conducted a systematic review and meta-analysis to address the efficacy of off-label use of atypical antipsychotics for dementia. The review

revealed that from 1995 to 2008, off label atypical antipsychotics doubled in prescribing rates from 6.2 million to 14.8 million. The eight drugs investigated were aripiprazole, asenapine, iloperidone, olanzapine, paliperidone, quetiapine, risperidone, and ziprasidone. The systematic review revealed that death risks increased by 3.5% with the use of these drugs compared to 2.3% in placebo. With olanzapine and risperidone, there was greater occurrence of cardiovascular, vasodilatation, and edema symptoms. Risperidone had significant signs and symptoms for increased stroke risks. Health risks were increased incident of diabetes, sedation, fatigue, extra pyramidal symptoms, urinary tract infections, decreased cognitive functions, orthostatic dizziness, confusion seizures and headaches. Overall, of the four large studies done, the risk of death increased with conventional antipsychotics: two smaller studies showed increased with both types of drugs, and the findings of increased mortality were found for both classifications of drugs. A small but statistically significant benefit for treatment in behaviors in dementia patients was found in aripiprazole, olanzapine, and risperidone but harmful effects of the drugs were also statistically significant in the elderly. Maher et al. (2011) concluded that off-label atypical antipsychotic drug use in the elderly with dementia is associated with adverse outcomes and are statistically significant in increasing risk of death, showing that use of these drugs and adverse effects are related. Decisive research on the atypical antipsychotics and their serious risks to the elderly with dementia was now evident. Despite warnings from the FDA and mounting evidence from researchers prescribing of these drugs to dementia residents increased.

Evidence of Use

Evidence was available that the off-label atypical antipsychotic drugs were being widely used for dementia in the elderly. The National Veterans Administration (VA) set out to discover how many elderly veterans were receiving these drugs for dementia. A multivariate logistic regression method was done on the VA database looking for at least one prescription of off label use from 2006 until 2007. The study of off-label use of antipsychotic drug use in the VA system revealed evidence, like many other care settings, that the elderly with dementia are commonly prescribed these drugs (Leslie, Mohamed, & Rosenheck, 2009). Seven drugs were examined in this study: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, and ziprasidone. Diagnosis was considered with schizophrenia and bi-polar being excluded. The sample size was 279,778; of that number 60.2% (168,442) had no diagnosis to be prescribed the drugs. Prescribing for post-traumatic stress syndrome (PTSD) was over 40%: 39.5% was for minor depression, 23.4% received the drugs for major depression, 20% for anxiety: 20% for alcohol and 15.1% for drug dependency. The study acknowledged the fact that the ratios of patients in groups were over 100% and the extent of the co-morbidities within the patient population. In quetropine use, the largest group receiving the drug was organic brain syndrome and Alzheimer's dementia. If the veteran had PTSD, psychosis or organic brain syndrome or Alzheimer's, their odds for being prescribed these drugs increased (Leslie et al., 2009). Although indication for use of these drugs in dementia was absent, prescribing rates continued to increase. The OIG (2011) report was now verified by the VA report that nursing home dementia residents have been administered these atypical

antipsychotics and the prescribing rates have varied across the country regardless of indication of use.

A systematic review meta-analysis conducted by Chen et al. (2010) supported the evidence of variation rates in the nursing homes in the United States (U.S.). Data was collected from a national database of MDS forms and prescription data records. The forms were collected from 2005 through 2006. Sample size was 16,586 from 1257 nursing homes and pharmacy claims were 66,181. In 2006, more than 29% of nursing home residents received at least one antipsychotic drug with 32% having no indication for use (Chen et al., 2010). When facilities have a high rate of prescribing, it was found that the resident would be 1.37 times more likely to receive these drugs than those residents in low prescribing facilities. Race was also an indicator of prescribing rates and confirmed in the VA research. Chen et al. (2010) found the white race was 11% more likely to get these drugs than blacks. Of those without psychosis, whites were 30% more likely than blacks and 22% more likely than Hispanics. Dual eligible patients, those with Medicare and Medicaid, were also more likely to receive antipsychotic drugs. Once again the conclusion of this study supported evidence of variation of prescribing in nursing homes related to previous prescribing rates and race.

In 2012, the Beers Criteria for potentially inappropriate medications (PIM) for nursing home residents was revised by an expert panel of geriatricians and pharmacotherapists (American Geriatrics Society, 2012). The systematic review and evidence grading of classification of PIM's was to update the previous Beers Criteria. This update was considered necessary based on the evidence that despite warnings these drugs continued to be first line treatment for the elderly. The drugs were classified in

three categories: those medications that were potentially inappropriate for use, those drugs which exacerbated existing conditions and those that needed caution when prescribing for the older adult. The new Beers Criteria linked with the American Geriatric Society allows for best practice and clearer system updates from experts to guide policy, research, and clinical practice (American Geriatric Society, 2012). A total of 53 medications are included in the updated Beers Criteria, under the three categories of PIM. The Beers Criteria is considered a clinical guide to drugs that are more harmful than beneficial to the older adult.

Regardless of the warnings, neurologists have many questions about the OIG report and the overuse of these drugs. These off label antipsychotic drug use are seen as either a means of restraint or a way to save money by using cheaper non-conventional medications (Samson, 2011). Dr. Louis Cooper, professor of neurology at Harvard Medical School, sees these drugs as medical straightjackets and is largely unmonitored once given. Dr. Cooper felt a lack of adequate funding to manage the problem residents in nursing homes was a major rationale in using the atypical antipsychotic drugs (Samson, 2011). Dr. Nair, chief of Neurology at the Alzheimer's Medical Center, thought the data was incomplete and felt conventional drugs were more harmful. He felt this was a cost issue, and since no drug has been approved for behavior in dementia, the report was generated to cut costs. Dr. Nair felt these drugs should be used when non-pharmacological attempts have failed and the behavior becomes unmanageable (Samson, 2011).

Although there was a divide on the use of these drugs and how they are prescribed, one issue remained the same: there was a need to have recommended

treatments that are safe and effective when treating the elderly with dementia. With such differing opinions and lack of comparative studies for pharmacological and non-pharmacological treatments, what is the recommended treatment for elderly residents with dementia?

Treatment Recommendations

In 2006, the VA Office of Geriatrics and Extended Care (OGEC) directed a committee to ask key questions concerning dementia care for the veterans related to non-pharmacological treatment in behaviors compared to pharmacological treatments (O'Neil et al., 2011). Three key questions were considered: the effectiveness, safety, and costs of non-pharmacological treatment in dementia versus pharmacological treatment. (O'Neil et al., 2011). Studies included cognitive, exercise, animal assisted, massage, music, animal assisted therapy, memory, acupuncture, aromatherapy, and behavioral management interventions were all considered. Other areas reviewed were related to techniques for prevention of wandering, agitation, and inappropriate sexual behaviors using barriers, environmental modifying, and distraction. Conclusions were considered varied as to effectiveness of treatment of behavior and psychological symptoms of dementia (BPSD). In the cognitive area, validation therapy showed some significance compared with other therapies. Aromatherapy showed some promise in decreasing agitation: no differences were found for exercise, massage, or acupuncture and only mixed reviews for light therapies. No evidence on the environmental modification and unclear evidence in the barrier or other treatments for behaviors management. Very little information was found concerning cost related research. Overall this review suggested more rigorous evidence

is needed using blinding methods and management of treatments being standardized to produce consistent results.

Khan and Curtice (2011) conducted a pilot project in the United Kingdom to produce evidence for non-pharmacological treatment to be used initially. It was conducted in four care homes across the nation. Sessions were held for six months and each home had six sessions conducted. Training was done to prepare caregivers and staff with knowledge to intervene with non-pharmacological techniques of relaxation, distraction, nostalgic thoughts and art, music therapy with person centered focus. Monitoring also occurred with all psychotropic medication therapy. Significant findings were the need for a team approach, effective training was essential in dealing with BPSD for all staff and avoidance of an easy quick solution using psychotropic drugs to manage BPSD (Khan & Curtice, 2011). Lindsey (2009) revealed in her systematic review the importance of knowledge and a collaborative relationship between nurses and physicians. Person centered care is part of the emphasis placed on nurses and all caregivers to improve quality and safety for the patients with dementia.

Person-Centered Care

The need to individualize care is part of person-centered care model that has been instituted in most healthcare settings. Suhonen, Alikleemola, and Katajisto (2010) descriptive design study considered individualized care with the goal to describe the perceptions of nursing in the long term care and long term in-patient wards. The Individualized Care Scale-Nurse was used to collect data from 283 nurses. In the clinical situations, nurses felt they were using individualized treatment and care of their elderly residents. They recognized that individual control of decisions was lacking in and during

nursing activities. Although nurses perceived they provided individual care, generally this was not evident in the assessment of practice overall. This study did produce improved results on individualized care from nurses compared to previous studies. In the treatment of the elder dementia resident, individualized person-centered care given by knowledgeable nurses is imperative to monitoring and decreasing unnecessary antipsychotic drug use for the improvement of their safety and quality of life.

In Zee and Burkett's (2008) critically appraised paper of behavior management, they proposed that once a person begins into dementia behavioral problems, it is usually two years to nursing home placement. Behavior management then becomes an essential part of treatment. One of the Office of Inspector General's (2011) recommendations was alternative methods for compliance, which included education and training for nursing home staff in dealing with behaviors in dementia. Environment plays a key part in decreasing behaviors (Zee & Burkett, 2008). These behaviors can include pacing, wandering, agitation, aggression, and depression. Some of the suggestions to decrease these behaviors include a reduction of choice, various cues, and redirecting. Non-confrontational management of behaviors is important and always with resident safety in mind. In conclusion Zee and Burkett (2008) emphasize treating underlying needs of the resident, if needed treating BPSD with low dose antipsychotic drugs and only with atypical antipsychotics when benefits are clearly evident and there are few side effects.

Ballard and Corbett (2010) suggested that first line treatment should be non-pharmacological interventions. This systematic review considered meta-analysis and cohort studies previously done. When compared to reviews on non-pharmacological studies, systematic reviews of 162 studies and RCT were evaluated. Ballard and Corbett

(2010) found that person-centered care, enjoyable activities and exercise decreased BPSD. Treatment with low dose atypical antipsychotics when needed has not been ruled out as a treatment but is not suggested as a first line treatment. It is the project administrator's opinion that non-pharmacological interventions are the alternative interventions when dealing with the behaviors, as recommended by the OIG (2011) report.

Cognitive Stimulation Therapy

Aguirre et al. (2012) randomized control study of Cognitive Stimulation Therapy (CST), followed 272 dementia participants for seven weeks to determine the reasons that might predict their response to the CST. The residents were from multiple settings including care homes, day centers, and mental health centers located within the communities. The participants were randomly selected into two groups, decreasing the intra class correlation, with both groups receiving the CST. The interaction included exciting language interchanges, reminiscing, thinking sessions with points of references, and with a person-centered focus. Quality of life, cognition, behavioral disturbances, and activities of daily living (ADL) were all measured. Results for the study revealed when compared to previous RCT of cognitive stimulation therapy, this study showed significant changes in scoring. Quality of life indicator scores increased after CST. Significance of this study could lie in the person-centered approach, as Lindsey (2009) review stated. An unexpected finding was how 80 years old and older had scores that showed positive effect from cognitive stimulation therapy. Reflections from researchers concerning the age group related to overall lack of stimulation compared to those younger and changes that occur with age, not dementia related, have to be considered.

Exercise

A non-pharmacological intervention that has shown some promise is exercise. At the time of publication, Cerga-Pashoi et al. (2010) was conducting an ongoing study implementing incremental walking exercise with 146 participants. Two randomized groups participated, one received the walking and one received treatment as usual. The program is for 6-12 week periods, with a 20-30 minute walking regime with a qualified exercise therapist. Measures were taken for physiological and psychological effects at the 6 and 12 week timeframes. Zee and Burkett (2008) found that indications are that exercise is neuro-protective for reducing risk in dementia and has shown promise in dementia care. The NeuroPsychiatric Inventory tool (NPI), developed for assessment of BPSD is being used in the assessment of areas of quality of life, usage of psychotropic medications, placement into care facility, level of transience of life, and burden that the care givers felt (American Psychological Association, 2013). This study, if outcomes are positive, would add to the evidence, using a valid and standardized tool. The larger systematic reviews felt previous trials were deficient in using valid tools.

Aromatherapy

The non-pharmacological intervention aromatherapy has shown some effectiveness with dementia in the large systematic review by the VA (O'Neil et al., 2011) and the review by Ballard & Corbett (2010). In both reviews, aromatherapy had positive effects when treating agitation in dementia. Bidewell and Chang's (2011) systematic review on dementia treatments in residential care included aromatherapy. Agitation was defined as an unmet need and relationship of the resident to the environment, whether it was an internal or external stimuli. There were 241 studies out

of 3,100 that met criteria. Lavender was found in one review to also have positive effects on BPSD. However, similar to other reviews, only one study was felt to be rigorous enough to produce evidence to show a favorable response when using aromatherapy for agitation. Bidewell and Chang (2011) also considered aromatherapy as a pharmacological treatment, which was an unexpected conclusion. Overall, the conclusion from the systematic review was that no one treatment method was found to be effective and the high grade level studies remain scarce. As with many other non-pharmacological studies, the trials are not considered high grade to produce the evidence needed.

Music

Music therapy has been used as a non-pharmacological intervention with dementia residents. In the previous VA systematic review (O'Neil et al., 2011) music therapy had questionable results. Cook, Moyle, Shum, Harrison, and Murfield (2010) randomized cross over design study questioned music and the validity of treatment for agitation in dementia and to improve emotional and quality of life. Participants were placed in music or reading groups and then switched at half way point. The study was conducted in two mixed long term care facilities and researchers were blinded to patient's characteristics. The analysis of the study revealed no statistical significance in either arm of the study to decreasing agitation in the residents. There was an increase in verbal aggression and researchers felt that the therapies helped patients find their voice again. Nevertheless, the non-pharmacological intervention had a significant result in that both interventions caused an increase of verbalization of residents.

Communication

Communication is a powerful tool that is used every day by all people and effective communication is essential to all who provide care to others. Williams, Herman, Gajewski, and Wilson (2009) conducted an observational study to address the use of elderspeak and its effect on dementia residents. Elderspeak, defined as infantilizing communication (baby talk), is used during ADL's with the dementia residents often by the nursing staff giving care (Williams et al., 2009). The study examined the use of elderspeak and the correlation to resistance to care (RTC) compared to normal talk with dementia residents. RTC was defined as aggression, vocal eruptions, and pulling away. The study design was analyzed using psycholinguistic, observational, and behavioral methods. Video and audio recordings were conducted on 80 interactions between staff and residents during ADL's. Measurements were made using the Systematic Analysis of Language Transcripts (SALT) computer program and the Resistiveness to Care Scale (RTCS). Conclusions were that a temporal relationship does exist between elder speak and increase RTC behavior in comparison to normal talk and RTC.

Recommendations have been made to include non-pharmacological treatments for patients with early stage/mild to moderate dementias. Burgener, Buettner, Beattie, and Rose (2009) consensus report supports community based treatment modalities, using non pharmacological interventions, to treat dementia on a national level. The report was based on 150 research articles using non-pharmacological interventions in six areas. The areas included support early in the disease, cognitive interventions, and exercise programs that involve writing and art, promotion of health, program utilizing sleep, and

hygiene aid. It was determined in the report that increased access to community based interventions would decrease the stigma that society places on dementia, reduce the over medication of these people, and help people to achieve more normalized lives. Some studies suggested that these interventions can slow cell destruction and maintains some neural abilities. Giving the long term programs accessibility to help maintain dementia patients in the home improves the quality of life. Identifying the caregivers as essential partakers of the therapies also would increase positive outcomes. Other suggestions in this report were the application of evidence based protocols for clinical practice for non-pharmacological interventions to be a part of treatment for early stage dementia.

Goal

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) started a quality initiative in 2012 to improve the quality of care in skilled nursing homes and assisted living communities across the United States (American Health Care Association & National Center for Assisted Living, 2013). These goals included the reduction of off-label antipsychotics by 15% nationwide. This quality initiative was in line with the Inspector General's report, Department of Health and Human Service, the Senate Committee on Aging, and CMS goal of quality of life issue for residents and families. The Hand-in-Hand project attempted to produce outcomes to support the use of non-pharmacological interventions in treatment of dementia (American Health Care Association & National Center for Assisted Living, 2013).

Literature Gaps

Literature gaps were in the non-pharmacological studies, studies being conducted did not produce rigorous high grade evidence to support its use in clinical treatment.

Many studies were of qualitative design and were not random controlled trials that produced enough empirical data. A major gap in the literature was the cost comparison between using pharmacological or non-pharmacological interventions to treat dementia. Pharmacological costs were available but very few, if any, studies were mentioned in the literature on actual costs for non-pharmacological treatments.

Strengths and Limitations of Literature

Strength of the literature for this review was the amount of data from systematic reviews and the multiple databases used for the research. Multiple databases used for literature including Pub Med, Cumulative Index to Nursing and Allied Health (CINAHL), PsycInfo, Cochran Database of Review of Effectiveness (DARE), Cochrane Central Register of Controlled Trials (CENTRAL) and MEDLINE. Reputable governmental and private agencies conducted many of the reviews, especially the pharmacological reviews. Several of the studies were large studies with large samples with many levels of evidence.

Limitations in the literature were heavily weighed on the non-pharmacological research. Many of the reviews spoke of the lack of high grade evidence, problems with the scientific method of the studies and an overall lack in the literature of studies being conducted or evidence available to support non-pharmacological interventions in the treatment of dementia.

Theoretical Framework

The conceptual framework for this project is Betty Neuman's Care Systems Model that is based on relationships of stress, response to the stress and constructs a new system to deal with the stressors (Neuman Systems Model, 2013). The system is

considered universal in its design and adaptable in many ways. Neuman's design is centered on the premise that three lines of resistance: one representing the internal factors, normal line helping the patient maintain equilibrium, and a flexible one to help quickly change and adapt (Neuman Systems Model, 2013). In the theory, the nurse's interventions are involved in prevention. These preventions are primary, secondary, and tertiary. Normal lines preventions help protect, secondary preventions give strength to the internal lines, helping the reactions and resistance to stressors. Tertiary helps the patient to adapt, become more constant and return to a state of wellness (Neuman Systems Model, 2013). This capstone project used the primary prevention by using non-pharmacological intervention for management of stressors. By using communication and distraction methods the internal lines that react to stress can be managed by staff, utilizing the secondary prevention method in Neuman's theory. In the tertiary level of the project, consistent reinforcement of the non-pharmacological interventions help the resident adapt, maintain and return to their individualized equilibrium.

Please refer to Figure 1 for Neuman's Care Systems Model.

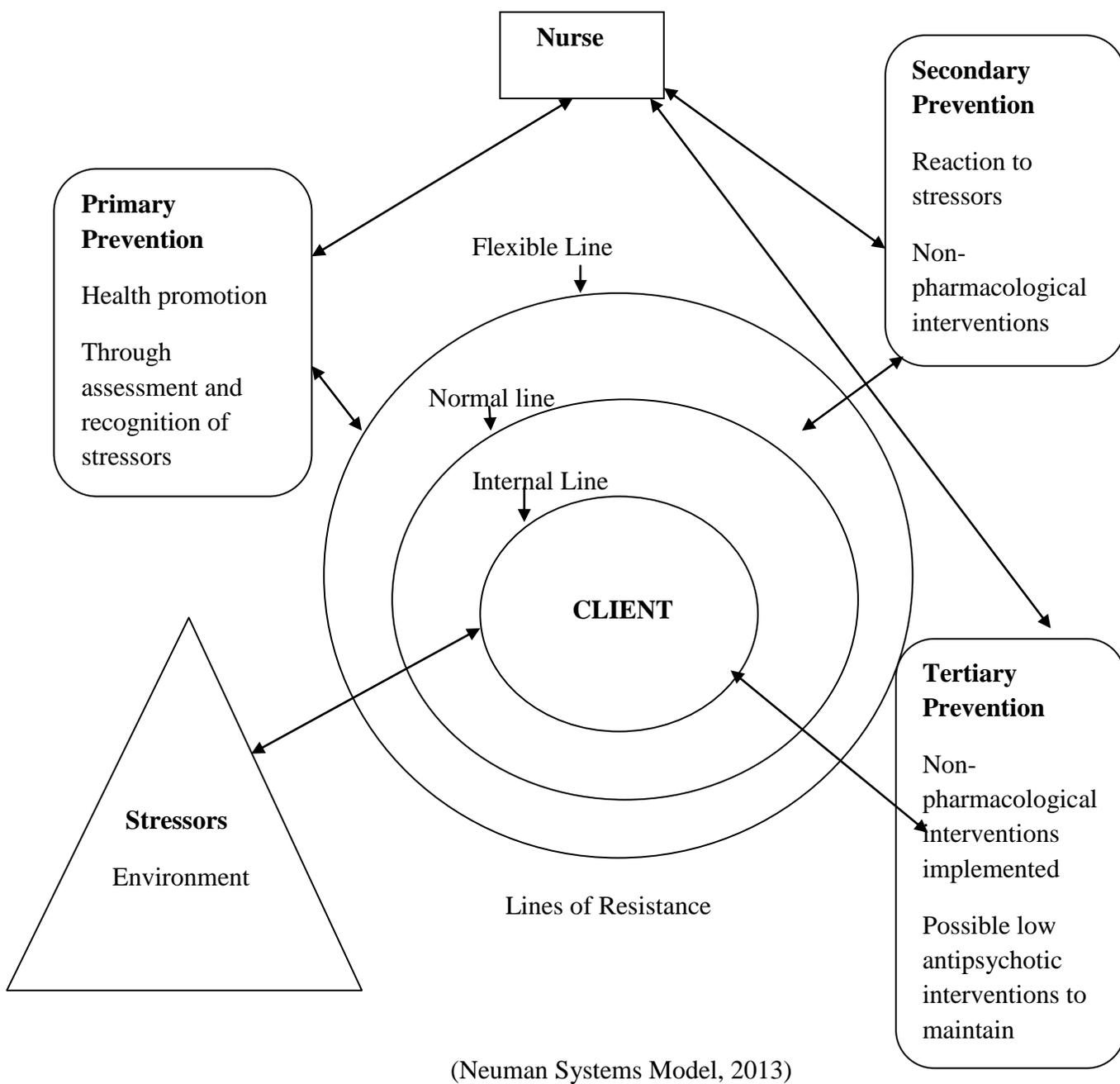


Figure 1. Neuman's Care System Model

Summary

Current literature has large studies and multi-level grade research in the pharmacological treatment of dementia with antipsychotics. Atypical antipsychotic drugs should be limited, closely monitored, and discontinued when possible when associated with treatment for dementia in the elderly. Costs in dollars and quality of lives will have a far-reaching impact on society. One consideration in effective treatment of BPSD is by non-pharmacological interventions. The challenge today is to demonstrate positive outcomes using non-pharmacological interventions and generate data for potential savings in dollars and lives.

CHAPTER III

Project Description

Project Implementation

The capstone project included a retrospective chart review on the antipsychotic drug use in the long-term care facility. Information from the executive summary of consultant pharmacists report on tracking psychoactive and hypnotic drug utilization was obtained. This report is compiled monthly and three consecutive months were used for needs data. The executive summary also used post project implementation to determine any changes in medication orders.

A Brief Interview of Mental Status (BIMS) is completed on every new admission into the nursing facility at five days, 15 days, at 30 days, and again at 90 days. BIMS is completed electronically on all residents and also by exception, when changes occur in behavior. The BIMS test is a 15 point measure of both memory and orientation (Chodosh et al., 2008). Data was collected at the beginning of the project from the BIMS on the above mentioned areas. Previous BIMS data provided a baseline to analyze any changes in the areas of cognition and mood after implementation of the training in Hand In Hand. Data was compared on all new admissions prior to training and within the 90 day period following staff training.

The Center for Medicare and Medicaid Services (CMS) (2013) has recently made available Hand In Hand training modules to all nursing homes to emphasize person-centered care and prevention of abuse in dementia persons (CMS, 2013). The Hand In Hand modules are focused on the principles of maintaining a process that includes the ability of the care giver to listen, test, reevaluate, change, and adapt their methods and

organization style to de-institutionalize the nursing home environment (CMS, 2013). Emphasis is placed being where the resident is, listening skills, redirecting behaviors, recognizing needs, and adapting the care to meet the resident's needs. The Hand In Hand was developed for primary caregiver training but CMS is suggesting that all personnel take part in the training. In this training, personnel within the facility that have interaction with residents with dementia received the training. Hand In Hand training sessions are divided into six one-hour sessions with DVD scenarios and a debrief session afterwards. Administration assigned staff during several two-hour sessions throughout the day to attend. Training took place over a two week period until all scheduled direct care staff completed a session. Self-evaluations were included in post training as part of the modules.

Data was collected on the residents' Brief Interview of Mental Status (BIMS) and executive pharmacy summaries for the following three months. Resident records including BIMS, pharmacy reviews were also evaluated before and after the training was completed. Statistical data was analyzed including demographics, cognitive status, and mood from the BIMS. The BIMS tool is considered to be a good tool for cognitive assessment and accurate in identifying impairments in cognition (Chodesh et al., 2008; Tucker, 2013). Pharmacy records were analyzed before and after for change in medication treatments.

Setting

The setting is in a long-term rehabilitation nursing center in the eastern United States. The facility is corporate owned and has approximately 130 Medicare and Medicaid funded beds and 20 private pay beds available. Long term stays and short term

rehabilitation services are delivered in the facility. It serves a community of approximately 270,000 people not including rural areas within close proximity.

Sample

The sample size for chart reviews was fifty (N=50) residents that were being treated with atypical antipsychotics or other sedative/hypnotic medications. The sample size did change at implementation of the capstone project, due to new admissions, discharges and mortality rates.

Project Design

Phase I

This project began with the chart review of data from the Brief Interview of Mental Status and pharmacy review records for baseline data. Implementations of the Hand In Hand training modules, in the nursing facility, were then scheduled. Stakeholders are residents, family members, staff, providers, and owners of the facility. The goal was to train 80% of staff including nursing, nursing assistants, administration, and ancillary staff. Six Hand In Hand training modules were conducted over a three day period at the beginning of October, 2013. Modules are self-contained with debriefing sessions and self-evaluation for the participants.

Administrative staff ensured all patient information was de-identified from the facility for the capstone project. A numerical code was implemented to represent each resident in the project. Brief Interview of Mental Status (BIMS) was used for data collection on cognitive and mood data, as well as, monthly Pharmacy Review Summaries used to analyze the atypical antipsychotic drugs given monthly.

Phase II: Data Collection and Analysis

Phase II was done post training, data from Brief Interview of Mental Status (BIMS) evaluations and pharmacy executive summaries were obtained at mid-January, 2014. Data was collected from the cognitive and mood elements of the BIMS. Pharmacy Review Summaries were collected from the previous three months, before training and for the three months post training. Statistical analysis using Statistical Package for the Social Sciences (SPSS) version 22 software was used to evaluate the data.

Phase III: Defense

Project findings were written for dissemination and an oral presentation given.

Protection of Human Subjects

All records of nursing facility, residents Brief Interview of Mental Status, and Pharmacy Reviews were de-identified and Institutional Review Board approval was obtained prior to implementation of the project.

Instruments

The Brief Interview of Mental Status (BIMS), Mood data tool, Pharmacy Review Summary and Hand In Hand training modules were used in the project data collection. The Centers for Medicare and Medicaid provide the BIMS and Mood tools, as part of the Minimum Data Set, for the nursing center to evaluate residents. This tool is done electronically and on the intranet within the facility. BIMS and Mood data was accessed and data retrieved using the facility system. Pharmacy reports are generated monthly by the pharmacists providing medications for the facility and distributed to facility

Administration. The administration staff provided copies of six months of Pharmacy Review Summaries for the project.

Data Analysis

Statistical Package for the Social Sciences (SPSS) version 22 analyzed the demographic, cognitive, and mood of each sample. Data was analyzed by descriptive statistics using the paired sample *t* test. A *p* value of $<.05$ was considered significant for all tests. Pharmacy review records from previous reviews and post training reviews were analyzed for average and variances.

Timeline

At the beginning of October, 2013, the most recent quarterly Brief Interview of Mental Status (BIMS) and Pharmacy Review Summaries were collected on the dementia patients in the nursing facility. Implementation of the Hand In Hand training modules began in October 2013. Post training BIMS and Pharmacy Review Summaries were collected. Data was then analyzed using SPSS. Please refer to Project Timeline in Figure 2.

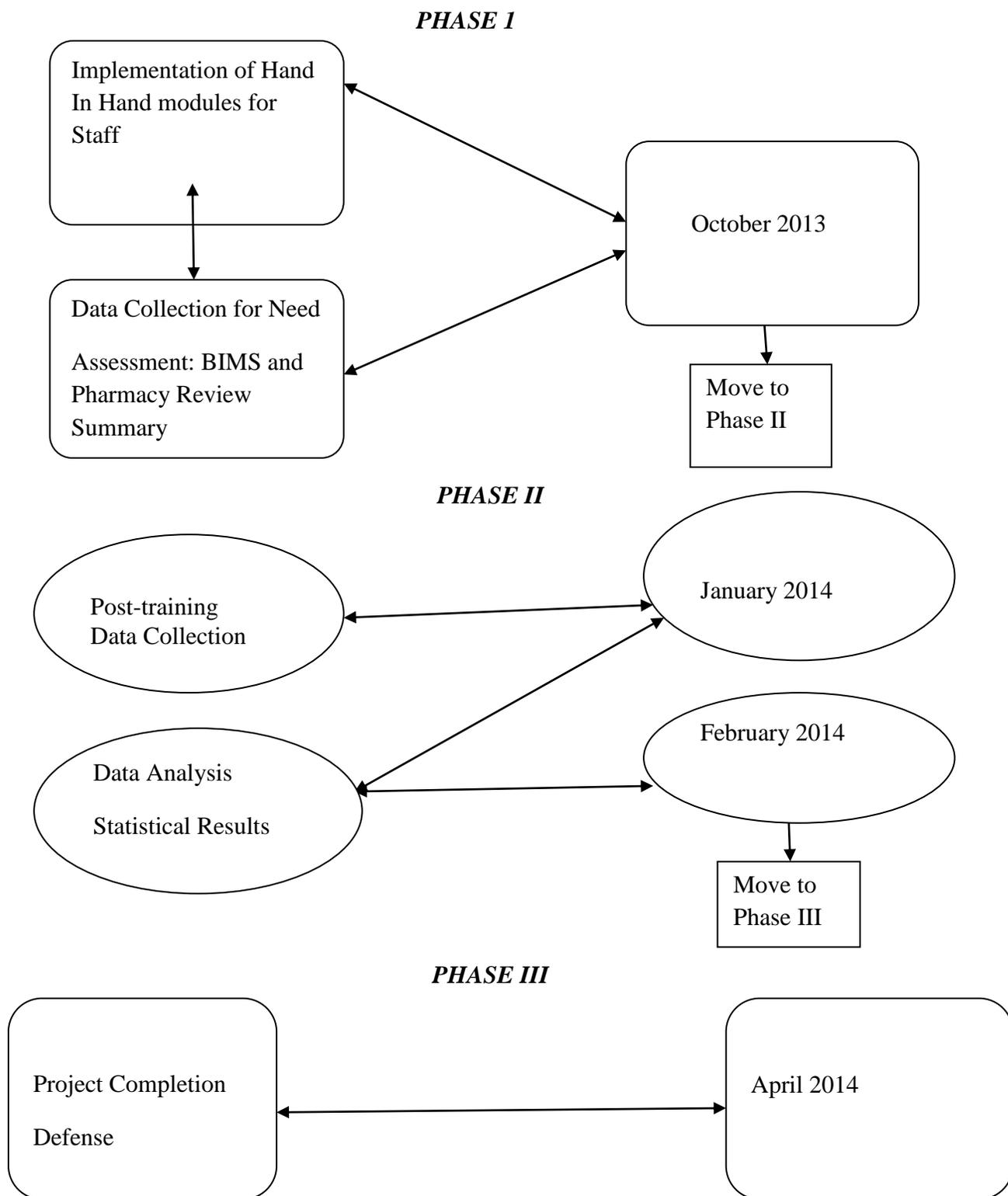


Figure 2. Timeline

Budget

The following were the costs for the project. Materials and supplies for the Hand In Hand training were available from the nursing facility. Costs for transportation to the facility were incurred; approximately \$40 for gas times the training and data collection was approximately \$200 dollars. Data collection is already in place through the nursing home Brief Interview of Mental Status (BIMS) and Pharmacy Review Summaries. Administrative staff were available to run reports. These are standard reports readily available at no additional costs. A statistician to analyze the data was available at no cost.

Limitations

Limitation of this capstone project included sample size of residents with dementia and the setting, one nursing home facility. Potential limitations can also be related to accuracy of BIMS data collection from the MDS, due to subjectivity of the MDS nurse. A time limitation was also a factor since residents records were analyzed for three months of data. The study would benefit from a larger sample size of dementia patients in multiple nursing facilities and a time frame of at least one year.

Summary

As costs continue to rise for health care across the United States and the population ages, new and innovative ways to manage care, increase quality, and contain costs will be essential for all people. Atypical antipsychotics have been shown to increase risks, increase costs, and lower the quality of life in the elderly with dementia. Non-pharmacological studies have shown some promise in the treatment of dementia. This project was intended to demonstrate that the non-pharmacological Hand In Hand training

might potentially modify behaviors and help to reduce the high risk atypical antipsychotic use for BPSD. The focus was to confirm the impact that the Hand In Hand intervention had on behavior and disseminate the results to medical staff for potential changes to medication regimens. In the future, these implications may help guide atypical antipsychotic medication reduction or provide direction for short term medication of atypical antipsychotics for dementia residents.

CHAPTER IV

Results

The Hand In Hand capstone project was designed to use a non-pharmacological training with long-term nursing staff to improve behavior and psychological symptoms in dementia (BPSD) residents. A pre and post chart review was done after training with the staff, to evaluate the Brief Interview of Mental Status (BIMS) and mood scoring on residents. Cognitive function and mood are determined in the BIMS tool. Pharmacy Review Summaries were also evaluated to determine changes related to antipsychotic medication orders. The descriptive statistics paired sample *t* test method was used to determine any changes in scores of the BIMS tool.

Measures

The Brief Interview of Mental Status (BIMS) measures cognitive patterns with a scoring range of 00-15. The score 99 or four or more 0's is given by the coder on the BIMS tool for any resident unable to complete the questions. Ranges for scores are graded on a scale of: 13-15 indicates cognitive intact function, 8-12 there is moderate impairment, and 0-7 indicates severe impairment. The Mood tool measures in two categories i.e. symptom presence and frequency. The tool scores each side. The "presence" side has a total of 0(no) or 1 (yes). The "frequency" score ranges from 0 to 3, depending on how many total days the symptoms occur. Together the scores add to a range from 00-27. The lower the score (00) indicates no problem with mood and the higher the total score the more indication of increased mood problems. Residents are asked the nine questions concerning depressed feelings, little interest, poor appetite, suicidal thoughts, sleep problems, loss of energy, bad feelings of self, problems with

concentration, and noticeable changes in movement or speech. These are scored on the frequency of occurrence. If the resident is unable or unwilling to respond to the questions they receive a 99 or a 4 zero's score on the Mood tool.

Sample

In total, only six (N=6) dementia residents from the Pharmacy Review Summary, on residents receiving mood-altering medications, met the inclusion criteria. Average age ranged from 81 to 94 years old, with one (N= 1) male and five (N=5) females.

Non-respondents

Fifty (N=50) charts were reviewed for mood altering medications, dementia diagnosis, and atypical antipsychotic medications. Of the charts reviewed, seven (N=7) residents were short-term rehabilitation and were discharged and three (N=3) dementia residents died during the project. The residents that did not meet criteria due to a depression diagnosis, although they received atypical antipsychotic medications, were a total of three (N=3). Five (N=5) residents with the dementia diagnosis were receiving sedative or hypnotics. Nineteen (N=19) did not meet criteria, either the dementia or atypical antipsychotic medication regime, for the project. There were two (N=2) residents receiving the medications for approved diagnosis of schizophrenia and one (N=1) had a psychosis that was receiving the atypical antipsychotic medications. One (N=1) resident was receiving atypical antipsychotic medication without any related diagnosis. There were two (N=2) residents who had dementia diagnosis and atypical antipsychotic medication but were unable to complete the Brief Interview of Mental Status (BIMS) or Mood tool. One (N=1) resident had pre BIMS and Mood but no post documentation. Please refer to Table 1.

Table 1

Chart Review of Targeted Sample

Charts reviewed	50
Discharged	7
Deaths	3
Depression Diagnosis	3
Sedative/Hypnotic Medications	5
Did not meet criteria	19
Approved diagnosis	3
No related diagnosis	1
Unable to complete tool	2
No documentation for Post results	1
Total cases utilized (N)	6

Pharmacy Review summaries were collected for three months prior to training and for three months post training. The number of residents receiving atypical antipsychotic medication was collected for three months prior to training and for three month post training. The numbers were then averaged for pre and post months.

The project goal for Hand In Hand training was 80% of facility staff. Training took place in the facility over three days and a total of 101 attended out of 175 employees, (57.7%) attendance. Direct care nursing staff attendance was 67, (66%) attendance. Other staff members attending made up the 34% of the Hand In Hand training classes. Please refer to Figure 3.

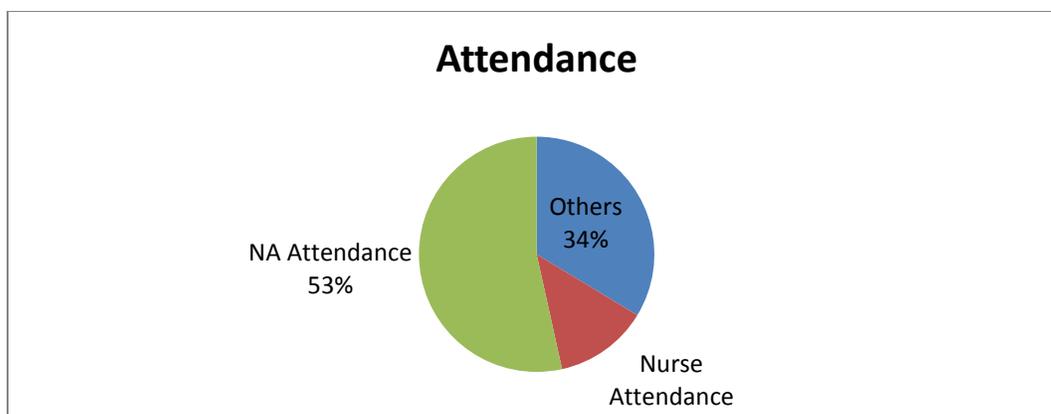


Figure 3. Hand In Hand Training Attendance by Staff

Descriptive Statistics

A retrospective chart review was used for pre and post Brief Interview of Mental Status (BIMS) and Mood scores for this project. A paired-samples *t*-test was conducted to compare the intervention of non-pharmacological Hand In Hand training, comparing the pre-BIMS and Mood scores and to the post training BIMS and Mood scores. There was a statistical significance between the scores for pre average BIMS ($M=7.438$, $SD=4.0975$) and post average BIMS score ($M = 4.750$, $SD = 2.3611$) scores; $t(5) = 3.064$, $p = .028$. The Mean scores may indicate a decrease in cognitive function level based on scoring criteria. The scoring criteria rates 13-15 as cognitive function intact, 8-12 as moderate impairment and 0-7 as severe impairment. The variance in pre and post Mean indicate a decrease in scoring. Please refer to Table 2.

Although the paired sample size was inadequate for this project, the Mood mean scores before and after interventions were calculated as Mean=2.50 and $M=.00$, $t(5) = 1.464$, $p=.203$. Mean scores for Mood is not in true value scores but denotes the

scoring mechanism of the tool, which is 00-27. The .00 not being statistical but indicating the variance between the pre and post Means. These results suggest that the Hand In Hand non-pharmacological training does not decrease the behavioral or psychological symptoms in the elderly dementia residents or mood.

Table 2.

Results of Pre and Post Average Brief Interview of Mental Status Scores

PreBIMS		PostBIMS	
(N)	6	(N)	6
Mean	7.483	Mean	4.750
SD	4.0975	SD	2.3611
<i>t</i> /df	(5)=3.064		
<i>p</i>	.028		

p<.05 for statistical significance

Major Findings

Due to the small sample size, these results suggest that the Hand In Hand non-pharmacological training does not decrease the behavioral or psychological symptoms in the elderly dementia residents or mood and cognitive function decreased during the post training. Similar results may not be reflective of a larger population sample.

The Pharmacy Review Summary report for pre-training intervention and post training scores were averaged for three months. Resident records reviewed for three months pre training (July, August, and September) were averaged and revealed that

15.866 residents received atypical antipsychotic medications. Post training records for 3 months (October, November, and December) revealed that 15.773 residents received the medications, a difference of .093. These results show very little change in the use of medications, but also do not show an increase in administration of atypical antipsychotic medications. Please refer to Table 3.

Table 3.

Pharmacy Review Summary Regarding Use of Atypical Antipsychotic Medications

<u>Pharmacy Review Summary</u>			
Pre-Pharmacy Record: (3 months) Number Receiving Atypical Antipsychotics Before Training	15.2	16.1	16.3
Post-Pharmacy Record: (3 months) Number Receiving Atypical Antipsychotics After Training	15	16.2	16
Record of Patients Reviewed			50

Summary

The retrospective chart review done on the project produced a small sample size for the project. The small sample did produce statistically significant results using the paired sample *t* test for the Brief Interview of Mental Status but not the Mood scores. Pharmacy Review Summary revealed very little difference in atypical antipsychotic medication administration for dementia residents. However, there was no increase in the medication administration to the dementia residents post training intervention.

CHAPTER V

Discussion

The capstone project was to determine relationship of the Hand In Hand intervention to a decrease of behavior and psychological symptoms of dementia resident in long-term care. Training was implemented in a long-term care facility with direct care staff and pre and post data was collected on the Brief Interview of Mental Status (BIMS) and Mood tools from the Minimum Data Sets (MDS). Descriptive statistical data was done using the paired sample t tests on the BIMS and Mood data. Pharmacy Review Summaries were also collected and averaged for pre and post training to determine any changes in atypical antipsychotic medication administration.

Implication of Findings

Can non-pharmacological intervention training of direct care staff decrease behavior and psychological symptoms in elderly dementia residents and potentially demonstrate a need for reduction in atypical antipsychotic medication use?

The project results did show some difference in the mean of pre Brief Interview of Mental Status (BIMS) and Mood scores when compared to post scoring. The BIMS mean scores went down, indicating a decrease in the residents cognitive function level. The Mood mean scores also went down, although paired sample size was inadequate, and might be a possible indication of improved mood in the elderly dementia residents. One finding that was small but important was that the administration of atypical antipsychotic medications did not increase from the three months pre training and the three months post training, based on the Pharmacy Review Summaries. This is important in the initiative to monitor and decrease the use of these drugs, (Kohen, et al., 2010; Lindsey, 2009).

The findings also mirror another project with non-pharmacological treatments; the lack of rigorous scientific design (O'Neil et al., 2011). The project did not have a random control design to produce empirical data. Training tools and evaluation tools from Centers for Medicare and Medicaid Services (CMS), which did not produce a cost factor, is an area missing in the literature on non-pharmacological treatments. Due to these tools being indicated for use by CMS, this project did not add to the literature on costs.

Application to Theoretical/Conceptual Framework

The findings were congruent with the primary, secondary, and tertiary model phases of Neuman's Care Systems Model (Neuman Systems Model, 2013). The primary prevention was on health promotion and the ability of direct care staff to recognize the stressors that might trigger behavior and psychological symptoms in dementia residents. The Hand In Hand training aided in the secondary line of prevention with a non-pharmacological intervention to help the resident react to internal and external stressors. As the non-pharmacological interventions were implemented and reinforced by staff, the tertiary prevention level was executed to help the resident adapt to change and return to a wellness state. Betty Neuman's Care System Theory was an appropriate framework for the interventions utilized to help the residents manage stress, communicate effectively and use other methods to help the resident adapt to changes in their environment and maintain equilibrium.

Limitations

The findings of this project were impacted by the small sample size and limitation of one nursing home. Availability of training time and staff numbers for training also influenced the time for data collection. Unexpected administrative turnover in key areas

related to education and data collection, delayed training and collection of data.

Additional projects with larger sample size, multiple nursing facilities, dementia units, and various data collection methods may produce statistically significant outcomes for non-pharmacological interventions in dementia.

Another area for consideration is the development of tools for evaluating symptoms that capture the data thoroughly, succinctly, and in multiple formats.

Documented on one Mood tool, the nurse had noted that the resident stated “I can’t hear you! Oh just forget it”. This score then became a 99 because the resident refused to complete the questions. When working with the elderly, nurses need to consider all the sensory deficits and design a universal tool to use that works for alternative communication needs.

Implications for Nursing

The results of this project have significance to nursing for improvement in the person-centered care of the elderly dementia resident. Results have shown a need to explore ways to improve the behavior and psychological symptoms in dementia (BPSD) through non-pharmacological treatments using educational tools to help direct care staff. The findings support the need for non-pharmacological intervention projects designed as rigorous scientific methods to capture empirical data. If a transition to a non-pharmacological treatment of BPSD is to be achieved, then new protocols and modalities of treatment need to be developed and supported by empirical evidence.

Recommendations

Additional projects and studies using the implementation of Hand In Hand training for direct care staff, on dementia units in multiple facilities, would be helpful in

adding to the statistical data. The need to extend the time frame for the study should help to produce more significant data. Development of diverse tools for sensory deficits and random controlled design could support the need for increased usage of non-pharmacological interventions in dementia care.

Conclusion

This project was done to show a correlation between the non-pharmacological intervention Hand In Hand training and behaviors and psychological symptoms in elderly dementia residents. The training was completed with 66% of direct care staff within the long term nursing center. Collection of Brief Interview of Mental Status (BIMS) and Mood data from the Minimum Data Sets were collected pre and post training and descriptive statistics were used to analyze the data. Although statistical significance was shown on the paired sample *t* test with the BIMS score, there was a decrease on the Mean scores for pre and post scores which may denote a decline in cognitive function based on the variance between Mean and the tools scoring criteria. This decrease in Mean mood scores indicated a possible improvement after the training. More rigorous and empirical testing is warranted to support conclusive results. However, the Pharmacy Review Summaries did not show any increase in prescriptions for atypical antipsychotic treatment for the dementia residents. The findings may indicate that direct care staff used the non-pharmacological training in the daily care of the elderly dementia resident and that conservative prescribing of atypical antipsychotic medications are also part of the equation. This project adds to the essential need for more projects and studies in the non-pharmacological treatment of behavior and psychological symptoms of dementia in elderly residents.

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Appendix A

OIG Statistics on Off Label Atypical Antipsychotics Claims

Generic Name of Drug	Claims	Dollar Amount
Quetiapine	627,661	\$85,847,131
Risperidone	536,600	\$87,161,507
Olanzapine	356,695	\$94,055,067
Aripiprazole	83,756	\$29,565,887
Ziprasidone	44,681	\$10,067,477
Clozapine	27,294	\$1,691,718
Olanzapine/Fluoxetine	1,521	\$431,799
Paliperidone	666	\$207,731
Total	Claims	Costs
	1,678,874	\$309,028,317

Source: (OIG Report, 2011)

Appendix B

Claims for Medicare of Atypical Antipsychotics (Number/Percentage)

Claim for drug indication	Number	Percentage
For off-label conditions	1,197,442	83.1%
In condition presence specific to FDA box warning	1,263,641	87.7%
Off-label conditions and with FDA warning	1,088,260	75.5%
Off-label conditions and/or specific FDA warnings	1,372,823	95.3%
Neither off-label or specific FDA box warning conditions present	68,277	4.7%
Total (net)	1,441,100*	100%
Records that were not reviewed	237,744	n/a
Total Claims	1,678,874	n/a

Source: (OIG Report, 2011)

*Projection is based on reviewed records only and do not reflect size of population in Appendix A

Appendix C

Invalid Medicare Claims

Error Reasons	Number	Percentages	Dollar Amount
Drug claimed was not documented*	3,808	0.3%	\$559,333
Drug claimed was not for medically accepted use	722,975	50.2%	\$115,919,685
Total errors	726,783	50.5%	\$116,479,018

Source: (OIG Report, 2011)

*Undocumented claims for table completion. Three were undocumented which was too low for 95% confidence interval statistically.

Appendix D

Unnecessary Medical Claims by CMS Standards

Reasons for not meeting CMS Standards	Number	Percentage	Dollar Amount
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Excessive dosage	150,106	10.4%	\$36,050,851
Excessive time	135,199	9.4%	\$29,369,213
No adequate indicator for use	115,818	8.0%	\$21,396,226
No adequate monitoring	110,949	7.7%	\$18,150,616
Adverse effects present requiring a lower or termination of drug	67,923	4.7%	\$11,479,869

Total (gross*)	579,994	40.2%	\$116,446,775
Overlapping	262,023	18.2%	\$53,251,792
Total (net)	317,971	22.1%	\$63,194,984

Source: (OIG Report, 2011)

*Sums not exact due to rounding of numbers