COMPARISON OF VITAMIN D_3 (CHOLECALCIFEROL) AND VITAMIN D_2 (ERGOCALCIFEROL) ON FALL REDUCTION IN NURSING HOME RESIDENTS

by

My Linh Waldrop

A doctoral scholarly project submitted to the faculty of
The University of North Carolina at Charlotte
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Approved by:

____
Meredith Troutman-Jordan, PhD, PMHCNS
Chair
School of Nursing

____
Boyd Davis, PhD
Department of English

____
Elizabeth Scism, DNP, MSN, FNP-C
Optum CarePlus

____
Maureen Brown, PhD
Department of Political Science and Public Administration

ABSTRACT

MY LINH WALDROP. Comparison of vitamin D_3 (cholecalciferol) and vitamin D_2 (ergocalciferol) on fall reduction in nursing home residents.
(Under the direction of DR. MEREDITH TROUTMAN-JORDAN)

Vitamin D has been proven to reduce fall rates by 15%-20% for nursing home residents. However, vitamin D is still not considered a standard for fall prevention due to vitamin D type and dosage not having been established in the literature. The purpose of this project is to retrospectively examine the relationship between vitamin D_3 50,000 units and vitamin D_2 50,000 units and falls occurring in the nursing home setting over a six-month period. Data were collected from April 2014 to September 2014 from two nursing homes in North Carolina. Total of 70 residents met the inclusion/exclusion criteria. Fall rates were 4 of 35 (11%) for vitamin D_3 and 7 of 35 (20%) for vitamin D_2. This slight difference was not statistically significant (x^2=0.43, p=0.511, df=1). The fall rate vitamin D level of <30 was 2 of 12 (17%) and 2 of 14 (14%) for >31. This slight difference was not statistically significant (p=1.00). There were no fractures or emergency department visits related to falls over this six-month period. Even though the project did not finding statistically significant differences between vitamin D_3 and vitamin D_2 and fall rates, the rate of falls decreased significantly after vitamin D was initiated for these two nursing homes. Vitamin D supplementation should be incorporated into practice for patients in the nursing home, especially for those residents with high risks for falling. Initiating patients on a vitamin D regimen can lead to a decrease in healthcare costs related to fall morbidity and mortality.

ACKNOWLEDGMENTS

I would like to thank my chair, Meredith Troutman-Jordan for her dedication and assistance throughout this project. Also, I would like to thank my committee members, Dr. Maureen Brown, Dr. Boyd Davis and Dr. Elizabeth Scism, for helping me stay on course.

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CHAPTER 1: INTRODUCTION

Fall-related injuries are a major health concern for nursing home residents. One out of two will have a fall during his/her stay in the nursing home (Kalyani, 2010). In 2009, there were 2.4 million older adults reported of having non-fatal fall injuries and more than 662,000 requiring hospitalization (CDC, 2012). The CDC in 2012 projected that the health care costs related to falls were expected to rise due to increasing numbers of seniors living in nursing homes. In 2011, there were 1,703,486 seniors living in nursing homes with a projected increase to 3 million by 2030 (CDC, 2012). The immediate direct average cost per fall is between $9,113 and $13,507. Even more costly are patients who are 72 years of age or older, whose typical health care cost average $19,400 per fall, not including doctor service fees (CDC, 2012). The estimated annual cost of fall-related injuries will rise to $54.9 billion by the year 2020 (CDC, 2012). Aside from the financial costs, fall-related injuries greatly impact nursing home residents by causing disability, functional decline, reduced quality of life, and increased morbidity and mortality.

Nursing home residents have multiple known risk factors that lead to falls, such as advancing age, hazardous environment, medications and chronic disease states (Kalyani, 2010). Nonetheless, falls are typically caused by abnormalities in muscle strength, gait, and balance. Certain risk factors pose more risk for future falls, including low vitamin D levels that can cause impairment in muscle function. Nursing home residents have the highest risk for low levels of vitamin D because they have little or no sun exposure, lack in dietary intake, and lower cutaneous synthesis of vitamin D (Kalyani, 2010). Low levels of vitamin D in nursing home residents are evident in data from the HMO health insurance company. The company recommends all enrollees be put on vitamin D_3 50,000 units monthly for fall prevention.

However, in 2012, the CDC reported that vitamin D as an intervention for falls is still controversial. This could be due to the fact that the most effective type of vitamin D and dose in fall reduction have yet to be established in literature (Bischoff-Ferrari, 2004; Kalyani, 2010). There is a lack of studies looking specifically at 50,000 units of vitamin D_3 and 50,000 units vitamin D_2 administered monthly in relation to fall reduction.

Problem Statement

Over a decade of research has yielded rich evidence to support vitamin D therapy in fall reduction for residents in the nursing home setting. Vitamin D therapy is inexpensive, safe and well tolerated. However, the dose, type and frequency vary from one nursing home to another. Therefore, a standardized intervention that is inexpensive, well tolerated, and effective is necessary to reduce the number of fall incidents and thus lower healthcare costs. This project aims to reduce controversies on vitamin D as an independent factor and to help establish a basis of knowledge on effective dose and type of vitamin D to reduce falls for nursing home residents.

Purpose

The purpose of this project is to examine the relationship between vitamin D_3 and vitamin D_2 and falls occurring in the nursing home setting.

Clinical Question

In nursing home residents, what is the relationship between 50, 000 units of vitamin D_3 administered monthly, compared to 50,000 units of vitamin D_2 administered monthly and the occurrence of falls over a 6 month time period?

Project Hypothesis

Residents on vitamin D_3 will have less falls and a higher 25(OH)D concentration than those on vitamin D_2.

Project Objectives

The short-term objectives are to reduce falls by 15%-20% within 6 months, reduce ED visits for falls with injuries, and improve 25(OH) levels within 6 months. The long-term objectives are to standardize the vitamin D supplement for nursing home residents, reduce hip fracture incidences by 4%-5% annually, and reduce healthcare cost and improve resident quality of life.

CHAPTER 2: LITERATURE REVIEW

Numerous evidences in the literature not only support vitamin D supplement for osteoporosis prevention but also for fall reduction in nursing home residents by 14-22%. More specifically, fall reduction from muscle strength improvement with vitamin D therapy has been widely supported by numerous studies. A meta-analysis with 1,237 participants in 5 randomized controlled-trials (RCTs) has shown that vitamin D improves muscle strength and postural stability, which leads to fall reduction by 22% (pooled corrected OR, 0.78%; 95% CI, 0.64-0.92) (Bischoff-Ferrari, 2004). Another larger meta-analysis, consisting of 10 RTCs with 2,932 participants, showed that adequate vitamin D improved muscle strength and function and reduced falls by 14% (RR=0.86, 95% CI, 0.79-0.93) (Kalyani, 2010). Kalyani's meta-analysis of 10 RTCs, including 5 from Bishchoff-Ferrari et al, showed statistical significance for fall reduction with the vitamin D group versus calcium alone or placebo (Kalyani, 2010). In addition, RCTs done by Bischoff (2003) and Pfeifer (2000) showed vitamin D improved body sway and secondary hyperparathyroidism while also reducing fractures by 8 to 12 weeks on therapy. Flicker et al (2003) found a positive relationship between vitamin D levels and cognitive functioning, which may influence the risk of falls and fracture.

Furthermore, most of these RCTs have made assumptions that cholecalciferol, vitamin D_3, and ergocaleciferol, vitamin D_2, are equally effective and therefore used them interchangeably in studies. Serum 25 hydroxyvitamin D (25(OH)D) is used to monitor participants vitamin D status (Holick, 2007). The vitamin D status, or 25(OH)D levels, were not examined in most of these studies, resulting in vitamin D_3 being more favorable than vitamin D_2 without statistical significance in Kalyani et al with (RR 0.89, CI 95%, 0.80-1.00, P=0.34) (Kalyani, 2010). In addition, Jackson et al (2007) stated it would be helpful to analyze the effect of vitamin D_3 therapy on the difference in serum 25(OH)D levels and how these levels relate to risk of falls and fractures. Investigators in fall reduction studies have used either vitamin D_3 or vitamin D_2 for comparison to calcium alone or to a placebo. Additionally, most of the studies fail to measure serum 25(OH)D before and after treatment for comparison.

Vitamin D_3 is derived from sun exposure and fish consumption while vitamin D_2 is derived from plants through ultraviolet exposure (Zarowitz, 2008). There were a few studies that looked at vitamin D_3 compared to vitamin D_2 using serum 25(OH)D concentration as an indicator of vitamin D status. One study concluded that vitamin D_3 has higher bioactivity, longer duration of action, and 33% more potency than vitamin D_2 (Tjellesen, 1986). Armas, et al (2004) further assessed that 50,000 units of vitamin D_2 is equivalent to 15,000 units of vitamin D_3 from a longitudinal evaluation over 28 days using 25(OH)D concentration following a single dose of vitamin D_3 or D_2. This study demonstrated that initially serum 25(OH)D concentrations were similar, but after the third day vitamin D_2 serum 25(OH)D concentration declined rapidly compared to vitamin D_3 (Armas, 2004). Armas' study is consistent with an earlier study done by Tjellesen, et al. Both concluded that vitamin D_3 is superior to vitamin D_2 in potency, duration and bioactivity. This is further evident in the reformulation of Citracal, a well known oral calcium and vitamin D supplement, with vitamin D_3 instead of vitamin D_2 (Zarowitz, 2008).

The current established reference for serum 25(OH)D is 20-100ng/ml (Holick, 2007). Vitamin D levels are defined as 25(OH)D <20ng/ml being deficient and >150 ng/ml being toxic. The level <20ng/ml results in secondary hyperparathyroidism, which leads to rapid bone turn over and reduced bone density (McKenna, 1998). A prospective cohort descriptive study in a fall clinic population suggested that serum 25(OH)D should be >40 ng/ml in order to see non-vertebral fractures reduced (Dhesi, 2002). In addition, low serum concentration of vitamin D has been associated with increased hip fractures based on a nested case-control study (Cauley, 2008). The vitamin D dose >800 IU daily has been recommended and anything less than that has not been shown to be effective in fall reduction (Bischoff-Ferrari, 2004; Kalyani, 2010). Although there is lack of consensus on 25(OH)D levels, most experts agree that optimal benefits for 25(OH)D levels ranges from 30ng/ml to 60ng/ml (Holick, 2007).

Vitamin D is well tolerated, safe, and has minimal risks when taken orally. Intoxication is rare but can occur when taken at excessively high doses. There have been a few reported cases of Vitamin D intoxication. For example, an accidental administration of 2.4 million IU vitamin D daily times 4 days to a 2 year-old boy caused hypercalcemia and hypertension (Barrueto, 2005). Another intoxication case described the inadvertent or intentional mixing of crystalline vitamin D_3 into table sugar by a family with intake of 1,680,000 IU daily for several months (Vieth, 2002). Signs of intoxication include but are not limited to pain, conjunctivitis, anorexia, fever, chills, thirst, vomiting, and weight loss (Hathcock, 2007). Intoxication can occur when serum 25(OH)D measures >150ng/ml, which requires at least 50,000 IU of vitamin D administered daily (Dhesi, 2002; Holick, 2007). The lack of adverse effects in clinical trials makes vitamin D therapy generally safe and well tolerated. Therefore it can be used with confidence.

Theoretical Framework

The Academic Center for Evidence-based Practice (ACE) Star Model of Knowledge Transformation, developed by Stevens in 2004, will be used as a guide in this DNP scholarly project. The ACE Star model is set up to bridge research and practice with the main goal of achieving best outcomes and improving care and patient safety. This model fits well with the current project because it has similar goals and purposes. The ACE Star model is listed in Appendix A.

The ACE Star model consists of five major stages of knowledge transformation. The first, discovery, is the stage in which the clinician discovers the health problem using PICOT format inquiry. The second stage, summary, involves critical appraisal of the evidence and formulation of a synthesis table to generate meaningful evidence to translate. The third stage, translation, summarizes evidence generated to help providers and facilities to establish standards for therapy. The fourth stage, integration, combines information to change the practice at the facility and organizational practices through formal and informal methods. The last stage, evaluation, is where the evaluation of evidence-based practice (EBP) on patient outcomes, provider and patient satisfaction, efficacy, efficiency, economic analysis, and health status impact occurs.

In summary, the process of this project includes the use of current research evidence to help summarize, translate, integrate and evaluate the current practice's effectiveness in promoting health and improving outcome and safety. The process is congruent with the five stages of the ACE Star model and will be used to guide this project.

CHAPTER 3: METHODOLOGY

A retrospective cohort design collected data from patients' charts from April 2014 to September 2014 in two nursing homes in North Carolina. In preparation for the data collection, an in-service training was provided to the medical director, pharmacists, administrators, directors of nursing (DON) and nurses over a course of one month to familiarize them with the study. This ensured participants were on the correct vitamin D as ordered and satisfied the data collection requirements. Following the initial in-service, a series of meetings with the DON, administrator and staff were held to review the project process and ensure administration of the appropriate vitamin D. The meetings also allowed the opportunity for staff to ask questions and assess for potential issues to the DNP project. It is imperative for staff to fill out the incident report provided by the facility for all falls that meet the definition of a fall. A fall is defined as "an unintentional coming to rest on lower ground, floor or lower level" (Bischoff et al, 2003).

The organization strategic plan was addressed in the initial in-service. The facility's goals are to reduce falls and fall-related injuries for all residents. A Balanced Scorecard was presented to the senior clinical staff at the facility to ensure buy-in. The project objectives were congruent with facility's mission and values. To ensure fidelity of the project implementation, a written protocol was implemented to ensure all current and new residents are on vitamin D therapy. "Vitamin D day" is set on the 15^{th} day of the month to ensure consistency of timing for all residents. Annual levels of 25(OH)D were ordered and vitamin D titrated according to the current guideline.

Participants

The inclusion criteria were residents over 60 years of age, living in a nursing home, on either vitamin D_3 50,000 units monthly or vitamin D_2 50,000 units monthly, and not bed-bound. Residents of age less than 60, residents not on vitamin D_3 50,000 units or vitamin D_2 50,000 units monthly, residents with hyperpituitarism, not living in a nursing home, and bed-bound patients were excluded from the study due to having a lower risk for falls. The age range was from 61 to 99 and the average was 82 years old with 26 male and 44 female. Seventy participants met the inclusion and exclusion criteria for this project. There were 27 participants having more than three comorbidities and 17 participants on both pain and antipsychotic medications. Only 30 out of 70 participants had 25(OH)D levels available on record.

Setting

Two nursing homes with 120 beds in North Carolina will be used. All nursing homes were for-profit facilities. The nursing homes are located in urban areas and have approximately 90-100 residents living in each nursing home during the data collection period. On the average, there were approximately 30-35 falls per month per facility, which is about a 30%-35% fall rate per facility.

Instruments

The investigator collected data using a Microsoft Excel spreadsheet to record “1” for fall(s) and “0” for no fall over the course of the last 6 month period. The secondary endpoint was fractures. The investigator was to record “1” for fracture(s) or “0” for no fracture over the last 6 month period. Other health-related information such as age, gender, ethnicity, medications, and comorbidities were extracted from the residents' electronic health records for demographic characteristics and confounder factors.

Ethical Considerations

The institutional review board of the University of North Carolina at Charlotte has approved the project. The data was coded so all participants remained unidentifiable.

Data Analysis

Data was recorded in Excel and imported into SPSS for analysis. Results with p values <0.05 were considered statistically significant. Alpha was set at 0.05. The data was coded at a nominal level. Yates' chi-squared test was used to compare fall rates between vitamin D_3 and vitamin D_2 for nominal data with two treatment groups. Fisher's exact test was used to detect association between 25(OH)D and fall rates. Logistic regression was conducted to determine the input of age, comorbidities, and medications on the likelihood of having a fall.

CHAPTER 4: RESULTS

The fall rate was stratified by the type of vitamin D (vitamin D_3 and vitamin D_2). Fall rates were 4 of 35 (11%) and 7 of 35 (20%) respectively. This slight difference was not statistically significant (x^2=0.43, *p*=0.511, df=1). Results are shown on table 1. The fall rates associated with the level 25(OH)D (<30 and >31) were 2 of 12 (17%) and 2 of 14 (14%), respectively. This slight difference was not statistically significant (*P*=1.00). Results are shown on table 2. Forty participants were missing 25(OH)D levels on their charts. There were no fractures or emergency department visits related to falls over the six-month period for residents on either vitamin D3 50,000 units or vitamin D_2 50,000 units monthly. Logistic regression was conducted to determine the impact of age, comorbidities and medications on fall rates. Regression results indicated that age, comorbidities and medications were relatively weak predictors of fall rates (-2log likelihood=54.676, Nagelkerke R^2=0.146, Cox and Snell R^2 0.085, Hosmer and Lemeshow test = 0.804. The model correctly classified 84.3% of the cases. The odds ratio for falls was significant when age was greater than 81 years (*P*=0.044, 95% CI 0.028-0.951). Regression coefficients are presented in table 3.

Discussion

Nursing home residents have a low concentration of vitamin D due to lack of sunlight exposure, lack in dietary intake and decreased skin synthesis. Even with a vitamin D supplement some participants still had low vitamin D levels. Low vitamin D levels are associated with high levels of parathyroid hormone, causing excessive bone remodeling, decrease in muscle strength and response time, which increase the risk of falls and fractures (Flicker et al, 2003). Even though the project did not find statistical significance between vitamin D_3 50,000 units and vitamin D_2 50,000 units and fall rates, the rate of falls decreased significantly after vitamin D was initiated for these two nursing homes. On the average, the fall rate over six months was approximately 15.5% for residents who are either on vitamin D_3 50,000 units monthly or vitamin D_2 50,000 units monthly. Overall, there was a 15% fall reduction after vitamin D therapy initiation. This is in line with previous results of studies from Bischoff (2004), Jackson et al. (2007), and Kalyani's (2010) systematic review and meta-analysis. Fortunately, there were no fractures or ED visits associated with falls reported. This supports current evidence that vitamin D therapy decreases fractures and ED visits.

The confounding factors such as age, comorbidities and medications were controlled using logistic regression and showed as a weak predictor for falls. Only age greater than 81 years has a stronger predictor compared to comorbidities and medications. For this project, the sex, comorbidities and medications did not have high predictive value for fall rates.

There are limitations to this project. First, the project had a small sample because of time limitations and lack of resources to have adequate power, which may have contributed to the non-statistical significance to the outcome reported. Second, there were 40 missing 25(OH) levels from the charts. Additionally, the time of the 25(OH) levels drawn was different for each participant. Lacks of staffing and high staffing turn over were also noted during the time of data collections. This could translate to higher fall rates. This initial project requires confirmation with a larger sample and better compliance with vitamin D levels drawn.

CHAPTER 5: IMPLICATIONS

Overall, vitamin D supplements are an effective intervention for fall reduction in nursing home residents. The vitamin D type and effective dosing for fall reduction are still yet to be determined. However, vitamin D supplements should be incorporated into practice for those providers who are caring for patients in the nursing home, especially for those residents with a high risk for falling. Since vitamin D is inexpensive and well tolerated, decreasing falls by putting patients on vitamin D supplements could lead to decreased healthcare costs related to fall morbidity and mortality.

Summary

In summary, vitamin D was shown as beneficial to nursing home residents for fall reductions, decreased fractures and hospital visits congruent with previous studies. The vitamin D dose and type are yet to be standardized. More studies with a larger sample size are needed in determining the best type of vitamin D and dose for nursing home residents.

Table 1: Yates's chi-squared test

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.971[a]	1	.324		
Continuity Correction[b]	.431	1	.511		
Likelihood Ratio	.981	1	.322		
Fisher's Exact Test				.513	.256
Linear-by-Linear Association	.957	1	.328		
N of Valid Cases	70				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 5.50.

Table 2: Fisher's exact test

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.021[a]	1	.886		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.021	1	.886		
Fisher's Exact Test				1.000	.648
Linear-by-Linear Association	.020	1	.888		
N of Valid Cases	30				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 1.87.

Table 3: Regression coefficients

Variables in the Equation

		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
								Lower	Upper
Step 1[a]	Medications(1)	-1.313	.806	2.654	1	.103	.269	.055	1.306
	Comorbidities (1)	.290	.721	.161	1	.688	1.336	.325	5.491
	Age(1)	-1.817	.902	4.062	1	.044	.163	.028	.951
	Constant	-.352	.819	.184	1	.668	.703		

a. Variable(s) entered on step 1: Medications, Comorbidities, Age.

Table 4: Levels of evidence synthesis table

X (copy symbol as needed)	1	2	3	4	5	6	7	8	9	10	11	12	13
Level I: Systematic review or meta-analysis	x	x	x	x	x								
Level II: Randomized controlled trial						x							
Level III: Controlled trial without randomization							x						
Level IV: Case-control or cohort study								x	x				
Level V: Systematic review of qualitative or descriptive studies													
Level VI: Qualitative or descriptive study (includes evidence implementation projects)										x			
Level VII: Expert opinion or consensus											x	x	x

1= Jackson C., et al (2007); 2=Gaugris, S., et al (2005); 3= Kalyani, R., et al (2010); 4=Bischoff-Ferrari, H., et al (2004); 5= Rejnmark, L. (2011); 6= Bischoff. H., et al (2003); 7= Laura A., et al (2006); 8=Cauley, J., et al (2008); 9= Doorn, C., et al (2003); 10=Dhesi, J., et al (2002); 11=Krulish, L., et al (2008); 12=Mcinnes, L., et al (2005); 13=Zarowitz, B. (2008)

Table 5: Outcome synthesis table

Outcomes Synthesis Table

↑↓—(select symbol and copy as needed)	1	2	3	4	5	6	7	8	9	10	11	12	13
Falls	↓ AB	–	↓ AB	↓ AB	↓ C ,	↓ AB	-	–	↑ B	↑ B	↑ C	↓ C	-
Fall with fractures	↓ AB	–	–	–	—	–	-	↑ B	–	–	–	–	-
Favor Vit. D3 over D2	✔	–	✔C	–	✔	–	✔	–	–	–	–	✔	✔
Cognitive Function	–	–	–	–	–	–	-	–	↓ B	–	–	–	-
Muscle strength	–	–	–	↑ AB	↑	↑ AB	-	–	–	–	–	↑ C	-
25(OH)D	–c	↓ AB	–	–	↑	↑	↑ B	↓	–	↓ B	–	–	-

1= Jackson C., et al (2007); 2=Gaugris, S., et al (2005); 3= Kalyani, R., et al (2010); 4=Bischoff-Ferrari, H., et al (2004); 5= Rejnmark, L. (2011); 6= Bischoff. H., et al (2003); 7= Laura A., et al (2006); 8=Cauley, J., et al (2008); 9= Doorn, C., et al (2003); 10=Dhesi, J., et al (2002); 11=Krulish, L., et al (2008); 12=Mcinnes, L., et al (2005); 13= Zarowitz, B. (2008)

A. Higher-level evidence B. Statistically significant finding C. Statistical significant not reported D. No falls reduction – Did not measure

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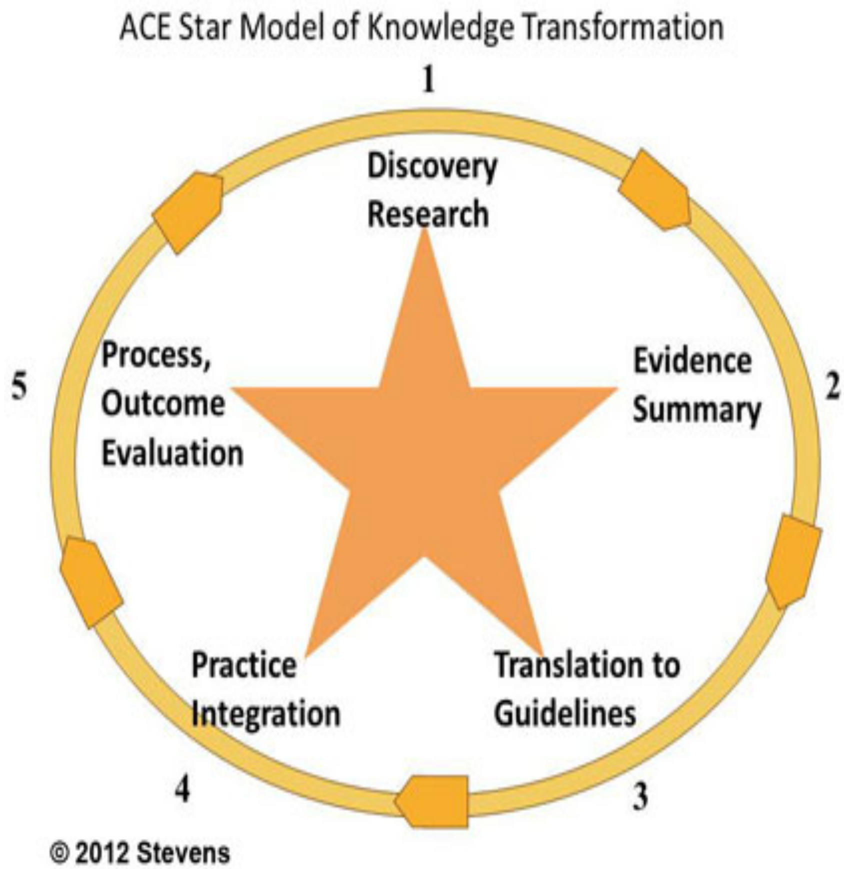
APPENDIX A: THEORETICAL FRAMEWORK



APPENDIX B: IRB LETTER OF APPROVAL

UNC CHARLOTTE

Research and Economic Development
Office of Research Compliance
9201 University City Blvd, Charlotte, NC 28223-0001
t/ 704.687.1876 f/ 704.687.0980 http://research.uncc.edu/compliance-ethics

Institutional Review Board (IRB) for Research with Human Subjects

Certificate of Approval

Protocol #	**14-05-08**		
Protocol Type:	**Expedited**	5	
Title:	**Comparison of Vitamin D3 (Cholecalciferol) and Vitamin D2 (Ergocalcifero) on Fall Reduction in Nursing Home Residents**		
Initial Approval:	**7/29/2014**		
Responsible Faculty	**Dr. Meredith**	**Troutman-Jordan**	**School of Nursing**
Investigator	**Ms. My Linh**	**Waldrop**	**School of Nursing**

After careful review, the protocol listed above was approved by the Institutional Review Board (IRB) for Research with Human Subjects under 45 CFR 46.111. This approval will expire one year from the date of this letter. In order to continue conducting research under this protocol after one year, the "Annual Protocol Renewal Form" must be submitted to the IRB. This form can be obtained from the Office of Research Compliance web page http://research.uncc.edu/compliance-ethics/human-subjects.

Please note that it is the investigator's responsibility to promptly inform the committee of any changes in the proposed research prior to implementing the changes, and of any adverse events or unanticipated risks to subjects or others.

Amendment and Event Reporting forms are available on our web page at: http://research.uncc.edu/compliance-ethics/human-subjects/amending-your-protocol.

M. Ly [signature] 8/5/14
Dr. M. Lyn Exum, IRB Chair Date