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**Relationships Among Quality of Life, Self-Care, and Affiliated
Individuation in Persons on Chronic Warfarin Therapy**

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**Relationships Among Quality of Life, Self-Care, and Affiliated
Individuation in Persons on Chronic Warfarin Therapy**

by

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Dedication

This work is dedicated to my grandmothers, Carol Bernice Johnson Marrs and Frances Ernestine Walters Starling. You are two of the most influential women in my life. My Grandmother Marrs awakened the nurse inside me, helping me to realize nursing is a passion and calling, not just a job. She told me to always remember to do something good with my life and love doing it, or it would all be for nothing. My Grandmother “Gran Gran” Starling taught me what determination and hard work can do. She accomplished so much in her life as a business woman and single mother, succeeding in a man’s world in a time when that was hard to do and frowned upon. She is a role model for me, especially when I was beginning my adult life.

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Relationships Among Quality of Life, Self-Care, and Affiliated Individuation in Persons on Chronic Warfarin Therapy

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This descriptive, correlational, cross-sectional study explored the relationships among the variables self-care action, self-care knowledge, and affiliated individuation and quality of life for persons on chronic warfarin therapy. This study also explored the moderating effects of self-care knowledge and affiliated individuation on quality of life.

This research was guided by a theoretical framework based on modeling and role-modeling theory (Erickson, Tomlin, & Swain, 1983). The sample consisted of 83 adults between the ages of 30 to 91 years. The majority of participants were Caucasian, educated, retired and almost evenly distributed between male and female. Each subject completed the following instruments: the Oral Anticoagulation Knowledge (OAK) test, the Duke Anticoagulation Satisfaction Scale (DASS), the Basic Needs Satisfaction Inventory (BNSI), and the generic quality of life survey (SF36v2).

Data was analyzed using correlation and hierarchical multiple regression analysis. Results indicated significant correlations among most of the study variables. Self-care action significantly explained variances in all but two quality of life variables. Self-care knowledge and affiliated individuation had statistically significant moderating effects on the DASS negative impact and hassles/burdens subscales. Self-care knowledge also demonstrated a significant moderating effect on the SF36v2 physical function subscale.

These findings support the concepts proposed by the study's theoretical framework. This research serves as validation of Acton's (1997) study findings for the concept of affiliated individuation and its value as a self-care resource in a specific clinical population.

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CHAPTER ONE: INTRODUCTION

Warfarin Background

For more than 60 years, the drug warfarin has been the most widely used oral anticoagulant in the world. The parent compound of today's warfarin was discovered by Karl Paul Link and associates at the University of Wisconsin in the early 1940s. Cattle deaths from a hemorrhagic condition had been plaguing the Midwest for several years. The culprit was identified as spoiled sweet clover hay, leading to the subsequent naming of the condition as "sweet clover disease" (Wisconsin Alumni Research Foundation, 2009, Link, 1959).

When the cattle ingested the spoiled hay they manifested internal bleeding symptoms within 15 days and usually died after 30-50 days. In February of 1933, an exasperated farmer by the name of Ed Carlson came to Link's laboratory looking for help with a pail full of uncoagulated blood, a pile of spoiled hay, and a dead cow in the bed of his truck. Link was moved by the farmer's plight, and he did have an interest in sweet clover disease, but isolating the hemorrhagic agent was not where his primary research interests were focused at that time.

Despite this, the incident with Carlson had a profound impact on Link and his senior student, Eugen Wilhelm Schoeffel. They collected the blood and hay and immediately started preparing it for analysis, not leaving the lab until late in the evening. Work progressed as the weeks passed and was further assisted when the search for the compound was eventually funded by a grant from the Wisconsin Alumni Research Foundation (Wisconsin Alumni Research Foundation, 2009, Link, 1959).

In 1941, Dr. Link and his team of scientists isolated the compound named "dicoumarol", which was patented by the Wisconsin Alumni Research Foundation as they provided the majority of the funding for the research. Several years later, a stable, quick-acting variation of dicoumarol called "warfarin" was introduced as a rodenticide (rat poison). The implications for use in humans began to be explored in 1951, after a sailor used rat poison to commit suicide but failed to die.

In 1955, President Dwight Eisenhower was one of the first patients to be given the drug warfarin after suffering a heart attack. The first randomized, controlled trial was done in 1960. Today, multiple studies using the drug warfarin continue, as it is the mainstay for oral anticoagulation (Ansell, et al., 2008, Sidhu & O'Kane, 2001, Wardrop & Keeling 2008, Scully, 2002, Wisconsin Alumni Research Foundation, 2009, Link, 1959).

WARFARIN USE, MONITORING, AND PATIENT SAFETY

There are millions of Americans on warfarin for long-term oral anticoagulation therapy. Warfarin, which is a vitamin K antagonist, produces its anticoagulation effect by interfering with the conversion of vitamin K and the liver's ability to provide carboxylation. With the effect of warfarin, the liver produces only partially carboxylated proteins that reduce the coagulation activity. This process affects clotting factors II, VII, IX, and X, since they are vitamin K-dependent. Because warfarin is a vitamin K antagonist, the administration of vitamin K can reverse the effects of warfarin and is frequently used in this capacity. Warfarin is highly water-soluble and absorbs quickly from the gastrointestinal tract, allowing for high bioavailability that reaches peak blood concentrations within 90 minutes after administration (Ansell, et al., 2008).

Warfarin is used to reduce thrombotic risks such as strokes and pulmonary emboli in persons with conditions such as mechanical heart valves, atrial fibrillation, deep vein thrombosis, and genetic clotting disorders. The use of warfarin can be complicated due to its narrow therapeutic range, wide variability in dosage from person to person, and a high interaction rate with many foods and virtually all drugs. Maintenance of the therapeutic range requires diligence from both a provider and a patient. These attributes make warfarin a predictably unpredictable and risky drug (Ansell, et al., 2008, Sidhu & O'Kane, 2001).

The key to safe and effective long-term oral anticoagulation therapy with warfarin is maintaining a therapeutic blood level within a specified range measured by the international normalized ratio (INR). The INR therapeutic range typically varies anywhere from 2.0 to 3.5 and may be changed depending on a patient's condition or diagnosis. Variances under 2.0 or over 4.5

(generally accepted as the highest INR allowed without intervention) increase the risk of either thromboembolic or hemorrhagic complications. Subsequently, maintaining a patient in the therapeutic range is the primary objective in warfarin management (Ansell, et al., 2008).

Because of its unpredictable nature, maintaining a therapeutic range with warfarin can be difficult. Monitoring of the INR must be done anywhere from every 2 to 3 days to every other month, depending on a patient's situation and metabolism of warfarin. Often, this will require multiple visits to a physician's office, clinic, or lab for blood draws. After the INR is determined, the provider or clinic will adjust the person's dose accordingly (Ansell, et al., 2008, Heneghan, et al., Sidhu & O'Kane, 2001).

Alterations in the metabolism of warfarin by individuals can occur for many reasons. The most common alterations are caused by additional medications being prescribed by other providers or dietary habits that change or become erratic due to vacationing or illness. Patients who become ill or have complications from preexisting conditions and co-morbidities can also experience alterations in the metabolism of warfarin. These alterations in warfarin will be reflected in the INR level, which can quickly fluctuate to extremes. The fluctuation of the INR places an individual at risk for serious, life-threatening complications such as stroke, pulmonary emboli, venous thrombosis (low INR) and bruising, hematoma, and severe bleeding such as subdural hematoma (high INR). Therefore, testing frequency is usually determined by a provider based on the INR history of an individual patient. Some individuals who, over time, have attained a relatively stable INR history will only be monitored every 6 to 8 weeks (Ansell, et al., 2008, Heneghan, et al., Sidhu & O'Kane, 2001).

Knowledge and Quality of Life

It is essential that persons taking the drug warfarin have adequate knowledge concerning the action, side effects, and management of the drug. Knowledge is also a crucial part of successfully maintaining a therapeutic INR range, which in turn helps prevent the development of complications related to oral anticoagulant therapy. Due to the need for an awareness of

dietary management, potential drug interactions, identification of potential complications, activity limitations, and consistent follow-ups with a health care provider, education must be given not only when warfarin is first prescribed but also in an ongoing manner that reinforces the educational content. Several studies have indicated that the better educated a patient is about the drug warfarin, the better the INR therapeutic time in range percentage is (Ansell, et al., 2008, Samsa, et al., 2004, Zoella, Brodeur, Dominelli, Haines, & Allie, 2006, Soliman Hamad, Van Eekelen, Van Agt, Van Strten, 2009).

There are so many safety requirements for the management of long-term oral anticoagulant therapy that it understandably affects the quality of life for the individual taking warfarin. The need for regular blood testing requires multiple visits to have labs drawn. Many times, these appointments interfere with school, employment, and leisure time activities. In addition to the lab visits, there is the wait for the results and the subsequent call from the provider to maintain, increase, or reduce the dose for the following time interval. If the INR is extremely high, a visit to the emergency room may follow, due to the high risk of hemorrhagic complications. Restrictions in lifestyle include limiting alcohol intake, activity restrictions such as the elimination of contact sports, and the need to wear identification, such as an alert bracelet, that identifies that the person is on the drug warfarin.

Anxiety is another aspect of warfarin therapy. Many patients are concerned about their risk of bleeding and/or clotting. This anxiety tends to be highest when a patient is first placed on warfarin, making life stressful and difficult for this patient population (Ansell, et al., 2008, Samsa, et al., 2004, Zoella, et al., 2006, Soliman, et al., 2009).

Problem Statement

As an anticoagulant, warfarin is listed among the top five drugs associated with accidental deaths and other adverse events resulting in harm to a patient. Following media attention received by other anticoagulants, The Joint Commission (TJC) added anticoagulant safety to their list of patient safety goals to be fully implemented by January 1, 2009. Patient safety goal 3E (“Reduce the likelihood of patient harm associated with the use of anticoagulant therapy”) mandates that hospitals reduce the risk of incidents that result in the harm or death of a patient. One of the primary risk reduction strategies for warfarin is enhancing patient education. Patients who are educated and can participate in the management of their warfarin have lower rates of thromboembolic events and death (Ansell, et al., 2008, The Joint Commission, 2008).

Similarly, in the outpatient setting, patients taking warfarin face the same complications but have fewer immediate resources to assist them with anticoagulation management. At home, the day-to-day compliance with rules, restrictions, and monitoring for adverse effects related to warfarin becomes the sole responsibility of the patient. Using theoretical concepts from modeling and role-modeling theory (MRM), this responsibility can be demonstrated through self-care knowledge, self-care actions, and the availability of self-care resources. As an essential component of warfarin management, education is a critical element for increasing patient self-care knowledge (Erickson, Tomlin, & Swain, 1983).

Even with its established importance, patient education concerning warfarin occurs in most settings where it is prescribed, but at times, there is very little effort put into the education process. The format and structure of educational materials and programs vary greatly, and there is limited research to determine if the education provided is effective (Newall, Monagle, & Johnston, 2005).

Warfarin education may also have a direct impact on quality of life. The more a patient knows about the effects, restrictions, possible food/drug interactions, and potential adverse events, the higher the potential there is for either anxiety and fear or confidence and feelings of

control and independence. A patient on warfarin is dependent on the health care system for assistance with monitoring their INR and the management of any adverse events.

The optimal plan is for patients to access the health care system when appropriate but remain independent of it. In this instance, accessing the health care system is seen as a resource. This process has been defined in Erickson's MRM theory as "affiliated individuation", defined as the need to be dependent on and simultaneously independent of support systems (Erickson, et al., 1983, Samsa, et al., 2004).

Research regarding the effect of education on self-care knowledge, self-care resources, self-care actions, and quality of life for persons taking the drug warfarin has been insufficient. No single study has examined all these variables and how they interact with one another. It has been long understood that patients on warfarin need to be educated, but little attention is paid to whether or not the education that is provided has any impact on the quality of life for these individuals. The old saying of "what you don't know may hurt you" is particularly applicable to a patient on warfarin.

Purpose

Several studies have examined knowledge levels and the level of INR control for persons on long-term oral anticoagulation therapy with the drug warfarin (Ansell, et al., 2008, Samsa, et al., 2004, Zoella, et al., 2006, Soliman et al., 2009). Quality of life for patients taking warfarin has also been examined (Samsa, et al., 2004). Additionally, limited studies on the concept of affiliated individuation have been conducted (Acton, 1997, Acton & Miller, 1996), but there are no studies examining the relationships of self-care (self-care knowledge, self-care resources, self-care action) levels, affiliated individuation as a self-care resource, and quality of life for persons on warfarin.

The purpose of this study is to investigate the relationships between the concepts of self-care knowledge, self-care actions, affiliated individuation as a self-care resource, and quality of life for persons taking the oral anticoagulant warfarin. Specifically, this study will explore the

effects of the variables self-care knowledge and affiliated individuation as a self-care resource on the variables self-care action and quality of life in persons taking the oral anticoagulant warfarin. This study will further examine the moderating effects of the variables affiliated individuation and self-care knowledge on the variables self-care action and quality of life.

Significance

The effects of long-term warfarin therapy on quality of life have been examined in limited studies. Most studies indicate that warfarin therapy impairs or reduces a patient's quality of life because of the danger inherent in taking a drug requiring multiple interventions to maintain safe therapy. Frequent monitoring requirements, restrictions in diet and activity, the risk of uncontrolled bleeding, and severe thromboembolic events are just some of the concerns a patient on warfarin must be aware of (Samsa, et al., 2004). It is reasonable to assume that these restrictions and invasive procedures would affect the day-to-day quality of life for that person.

The significance of this study is that it investigates relationships between the variables self-care knowledge and affiliated individuation and their effects on self-care action and quality of life for persons taking the oral anticoagulant warfarin. Study of these variables will assist in the identification of key target areas for future educational and safety interventions for persons on warfarin.

Theoretical Framework

MODELING AND ROLE-MODELING THEORY

The theoretical framework of MRM is a synthesis of theories that includes stress adaptation, humanistic psychology, psychosocial and cognitive development, object relations, and attachment and loss (Raudonis & Acton, 1997). As a result, the theory is well suited for adaptation into a clinical practice theory, since it focuses on interventions (developed during the role-modeling phase) based on the evaluation of information (obtained during the modeling process) to manage and reduce the stressors that are experienced by a patient (Acton, 1997).

MRM is a holistic nursing theory. The major assumptions of the theory build the conceptual framework that supports the model assertions. One of the main assumptions of MRM theory is that people are holistic. There are strong and continuous mind-body interactions that are both inherent and learned. Holism implies that a person is seen as a total unit made up of the body, mind, emotions and spirit working together, not as individual parts. A person's mind-body interactions are motivated by the need to grow and develop across the life span.

Another assumption is that stress is a part of life and that stress will affect health. Further assumptions are that a nurse or caregiver should be a facilitating agent for patients, not just someone performing tasks and deciding what interventions are best for the patient. A nurse's interactions with a patient should be an interpersonal process that facilitates the patient to mobilize all available resources that he or she perceives will aid in recovery. No two patients will have the exact same experience or perceptions of what "healthy" means and what interventions they think will help them return to that perceived level of health (Erickson, et al., 1983).

The major constructs in MRM theory are facilitation, nurturance, and unconditional acceptance. The major concepts for the purposes of this paper are self-care knowledge, self-care resources, self-care action, and affiliated individuation (Erickson, et al., 1983).

Modeling is the process a nurse uses to develop an image and understanding of a patient's world from the patient's perspective. The nurse analyzes the data gathered from the patient and uses it to build a picture of the world from the patient's point of view. Role-modeling is a process in which the nurse will synthesize data collected about a patient and use it to develop and plan interventions that are unique to the patient's needs and his or her particular health-related situation. The information obtained during the modeling process will be used to build an intervention in a way that fulfills the perceived needs of the patient from the patient's perspective (Erickson, et al., 1983, Marriner-Tomey, 1994).

The aim of MRM is not to lead a patient to the goals the nurse has set but rather to facilitate healing by using the interventions developed by and based on the patient's model of his or her world. This promotes growth and optimal self-healing for the patient (Acton, 1997). In

addition to growth and self-healing, MRM's goals are to build trust, engender a positive outlook on life, build and nurture strength, and promote patient control. This is achieved through unconditional acceptance of the patient by the nurse, allowing for mutual goal attainment (Erickson, et al., 1983, Hertz & Anschutz, 2002, Baas, 1992).

Self-Care

One major concept of particular importance in MRM is self-care, a central concept in MRM theory. Self-care is comprised of three components: (a) self-care knowledge, (b) self-care resources, and (c) self-care actions. Self-care knowledge is the information an individual possesses that can promote wellness, healing, and growth. Self-care knowledge may include knowledge that is both known and not known. Self-care knowledge exhibited by a patient may not always be logical, or it may not be seen as acceptable by health care professionals. The point is that health professionals need to understand what it is about that knowledge that a patient finds helpful or healing (Erickson, et al., 1983, Hertz & Baas, 2006).

Assisting in the development of a patient's self-care knowledge can be achieved in many different ways. A description of the situation must be obtained from a patient. After this assessment and evaluation, the perspectives of the caregiver should be shared with the patient to ascertain that the correct issues have been identified. When the correct issues have been identified, the nurse must then assess the patient's knowledge and feelings about what might help the situation (Erickson, et al., 1983).

The patient may have a vast amount of knowledge or very little. In cases of the latter, interventions for patient education may be needed to increase the patient's knowledge. Primarily healthcare providers need to encourage patients to pay attention to their health and what their bodies may be trying to tell them. Educating patients to recognize and understand changes in their health, as well as cues to potential problems, enhances self-care knowledge.

With this additional information, a patient can draw on this knowledge base to determine if he or she needs to utilize self-care resources (Hertz & Baas, 2006). Training and education of

the patient may be seen as a type of self-care resource, as it is a source of self-care knowledge; however, it may also be seen as a self-care action if the patient seeks additional knowledge to promote healing and health.

Self-care resources can be represented by many different things. Any person, place, or thing can be a potential resource for a patient. Resources help patients heal, get through difficult times, and create other resources to store for later use. Having adequate self-care resources allows a patient to face challenges with feelings of confidence and control. Many times, the resources accessed by a patient may contradict what would seem appropriate to some health care providers. The goal, then, is to assess why the patient considers the resource helpful and assist him or her in channeling the resources to achieve the most positive result for the patient (Hertz & Baas, 2006).

Self-care actions are the result of the integration of self-care knowledge and self-care resources. A patient must mobilize these resources to manage the myriad of potential health problems that can be encountered. Since all human beings have different views on what it means to be healthy, the utilization of self-care action will be based on those needs as perceived by the patient (Hertz & Baas, 2006). A simple example of mobilizing resources may be described as follows. Three different people get sick with a cold. One person believes chicken soup will help her recover faster, while the second one thinks hot tea is best, and finally, the third uses a multivitamin. Regardless of which action may be seen as “right” in the eyes of the health care provider, it is the knowledge of the patient that is accessed and acted upon that assists the patient in regaining what he or she conceives of as a healthy state of being.

In times of stress, a patient will use his or her knowledge and resources to reduce the stressors and return to a state of health as he or she perceives it. Returning to a healthy state of being may be evaluated in terms of measuring outcomes. In the case of a patient on warfarin, the outcome measurements for successful self-care may be measured in the control of the INR within the therapeutic range. Based on these concepts, with adequate knowledge, resources, and

actions, a patient taking warfarin should have good outcomes as far as time in the therapeutic range for the INR.

Affiliated Individuation

Another integral concept from MRM theory is affiliated individuation. Based in object relations theory, affiliated individuation is the attachment or relationship that is shared between individuals, described by Erickson (1983) as relationships where there is a need for the relationship, but there is also independence from that relationship. An example of this is the relationship between parents and children. Children need their parents but also need to have independence from them to grow and mature as individuals. Simply put, affiliated individuation is the instinctual need to be able to be dependent on resources and support systems while at the same time maintaining independence from them (Erickson, et al., 1983).

Developing positive affiliations with various services, friends, and family allows for consistent need satisfaction. This allows an affiliated individual to access those resources in times of stress (illness) to help control the harmful effects of the illness (stressors) (Acton, 1997). This leads to health and growth as discussed earlier regarding the concept of self-care. An affiliated individual may also recognize the need to access resources beyond his or her capabilities to handle, such as requiring inpatient care. This would be a situation in which a health care provider needs to be contacted.

For example, one study found affiliated individuation mediated the stress and burden of caregivers for Alzheimer's patients. Caregivers with higher levels of affiliations (resources) had lower levels of stress and burden (Acton, 1997). Health and well-being depend on learning to cope with stressors by mobilizing resources by self-care actions and affiliated individuation (Raudonis & Acton, 1997).

For the purposes of this study, affiliated individuation is conceptualized as a self-care resource. Persons on warfarin use this resource to meet their unique needs, such as frequent blood testing, trips to the doctor, and many other needs listed earlier in this paper. This, in turn,

decreases stress, increases quality of life, and most importantly increases the amount of time a person's INR stays in the therapeutic range. Remaining in the therapeutic range reduces the risk of complications such as bleeding and thrombotic events.

High levels of affiliation and individuation indicate that needs are satisfied. Needs satisfaction builds self-care resources, reducing stress and increasing quality of life. The reverse is also conceptually possible. Unmet needs may result in a lack of self-care resources, and the resultant increased stress may decrease quality of life for those individuals who have low levels of affiliated individuation.

The application of these concepts may be represented in a theoretical model and used to determine how levels of affiliated individuation impact quality of life, stress, and the relationship between affiliated individuation, knowledge, and self-care for persons taking the drug warfarin.

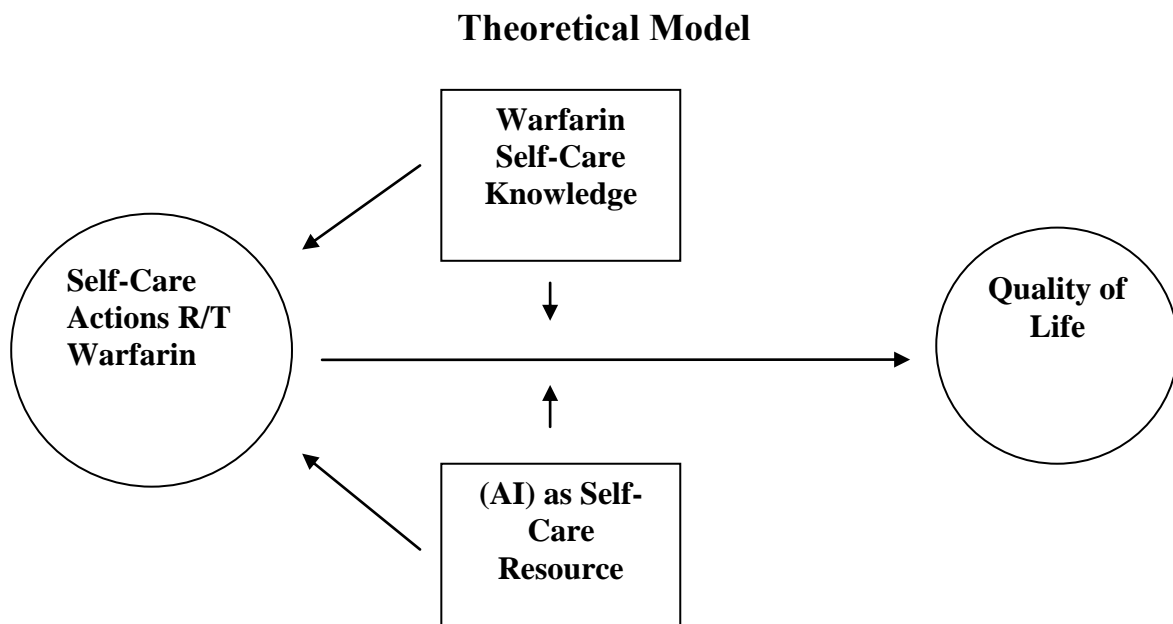


Figure 1: Model for application of affiliated individuation as a self-care resource.

WARFARIN SELF-CARE KNOWLEDGE, SELF-CARE RESOURCES, AND POTENTIAL FOR SELF-CARE ACTION

In Figure 1, arrows are drawn from warfarin self-care knowledge towards warfarin self-care actions. The amount of knowledge a patient has about the drug warfarin influences the potential for warfarin-related self-care actions. Examples of self-care knowledge include a basic overview of warfarin, including side effects, interactions, and monitoring requirements. Safety education includes activities to avoid, signs and symptoms indicative of hyper-therapeutic or sub-therapeutic INR, when to notify health care providers, and information about the safe handling of warfarin.

The model demonstrates a similar effect with affiliated individuation as a self-care resource, in which the availability of resources will also affect self-care actions related to warfarin. Self-care resources include any person, place, or thing that a patient considers a resource for coping with perceived problems and stressors in order to return to a previous state of health.

Affiliated individuation represents an internalized resource sometimes referred to as “inner strength” (Acton, 1993, pg17). A patient’s ability to affiliate with resources such as health care institutions, medical providers, and labs, while, also maintaining independence or individuation from those resources during self-care actions, is directly related to the individual’s quality of life, stress, and well-being.

The model also shows that quality of life is directly influenced by self-care action. Self-care action taken in response to identified needs may increase quality of life by reducing warfarin-related adverse effects. Levels of self-care knowledge and self-care resources (affiliated individuation) moderate the degree of self-care action taken by a patient in response to a warfarin-related health care need.

Without self-care knowledge and affiliated individuation as resources to draw upon, a person taking warfarin may not feel the need to take preventive action, since there may be no recognition of a possible adverse effect. This situation would make self-care actions ineffective

in improving quality of life due to the lack of self-care knowledge and affiliated individuation as a self-care resource.

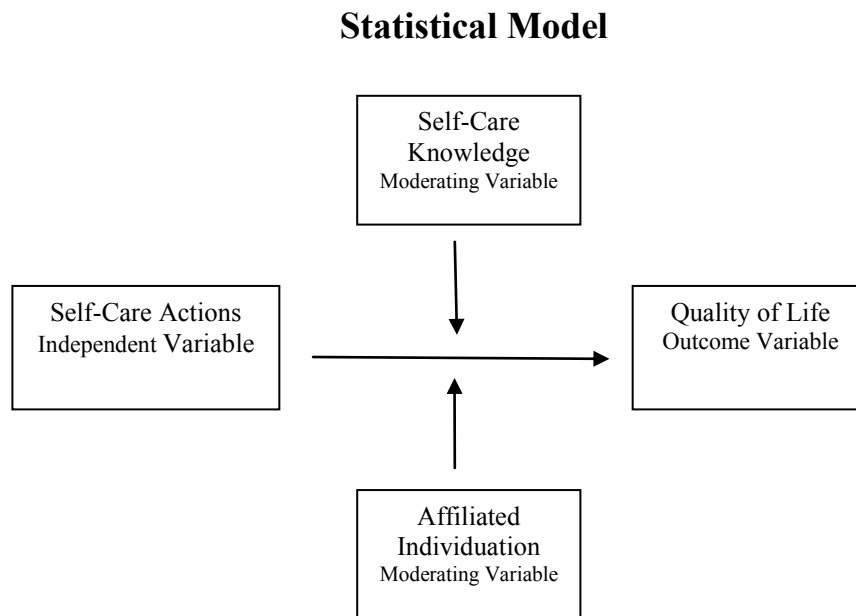


Figure 2: Statistical model of the moderating effect of self-care knowledge and affiliated individuation.

In the statistical model, Figure 2, it is proposed that self-care knowledge and affiliated individuation as a self-care resource moderate the relationship between self-care action and quality of life for persons taking warfarin. In Bennett's (2000) article on mediator and moderator variables, she notes that, in the absence of strong empirical evidence, testing for moderating effects can help identify variables that strengthen or weaken relationships between the independent and outcome variables. Self-care knowledge is conceptualized as a resource that affects the degree to which self-care action is initiated, subsequently having a moderating effect on quality of life.

Affiliated individuation may also have a strong moderating effect on quality of life. A person on warfarin is dependent on many different aspects of health care, including frequent trips to the provider, multiple lab tests, and emergency room visits when there are complications. The need to rely on these resources and also maintain independence is the essence of affiliated

individuation. Affiliated individuation as a self-care resource helps an individual cope with the stressors associated with warfarin use, thus moderating the effect of self-care action on quality of life.

Predicting the association between self-care action and quality of life for persons taking warfarin depends on the value of the moderating variables self-care knowledge and affiliated individuation. Due to the lack of empirical evidence in this area of nursing research, determining which variables most strongly predict quality of life will be valuable for the future development of nursing interventions designed to increase quality of life for persons on warfarin (Bennett, 2000, Baron & Kenny, 1986).

Research Questions

1. What are the relationships among self-care knowledge, affiliated individuation as a self-care resource, self-care actions, and quality of life for persons on long-term oral anticoagulation therapy?
2. What are the moderating effects of self-care knowledge and affiliated individuation as a self-care resource on self-care action and quality of life for persons on long-term oral anticoagulation therapy?
3. Which self-care variable (self-care knowledge or affiliated individuation) most strongly moderates quality of life?

Definitions

Relevant concepts are defined as follows:

Affiliated Individuation

The need to be dependent upon support systems while simultaneously maintaining independence from them. This inherent need, when satisfied, becomes a self-care resource that can be accessed to help individuals cope with stressors such as alterations in health. Affiliated individuation will be measured using subscales of the Basic Needs Satisfaction Inventory

(BNSI), identified as safety/security combined with love/belonging for affiliation and esteem/self-esteem combined with self-actualization to measure individuation (Erickson, 2006, Acton, 1993, Andrews & Withey, 1974).

International Normalized Ratio (INR)

A system developed by the World Health Organization to standardize reporting of clotting time for the drug warfarin, so patients can get comparable tests where-ever they happen to be.

Quality of Life

A subjective indication of well being in which a patient on warfarin has the ability to enjoy life's normal activities as much as possible within the guidelines of warfarin management. Quality of life for individuals on warfarin will be measured using the SF-36v2 Health Survey and the Duke Anticoagulation Satisfaction Scale (DASS).

Self-Care Action

An individual's mobilization and use of self-care knowledge and self-care resources to meet perceived needs. Self-care actions are individualized and include a wide variety of things a person may do to care for him or herself. Self-care action will be measured by a subscale of the Oral Anticoagulation Knowledge (OAK) test named "OAK self-care action" (Erickson, 2006, Zoella, et al., 2006).

Self-Care Knowledge

An individual's knowledge of what is needed to help him or her grow, develop, and heal. This knowledge includes the awareness of personal needs to maintain health, as well as an understanding of what is not needed. Self-care knowledge will also be measured by a subscale of the Oral Anticoagulation Knowledge (OAK) test named "OAK self-care knowledge" (Erickson, 2006, Zoella, et al., 2006).

Self-Care Resources

The internal and external resources available to help an individual through difficult situations and maintain the individual's perceived optimum level of health. Self-care resources include affiliated individuation, which is a resource that may be accessed in times of need.

Assumptions

For the purpose of this study, the following assumptions are made:

1. Study participants will honestly and accurately answer the self-report questions used in this study.
2. Both self-care knowledge and self-care resources must be available to have successful self-care actions.
3. Self-care action is integrated with affiliated individuation using a person's inner strength to perform an action while maintaining independence.
4. Warfarin management is a complex process for any patient.
5. All concepts in the theoretical framework can be measured in a quantitative manner.

Limitations

The results of this study cannot be generalized to all persons taking the drug warfarin because the majority of the convenience sample was obtained from residents residing in the central Texas area they may not be reflective of a more diverse sample.

Because this study used a descriptive, correlational, cross-sectional design, the representation of the knowledge, quality of life, affiliation, and individuation may not reflect all aspects of life with warfarin.

Summary

This chapter has introduced the topic of this study, including the history and background of the drug warfarin and its uses, the problem statement, purpose, theoretical framework, research questions, definitions, assumptions, and limitations of the study. The purpose of this

study was to investigate the relationships among the concepts of self-care knowledge, self-care actions, affiliated individuation as a self-care resource, and quality of life for persons taking the oral anticoagulant warfarin. Specifically, this study explored the effects of the variables self-care knowledge and affiliated individuation as a self-care resource on the variables self-care action and quality of life in persons taking the oral anticoagulant warfarin. This study further examined the moderating effects of the variables affiliated individuation and self-care knowledge on the variables self-care action and quality of life.

CHAPTER TWO

Review of the Literature

This chapter reviews the literature related to the major theoretical concepts that were examined in this study. The concepts derived from a theoretical framework based on Erickson's (1983) modeling and role modeling (MRM) theory. The concepts include self-care knowledge, self-care resources, and self-care actions. Literature was also examined for affiliated individuation, another modeling and role modeling concept. This concept is defined as inherent needs that, when satisfied, become self-care resources for an individual. Selected literature is presented on quality of life as it relates to chronic health conditions and potential positive impact of the modeling and role modeling concepts.

Self-Care and Conceptual Progression

SELF-CARE

There is an abundance of literature related to the concept of self-care. Much of this literature utilizes theory to describe relationships between self-care and health. The research on the concept of self-care is still an evolving area of research, with most having been conducted over the last 25 years. In the hallmark meta-analysis done by Woods (1989), the concept of self-care was linked with health and well-being using four different perspectives. These included the clinical, role performance, adaptive, and eudemonistic perspectives. It is the third and fourth perspectives that seem most appealing to nursing researchers. The third perspective, adaptive, lends itself well to nursing, since the focus is on adaptation, self-care, and self-efficacy. The fourth perspective, eudaemonistic, has also been popular in nursing due in large part to the focus

on health promotion and the use of self-care to promote well-being from a holistic perspective (Woods, 1989).

Woods (1989) defined self-care as “a person’s attempts to promote optimal health, prevent illness, detect symptoms at an early date, and manage chronic illness” (p. 2). Woods suggested that few studies actually conceptualized a link between self-care and a strong impact on a person’s health and urged for more research to be conducted in this area. A criticism of Woods’ meta-analysis was that, although it was comprehensive, there was a weakness in linking self-care to improved health. Woods’ analysis suggested that a person, possibly a health care provider, must define what self-care activity is needed; the patient is then responsible for implementing the self-care behavior for self-care to actually occur (Hertz, 1991). In contrast, MRM theory assists a nurse in understanding a client’s view of the world and enables the nurse to use the client’s information based on that view to facilitate interventions for optimal health from the client’s perspective (Erickson, et. al., 1983).

SELF-CARE AND THE RELATIONSHIP TO SELF-CARE RESOURCES, SELF-CARE KNOWLEDGE, SELF-CARE ACTIONS AND QUALITY OF LIFE

The theoretical framework of MRM theory is a synthesis of theories that include stress adaptation, humanistic psychology, psychosocial and cognitive development, object relations, and attachment and loss. (Erickson, et. al., 1983, Raudonis & Acton, 1997). As a result, the theory is well suited for adaptation into a multitude of disease-specific clinical practice theories. MRM theory is also suited for disease-specific study because the treatment plans or interventions are based on a patient’s perceived needs obtained during interactions with the client (Acton, 1997).

One of the main assumptions of MRM theory is that people are holistic and that there are strong and continuous mind-body interactions that are both inherent and learned. Holism implies that a person is seen as a total unit made up of the body (biophysical), mind (cognitive), emotions (psychological), and spirit (social) as subsystems working together, not as individual

parts separate from each other. A person's mind-body interactions are motivated by basic needs that are described by Maslow (1968). The need to grow and develop across the life span drives behavior to meet these needs, and these needs are only met when the client perceives they have been met. In theory, once these needs have been met, growth occurs, and an individual moves on to the next stage in the hierarchy. Therefore, when basic needs are met, an individual will grow and develop.

Self-care according to Erickson's MRM theory has been defined as "the personal understanding of what is needed to help us grow, develop, or heal" (p. 98). Self-care consists of three interconnected components: self-care knowledge, self-care resources, and self-care actions (Hertz & Baas, 2006). Based on MRM theory and the concepts of self-care, the clinical application of the theoretical model utilizing affiliated individuation as a self-care resource for persons on warfarin will be helpful in assisting this population to remain in a state of equilibrium, health, and safety. Safe anticoagulation relies on the educated, self-aware patient who not only knows when to access health care but is also able to remain independent from it and live as he or she desires (Erickson, et. al., 1983, Hertz, 1991, Goldstein, 2008).

While nursing research based on Erickson's (1983) MRM theory and its' concept of self-care in the area of long-term oral anticoagulation has not been found, there has been atheoretical research in the area of anticoagulation, primarily focusing on patient knowledge of anticoagulation. These studies found that higher patient knowledge was strongly correlated with increased therapeutic time in range for the INR and fewer adverse bleeding and clotting events (Samsa, et al., 2004, Zoella, et al., 2006, Davis, Billett, Cohen, & Arnsten, 2005, Barcellona, Contu, & Marongiu, 2002, Tang, et al., 2003).

Due to a lack of theory-based nursing research on self-care and quality of life for persons on warfarin, this review explored other research related to these self-care concepts both independently and with their effects on quality of life. There are multiple studies on self-care and quality of life for other groups of individuals that have health-related similarities to persons on warfarin. Examples of these populations include persons with heart disease and/or hypertension,

the elderly, and caregivers (Baas, 2004, Matsui & Capezuti, 2008, Baas, 1992, Hertz, 1991, Erickson & Swain, 1990).

In a 2002 paper, Hertz and Anschutz discussed findings from two different studies. The first study tested the theoretical relationships among perceived enactment of autonomy (PEA), the self-care knowledge concept of control, self-care resources, and morale as indicators of self-care action. The second study replicated the test of relationships with a different sample and the different concept of life satisfaction as a measure of self-care action. The concepts to measure holistic health were changed to activity participation and functional abilities (Hertz & Anschutz, 2002).

A sample of 296 community-dwelling older adults ranging in age from 60 to 89 years participated in the first study. The sample was made up of primarily women (80%) and Caucasians (99%), with a large percentage either living alone or with a spouse (89%). The participants completed a series of three instruments and a demographic data sheet. The instruments used were the Hertz Perceived Enactment of Autonomy Scale (HPEAS), which was developed by Hertz (1991) to measure the potential for self-care action; the Perceived Control Subscale, derived from the Goldberg Health Questionnaire; the Revised Philadelphia Geriatric Center (PGC) Morale Scale; and a demographic data sheet. All instruments were found to be valid and reliable (Hertz & Anschutz, 2002).

Using Pearson correlations, PEA was positively correlated with the self-care knowledge concept of control and morale ($p < 0.001$). The stepwise method of multiple regression was used to determine significant predictors of PEA from the demographic data sheet variables, morale, and perceived control scores. The variables morale, gender, age, perceived control, and education level significantly predicted and accounted for 39% of the variance in PEA, $F(5,257) = 34.6$, $p < 0.001$). In addition, being a woman, younger, having higher levels of morale, perceived control, and education predicted increased PEA (Hertz & Anschutz, 2002).

The second study consisted of 47 participants between the ages of 63 to 94 years. As in the first study, the participants were mostly female (85%) and Caucasian (98%). The HPEAS

was again used to measure PEA; the Life Satisfaction Index-Form A (LSIA) was used to measure the self-care knowledge concept of life satisfaction. Life satisfaction was defined as pleasure and meaning in daily activities, positive self-image, and optimistic attitudes and moods, for the purpose of this study (Hertz & Anschutz, 2002).

One-way ANOVA found significant differences in total HPEAS score for participants' ability to shop, $F(2,42) = 3.61, p = 0.04$) and the amount of participation in facility activities, $F(2,43) = 4.29, p = 0.02$). Those participants who relied on others to help them with shopping had higher mean HPEAS scores ($M = 94.8, SD = 12.0$) than those who had no help with shopping ($M = 84.2, SD = 8.0$). And those who frequently participated in facility activities had higher mean HPEAS scores ($M = 91.4, SD = 11.2$) than those who rarely participated in activities ($M = 83.7, SD = 4.9$) (Hertz & Anschutz, 2002).

Matsui and Capezuti (2008) conducted a descriptive correlational study to examine the relationship between perceived enactment of autonomy (PEA) and self-care resources. PEA is defined as a person's ability to sense and recognize the need for behaviors and actions to meet perceived needs which are ultimately a part of self-care action. For this study, 120 community dwelling older adults were recruited from six senior centers in Manhattan, New York. Participants completed a 73-item questionnaire containing demographic questions and the three following surveys: the Hertz Perceived Enactment of Autonomy Scale (HPEAS), the Multidimensional Scale of Perceived Social Support (MSPSS), and the Barthel Index (BI). All the instruments were found to be valid and reliable. The examination of the relationships between self-care resources and PEA found internal self-care resources were significantly correlated in the areas of white race ($p = 0.002$), living arrangement ($p = 0.033$), and functional status ($p = 0.044$). External self-care resources were significantly correlated in the areas of social support and satisfaction with services ($p < 0.001$), and respect for preferences ($p = 0.026$).

The significantly related variables were then analyzed using a linear multiple regression model. In this model, it is interesting to note that only race ($p < 0.01$), service satisfaction ($p < 0.05$), and social support ($p < 0.05$) were found to be significant predictors of PEA. Social

support as an external self-care resource included three subscales (family, friends, and significant others) and was the most significant predictor of PEA (Matsui & Capezuti, 2008). The concept of social support has been studied previously and has been found to be a significant predictor of PEA (Matsui & Capezuti, 2008, Hertz & Anschutz, 2002, Hertz, 1991).

The findings in both of these studies support the theoretical relationships between PEA and the self-care knowledge concepts of perceived control and life satisfaction. The study participants were very similar and lacking in diversity, but even with those weaknesses, the findings from the ANOVA support the findings in Matsui and Capezuti's (2008) research that found the self-care resource of social support to be a significant predictor of PEA. Both studies indicate that strong supportive environments are representative of self-care knowledge, self-care actions, and self-care resources (Hertz & Anschutz, 2002, Matsui & Capezuti, 2008).

These study findings support the theoretical tenants of MRM theory and the concepts of self-care. Self-care knowledge consists of what people know about themselves and what they think it will take to make them well. Self-care resources are both internal and external and are used to cope with illness and stressors through self-care actions. When self-care knowledge and self-care resources are enhanced, health is improved through self-care actions, and when limited, health and recovery are impaired due to lack of effective self-care actions and a lack of self-care resources. Due to the simplistic interconnection of these concepts, MRM theory allows for use of clinical research models that may develop interventions to improve health, well-being, and quality of life in many different populations, including those on long-term anticoagulation with warfarin.

QUALITY OF LIFE AND SELF CARE

Many issues including multiple time consuming visits to see the doctor and lab, daily worries over diet and what to eat, scheduling vacations and trips around visits related to warfarin, and varying degrees of fear and anxiety related to possible uncontrolled bleeding. These are just a few of the issues that people taking the drug warfarin on a long-term basis deal with as a

routine part of life. Even though the modifications and surveillance that surround the use of warfarin are accepted as necessary by all involved, these factors can also influence a person's quality of life. Unfortunately, much of the literature on quality of life for persons taking warfarin is part of larger studies on self-management. In this context, self-management refers to the actual management of the dose of warfarin based on the INR by a patient using a point-of-care INR meter and algorithms or other methods to determine the warfarin dose based on the INR result (Hennigan, et al., 2006).

Quality of life for the purpose of this study is defined as a subjective indication of well-being in which a patient has the ability to enjoy life's normal activities. Literature on self-care and quality of life exists in several different patient populations that are similar in many respects to people on warfarin. The most similar of these chronic health conditions to the use of warfarin is heart failure. Persons with heart failure (HF) must learn to manage aspects of the disease in order to maintain their optimum state of health. This requires management of diet, medications, monitoring weight, and knowledge of situations that require consultation with providers and/or the need for emergency care. HF and other heart-related health research offer a good comparison of self-care and quality of life for the purpose of this review (Baas, 2004, Macabasco, et al., 2011, Seto, et al., 2011, Buck, et al., 2011).

Baas (2004) studied self-care knowledge, self-care resources, activity level, and demographic variables such as age, gender, and left ventricular ejection fraction (LVEF) as possible predictors of quality of life (QOL) in persons three to six months following myocardial infarction (MI). The sample size of this ex post facto correlational study consisted of 84 participants ranging in age from 36 to 81 years old. The majority of the sample was male (69%) and Caucasian (90%). The participants completed three instruments: the Self-Care Resource Inventory (SCRI); the Index of Well-Being; the Human Activity Profile (HAP); and a demographic data sheet (Baas, 2004).

Multiple regression analysis was used to explain the variance in QOL. The predictor variables included activity, SCRI-Availability, SCRI-Needs (subscales of the SCRI), age, and

LVEF. SCRI-Availability ($p < 0.001$) was the first variable in the model accounting for 21% of the variance in QOL. The next variables that entered the model were activity level ($p = 0.006$) and SCRI-Needs ($p = 0.008$). The total variance in QOL accounted for by the three variables was 37% (Baas, 2004).

A large amount of variability in QOL was explained by variables that can be influenced through action and intervention on the part of a participant. Participants in this study may have realized or learned what they needed and responded with self-care actions, thus being successful in cardiac rehabilitation. Examples such as these support self-care concepts as defined and described in MRM theory (Baas, 2004).

Macabasco-O'Connell, et al. (2011), studied the relationships between literacy, knowledge, self-care behaviors, and HF-related quality of life for 605 HF patients. HF knowledge and self-care behaviors were measured using the Improving Chronic Illness Care Evaluation (ICICE), which was adapted for telephone use from the larger Minnesota Living with Heart Failure Questionnaire (MLHFQ) and other HF health status scales. HF-related knowledge questions included the definition of HF, how often a person with HF should weigh him or herself, symptoms of HF, safe salt intake, which foods are higher in salt, exercise, and responses to weight increases. Literacy was measured using the short Test of Functional Health Literacy in Adults (TOFHLA), which is a 36-item, seven-minute timed test that categorizes either inadequate/marginal literacy or adequate literacy.

Multivariate linear regression analysis was conducted to investigate the relationships between HF, literacy, knowledge, and self-care while controlling for potential confounding variables such as race, ethnicity, sex, insurance status, and income. Education was not controlled due to the bidirectional relationship between education and literacy. T-tests were used for comparing differences in the continuous data, and structural equation modeling (SEM) was conducted to determine whether the variables of HF knowledge, salt knowledge, self-care behaviors, and self-efficacy mediated the relationship between literacy and HF quality of life (Macabasco, et al., 2011).

Patients with adequate literacy had higher general HF knowledge (mean score 6.2 vs. 5.5, adjusted difference 0.63 [CI 0.97, 0.29]) and HF self-care behaviors (mean score 5.3 vs. 4.2, adjusted difference 0.59 [CI 0.96, 0.22]). Higher literacy patients reported higher scores on self-care behaviors such as having a scale at home (58% vs. 43%, $p < 0.001$), weighing everyday (32% vs. 16%, $p < 0.001$), eating foods lower in salt (84% vs. 76%, $p < 0.014$), having been taught to manage diuretics (45% vs. 34%, $p < 0.008$), and actually performing management of diuretics (47% vs. 28%, $p < 0.001$). Also, higher literacy patients knew what to do for a weight gain of more than four pounds (73% vs. 49%, $p < 0.001$) (Macabasco, et al., 2011).

Lower literacy was associated with lower knowledge, lower self-care behaviors, and over-all lower HF quality of life. The results of SEM found no effects from HF knowledge, salt knowledge, self-care behaviors, and self-efficacy to explain the difference in literacy-related HF quality of life (Macabasco, et al., 2011).

Seto, et al. (2011), conducted a mixed methods study describing and examining relationships between self-care practices and quality of life for 94 HF patients in a multidisciplinary clinic. Barriers to self-care practices and quality of life were also examined. Self-care was measured using the Self-Care of Heart Failure Index (SCHFI), and quality of life was measured with the MLHFQ.

Overall, not all areas of self-care correlated with quality of life. Better self-care was associated with older age, lower ejection fraction, and higher self-care confidence ($p < 0.005$). Better quality of life was associated with higher self-care confidence, older age, being employed, better functional capacity, and having fewer comorbidities ($p < 0.001$) (Seto, et al., 2011).

Interestingly, during qualitative interviews, four barriers to self-care were identified: (1) lack of self-care education; (2) financial constraints; (3) no perceived benefit in self-monitoring; and (4) low self-efficacy. When these findings are applied to the theoretical model in this study, self-care knowledge (education), self-care resources (financial), and self-care actions (no perceived benefit) are all related to levels of quality of life. Examples such as these support the

development of interventions that focus on aspects that may be improved, such as education (Seto, et al., 2011).

In a 2011 study by Buck, et al., relationships were explored between self-care and quality of life in older adults with advance HF. This study was a secondary analysis of previously collected data from nine studies across the United States and one from Australia. The final sample consisted of 207 older adults over the age of 65 with advanced HF (either class III or IV) using the New York Heart Association HF classification. The two instruments used were the SCHFI and the MLHFQ. The SCHFI measures self-care maintenance, self-care management, and self-care confidence, with a scale score that ranges from 1-100. The MLHFQ is a widely used instrument that gives results in three different subscales: physical, emotional, and MLHFQ total (Buck, et al., 2011).

Analyses included descriptive, bivariate, and explanatory analyses. Bivariate analyses were performed to compare the baseline SCHFI and MLHFQ scores using both continuous measures of quality of life and the associations between HF self-care and better or worse quality of life using below-median and above-median MLHFQ scores. Multivariate linear modeling and logistic modeling were used to describe the relationship between baseline HF self-care scores and quality of life controlling for predetermined patient characteristics derived from previous analysis of this data (Buck, et al., 2011).

No significant correlations were found between self-care maintenance, management, and quality of life. There were significant associations between self-care confidence and total ($r = -0.211$; $p = 0.002$), physical ($r = -0.189$; $p = 0.006$), and emotional ($r = -0.201$; $p = 0.004$) for quality of life in patients reporting above-median quality of life scores (58.8 [19.2] vs. 52.8 [19.6]; $p = 0.028$). Self-care was an independent determinant of total ($\beta_s = -3.191$; $p = 0.002$), physical ($\beta_s = -2.346$; $p = 0.002$), and emotional ($\beta_s = -3.182$; $p = 0.002$) quality of life scores, controlling for previous SCHFI scores, age, gender, and NYHA class (Buck, et al., 2011).

There was a significant association between self-care confidence and quality of life scores. With each one-point increase in self-care confidence, the chances for reduced quality of

life decreased. This relationship was not found with self-care management or maintenance. This led researchers to the hypothesis that self-care confidence mediated and moderated the relationship between self-care and outcomes (Buck, et al., 2011).

As with HF, quality of life for a person on warfarin is a subjective indication of well-being in which a person has the ability to enjoy life's normal activities. Quality of life may be enhanced for persons on warfarin by continuing to explore relationships with self-care concepts, then using the results and associated research to improve and develop new interventions to improve quality of life for persons on long-term warfarin.

Affiliated Individuation

Affiliated individuation (AI) is defined as the instinctual need to be able to be dependent on resources and support systems while maintaining independence from them (Erickson, et al., 1983). Developing positive affiliations with various services, friends, and family allows for consistent need satisfaction. As a result of this, AI can be considered a self-care resource. This enables a strongly affiliated and or individuated person to access resources, either internal or external, in times of stress and illness to control, reduce, or eliminate their harmful effects (Acton, 1997).

An early, unpublished study (Acton, Erickson, Kinney, Irvin, & Hopkins, 1991) focused on the relationships between perceived support, perceived control, life satisfaction, and AI among 230 health fester participants. Participants completed a battery of self-report questionnaires. Results were collected and analyzed. Regression analysis indicated that AI was a significant predictor of both support $R^2 = 0.38$ ($p < 0.001$) and control $R^2 = 0.35$ ($p < 0.001$). Support and control were both significant predictors of life satisfaction accounting for 23% (support) and 21% (control) of the variance in life satisfaction (Acton, 1993, Acton & Miller, 1996).

Hierarchical multiple regression was performed to test the moderating effect of AI on the relationship between stress and life satisfaction. The interactions of stress and affiliation ($p =$

0.04); stress and individuation ($p = 0.08$); and stress and AI ($p = 0.05$) were all significant predictors of life satisfaction, accounting for 64% of the variance (Acton, 1993).

Acton and Miller (1996) conducted a descriptive, correlational study that included both quantitative and qualitative data from 26 caregivers of adults with dementia. The caregivers were mostly female (77%) and Caucasian (96%). All participants took part in a semi-structured interview for the collection of qualitative data. Questions were designed to have the caregivers describe their perceptions of their current situations. Participants were given the Basic Needs Satisfaction Inventory (BNSI) and a demographic data sheet with instructions to be completed at home and mailed back via a self-addressed, stamped envelope. Participants were then assigned to support groups. The BNSI was completed at 6 months and 12 months after the participants' admission to the support group. Subscales of the BNSI were then used to measure affiliation and individuation. Interviews were conducted again at the end of the 12-month support group intervention (Acton & Miller, 1996).

BNSI data was analyzed using repeated measures of the MANOVA at the initial, 6-month, and 12-month intervals. Within-subject variance had no statistically significant differences, and mean scores remained stable across time. Qualitative data was analyzed using an inductive process. Words, phrases, and descriptors were identified to discover the meaning of the data. During the analysis, comparisons were done that identified categories and concepts that were analogous to the theoretical definition of AI (Acton & Miller, 1996).

While not statistically significant, there was evidence in the qualitative data suggesting that support groups helped caregivers maintain resources. The qualitative data indicated that there was growth in the caregivers' resources. Caregivers described not just being able to maintain their resources but also actual growth and healing, which increased those resources. This work supports the assertions that repeatedly meeting needs builds self-care resources that can be later used to cope with illness, stress, or other healing that may be needed (Acton & Miller, 1996).

In a 1997 study, Acton studied 107 caregivers of Alzheimer's-type dementia, this study provides the most in-depth analysis of AI to date. A large proportion of the subjects were female (75%) and Caucasian (95%). The average caregiver was 63 years old and married (90%) at the time of the study. Participants completed a packet of questionnaires and returned them by mail to the researcher. The questionnaires consisted of several instruments, including the Memory and Behavior Problem Checklist (MBPC); Burden Interview (BI); Goldberg General Health Questionnaire (GHQ); and the Basic Needs Satisfaction Inventory (BNSI). All instruments were found to be valid and reliable (Acton, 1997).

The mean scores of perceived stress and burden indicated that caregivers were experiencing high levels of perceived stress ($M = 73.52$) and moderately high levels of burden ($M = 41.67$). Additionally, the Pearson correlation between stress and burden was $r = 0.55$, $p < 0.01$, indicating that the individuals experiencing higher levels of stress also had higher levels of burden. Additionally, correlations between stress and life satisfaction ($r = 0.29$, $p < 0.01$) and burden and life satisfaction ($r = 0.35$, $p < 0.01$) indicated that participants with higher levels of stress and burden had lower levels of life satisfaction. Mean scores (scales were re-coded, so lower numbers indicate higher levels of the variable) for affiliation ($M = 33.90$), individuation ($M = 33.21$), and life satisfaction ($M = 11.14$) indicated moderate levels of AI and high levels of life satisfaction. Correlations between affiliation and life satisfaction ($r = 0.48$, $p < 0.01$) and individuation and life satisfaction ($r = 0.62$, $p < 0.01$) indicated that participants with higher levels of AI also had higher levels of life satisfaction (Acton, 1997).

To determine whether the effects of stress and burden on life satisfaction are reduced in caregivers with high levels of AI, hierarchical regression was used to test the effects of the variables affiliation and individuation. AI was found to be a significant predictor of life satisfaction. With stress entered at step 1 and affiliation and individuation entered at step 2, correlational analysis showed that stress was significantly related to affiliation ($r = 0.37$, $p < 0.01$); individuation ($r = 0.37$, $p < 0.01$); and life satisfaction ($r = 0.29$, $p < 0.01$). In this regression, stress explained only 9% of the variance in life satisfaction, while AI added another

30%, for a total R^2 of 0.39. When the entry order was reversed, AI explained 38% of the variance in life satisfaction; stress only added 1% to the explained variance. This indicated that AI reduced the variance in life satisfaction explained by stress by 8%, which resulted in a non-significant F change ($F_{chg} = 0.99$, $p = 0.32$).

When the same regression analysis was performed using the independent variable burden, there was a significant relationship with affiliation ($r = 0.57$, $p < 0.01$); individuation ($r = 0.56$, $p < 0.01$); and life satisfaction ($r = 0.35$, $p < 0.01$). In this regression, burden explained 13% of the variance in life satisfaction, while AI added another 26%, for a total R^2 of 0.39. When the entry order was reversed, AI explained 39% of the variance in life satisfaction, and burden did not add to the variance. This indicated that AI reduced the variance in life satisfaction explained by burden by 13% ($F_{chg} = 0.02$, $p = 0.87$) (Acton, 1997).

People have an inherent need to be independent, which develops across the life span as they discover who they are and learn to interact with others in their world. The interaction with others, who can be family, friends, and anyone else who touches a person's life, helps them to develop a sense of connectedness. When the need to be independent and the need to connect with others interface, we have the need for AI, which, when in balance, creates a sense of meaning, balance, and self-actualization (Erickson, Erickson, & Jenson, 2006).

Discussion

Increases in self-care knowledge, self-care resources, and self-care actions may increase positive outcomes when applied to persons on warfarin. When Woods (1989) proposed looking at health and wellness from a eudaemonistic or holistic perspective, MRM theory was still relatively new and, at the time, considered a mid-range theory (Marriner-Tomey, 1994). Since then, multiple studies have been conducted using MRM concepts of self-care, PEA, and AI (Matsui & Capezuti, 2008, Hertz & Anschutz, 2002, Hertz, 1991, Hertz & Baas, 2006, Baas, 2004). This is the support structure that makes MRM theory and the concepts of self-care perfect for the warfarin population. Safety for this population has been directly linked to the knowledge

of the individual (Ansell, et al., 2008, Samsa, et al., 2004, Zoella, et al., 2006, Soliman, et al., 2009). Therefore, increasing self-care knowledge and resources significantly increases the safety of an individual on warfarin.

The concept of control when discussing this population is often not used in the MRM theoretical framework but rather as a term for control of the INR. Maintaining control of the INR for a person taking the drug warfarin is a priority, regardless of the reason they are taking it. This narrow therapeutic range for the INR can make it challenging for a patient and a provider, given all of the physiological and environmental elements that can affect the level of the INR.

This study proposes that higher levels of self-care knowledge and affiliated-individuation as a self-care resource leads to desirable self-care actions which result in better quality of life with fewer adverse reactions and events associated with warfarin.

Conclusion

The use of theoretical frameworks to guide clinical practice allows a practitioner to explore various constructs and concepts, as well as their relationships, as they affect relevant theoretical populations. Information obtained during these studies can be used to develop and structure interventions and activities related to increasing knowledge, improving resources, increasing the time in therapeutic range, and decreasing adverse effects. Improvement in all of these areas increases the safety and well-being of persons on long-term warfarin therapy.

CHAPTER THREE

METHODOLOGY

Chapter Three contains a description of the research study design. This is followed by a description of the sample and recruitment procedures. Informed consent methods and procedures used to maintain confidentiality are discussed. The instruments used in the study are discussed including the psychometric properties of each. Then the chapter concludes with a discussion and review of the data analysis procedures conducted.

Research Design

The two primary purposes of this study were first to explore the relationships among the independent variables self-care action, self-care knowledge, and affiliated individuation for persons on chronic Warfarin therapy and the outcome variable quality of life. Then secondly, to explore the moderating effects of self-care knowledge and affiliated individuation on quality of life, then determine which variable has the strongest moderating effect.

The research design was a descriptive correlational cross-sectional design. The research was non-experimental, having no manipulation or control over independent variables. Kerlinger (1992) identified three weaknesses in non-experimental correlational research: (a) the inability to manipulate independent variables, (2) the lack of randomization, and (3) the possibility of improper interpretation. Improper interpretation may take many forms and includes a wide variety of possible explanations for the findings. This possibility is reduced when using theoretical frameworks with strong hypotheses. Despite this, non-experimental research does have strengths and is well suited for the description and exploration of relationships between factors such as self-care action, self-care knowledge, affiliated individuation and quality of life for persons on chronic Warfarin therapy. The study was supported and guided by a theoretical framework based on Modeling Role Modeling theory. Other strengths of non-experimental

research make it a preferred method for research that does not lend itself to manipulation and gives the researcher the ability to collect large amounts of data about a subject. Finally, using non-experimental correlational research in nursing often provides practicality, looking for answers that can be applied to real problems encountered by nurses when caring for patients (Polit & Beck, 2004).

Sample and Setting

The population for this study included all persons over the ages of 18 on long-term oral anticoagulation therapy (greater than three months). After approval by the University of Texas Institutional Review Board (Appendix A), sample participants were recruited from a large central Texas anticoagulation clinic located in downtown Austin, Texas over a period of four weeks in July and August, 2012. The sample included residents from the surrounding Austin Texas metropolitan and rural areas. A permission letter from the Austin Heart clinical research director (Appendix B) was obtained. This allowed for placement of recruitment fliers (Appendix C) in the anticoagulation clinic rooms and permission for the researcher to be onsite during the anticoagulation clinic hours. Austin Heart, PLLC has a large research department with a staff of 14 full time employees. Austin Heart supported the study by providing a private office area to complete surveys and Austin Heart staff members assisted in recruitment of subjects.

Inclusion criteria for the study were:

1. Long term oral anticoagulation patient (on Warfarin for at least three months by self-report).
2. Over the age of 18.
3. Able to read and understand English.
4. Willing to participate in the study.
5. Not be pregnant.

All persons who met inclusion criteria were allowed into the study. No participants from vulnerable populations such as minors, prisoners, students, or institutionalized persons were

recruited. Since Warfarin is a pregnancy class X drug, no pregnant females were patients at the clinic.

A statistical power analysis was performed to determine the minimum sample size needed to analyze relationships and moderating effect for three predictor variables self-care action, self-care knowledge, and affiliated individuation as well as one dependent variable which was quality of life. The power analysis an effect size of 0.35, an Alpha of 0.05, and a power of 0.80 determined that a sample size of 39 subjects would be adequate. Given the number of variables and to accommodate missing data the sample size of 70 was selected yielding a 10:1 sample to variable ratio. A large effect size of 0.35 is considered appropriate when the researcher anticipates a strong relationship or association between the independent and dependant variables (Duffy, 2006). This research is similar to Acton's (1997) study in which affiliated individuation strongly correlated with well-being and burden. At the conclusion of data gathering, the total number in the sample was 83 participants.

The sample was recruited in two ways over a period of four weeks. The first was by referral from the Austin Heart staff. The procedure involved information about the study being placed in the clinic lobby; after the patient was seen by the clinician they were given basic information about a nursing study being conducted for persons on Warfarin and asked if they were interested in receiving more information about participating in the study from the primary investigator or research assistant.

The primary investigator enlisted two senior undergraduate nursing students with research experience to assist in subject recruitment, and distribution and collection of instrument packets. Both assistants were trained by the primary investigator and signed a written procedure agreement (Appendix D). The research assistants were paid a small stipend to cover gas and incidental expenses.

If the participant agreed to participate they were allowed the option of completing the instrument packet at the clinic or completing it at home and returning it by mail. This allowed

those with time constraints or fatigue to complete the packet at home and return it in a pre-paid envelope.

Procedures and Human Subjects Protection

After training by the researcher, the clinic staff approached potential subjects using the approved recruitment advertising (Appendix C) and directing interested individuals to the primary investigator or the research assistant. Austin Heart staff was not responsible for educating the potential subject about the study, determining eligibility, or collecting completed instruments. The primary investigator or one of the research assistants screened potential subjects using eligibility criteria. The potential subjects were then educated about the study's purpose, data collection process, expected risks and benefits, and procedures to ensure confidentiality. After any questions were addressed, if the subject wished to participate, the instrument was administered or given to the subject to take home and return by mail.

The study consent (Appendix E) was placed in the instrument packet on the first two pages. The completion and return of the packet by the participant was regarded as implied consent to participate in the study. The participant was instructed to remove and keep the consent before returning the completed instrument packet.

The privacy and confidentiality of the study participants was protected using a numbering system. The participants were given a numbered instrument packet. Contact information was only collected from those subjects choosing to return the instrument packet by mail. The inclusion of the return address was voluntary and upon its return allowed the ten dollar gift card to be mailed back to the participant. The contact information remained in the personal possession of the primary investigator during the study under lock and key in the primary investigator's office. The personal contact information was destroyed by shredding at the end of the study. The instruments only had the corresponding packet number visible when data entry began.

The instrument packet consisted of four data collection instruments with a cumulative total of 108 questions. With the addition of the demographic and health history instrument

(Appendix F) the total number of questions were 124. The four questionnaires consisted of the: Oral Anticoagulation Knowledge (OAK) test (Appendix G); Duke Anticoagulation Satisfaction Scale (DASS) (Appendix H); Basic Needs Satisfaction Inventory (BSNI) (Appendix I); and the generic quality of life survey the (SF36v2) (Appendix J). The instrument was presented to the participant in a staple bound booklet with a cover containing the name of the study and the primary researcher's name, credentials and institution of study. The completion of the instruments averaged approximately 45 minutes. All participants were reimbursed for their time and trouble with a \$10.00 Visa gift card at the end of the data collection process. Those returning the packet by mail included mailing address so that upon receipt of the packet the gift card could be mailed to the respondent. The mailing address for the participant was shredded at the end of the study.

Risks and Benefits

Potential risks in this study were as follows:

1. Possible loss of confidentiality. All steps to maintain confidentiality were be taken such as numbering the instrument packets and keeping all identifiable information in a secure locked location with only primary investigator access. This included mailing addresses from participants returning instruments by mail.
2. Loss of time in relation to filling out the instrument packet. The average time to fill out the packet was approximately 45 minutes. The participant did have the option of mailing the completed instrument.
3. Fatigue during completion of instrumentation packet. No study participants became fatigued while filling out the packets at the clinic. There were two participants who ran out of time and chose to finish the packet at home and were given pre-postage paid envelopes.

There were no direct tangible benefits to participating in this research. An indirect benefit to participating in this study was the personal satisfaction of helping improve knowledge and quality of life for persons on warfarin.

Instrumentation

All instruments were delivered in English. One participant requested the questions be read to him by a research assistant due to low vision issues. Demographic information was collected about participant age, gender, marital status, education, working status, income, duration of time on Warfarin, reason for anticoagulant therapy, co-morbidities, initial education on Warfarin, and who monitors and adjusts Warfarin dosage. The demographic data collection instrument was developed by the primary investigator and the results are discussed in detail in chapter four.

THE ORAL ANTICOAGULATION KNOWLEDGE TEST (OAK)

Both self-care action and self-care knowledge were measured using the Oral Anticoagulation Knowledge (OAK) test developed by Zoella, et al., (2006) to examine patient knowledge regarding Warfarin. Permission to use and manipulate the OAK test was obtained from Michael R. Brodner, Pharm. D. one of the primary investigators in the original study (Appendix K). The OAK test is a 20 item test in a multiple choice format.

Content validity for the OAK test was assessed using content experts in anticoagulation from the beginning of the instrument development. Experts participated in the development of domains, item topics, and question formulation. Construct validity was determined using the contrasted groups' method, using the assumption that subjects on Warfarin should have higher scores than those subjects not on Warfarin. The mean scores of the subjects on Warfarin was 72% while the mean scores of the subjects not on Warfarin was 52%, which is significantly higher ($p < 0.001$) for the subjects on Warfarin. This difference supports construct validity of the OAK test (Zeolla, et al., 2006).

Reliability of the OAK test was evaluated in several ways. A common way to test reliability of an instrument is to test it on two different occasions separated by an acceptable time period that is neither too short nor too long. Too short a time period may allow participants to remember responses to questions and too long a time period may cause variables to change. Time intervals depend on the type of questions, subject being studied, and other variables that must be taken into consideration by the researchers (Streiner & Norman, 2003).

The OAK test developers performed test-retest reliability over a time period of 2-3 months. The researcher reported a Pearson correlation coefficient of 0.80 which was felt to be acceptable. The student's t-test was used to calculate and compare the mean scores of participants taking Warfarin with those who did not take Warfarin. In addition to test-retest a Kuder-Richardson 20 (KR-20) was calculated for the instrument. The KR-20 score for the participants on Warfarin was 0.76 and for the non-Warfarin participants the score was 0.56 indicating good reliability. The OAK test was divided into subscales for the measurement of self-care action and self-care knowledge. These subscales were examined by the researcher and found to fit the description of self-care action and self-care knowledge described in chapter one. Face validity was confirmed after examination of the subscales by an expert in affiliated individuation.

Self-care action was initially to be measured using a subscale containing (items 3, 11, 14, 16, 17, 18) of the OAK test. This subscale had an initial unacceptable internal consistency with an alpha of .10. The alpha is assumed low as a result of the limited number of items and the weak item analysis correlations. One item, question 11 "Because I am on Coumadin (Warfarin) I seek immediate medical attention ____" was removed from the subscale having an item correlation of only 0.023. Many participants gave incorrect responses and may have found this question confusing due to the lack of definition for "immediate medical attention" which could be defined as going to the emergency room or a call to the primary care provider. After removal of this item the resulting alpha improved greatly but remained unacceptable at 0.46. The researcher felt that it was acceptable to continue the analysis understanding that the results might require greater scrutiny.

Self-care knowledge was measured using the remaining questions (items 1, 2, 4, 5, 6, 7, 8, 9, 10, 12, 13, 15, 19, 20) in the OAK test. This subscale had an initial acceptable internal consistency as evidenced by an alpha of 0.75. Item correlation analysis indicated a weak item correlation (0.023) for question six “When is it safe to take a medication that interacts with Coumadin (Warfarin)?” which was felt to be misleading for patients who are educated not to take medications that interact with Warfarin unless directed to so by their primary care provider. The item was removed increasing the alpha to 0.78 which again is acceptable.

DUKE ANTICOAGULATION SATISFACTION SCALE (DASS)

Quality of life for persons on Warfarin was measured using the Duke Anticoagulation Satisfaction Scale (DASS) developed by Samsa, et al. (2006). Permission to use the instrument was obtained by the primary investigator (Appendix L). The DASS is a 25 item condition specific survey with seven possible responses that range from “not at all” to “very much”. The questions have been arranged to correspond to three dimensions pertaining to long term anticoagulation as determined by the authors by factor analysis. These identified dimensions are negative Impact (limitations and hassles/burdens) and positive psychological impacts. The positive effect subscale was not used in the analysis. Item content in the DASS varies from general to specific questions.

The 27 item version of the DASS was initially administered to 262 patients. Three other scales were administered with the DASS: the SF-36 (generic quality of life), the PSQ-18 (satisfaction with medical care) and the SDS-5 (tendency to give socially desirable responses). Six items were reverse coded so lower scores indicated greater satisfaction. After this initial study two items were dropped leaving the final version of the DASS with 25 items. An additional study was performed on 105 patients to assess the test-retest reliability. The intra-class correlation coefficient for test-retest reliability was 0.80. This was deemed acceptable by the researchers (Samsa, et al. 2004).

The internal consistency Cronbach's alpha coefficients for the overall DASS score were 0.88. The Cronbach's alpha coefficients for the positive impact sub-scale were 0.78, negative impact sub-scale was 0.91, and the limitation sub-scale was 0.87, and the hassles sub-scale was 0.88. These scores correlated with similar sub-scales from the SF-36 (Samsa, et al. 2004).

In this study the DASS subscales negative impact and its subscales limitations and hassles/burdens were used as quality of life indicators for those persons on Warfarin. All of the DASS subscales used in the study had acceptable internal consistency. The results from the DASS subscales were correlated with the results from the generic quality of life instrument SF36v2 given the limited number of studies using the DASS (Samsa, et al. 2004).

SF-36v2 HEALTH SURVEY (SF36v2)

Generic quality of life was measured using the SF-36 version 2.0 (SF36v2). License to use the instrument was obtained through Quality Metrics incorporated (Appendix M). The SF-36v2 is a widely used and validated generic health survey consisting of 36 questions pulled from a large group of questions used in the Medical Outcomes Study (Ware & Sherbourne, 1992). The SF-36v2 measures reported quality of life with question items in the following eight domains: physical functioning (10 items), role limitations due to physical health (4 items), physical pain (2 items), general health perceptions (5 items), vitality (4 items), social functioning (2 items), role limitations due to emotional problems (3 items), and mental health (5 items), and a single item assessing changes in perceived health over the last 12 months (Fryback, et al. 2007, Hays, et al. 2009). The SF-36v2 also has two psychometrically based component factors: physical health (PCS) and mental health (MCS) which allow for cross-study comparisons with other disease specific quality of life instruments (Ostroff, et al. 2011, Klamroth, et al. 2011).

There is a large amount of research supporting the reliability and consistency of the SF-36v2. The instrument has been used successfully in multiple studies involving persons with chronic conditions that can impact quality of health including Soliman's (2009) study measuring quality of life for patients that self-manage Warfarin and Samsa's (2004) Warfarin quality of life

new instrument validation study. Other recent quality of life studies included person with other chronic conditions including hemophilia A, lung cancer, and coronary artery disease (Garster, et al. 2009, Klamroth, et al. 2011, Ostroff, 2011). A study conducted by (Fryback, 2007) used the SF-36v2 to gather data on age-by-gender norms for older adults since it has been described as the most widely used generic health status measure in the world.

The subscales of the SF36v2 that were used in this study were based on the highest significant correlations with the predictor variables. The subscales used were physical function ($\alpha = 0.94$), role-physical ($\alpha = 0.92$), bodily pain ($\alpha = 0.89$) and role-emotional ($\alpha = 0.92$). All the subscales had high internal consistency scores.

BASIC NEEDS SATISFACTION INVENTORY (BNSI)

The Basic Needs Satisfaction Inventory (BNSI) was used to measure affiliated individuation. It was derived from the Quality of Life Index by Andrews and Withey (1974). The inventory contains 27 items that have responses in a Likert scale with 1 being “terrible” and 7 being “delighted”. Kline (1988) combined items forming subscales to reflect need satisfaction based on Maslow. These categories include physiological needs, safety-security needs, love-belongingness needs, esteem/self-esteem needs, and self-actualization needs.

These subscales were further developed and tested by Acton (1993) as a means of measuring affiliated individuation. Combining safety/security and love/belonging (items 3, 4, 6, 10, 12, 14, 15, 17, 22, 23, and 24) forms an 11 item subscale to measure affiliation. Combining esteem/self-esteem and self-actualization (items 5, 7, 8, 9, 11, 13, 16, 20, 26, and 27) forms a 10 item subscale to measure individuation. These scales were tested in Acton’s (1993) study of well-being in caregivers of adults with dementia. The Cronbach’s alpha for affiliation was 0.88 with the lowest item to total correlation of .40. The Cronbach’s alpha for individuation was 0.90 with the lowest item to total correlation of 0.54 (Acton, 1997).

The subscales for affiliation and individuation were combined to measure affiliated individuation. The subscale had a high internal consistency ($\alpha = 0.95$). Instruments, variables, and subscales are outlined in Table 3.1 below.

Table 3.1 Instruments, Variables, and Subscales

Variable	Instrument	Total Items	Subscale Items
Affiliation	BSNI	27	Items 3, 4, 6, 10, 12, 14, 15, 17, 22, 23, 24
Individuation	BSNI	27	Items 5, 7, 8, 9, 11, 13, 16, 20, 26, 27
Self-care Knowledge	OAK Test	20	Items 1, 2, 4, 5, 6, 7, 8, 9, 10, 12, 13, 15, 19, 20
Self-care Action	OAK Test	20	Items 3, 11, 14, 16, 17, 18
Quality of Life for Persons on Warfarin	DASS	25	
	Negative Impact		Items 1a-1e, 2a 2d, 4d 3a-3g, 4g, 4i
	Limitations		Items 1a-1e, 2a 2d, 4d
	Hassles/Burdens		Items 3a-3g, 4g, 4i
	Positive Effects		Items 3h, 4a, 4b, 4f, 4h, 4j
Quality of Life- Generic	SF36v2	36	
	Physical Health		PF, RP, BP, GH
	Physical Functioning (PF)		Items 3a-j
	Role-Physical (RP)		Items 4a-d
	Bodily Pain (BP)		Items 7, 8
	General Health (GH)		Items 1, 11a-11d
	Mental Health		VT, SF, RE, MH
	Vitality (VT)		Items 9a, 9e, 9g, 9i
	Social Functioning (SF)		Items 6, 10
	Role Emotional (RE)		Items 5a-5c
	Mental Health (MH)		Items 9b, 9c, 9d, 9f, 9h

Data Analysis

Quantitative data was entered into SPSS/PC v. 20.0. All data was checked for accuracy, there was some missing data primarily from participants who mailed back the packet. The missing data occurred randomly and was not replaced with a respondent mean. Descriptive statistics were analyzed for demographic variables. Frequencies, means, and standard deviations were completed to describe the characteristics of the sample which are discussed in detail in chapter four. SPSS was also used to determine the Cronbach's alpha reliability and internal

consistency of the instruments and subscales. Acceptable internal consistency of the instruments was determined by Cronbach alpha of 0.70 or more.

Research Questions

The research questions were analyzed using the following procedures.

Research Question 1: What are the relationships among self-care knowledge, affiliated individuation as a self-care resource, self-care actions, and quality of life for persons on long-term oral anticoagulation therapy? To address this question, bivariate correlation procedures were done using a two-tailed alpha of .05. A two-tailed alpha was used since there was no direction indicated for the variables in the question (Field, 2005, Kerlinger, 1992, Meyers, Gamst, & Guarino, 2006). Multiple regression analysis was also performed to examine relationships among Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as predictor variables on the quality of life variables from the DASS and SF36v2 subscales.

Research question 2: What are the moderating effects of self-care knowledge and affiliated individuation as a self-care resource between self-care action and quality of life for persons on long-term oral anticoagulant therapy? To address this question hierarchical multiple regression procedures were conducted and analyzed. Hierarchical multiple regression allows the researcher to use a theoretical model to determine the order in which variables are entered into the equation (Munro, 2005, Meyers, et al., 2006). Results and assumptions for hierarchical multiple regression procedures in this study are discussed in detail in chapter four.

Research question 3: Which self-care variable (self-care knowledge or affiliated individuation) most strongly moderates quality of life? This question was addressed using the outcome of the analysis for research question 2.

Summary

This study used a descriptive correlational cross-sectional design. The research was non-experimental, having no manipulation or control over independent variables. Participants were

recruited from a large anticoagulation clinic serving the Austin, Texas metropolitan and surrounding rural areas. All persons meeting inclusion criteria were allowed to participate in the research study. Informed consent was implied when the instrument packet was returned to the primary investigator or research assistant. No medical records were accessed and personal information was shredded at the end of the study. Instruments and subscales are summarized in Table 3.1. Data analysis included computation of descriptives and frequencies of the data, bivariate correlation procedures were implemented. Multiple and hierarchical regression procedures were also conducted to analyzed relationships among the variables and evaluated moderating effects.

CHAPTER FOUR

FINDINGS

This chapter describes the findings of this study, which examines the associations between self-care knowledge, self-care actions, and affiliated individuation and their effects on quality of life for persons on long-term oral anticoagulation therapy using the drug warfarin (also known as Coumadin).

The first section of this chapter describes the sample and its characteristics. This includes the study participants' demographics, disease processes, warfarin knowledge, and outcome measurements. The remaining sections present the quantitative findings pertaining to the research questions. The research questions for this study are:

1. What are the relationships among self-care knowledge, affiliated individuation as a self-care resource, self-care actions, and quality of life for persons on long-term oral anticoagulation therapy?
2. What are the moderating effects of self-care knowledge and affiliated individuation as a self-care resource between self-care action and quality of life for persons on long-term oral anticoagulation therapy?
3. Which self-care variable (self-care knowledge or affiliated individuation) most strongly moderates quality of life?

Sample Characteristics

DESCRIPTION OF THE SAMPLE

The respondent sample consisted of 83 study participants currently taking warfarin. The participants were recruited from a large central Texas anticoagulation clinic. Respondents were between 30 and 91 years old; the mean age was 68.72 (SD = 14.4). Respondents reported taking warfarin between 0.4 and 32 years; the mean number of years was 7.6 (SD = 6.6).

As shown in Table 4.1, there were slightly more females (54.2%) than males. The majority of the respondents were white (78.3%), married (62.7%), retired (61.4%), and had Medicare with supplemental insurance (62.7%). Slightly less than half had at least a college degree (42.2%) and earned \$60,000 or more (41.9%).

Table 4.1.
Demographic Characteristics for the Sample Participants (N = 83)

Characteristic Variables	Frequency	Mean±SD (Range)
Gender		
Male	38 (45.8%)	
Female	45 (54.2%)	
Age in Years		68.7±14.3 (30-91)
Years on Warfarin		7.61±6.55 (.4-32)
Race		
White	65 (78.3%)	
Black	14 (16.8%)	
Hispanic	3 (3.6%)	
Asian	1 (1.2%)	
Highest level of education		
Less than high school	6 (7.2%)	
High school	30 (36.1%)	
Trade school	12 (14.5%)	
College degree	19 (22.9%)	
Graduate degree	16 (19.3%)	
Marital status		
Married	52 (62.7%)	
Single	9 (10.8%)	
Divorced	13 (15.7%)	
Widowed	9 (10.8%)	
Employment status		
Full-time	20 (24.1%)	
Part-time	1 (1.2%)	
Disability	7 (8.4%)	
Unemployed	2 (2.4%)	
Homemaker	2 (2.4%)	
Retired	51 (61.4%)	
Health insurance		
Private	21 (25.3%)	
Medicare with supplement	52 (62.7%)	
Medicare alone	3 (3.6%)	
Medicaid	2 (2.4%)	
No insurance	4 (4.8%)	
Missing Data	1 (1.2%)	
Income		
Less than \$40,000	30 (36.1%)	
\$40,000 to \$60,000	16 (19.3%)	
\$60,000 to \$80,000	10 (12.0%)	
\$80,000 to \$100,000	13 (15.7%)	
Over \$100,000	10 (12.0%)	
Missing	4 (4.8%)	

As shown in Table 4.2, the majority of participants required anticoagulation for atrial fibrillation (49.4%), heart valve surgery (28.9%), and blood clots and stroke (15.7%). All the participants but one knew the condition they were being treated for. Values reflect that several participants had more than one condition requiring anticoagulation (for example, atrial fibrillation and blood clots).

Co-morbidities ranged from diabetes (26.5%), with the highest incidence, to heart failure (22.9%), stroke (16.9%), cancer (15.7%), lung disease (12%), and kidney disease (6%). Several participants had multiple co-morbidities. Only 15.7% of participants reported any serious bleeding, and 73.5% of participants used a pill organizer to keep track of their medications.

Physicians (69.9%) provided the first point of patient education on warfarin, while nurses were second (27.7%), followed by hospitals (8.4%) and pharmacists (3.6%), respectively. When it came to adjusting the dose of warfarin, most participants' adjustments were made in a clinic (88%) by a nurse.

DESCRIPTION OF THE STUDY VARIABLES

As shown in Table 4.3, the number of correct responses of study participants for the OAK self-care knowledge subscale ranged from two to 14; the mean score was 10.46 (SD = 2.69), indicating that participants had above-average self-care knowledge related to warfarin. The OAK self-care knowledge subscale had an initially acceptable internal consistency, as evidenced by an alpha of 0.75. Item correlation analysis indicated a weak item correlation (0.023) for question six ("When is it safe to take a medication that interacts with Coumadin (warfarin)?"), which the researcher felt was misleading for patients who are educated not to take medications that interact with warfarin unless directed to do so by their primary care provider. The item was removed, increasing the alpha to 0.78, which is acceptable.

Table 4.2.
Frequencies and Percentages for the Disease and Treatment Variables

Variables	Frequency	N(Percent)
Condition requiring anticoagulation		
Atrial fibrillation	41	82(49.4%)
Heart valve surgery	24	82 (28.9%)
Blood clots	13	82 (15.7%)
Stroke	5	82 (6%)
Other/I don't know	9	82 (10.9%)
Comorbidities		
Stroke	14	82 (16.9%)
Heart failure	19	82 (22.9%)
Lung disease	10	82 (12%)
Kidney disease	5	82 (6%)
Diabetes	22	82 (26.5%)
Cancer	13	82 (15.7%)
Major bleeding		
Yes	13	82 (15.7%)
No	69	82 (83.1%)
Initial anticoagulant education		
Doctor	58	82 (69.9%)
Nurse	23	82 (27.1%)
Pharmacist	3	82 (3.6%)
Hospital	7	82 (8.4%)
Other	2	82 (2.4%)
No Education	2	82 (2.4%)
Dose adjustment (who does it)		
Doctor	12	82 (14.5%)
Pharmacist	1	82 (1.2%)
Nurse at clinic	73	82 (88%)
I do my own.	1	82 (1.2%)
Use a pill organizer		
Yes	61	82 (73.5%)
No	21	82 (25.3%)

The OAK self-care action subscale's possible correct responses ranged from one to six; the mean score was 4.58 (SD = 1.24), again indicating that participants had above-average self-care actions related to their warfarin treatment. This subscale had an initially unacceptable internal consistency, with an alpha of 0.10. The alpha is assumed to be low as a result of the limited number of items and the weak item analysis correlations. One item, question 11 ("Because I am on Coumadin [warfarin], I seek immediate medical attention ____"), was removed from the subscale, having an item correlation of only 0.023. Many participants gave incorrect responses and may have found this question confusing, due to the lack of a definition for "immediate medical attention," which could be defined as going to the emergency room or

calling a primary care provider. After removal of this item, the resulting alpha improved greatly but remained unacceptable at 0.46.

BNSI affiliation/individuation subscale scores ranged from 52 to 147, with a mean score of 117.66 (SD = 17.4), indicating average affiliation/individuation scores and acceptable internal consistency with a high alpha of 0.95.

The subscale used for quality of life for persons on warfarin will be the DASS Negative Impact subscale. The subscale scores ranged from 17 to 79, with a mean of 30.66 (SD = 13.26) indicating slightly below-average negative impact scores with a strong internal consistency alpha of 0.89. The instrument is scored on a scale, with lower scores indicating fewer problems, higher satisfaction, and better quality of life. Thus, in this instrument, below-average scores indicate above-average quality of life. The negative impact subscale can be further examined by dividing the instrument into subscales for hassles/burdens and for limitations.

The DASS hassles/burdens subscale scores ranged from nine to 48, with a mean of 15.56 (SD = 8.65), indicating below-average hassles/burdens scores with a strong internal consistency alpha of 0.90. The DASS limitations subscale scores ranged from eight to 33, with a mean of 15.04 (SD = 6.33), indicating average limitation scores with an acceptable internal consistency alpha of 0.77.

The SF36v2 subscales'- (physical functioning, role-physical, bodily pain, and role-emotional), weighted scores ranged from 10 to 100 for physical functioning and zero to 100 for the other three. The physical functioning subscale had a mean of 54.40 (SD = 30.40), indicating average physical function scores with a very acceptable internal consistency alpha of 0.94. The role-physical subscale had a mean of 58.30 (SD = 31.84), indicating mildly above average role-physical scores and another very acceptable internal consistency alpha of 0.92. The bodily pain subscale had a mean score of 61.12 (SD = 27.13), indicating above-average pain scores. Internal consistency was acceptable, with an alpha of 0.89. The last subscale role-emotional, had a mean score of 78.15, indicating high role-emotional, scores with an acceptable internal consistency alpha of 0.92. The descriptive statistics are shown in Table 4.3.

Table 4.3.
Descriptive Statistics and Cronbach's Alpha for the Study Instruments

Instrument	N*	Range	M	SD	α
OAK Self-Care Knowledge	65	2-14	10.46	2.69	0.78
OAK Self-Care Action	78	1-6	4.58	1.24	0.46
BNSI Affiliated Individuation	80	52-147	117.66	17.4	0.95
DASS					
Negative Impact	78	17-79	30.66	13.26	0.89
Hassles/Burdens	80	9-48	15.56	8.65	0.90
Limitations	81	8-33	15.04	6.33	0.77
SF36v2					
Physical Functioning	81	10-100	54.40	30.40	0.94
Role-Physical	82	0-100	58.30	31.84	0.92
Bodily Pain	83	0-100	61.12	27.13	0.89
Role-Emotional	82	0-100	78.15	26.37	0.92

*Missing data dropped from analysis

Questions

A total of three research questions were proposed for this study.

QUESTION ONE

The first research question ("What are the relationships among self-care knowledge, affiliated individuation as a self-care resource, self-care actions, and quality of life for persons on long-term oral anticoagulation therapy?"). To answer the question, bivariate correlation procedures were done using a two-tailed alpha of 0.05. A two-tailed alpha was used because there was no direction indicated for the variables in the question (Field, 2005, Kerlinger, 1992, Meyers, et al., 2006).

Table 4.4 reveals multiple significant correlations among the variables. Self-care action was significantly correlated with DASS negative impact ($r = -0.30, p \leq 0.01$) and limitation scores ($r = -0.39, p \leq 0.01$), meaning higher self-care action scores are associated with lower negative impact and limitations scores. The DASS scoring is coded so that the lower the score, the fewer limitations the participants experienced. Self-care action was also significantly correlated with the SF36v2 quality of life measures of physical functioning ($r = 0.29, p \leq 0.01$), role-physical ($r = 0.28, p \leq 0.05$), and role-emotional ($r = 0.41, p \leq 0.01$). In this case, higher

self-care action scores are associated with increased physical functioning, role-physical, and role-emotional scores. Self-care knowledge was significantly correlated with self-care action ($r = 0.55, p \leq 0.01$), indicating increased warfarin knowledge is associated with increased actions related to warfarin. Self-care knowledge was also significantly related with the DASS hassles/burdens subscale ($r = -0.31, p \leq 0.05$) indicating higher self-care knowledge scores were associated with fewer hassles/burdens. Self-care knowledge was also significantly correlated with three of the SF36v2 subscales used to measure generic quality of life. They are as follows: role-physical ($r = 0.37, p \leq 0.01$), bodily pain ($r = 0.27, p \leq 0.05$) and role-emotional ($r = 0.34, p \leq 0.01$). Significant correlations indicate higher knowledge scores are associated with improved role-physical, bodily pain, and role-emotional health scores on the SF36v2.

Affiliated individuation was significantly correlated with DASS negative impact ($r = -0.25, p \leq 0.05$) and hassles/burdens ($r = -0.27, p \leq 0.05$). This indicated that higher levels of affiliated individuation were associated with fewer hassles/burdens being experienced. Affiliated individuation was also significantly correlated with self-care knowledge ($r = 0.36, p \leq 0.01$), indicating that those individuals with higher affiliated individuation also appeared to have higher self-care knowledge scores. Additional correlations were found between affiliated individuation and three of the SF36v2 quality of life measures role-physical ($r = 0.32, p \leq 0.01$), bodily pain ($r = 0.39, p \leq 0.01$), and role-emotional ($r = 0.25, p \leq 0.05$). Higher affiliated individuation scores were associated with higher role-physical, bodily pain, and role-emotional scores.

Additional analysis also found that the DASS limitations significantly correlated with the SF36v2 variables physical functioning ($r = -0.26, p \leq 0.05$), bodily pain ($r = -0.23, p \leq 0.05$), and role-emotional ($r = -0.29, p \leq 0.01$). This suggests that persons on warfarin with lower (better) DASS limitations scores are associated with improved scores on physical functioning,

bodily pain, and role-emotional subscales. In addition, DASS hassles/burden scores correlated with bodily pain ($r = -0.25$, $p \leq 0.05$) and role-emotional scores ($r = -0.26$, $p \leq 0.05$).

Table 4.4
Bivariate Correlation Analysis between Study Variables

Variables	1. r(n)	2. r(n)	3. r(n)	4. r(n)	5. r(n)	6. r(n)	7. r(n)	8. r(n)	9. r(n)	10. r(n)
1. OAK Self-care Action		.55** (65)	.20 (77)	-.30** (74)	-.22 (75)	-.39** (77)	.29** (78)	.28* (77)	.19 (78)	.41** (77)
2. OAK Self-care Knowledge			.36** (64)	-.25 (62)	-.31* (63)	-.13 (64)	.18 (65)	.37** (64)	.27* (65)	.34** (64)
3. Affiliated Individuation				-.25* (75)	-.27* (77)	-.16 (78)	.12 (80)	.32** (79)	.39** (80)	.25* (79)
4. DASS Negative Impact					.93** (78)	.85** (78)	-.15 (78)	-.17 (77)	-.28* (78)	-.30* (77)
5. DASS Hassles/Burdens						.59** (78)	-.03 (80)	-.10 (79)	-.25* (80)	-.26* (79)
6. DASS Limitations							-.26* (81)	-.19 (80)	-.23* (81)	-.29** (80)
7. SF36v2 Physical Functioning								.74** (82)	.59** (83)	.44** (82)
8. SF36v2 Physical Role									.63** (82)	.56** (82)
9. SF36v2 Bodily Pain										.32** (82)
10. SF36v2 Emotional Role										

Note. * $p \leq .05$, ** $p \leq .01$ (All two-tailed)

Hierarchical multiple regression analysis was also performed to examine relationships among self-care action, self-care knowledge, and affiliated individuation as predictor variables on the DASS negative impact subscale. The DASS negative impact subscale is further broken down into the DASS hassles/burdens and DASS limitations subscales. In addition, the SF36v2 generic quality of life subscales physical functioning, role-physical, bodily pain and role-emotional will be examined for relationships among the predictor variables. Selection of the SF36v2 subscales was based on those that had the largest bivariate correlations.

Assumptions regarding regression analysis include that the sample represents the population to be studied, is normally distributed, has homoscedasticity, and has a linear distribution (Meyers, et al., 2006, Munro, 2005). The assumptions for correlation and regression analysis were evaluated several different ways. Kolmogorov-Smirnov and Shapiro-Wilk tests were analyzed, finding significance and therefore a deviation from normality. For larger samples greater than 60, it is acceptable to use visual tools to determine normality, since larger sample sizes tend to have significance on normality testing when the deviation is small and essentially non-significant (Field, 2005, Kerlinger, 1992, Meyers, et al., 2006, Tabachnick & Fidell, 2001). Therefore, distribution and residual plots of the variable sample were examined. Histograms found the sample to be closely bell-shaped. The sample was randomly scattered and fell close to a straight line.

Multicollinearity was assessed by examination of predictor variables in the correlation matrix, tolerance and variance inflation factor (VIF). Bivariate correlations did not exceed 0.80, which would be concerning. Tolerance (TOL) values of 0.01 or less would indicate multicollinearity, as well as a VIF greater than 10 (Field, 2005, Kerlinger, 1992, Meyers, et al., 2006, Tabachnick & Fidell, 2001). The VIF in the regression analysis ranged from 1.16 to 1.75, well below the value of 10. Tolerance ranged from 0.57 to 0.87, which is acceptable.

Using the theoretical model as a guide, self-care action was placed into the model at step one. Self-care knowledge and affiliated individuation were entered into the model at the second step, and two interaction terms (self-care action x self-care knowledge and self-care action x affiliated individuation) were added on the third step.

The results of the hierarchical regression analysis using negative impact as the dependent variable are outlined in model 2, Table 4.7 (displayed under research question two). Overall, the

model was significant ($F [3,57] = 2.801, p < 0.05$). R^2 for the model was 0.128 indicating 12.8% of the variation in the DASS negative impact score was explained by the three variables. Self-care action was a statistically significant predictor of DASS negative impact scores ($p < 0.05$), while self-care knowledge ($p > 0.05$) and affiliated individuation ($p > 0.05$) were not significant predictors in the model. The standardized regression coefficient for self-care action was -0.323, indicating it is a stronger predictor variable than self-care knowledge or affiliated individuation. This would suggest that persons on warfarin with higher self-care action scores would have lower (therefore improved) negative impact scores. This is a logical outcome for persons on warfarin. If a person fails to act on signs or symptoms that could indicate a problem with oral anticoagulant therapy, the results of that failure to act could be harmful. Conversely, if actions are taken to intervene in problems when first noticed, the outcomes would intuitively be more positive and helpful in avoiding negative outcomes. For example, a person may notice that his or her gums have been bleeding more than normal, and there are more bruises than usual. Taking action to call a health care provider and having labs done to check the level of the INR are proactive steps, with the results being acted upon expeditiously. If the INR is above the therapeutic range, depending on how high it is, certain actions can be taken to stop the INR from increasing and then help reduce it to the range needed to continue to provide safe anticoagulation for that person.

When the DASS negative impact scale is divided into the DASS limitations and DASS hassles/burdens subscales, there are interesting results. The analysis using DASS limitations as the dependent variable is summarized in Table 4.8 (displayed under research question two). Overall, the model was significant ($F [3,59] = 4.606, p < 0.01$). The R^2 for the model was 0.190 indicating that 19% of the variation in the DASS limitations scores was explained by the three

variables. Self-care action was a statistically significant predictor of DASS limitations scores ($p < 0.001$), while self-care knowledge ($p > 0.05$) and affiliated individuation ($p > 0.05$) were not significant predictors in the model. The standardized regression coefficient for self-care action was -0.506, indicating that self-care action is a stronger predictor variable than both self-care knowledge and affiliated individuation. These results suggest that persons on warfarin with higher self-care action scores would have lower limitations scores. As discussed above, this would be logical because appropriate self-care actions would help prevent bad outcomes, which may limit the lifestyle freedoms enjoyed by people not taking warfarin.

Examination results for the DASS hassles/burdens subscale is summarized in Table 4.9 (displayed under research question two) shows that, overall, the model was not statistically significant ($F [3,56] = 2.43$, $p > 0.05$), indicating that none of the variables in the multivariate model were significant predictor of hassles/burdens scores, although both affiliated individuation and self-care knowledge had small but significant zero order correlations with hassles/burdens. This would indicate that of the two subscales, limitations for persons on warfarin are more associated with increased self-care action scores than hassles/burdens. This is also a logical outcome given that there are so many rules and requirements that accompany warfarin therapy. The monitoring, diet, and activity restrictions, to name a few “musts” that go with taking warfarin, could be considered hassles and somewhat burdensome for a person on warfarin.

In Table 4.10 (displayed under research question two), the results for the regression analysis using the SF36v2 physical functioning scale as the dependent variable are outlined. The overall model was statistically significant ($F [3,60] = 3.52$, $p < 0.05$). The R^2 was 0.150 indicating that 15% of the variation in the SF36v2 physical functioning score could be explained by the model variables. Self-care action was again a statistically significant predictor of physical

functioning scores ($p < 0.01$) while affiliated individuation ($p > 0.05$) and self-care knowledge ($p > 0.05$) were non-significant. The standardized regression coefficient for self-care action was 0.414, indicating that self-care action is the stronger predictor for physical functioning in the model. For a generic quality of life scale, action may supersede the need for self-care knowledge because this instrument was not specifically designed for warfarin patient populations.

In model 1 of the regression analysis in Table 4.11 (displayed under research question two) with SF36 Role Physical as the dependent variable, self-care action was a statistically significant predictor ($F [1,61] = 11.33$, $p < 0.01$) with an R^2 of 0.157, meaning 15.7% of the variance in the model could be explained by self-care action. When the variables self-care knowledge and affiliated individuation were entered in model two of the analysis, affiliated individuation made a significant unique contribution to the model variance. The overall model was statistically significant ($F [3,59] = 9.40$, $p < 0.001$). The R^2 was 0.323, therefore, 32% of the variation in the role-physical scores could be explained by the three variables. The $R^2\Delta$, also statistically significant, added to the model ($R^2\Delta = 0.167$) by increasing the explanation of variance by 16.7%. Both self-care action ($p < 0.05$) and affiliated individuation ($p < 0.01$) were statistically significant predictors of role-physical scores, while the variable self-care knowledge ($p > 0.05$) was non-significant. The standardized regression coefficient for self-care action was 0.324 and for affiliated individuation, it was 0.391. These results indicate that after controlling for self-care action, affiliated individuation is a significant and unique predictor for role-physical in the model. Perhaps this can be explained as the inherent need to maintain control and identity that is inherent in the concept of affiliated individuation. Thus, higher self-care action and affiliated individuation scores would be associated with improved role-physical scores.

Table 4.12 (displayed under research question two) exhibits the results for the regression analysis using the SF36v2 bodily pain scale as the dependent variable. In model 1 of the analysis, self-care action was a significant predictor of bodily pain ($F [1,62] = 4.05, p < 0.05$), with an R^2 of 0.061, meaning 6.1% of the variance in the model could be explained by self-care action. With the addition of the variables affiliated individuation and self-care knowledge in model 2, the model is again statistically significant ($F [3,60] = 4.61, p < 0.01$). The R^2 was 0.187, indicating that 18.7% of the variation in the SF36v2 bodily pain score could be explained by the model variables. The $R^2\Delta$ was also statistically significant when the two variables were added to the model ($R^2\Delta = 0.126$), contributing 12.6% to the variation explanation. Affiliated individuation became the most statistically significant predictor of bodily pain scores ($p < 0.01$), while self-care action ($p > 0.05$) and self-care knowledge ($p > 0.05$) were not significant. The standardized regression coefficient for affiliated individuation was 0.336; indicating that after controlling for self-care action, when added to the model, affiliated individuation became the sole unique significant predictor for bodily pain.

This finding is interesting with respect to affiliated individuation being the only significant predictor in the model. The mind-body-spirit connection inherent in modeling and role-modeling theory's concept of affiliated individuation may make this resource effective not only in pain management but also in stress reduction and general well-being.

The regression results using the SF36v2 role-emotional as the dependent variable are displayed in Table 4.13 (displayed under research question two). In the first step of the analysis, self-care action was again a significant predictor of role-emotional ($F [1,62] = 15.59, p < 0.001$), with an R^2 of 0.204, meaning 20.4% of the variance in the model could be explained by self-care action. In the second step, the overall model was again highly statistically significant ($F [3,59] =$

7.23, $p < 0.001$), the R^2 was 0.269, indicating that 26.9% of the variation in the SF36v2 role-emotional score could be explained by the three model variables. The $R^2\Delta$ was not statistically significant when affiliated individuation and self-care knowledge were added to the model ($R^2\Delta = 0.065$) adding only 6.5% to the model variance. Both self-care action ($p < 0.01$) and affiliated individuation ($p < 0.05$) were statistically significant predictors of role-emotional scores, while the variable self-care knowledge ($p > 0.05$) was not significant. The standardized regression coefficient for self-care action was 0.416 and for affiliated individuation was 0.251, indicating self-care action remains the strongest predictor variable, followed by an additional significant prediction contribution from affiliated individuation for role-emotional scores.

Being able to perform self-care actions may be enhanced by the addition of affiliated individuation. As discussed for the previous results on bodily pain, affiliated individuation is closely associated with well-being. We could speculate that well-being and emotional health are also closely connected. Potentially, a person on warfarin would have the ability to perform self-care actions while simultaneously remaining independent of the healthcare system. This concept is also centered on well-being and good emotional health. High levels of self-care action and affiliated individuation in persons on warfarin would be associated with better emotional scores.

Table 4.5 displays a summary of the results from all of the regression procedures. It is apparent that in linear regression models self-care action is the most strongly related predictor variable. This may be attributed in part to the need for action as part of any health care regime. A person on warfarin will not remain healthy without some degree of self-care-related action on his or her part. Results from hierarchical regression analysis allowed for the identification of other valuable variables such as affiliated individuation, that when self-care action is controlled for, become statistically significant contributors to the model variance. The contribution by the

variable affiliated individuation was evident in three out of the four SF36v2 subscales. This finding is interesting and may be attributed in part to the large role affiliated individuation may play in overall well-being. This will be discussed in greater detail in Chapter Five.

Table 4.5.
Summarized Results of Hierarchical Multiple Regression Analysis for Research Question One

Variable	Self-Care Action	Affiliated Individuation	Self-Care Knowledge
DASS Negative Impact	$\beta = -0.32$ $p = 0.005$	NS	NS
DASS Limitations	$\beta = -0.506$ $p = 0.001$	NS	NS
DASS Hassles/Burdens	NS	NS	NS
SF36v2 Physical Function	$\beta = 0.414$ $p = 0.006$	NS	NS
SF36v2 Physical Role	$\beta = 0.324$ $p = 0.016$	$\beta = 0.391$ $p = 0.001$	NS
SF36v2 Bodily Pain	NS	$\beta = 0.336$ $p = 0.01$	NS
SF36v2 Emotional Role	$\beta = 0.416$ $p = 0.001$	$\beta = 0.251$ $p = 0.04$	NS

QUESTION TWO

The second research question (“What are the moderating effects of self-care knowledge and affiliated individuation as a self-care resource between self-care action and quality of life for persons on long-term oral anticoagulation therapy?”) was answered using hierarchical multiple regression procedures.

The hierarchy of variable entry was based on the conceptual model for the study. In the model self-care actions directly influence quality of life. Self-care knowledge and affiliated individuation both influence self-care actions thus also impacting quality of life. Self-care action was entered into Model 1. Affiliated individuation and self-care knowledge were entered into Model 2. The interaction variable for affiliated individuation and self-care action and the interaction variable for self-care knowledge and self-care action were entered into Model 3. The initial analysis resulted in multicollinearity when the interaction terms were entered into the models. An example of this is displayed in Table 4.6.

The overall model was statistically significant ($p < 0.05$), but the interaction terms were not significant contributors to the model. The VIF for both interaction terms was also greater than 10, indicating high multicollinearity. This is to be expected in non-experimental social

science data because the independent variables are usually highly correlated (Lewis-Beck, 1980, Berry, & Feldman, 1985, Tabachnick, & Fidell, 2001).

To reduce the chances of multicollinearity affecting the analysis, the predictor and moderator variables were centered in Model 3. Centering is done by subtracting the mean from each score on the variable to create a new variable representing a deviation score. This facilitates the interpretation of the analysis by using the mean score instead of zero for each distribution (Meyers, et al., 2006, Lewis-Beck, 1980, Berry & Feldman, 1985, Miles & Shevlin, 2007, Tabachnick, & Fidell, 2001).

Table 4.6.

Hierarchical Multiple Regression Analysis Multicollinearity Example for Model 3 for Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-care Action as Interaction Variables on Quality of Life Scale: DASS Negative Impact.

Variables	B	SE B	β	Sig.	TOL	VIF
Model 3						
Self-Care Action (SCA)	-11.11	4.22	-1.14	0.011	0.078	12.84
Affiliated Individuation (AI)	-.281	0.20	-0.403	0.169	0.176	5.67
Self-Care Knowledge (SCK)	-.407	1.27	-0.093	0.750	0.174	5.75
Affiliated Individuation x Self-Care Action	0.004	0.003	0.804	0.197	0.039	25.77
Self-Care Knowledge x Self-care Action	0.001	0.003	0.201	0.716	0.049	20.49

R = 0.435; R² = 0.189; Adjusted R² = 0.115; F (5,55) = 2.566, p = 0.037

Centering of the variables for Model 3 in the regression analysis for moderating effects was completed. The hierarchical regression analyses for all the dependent variables were re-run. The results are presented starting with Table 4.7.

Moderating effects analysis for the DASS negative impact scale found the final model was significant (F [5,55] = 5.04, p = 0.001). This model explained 31.4% (R² = 0.314) of the variance in negative impact scores. The R² Δ significantly improved with the addition of the interaction variables (R² Δ = 0.186). This increased the explanation for the model variance by 18.6%. Self-care action was the only independent predictor variable that significantly predicted negative impacts (p < 0.05). When added to the model the interaction variables affiliated

individuation ($p < 0.05$) and self-care knowledge ($p < 0.01$) were both statistically significant. This indicated that both interaction variables contributed to the prediction of negative impact scores. The standardized regression coefficient for the self-care knowledge x self-care action moderator variable was 0.403. For affiliated individuation x self-care action moderator variable it was 0.258, indicating that while both variables had significant moderating effects; self-care knowledge had the strongest moderating effect on negative impact scores, followed by affiliated individuation.

Table 4.7.
Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-Care Action as Interaction Variables on Quality of Life Scale: DASS Negative Impact

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	-3.483	1.18	-0.353	0.005
Model 2				
Self-Care Action (SCA)	-3.133	1.48	-0.32	0.039
Affiliated Individuation (AI)	-0.020	0.94	-0.029	0.828
Self-Care Knowledge (SCK)	-0.220	0.71	-0.050	0.759
Model 3				
Self-Care Action (SCA)	-3.483	1.38	-0.359	0.014
Affiliated Individuation (AI)	-0.030	0.10	-0.043	0.756
Self-Care Knowledge (SCK)	0.791	0.76	0.181	0.301
Affiliated Individuation x Self-Care Action	0.162	0.80	0.258	0.046
Self-Care Knowledge x Self-care Action	1.011	0.36	0.403	0.007

Beta weights and values are shown from Model 3.

Model 1: $R = 0.353$; $R^2 = 0.125$; Adjusted $R^2 = 0.110$; $F(1,59) = 8.43$, $p = 0.005$

Model 2: $R = 0.358$; $R^2 = 0.128$; Adjusted $R^2 = 0.083$; $F(3,57) = 2.80$, $p = 0.048$; $R^2\Delta = 0.004$

Model 3: $R = 0.561$; $R^2 = 0.314$; Adjusted $R^2 = 0.252$; $F(5,55) = 5.04$, $p = 0.001$; $R^2\Delta = 0.186$

Self-care action is the most statistically significant variable in predicting negative impact scores. When you add the interaction variable self-care knowledge x self-care action, the amount of self-care action, while still significant, becomes less important in the prediction of negative impact scores as the levels of self-care knowledge increase. Lack of action alone would intuitively increase the negative impact of warfarin management. When a person taking warfarin is more knowledgeable about self-care, negative impact would theoretically decrease accordingly related to the level of self-care knowledge as demonstrated in Illustration 4.1.

There is a similar effect noted with affiliated individuation, with increased affiliated individuation the importance of self-care action in the model decreases as seen in Illustration 4.2, but the interaction while significant is not as significant a moderator as self-care knowledge.

Illustration 4.1

Moderating Effect for Self-Care Knowledge on DASS Negative Impact

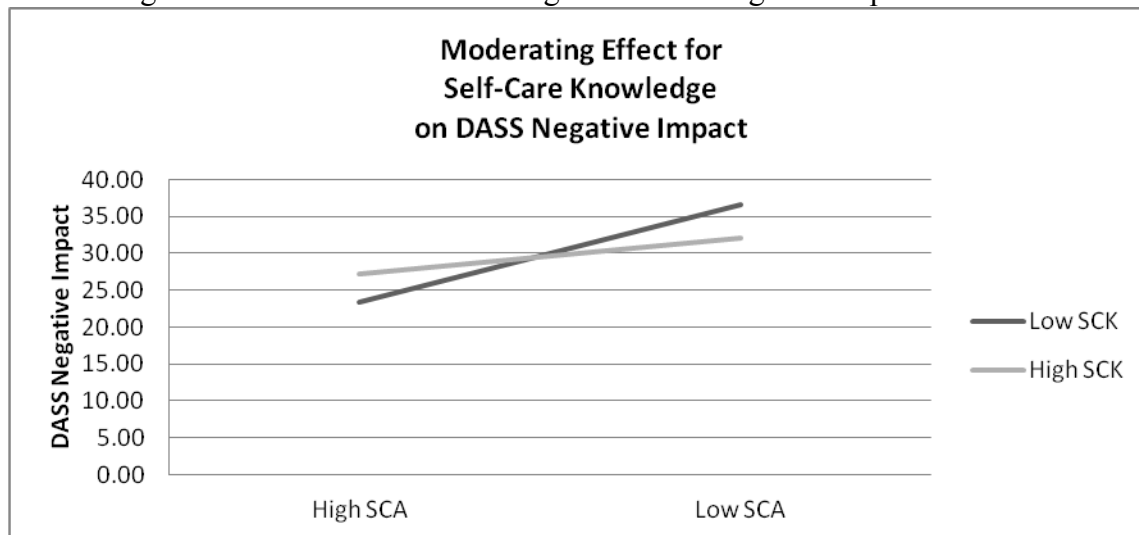
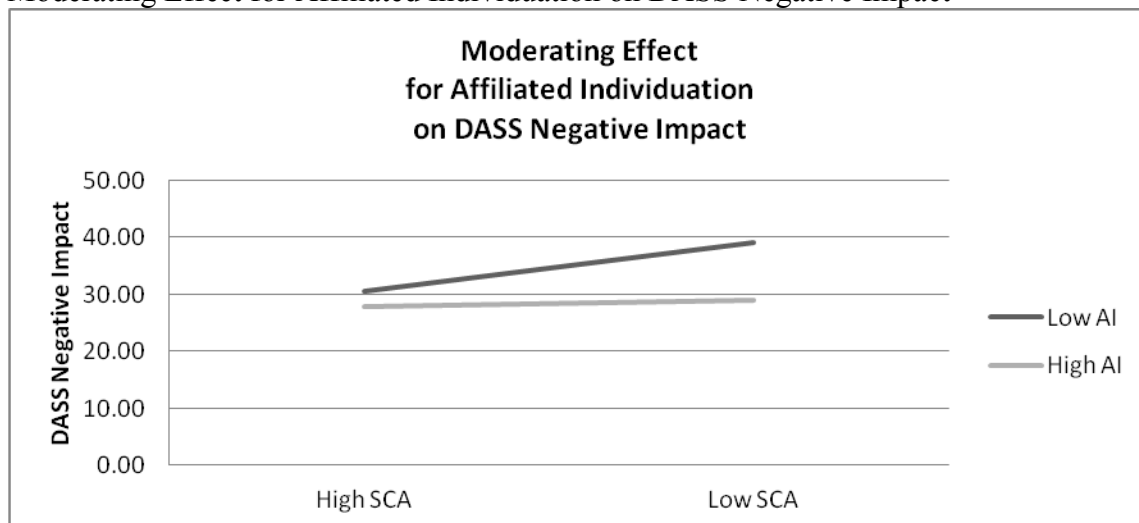


Illustration 4.2.

Moderating Effect for Affiliated Individuation on DASS Negative Impact



The analyses for moderating effects for the DASS limitations scale are shown in Table 4.8. Overall, the model was significant ($F [5,57] = 3.282, p = 0.01$). The model explained 22.4% ($R^2 = 0.224$) of the variance in limitations scores. Self-care action was the only predictor

variable that significantly predicted limitations ($p < 0.001$). Neither affiliated individuation ($p > 0.05$) nor self-care knowledge ($p > 0.05$) moderator variables were statistically significant and did not improve the prediction of limitations scores. The $R^2\Delta$ was also not significantly improved with the addition of the moderator variables ($R^2\Delta = 0.034$). Therefore, with this analysis, there was no moderating effect demonstrated by self-care knowledge or affiliated individuation on self-care action for the prediction of DASS limitation scores.

Table 4.8

Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-care Action as Interaction Variables on Quality of Life Scale: DASS Limitations

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	-2.133	0.60	-0.416	0.001
Model 2				
Self-Care Action (SCA)	-2.598	0.73	-0.506	0.001
Affiliated Individuation (AI)	-.018	0.05	-0.045	0.722
Self-Care Knowledge (SCK)	0.410	0.37	0.170	0.270
Model 3				
Self-Care Action (SCA)	-2.702	0.74	-0.526	0.001
Affiliated Individuation (AI)	-.012	0.06	-0.030	0.837
Self-Care Knowledge (SCK)	0.584	0.44	0.242	0.185
Affiliated Individuation x Self-Care Action	0.048	0.05	0.140	0.288
Self-Care Knowledge x Self-Care Action	0.192	0.21	0.139	0.361

Model 1: $R = 0.416$; $R^2 = 0.173$; Adjusted $R^2 = 0.159$; $F(1,61) = 12.73$, $p = 0.001$

Model 2: $R = 0.436$; $R^2 = 0.190$; Adjusted $R^2 = 0.149$; $F(3,59) = 4.606$, $p = 0.006$; $R^2\Delta = 0.017$

Model 3: $R = 0.473$; $R^2 = 0.224$; Adjusted $R^2 = 0.155$; $F(5,57) = 3.282$, $p = 0.011$; $R^2\Delta = 0.034$

Moderating effects analysis for the DASS hassles/burdens scale (shown in Table 4.9) found that the model was statistically significant ($F[5,56] = 8.051$, $p = 0.001$). This model explained 41.8% ($R^2 = 0.418$) of the variance in hassles/burdens scores. The $R^2\Delta$ significantly improved with the addition of the moderator variables ($R^2\Delta = 0.307$), increasing the explanation for the model variance by 30.7%. None of the predictor variables entered into the model were significant predictors of hassles/burdens ($p > 0.05$). When the moderator variables affiliated individuation ($p < 0.005$) and self-care knowledge ($p < 0.001$) were entered into the model, there was statistically significant improvement in the prediction of hassles/burdens scores. The standardized regression coefficient for the interaction of moderator variable self-care knowledge

with self-care action was 0.517. The standardized regression coefficient for affiliated individuation as a moderator was 0.334, indicating that while both variables had moderating effects; self-care knowledge has the strongest moderating effect, followed by affiliated individuation, on hassles/burdens scores. This supports earlier results that improved self-care knowledge enhances self-care action in persons on warfarin. While affiliated individuation also helps influence the decision to act, knowing when to act is the most strongly associated predictor in lowering hassles and burdens for persons on warfarin.

Table 4.9.

Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-care Action as Interaction Variables on Quality of Life Scale: DASS Hassles/Burdens

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	-1.651	0.73	-0.280	0.028
Model 2				
Self-Care Action (SCA)	-0.957	0.90	-0.162	0.290
Affiliated Individuation (AI)	-0.011	0.06	-0.026	0.847
Self-Care Knowledge (SCK)	-0.547	0.43	-0.206	0.209
Model 3				
Self-Care Action (SCA)	-1.248	0.76	-0.212	0.106
Affiliated Individuation (AI)	-0.019	0.05	-0.044	0.731
Self-Care Knowledge (SCK)	0.248	0.42	0.093	0.556
Affiliated Individuation X Self-Care Action	0.128	0.04	0.334	0.005
Self-Care Knowledge X Self-care Action	0.788	0.20	0.517	0.000

Model 1: $R = 0.280$; $R^2 = 0.078$; Adjusted $R^2 = 0.063$; $F(1,60) = 5.095$, $p = 0.028$

Model 2: $R = 0.334$; $R^2 = 0.112$; Adjusted $R^2 = 0.066$; $F(3,58) = 2.427$, $p = 0.075$; $R^2\Delta = 0.033$

Model 3: $R = 0.647$; $R^2 = 0.418$; Adjusted $R^2 = 0.366$; $F(5,56) = 8.051$, $p = 0.000$; $R^2\Delta = 0.307$

Self-care action on its own is the most important variable in predicting hassles/burdens scores even though we see a non-significant contribution from self-care knowledge. When moderated by higher levels of self-care knowledge, the level of self-care action becomes less important in the prediction of hassles/burdens scores. Hassles/Burdens for persons on warfarin would theoretically decrease when moderated by self-care knowledge as demonstrated in Illustration 4.3.

Illustration 4.3

Moderating Effect for Self-Care Knowledge on DASS Hassles/Burdens

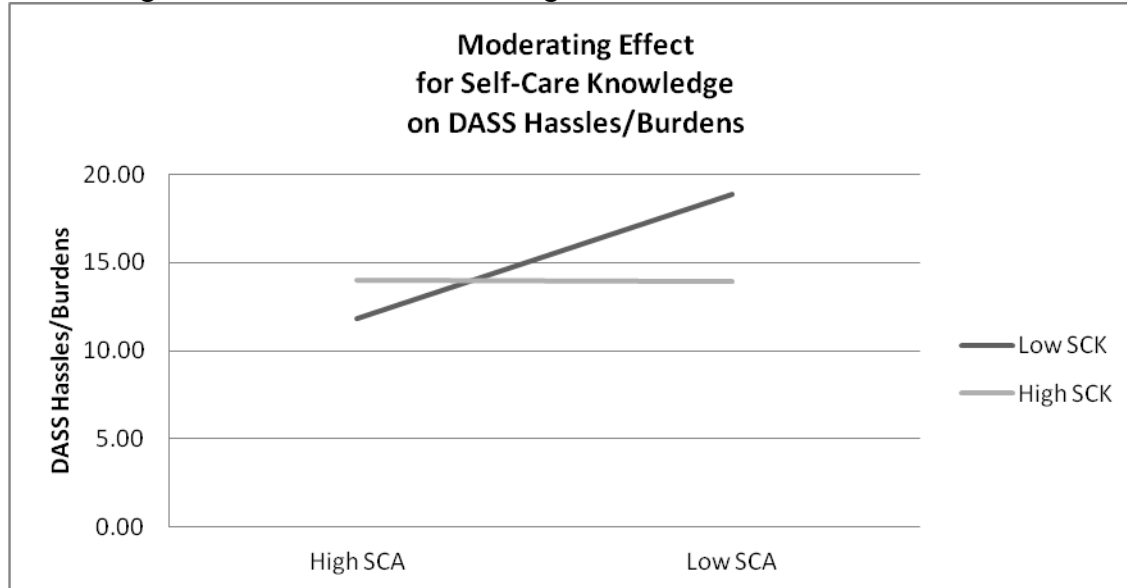
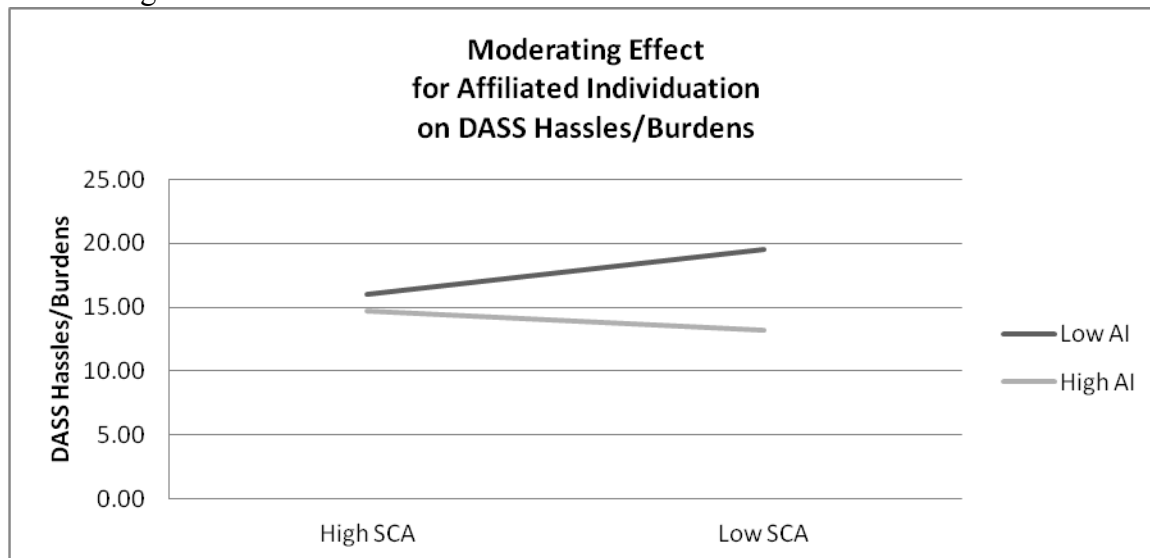


Illustration 4.4

Moderating Effect for Affiliated Individuation on DASS Hassles/Burdens



There is a similar effect noted in self-care action when moderated by affiliated individuation, with increased levels of affiliated individuation the importance of self-care action in predicting hassles/burdens scores decreases, as seen in Illustration 4.4. The interaction of affiliated individuation represents the classic definition of a moderating variable. In model two we saw no relationship between affiliated individuation and the outcome variable but, the interaction effect is significant.

Moderating effects analysis for the SF36v2 physical functioning scale (shown in Table 4.10) found that the final model was significant ($F [5,58] = 4.608, p = 0.001$). This model explained 28.4% ($R^2 = 0.284$) of the variance in negative impact scores. The $R^2\Delta$ significantly improved with the addition of the moderator variables ($R^2\Delta = 0.135$). This increased the explanation for the model variance by 13.5%. Self-care action was the only predictor variable that significantly predicted negative impacts ($p < 0.01$). Its interaction with the self-care knowledge variable was statistically significant ($p < 0.05$), with a standardized regression coefficient of 0.372, indicating that self-care knowledge moderates the prediction of physical functioning. The affiliated individuation interaction variable was not statistically significant and did not moderate the prediction of physical functioning scores. Therefore, with this analysis, there was a moderating effect demonstrated by self-care knowledge but not affiliated individuation.

Table 4.10.

Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-Care Action as Interaction Variables on Quality of Life Scale: SF36v2 Physical Functioning

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	9.675	2.98	0.381	0.002
Model 2				
Self-Care Action (SCA)	10.522	3.66	0.414	0.006
Affiliated Individuation (AI)	0.120	0.25	0.063	0.627
Self-Care Knowledge (SCK)	-0.846	1.84	-0.071	0.647
Model 3				
Self-Care Action (SCA)	10.020	3.48	0.394	0.006
Affiliated Individuation (AI)	0.060	0.26	0.031	0.821
Self-Care Knowledge (SCK)	1.725	2.05	0.145	0.403
Affiliated Individuation X Self-Care Action	0.320	0.21	0.187	0.138
Self-Care Knowledge X Self-care Action	2.552	0.99	0.372	0.012

Model 1: $R = 0.381$; $R^2 = 0.145$; Adjusted $R^2 = 0.131$; $F (1,62) = 10.519, p = 0.002$

Model 2: $R = 0.387$; $R^2 = 0.150$; Adjusted $R^2 = 0.107$; $F (3,60) = 3.521, p = 0.020$; $R^2\Delta = 0.005$

Model 3: $R = 0.533$; $R^2 = 0.284$; Adjusted $R^2 = 0.223$; $F (5,58) = 4.608, p = 0.001$; $R^2\Delta = 0.135$

Moderating effects analysis for the SF36v2 role-physical subscale (shown in Table 4.11) found that the model was significant ($F [5,57] = 5.665, p = 0.001$). This model explained 33.2% ($R^2 = 0.332$) of the variance in negative role-physical. The $R^2\Delta$ was not significantly improved

with the addition of the interaction variables ($R^2\Delta = 0.009$). The predictor variables self-care action ($p < 0.05$) and affiliated individuation ($p < 0.05$) were statistically significant in predicting role-physical scores. Neither affiliated individuation ($p > 0.05$) nor self-care knowledge ($p > 0.05$) moderator variables were statistically significant and did not improve the prediction of role-physical scores. Therefore, with this analysis, there was no moderating effect demonstrated by self-care knowledge or affiliated individuation.

The overall model displayed in Table 4.12 was statically significant. Self-care action and affiliated individuation were both statistically significant predictors of bodily pain. However, none of the predictor variables or interaction variables was statistically significant in the final model.

Table 4.11.

Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-care Action as Interaction Variables on Quality of Life Scale: SF36v2 Role-Physical

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	10.258	3.05	0.396	0.001
Model 2				
Self-Care Action (SCA)	8.399	3.40	0.324	0.016
Affiliated Individuation (AI)	0.770	0.227	0.391	0.001
Self-Care Knowledge (SCK)	0.717	1.71	0.058	0.677
Model 3				
Self-Care Action (SCA)	8.568	3.50	0.331	0.017
Affiliated Individuation (AI)	0.691	0.26	0.350	0.011
Self-Care Knowledge (SCK)	1.726	2.09	0.140	0.413
Affiliated Individuation X Self-Care Action	-0.038	0.21	-0.022	0.859
Self-Care Knowledge X Self-care Action	0.854	0.99	0.122	0.393

Model 1: $R = 0.396$; $R^2 = 0.157$; Adjusted $R^2 = 0.143$; $F(1,61) = 11.329$, $p = 0.001$

Model 2: $R = 0.569$; $R^2 = 0.323$; Adjusted $R^2 = 0.289$; $F(3,59) = 9.395$, $p = 0.000$; $R^2\Delta = 0.167$

Model 3: $R = 0.576$; $R^2 = 0.332$; Adjusted $R^2 = 0.273$; $F(5,57) = 5.665$, $p = 0.000$; $R^2\Delta = 0.009$

Table 4.12.

Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-Care Action as Interaction Variables on Quality of Life Scale: SF36v2 Bodily Pain

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	5.221	2.60	0.248	0.049
Model 2				
Self-Care Action (SCA)	3.926	2.97	0.186	0.191
Affiliated Individuation (AI)	0.532	0.20	0.336	0.010
Self-Care Knowledge (SCK)	0.556	1.49	0.056	0.711
Model 3				
Self-Care Action (SCA)	4.435	3.00	0.210	0.145
Affiliated Individuation (AI)	0.380	0.23	0.240	0.101
Self-Care Knowledge (SCK)	2.182	1.77	0.220	0.222
Affiliated Individuation X Self-Care Action	-0.099	0.18	-0.070	0.593
Self-Care Knowledge X Self-care Action	1.421	0.85	0.249	0.100

Model 1: $R = 0.248$; $R^2 = 0.061$; Adjusted $R^2 = 0.046$; $F(1,62) = 4.049$, $p = 0.049$

Model 2: $R = 0.433$; $R^2 = 0.187$; Adjusted $R^2 = 0.147$; $F(3,60) = 4.606$, $p = 0.006$; $R^2\Delta = 0.126$

Model 3: $R = 0.474$; $R^2 = 0.225$; Adjusted $R^2 = 0.158$; $F(5,58) = 3.369$, $p = 0.010$; $R^2\Delta = 0.038$

Table 4.13

Hierarchical Multiple Regression Analysis of Self-Care Action, Self-Care Knowledge, and Affiliated Individuation as Predictor Variables. Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-Care Action as Interaction Variables on Quality of Life Scale: SF36v2 Role-Emotional.

Variables	B	SE B	β	Significance
Model 1				
Self-Care Action (SCA)	9.776	2.48	0.451	0.000
Model 2				
Self-Care Action (SCA)	9.019	2.95	0.416	0.003
Affiliated Individuation (AI)	0.414	0.20	0.251	0.040
Self-Care Knowledge (SCK)	0.183	1.49	0.018	0.903
Model 3				
Self-Care Action (SCA)	9.264	3.06	0.428	0.004
Affiliated Individuation (AI)	0.379	0.23	0.230	0.104
Self-Care Knowledge (SCK)	0.246	1.83	0.024	0.893
Affiliated Individuation X Self-Care Action	-0.076	0.19	-0.052	0.683
Self-Care Knowledge X Self-care Action	0.023	0.87	0.004	0.979

Model 1: $R = 0.451$; $R^2 = 0.204$; Adjusted $R^2 = 0.190$; $F(1,61) = 15.590$, $p = 0.000$

Model 2: $R = 0.518$; $R^2 = 0.269$; Adjusted $R^2 = 0.232$; $F(3,59) = 7.229$, $p = 0.000$; $R^2\Delta = 0.065$

Model 3: $R = 0.521$; $R^2 = 0.271$; Adjusted $R^2 = 0.207$; $F(5,57) = 4.237$, $p = 0.002$; $R^2\Delta = 0.002$

The final model to predict the SF36v2 role-emotional scale (shown in Table 4.13) was significant ($F[5,57] = 4.237$, $p = 0.01$). This model explained 27.1% ($R^2 = 0.271$) of the variance in role-emotional. The $R^2\Delta$ association with the moderator terms did not significantly improve the prediction ($R^2\Delta = 0.002$). Self-care action ($p < 0.05$) and affiliated individuation (p

< 0.05) were the only significant predictors of role-emotional scores. Neither the affiliated individuation ($p > 0.05$) nor self-care knowledge ($p > 0.05$) interaction variables were statistically significant and did not improve the prediction of role-emotional scores. Therefore, with this analysis, there was no moderating effect demonstrated by self-care knowledge or affiliated individuation. With these findings, as well as the other non significant findings for the SF36v2 subscales, there is a possibility that the importance of the predictor variable self-care knowledge is not as impactful to generic, everyday quality of life such as that measured by the SF36v2 except as a moderator in the prediction of physical functioning. Conversely, affiliated individuation demonstrated significant main effects on role-physical, bodily pain, and role-emotional subscales. Even in light of this, we have seen much more significant effects with the variables when they are applied to the unique issues experienced by the population of individuals taking the anticoagulant warfarin.

QUESTION THREE

The third research question (“Which self-care variable self-care knowledge or affiliated individuation most strongly moderates quality of life?”) was also answered using hierarchical regression analysis.

The cumulative results of the moderating effects from the final hierarchical regression models for all of the dependent variables are summarized in Table 4.14. Affiliated individuation demonstrated a moderating effect for the DASS negative impact and DASS hassles/burdens scores. There was no moderating effect demonstrated for the DASS limitations scores or for any of the SF36v2 subscales. Self-care knowledge demonstrated moderating effects for both the DASS negative impact and DASS hassles/burdens scores, as well as the SF36v2 physical functioning subscale scores. Examination of beta weights for both interaction variables finds that the self-care knowledge moderating effect was stronger than that of affiliated individuation.

Table 4.14.

Moderating Effects for Affiliated Individuation x Self-Care Action and Self-Care Knowledge x Self-Care Action Interaction on Dependent Variables

Dependent Variable	Affiliated Individuation x Self-Care Action		Self-Care Knowledge x Self-Care Action	
	β	Sig.	β	Sig.
DASS Negative Impact	0.258	0.046	0.403	0.007
DASS Limitations	0.140	NS	0.139	NS
DASS Hassles/Burdens	0.334	0.005	0.517	0.000
SF36v2 Physical Functioning	0.187	NS	0.372	0.012
SF36v2 Role-Physical	-0.022	NS	0.122	NS
SF36v2 Bodily Pain	-0.070	NS	0.249	NS
SF36v2 Role-Emotional	-0.052	NS	0.004	NS

Summary

This chapter presents the results of the research study. Procedures for data analysis were presented with findings. There were moderate relationships among most of the study variables. The strongest predictor of quality of life in a person on the anticoagulant warfarin was self-care action. In the generic quality of life measurements self-care action and affiliated individuation were both strong predictors of quality of life in three out of the four SF36v2 subscales. There was a statistically significant moderating effect demonstrated by both affiliated individuation x self-care action and self-care knowledge x self-care action interaction variables on both warfarin and generic quality of life subscales.

CHAPTER FIVE

Discussion and Implications

The discussion, conclusions and implications of this study are presented in this chapter. The chapter begins with an overview of the study, followed by a discussion of threats to the external and internal validity of the findings. Each research question is discussed separately, followed by a general discussion of the relationship of the findings to the literature. The last section presents the implications of the study related to nursing theory, research, and practice.

OVERVIEW

The purpose of this study was to investigate the relationships between the concepts of self-care actions, self-care knowledge, affiliated individuation as a self-care resource, and quality of life for persons taking the oral anticoagulant warfarin. Specifically, this study explored moderating effects for the variables self-care knowledge and affiliated individuation as a self-care resource on the outcome variable quality of life for persons taking warfarin. The sample consisted of 83 adults taking warfarin for at least three months who were willing to complete the instrument packet.

Study results indicate that significant relationships exist among the predictor variables self-care action, self-care knowledge, and affiliated individuation and the outcome variable quality of life. Self-care action explained significant variances in five of the eight quality of life subscales. When self-care knowledge and affiliated individuation were added to the model, self-care knowledge was not a significant independent predictor of quality of life in any of the instrument subscales. Affiliated individuation was a significant predictor in three of the SF36v2 subscales, and there was a significant moderating effect when self-care knowledge and affiliated individuation interaction terms were entered into the third model. Self-care knowledge and affiliated individuation demonstrated moderating effects on the DASS negative impact and DASS hassles/burdens subscales. Self-care knowledge also had a significant moderating effect on the SF36v2 physical function subscale.

Discussion of Findings

THREATS TO EXTERNAL VALIDITY

External validity is the degree to which a study can be generalized to populations and settings other than the one used or represented in the study (Polit & Beck, 2004). There are several areas that must be addressed related to generalizability in this study. First, the sample should match the population of the demographic area in which it is conducted. Second, there should be no interaction between the sample selection and the study variables.

The study was conducted in a large anticoagulation clinic in the greater central Texas region. Individuals were approached by the clinic staff after their visit was over. Those who were interested in participating were educated about the study and administered the instrument packet immediately or given a self-addressed stamped envelope to return by mail. Return of the packet was considered consent, and upon completion, the participant received a ten-dollar gift card for time and trouble.

After analysis of the data, the first area of concern for external validity is age. The mean age for the study participants was 68.72 years (SD = 14.37, Range = 30-91). The percentage of adults over the age of 65 in the study area is 7%. Data for the average age of persons on warfarin in this area of Texas was not available. For comparison data, the mean age of subjects in the DASS development study by Samsa, et al., (2004) was 68.7 years. This sample was not homogenous within the location of the study, but the sample was homogenous within similar studies conducted with other individuals being treated with warfarin. This finding is logical given that the guidelines for prescribing warfarin are highly correlated with conditions more commonly associated with older persons, such as atrial fibrillation, heart valve surgery, and venous thromboembolism (Ansell, et al., 2008, U.S. Census Bureau, 2010).

The gender distribution of study participants was closely matched, not only to central Texas; but also the state of Texas as well. The study had more females than males but was reasonably close to the findings for the region and state. There was no threat identified for external validity related to gender (U.S. Census Bureau, 2010).

The majority of study participants were white (78.3%). This resembles findings for the region and state. The percentage of white participants reported in the DASS validation study conducted by Samsa, et al., (2004) was (78%) and almost identical to this study's sample. Black study participants made up (16.9%) of the study sample; this is a better representation than that of the local (8.1%) or state area (11.8%) population percentage. Hispanics are underrepresented, making up only (3.6%) of the sample, while the central Texas area population is (35.1%) Hispanic. The threat to external validity from race is the underrepresentation of Hispanics, Asians, American Indians, and other unrepresented races. The study results may not adequately represent these racial groups. Although many persons of Hispanic ethnicity were invited to participate in the study, the majority refused due to the time constraints of the family or friends that had driven them to the clinic. There were several Hispanic patients who did not qualify due to being non-English-speaking. Any future studies of this patient population should include instruments translated into the Spanish language (U.S. Census Bureau, 2010).

Forty-two percent of the sample had at least a college degree or higher. This is congruent with the Austin Texas area where the study was conducted, which boasts a (44.5%) college-educated general population. It is important to note that; overall, the state of Texas has a (26.1%) college-educated population. Subsequently, while there was no threat to external validity by education level (U.S. Census Bureau, 2010) in Austin Texas it could not be generalized to other areas of the state and country.

The majority (94%) of the study sample had some form of health insurance, with the most being on Medicare (66.3%). This is related in part to the study being conducted in a privately owned clinic. The threat to external validity is that uninsured and underinsured individuals are not well represented, and thus, the results of this study are not representative of that population.

The possibility of selection bias is another concern in this study. All the study participants completed and returned the instruments willingly. All study participants were in the clinic for management of warfarin. This indicates a high probability that they were attentive to

the need for monitoring and following orders from their health care providers. In addition, it may indicate adequate personal resources by their ability to get to the clinic and a probable, basic, understanding of the rationale behind the required INR monitoring. Persons on warfarin who lack the resources, motivation, or understanding of the need to monitor the INR may not have been represented and variability of the data was reduced.

THREATS TO INTERNAL VALIDITY

Internal validity is the inference that the independent variable is responsible for the observed effects on the dependent variable, rather than it being a random finding (Polit & Beck, 2004). The concerns related to internal validity in this study include history, sample selection, and instrumentation.

The stability of the subjects warfarin use is a concern because there was no review of medical records. The study relied on the memory and forthrightness of each individual. There was no way to identify whether the subjects had patterns of stable INRs and/or had participated fully in their warfarin management.

Sample selection concerns were related to the possibility that data obtained from a large anticoagulation clinic might differ from that of an oncology practice or a primary care office. Guidelines for the management of warfarin suggest that referring persons on warfarin therapy to clinics specializing in anticoagulation have better outcomes than those in primary care. Even with these research findings, there are specialists such as cardiologists and oncologists, as well as primary care providers, who are comfortable managing persons on warfarin (Ansell, et al., 2004).

A concern over sample selection is related to the possibility that access to potential subjects meeting the study criteria may not have occurred due to the researcher's inability to remain at the clinic for a longer period of time. Although the primary investigator and/or the research assistants came daily to the clinic for four weeks, some patients only come in every four to six weeks and could have easily missed the window of time the researcher and research assistants were present.

Discussion of Study Results

QUESTION 1

Research Question 1 asked: What are the relationships among self-care knowledge, affiliated individuation as a self-care resource, self-care actions, and quality of life for persons on long-term oral anticoagulation therapy? Bivariate correlation procedures and multiple regression analysis were used to answer this question.

Self-Care Action

As discussed in Chapter Four, the reliability for the OAK self-care action subscale was 0.46. (This was after the removal of item 11). Since the scale only consisted of six items to begin with, removing this item increased the alpha, but removal of additional items again lowered the alpha. The 0.46 alpha is felt to be related to the small number of items in the subscale and weak inter-item correlations. In light of this, results from the analyses using this subscale will require closer scrutiny. The decision to use the instrument was influenced by the presence of the strong theoretical framework driving the study, as well as the lack of other suitable warfarin self-care instruments.

Self-care action was highly correlated with self-care knowledge, the DASS negative impact and DASS hassles and burdens subscales, and the SF36v2 physical function, role-physical, and role-emotional subscales. When examined using regression analysis, self-care action was the only statistically significant predictor of quality of life in all of the instrument subscales. These results make sense when compared to the research study's theoretical model. In the theoretical model (depicted in Figure 1.0), self-care action directly influences quality of life. The model suggests that for a person on warfarin therapy, self-care action, when taken in response to identified needs, improves their quality of life by reducing warfarin-related stressors and adverse effects. In addition, self-care knowledge and affiliated individuation have directional arrows to self-care action as well as to strengthen the directional arrow from self-care action towards quality of life.

Self-care action, when initiated by a person on warfarin, can be strengthened by moderating effects from self-care knowledge and affiliated individuation to further improve quality of life. (The moderating effects of self-care knowledge and affiliated individuation are discussed in Research Question 2). A person's ability to identify and perform self-care action is improved by increased self-care knowledge and affiliated individuation. When self-care action is initiated, he or she will be able to benefit from action results while simultaneously maintaining independence. For example, a person on warfarin would be expected to know that excessive bruising might indicate an out-of-range INR. This would ideally prompt self-care action to seek assistance or, in some cases, initiate action immediately by testing his or her INR. The next self-care action would be decided based on the outcome of the INR test. In a recent meta-analysis, researchers found multiple studies supporting improved overall satisfaction and quality of life for persons who self-tested their INR. This form of self-care action also resulted in fewer adverse events related to long-term warfarin therapy (Bloomfield, et al., 2011).

Several studies conducted on self-care behaviors and practices among heart failure (HF) patients found similar influences by both internal and external factors, including resource availability, knowledge, age, and experience. The studies also found that even when study participants knew to do certain activities to maintain their health, many did not do them, resulting in alterations in health, or the participants gave what they knew to be socially desirable answers. Knowledge alone for these study participants was not enough; self-care activities (actions) were significant in the absence of knowledge, though there were significant reductions in hospital readmissions among participants who were more informed and had greater participation in self-care activities (Artinian, Magnan, Sloan, & Lange, 2002, Baas, 2004, Ni, et al., 1999, Schnell-Hoehn, Naimark, & Tate, 2009).

When self-care knowledge and affiliated individuation are added to model two, self-care knowledge and affiliated individuation contributed in some models, but self-care action was the strongest and most significant predictor variable for quality of life. The presence of self-care knowledge does not always ensure greater self-care action. Several studies have found a lack of

change in self-care behaviors in relation to increased self-care knowledge. A study on knowledge and its influence on self-care behaviors in HF patients found that out of 69 patients that knew they needed to weigh themselves every day, only 40 actually did weigh themselves (Ni, et al., 1999). In other studies, even low levels of education were correlated with self-care, but lack of self-care was attributable to many other factors such as social support, living alone, and low self-confidence. Even so, knowledge and self-care were correlated with better outcomes (Artinian, et al., 2002, Carlson, Riegel, & Moser, 2001).

According to MRM theory, it is the individual's perspective that drives interventions for optimal health, remembering that it is the person who decides what optimal health means to him or her and, in response to these decisions, what actions are required (Erickson, et al., 1983). The relationship between the self-care variables in the theoretical model is directional. It begins when the individual initiates self-care action. The results of this action impact quality of life. The decision to act is completely reliant on that person's perspectives and what interventions he or she feels are needed to maintain his or her perceptions of optimal health.

Self-Care Knowledge

The OAK self-care knowledge instrument had acceptable reliability, with an alpha of 0.78. Self-care knowledge was highly correlated with self-care action, this goes along with the premise that higher levels of self-care knowledge increase self-care actions by persons on warfarin. Self-care knowledge was also highly correlated with the DASS hassles/burdens subscale but not the DASS negative impact or DASS limitations subscales. There are significant correlations with all of the SF36v2 subscales except physical function. Unfortunately, when self-care knowledge is entered into the regression model at step two, there is no statistically significant contribution to the model.

Self-care knowledge is an important part of many programs to promote health and reduce readmissions to hospitals for specific patient populations. Several studies on self-care knowledge and patient education have been done for persons on warfarin. In a study on patients' warfarin

knowledge and control over the INR, for instance, Bloomfield's (2011) meta-analysis found that increased patient knowledge significantly improved outcomes in persons on warfarin (Bloomfield, et al., 2011, Samsa, et al., 2004, Zoella, et al., 2006). Self-care knowledge has also been strongly correlated with fewer exacerbations of symptoms and hospital readmissions in heart failure patients (Schnell-Hoehn, et al., 2009).

Since the OAK instruments are highly correlated to each other in this study, there is a possibility of overlap by self-care knowledge into self-care action, since intuitively you must have some level of knowledge to perform a self-care action in the first place. Multiple studies involving people taking warfarin and other similar patient populations found statistically significant associations among factors such as resources, low self-efficacy, and lack of self-care knowledge. This directly supports this study's findings for persons on warfarin, recognizing that increased self-care knowledge does improve health-related self-care actions for these individuals which logically would suggest better quality of life (Samsa, et al., 2004, Zoella, et al., 2006, Davis, et al., 2005, Barcellona, et al., 2002, Tang, et al., 2003, Baas, 2004, Matsui & Capezuti, 2008, Baas, 1992, Hertz, 1991, Erickson & Swain, 1990).

Affiliated Individuation

The correlations for affiliated individuation are similar to those for self-care knowledge. Affiliated individuation correlated with the self-care knowledge subscale, as well as the DASS negative impacts and DASS hassles/burdens subscales. There were also strong correlations to the SF36v2 subscales of role-physical, bodily pain, and role-emotional. When affiliated individuation is entered into the regression analysis in model two, it contributes to the explanation for the variance in quality of life for the SF36v2 subscales of role-physical, bodily pain, and role-emotional. There was no statistically significant contribution to the model for the DASS warfarin quality of life subscales.

The ability to access health care resources but remain and retain independence is the cornerstone definition of affiliated individuation. Higher levels of affiliated individuation have

been connected to higher levels of life satisfaction by reducing the effects of burden (Acton, 1997). Because of this connection, it is logical that affiliated individuation would help explain the variance in generic quality of life measures, especially when it comes to physical and emotional roles and bodily pain.

Affiliated individuation encompasses a sense of connection, attachment, meaning, and the development of relationships with the world around you that, when present in adequate amounts, becomes a resource in times of need (Acton, 1997, Erickson, et al., 2006). Affiliated individuation is a healthy balance between dependence and independence that is inherent in all individuals. Affiliated individuation allows a person to access his or her inner strength to connect with support systems to satisfy needs and take comfort in maintaining control in times of stress (Acton, 1997, Erickson, et al., 1983).

Studies using concepts similar to affiliated individuation in heart failure patients found that those with greater levels of self-efficacy and self-confidence used self-care knowledge and performed more self-care actions, producing better outcomes, including fewer hospitalizations (Carlson, et al., 2001, Ni, et al., 1999, Schnell-Hoehn, et al., 2009). These studies support the theoretical model by indicating that increases in affiliated individuation enhance self-care action's influence on quality of life.

QUESTION TWO

Research Question 2 asked: “What are the moderating effects of self-care knowledge and affiliated individuation as a self-care resource between self-care action and quality of life for persons on long-term oral anticoagulant therapy?”

A moderator is an independent variable that affects the strength or direction of another independent variable. Thus, the association of the independent variable on the outcome variable will depend on the value of the moderating variable (Bennett, 2000, Barron & Kenny, 1986). Moderators are an important part of the data analysis process, bringing new information and ideas to light. Moderators can assist in the identification of more appropriate research methods

and identify special populations that may not respond to standard treatment interventions (Kraemer, Wilson, Fairburn, & Agras, 2002).

Inadequate testing for moderator effects has been noted in multiple studies. In a review of the literature, in 89 randomized clinical trials (RCTs) of patient blood glucose monitoring and diabetes control, the authors found a lack of testing for both moderators and mediators, citing a possible reason being a bias in the way medical investigators view the purpose of RCTs. Because the emphasis on testing for moderators has been weak, the underlying studies have not been effective due to weak hypotheses and would often yield weak, nonsignificant moderating results (Kraemer, et al., 2002). In a recent integrative review on colorectal cancer screening, 33 RCTs were reviewed. The authors also cited a lack of evaluation on intervention variables for both mediating and moderating effects (Rawl, Menon, Burness, & Breslau, 2012).

Subsequently, research that could have generated new hypotheses, ideas, and additional research was not evaluated for additional clinical significance (McAndrew, Schneider, Burns, & Leventhal, 2007). One reason cited was a problem with ambiguity between mediators and moderators and their directionality (Kraemer, Stice, Kazdin, Offord, & Kupfer, 2001). In another article, Kraemer, et al., (2002) proposed the consistent use of theory to identify possible mediators and moderators; this, in turn, would generate new hypotheses that would broaden the scope of the research area. After moderators are identified, they should be tested in their own right (Kraemer, et al., 2001, Kraemer, et al., 2002).

This study's data collection and analysis were guided by strong theoretical and moderating models. The variables identified as potential moderators were felt to have the potential to strengthen the relationship between self-care action and quality of life. Analysis of the interaction variables found statistically significant moderating effects for both self-care knowledge and affiliated individuation with the DASS negative impact and DASS hassles/burdens subscales. While both interaction variables were significant, self-care knowledge had the strongest moderating effect of the two variables. Self-care knowledge also had a significant moderating effect on the SF36v2 physical function subscale.

It is interesting that the moderating effects of self-care knowledge and affiliated individuation were primarily for the warfarin DASS quality of life subscales. As discussed in Chapter One, persons on warfarin face unique situations in regard to their health. They are required to be vigilant about their medications, diet, activity, follow-up appointments, watching for signs of clotting/bleeding, careful about alcohol consumption, and numerous other issues that can directly affect quality of life. The OAK subscales capture the essence of the issues that are everyday life for the person on warfarin. The lack of a moderating effect on the majority of the generic quality of life scales may be due in part to the fact that they are “generic”, and while highly reliable the SF36v2 was not developed for condition specific research. An additional possibility for the lack of moderating effect for affiliated individuation could be the strong independent effects of affiliated individuation in model two.

The presence of a strong moderating effect by self-care knowledge is logical, given the results from Research Question 1. While self-care action was the only statistically significant predictor variable for all quality of life subscales in model one, when entered into model three, self-care knowledge does not significantly contribute to the model. But the self-care knowledge interaction variable has a statistically significant effect on quality of life for persons on warfarin.

Additional studies finding moderating effects for self-care knowledge on quality of life have not been found. There are studies in which education moderated other aspects of life. In one study, on men with prostate cancer, low education levels significantly moderated the ability to educate the men about prostate cancer. The study also found that extrinsic religiosity moderated uncertainty by improving doctor-patient communication and patient involvement in treatment; reducing uncertainty and improving communication could be considered improvements in quality of life (Mishel, et al., 2003).

The moderating effect found on the SF36v2 physical function subscale validates the moderating effect findings for the DASS subscales. That self-care knowledge plays an important role in health and well-being generally is of special importance for persons on warfarin, due to the increased management requirements inherent in this patient population. Identifying specific

needs for certain patient populations is not limited to those on warfarin. Research on patient education in colorectal cancer screening, consisting of a brochure followed by a letter, had moderating effects for men but not women, thus gaining valuable insight into the special needs of this population (Hart, et al., 1996). A study of colorectal cancer screening in male African-American church members found that there were moderating effects noted for videotaped education over that of lay educators. This effect measured the degree of exposure to education and the resulting effects on screening rates (Campbell, et al., 2004).

The moderating role of self-care knowledge enhances the ability of a person on warfarin to recognize the need for, and ability to, implement a self-care-related action. After the action, this person must again use his or her self-care knowledge to decide if additional action is warranted or if the situation has resolved. This ability to consistently re-evaluate the need for action, while having the confidence to act while maintaining control, is related in part to the moderating effect of the variable affiliated individuation.

The statistically significant moderating effects found for affiliated individuation make sense in light of its definition. Affiliated individuation is the instinctual need to be able to depend on support systems and resources while simultaneously maintaining independence from them (Erickson, et al., 1983). A person on warfarin must be able to access resources such as the lab, doctor's office, or emergency room but at the same time retain the control that goes with the decision-making process. For those on warfarin, higher levels of affiliated individuation work as an internal resource, enhancing quality of life and allowing for the application of self-care knowledge to a situation in order to stimulate self-care action. As a self-care resource, affiliated individuation allows for need satisfaction but not at the cost of independence (Acton, 1997). This is important for a person prescribed warfarin, given the large number of stressors and burdens associated with warfarin management. Also this is especially interesting given both affiliated individuation and self-care knowledge moderated the DASS hassles/burdens subscale and not the DASS limitations subscale.

While persons on warfarin may not feel overly limited by the medication they do feel some degree of hassle and burden. As levels of self-care knowledge and affiliated individuation increase, we find significant reductions in hassles and burdens experienced by persons on warfarin. This could be in part due to the nature of the care required for warfarin patients. Multiple trips to the clinic, lab tests, dose adjustments, and dietary restrictions are just a few of the continual hassles. Bleeding, bruising, travel limitations, activity limitations, and reproduction issues are examples of the burdens this population experiences.

The moderating effects of affiliated individuation in other populations have not been found, but moderating effects for similar variables that, in sufficient quantities, could also be seen as self-care resources were found. Moderating effects for anxiety were found in a study to improve stroke self-care. Increased anxiety was associated with increased smoking. Targeting treatment of anxiety in persons trying to quit smoking was an important outcome of the study (Evans-Hudnall, et al., 2012). In another study evaluating dyspnea in American heart failure patients, depression and anxiety were found to significantly moderate dyspnea and ejection fraction. Regardless of the ejection fraction, depression and anxiety worsened dyspnea. Conclusions from the study suggest that treatment of depression and anxiety would, in this study, lessen symptoms of dyspnea (Huang, et al., 2013). Additionally, perceived empathy from the doctor moderated the understanding of information in Taiwanese orthopedic patients. The more patients felt the doctor connected with them and understood their concerns, the more the patients were able to understand and retain pre-operative education (Chu & Tseng, 2013). While not identical to affiliated individuation, the treatment of anxiety and depression and the presence of empathy from caregivers provide examples of similar moderating effects that like affiliated individuation, could be considered resources for specific patient populations.

QUESTION THREE

Research Question 3 asked: “Which self-care variable (self-care knowledge or affiliated individuation) most strongly moderates quality of life?” The self-care variable that most strongly

moderates quality of life was determined to be self-care knowledge, followed by affiliated individuation. Findings from this study are consistent with the statistical model predicting the moderating effects for self-care knowledge and affiliated individuation on quality of life for persons on warfarin.

It is logical that self-care knowledge would have stronger moderating effects, given the need for that knowledge to implement strategies for self-care. Affiliated individuation would appear to be a “silent partner” in a supporting role as demonstrated by the significant main effects in model two. Affiliated individuation, when used as a resource, is the driver of self-care action. In the theoretical model, affiliated individuation alone was not a significant predictor of quality of life. But, when used as a resource with self-care knowledge, its moderating effects are clinically significant for this population.

Aspects of affiliated individuation may be affected by levels of depression and anxiety. Reducing levels of anxiety and depression have been shown to significantly moderate the education of orthopedic patients and those with dyspnea in heart failure, as well as the reduction of smoking in stroke patient populations (Evans-Hudnall, et al., 2012, Huang, et al., 2013, Chu & Tseng, 2013). These patient populations are sensitive to self-care interventions and the roles played by emotional issues that may affect self-confidence and feelings of control. This research and that of Acton’s (1997) study, supports the assertion that affiliated individuation is a self-care resource that provides a person with the ability to maintain control over his or her health by accessing resources but not becoming dependent on them. It serves as a particularly strong resource for people on warfarin.

Implications for Nursing

NURSING THEORY

Researchers have found a lack of theory-based hypotheses for moderating effects, limiting the generation of new research (McAndrew, et al., 2007, Kraemer, et al., 2002). In this study, theory guided research. Subsequently, findings have created new research opportunities

for self-care action, self-care knowledge, and affiliated individuation. The findings also support the application of MRM theory in research involving different clinical populations (Erickson, et al., 1983, Acton, 1997).

According to MRM theory, a nurse should be a facilitator for patients, not just someone performing preordained tasks for patients based on what the nurse or predetermined protocols feels is most important. The nurse's interactions with patients should be an interpersonal process that facilitates an individual to mobilize resources that will aid in his or her own recovery (Erickson, et al., 1983).

The study supports the major concepts in the MRM theory and the theoretical model by the significant findings and interactions of self-care knowledge, self-care resources (affiliated individuation), and self-care action for people on warfarin. MRM theory contends that a person's ability to manage stressors is directly related to his or her ability to satisfy needs. To satisfy needs, a person must have the resources available to meet these needs, and meeting needs requires action (Erickson, et al., 1983). In light of this, it is not surprising that self-care action was significantly associated with all of the quality of life subscales. While self-care knowledge and affiliated individuation were not consistently significant after being added to the hierarchical regression model, both had significant moderating effects on warfarin-specific quality of life instruments.

The significance and role of each variable has been studied. The application of MRM theory to these variables would allow a nurse to evaluate the needs of people taking warfarin. In addition, any evaluation would be holistic and from the point of view of a person taking warfarin. After collection of information, the nurse would analyze it and develop specific interventions to manage and/or reduce deficiencies perceived by that individual. Developing a personal understanding of what is needed by someone taking warfarin allows a connection that will assist him or her in remaining in a state of equilibrium and optimum health (Erickson, et al., 1983).

For example, say a nurse is assessing Tom, who is taking warfarin for a DVT. Using MRM theory, the nurse discovers that he has been avoiding all green vegetables in his diet. From his perspective, the fear of making the warfarin ineffective was increased in the presence of the dietary restrictions. He felt unable to confidently decide what green vegetables he could eat, so he decided to avoid all of them. Understanding this, the nurse could guide Tom by educating him about his diet in a safe environment, give him examples of meals that are acceptable, and allow him to practice developing personal menus for home using foods he was familiar with in a safe, accepting environment free of judgment. In this example, we see education used to increase self-care knowledge and support and acceptance used to enhance affiliated individuation to promote self-care actions.

Multiple studies have utilized MRM theory for the study of self-care and quality of life. These studies allowed for the development of interventions for heart failure patients, caregivers, and the elderly (Baas, 2004, Matsui & Capezuti, 2008, Baas, 1992, Hertz, 1991, Erickson & Swain, 1990). The application of MRM theory-based nursing care can assist nurses in modeling persons taking warfarin. Modeling is the application of knowledge to understand that person's world from his or her perspective. Understanding feelings related to warfarin might include the frustration, anxiety, worry, fear, and aggravation that are often encountered by warfarin users during routine management of the drug's effects. Then, the nurse would have the information needed to role-model by nurturing and facilitating interventions that are centered on that person's need for optimal health to improve self-care and quality of life (Erickson, et al., 1983).

NURSING PRACTICE

An important factor for nursing practice is the support for the tenants of MRM theory. The findings from this study support the importance of self-care action (the physical act to improve health), self-care knowledge (the education and understanding of the reasoning behind the action), and affiliated individuation (the ability to act but retain independence) on quality of life (therapeutic INR, fewer adverse events, decreased stress and anxiety) for persons on

warfarin. Nursing research has long recognized the need and importance of patient education, especially in special populations of patients (such as those with myocardial infarction or, heart failure, and patients on warfarin) who have unique issues relating to their disease process, types of medication, or treatments they require for their condition (Hennigan, et al., 2006, Baas, 2004, Macabasco, et al., 2011, Seto, et al., 2011, Buck, et al., 2011).

Often, patients are overwhelmed with information and have multiple (disease, medications, dietary, and treatment-related) education needs at one period of time, even though in most cases the information will be needed over a long period of time. The results of this study can improve the ability of healthcare providers to approach each person as unique, modeling his or her world and providing patient-centered care that will include targeted interventions to improve overall health. Satisfaction of the need for safety and complete acceptance will allow patients to draw on these resources later, thus becoming able to perform self-care activities (Erickson, et al., 1983, Acton, 1997).

This study highlights the importance of condition-specific education and the need for a nurse to have a unique understanding of how warfarin affects patients. The nurse's interactions with a patient on warfarin should be an interpersonal process that facilitates the patient to recognize and mobilize all available resources that he or she perceives will aid in his or her own recovery. The modeling process is most important here due to the unique and often varied experiences people have had while taking warfarin. What warfarin treatment means to one person will not be the same for another. In addition, people on warfarin may be unfamiliar with what interventions may be needed to maintain their perceived level of health while preventing complications (Erickson, et al., 1983).

Nurse assessments of people on warfarin must be from the person's perspective regarding their greatest educational needs, what resources they require, and their feelings of affiliated individuation or ability to access healthcare resources but retain independence and control over their health. Using this information, the nurse can develop interventions that assess education

levels and affiliated individuation potential, and the nurse will also be able to assist patients in developing strategies to balance the demands of safe warfarin use with those of everyday life.

NURSING RESEARCH

The results of this study have multiple implications for further nursing research. This study should be replicated with a larger and more diverse population, paying special attention to increasing the number of Hispanic and rural participants. The independent variables in this study need to be explored in relation to the demographic variables through secondary analysis. This is especially true for income, education, race, and age. This analysis would be more productive if done on a study with a much larger number of participants.

Replication of this study should be done in other populations of patients with unique health issues, such as persons with HF, asthma, or diabetes. Outcomes of these studies could validate the importance of self-care action, self-care knowledge, and affiliated individuation as a self-care resource. Interventions could then be developed to improve quality of life for specific populations, with a diagnosis requiring increased education and self-care awareness from a patient. Additional studies would further support the assumptions in Chapter One stating that MRM theory is acceptable for clinical practice research and especially so for more complicated patient populations.

Development of instruments designed to measure levels of self-care action and affiliated individuation might also be helpful for future research, given the positive results of both this study and Acton's (1997) study. Additional studies using affiliated individuation as a resource are needed to validate the results from these previous studies.

Qualitative research would be valuable in determining whether "the meaning" of affiliated individuation followed the major domains of the concept outlined as self-actualization, esteem/self-esteem, love/belonging, and safety/security by Erickson (1983). The lived experiences of persons on long-term anticoagulant therapy might be useful in determining priorities for interventions to reduce stress, anxiety, and burdens.

Summary and Conclusion

The advancement of health care has brought many changes in how patients are treated. There are more and more developments that are allowing people with chronic conditions to move away from dependence on healthcare and into a more autonomous role in managing their own health conditions. With this advancement comes a greater need to educate and evaluate people in order to ascertain their abilities to manage their conditions in an outpatient environment. This is especially true for people taking warfarin.

Great progress has been made in the management of warfarin, and practitioners have slowly started moving towards more standardized procedures for testing, education, and the other myriad of issues associated with warfarin management. The results of this study could be used to develop assessment tools that could evaluate a patient's level of self-care potential and his or her educational needs. This would allow nurses to concentrate educational interventions specific to the area of need saving time and boosting educational productivity and the retention of information.

The assessment of affiliated individuation would assist in developing guidelines to determine which individuals are best suited for more independent roles in their health and the appropriateness for more independent self-management programs, such as point-of-care INR self-testing in the home with self-management of doses.

This chapter discussed the findings of a descriptive, correlational, cross-sectionally designed study that examined the relationships between self-care action, self-care knowledge, and affiliated individuation as a self-care resource for persons on chronic warfarin therapy. The results were discussed and compared to previous research. Limitations and conclusions were reviewed, recommendations for future research were posited, and implications for nursing theory and practice were discussed. This study is an early step towards developing interventions to improve quality of life for persons on chronic warfarin therapy.

Appendix A: University of Texas at Austin IRB Approval Letter



OFFICE OF RESEARCH SUPPORT

THE UNIVERSITY OF TEXAS AT AUSTIN

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FWA # 00002030

Date: 06/18/12

PI: Leigh A Goldstein

Dept: Nursing

Title: Relationships among Quality of Life, Self-care, and
Affiliated Individuation in Persons on Chronic
Warfarin/Coumadin Therapy: Testing a New Theoretical
Framework Derived from Modeling and Role-Modeling Theory

Re: IRB Expedited Approval for Protocol Number 2012-03-0111

Dear Leigh A Goldstein:

In accordance with the Federal Regulations the Institutional Review Board (IRB) reviewed the above referenced research study and found it met the requirements for approval under the Expedited category noted below for the following period of time: 06/15/2012 to 06/14/2013. *Expires 12 a.m. [midnight] of this date.* If the research will be conducted at more than one site, you may initiate research at any site from which you have a letter granting you permission to conduct the research. You should retain a copy of the letter in your files.

Expedited category of approval:

- ☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review). (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- ☐ 3) Prospective collection of biological specimens for research purposes by non-invasive means. Examples:
 - (a) Hair and nail clippings in a non-disfiguring manner.

- (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - (c) Permanent teeth if routine patient care indicates a need for extraction.
 - (d) Excreta and external secretions (including sweat).
 - (e) Uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue.
 - (f) Placenta removed at delivery.
 - (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
 - (h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
 - (i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
 - (j) Sputum collected after saline mist nebulization.
- ☐ 4) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).
Examples:
- (a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
 - (b) Weighing or testing sensory acuity.
 - (c) Magnetic resonance imaging.
 - (d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.
 - (e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- ☐ 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.
- ☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- ☒ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.
- ☒ Use the attached approved informed consent document(s).
- ☒ You have been granted a Waiver of Documentation of Consent according to 45 CFR 46.117 and/or 21 CFR 56.109(c)(1).

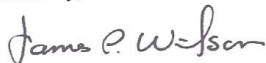
☐ You have been granted a Waiver of Informed Consent according to 45 CFR 46.116(d).

Responsibilities of the Principal Investigator:

1. Report immediately to the IRB any unanticipated problems.
2. Submit for review and approval by the IRB all modifications to the protocol or consent form(s). Ensure the proposed changes in the approved research are not applied without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. Changes in approved research implemented without IRB review and approval initiated to eliminate apparent immediate hazards to the subject must be promptly reported to the IRB, and will be reviewed under the unanticipated problems policy to determine whether the change was consistent with ensuring the subjects continued welfare.
3. Report any significant findings that become known in the course of the research that might affect the willingness of subjects to continue to participate.
4. Ensure that only persons formally approved by the IRB enroll subjects.
5. Use only a currently approved consent form, if applicable.
Note: Approval periods are for 12 months or less.
6. Protect the confidentiality of all persons and personally identifiable data, and train your staff and collaborators on policies and procedures for ensuring the privacy and confidentiality of subjects and their information.
7. Submit a Continuing Review Application for continuing review by the IRB. Federal regulations require IRB review of on-going projects no less than once a year a reminder letter will be sent to you two months before your expiration date. If a reminder is not received from Office of Research Support (ORS) about your upcoming continuing review, it is still the primary responsibility of the Principal Investigator not to conduct research activities on or after the expiration date. The Continuing Review Application must be submitted, reviewed and approved, before the expiration date.
8. Upon completion of the research study, a Closure Report must be submitted to the ORS.
9. Include the IRB study number on all future correspondence relating to this protocol.

If you have any questions contact the ORS by phone at (512) 471-8871 or via e-mail at orsc@uts.cc.utexas.edu.

Sincerely,



James Wilson, Ph.D.
Institutional Review Board Chair

Appendix B: Letter of Permission for Research Location



Polly Mock, RN, CCRC
Clinical Research Manager
Austin Heart PLLC
3801 N. Lamar, Suite 300
Austin, TX 78756

February 8, 2012

University of Texas at Austin School of Nursing
1700 Red River Street
Austin, TX 78701

RE: Leigh A. Goldstein, MSN, APRN-BC, OCN, ONC

To Institutional Review Board, University of Texas at Austin:

This letter is to inform you that University of Texas at Austin School of Nursing doctoral candidate Leigh A. Goldstein, MSN, APRN-BC, ONC, OCN has been granted permission to recruit participants for her dissertation research study entitled "Relationships among Quality of Life, Self-care, and Affiliated Individuation in Persons on Chronic Warfarin/Coumadin Therapy: Testing a New Theoretical Framework Derived from Modeling and Role-Modeling Theory" at Austin Heart PLLC pending full IRB approval for Mrs. Goldstein study.

The recruitment of participants will consist of placing posters in the Coumadin Clinic with contact information and on site recruitment by the researcher. There will be no access to patient medical record information and all HIPPA guidelines will be followed. I/We have received copies of all materials that will be displayed and approve of them.

Austin Heart PLLC reserves the right to withdraw permission at any time without notice. Austin Heart PLLC will not provide financial or manpower resources for this study.

Please e-mail me at Polly.Mock@HCAhealthcare.com should you need to contact me regarding this letter of permission.

Sincerely,

Polly Mock, RN, CCRC
Clinical Research Manager
Austin Heart PLLC

Appendix C: Recruitment Flier

Are you currently taking the medication Coumadin/warfarin?

Seeking Study Participants

Purpose of the study: To explore quality of life and self-care for persons on long term warfarin therapy.

What does the study involve?

- ❖ Complete a series of short questionnaires (about one-half to one hour).
- ❖ Return the completed questionnaire booklet to the researcher.
- ❖ All information is strictly confidential.
- ❖ Upon completion of the questionnaire packet you will receive a \$10 gift card for time and trouble.

Contact:

Leigh A. Goldstein, MSN, ANP-BC, ONC, OCN (Doctoral Candidate)
University of Texas at Austin School of Nursing
Phone (512) 968-1812 or Email: lgoldstein@mail.nur.utexas.edu

Appendix D: Research Assistant Procedure Agreement

Procedure Agreement

This procedure has been developed to provide consistent data collection practices. All questions concerning this procedure should be directed to Leigh A. Goldstein, MSN, ANP-BC, ONC, OCN at (512) 968-1812 or send an email to lgoldstein@mail.nur.utexas.edu.

When individuals express interest in the study the following steps must be followed:

1. Determine if the individual fulfills the inclusion criteria
 - a. Long term oral anticoagulation patient (on warfarin greater than three months by self report).
 - b. Over the age of 18.
 - c. Able to read and understand English.
 - d. Willing to participate in the study.
2. Explain the purpose of the study and what they will be asked to do to participate in the study.
 - a. General purpose of study
 - b. Review privacy protection procedures
 - c. Average time commitment of one-half to one hour
 - d. Review the consent process
 - e. Ten dollar gift card on completion of the study

If the individual agrees to participate as a study subject the next steps must be followed:

1. Investigator will ascertain if the subject is able to fill out the instrument now or if they will need to do it at home (see section on taking home).
2. Investigator will perform a detailed review of the information form. The return of the study packet implies consent for participation (first two pages of the instrument packet, instruct them to remove and keep).
3. Investigator will give a description of the information that will be collected by the instruments.
4. Investigator will provide an orientation on filling out the different instruments included in the packet.
5. Investigator will give the packet to the subject and seat them in the designated area to fill out packet.
6. Investigator will collect the instrument packet when completed.
7. Investigator will distribute the ten dollar gift card.

If the individual needs to fill out packet at home these additional steps must be followed:

1. Investigator will collect subject's address and phone number and enter into log (Attachment E)
2. Investigator will mail the instrument packet to the subject with a self addressed stamped envelope SASE (if in person, it will be given to them)

3. Investigator will perform a detailed review of the consent either in person before they go home or by telephone. The return of the study packet implies consent for participation (first two pages of the instrument packet, instruct them to remove and keep)
4. Investigator will instruct subject to use SASE to return the packet as soon as they are done filling it out.
5. Investigator will inform subject that on receipt of the instrument packet the ten dollar gift card will be mailed to them.

General guidelines:

1. All questions related to the study should be directed to the primary investigator.
2. All completed instrument packets will be collected by the primary investigator as soon as possible and remain in sole possession of the primary investigator.
3. All contact information on study subject will remain confidential and will not be disclosed or discussed with anyone but the primary investigator.

I understand and agree to the above procedure:

Signature _____ Date _____

Appendix E: Study Consent

Title: Relationships among Quality of Life, Self-care, and Affiliated Individuation in Persons on Chronic Warfarin Therapy.

Conducted By: Leigh A. Goldstein, MSN, ANP-BC, ONC, OCN
Of The University of Texas at Austin: Doctoral candidate, School of Nursing
Telephone: (512)716-1908, Email: lgoldstein@mail.nur.utexas.edu

Introduction

The purpose of this form is to provide you information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. **If you decide to be involved in this study, returning this study questionnaire packet will be used as evidence of your willingness to participate.** Please remove the consent and keep for your records.

Purpose of the Study

You have been asked to participate in a research study about exploring the way knowledge and other health care resources impact self-care for persons on long term warfarin therapy. This information will be used to possibly develop ways to increase patient knowledge about warfarin and identify potential resources that will help improve quality of life while on warfarin. You are a potential participant in this study because you take the drug warfarin.

What will you to be asked to do?

If you agree to participate in this study, you will be asked to complete a study questionnaire packet containing five short surveys. **The return of the study packet implies consent for your participation.** This study will take from 30 to 60 minutes to complete. If you choose to participate you will be one of approximately 70 participants in this research study.

What are the risks involved in this study?

There are no foreseeable risks to participating in this study other than the time you spend completing the study questionnaire packet, possible loss of confidentiality, and possible fatigue. If you become fatigued, you may take a break from filling out the instrumentation packet and return to it later. You may do this as many times as needed. If at any time you become uncomfortable with this study or its instruments you may discontinue your participation at any time. The only cost of this study is your time.

What are the possible benefits of this study?

You will receive no direct benefit from participating in this study; however, you will have the personal satisfaction gained by assisting in the potential improvement of care for persons taking warfarin.

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with The University of Texas at Austin (University) in anyway.

If you would like to participate please complete the attached study questionnaire packet, remove and keep the first two pages (this information form) and return the packet to the researcher. **The return of the study packet implies consent for your participation.**

Will there be any compensation?

You will receive a \$10 dollar gift card for your time and trouble when you complete and return the study questionnaire packet.

What are my confidentiality or privacy protections when participating in this research study?

This study is confidential and all information collected will be treated in a confidential manner. The forms used in this study will be coded using a number system and will not include your name unless authorized by you for future contact. The records of this study will be stored securely in a locked cabinet and kept confidential. At the end of the study all records will be shredded and destroyed.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher Leigh A. Goldstein, MSN, APRN-BC, ONC, OCN at (512) 968-1812 or send an email to lgoldstein@mail.nur.utexas.edu. Or you may contact the supervising professor Gayle Acton, PhD, RN, CS at 512 471-9081 or send an email to gayle.acton@mail.utexas.edu. This study has been reviewed and approved by The University Institutional Review Board, the study number is _____.

Whom to contact with questions concerning your rights as a research participant?

For questions about your rights or any dissatisfaction with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

Appendix F: Demographic Instrument

DEMOGRAPHIC INFORMATION

I would greatly appreciate your taking a few minutes to answer the following questions: Fill in or circle the best answer.

What is your date of birth? _____

What gender are you?

- 1=Male
- 2=Female

What racial or ethnic group do you consider yourself belonging to?

- 1=White
- 2= Black or African American
- 3=Hispanic/Latino
- 4=Asian or Pacific Islander
- 5=Native American or Alaska Native
- 6=Other

What is your highest level of education?

- 1=Less than high school
- 2=High school graduate
- 3=Trade or technical school
- 4=College degree
- 5=Graduate degree

What is your marital status?

- 1=Married
- 2=Single
- 3=Divorced
- 4=Co-habiting Partner
- 5=Widowed

What is your employment status?

- 1=Employed Full Time
- 2=Employed Part Time
- 3=Not Working Because of Disability
- 4=Unemployed
- 5=Homemaker
- 6=Retired

What kind of health insurance do you have?

- 1=Private from employer
- 2=Medicare with supplement
- 3=Medicare alone
- 4=Medicaid
- 5=No health insurance, private pay

What income best describes your total household income?

- 1=Less than \$40,000
- 2=\$40,000 to \$60, 000
- 3=\$60,000 to \$80,000
- 4=\$80,000 to \$100,000
- 5=Over \$100,000

Why are you taking warfarin?

- 1=Atrial Fibrillation
- 2=Heart Valve Surgery
- 3=Blood Clots
- 4=Stroke
- 5=Other
- 6=I don't know

Have you ever been told you had any of the following conditions? (Circle all that apply)

- 1=Stroke
- 2=Heart Failure
- 3=Lung Disease
- 4=Kidney Disease
- 5=Diabetes
- 6=Cancer
- 7=None

Have you ever had major bleeding (required treatment in ER or hospital) since you have been on warfarin?

- 1=Yes
- 2=No

Do you use a pill organizer box for your medications?

- 1=Yes
- 2=No

Who did you get your first education about the drug warfarin?

- 1=Doctor
- 2=Nurse
- 3=Pharmacist
- 4=Hospital
- 5= Other
- 6=No education on warfarin

How many years have you been taking warfarin? _____

Who adjusts (changes) your warfarin dose after your blood test if needed?

- 1=Doctor
- 2=Pharmacist
- 3=Nurse at clinic
- 4=I do my own management
- 5=None, I stay on the same dose

What best describes the area you live in?

- 1=Urban area (large city)
- 2=Suburb (city near a large city)
- 3=Medium size town
- 4=Small town
- 5=Rural (in the country)

You are eligible to receive a ten dollar gift card for your time and trouble. In some cases this will require your mailing address. All personal information including names and addresses will be destroyed at the end of this study. Please indicate that you would like to receive the ten dollar gift card which may have to be mailed, or you may decline the ten dollar gift card

Appendix G: The Oral Anticoagulation Knowledge Test

The Oral Anticoagulation Knowledge Test Version 2

Instructions: For each question, circle the answer **that best reflects how you understand and manage your Coumadin (warfarin)**. Please answer all questions.

1. Missing one dose of warfarin:
 - a. Has no effect
 - b. Can alter the drug's effectiveness
 - c. Is permissible as long as you take a double dose the next time
 - d. Is permissible as long as you watch what foods you eat
2. I can distinguish between different strengths of warfarin tablets by what?
 - a. Color
 - b. Shape
 - c. Size
 - d. Weight
3. Since I am on warfarin therapy I contact the physician or healthcare provider who monitors it when:
 - a. Another physician adds a new medication
 - b. Another physician stops a current medication
 - c. Another physician changes a dose of a current medication
 - d. All of the above
4. Occasionally eating a large amount of leafy green vegetables while taking warfarin can:
 - a. Increase my risk of bleeding from Coumadin (warfarin)
 - b. Reduce the effectiveness of the Coumadin (warfarin)
 - c. Cause upset stomach and vomiting
 - d. Reduce my risk of having a blood clot.
5. Which of the following vitamins interacts with warfarin?
 - a. Vitamin B12
 - b. Vitamin A
 - c. Vitamin B6
 - d. Vitamin K
6. When is it safe to take a medication that interacts with warfarin?
 - a. If I take warfarin in the morning and the interacting medication at night
 - b. If my healthcare provider is aware of the interaction and checks my PT/INR ("Protime") regularly
 - c. If I take my warfarin every other day
 - d. It is never safe to take a medication the interacts with warfarin
7. The PT/INR ("Protime") test is:
 - a. A blood test used to monitor my warfarin therapy
 - b. A blood test that is rarely done while on warfarin
 - c. A blood test that checks the amount of vitamin K in my diet
 - d. A blood test that can determine if I need to be on warfarin
8. Warfarin may be used to:
 - a. Treat people that already have a blood clot
 - b. Treat people that have high blood sugar levels
 - c. Treat people with high blood pressure
 - d. Treat people with severe wounds

9. A patient with a PT/INR (“Protime”) value below their “goal range”:
- Is at an increase for the risk of bleeding
 - Is at an increase for the risk of having a clot
 - Is more likely to have a skin rash from the warfarin
 - Is more likely to experience side effects from warfarin
10. Taking a medication containing aspirin or other non-steroidal anti-inflammatory medications such as ibuprofen (Motrin®/Advil®) while I am on warfarin will:
- Reduce the effectiveness of the warfarin
 - Increase my risk of bleeding from the warfarin
 - Cause a blood clot to form
 - Require me to increase my dose of warfarin
11. Because I am on warfarin I seek immediate medical attention:
- When I skip more than two doses of warfarin in a row
 - When I notice blood in my stool when going to the bathroom
 - When I experience a minor nose bleed
 - When I develop bruises on my arms or legs
12. Skipping even one dose of my warfarin can:
- Cause my PT/INR (“Protime”) to be above the “goal range”
 - Increase my risk of bleeding
 - Cause my PT/INR (“Protime”) to be below the “goal range”
 - Decrease my risk of having a clot
13. Drinking alcohol while taking warfarin:
- Is safe as long as I separate your dose of warfarin and the alcohol consumption
 - May affect my PT/INR (“Protime”)
 - Does not affect my PT/INR (“Protime”)
 - Is safe as long as I am on a low dose
14. When I am on a stable dose of warfarin, I check my PT/INR (“Protime”) once _____?
- A week
 - A month
 - Every other month
 - Every 3 months
15. It is important as a patient on warfarin to monitor for signs of bleeding:
- Only when my PT/INR (“Protime”) is above the goal range
 - At all times
 - Only when my PT/INR (“Protime”) is below the goal range
 - Only when I miss a dose
16. If I miss a dose of warfarin I fix it by _____?
- Doubling up the next day
 - Taking the next scheduled dose and tell my healthcare provider
 - Call my healthcare provider immediately
 - Discontinue warfarin altogether
17. When it comes to diet, since I am taking warfarin I:
- Never eat foods that contain large amounts of vitamin K
 - Keep a diary of all of the foods I eat
 - Consistently eat a diet that includes all types of food
 - Increase the amount of vegetables I eat

18. Each time I get my PT/INR (“Protime”) checked, I:
- a. Skip my dose of warfarin on the day of the test
 - b. Avoid eating high fat meals on the day of the test
 - c. Avoid foods high in vitamin K on the day of the test
 - d. Tell my doctor if I missed any doses of warfarin
19. Which of the following over-the-counter products is most likely to interact with warfarin?
- a. Nicotine replacement therapies
 - b. Herbal/dietary supplements
 - c. Allergy medications
 - d. Calcium supplements
20. A patient with a PT/INR (“Protime”) value above the “goal range”:
- a. Is at an increased risk of having a clot
 - b. Is more likely to have a drowsiness and fatigue from warfarin Is at an increased risk of bleeding
 - c. Is less likely to experience side effects from warfarin

Appendix H: Duke Anticoagulation Satisfaction Scale

Duke Anticoagulation Satisfaction Scale (DASS)

We would like to know how your anti-clot treatment (warfarin) affects you, and what you know and feel about your anti-clot treatment. Please check the answer that best fits your situation. If a question does not apply to you, then check “not much”.

All items have 7 response categories:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

When you have anti-clot treatment you tend to bleed or bruise more easily. You may limit your activities as a result. **Limit** means you do less of the activity, or no longer perform the activity at all.

1. How much does the possibility of bleeding or bruising limit you from taking part in **physical activities** (for example, housework, gardening, dancing, sports, or anything else you would usually do)?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

2. How much does the possibility of bleeding and bruising limit you from **traveling**?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not at all	a little	somewhat	moderately	quite a bit	a lot	very

3. How much does the possibility of bleeding or bruising limit you from getting the **medical care** you need (for example, visiting the dentist, chiropractor, or doctor of your choice)?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

4. How much does the possibility of bleeding or bruising limit your ability to **work for pay**?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

5. **Overall**, how much does the possibility of bleeding and bruising affect your daily life?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

Being on anti-clot treatment may mean changing some of your other habits as well.

6. How much does anti-clot treatment limit your **choice of food** (diet)?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

7. How much does anti-clot treatment limit the **alcoholic beverages** you might wish to drink?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

8. How much does anti-clot treatment limit the **over-the-counter medications** (for example, aspirin, ibuprofen, vitamins) you might wish to take?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

9. **Overall**, how much does anti-clot treatment affect your daily life?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

10. How much of a hassle (inconvenience) are the **daily tasks** of anti-clot treatment?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

11. How much of a hassle (inconvenience) are the **occasional tasks** of anti-clot treatment?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

Considering anti-clot treatment as a whole(that is, both the daily and occasional tasks), please answer the following.

12. How **complicated** do you find your anti-clot treatment to be?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

13. How **time-consuming** do you find your anti-clot treatment to be?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

14. How **frustrating** do you find your anti-clot treatment to be?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

15. How **painful** do you find your anti-clot treatment to be?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

16. **Overall**, how much of a burden do you find your anti-clot treatment to be?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

17. **Overall**, how **confident** are you about handling your anti-clot treatment?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

These last questions ask what you know and feel about your anti-clot treatment.

18. How well do you feel that you **understand the medical reason** for your anti-clot treatment?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

19. How much do you **feel reassured** because of your anti-clot treatment?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

20. How much do you **worry about bleeding and bruising**?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

21. Overall, how much has anti-clot treatment had a **positive impact** on your life?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

22. Overall, how much has anti-clot treatment had a **negative impact** on your life?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

23. **Overall**, how **satisfied** are you with your anti-clot treatment?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

24. Compared with other treatments you have had, how **difficult is your anti-clot treatment to manage?**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

25. How likely would you be to **recommend** this form of anti-clot treatment to someone else with your disease or medical condition?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
not much	a little	somewhat	moderately	quite a bit	a lot	very

Appendix I: Basic Needs Satisfaction Inventory

Basic Needs Satisfaction Inventory

The purpose of this questionnaire is to ask how you feel about your life. Please include the feelings you have now taking into account what has happened in the last 6 months. There is no right or wrong answer.

1	2	3	4	5	6	7
Terrible	Unhappy	Mostly Dissatisfied	Mixed	Mostly Satisfied	Pleased	Delighted

How do you feel about:

1. The physical comfort of your home -- heat, water, lighting, etc.	1	2	3	4	5	6	7
2. Your level of physical activity.	1	2	3	4	5	6	7
3. Your family life - - your spouse, your marriage, children if any	1	2	3	4	5	6	7
4. The chance to know people with whom you feel comfortable	1	2	3	4	5	6	7
5. The extent you are developing yourself & broadening your life	1	2	3	4	5	6	7
6. How secure you are from people who might steal or destroy your property	1	2	3	4	5	6	7
7. The amount of respect you get from others	1	2	3	4	5	6	7
8. Yourself.	1	2	3	4	5	6	7
9. The way you handle the problems that come up in your life	1	2	3	4	5	6	7
10. How much you are accepted and included by others	1	2	3	4	5	6	7
11. The way other people treat you.	1	2	3	4	5	6	7
12. Close adult relatives -- people like parents, or siblings	1	2	3	4	5	6	7
13. The chance you have to enjoy pleasant or beautiful things	1	2	3	4	5	6	7
14. The reliability of the people you depend on	1	2	3	4	5	6	7
15. Your safety.	1	2	3	4	5	6	7
16. How creative you can be.	1	2	3	4	5	6	7
17. The amount of friendship and love in your life.	1	2	3	4	5	6	7
18. Your sex life.	1	2	3	4	5	6	7
19. Your own health and physical condition.	1	2	3	4	5	6	7
20. The amount of fun and enjoyment you have	1	2	3	4	5	6	7
21. The sleep you get.	1	2	3	4	5	6	7
22. How secure you are financially.	1	2	3	4	5	6	7
23. How dependable and responsible people around you are	1	2	3	4	5	6	7
24. The extent to which your world seems consistent and understandable	1	2	3	4	5	6	7
25. The extent to which your physical needs are met	1	2	3	4	5	6	7
26. The way you spend your spare time, your non-working activities	1	2	3	4	5	6	7
27. Your life as a whole.	1	2	3	4	5	6	7






Appendix J: SF36v2 Generic Quality of Life Survey

Your Health and Well-Being






This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. *Thank you for completing this survey!*

For each of the following questions, please mark an ☐ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
				
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
				
<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot ▼	Yes, limited a little ▼	No, not limited at all ▼
a <u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
b <u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
c Lifting or carrying groceries	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
d Climbing <u>several</u> flights of stairs	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
e Climbing <u>one</u> flight of stairs	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
f Bending, kneeling, or stooping	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
g Walking <u>more than a mile</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
h Walking <u>several hundred yards</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
i Walking <u>one hundred yards</u>	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3
j Bathing or dressing yourself	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

All of the time ▼	Most of the time ▼	Some of the time ▼	A little of the time ▼	None of the time ▼
-------------------------	--------------------------	--------------------------	------------------------------	--------------------------

- a Cut down on the amount of time you spent on work or other activities.....☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5
- b Accomplished less than you would like☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5
- c Were limited in the kind of work or other activities.....☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5
- d Had difficulty performing the work or other activities (for example, it took extra effort)☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼

- a Cut down on the amount of time you spent on work or other activities.....☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5
- b Accomplished less than you would like☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5
- c Did work or other activities less carefully than usual.....☐ 1.....☐ 2.....☐ 3.....☐ 4.....☐ 5

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

7. How much bodily pain have you had during the past 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very severe
▼	▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time	
	▼	▼	▼	▼	▼	
a	Did you feel full of life?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b	Have you been very nervous?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c	Have you felt so down in the					

- dumps that nothing could
cheer you up? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
- d Have you felt calm and
peaceful? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
- e Did you have a lot of energy? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
- f Have you felt downhearted
and depressed? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
- g Did you feel worn out? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
- h Have you been happy? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
- i Did you feel tired? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
b I am as healthy as anybody I know	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
c I expect my health to get worse	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
d My health is excellent.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

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 (SF-36v2® Health Survey Standard, United States (English))

Appendix K: OAK Permission Letter

Leigh Goldstein

From: Brodeur, Michael [Michael.Brodeur@acphs.edu]
Sent: Tuesday, September 27, 2011 11:36 AM
To: Leigh Goldstein
Subject: RE: Alterations in the OAK test

Follow Up Flag: Follow up
Flag Status: Flagged

Leigh,

The changes you made are fine in my opinion. In theory any changes to the instrument could affect its validity, but these seem fine from a common sense standpoint. Good luck! Michael

Michael R. Brodeur, Pharm.D., CGP, FASCP
Associate Professor
Department of Pharmacy Practice
Albany College of Pharmacy and Health Sciences
106 New Scotland Ave
Albany, NY 12208
Phone: 518-694-7386
michael.brodeur@acphs.edu

From: Leigh Goldstein [mailto:lag65@austin.rr.com]
Sent: Sunday, September 25, 2011 4:52 PM
To: Brodeur, Michael
Subject: Alterations in the OAK test

Hello Dr. Brodeur,

Just an update on the OAK test, I have had to adjust some of the questions to reflect what people actually do not what they should do. This way it will help me to better measure self-care actions.

If you have a moment would you please look at the instrument and see if it would still be OK for me to use it with the changes I have made?

I have highlighted the changes in red and italicized the self-care action subscale.

Thank you,
Leigh Goldstein, MSN, APRN-BC, ONC, OCN

Appendix L: DASS Permission Letter

Leigh Goldstein

From: Greg Samsa, Ph.D. [greg.samsa@duke.edu]
Sent: Wednesday, August 31, 2011 8:22 AM
To: Leigh Goldstein
Subject: RE: Instrument request
Attachments: image001.gif

You are welcome to use the instrument.

From: Leigh Goldstein [mailto:lag65@austin.rr.com]
Sent: Tuesday, August 30, 2011 7:54 PM
To: Greg Samsa, Ph.D.
Cc: leigh.goldstein@stdavids.com
Subject: RE: Instrument request

Hello Dr. Samsa,
Several years ago you sent me a copy of the DASS to review for possible use in my dissertation. I would like to obtain formal permission to use the DASS in my study titled: Relationships among Quality of Life, Self-care, and Affiliated Individuation in Persons on Chronic Warfarin Therapy: Testing a New Theoretical Framework Derived from Modeling and Role-Modeling Theory. Upon reviewing the instruments I realized I did not actually get permission. Please let me know if this is possible and what if anything you may need from me. I will be happy to share all data collected.

Sincerely,
Leigh A. Goldstein, MSN, APRN-BC, ONC, OCN
Doctoral Candidate
University of Texas at Austin School of Nursing

From: Gregory P Samsa [mailto:samsa001@mc.duke.edu]
Sent: Tuesday, March 11, 2008 3:05 PM
To: Goldstein Leigh
Subject: Re: Instrument request

A copy is attached.

"Goldstein Leigh" <Leigh.Goldstein@stdavids.com>

02/13/2008 12:09 PM

To: <samsa001@mc.duke.edu>
cc

Subject: Instrument request



Appendix M: SF36v2 License Agreement

SF-36v2 LICENSE AGREEMENT - DETAILS

Licensee: License Number: QM008374

N/A

Master License

Term:

License Term: 07/01/11 to 06/30/12

Amendment to: N/A

University of Texas Austin

Leigh Goldstein

3408 Cortina Lane

Round Rock, Texas 78681

The Relationships among Stress, Quality of Life,
Knowledge, Self-care, and Affiliated Individuation
in Persons on Chronic Warfarin Therapy: Testing a
Approved Purpose Study Name:

Protocol:

Govt. ID:

Study Type:

Clients Reference:

Licensed Surveys (Modes) and Services:

Item Description Mode of Admin Quantity Fees

PROJ01 Project Registration Paper 1

ES0220 SF-36v2, Standard Recall Paper 1

Approved Languages:

United States (English)

ADM012 Subjects participating 100

ADMINS Administrations (100 subjects x 1 admin) 100

SS040 Scoring Software v4 1

SS047 SF-36v2: Scoring Credits (v4.0) 100

SS997 MSE (Missing Score Estimator) 100

EM020 SF-36v2 Clinical Trial Guide eManual 1

Approved Languages:

United States (English)

Unfunded Student Discount

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